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, 2018

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 1-9341

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	**Name of each exchange on which registered**
Common Stock, $.01 par value	**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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 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, 2018 was $42,671,764. Shares of voting stock held by each officer and director and by each person who, as of June 30, 2018, 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 25, 2019, the registrant had 17,235,267 shares of Common Stock outstanding.

Documents Incorporated by Reference: Certain portions of the registrant's definitive Proxy Statement for its 2019 Annual Meeting of Stockholders are incorporated by reference into Items 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 Company's ability to defend itself in litigation matters, 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. Unless the context otherwise requires, the terms "iCAD", "Company", "we", "our" "registrant", and "us" means iCAD, Inc. and any 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 and Cancer 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 oncology market. The Company's strategy is to provide customers with a broad portfolio of innovative oncology solutions that address the two primary stages of the cancer care cycle, namely detection and treatment. The Company believes that its products can enable early detection and earlier targeted intervention, which could result in market demand and drive adoption of iCAD's solutions.

Cancer Detection Segment

Background and Overview

Approximately 40 million mammograms were performed in the United States in 2017. 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. Observational errors are responsible for more than half of cancers missed, and computer aided detection ("CAD"), has been proven to reduce the risk of observational errors in mammography. Mammography CAD uses sophisticated algorithms to analyze image data and mark suspicious areas in the image that may indicate cancer. CAD assists radiologists' review by identifying areas that warrant a second look or possibly contain a significant abnormality. Although CAD has potential applications for many types of cancer detection and diagnosis, as a medical imaging tool it has demonstrated the most success as an adjunct to mammography.

Digital breast tomosynthesis ("DBT") is rapidly replacing full-field digital mammography in screening due to its clinical value in cancer detection, but it also presents significant workflow challenges to radiologists who face the additional workload and time required to accurately read the extensive amounts of 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. CAD has the potential to address many of these challenges.

The Company offers a variety of CAD and breast density assessment solutions for use with mammography, breast tomosynthesis, and CT imaging, at both the detection and diagnosis stages of the cancer care cycle. These products have the potential to help radiologists better detect cancer and improve workflow efficiency. The Company completed development of a tomosynthesis CAD and workflow tool in 2015 and launched the product in the European market in April 2016, HealthCanada in June 2016 and in the United States after FDA clearance 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 tomosynthesis breast density solution received FDA clearance in December 2018. The Company believes that the CAD and breast density assessment solutions for breast tomosynthesis may represent a significant growth opportunity, given the large number of installation opportunities for CAD and breast density assessment solutions. The Company anticipates that CAD for tomosynthesis will become the standard of care in the near future, similar to what CAD for 2D mammography is today in the U.S. As of 2018, the U.S. alone had approximately 8,704 certified facilities providing mammography screening, which contained approximately 20,073 accredited full field digital mammography ("FFDM") and tomosynthesis mammography units. The majority of these centers are using 2D digital mammography FFDM systems and we believe approximately 36% of the units are digital breast tomosynthesis units.

The Company believes that there is also growth opportunity for mammography CAD in international markets, both from the analog to digital conversion and as more countries adopt the practice of radiologists using CAD, rather than having two radiologists read each case. Furthermore, most Western European countries have or are planning to implement mammography screening programs, which is likely to increase the number of mammograms performed in those countries. Although sales of the Company's CAD solutions

for two-dimensional mammography have been historically lower in Europe than in the U.S., the Company believes that its CAD solutions for use with three-dimensional tomosynthesis may be adopted with a higher attachment rate, due to workflow improvements and reading time reduction offered by the solutions.

Cancer Detection Products

iCAD develops and markets a comprehensive range of high-performance Artificial Intelligence cancer detection and workflow solutions for digital mammography systems worldwide. iCAD's PowerLook Mammo Detection (also known as SecondLook Digital) is based on sophisticated patented algorithms that analyze the data, automatically identifying and marking suspicious regions in 2D full field digital mammography images. The solution provides the radiologist with a "second look" which helps the radiologist detect actionable missed cancers earlier than screening mammography alone. PowerLook Mammo Detection detects and identifies suspicious masses and micro-calcifications utilizing image processing, pattern recognition and artificial intelligence techniques. Information from thousands of mammography images are incorporated into these algorithms enabling the product to distinguish between characteristics of cancerous and normal tissue. This should result in earlier detection of hard-to-find cancers, improved workflow for radiologists, and higher quality patient care.

PowerLook.

PowerLook analyzes two-dimensional full-field digital mammography images and automatically identifies and marks suspicious masses and micro-calcifications. This provides a radiologist with a "second look" that detects potentially actionable missed cancers earlier than screening mammography alone. PowerLook uses sophisticated, patented algorithms together with image processing, pattern recognition and artificial intelligence techniques. These algorithms incorporate data from thousands of mammography images, 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.

PowerLook is offered through the PowerLook Breast Health Solutions platform (the "PowerLook Platform"), which is the first product suite of its kind to integrate cancer detection and breast density assessment software. The assessment software, or PowerLook Density Assessment, aids radiologists by standardizing their approach to breast density assessment and categorization. PowerLook Density Assessment provides an automated, consistent and standardized reporting tool, 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 PowerLook software platform received FDA clearance in August 2018.

PowerLook also includes a server platform, which receives patient studies from the imaging modality, performs analysis and sends the results to picture archive and communication systems ("PACS") and/or review workstations. As workflow and efficiency are critical in digital imaging environments, PowerLook comes with a powerful and flexible DICOM connectivity solution, which enables universal compatibility with leading PACS and review workstations. iCAD has worked with its OEM partners to ensure optimal integration into the graphical user interface of

their PACS and review workstations. The algorithms in the product have also been optimized for each digital imaging provider based upon characteristics of their unique detectors. All of these features reduce the need for separate CAD servers and result in lower hardware and service costs for the end-customer.

The Company expects additional modules to be released and integrated into the PowerLook platform in the future, and anticipates that all future breast imaging offerings will be built upon the PowerLook platform.

Breast Tomosynthesis

Digital Breast Tomosynthesis ("DBT") was introduced in the United States in 2010 by Hologic, Inc., followed by GE Healthcare which received FDA approval for their tomosynthesis system in August 2014. Siemens approval followed in April 2015, and Fuji was approved in early 2017. Tomosynthesis has been demonstrated to have multiple advantages over traditional 2D mammography. It has improved tissue visualization and detection and results in lower recall rates for patients. Tomosynthesis improves the sensitivity and specificity of cancer diagnosis when compared to mammography. Clinical studies indicate that digital breast tomosynthesis improves the ability to distinguish malignant from benign tumors and can detect early signs of cancer hidden by overlapping tissues. This helps reduce the overall number of biopsies performed and the call back rates. Initial studies have indicated that tomosynthesis has the ability to detect 41% more invasive cancers than conventional mammography, and it also reduces false-positives by up to 40%.

Artificial intelligence can play an important role in improving the accuracy and efficiency of reading breast tomosynthesis cases by automatically identifying breast masses and micro-calcifications. In 2015, the Company completed development of its cancer detection and workflow solution for DBT to aid radiologists in their review of DBT as a means of improving lesion detection and reducing the time to read the large tomosynthesis datasets. The initial solution is developed for use with GE Healthcare's digital breast tomosynthesis for the detection of soft tissue densities (masses, architectural distortions and asymmetries). In January 2017, the Company submitted an amendment to its original PMA application for its 3D tomosynthesis product and the Company received FDA Approval in March of 2017.

In early 2018, the Company received CE mark for its multi-vendor, artificial intelligence DBT cancer detection and workflow solution, ProFound AI. The product also received clearance for clinical use in Canada in mid-2018. ProFound AI is a deep learning algorithm that is specifically designed to detect malignant soft-tissue densities and calcifications in DBT exams by analyzing all of the DBT data. Also in early 2018, the Company completed a large multi-reader, multi-case crossover design clinical reader study, which concluded that ProFound AI increases radiologist clinical performance by improving radiologist sensitivity by an average of 8%, improving radiologist specificity by an average of 6.9% and reducing recalls in non-cancer cases by average of 7.2%. The reader study also showed that the product can reduce DBT reading times by an average of 52.7%. Based on these reader study results, ProFound AI received clearance in the US by the FDA in December 2018.

The Company will continue to focus on advancing the performance of its ProFound AI for DBT solution through training on larger datasets as well as expanding support to other DBT manufactures. The Company is also developing a ProFound AI solution for 2D mammography images for the European market where 2D mammography remains the primary procedure for breast cancer screening. The ProFound AI 2D product is expected to be available in the spring of 2019.

ProFound AI

ProFound AI is a deep learning algorithm specifically designed to detect malignant soft-tissue densities and calcifications in digital breast tomosynthesis ("DBT"). In early 2018, the Company completed a large multi-reader, multi-case crossover design clinical reader study, which found that ProFound AI increased radiologist clinical performance by improving radiologist sensitivity by an average of 8%, improved radiologist specificity by an average of 6.9% and reduced recalls in non-cancer cases by an average of 7.2%. The reader study also showed that ProFound AI reduced DBT reading times by an average of 52.7%.

Based on these reader study results, ProFound AI received FDA clearance in December 2018. The product received a CE mark in March 2018, and also received clearance for clinical use in Canada in mid-2018. The Company already has an OEM relationship with GE Healthcare's mammography systems, and expects to use ProFound AI to expand its OEM partnerships with other mammography system providers.

The Company plans to focus on advancing the performance of ProFound AI by training on larger datasets and expanding support to additional DBT manufacturers. The Company is also developing a ProFound AI solution for two-dimensional mammography images. This solution is targeted at the European market, where two-dimensional mammography remains the primary procedure for breast cancer screening, and is expected to be available in the spring of 2019.

In February 2019, iCAD announced its intention to work with researchers from Sweden's Karolinska Institute to develop and commercialize an innovative, AI-based breast cancer risk assessment model designed to identify a woman's risk of developing an interval cancer which are cancers detected or present within 12 months after a mammographic screening in which findings are considered normal. The model is driven primarily by data from existing mammography images.

VeraLook

VeraLook is an FDA-cleared CAD solution designed to support detection of colonic polyps in conjunction with CT colonography ("CTC"). The product is distributed with advanced visualization reading workstations manufactured by Vital Images (a Toshiba Medical System Group company) 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 reduced specificity of readers by 2.5%. The clinical relevance of VeraLook was improved reader performance while maintaining high reader specificity.

VeraLook received FDA clearance in 2010, and market authorization by the National Medical Products Administration in China in 2014.

Computed Tomography Applications and Colonic Polyp Detection

CT Colonography ("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.

CTC is a less invasive technique than traditional colonoscopy for imaging the colon. 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. Computer Aided Detection ("CAD") technology can play an important role in improving the accuracy and efficiency of reading CTC cases by automatically identifying potential polyps. 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**.**

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 stages of 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. Global incidence rates of new cancer cases are rising, primarily due to aging populations and changing lifestyle habits. However, survival rates are also improving as a result of earlier detection and enhanced treatment options.

The three main types of radiation therapy are external beam radiation therapy ("EBRT"), brachytherapy, or sealed source radiation therapy, and systemic radioisotope therapy or unsealed source radiotherapy. EBRT involves a radiation source positioned outside the body, while brachytherapy uses sealed radioactive sources placed precisely inside the body in the treatment area, and systemic radioisotopes 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 50 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

Products

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. 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 Xoft System is a disruptive radiation oncology treatment solution with significant cost, mobility, and treatment time advantages over its competitors or other standards of care. While the primary applications of this system currently are localized breast cancer treatment using a ten to fifteen-minute breast Intraoperative Radiation Therapy (“IORT”) protocol and the treatment of non-melanoma skin cancers (“NMSC”), the Xoft System platform can also be used to treat a wide and growing array of additional cancers, including gynecological and other non-breast IORT clinical indications.

The Xoft System delivers clinical dose rates similar to traditional radioactive systems. However, because of the electronic nature of the Xoft technology, the dose fall-off is faster. This lowers the radiation exposure outside of the targeted area, and eliminates the need for a shield 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 (including the operating room where IORT is delivered) under radiation oncology supervision. 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.

The Xoft System 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. In August 2018, the Xoft System received

regulatory consent from India's Atomic Energy Regulatory Board ("AERB"), 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 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.

The Company continues to make enhancements to the Xoft System controller, including upgrades to the software interface and the high voltage connection. In 2016, the Company unveiled the Streamlined Module for Advanced Radiation Therapy ("SMART") platform for the Xoft System, which uses the Axxent Hub cloud-based oncology collaboration software solution. The SMART platform is an adaptive, patient-centric solution 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 Accelerated Partial Breast Irradiation ("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 non-melanoma skin cancers. The flexible single-use breast IORT and APBI applicators are offered in a variety of sizes 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 and the treatment of NMSC. However, the Xoft System can also be used to treat a wide and growing array of additional cancers, including gynecological 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.

Of the approximately 300,000 women who are diagnosed with breast cancer every year in the U.S., the majority, about 180,000 (60%), are diagnosed with early stage breast cancer. Of those with early stage breast cancers, over 100,000 (about 60%) are candidates for treatment with eBx. Currently, a majority of early stage breast cancer patients who are treated with radiation therapy follow a five-to-seven-week daily protocol of traditional external beam radiation, while a small portion are treated with a five-day protocol using 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 APBI, which can be delivered twice daily for five days.

There are approximately 3.5 million cases of NMSC diagnosed annually in the U.S. Of those cases, approximately 20%-30% have specific diagnoses and lesion characteristics that make such patients potential candidates for electronic brachytherapy treatment. 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. Recent 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 excellent cosmesis for eligible NMSC patients. On January 4, 2018, the Company adopted a plan to discontinue offering radiation therapy professional services to practices that provide the Company's electronic brachytherapy solution for the treatment of NMSC under the subscription service model within the Therapy Segment. As a result, the Company ceased offering the subscription service model to customers. The Company will continue to offer its capital sales model for both skin cancer treatment and IORT, which provides a brachytherapy system and related source and service agreements The discontinuance of the subscription service model reduced radiation therapy professional services delivery costs, decreased cash burn, and re-focused the Company on the higher margin capital product and service offerings

There are approximately 50,000 new cases of endometrial cancer each year in the U.S. and nearly 300,000 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 ("ESTRO") annual meeting. Researchers from Miguel Servet University Hospital in Zaragoza, Spain presented promising study results demonstrating excellent 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.

Additionally, electronic brachytherapy is appropriate for use in other IORT clinical settings where surgical resection is unable to completely eliminate all cancer cells. In the U.S. and international settings, the Company believes that IORT for prostate, pelvic, gastrointestinal, abdominal, spinal, and soft tissue sarcoma applications remains a potential market given the minimal shielding requirements associated with this treatment modality. 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, et al. of Hoag Memorial Hospital Presbyterian in Newport Beach, CA 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, concluding that IORT safely delivers radiation and 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 (DCIS) treated with IORT. The data showed a 2.1% recurrence rate with relatively few complications and again concluded that x-ray based IORT is a promising treatment modality that greatly simplifies 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 have been seven ipsilateral breast tumor events (IBTE), 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 showed the benefits of IORT compared to external beam radiation therapy (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 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 determined IORT to be the preferred method of treatment.

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 2013-2015, 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.

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 using different technology. 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 significantly lower – 2 percent – 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.

Preliminary results of the Company's ExBRT clinical trial continue to demonstrate that IORT using the Xoft System is safe with excellent local control and cosmesis, and low morbidity. Analysis of the international, multi-center trial was unveiled during an oral presentation at the 60th American Society for Radiation Oncology (ASTRO) annual meeting at the Henry B. Gonzalez Convention Center in San Antonio, Texas. In the presentation, A.M. Nisar Syed, MD, Principal Study Investigator, and 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 1,201 patients between May 2012 and July 2018 at 28 international and United States-based institutions. With a median follow up of two years, less than one percent of patients had cancer regrowth (ipsilateral recurrence) or developed new primary cancers in the other breast. Treatment was well tolerated with grade 3, 4 and 5 adverse events occurring in only 37 patients. Mean treatment time was 10.5 minutes.

Since 2016, electronic brachytherapy for the treatment of NMSC has been reimbursed under a skin-specific Category III CPT code. Reimbursement for the treatment delivery is 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 U.S. Medicare Administrative Contractors. There are several Medicare Administrative Contractors that have published rates for the 0394T code and others that reimburse on a case-by-case basis.

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.

The Company supports breast IORT through its ongoing ExBRT Clinical Trial, a post-market clinical trial that enables facilities interested in treating early stage breast cancer patients with the Xoft System to participate in a common clinical protocol and follow enrolled patients for up to

ten years. The ExBRT study is led by brachytherapy and breast care physicians, including breast surgeons, radiation oncologists, pathologists, and medical physicists from leading U.S. breast cancer care institutions. In February 2018, the study completed enrollment of 1,200 patients at 27 centers in the U.S. and Europe. Clinical results from the ExBRT study are expected to be presented at key medical conferences during 2019.

Major Customers and Regional Markets

	Percent of Export sales		
Region	**2018**	**2017**	**2016**
Europe	51%	68%	36%
Taiwan	22%	11%	19%
Canada	7%	5%	15%
China	0%	9%	21%
Other	20%	7%	8%
Total	100%	100%	100%
Total Export sales	$3,255	$3,931	$2,323

Significant export sales in Europe are as follows:

	Percent of Export sales		
Region	**2018**	**2017**	**2016**
France	36%	41%	15%
Spain	8%	9%	7%
Germany	3%	7%	3%
Bulgaria	1%	2%	3%
United Kingdom	0%	2%	3%

OEM partners generated approximately 47% of detection revenue and 31% of revenue overall. GE Healthcare was the largest single customer with approximately $6.1 million in 2018, $7.1 million in 2017, and $3.9 million in 2016, or 24%, 25%, and 15% of total revenues, respectively.

Sales and Marketing

Cancer Detection

In the U.S., iCAD sells its mammography products through a direct regional sales force and through the Company's OEM partners, which include GE Healthcare, Fuji Medical Systems, and Siemens Medical Systems. In Europe, iCAD has also developed reseller relationships with regional distributors, which we plan to expand.

The VeraLook CTC CAD product is distributed by Vital Images and Philips Healthcare, which integrate the Company's solutions with their products in the U.S.

As part of its sales and marketing efforts, iCAD engages in a variety of public relations and local outreach programs with numerous customers. We continue 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. Xoft has established partnerships in Australia, Bulgaria, Canada, China, Hong Kong, Macau, Egypt, Saudi Arabia, India, Italy, Mexico, Portugal, Russia, South Korea, Spain, Sweden, Switzerland, The Netherlands, Luxemburg, Taiwan, Turkey, United Kingdom and Ireland, and is actively exploring market entry in South and Central 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 these competitors are well established in the healthcare market. In addition, some companies have developed or may develop technologies or products that could compete with the products the Company manufactures and distributes or that would render 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. These and other competitive pressures could have a material adverse effect on the Company's business.

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, and Densitas (Halifax, NS, Canada). The Company believes that its market leadership in mammography CAD and density assessment and strong relationships with its strategic partners will provide it with a competitive advantage in the mammography CAD and density assessment market.

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 U.S., and Siemens Medical received FDA clearance for CTC CAD in 2014. 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 CAD provides 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. IntraOp Medical (Sunnyvale, CA) is another competitor in the high dose rate ("HDR") radiation therapy 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 (Boca Raton, FL) Surface Radiation Therapy ("SRT") system and Elekta's Esteya system), surgical treatment options and traditional radiation therapy.

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, physics 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 software and hardware systems and related accessories are regulated as medical devices in all of the jurisdictions where it operates, and its customers are subject to applicable mammography provider quality standards. In the US, the Company must comply with the medical device regulations as amended under the US Food Drug and Cosmetic Act. The Act governs, among other things, quality standards for product development, testing, labeling, storage, pre-market clearance or approval, advertising and promotion, sales and distribution, and post-market surveillance of safety. 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. Increasingly, medical device manufacturers are adopting globally harmonized quality standards for medical devices as developed by the International Organization for Standardization ("ISO"), and risk management standards for medical devices. Manufacturers of software as a medical device ("SaMD") are further subject to specific security standards. There is no guarantee that future products or modifications of current products will meet relevant requirements such as these for lawful commercialization of our products in the jurisdictions where the Company operates.

The US FDA's Quality System Regulations require that the Company's operations follow extensive design, testing, control, documentation and other quality assurance procedures throughout the product lifecycle. The Company is subject to FDA regulations covering labeling and adverse event reporting as well as FDA's general prohibition against promoting products for unapproved or "off-label" uses.

The Company's manufacturing processes, facilities, and personnel located both within and outside the US are subject to periodic inspections by the US FDA and corresponding state health and safety agencies. The Company must also comply with similar requirements, including site inspections by regulators from other jurisdictions where it operates. Failure to comply fully with applicable

regulations could cause regulators to take some enforcement action. In the US, for example, enforcement could include delayed marketing clearance or approval, receipt of an FDA 483 deficiency notification at the conclusion of a facility inspection, Warning Letters, product seizures, import/export refusal, civil monetary penalties, injunctions, and criminal prosecution.

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 govern exports, and are collectively referred to as "Export Controls." In brief, these regulate the shipment or transfer, by whatever means, of controlled items, software, technology, or services out of the United States.

The Company is also subject to a variety of federal and state regulations in the US and the regulations in other jurisdictions which broadly relate to our interactions with healthcare practitioners, government officials, purchasing decision makers, and other stakeholders across healthcare systems. These regulations include among others, the following:

- anti-kickback, false claims, and physician self-referral statutes;
- US state laws and regulation 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 US Foreign Corrupt Practices Act, ("FCPA"), the UK Anti-Bribery Act; the Canadian Corruption of Foreign Public Officials Act ("CFPOA"), and guidances promulgated by respected multi-national groups, such as the United Nations Convention Against Corruption, and the Organization for Economic Cooperation and Development ("OECD") 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 US Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, ("HITECH"), the General Data Protection Regulation ("GDPR") in the EU, and the Personal Information Protection and Electronic Documents Act ("PIPEDA") in Canada; and
- healthcare reform laws in the US, such as the Affordable Care Act ("ACA") and the 21st Century Cures Act 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 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 associated with the violation, potentially including 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 oftentimes 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, Centers for Medicare & Medicaid Services (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 likelihood of allegations of non-compliance is increased by the fact that under certain federal and state laws applicable to our business, individuals, known as relators, may 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.

Any action against us alleging a violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's time and attention from the operation of our business.

In addition, the laws and regulations impacting or affecting our business may change significantly in the future. Any new laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. Also, the regulatory environment applicable to our business may change in a way that restricts or adversely impacts 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 US 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, and complying with these laws may result in a material adverse effect upon our business, financial condition and results of operations.

Additionally, in order to market and sell our products in certain countries outside of the U.S., we must obtain and maintain regulatory approvals and comply with the regulations of each specific country. As noted above, These regulations, including the requirements for approvals, and the time required for regulatory review vary by country. Obtaining and maintaining foreign regulatory approvals is an expensive and time-consuming process. We cannot be certain that we will be able to obtain the necessary regulatory approvals timely or at all in any foreign country in which we plan to market our products.

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.

Reimbursement in the US

The federal and state governments of the United States establish guidelines and pay reimbursements to hospitals, free-standing clinics (Independent diagnostic treatment facilities ("IDTFs")), and medical professionals for diagnostic examinations and therapeutic procedures under the federal Medicare program and the joint federal/state Medicaid program.

The federal government reviews and adjusts coverage policies and reimbursement levels periodically and also considers various Medicare and other healthcare reform proposals that could significantly affect both private and public reimbursement for healthcare services in hospitals and free-standing clinics. State government reimbursement for services is determined pursuant to each state's Medicaid plan, which is established by state law and regulations, subject to requirements of federal law and regulations.

Third-Party Reimbursement

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, such as 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. These third-party payers may deny coverage if they determine that a device used in a procedure was not medically necessary, was not used in accordance with cost-effective treatment methods, as determined by the third-party payer, was not used in a manner supported by medical professional society treatment guidelines or third-party reviews of the published, peer reviewed literature, or was used for an unapproved indication. They may also pay an inadequate amount for the procedure which could cause healthcare providers to use a lower cost competitor's device or perform a medical procedure without our device.

Reimbursement decisions by particular third-party payers depend upon a number of factors, including each third-party payer's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational (i.e., that its use is supported by relevant evidence in the peer reviewed literature.)

Many third-party payers use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the U.S. Medicare program, as guidelines in setting their coverage and reimbursement policies. Medicare periodically reviews its reimbursement practices for various products. As a result, there is no certainty as to the future Medicare reimbursement rate for our products. In addition, those third-party payers that do not follow the CMS guidelines may adopt different coverage and reimbursement policies for our current and future products. It is possible that some third-party payers will not offer any coverage for our current or future products.

Furthermore, 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. If third-party payers deny coverage or reduce their current levels of payment, or if our production costs increase faster than increases in reimbursement levels, we may be unable to sell our products on a profitable basis.

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 the U.S. 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.

The provisions of the Affordable Care Act went into effect in 2012 and in subsequent years. We are continuing to evaluate the law's impact on our business. 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. However, it is uncertain at this point what negative unintended consequences these provisions aimed at improving quality and decreasing costs might have on patient access to new technologies. Other elements of this legislation, including comparative effectiveness research, payment system reforms (including shared savings pilots) and other provisions, could meaningfully change the way healthcare is delivered and paid for in the US, 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. We are evaluating the effect that Trump Administration changes to the Affordable Care Act 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.

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 material to its ongoing programs that expire between 2020 and 2029. These patents help the Company maintain a proprietary position in its markets. 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 and digitizer technologies and products, including cancer detection solutions for tomosynthesis, CAD for CT colonography and lung and CAD for MRI breast and prostate, as well as Xoft's current and future eBx technologies and products. 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. The Company believes it has all the necessary licenses from third parties for software and other technologies in its products; however, it cannot assure that current or future patent applications will issue with the full scope of the claims sought, if at all, or whether any patents issued will be challenged or invalidated.

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

The Company incurred $9.6 million, $9.6 million, and $10.3 million of research and development expense including depreciation and amortization, during the years ended December 31, 2018, 2017 and 2016, respectively. Research and development expenses are primarily attributed to personnel, consulting, subcontract, licensing and data collection expenses relating to the Company's new product development and clinical testing.

Employees

As of December 31, 2018, the Company had 97 employees, of whom 95 are full time employees, with 31 involved in sales and marketing, 19 in research and development, 35 in service, manufacturing, technical support and operations functions, and 12 in administrative functions. None of the Company's employees is represented by a labor organization. The Company considers our relations with employees to be good.

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. The Company 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 its 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 Securities and Exchange Commission (SEC). You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site 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 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.

We have incurred significant losses from inception through 2018 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 $9.0 million in 2018 and have an accumulated deficit of $210.8 million at December 31, 2018. We may not be able to achieve profitability.

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 U.S. 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 U.S. The rights provided by a patent are finite in time. The Company has certain patents material to its ongoing programs that expire between 2020 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.

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, captioned Yeda Research and Development Company Ltd. v. iCAD, Inc. and Invivo Corporation, Case No. 1:18-cv-08089-GBD, asserting various claims against the Company and Invivo. 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.

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 U.S., the Centers for Medicare and Medicaid Services ("CMS") establishes coverage and reimbursement policies for healthcare providers treating Medicare and Medicaid beneficiaries. Under current CMS policies, varying reimbursement levels have been established for our products and treatments. Coverage policies for Medicare patients may vary by regional Medicare carriers in the absence of a national coverage determination and reimbursement rates for treatments varies 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. 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.

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. In addition, we may not be able to successfully develop or obtain FDA clearance for our proposed products.

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 2018 our OEM partners accounted for 31% of our total revenue in 2018, with one major customer, GE Healthcare accounting for 24% of our revenue. In addition, in

2018, five customers accounted for 33% of our total revenue, which includes both OEM partners and direct customers. 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.

The markets for our newly developed products and treatments and newly introduced enhancements to our existing products and treatments may not develop as expected.

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:

- 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 US 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.

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, 2018

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.

The healthcare industry is highly regulated, and government authorities may determine that we have failed to comply with applicable laws, rules or regulations.

Both in the US 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. Many healthcare laws are complex, and their application to specific services and relationships may not be clear. Further, healthcare laws differ from jurisdiction to jurisdiction and it is difficult to ensure our business complies with evolving laws in all jurisdictions. In addition, we believe that our business will continue to be subject to increasing regulation, the scope and effect of which we cannot predict. Legislatures and governmental agencies periodically consider proposals to revise or create additional statutory and regulatory requirements. Such proposals, if implemented, could impact our operations, the use of our services, and our ability to market new services, or could create unexpected liabilities for us.

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. For example, regulatory authorities or other parties may assert that our arrangements with the physician practices to which we lease equipment and provide services violate anti-kickback, fee splitting, or self-referral laws and regulations and could require us to restructure these arrangements, which could have a material adverse effect on our business, financial condition, results of operations, cash flows and the trading price of our common stock. Such investigations, proceedings and challenges could also result in substantial defense costs to us and a diversion of management's time and attention. In addition, violations of these laws are punishable by monetary fines, civil and criminal penalties, exclusion from participation in government-sponsored healthcare programs, and forfeiture of amounts collected in violation of such laws and regulations, any of which could have a material adverse effect on our business, financial condition, results of operations, cash flows and the trading price of our common stock.

We may incur substantial costs defending our interpretations of US 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 US government-sponsored health care programs such as Medicare and Medicaid.

Our operations, including our arrangements with healthcare providers, are subject to extensive US federal and state government regulation and are subject to audits, inquiries and investigations from government agencies from time to time. Those laws may 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.

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, US 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, our arrangements and business practices may be the subject of government scrutiny or be found to violate applicable laws. If US federal or state government officials challenge our operations or arrangements with third parties that we have structured based upon our interpretation of these laws, rules and regulations, such challenge could potentially disrupt our business operations and we may incur substantial defense costs, even if we successfully defend our interpretation of these laws, rules and regulations. 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 with third parties, it may have a material adverse effect on our business, financial condition and results of operations.

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 exclusion from such programs as a result of a violation of these laws could have a material adverse effect on our business.

Once our products are sold, we must comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including false claims laws, anti-kickback laws and physician self-referral laws, rules and regulations. 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 exclusion from such programs as a result of a violation of these laws could have a material adverse effect on our business.

US Anti-Kickback Statutes

The federal health care program Anti-Kickback Statute 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 Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The statutory penalties for violating the Anti-Kickback Statute include imprisonment for up to five years and criminal fines of up to $25,000 per violation. In addition, through application of other laws, conduct that violates the Anti-Kickback Statute can also give rise to False Claims Act lawsuits, civil monetary penalties and possible exclusion from Medicare and Medicaid and other federal healthcare programs. In addition to the Federal Anti-Kickback Statute, 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. Additionally, we could be subject to private actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions which, among other things, allege that our practices or relationships violate the Anti-Kickback Statute.

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 recently 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 plea or deferred prosecution agreements.

With respect to the federal Anti-Kickback Statute, 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 Anti-Kickback Statute. We train and educate employees and marketing representatives on the Anti-Kickback Statute and their obligations thereunder, and we endeavor to comply with the applicable safe harbors. However, some of our arrangements, like many other common and non-abusive arrangements, may implicate (or potentially implicate) The Anti-Kickback Statute are not covered by a safe harbor, but nevertheless do not implicate any of the Statute's principal policy objectives and, as such, likely do not pose a material risk of program abuse or warrant the imposition of sanctions. 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 Anti-kickback Statute. Allegations of Violations of the Anti-Kickback Statute 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 Anti-Kickback Statute.

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, and any person collecting any amounts in connection with an unlawful referral is obligated to refund these amounts. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to $100,000 for each such arrangement or scheme. The penalties for violating the Stark Law also include civil monetary penalties of up to $15,000 per service, 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 federal health care program but also with respect to 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. We attempt to structure our relationships to meet an exception to the Stark Law, but the regulations implementing the exceptions are detailed and complex, and we cannot provide assurance that every relationship complies fully with the Stark Law. Unlike the Anti-Kickback Statute, 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.

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, which could have a material adverse effect on our business, financial condition and results of operations.

False Claims Laws

The federal False Claims Act, or 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. The qui tam or "whistleblower" provisions of the False Claims Act 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. In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. Additionally, if we violate the Anti-Kickback Statute or Stark Law, or if we improperly bill for our services, or 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 civil False Claims Act.

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 between $5,000 and $10,000 (adjusted for inflation) for each separate false claim. Actions filed under the FCA can be brought by any individual on behalf of the government, a "qui tam" action, and this individual, known as a "relator" or, more commonly, as a "whistleblower," may share in any amounts paid by the entity to the government in damages and penalties or by way of settlement. In addition, certain states have enacted laws modeled after the FCA, and this legislative activity is expected to increase. Qui tam actions have increased significantly in recent years, 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 as a result of investigations arising out of such actions.

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 Federal Patient Protection and Affordable Care Act, 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. In addition, 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.

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 Patient Protection and Affordable Care Act (the "PPACA"). The PPACA 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. Specifically, beginning in 2013, the medical device industry was required to subsidize healthcare reform in the form of a 2.3% excise tax on United States sales of most medical devices. In December 2015, as part of the Omnibus Appropriations Act, collection of the medical device excise tax was suspended thru 2017. That postponement has been extended again for 2018 and 2019. We are unable to predict whether the postponement will be continued beyond 2019. While the PPACA 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.

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. If this consolidation trend continues, it could reduce the size of our potential customer base and give the resulting enterprises greater bargaining or purchasing power, which may lead to erosion of the prices for our systems or decreased margins for our systems. In addition, when hospitals and imaging centers combine, they often consolidate infrastructure, and consolidation of our customers could result in fewer overall customers.

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

Our CAD systems and Axxent eBx systems are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act. In addition, our manufacturing operations are subject to FDA regulation and we are also subject to FDA regulations covering 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 U.S. 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 Axxent eBx 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 FDA approvals for our currently offered products. Before we are able to commercialize any new product, we must obtain regulatory approvals for each indicated use for that product. 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.

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, the FDA and similar governmental authorities in other countries may press us to implement 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 The Health Insurance Portability and Accountability Act of 1996, as amended, and the regulations that have been issued thereunder ("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 (1) result in legal claims or proceedings, liability under laws that protect the privacy of personal information and regulatory penalties, (2) disrupt our operations and the services we provide to our customers and (3) 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 all 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.

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.

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

Various statutes and rules in the U.S., 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 requires substantial financial resources. Failure to comply with these laws may result in, among other things, civil and criminal liability, negative publicity, restrictions on further use of data, and/or liability under contractual warranties. In addition, changes in these laws (including newly released interpretations of these laws by courts and regulatory bodies) may limit our data access, use and disclosure, and may require increased expenditures by us.

The European Union’s General Data Protection Regulation (“GDPR”), took effect in May 2018 and 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.

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.

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.

Our 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.

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 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.

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.

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 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, 2018 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.

An inability to meet the requirements of Section 404 could adversely affect investor confidence and, as a result, our stock price.

We are required to comply with the requirements of Section 404. Although we have implemented procedures to comply with the requirements of Section 404, there is no assurance that we will continue to meet the requirements. Failure to meet the ongoing requirements of Section 404, our inability to comply with Section 404's requirements, and the costs of ongoing compliance could have a material adverse effect on investor confidence and our stock price.

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 13% of our revenue for 2018. 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.

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.

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, or the Securities Act, and may become freely tradable. We have also registered shares that are issuable upon the exercise of options and warrants, and the conversion of debentures. If holders of options, or warrants or debentures 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

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 and debentures that are exercisable or convertible into a significant number of shares of our common stock. Should existing holders of options or debentures exercise or convert their securities into 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.

Provisions in our corporate charter 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.

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.

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 and Security Agreement entered into on August 7, 2017, as amended, Silicon Valley Bank agreed to provide $13 million in financing to the Company, with Silicon Valley Bank making revolving loans to the Company in the principal amount of up to $4 million and providing a term loan facility up to $9 million to be drawn in two tranches. The Loan Agreement:

- requires us to dedicate a substantial 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 maintain net revenues ranging from $11.4 million to $14.5 million for each calendar quarter ended until December 31, 2019. Failure to maintain these revenues could result in acceleration of the indebtedness under the Loan Agreement;
- requires us to achieve adjusted EBITDA ranging from negative $3.5 million to negative $2.0 million for each calendar quarter until December 31, 2019. Failure to achieve the adjusted EBITDA amount could result in acceleration of the indebtedness under the Loan Agreement;
- requires us to agree by a certain date with Silicon Valley Bank regarding minimum revenue levels for the 2020 calendar year. Failure to agree will result in acceleration of the indebtedness under the Loan Agreement;
- requires us to provide by a certain date certain financial information in connection with revenue for the 2019 and 2020 calendar years. Failure to agree will result in acceleration of the indebtedness under the Loan Agreement to April 30 of the applicable following year; and;

On December 20, 2018, the Company entered into a Securities Purchase Agreement, pursuant to which it issued unsecured subordinated convertible debentures (the "Debentures") to certain institutional and accredited investors of the Company, in an aggregate principal amount of approximately $6.5 million. Subject to certain qualifications, the Debentures restrict our ability to incur indebtedness, place liens on our assets, repay indebtedness other than the Debentures or pay dividends.

The Loan Agreement and the Debentures:

- 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 or Debentures prior to their 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 (other than intellectual property) 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.

In the event that we were to fail in the future to make any required payment under the Debentures or fail to comply with certain covenants contained in the Debentures, in some cases subject to applicable cure periods, we would be in default regarding the Debentures. Such default would entitle the holders of the Debentures to payment of the outstanding principal amount, all unpaid interest and certain additional amounts. This could significantly diminish the market value and marketability of our common stock.

Item 1B. Unresolved Staff Comments.

Not applicable

Item 2. Properties.

The Company's executive offices are leased pursuant to a five-year lease (the "Lease") that commenced on December 15, 2006, with renewals in January 2012 and August 2016, referred to as the "August 2016 Lease Renewal", consisting of approximately 11,000 square feet of office space located at 98 Spit Brook Road, Suite 100 in Nashua, New Hampshire (the "Premises"). The August 2016 Lease Renewal provides for an annual base rent of $184,518 for the period from March 2017 to February 2020. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the Premises.

The Company leases a facility consisting of approximately 24,350 square feet of office, manufacturing and warehousing space located at 101 Nicholson Lane, in San Jose, CA. This lease commenced September 2012 and provided for an annual payment of $295,140 through September 2017 in equal monthly installments. In September 2016, the Company extended this lease for the period from October 2017 to March 2020 with annual payments of $540,588 from October 2017 to September 2018, $558,120 from October 2018 to September 2019 and $286,368 for the period from October 2019 to March 2020, with all amounts payable in equal monthly installments. 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. 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.

In December 2016, the Company entered into an Asset Purchase Agreement, referred to in this Section as the Agreement, with Invivo Corporation, referred to in this Section as 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.

On September 5, 2018, third-party Yeda Research and Development Company Ltd., referred to in this Section as Yeda, filed a 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 Agreement. In the Complaint, Yeda asserts 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. The Company is awaiting a decision from the Court. To the extent that the Complaint is not dismissed in its entirety, the Company will vigorously defend against the claims asserted by Yeda. The amount of the loss, if any, cannot be reasonably estimated at this time. Any amounts owed by the Company in connection with its indemnification obligations to Invivo related to this action may reduce the $350,000 holdback under the Asset Purchase Agreement.

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 we 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 our 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.

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". The following table sets forth the range of high and low sale prices for each quarterly period during 2018 and 2017.

Fiscal year ended December 31, 2018	High	Low
First Quarter	$4.10	$2.93
Second Quarter	4.06	2.98
Third Quarter	3.65	2.80
Fourth Quarter	4.68	2.42
Fiscal year ended December 31, 2017		
First Quarter	$5.11	$3.19
Second Quarter	6.07	3.95
Third Quarter	4.67	3.13
Fourth Quarter	4.89	3.29

As of March 11, 2019, there were 211 holders of record of the Company's common stock. In addition, the Company believes that there are in excess of 3,300 holders of its common stock whose shares are held in "street name".

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 Silicon Valley Bank and its unsecured convertible debentures issued in December 2018 each restrict the Company's present ability to pay dividends.

See Item 12 of this Form 10-K for certain information with respect to the Company's equity compensation plans in effect at December 31, 2018.

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 taxing authorities on behalf of our employees. The Company had the following repurchases of securities in the quarter ended December 31, 2018:

Month of purchase	Total number of shares purchased (1)	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum dollar value of shares that may yet be purchased under the plans or programs
October 1 - October 31, 2018	6,761	$ 3.08	$ —	$ —
November 1 - November 30, 2018	99	$ 2.88	$ —	$ —
December 1 - December 31, 2018	7,377	$ 3.95	$ —	$ —
Total	14,237	$ 3.53	$ —	$ —

(1) Represents shares of common stock surrendered by employees to the Company to pay employee withholding taxes due upon the vesting of restricted stock. These transactions are exempt under Section (4)(a)(2) of the Securities Act.

Recent Sales of Unregistered Securities. In December 2018, the Company issued unsecured subordinated convertible debentures with an aggregate principal amount of approximately $7.0 million in a private placement. See "Liquidity and Capital Resources" in Item 7 of this Form 10-K for certain information with respect to these securities.

Item 6. Selected Financial Data.

The following selected consolidated financial data is not necessarily indicative of the results of future operations and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K (amounts in thousands).

Selected Statement of Operations Data

	Year Ended December 31,				
	2018	2017	2016	2015	2014
Total Revenue	$25,621	$ 28,102	$ 26,338	$ 41,554	$43,924
Gross margin	19,430	18,176	18,518	29,350	31,227
Gross margin %	75.8%	64.7%	70.3%	70.6%	71.1%
Total operating expenses	27,560	32,344	28,488	59,429	30,412
Income (loss) from operations	(8,130)	(14,168)	(9,970)	(30,079)	815
Other (expense) income, net	(845)	(106)	(53)	(2,352)	(1,671)
Net loss	$ (9,017)	$(14,256)	$(10,099)	$(32,447)	$ (1,009)
Net income (loss) per share					
Basic	$ (0.54)	$ (0.87)	$ (0.63)	$ (2.07)	$ (0.07)
Diluted	$ (0.54)	$ (0.87)	$ (0.63)	$ (2.07)	$ (0.07)
Weighted average shares outstanding					
Basic	16,685	16,343	15,932	15,686	14,096
Diluted	16,685	16,343	15,932	15,686	14,096

Selected Balance Sheet Data

	As of December 31,				
	2018	2017	2016	2015	2014
Cash and cash equivalents	$12,185	$ 9,387	$ 8,585	$15,280	$32,220
Total current assets	21,220	21,209	19,933	27,767	44,616
Total assets	31,737	32,131	38,651	48,640	93,770
Total current liabilities	13,245	12,070	12,855	14,279	22,049
Long term deferred revenue	331	506	668	1,079	1,525
Notes and lease payable, long term	4,265	5,146	—	86	6,622
Convertible debentures payable to non-related parties, at fair value	6,300	—	—	—	—
Convertible debentures payable to related parties, at fair value	670	—	—	—	—
Stockholders' equity	$ 6,896	$14,276	$25,038	$32,746	$62,779

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

Results of Operations

Overview

iCAD, Inc. is a provider of advanced image analysis, workflow solutions and radiation therapy for the early identification and treatment of cancer. The Company reports in two segments — Cancer Detection ("Detection") and Cancer Therapy ("Therapy").

In the Detection segment, the Company's solutions include advanced image analysis and 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 mammography, Magnetic Resonance Imaging (MRI) and Computed Tomography (CT).

The Company intends to continue the extension of its image analysis and clinical decision support solutions for mammography, 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.

In the Therapy segment, the Company offers an isotope-free cancer treatment platform technology. The Xoft Electronic Brachytherapy System ("Xoft System") can be used for the treatment of early-stage breast cancer, endometrial cancer, cervical cancer and skin cancer. We believe the Xoft System platform indications represent strategic opportunities in the United States and International markets to offer differentiated treatment alternatives. In addition, the Xoft System generates additional recurring revenue for the sale of consumables and related accessories which will continue to drive growth in this segment.

On January 4, 2018, the Company adopted a plan to discontinue offering radiation therapy professional services to practices that provide the Company's electronic brachytherapy solution for the treatment of NMSC under the subscription service model within the Therapy Segment. As a result, the Company will no longer offer the subscription service model to customers. The Company will continue to offer its capital sales model for both skin cancer treatment and IORT, which provides a brachytherapy system and related source and service agreements. The discontinuance of the subscription service model reduced radiation therapy professional services delivery costs, decreased our cash burn, and re-focused the Company on the higher margin capital product and service offerings.

Based on the decision to discontinue offering radiation therapy professional services within the Cancer Therapy Segment, the Company revised its forecasts related to the Therapy segment, which we deemed to be a triggering event. As a result, the Company recorded a goodwill and long-lived asset impairment charge of approximately $2.0 million for the period ended December 31, 2017 (see Note h and Note i to the consolidated financial statements for additional discussion).

In connection with the preparation of the financial statements for the third quarter ended September 30, 2017, the Company evaluated the Therapy reporting unit for both long-lived asset and goodwill impairment. As a result of this assessment, the Company recorded a material impairment charge in the Therapy reporting unit (see Note h and Note i to the consolidated financial statements for additional discussion).

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 manufacturing facilities in Nashua, New Hampshire and, an operations, research, development, manufacturing and warehousing facility in San Jose, California.

Critical Accounting Policies

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 on-going 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 and the fair value of convertible notes. 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.

The Company's critical accounting policies include:

- Revenue recognition;
- Allowance for doubtful accounts;
- Inventory;
- Valuation of long-lived and intangible assets;
- Goodwill;
- Stock based compensation; and
- Income taxes; and

Revenue Recognition

Revenue Recognition upon the adoption of ASC 606

On January 1, 2018, the Company adopted FASB Accounting Standards Codification ("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. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605.

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 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. Components of certain fixed fee service contracts are accounted for as a lease in accordance with ASC 840, “Leases” (“ASC 840”). 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.

Revenue Recognition prior to the adoption of ASC 606

Prior to the adoption of Topic 606, revenue was recognized when delivery occurred, persuasive evidence of an arrangement existed, fees were fixed or determinable and collectability of the related receivable was probable, in accordance with Topic 605. For product revenue, delivery was considered to occur upon shipment provided title and risk of loss had passed to the customer. Services and supplies revenue was considered to be delivered as the services were performed or over the estimated life of the supply agreement.

The Company recognized revenue from the sale of its digital, film-based CAD and cancer therapy products and services in accordance with ASC Update No. 2009-13, "Multiple-Deliverable Revenue Arrangements" ("ASU 2009-13"), ASC Update No. 2009-14, "Certain Arrangements That Contain Software Elements" ("ASU 2009-14") and ASC 985-605, "Software" ("ASC 985-605"). Revenue from the sale of certain CAD products was recognized in accordance with ASC 840 "Leases" ("ASC 840"). For multiple element arrangements, revenue was allocated to all deliverables based on their relative selling prices. In such circumstances, a hierarchy was used to determine the selling price to be used for allocating revenue to deliverables as follows: (i) vendor-specific objective evidence of fair value ("VSOE"), (ii) third-party evidence of selling price ("TPE") and (iii) best estimate of the selling price ("BESP"). VSOE generally existed only when the deliverable was sold separately and was the price actually charged for that deliverable. The process for determining BESP for deliverables without VSOE or TPE considered multiple factors depending upon the unique facts and circumstances related to each deliverable including relative selling prices, competitive prices in the marketplace and management judgment.

The Company uses customer purchase orders that are subject to the Company's terms and conditions or, in the case of an Original Equipment Manufacturer ("OEM") are governed by distribution agreements. In accordance with the Company's distribution agreements, the OEM does not have a right of return, and title and risk of loss passes to the OEM upon shipment. The Company generally ships Free On Board shipping point and uses shipping documents and third-party proof of delivery to verify delivery and transfer of title. In addition, the Company assessed whether collection was probable by considering a number of factors, including past transaction history with the customer and the creditworthiness of the customer, as obtained from third party credit references.

If the terms of the sale included customer acceptance provisions and compliance with those provisions could not be demonstrated, all revenue was deferred and not recognized until such acceptance occurred. The Company considered all relevant facts and circumstances in determining when to recognize revenue, including contractual obligations to the customer, the customer's post-delivery acceptance provisions, if any, and the installation process.

The Company had determined that iCAD's digital and film based sales generally follow the guidance of FASB ASC Topic 605 "Revenue Recognition" ("ASC 605") as the software has been considered essential to the functionality of the product per the guidance of ASU 2009-14. Typically, the responsibility for the installation process lies with the OEM partner. On occasion, when iCAD is responsible for product installation, the installation element was considered a separate unit of accounting because the delivered product has stand-alone value to the customer.

Revenue from certain CAD products was recognized in accordance with ASC 985-605. Sales of this product includes training, and the Company had established VSOE for this element. Product revenue was determined based on the residual value in the arrangement and was recognized when delivered. Revenue for training was deferred and recognized when the training had been completed.

Sales of the Company's Therapy segment products typically include a controller, accessories, source agreements and services. The Company allocated revenue to the deliverables in the arrangement based on the BESP in accordance with ASU 2009-13. Product revenue was generally recognized when the product had been delivered and service and source revenue was typically recognized over the life of the service and source agreements. The Company includes the following in service and supplies revenue: the sale of physics and management services, the lease of electronic brachytherapy equipment, development fees, supplies and the right to use the Company's AxxentHub software. Physics and management services revenue and development fees were considered to be delivered as the services are performed or over the estimated life of the agreement. The Company typically bills items monthly over the life of the agreement except for development fees, which are generally billed in advance or over a 12 month period and the fee for treatment supplies which is generally billed in advance.

The Company deferred revenue from the sale of certain service contracts and recognized the related revenue on a straight-line basis in accordance with ASC Topic 605-20, "Services". The Company provided for estimated warranty costs on original product warranties at the time of sale.

See Note 1 for details of the Company's adoption of Topic 606 and accounting policies related to revenue recognition.

Allowance for Doubtful Accounts

The Company's policy is to maintain allowances for estimated losses from the inability of its customers to make required payments. Credit limits are established through a process of reviewing the financial results, stability and payment history of each customer. Where appropriate, the Company obtains credit rating reports and financial statements of customers when determining or modifying credit limits. 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 to the Company, it believes the allowance for doubtful accounts as of December 31, 2018 is adequate.

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 provision for excess and/or obsolete inventory primarily based upon historical usage of its inventory as well as other factors.

Goodwill

In accordance with FASB 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 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 ("CEO"). 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 Cancer Detection ("Detection") and Cancer Therapy ("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.

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.

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 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.

In January 2018, the Company adopted a plan to discontinue offering radiation therapy professional services to practices that provide the Company's electronic brachytherapy solution for the treatment of NMSC under the subscription service model within the Therapy Segment. As result, the Company will no longer offer the subscription service model to customers. Based on the decision to discontinue offering radiation therapy professional within the Therapy Segment, the Company revised its forecasts related to the Therapy segment, which we deemed to be a triggering event.

The Company elected to early adopt ASU 2017-04, "Intangibles—Goodwill and Other: Simplifying the Test for Goodwill Impairment" ("ASU 2017-04") during the year ended December 31, 2017, which affected the impairment tests performed during that period. ASU 2017-04 specifies that goodwill impairment is the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. In accordance with ASU 2017-04, the fair value of the Therapy reporting unit as of the fourth quarter of 2017 was $0.1 million and the carrying value was $2.1 million. The deficiency exceeded the carrying value of goodwill and the balance of $1.7 million was recorded as an impairment charge in the fourth quarter ended December 31, 2017.

As a result of the underperformance of the Therapy reporting unit as compared to expected future results, the Company determined there was a triggering event in the third quarter of 2017. As a result, the Company completed an interim impairment assessment. The interim test resulted in the fair value of the Therapy reporting unit being less than the carrying value of the reporting unit. The fair value of the Therapy reporting unit was $3.5 million and the carrying value was $7.5 million. The deficiency of $4.0 million was recorded as an impairment charge in the third quarter ended September 30, 2017. The Company did not identify a triggering event within the Detection reporting unit and accordingly did not perform an interim test.

The Company performed the annual impairment assessment at October 1, 2018 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 648%. Goodwill for the Therapy reporting unit was fully impaired as of 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 completed an interim goodwill impairment assessment for the Therapy reporting unit in the third quarter of 2017 and noted that there was an impairment of goodwill. As a result, the Company determined this was a triggering event to review long-lived assets for impairment. Accordingly, the Company completed an analysis pursuant to ASC 360-10-35-17 and determined that the carrying value of the asset group exceeded the undiscounted cash flows, and that long-lived assets were impaired. The Company recorded long-lived asset impairment charges of approximately $0.7 million in the third quarter ended September 30, 2017 based on the deficiency between the book value of the assets and the fair value as determined in the analysis. The Company has determined the “Asset Group” to be the assets of the Therapy segment, which the Company considered to be the lowest level for which the identifiable cash flows were largely independent of the cash flows of other assets and liabilities. The Company also completed a goodwill assessment in the fourth quarter of 2017, and in connection with that assessment, the Company completed an analysis pursuant to ASC 360-10-35-17 and determined that the 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 for the year ended December 31, 2018.

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 granted performance based restricted stock during 2017 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, 2018 and 2017 as it is more likely than not that the deferred tax asset will not be realized.

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.

In addition, uncertain tax positions and tax related valuation allowances assumed in connection with a business combination are initially estimated as of the acquisition date and the Company revaluates these items quarterly, with any adjustments to preliminary estimates being recorded to goodwill, provided that the Company is within the measurement period (which may be up to one year from the acquisition date) and continues to collect information in order to determine their estimated values. Subsequent to the measurement period or final determination of the tax allowance's or contingency's estimated value, changes to these uncertain tax positions and tax related valuation allowances may affect the provision for income taxes presented in the Company's statement of operations.

Year Ended December 31, 2018 compared to Year Ended December 31, 2017

Revenue. Revenue for the year ended December 31, 2018 was $25.6 million compared with revenue of $28.1 million for the year ended December 31, 2017, a decrease of $2.5 million or 8.8%. Therapy revenue decreased $1.0 million and Detection revenue decreased $1.4 million.

The table below presents the components of revenue for 2018 and 2017 (in thousands):

	For the year ended December 31,			
	2018	2017	Change	% Change
Detection revenue				
Product revenue	$10,783	$11,649	$ (866)	(7.4)%
Service and supplies revenue	6,081	6,661	(580)	(8.7)%
Subtotal	16,864	18,310	(1,446)	(7.9)%
Theraphy revenue				
Product revenue	2,328	1,905	423	22.2%
Service and supplies revenue	6,429	7,887	(1,458)	(18.5)%
Subtotal	8,757	9,792	(1,035)	(10.6)%
Total revenue	$25,621	$28,102	$(2,481)	(8.8)%

Detection revenues decreased 7.9% or $1.4 million from $18.3 million for the year ended December 31, 2017 to $16.9 million for the year ended December 31, 2018. Detection product revenue decreased by $0.9 million and Detection service revenue decreased $0.6 million. The $0.8 million decrease in Detection product revenue is due primarily to a $1.1 million decrease in OEM system sales offset by a $0.3 million increase in direct product sales. Detection service and supplies revenue decreased $0.6 million which is due primarily to the conversion and upgrade cycle from Secondlook digital to Tomo and 3D CAD.

Therapy revenue decreased 10.6% or $1.0 million to $8.8 million for the year ended December 31, 2018 from $9.8 million in the year ended December 31, 2017. The decrease in Therapy revenue was due to a decrease in Therapy service and supplies revenue of $1.5 million offset by an increase in Therapy product revenue of $0.4 million.

The increase in Therapy product revenue for the year ended December 31, 2018 is due primarily to an increase in controller sales in 2018. The decrease in Therapy service revenue is due to the decision to exit the Skin subscription business in January 2018.

Gross Profit. Gross profit was $19.4 million for the year ended December 31, 2018 compared to $18.2 million for the year ended December 31, 2017, an increase of $1.3 million. Therapy gross profit increased $2.7 million from $2.0 million in the year ended December 31, 2017 to $4.7 million in the year ended December 31, 2018. Detection gross profit decreased $1.5 million from $16.2 million in the year ended December 31, 2017 to $14.7 million in the year ended December 31, 2018. Detection gross profit decreased due primarily to the decrease in Detection sales.

Therapy gross profit increased due to the exit of the Skin subscription business which had an increased cost associated with the service delivery model that provided electronic brachytherapy solutions for the treatment of NMSC to Dermatology practices. In addition, the Company recorded an inventory reserve in cost of revenue for the year ended December 31, 2017 of approximately $1.0 million which is composed of $0.5 million in product and $0.5 million in service. In January 2018, the Company announced that the services to provide electronic brachytherapy solutions for the treatment of NMSC to Dermatology practices would be discontinued.

Gross profit percent was 75.8% for the year ended December 31, 2018 compared to 64.7% for the year ended December 31, 2017. Cost of revenue for the year ended December 31, 2017 includes the inventory reserve of $1.0 million, as noted above. 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 2018 and 2017 were as follows (in thousands):

	For the year ended December 31,			
	2018	2017	Change	% Change
Products	$ 2,161	$ 2,660	$ (499)	(18.8%)
Service and supplies	3,627	6,229	(2,602)	(41.8%)
Amortization and depreciation	403	1,037	(634)	(61.1%)
Total cost of revenue	6,191	9,926	(3,735)	(37.6%)
Gross profit	$19,430	$18,176	$ 1,254	6.9%
Gross profit %	75.8%	64.7%	11.2%	

	For the year ended December 31,			
	2018	2017	Change	% Change
Detection gross profit	$14,709	$16,218	$(1,509)	(9.3%)
Therapy gross profit	4,721	1,958	2,763	141.1%
Gross profit	$19,430	$18,176	$ 1,254	6.9%

Operating Expenses:

Operating expenses for 2018 and 2017 are as follows (in thousands):

	For the year ended December 31,			
	2018	2017	Change	% Change
Operating expenses:				
Engineering and product development	$ 9,445	$ 9,327	$ 118	1.3%
Marketing and sales	8,693	10,503	(1,810)	(17.2%)
General and administrative	9,117	7,877	1,240	15.7%
Amortization and depreciation	305	452	(147)	(32.5%)
Gain on sale of MRI assets	—	(2,508)	2,508	—
Goodwill and long-lived asset impairment	—	6,693	(6,693)	—
Total operating expenses	$27,560	$32,344	$(4,784)	(14.8%)

Engineering and Product Development. Engineering and product development costs for the year ended December 31, 2018 increased by $0.1 million or 1.3%, from $9.3 million in 2017 to $9.4 million in 2018. Therapy engineering and product development costs decreased by approximately $1.0 million and Detection engineering and product development costs increased by $1.1 million. The decrease in the Therapy segment is due primarily to a decrease in consulting costs and personnel expenses. The increase in Detection research and development expense is due to an increase in clinical expenses, consulting costs and personnel expenses.

Marketing and Sales. Marketing and sales expense for the year ended December 31, 2018 decreased by $1.8 million or 17.2%, from $10.5 million in 2017 to $8.7 million in 2018. Therapy marketing and sales expenses decreased approximately $2.2 million offset by an increase in Detection marketing and sales expenses of $0.4 million. The increase in Detection marketing and sales expense is due to an increase in personnel costs. The decrease in Therapy marketing and sales expense was due primarily to a decrease in personnel expenses, consulting costs, trade show expenses and stock compensation expense.

General and Administrative. General and administrative expenses for the year ended December 31, 2018 increased by $1.2 million or 15.7%, from $7.9 million in 2017 to $9.1 million in 2018. The increase in general and administrative expenses was due primarily to increases in severance costs, legal costs and bad debt expenses.

Amortization and Depreciation. Amortization and depreciation decreased by $0.2 million from $0.5 million to $0.3 million. The decrease is due primarily to the impairment of intangible assets and reductions due to assets that have become fully depreciated.

Gain from sale of MRI assets. The Company entered into an Asset Purchase Agreement with Invivo Corporation to sell certain MRI assets in December 2016 and the transaction closed on January 30, 2017. As a result, the Company recorded a gain on sale from MRI assets of $2.5 million in the first quarter of 2017.

Goodwill and long-lived asset impairment. The Company recorded an impairment charge of $4.7 million in the third quarter of 2017 and a goodwill and long-lived asset impairment charge of $2.0 million in the fourth quarter of 2017 for a total of $6.7 million in 2017. There were no impairment charges during fiscal year 2018.

Other Income and Expense (in thousands)

	For the year ended December 31,			
	2018	2017	Change	Change %
Interest expense	$(504)	$(124)	$ (380)	306.5%
Interest income	110	18	92	511.1%
Financing costs	(451)	—	(451)	—
	$(845)	$(106)	$ (739)	697.2%
Income tax (benefit) expense	$ 42	$ (18)	$ 60	(333.3)%

Interest Expense. The Company recorded $504,000 of interest expense in 2018 as compared with $124,000 of interest expense during the year ended December 31, 2017. In August 2017, the Company closed a debt facility with Silicon Valley Bank and as a result, interest expense has increased.

Interest income. Interest income of $110,000 and $18,000 for the years ended December 31, 2018, and 2017, respectively, reflects income earned from our money market accounts.

Financing costs. The Company recorded $451,000 of expenses in 2018 in connection with the subordinated convertible debt closed by the Company in December 2018.

Tax benefit (expense). The Company had tax expense of $42,000 for the year ended December 31, 2018 as compared to a tax benefit of $18,000 for the year ended December 31, 2017. Tax expense for the year ended December 31, 2018 is due primarily to state non-income and franchise based taxes. The tax benefit for the year ended December 31, 2017 is the result of applying for New Hampshire research and development credits, offset by state non-income and franchise based taxes.

Year Ended December 31, 2017 compared to Year Ended December 31, 2016

Revenue. Revenue for the year ended December 31, 2017 was $28.1 million compared with revenue of $26.3 million for the year ended December 31, 2016, an increase of $1.8 million or 6.7%. Therapy revenue increased $1.2 million and Detection revenue increased $0.6 million.

The table below presents the components of revenue for 2017 and 2016 (in thousands):

	For the year ended December 31,			
	2017	2016	Change	% Change
Detection revenue				
Product revenue	$11,649	$ 8,682	$ 2,967	34.2%
Service and supplies revenue	6,661	8,451	(1,790)	(21.2)%
Subtotal	18,310	17,133	1,177	6.9%
Therapy revenue				
Product revenue	1,905	1,789	116	6.5%
Service and supplies revenue	7,887	7,416	471	6.4%
Subtotal	9,792	9,205	587	6.4%
Total revenue	$28,102	$26,338	$ 1,764	6.7%

Detection revenues increased 6.9% or $1.2 million from $17.1 million for the year ended December 31, 2016 to $18.3 million for the year ended December 31, 2017. Detection product revenue increased by $3.0 million and Detection service revenue decreased $1.8 million. The increase in Detection product revenue is primarily due to a $4.1 million increase in digital CAD systems offset by a $1.0 million decrease in MRI products. The increase in digital CAD products is driven by increases in demand primarily from our OEM customers. In January 2017, we completed the sale of our MRI assets to Invivo. As a result MRI product revenue decreased $1.0 million and MRI service revenue decreased $0.9 million. Detection service and supplies revenue decreased $1.8 million due to decreases in MRI service revenue of $0.9 million and a decrease in digital service revenue of approximately $0.9 million. The decrease in digital service revenue is due primarily to the conversion and upgrade cycle from Secondlook digital to Tomo CAD.

Therapy revenue increased 6.4% or $0.6 million to $9.8 million for the year ended December 31, 2017 from $9.2 million in the year ended December 31, 2016. The increase in Therapy revenue was driven by an increase in Therapy product revenue of $0.1 million and an increase in Therapy service and supplies revenue of $0.5 million.

The increase in Therapy product and service revenue for the year ended December 31, 2017 is due primarily to an increase in international controller sales in 2017. The Company believes that the international market can continue to be a growth area for controller sales.

Gross Profit. Gross profit was $18.2 million for the year ended December 31, 2017 compared to $18.5 million for the year ended December 31, 2016, a decrease of $0.3 million, Therapy gross profit decreased $1.4 million from $3.4 million in the year ended December 31, 2016 to $2.0 million in the year ended December 31, 2017. Detection gross profit increased $1.1 million from $15.1 million in the year ended December 31, 2016 to $16.2 million in the year ended December 31, 2017. Detection gross profit increased due primarily to the increase in Detection product sales, which have higher gross profits than Detection service revenues.

Therapy gross profit decreased due to the increased cost associated with the service delivery model that provided electronic brachytherapy solutions for the treatment of NMSC to Dermatology practices. In addition, the Company recorded an inventory reserve in cost of revenue for the year ended December 31, 2017 of approximately $1.0 million which is composed of $0.5 million in product and $0.5 million in service. In January 2018, the Company announced that the services to provide electronic brachytherapy solutions for the treatment of NMSC to Dermatology practices would be discontinued. We believe that gross margins should improve in 2018 as a result of this decision.

Gross profit percent was 64.7% for the year ended December 31, 2017 compared to 70.3% for the year ended December 31, 2016. Cost of revenue for the year ended December 31, 2017 includes the inventory reserve of $1.0 million, as noted above. Cost of revenue for the year ended December 31, 2016 includes a credit of $0.5 million related to a refund of the Medical Device Excise Tax ("MDET"). 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 2017 and 2016 were as follows (in thousands):

	For the year ended December 31,			
	2017	2016	Change	% Change
Products	$ 2,660	$ 918	$ 1,742	189.8%
Service and supplies	6,229	5,713	516	9.0%
Amortization and depreciation	1,037	1,189	(152)	(12.8%)
Total cost of revenue	9,926	7,820	2,106	26.9%
Gross profit	$18,176	$18,518	$ (342)	(1.8%)
Gross profit %	64.7%	70.3%	(5.6%)	

	For the year ended December 31,			
	2017	2016	Change	% Change
Detection gross profit	$16,218	$15,113	$ 1,105	7.3%
Therapy gross profit	1,958	3,405	(1,447)	(42.5%)
Gross profit	$18,176	$18,518	$ (342)	(1.8%)

Operating Expenses:

Operating expenses for 2017 and 2016 are as follows (in thousands):

	For the year ended December 31,			
	2017	2016	Change	% Change
Operating expenses:				
Engineering and product development	$ 9,327	$ 9,518	$ (191)	(2.0%)
Marketing and sales	10,503	10,179	324	3.2%
General and administrative	7,877	7,675	202	2.6%
Amortization and depreciation	452	1,116	(664)	(59.5%)
Gain on sale of MRI assets	(2,508)	—	(2,508)	—
Goodwill and long-lived asset impairment	6,693	—	6,693	—
Total operating expenses	$32,344	$28,488	$ 3,856	13.5%

Engineering and Product Development. Engineering and product development costs for the year ended December 31, 2017 decreased by $0.2 million or 2.0%, from $9.5 million in 2016 to $9.3 million in 2017. Therapy engineering and product development costs decreased by approximately $0.4 million and Detection engineering and product development costs increased by $0.2 million. The decrease in the Therapy segment is due primarily to a decrease in personnel expenses, consulting costs and clinical trial expenses. The increase in Detection research and development expense is due to an increase in personnel expenses, primarily stock compensation.

Marketing and Sales. Marketing and sales expense for the year ended December 31, 2017 increased by $0.3 million or 3.2%, from $10.2 million in 2016 to $10.5 million in 2017. Therapy marketing and sales expenses decreased approximately $0.3 million and Detection marketing and sales expenses increased $0.6 million. The increase in Detection marketing and sales expense is due to an increase in commissions and stock compensation expense. The decrease in Therapy marketing and sales expense was due primarily to a decrease in personnel expenses.

General and Administrative. General and administrative expenses for the year ended December 31, 2017 increased by $0.2 million or 2.6%, from $7.7 million in 2016 to $7.9 million in 2017. The increase in general and administrative expenses was due primarily to increases in stock compensation expense, rent and consulting offset by a decrease in personnel expenses.

Amortization and Depreciation. Amortization and depreciation decreased by $0.6 million from $1.1 million to $0.5 million. The decrease is due primarily to the impairment of intangible assets and reductions due to assets that have become fully depreciated.

Gain from sale of MRI assets. The Company entered into an Asset Purchase Agreement with Invivo Corporation to sell certain MRI assets in December 2016 and the transaction closed on January 30, 2017. As a result, the Company recorded a gain on sale from MRI assets of $2.5 million in the first quarter of 2017.

Goodwill and long-lived asset impairment. The Company recorded an impairment charge of $4.7 million in the third quarter of 2017 and an impairment charge of $2.0 million in the fourth quarter of 2017 for a total of $6.7 million in 2017. There were no impairment charges during fiscal year 2016.

Other Income and Expense (in thousands)

	For the year ended December 31,			
	2017	2016	Change	Change %
Interest expense	$(124)	$(63)	$ (61)	96.8%
Interest income	18	10	8	80.0%
	$(106)	$(53)	$ (53)	100.0%
Income tax (benefit) expense	$ (18)	$ 76	$ (94)	(123.7)%

Interest Expense. The Company recorded $124,000 of interest expense in 2017 as compared with $63,000 of interest expense during the year ended December 31, 2016. In August 2017, the Company closed a debt facility with Silicon Valley Bank and as a result, interest expense has increased.

Interest income. Interest income of $18,000 and $10,000 for the years ended December 31, 2017, and 2016, respectively, reflects income earned from our money market accounts.

Tax benefit (expense). The Company had a tax benefit of $18,000 for the year ended December 31, 2017 as compared to tax expense of $76,000 for the year ended December 31, 2016. The tax benefit for the year ended December 31, 2017 is the result of applying for New Hampshire research and development credits, offset by state non-income and franchise based taxes. Tax expense for the year ended December 31, 2016 is due primarily to state non-income and franchise based taxes.

Segment Analysis

The Company operates in and reports results for two segments: Cancer Detection and Cancer 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, 2018, 2017, and 2016 are below (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Segment revenues:			
Detection	$16,864	$ 18,310	$ 17,133
Therapy	8,757	9,792	9,205
Total Revenue	$25,621	$ 28,102	$ 26,338
Segment gross profit:			
Detection	$14,709	$ 16,218	$ 15,113
Therapy	4,721	1,958	3,405
Segment gross profit	$19,430	$ 18,176	$ 18,518
Segment operating income (loss):			
Detection	$ 3,412	$ 6,401	$ 5,694
Therapy	(2,373)	(15,102)	(7,752)
Segment operating income (loss)	$ 1,039	$ (8,701)	$ (2,058)
General, administrative, depreciation and amortization expense	$ (9,169)	$ (7,975)	$ (7,912)
Interest expense	(504)	(124)	(63)
Financing costs	(451)	—	—
Gain on sale of MRI assets	—	2,508	—
Other income	110	18	10
Loss on debt extinguishment	—	—	—
Loss before income tax	$ (8,975)	$(14,274)	$(10,023)

Detection gross profit decreased to approximately $14.7 million or 87% of revenue for the year ended December 31, 2018 from $16.2 million or 89% of revenue for the year ended December 31, 2017. The decrease in Detection gross profit is due primarily to the decrease in revenue. Detection segment operating income for the year ended December 31, 2018 decreased by $3.0 million to $3.4 million from $6.4 million for the year ended December 31, 2017. The decrease in Detection segment operating income for the year ended December 31, 2018 as compared to the year ended December 31, 2017 was due primarily to the decrease in revenue and increased operating expenses for the year ended December 31, 2018 as compared to the year ended December 31, 2017. Detection operating expenses increased by $1.5 million to $11.3 million for the year ended December 31, 2018 as compared to $9.8 million for the year ended December 31, 2017, reflecting increased research and development and increased marketing and sales expenses, which is primarily clinical development costs, personnel related expenses and consulting costs.

Detection gross profit increased to approximately $16.2 million or 89% of revenue for the year ended December 31, 2017 from $15.1 million or 88% of revenue for the year ended December 31, 2016. Detection cost of sales also had a reduction of $0.2 million in 2016 related to Medical Device Excise tax refunds. Detection segment operating income for the year ended

December 31, 2017 increased by $0.7 million to $6.4 million from $5.7 million for the year ended December 31, 2016. The increase in segment operating income for the year ended December 31, 2017 as compared to the year ended December 31, 2016 was due primarily to the increase in revenue for the year ended December 31, 2017 as compared to the year ended December 31, 2016. Detection operating expenses increased by $0.4 million to $9.8 million for the year ended December 31, 2017 as compared to $9.4 million for the year ended December 31, 2016, reflecting increases in marketing and sales expenses, which is primarily increased commissions and personnel related expenses.

Therapy gross profit increased by approximately $2.7 million to $4.7 million or 54% of revenue for the year ended December 31, 2018 from approximately $2.0 million or 20% of revenue for the year ended December 31, 2017. The increase in Therapy gross profit is due primarily to the inventory reserve of $1.0 million and increased labor costs associated with the Therapy subscription business in the fiscal year ended December 31, 2017. Therapy operating expenses for the year ended December 31, 2018 were approximately $7.4 million as compared to $17.1 million for the year ended December 31, 2017. The decrease in operating expenses is due primarily to the goodwill and long-lived asset impairment charge of $6.7 million in the year ended December 31, 2017 as well as reductions in clinical expenses, consulting, personnel expenses and commissions. Therapy segment operating loss decreased to a loss of $2.4 million for the year ended December 31, 2018 from a loss of $15.1 million for the year ended December 31, 2017. The decrease in loss is due primarily to the impairment charges, and the increased labor costs related to the skin subscription business in the year ended December 31, 2017.

Therapy gross profit decreased by approximately $1.4 million to $2.0 million or 20% of revenue for the year ended December 31, 2017 from approximately $3.4 million or 37% of revenue for the year ended December 31, 2016. The decrease in Therapy gross profit is due primarily to the inventory reserve of $1.0 million and increased labor costs associated with the Therapy subscription business, which the Company exited in 2018. Therapy cost of sales also had a reduction of $0.3 million in 2016 related to Medical Device Excise tax refunds. Therapy operating expenses for the year ended December 31, 2017 were approximately $17.1 million as compared to $11.2 million for the year ended December 31, 2016. The increase in operating expenses is due primarily to the goodwill and long-lived asset impairment charge of $6.7 million offset by reductions in clinical expenses, research and development, and personnel expenses in marketing. Therapy segment operating loss increased to a loss of $15.1 million for the year ended December 31, 2017 from a loss of $7.8 million for the period ended December 31, 2016.

Liquidity and Capital Resources

The Company believes that its cash and cash equivalents balance of $12.2 million as of December 31, 2018, 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 had net working capital of $8.0 million at December 31, 2018. The ratio of current assets to current liabilities at December 31, 2018 and 2017 was 1.60 and 1.76, respectively. In December 2018, the Company successfully completed a $7 million private placement of unsecured subordinated convertible debentures. In January 2017, the Company closed an Asset Purchase agreement for $3.2 million with Invivo to sell certain MRI assets and received $2.9 million in cash, which was net of a $350,000 holdback in escrow. In August 2017 the Company entered into a debt facility that provided an initial term loan of $6.0 million and a $4.0 million revolving line of credit.

Net cash used for operating activities for the year ended December 31, 2018 was $3.9 million as compared to $7.3 million for 2017. The decrease in cash used for operating activities during the year ended December 31, 2018 was due primarily to the cash provided by operating assets and liabilities for 2018 of approximately $2.5 million as compared to cash used for changes in operating assets and liabilities of approximately $3.9 million, as well as an increased loss, net of adjustments, due to lower revenues in the fiscal year ended December 31, 2018. The change in operating assets was due primarily to a decrease in accounts receivable and inventories. We expect that changes in operating assets and liabilities will continue to be a significant driver of changes in cash used in or provided by operations.

The net cash used for investing activities for the year ended December 31, 2018 was $0.3 million, as compared to cash provided by investing activities of $2.5 million for the year ended December 31, 2017. The cash provided by investing activities in 2017 was due primarily to the proceeds from the sale of MRI assets. The cash used for investing activities in 2018 was due primarily to purchases of fixed assets.

Net cash provided by financing activities for the year ended December 31, 2018 was $7.0 million, which included the $7.0 million received from the convertible debentures. Net cash provided by financing activities for the year ended December 31, 2017 was $5.7 million, which was composed of $6.0 million received from the debt facility offset by taxes paid for restricted stock issuance.

The following table summarizes as of December 31, 2018, for the periods presented, the Company’s future estimated cash payments under existing contractual obligations, and the financing obligations as noted below (in thousands).

Contractual Obligations	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	5+ years
Operating Lease Obligations	$ 964	$ 781	$ 183	$ —	$ —
Capital Lease Obligations	26	15	11	—	—
Settlement Obligations	463	463	—	—	—
Notes Payable - principal and interest	6,957	2,275	4,682	—	—
Convertible Debentures - principal and interest	8,015	349	7,666	—	—
Other Commitments	2,323	2,136	85	28	74
Total Contractual Obligations	**$18,748**	**$ 6,019**	**$12,627**	**$ 28**	**$ 74**

Lease Obligations:

Operating Leases:

As of December 31, 2018, the Company had three lease obligations related to its facilities.

The Company's executive offices are leased pursuant to a five-year lease (the "Lease") that commenced on December 15, 2006, with renewals in January 2012 and August 2016, consisting of approximately 11,000 square feet of office space located at 98 Spit Brook Road, Suite 100 in Nashua, New Hampshire (the "Premises"). The August 2016 lease renewal provides for an annual base rent of $184,518 for the period from March 2017 to February 2020. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the Premises.

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 with annual payments of $295,140 through September 2017, with all amounts payable in equal monthly installments. In September 2016, the Company extended this

lease for the period from October 2017 to March 2020 with annual payments of $540,588 from October 2017 to September 2018, $558,120 from October 2018 to September 2019 and $286,368 for the period from October 2019 to March 2020, with all amounts payable in equal monthly installments. 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.

Capital 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.

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, 2018 the remaining liability for minimum royalty obligations totaling $0.4 million is recorded within accrued expenses and accounts payable.

Notes Payable:

On August 7, 2017, the Company entered into a Loan and Security Agreement, which has been modified by the First Loan Modification Agreement dated as of March 22, 2018, the Second Loan Modification Agreement dated as of August 13, 2018, the Third Loan Modification Agreement dated as of December 20, 2018, and the Fourth Loan Modification Agreement, dated as of March 15, 2019 (collectively, the “Loan Agreement”) with Silicon Valley Bank (the “Bank”) that provided an initial term loan facility (amounts borrowed thereunder, the “Initial Term Loan”) of $6.0 million and a $4.0 million revolving line of credit (amounts borrowed thereunder, the “Revolving Loans”). The Company also has the option to borrow an additional $3.0 million term loan under the Loan Agreement (amounts borrowed thereunder, the “Subsequent Term Loan” and together with the Initial Term Loan, the “Term Loan”), subject to meeting a Detection revenue minimum of at least $21.5 million for a trailing twelve month period ending on or prior to June 30, 2019.

The Company will begin repayment of the Initial Term Loan on March 1, 2019, in 30 equal monthly installments of principal, based on the amended terms of the Loan Agreement. The maturity date of the Initial Term Loan is August 1, 2021.

The Company will be required to begin repayment of the Subsequent Term Loan, if drawn, on October 1, 2019 and make 23 equal monthly installments of principal, as determined by the Third Loan Modification Agreement. The maturity date of the Subsequent Term Loan is August 1, 2021.

The maturity date of the Revolving Loans is March 1, 2022. However, the maturity date will become April 30, 2020 or April 30, 2021 if, after the Fourth Loan Modification Agreement, on or before March 15, 2020 or 2021, as applicable, the Company does not agree in writing to the Detection revenue and adjusted EBITDA covenant levels proposed by the Bank with respect to the upcoming 2020 or 2021 calendar year.

The outstanding Revolving Loans will accrue interest at a floating per annum rate equal to 1.50% above the prime rate for periods when the ratio of the Company's unrestricted cash to the Company's outstanding liabilities to the Bank, plus the amount of the Company's total liabilities that mature within one year is at least 1.25 to 1.0. At all other times, the interest rate shall be 0.50% above the prime rate. The outstanding Term Loans will accrue interest at a floating per annum rate equal to the prime rate.

If the Revolving Loans are paid in full and the Loan Agreement is terminated prior to the maturity date, then the Company will pay to the Bank a termination fee in an amount equal to two percent (2.0%) of the maximum revolving line of credit. If the Company prepays the Term Loans prior to the maturity date, then the Company will pay to the Bank an amount equal to 1.0% to 3.0% of the Term Loans, depending on when such Term Loans are repaid. In addition, the Loan Agreement requires the Company to pay a final payment of 8.5% of the Term Loans (which was increased by the Second Loan Modification Agreement from 8.0%) upon the earliest of the repayment of the Term Loans, the termination of the Loan Agreement and the maturity date. The Company is accruing such payment as additional interest expense. As of December 31, 2018, the accrued final payment is approximately $162,000 and is a component of the outstanding loan balance.

The Loan Agreement, as amended, required the Company to maintain minimum Detection revenues during the trailing six month period ending on December 31, 2018 of $8.75 million, and adjusted EBITDA during the trailing six month period ending on December 31, 2018 of $1.00. On December 20, 2018, in accordance with the Third Loan Modification agreement, the bank agreed to waive the covenants for the six month period ended December 31, 2018. Although the Bank has agreed to revise the covenants in prior periods, there is no guarantee that the Bank would be willing to revise the covenants in future periods.

Obligations to the Bank under the Loan Agreement or otherwise are secured by a first priority security interest in substantially all of the assets, including intellectual property, accounts receivable, equipment, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing, of each of the Company and Xoft, Inc. and Xoft Solutions LLC, wholly-owned subsidiaries of the Company.

Convertible Debentures:

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

The Company will pay interest to the Investors on the outstanding principal amount of the Convertible Debentures at the rate of 5.0% per annum, payable semi-annually on December 21st and June 21st, beginning on June 21, 2019, as well as on each conversion date (as to that principal amount then being converted) and on the maturity date. The Convertible Debentures mature on December 21, 2021.

At any time prior to the maturity date, the Convertible Debentures are convertible into shares of the Company's common stock at a conversion price of $4.00 per share, at the Investor's option, subject to certain anti-dilution adjustments. The Convertible Debentures contain a cap of shares to be issued upon the conversion of the Convertible Debentures at 19.99% of the issued and outstanding shares of the Company's Common Stock on December 21, 2018, unless shareholder approval of such issuance has been obtained. Upon the satisfaction of certain conditions, the Company has the right to cause the Investors to convert all or part of the then outstanding principal amount of the Convertible Debentures (a "Forced Conversion"). In connection with such Forced Conversion, the Company will be required to pay accrued but unpaid interest, an interest make whole amount determined based on the timing of the Forced Conversion and interest payments made to that date, liquidated damages and other amounts owing to the Investors under the Convertible Debentures. The conversion price in both the optional conversion and Forced Conversion provisions is subject to adjustment due to certain 'down-round' dilutive issuances as well for typical anti-dilutive actions, such as stock splits and stock dividends.

The Investors also have the right to require the Company to repurchase the Convertible Debentures, at a repurchase price that would be at least 115% of the then outstanding principal, plus any accrued but unpaid interest, upon the occurrence of an event of default, as defined in the SPA. The Convertible Debentures will also accrue interest upon an event of default at a rate of the lesser of 10.0% or the maximum permitted by law.

The Convertible Debentures also include certain liquidate damages provisions, whereby the Company will be required to compensate the Investors for certain contingent events, such as the failure to timely deliver conversion shares of common stock, failure to timely pay any accrued interest when due and failure to timely report public information.

The Convertible Debentures are unsecured and structurally subordinated to the Company's existing indebtedness. In connection with the issuance of the Convertible Debentures, the Company's subsidiaries entered into a Subsidiary Guarantee, dated as of December 20, 2018, for the benefit of the Investors, pursuant to which the subsidiaries guaranteed the Company's payments under the Convertible Debentures.

In connection with the issuance, on December 20, 2018, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Investors, pursuant to which the Company agreed to file a registration statement with the Securities and Exchange Commission ("SEC") to register the resale of shares of common stock underlying the Convertible Debentures on or prior to January 31, 2019. The Company will have to pay damages to the Investors if it fails to meet its obligations pursuant to the Registration Rights Agreement.

Certain Investors in the Convertible Debentures include directors and employees of the Company. These related parties purchased approximately 10% of the principal value of the Convertible Debentures, or $670,000. The Convertible Debentures issued to the related parties have substantially the same rights and provisions as the unrelated third party investors, with the exception of certain terms where the related parties received less favorable terms than the unrelated third parties (such as with determination of the make whole conversion rate, as defined in the SPA; or limits on the impact of potential 'down-round' adjustments to the conversion price).

Other Commitments:

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

Effect of New Accounting Pronouncements

Revenue Recognition

On January 1, 2018, the Company adopted the new accounting standard ASC 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. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605. See Note 1 for details of the impact of the Company's adoption of Topic 606 and the updated accounting policies related to revenue recognition.

Leases

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of

whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized over the term of the lease based on an effective interest method for a finance lease or on a straight line basis for an operating lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases unless it has elected as an accounting policy not to apply the recognition requirements under the new standard for leases with a term of 12 months or less (short-term leases). The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases.

For public companies, Topic 842 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period. The effective date for us is January 1, 2019. An entity may adopt the guidance either (1) retrospectively to each prior reporting period presented in the financial statements with a cumulative-effect adjustment recognized at the beginning of the earliest comparative period presented or (2) retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment. The Company will adopt the guidance retrospectively at the beginning of the period of adoption, January 1, 2019, through a cumulative-effect adjustment, and will not apply the new standard to comparative periods presented.

The new standard provides a number of practical expedients. Upon adoption, the Company will elect the transition package of practical expedients permitted within the new standard, which among other things, allows the carryforward of the historical lease classification. Further, upon implementation of the new guidance, the Company will elect the practical expedients for lessees to combine lease and non-lease components for all asset classes and adopt an accounting policy to not recognize right-of-use assets and lease liabilities for short-term leases for all asset classes. The Company will not elect the practical expedients to use hindsight in determining the lease term and assessing impairment of right-of-use assets. The Company will elect the practical expedients provided to lessors, including, in certain circumstances, to not separate nonlease components (which are accounted for under Topic 606) from the associated lease component, and to adopt an accounting policy to exclude sales and related taxes from consideration in the contract.

ASC 842 will impact the Company’s consolidated financial statements as the Company has operating lease arrangements for which it is the lessee. The Company has substantially identified a complete population of leases, including any embedded leases. Based on the Company’s portfolio of leases as of December 31, 2018, we estimate the impact of the adoption to be an increase in lease-related assets and liabilities of approximately $1.0 million on the Company’s consolidated balance sheet with no material impact on the results of operations, equity or cash flows. In addition, upon electing the practical expedient to combine lease and non-lease components under ASC 842, the Company does not expect the changes to lessor accounting to impact the amount or timing of revenue recognition, but will result in revenue to be recognized under ASC 606 because the nonlease component will be the predominant component in the arrangement. The Company has implemented new business processes and developed the appropriate controls related to the disclosures and accounting for leasing arrangements.

Financial Instruments

On January 1, 2018, the Company adopted FASB issued ASU 2016-01, "Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities" ("ASU 2016-01"), to update certain aspects of recognition, measurement, presentation and disclosure of financial instruments and applies to all entities that hold financial assets or owe financial liabilities. As a result of the adoption, the Company will be required to present the portion of the change in fair value of its financial liabilities measured using the fair value option that relates to changes in the Company's own credit risk as a component of other comprehensive income, rather than as a component of the change in fair value in current earnings. The Company did not have any financial instruments outstanding that would be impacted by ASU 2016-01 prior to the fourth quarter of 2018. The Company elected to account for the Convertible Debentures issued in December 2018 using the fair value option and considered the impact of ASU 2016-01 as part of that decision. The adoption of this standard did not have a material impact on the Company's financial statements for the year ended December 31, 2018.

In July 2017, the FASB issued ASU 2017-11, "Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815): (Part I.) Accounting for Certain Financial Instruments with Down Round Features, and (Part II.) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception" ("ASU 2017-11"). Among other provisions, ASU 2017-11 requires that when determining whether certain financial instruments should be classified as liabilities or equity instruments, an entity should not consider a down round feature. ASU 2017-11 also recharacterizes as a scope exception the indefinite deferral available to private companies with mandatorily redeemable financial instrument and certain noncontrolling interests, which does not have an accounting effect but addresses navigational concerns within the FASB Accounting Standards Codification. The provisions of the ASU related to down round features are effective for the Company for the fiscal year and interim periods therein beginning January 1, 2019. The Company does not currently expect that the adoption of ASU 2017-11 will have a material impact on its consolidated financial statements.

Stock Compensation

On January 1, 2018, the Company adopted FASB ASU 2017-09, "Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"). ASU 2017-09 specifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The adoption of this standard did not have a material impact on the Company's financial statements for the year ended December 31, 2018.

Statement of Cash Flows

On January 1, 2018, the Company adopted FASB ASU 2016-15, "Statement of Cash Flows (Topic 230)" ("ASU 2016-15"). This update is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The update requires cash

payments for debt prepayment or debt extinguishment costs to be classified as cash outflows for financing activities. It also requires cash payments made soon after an acquisition's consummation date (approximately three months or less) to be classified as cash outflows for investing activities. Payments made thereafter should be classified as cash outflows for financing activities up to the amount of the original contingent consideration liability. Payments made in excess of the amount of the original contingent consideration liability should be classified as cash outflows for operating activities. The adoption of ASU 2016-15 did not have a material impact on the consolidated financial statements.

On January 1, 2018, the Company adopted FASB ASU 2016-18, "Restricted Cash" ("ASU 2016-18"), which requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The amendments in this update should be applied using a retrospective transition method to each period presented. The adoption of this standard will change the presentation of the Company's statement of cash flows to include restricted cash balances with the non-restricted cash balances. The adoption of ASU 2016-18 did not otherwise have a material impact on the consolidated financial statements.

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, 2018.

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, 2018, 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, 2018.

(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, 2018, 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 following information includes information each director and executive officer has given us about his or her age, all positions he or she holds, his or her principal occupation and business experience for the past five years, and the names of other publicly-held companies of which he or she currently serves as a director or has served as a director during the past five years. In addition to the information presented below regarding each director's specific experience, qualifications, attributes and skills that led our Board to the conclusion that he or she should serve as a director, we also believe that all of our directors have a reputation for integrity, honesty and adherence to high ethical standards. They each have demonstrated business acumen and an ability to exercise sound judgment, as well as a commitment of service to iCAD and our Board.

There are no family relationships among any of the directors or executive officers of iCAD.

Name	Age	Position with iCAD	Director/Officer Since
Michael Klein	64	Chief Executive Officer, Chairman of the Board, and Director	2018
Rakesh Patel, MD	45	Director	2018
Andy Sassine	54	Director	2015
Susan Wood, MD	56	Director	2018
Richard Areglado	55	Interim Chief Financial Officer, V.P. and Corporate Controller	2019
Stacey Stevens	48	President	2006

The Company's Certificate of Incorporation provides for the annual election of all of its directors. The Board elects officers on an annual basis and our officers generally serve until their successors are duly elected and qualified.

Upon the recommendation of the Company's Nominating and Corporate Governance Committee, the Board of Directors fixed the size of the Company's Board at five directors. On January 7, 2019, Dr. Brem resigned from the board. There are currently four directors.

Mr. Michael Klein has served as the Chief Executive Officer at Inflection Point Consulting, an executive coaching and consulting firm with a focus on medical technology, biopharma and healthcare services, since December 2014. Prior to that, he was the Chief Executive Officer at US HIFU, LLC (f/k/a SonaCare Medical, LLC), a global leader in minimally invasive high intensity focused ultrasound technologies, from December 2011 to November 2014. From April 2011 to December 2011, Mr. Klein was the President of the Civco Radiation Oncology Division within Roper Industries, a diversified industrial company that produces engineered products for global niche markets. He was President and Chief Executive Officer of Xoft, Inc. ("Xoft"), a medical device company, a position he held from December 2004

until the sale of Xoft to the Company in December 2010. Prior to joining Xoft, from 2000 to 2004, Mr. Klein served as Chairman, President and Chief Executive Officer of R2 Technology, Inc., a breast and lung cancer computer aided detection company. Mr. Klein received a Bachelor of Arts degree from the University at Albany, SUNY. Mr. Klein also received his M.B.A. from the New York Institute of Technology and completed his post-graduate Executive Education Studies at Harvard University and Babson College. We believe Mr. Klein's qualifications to serve on our Board of Directors include his significant experience as an executive in the healthcare industry, his understanding of our products and markets and his previous tenure on our board.

Dr. Rakesh Patel has served as medical director of Radiation Oncology and Chair of the Multi-Disciplinary Breast Care Program at Good Samaritan Hospital since July 2013. In addition, he has served as co-founder of the TME Breast Care Network, a high-end physician peer-to-peer knowledge-sharing, research, education and consulting company, since January 2013. Dr. Patel has also served as Chief Executive Officer of Precision Cancer Specialists Medical Group, an organization whose core mission is to improve quality and access to advanced, targeted radiation therapy, since December 2016. He previously served on the board of directors of Radion, Inc., a company that improved quality of access for patients and doctors with an innovative e-collaboration platform, the assets of which were acquired by the Company in July 2014. Prior to that, Dr. Patel was the founder and served on the board of directors of BrachySolutions, Inc. (acquired by Radion Inc.), a telehealth company whose mission was to improve quality and access to advanced brachytherapy globally via custom e-learning modules. He holds a Bachelor of Science degree from the University of Notre Dame and an M.D. from Indiana University School of Medicine. Dr. Patel completed his radiation oncology residency at the University of Wisconsin-Madison. We believe Dr. Patel's qualifications to serve on our Board of Directors include his expertise in the medical field as well as his understanding of our products and market.

Mr. Andy Sassine currently serves as Chief Financial Officer of Arcturus Therapeutics, Ltd., which he also serves on its board of directors. Mr. Sassine also serves on the board of directors of Gemphire Therapeutics, Inc., a NASDAQ traded, clinical-stage biopharma focusing on developing and commercializing therapies for Dyslipidemia and NASH. Andy Sassine has served in various positions at Fidelity Investments from 1999 to 2012, rising to the position of Portfolio Manager. Prior to joining Fidelity, he served as a vice president in the Acquisition Finance Group at Fleet National Bank. Mr. Sassine previously served on the boards of MYnd Analytics, Inc., Acorn energy, Freedom Meditech, Inc., and MD Revolution. Mr. Sassine was a member of the Henry B. Tippie College of Business, University of Iowa Board of Advisors from 2009 till 2018 and served on the Board of Trustees at the Clarke Schools for Hearing and Speech from 2009 through 2014. Mr. Sassine holds a Bachelor of Arts degree from the University of Iowa and an MBA from the Wharton School at the University of Pennsylvania. We believe Mr. Sassine's extensive knowledge and experience as a fund manager and board member of other companies of a similar size to our company qualifies him to serve as a member of our Board of Directors.

Dr. Susan Wood has served as the President and Chief Executive Officer of Vida Diagnostics, Inc., a leader in precision imaging and AI for pulmonary medicine, since September 2009. Previously, she held the position of Executive Vice President of Marketing and

Technology for Vital Images, Inc., an innovative software company specializing in cardiovascular applications for advanced analysis software, from July 2005 until December 2008. Dr. Wood has been issued multiple patents in the field of computer-aided detection and quantitative imaging; authored numerous book chapters, peer-reviewed papers, abstracts, and served as an invited speaker at numerous conferences in the area of three-dimensional imaging of the thorax, quantitative imaging and computer-aided detection. She holds a Bachelor of Science in Engineering from the University of Maryland, College Park and an M.S. in Biomedical Engineering from Duke University. Additionally, Dr. Wood received her Ph.D. from the Johns Hopkins Medical Institutions, School of Hygiene and Public Health. We believe Dr. Wood's qualifications to serve on our Board of Directors include her expertise in the medical field her prior business experience in the medical field and her knowledge of our markets.

Audit Committee and Audit Committee Financial Expert

Our Board of Directors maintains an Audit Committee which is composed of Mr. Sassine (Chair), Dr. Wood and Dr. Patel. Our Board has determined that each member of the Audit Committee meets the definition of an "Independent Director" under applicable NASDAQ Marketplace Rules. In addition, the Board has determined that each member of the Audit Committee meets the independence requirements of applicable SEC rules and that Mr. Sassine qualifies as an "audit committee financial expert" under applicable SEC rules.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires certain of our officers and our directors, and persons who own more than 10 percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors, and greater than 10 percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of copies of such forms received by us, we believe that during the year ended December 31, 2018; all filing requirements applicable to all of our officers, directors, and greater than 10% beneficial stockholders were timely complied with.

Code of Ethics

We have developed and adopted a comprehensive Code of Business Conduct and Ethics to cover all of our employees. Copies of the Code of Business Conduct and Ethics can be obtained, without charge, upon written request, addressed to:

iCAD, Inc.
98 Spit Brook Road, Suite 100
Nashua, NH 03062
Attention: Corporate Secretary

Item 11. Executive Compensation.

The Company will furnish to the Securities and Exchange Commission a definitive proxy statement not later than 120 days after the end of the fiscal year ended December 31, 2018. The response to this item will be contained in our proxy statement for our 2019 annual meeting of stockholders under the captions “Executive Compensation,” “Compensation of Directors,” “Compensation Committee Interlocks and Insider Participation,” and “Compensation Committee Report,” and is incorporated herein by reference.

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

The response to this item will be contained in our proxy statement for our 2019 annual meeting of stockholders in part under the caption “Stock Ownership of Certain Beneficial Owners and Management” and in part below.

Equity Compensation Plans

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2018.

Plan Category:	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders:	1,983,477	$ 4.25	965,719
Equity compensation plans not approved by security holders (1):	0	$ 0.00	-0-
Total	1,983,477	$ 4.25	965,719

(1) Represents the aggregate number of shares of common stock issuable upon exercise of individual arrangements with non-plan option holders. See Note 6 of Notes to our consolidated financial statements for a description of our Stock Option and Stock Incentive Plans and certain information regarding the terms of the non-plan options.

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

The response to this item will be contained in our proxy statement for our 2019 annual meeting of stockholders under the captions “Certain Relationships and Related Transactions,” “Corporate Governance Matters — Director Independence” and “Compensation Committee Report, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The response to this item will be contained in our proxy statement for our 2019 annual meeting of stockholders under the caption “Ratification of Appointment of Independent Registered Public Accounting Firm,” 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 XX.

ii. Financial Statement Schedule - See Index on page XX. 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:

EXHIBIT INDEX

2(a) Agreement and Plan of Merger dated December 15, 2010 by and among the Registrant, XAC, Inc., Xoft, Inc. and Jeffrey Bird as representative of the Xoft, Inc.'s stockholders (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K for the event dated December 30, 2010). **

2(b) Asset Purchase Agreement by and between iCAD, Inc. and Radion, Inc., dated as of July 15, 2014. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K for the event dated July 15, 2014). **

2(c) Asset Purchase Agreement by and between iCAD, Inc. and DermEbx, a series of Radion Capital Partners, LLC, dated as of July 15, 2014. (incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K for the event dated July 15, 2014). **

2(d) Asset Purchase Agreement by and between iCAD, Inc. and Invivo Corporation. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K for the event dated December 22, 2016). **

3(a) Certificate of Incorporation of the Registrant as amended through June 16, 2015 (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 6, 2015).

3(b) Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3 (b) to the Registrant's Report on Form 10-K for the year ended December 31, 2007).

4(a) Registration Rights Agreement, dated as of December 29, 2011 (incorporated by reference to Exhibit 4.3 of the Registrant's report on Form 8-K filed with the SEC on January 3, 2012).

4(b) Form of Debenture (incorporated by reference to Exhibit 4.1 of the Registrant's report on Form 8-K filed with the SEC on December 27, 2018).

10(a) 2002 Stock Option Plan (incorporated by reference to Annex F to the Registrant's Registration Statement on Form S-4/A (File No. 333-86454)).*

10(b) 2004 Stock Incentive Plan (incorporated by reference to Exhibit B to the Registrant's definitive proxy statement on Schedule 14A filed with the SEC on May 28, 2004).*

10(c) Form of Option Agreement under the Registrant's 2002 Stock Option Plan (incorporated by reference to Exhibit 10.2 to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2004).*

10(d) Form of Option Agreement under the Registrant's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2004).*

10(e) 2005 Stock Incentive Plan (incorporated by reference to Exhibit B to the Registrant's report on Form DEF14A filed with the SEC on May 25, 2005).*

10(f) Form of Option Agreement under the Registrant's 2005 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's report on Form 8-K filed with the SEC on June 28, 2005).*

10(g) 2016 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2016).

10(h) Form of Indemnification Agreement with each of the Registrant's directors and officers (incorporated by reference to Exhibit 10.1 of Registrant's Quarterly report on Form 10-Q for the quarter ended September 30, 2014).

10(i) Lease Agreement dated December 6, 2006 between the Registrant 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 Registrant's Report on Form 10-K for the year ended December 31, 2006).

10(j) 2007 Stock Incentive Plan, as amended (incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed with the SEC on May 6, 2009). *

10(k) Form of Option Agreement under the Registrant's 2007 Stock Incentive Plan. (incorporated by reference to Exhibit 10(vv) to the Registrant's Report on Form 10-K for the year ended December 31, 2009)*

10(l) Form of Restricted Stock Agreement under the Registrant's 2007 Stock Incentive Plan. (incorporated by reference to Exhibit 10(ww) to the Registrant's Report on Form 10-K for the year ended December 31, 2009).*

10(m) Employment Agreement entered into as of September 25, 2012 between the Registrant and Kenneth Ferry (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on September 26, 2012) *

10(n) Employment Agreement entered into as of June 1, 2008 between the Registrant and Stacey Stevens (incorporated by reference to Exhibit 10.8 of the Registrant's report on Form 10-Q filed with the SEC on August 8, 2008). *

10(o) Employment Agreement dated as of June 1, 2008 between the Registrant and Jonathan Go (incorporated by reference to Exhibit 10.9 of the Registrant's report on Form 10-Q filed with the SEC on August 8, 2008). *

10(p) Change in Control Bonus Agreement dated October 29, 2015 between the Registrant and Ken Ferry (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 4, 2015).*

10(q) Change in Control Bonus Agreement dated October 29, 2015 between the Registrant and Stacey Stevens (incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 4, 2015).*

10(r) Asset Purchase Agreement dated December 16, 2016 between the Registrant and Invivo Corporation (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on December 22, 2016).

10(s) Employment Agreement dated November 4, 2016 between the Registrant and Richard Christopher (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on November 10, 2016).

10(t) First Amendment to Lease dated September 19, 2016 between the Registrant and The Irvine Company (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on September 21, 2016).

10(u) Employment Agreement dated December 22, 2016 between the Registrant and Kenneth Ferry (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on December 28, 2016).

10(v) Amendment No. 1 to Employment Agreement dated as of June 1, 2008 between the Registrant and Stacey M. Stevens (incorporated by reference to Exhibit 10.2 of the Registrant's report on Form 8-K filed with the SEC on December 28, 2016).

10(w) Loan and Security Agreement dated August 7, 2017 by and among Silicon Valley Bank, the Company, Xoft, Inc. and Xoft Solutions, LLC (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on August 10, 2017).

10(x)	2012 Stock Incentive Plan (incorporated by reference to Appendix B to the Registrant's definitive proxy statement on Schedule 14A filed with the SEC on April 9, 2012).*
10(y)	Amendment No. 1 to the 2012 Stock Incentive Plan (incorporated by reference to Appendix A to the Registrant's definitive proxy statement on Schedule 14A filed with the SEC on April 2, 2014).*
10(z)	First Loan Modification Agreement dated March 22, 2018 by and among Silicon Valley Bank, the Company, Xoft, Inc. and Xoft Solutions, LLC (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on March 23, 2018).
10(aa)	Second Loan Modification Agreement dated August 31, 2018 by and among Silicon Valley Bank, the Company, Xoft, Inc. and Xoft Solutions, LLC (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 10-Q filed with the SEC on August 14, 2018).
10(bb)	Third Loan Modification Agreement dated December 20, 2018 by and among Silicon Valley Bank, the Company, Xoft, Inc. and Xoft Solutions, LLC (incorporated by reference to Exhibit 10.4 of the Registrant's report on Form 8-K filed with the SEC on December 27, 2018).
10(cc)	Fourth Loan Modification Agreement dated March 18, 2019 by and among Silicon Valley Bank, the Company, Xoft, Inc. and Xoft Solutions, LLC (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on March 21, 2019).
10(dd)	Employment Agreement between the Company and Michael Klein dated November 19, 2018 (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on November 20, 2018).
10(ee)	Form of Securities Purchase Agreement by and among the Company and certain investors party thereto (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on December 27, 2018).
10(ff)	Form of Subsidiary Guarantee (incorporated by reference to Exhibit 10.2 of the Registrant's report on Form 8-K filed with the SEC on December 27, 2018).
10(gg)	Form of Registration Rights Agreement by and among the Company and certain investors party thereto (incorporated by reference to Exhibit 10.3 of the Registrant's report on Form 8-K filed with the SEC on December 27, 2018).
10(hh)	Cooperation Agreement between the Company and Andy Sassine dated October 18, 2018 (incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 10-Q filed with the SEC on November 14, 2018).
21	Subsidiaries

23	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, 2018 and December 31, 2017, (ii) Consolidated Statements of Operations for the twelve months ended December 31, 2018 and 2016 and 2015, (iii) Consolidated Statements of Cash Flows for the twelve months ended December 31, 2018 and 2017 and 2016, and (iv) Notes to Consolidated Financial Statements.
*	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. Summary.

None

SIGNATURES

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

Date: March 29, 2019

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

Pursuant to the requirements of the Securities Exchange Act of 1934, 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 29, 2019
/s/ R. Scott Areglado R. Scott Areglado	Interim Chief Financial Officer, Vice President and Corporate Controller (Principal Financial and Accounting Officer)	March 29, 2019
/s/ Rakesh Patel Rakesh Patel, MD	Director	March 29, 2019
/s/ Andy Sassine Andy Sassine	Director	March 29, 2019
/s/ Susan Wood Susan Wood, MD	Director	March 29, 2019

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders 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") and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, 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 and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ BDO USA, LLP
We have served as the Company's auditor since 1989.
Boston, Massachusetts
March 29, 2019

iCAD, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
	(in thousands except shares and per share data)	
Assets		
Current assets:		
Cash and cash equivalents	$ 12,185	$ 9,387
Trade accounts receivable, net of allowance for doubtful accounts of $177 in 2018 and $107 in 2017	6,403	8,599
Inventory, net	1,587	2,123
Prepaid expenses and other current assets	1,045	1,100
Total current assets	21,220	21,209
Property and equipment:		
Equipment	6,020	5,722
Leasehold improvements	62	62
Furniture and fixtures	308	305
Marketing assets	376	376
	6,766	6,465
Less accumulated depreciation and amortization	6,214	5,889
Net property and equipment	552	576
Other assets:		
Other assets	53	53
Intangible assets, net of accumulated amortization of $7,809 in 2018 and $7,433 in 2017	1,550	1,931
Goodwill	8,362	8,362
Total other assets	9,965	10,346
Total assets	$ 31,737	$ 32,131
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,154	$ 1,362
Accrued expenses	5,060	4,475
Notes payable - current portion	1,851	817
Capital lease payable, short-term portion	15	12
Deferred revenue	5,165	5,404
Total current liabilities	13,245	12,070
Other long-term liabilities	27	119
Deferred revenue, long-term portion	331	506
Notes payable, long-term portion	4,254	5,119
Convertible debentures payable to non-related parties, at fair value	6,300	—
Convertible debentures payable to related parties, at fair value	670	—
Capital lease - long-term portion	11	27
Deferred tax	3	14
Total liabilities	24,841	17,855
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 17,066,510 in 2018 and 16,711,512 in 2017; outstanding 16,880,679 in 2018 and 16,525,681 in 2017	171	167
Additional paid-in capital	218,914	217,389
Accumulated deficit	(210,774)	(201,865)
Treasury stock at cost, 185,831 shares in 2018 and 2017	(1,415)	(1,415)
Total stockholders' equity	6,896	14,276
Total liabilities and stockholders' equity	$ 31,737	$ 32,131

See accompanying notes to consolidated financial statements.

iCAD, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

	For the Years Ended December 31,		
	2018	2017	2016
	(in thousands except per share data)		
Revenue:			
Products	$ 13,111	$ 13,554	$ 10,471
Service and supplies	12,510	14,548	15,867
Total revenue	25,621	28,102	26,338
Cost of Revenue:			
Products	2,161	2,660	918
Service and supplies	3,627	6,229	5,713
Amortization and depreciation	403	1,037	1,189
Total cost of revenue	6,191	9,926	7,820
Gross profit	19,430	18,176	18,518
Operating expenses:			
Engineering and product development	9,445	9,327	9,518
Marketing and sales	8,693	10,503	10,179
General and administrative	9,117	7,877	7,675
Amortization and depreciation	305	452	1,116
Gain on sale of MRI assets	—	(2,508)	—
Goodwill and long-lived asset impairment	—	6,693	—
Total operating expenses	27,560	32,344	28,488
Loss from operations	(8,130)	(14,168)	(9,970)
Other expense			
Interest expense	(504)	(124)	(63)
Interest income	110	18	10
Financing costs	(451)	—	—
Other expense, net	(845)	(106)	(53)
Loss before income tax expense	(8,975)	(14,274)	(10,023)
Income tax (benefit) expense	42	(18)	76
Net loss and comprehensive loss	$ (9,017)	$ (14,256)	$ (10,099)
Net loss per share:			
Basic	$ (0.54)	$ (0.87)	$ (0.63)
Diluted	$ (0.54)	$ (0.87)	$ (0.63)
Weighted average number of shares used in computing loss per share:			
Basic	16,685	16,343	15,932
Diluted	16,685	16,343	15,932

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, 2015	15,923,349	$ 159	$211,512	$ (177,510)	$(1,415)	$ 32,746
Issuance of common stock relative to vesting of restricted stock, net of 27,299 shares forfeited for tax obligations	261,731	3	(117)	—	—	(114)
Issuance of common stock pursuant to stock option plans	75,583	1	197	—	—	198
Stock-based compensation	—	—	2,307	—	—	2,307
Net loss	—	—	—	(10,099)	—	(10,099)
Balance at December 31, 2016	16,260,663	$ 163	$213,899	$ (187,609)	$(1,415)	$ 25,038
Issuance of common stock relative to vesting of restricted stock, net of 55,115 shares forfeited for tax obligations	414,319	4	(245)	—	—	(241)
Issuance of common stock pursuant to stock option plans	36,530	—	79	—	—	79
Stock-based compensation	—	—	3,656	—	—	3,656
Net loss	—	—	—	(14,256)	—	(14,256)
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

See accompanying notes to consolidated financial statements.

iCAD, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	For the Years Ended December 31,		
	2018	2017	2016
		(in thousands)	
Cash flow from operating activities:			
Net loss	$ (9,017)	$(14,256)	$(10,099)
Adjustments to reconcile net loss to net cash used for operating activities:			
Amortization	383	494	983
Depreciation	325	995	1,322
Bad debt provision	225	45	177
Inventory obsolesence reserve	—	1,052	114
Stock-based compensation expense	1,505	3,656	2,307
Amortization of debt discount and debt costs	170	—	(23)
Gain from acquisition settlement	—	—	(249)
Goodwill and long-lived asset impairment	—	6,693	—
Interest on settlement obligations	—	26	82
Deferred tax	(12)	8	7
Loss on disposal of assets	12	52	10
Gain on sale of MRI assets	—	(2,158)	—
Changes in operating assets and liabilities, net of acquisition:			
Accounts receivable	2,003	(3,474)	2,201
Inventory	536	554	482
Prepaid and other assets	172	29	(504)
Accounts payable	(209)	(215)	(16)
Accrued expenses	494	(505)	309
Deferred revenue	(454)	(333)	(2,581)
Total adjustments	5,150	6,919	4,621
Net cash used for operating activities	(3,867)	(7,337)	(5,478)
Cash flow from investing activities:			
Additions to patents, technology and other	(15)	(5)	(12)
Additions to property and equipment	(301)	(390)	(337)
Acquisition of VuComp M-Vu CAD	—	—	(6)
Sale of MRI assets	—	2,850	—
Net cash provided by (used for) investing activities	(316)	2,455	(355)
Cash flow from financing activities:			
Issuance of common stock for cash, net			—
Stock option exercises	204	79	198
Taxes paid related to restricted stock issuance	(180)	(241)	(114)
Debt issuance costs	—	(74)	—
Principal payments of capital lease obligations	(13)	(80)	(946)
Proceeds from debt financing	—	6,000	—
Proceeds from convertible debentures	6,970	—	—
Net cash provided by (used for) financing activities	6,981	5,684	(862)
Increase (decrease) in cash and equivalents	2,798	802	(6,695)
Cash and equivalents, beginning of year	9,387	8,585	15,280
Cash and equivalents, end of year	$12,185	$ 9,387	$ 8,585
Supplemental disclosure of cash flow information:			
Interest paid	$ 294	$ 79	$ 70
Taxes paid	$ 51	$ 60	$ 67
Escrow due from MRI asset sale	$ —	350	—
Equipment purchased under capital lease	$ —	42	—

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 provider of advanced image analysis, workflow solutions and radiation therapy for the early identification and treatment of cancer.

The Company has grown primarily through acquisitions to become a broad player in the oncology market. Its solutions include advanced image analysis and 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 mammography, 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 mammography, 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 manufacturing and contract manufacturing facilities in New Hampshire and Massachusetts, 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.

In January 2018, the Company adopted a plan to discontinue offering radiation therapy professional services to practices that provide the Company's electronic brachytherapy solution for the treatment of non-melanoma skin cancer under the subscription service model within the Therapy Segment.

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) 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.

(c) 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, 2018 approximated $11.9 million.

(d) Financial instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, 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, 2018 and 2017.

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 4(b) for further details.

(e) 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, 2018 and 2017 is adequate.

The following table summarizes the allowance for doubtful accounts for the three years ended December 31, 2018 (in thousands):

	2018	2017	2016
Balance at beginning of period	$ 107	$ 172	$ 236
Additions charged to costs and expenses	225	45	177
Reductions	(155)	(110)	(241)
Balance at end of period	$ 177	$ 107	$ 172

(f) 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, 2018 and 2017, inventories consisted of the following (in thousands), which includes an inventory reserve of approximately $1.1 million and $1.2 million as December 31, 2018 and 2017, respectively.

	As of December 31,	
	2018	2017
Raw materials	$ 606	$ 992
Work in process	67	63
Finished Goods	914	1,068
Inventory	$ 1,587	$ 2,123

(g) 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

(h) 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.

In January 2018, the Company adopted a plan to discontinue offering radiation therapy professional services to practices that provide the Company's electronic brachytherapy solution for the treatment of non-melanoma skin cancer under the subscription service model within the Therapy Segment. As result, the Company no longer offers the subscription service model to customers. Based on the decision to discontinue offering radiation therapy professional services within the Therapy Segment, the Company revised its forecasts related to the Therapy segment, which the Company deemed to be a triggering event.

The Company elected to early adopt ASU 2017-04, “Intangibles – Goodwill and Other: Simplifying the Test for Goodwill Impairment” (“ASU 2017-04”) as of September 30, 2017 which affected both the third quarter and fourth quarter impairment tests. ASU 2017-04 specifies that goodwill impairment is the amount by which a reporting unit’s carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. In accordance with the standard, the fair value of the Therapy reporting unit as of the fourth quarter was $0.1 million and the carrying value was $2.1 million. The deficiency exceeded the carry value of goodwill and the balance of $1.7 million was recorded as an impairment charge in the fourth quarter of the year ended December 31, 2017.

As a result of the underperformance of the Therapy reporting unit as compared to expected future results, the Company determined there was a triggering event in the third quarter of 2017. As a result, the Company completed an interim impairment assessment. The interim test resulted in the fair value of the Therapy reporting unit being less than the carrying value of the reporting unit. The fair value of the Therapy reporting unit was $3.5 million and the carrying value was $7.5 million. The deficiency of $4.0 million was recorded as an impairment charge in the third quarter of the year ended December 31, 2017. The Company did not identify a triggering event within the Detection reporting unit and accordingly did not perform an interim test.

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 assessment at October 1, 2018 and compared the fair value of each reporting unit to its carrying value as of this date. The fair value exceeded the carrying value for the Detection reporting unit as of the date of this impairment assessment. 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 year ended December 31, 2018. 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.

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 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 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):

	Detection	Therapy	Total
Accumulated Goodwill	$ —	$ —	$ 47,937
Accumulated impairment	—	—	(26,828)
Fair value allocation	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	—	(13,981)	(13,981)
Balance at December 31, 2016	8,362	5,735	14,097
Impairment	—	(5,735)	(5,735)
Balance at December 31, 2017	8,362	—	8,362
	—	—	—
Balance at December 31, 2018	$ 8,362	$ —	$ 8,362
Accumulated Goodwill	699	6,270	49,171
Fair value allocation	7,663	13,446	—
Accumulated impairment	—	(19,716)	(40,809)
Balance at December 31, 2018	$ 8,362	$ —	$ 8,362

(i) 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.

The Company completed an interim goodwill impairment assessment for the Therapy reporting unit in the third quarter of 2017 and noted that there was an impairment of goodwill. As a result, the Company determined this was a triggering event to review long-lived assets for impairment. The Company determined the "Asset Group" to be the assets of the Therapy segment, which the Company considered to be the lowest level for which the identifiable cash flows were largely independent of the cash flows of other assets and liabilities. Accordingly, the Company completed an analysis pursuant to ASC 360-10-35-17 and determined that the carrying value of the asset group exceeded the undiscounted cash flows, and that long-lived assets were impaired. The Company recorded long-lived asset impairment charges of approximately $0.7 million in the third quarter of the year ended December 31, 2017 based on the deficiency between the book value of the assets and the fair value as determined in the analysis.

The Company also completed a goodwill assessment in the fourth quarter of 2017, and in connection with that assessment, the Company completed an analysis pursuant to ASC 360-10-35-17 and determined that the 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 for the years ended December 31, 2018 or 2016.

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 15 years. A summary of intangible assets for 2018 and 2017 are as follows (in thousands):

	2018	2017	Weighted average useful life
Gross Carrying Amount			
Patents and licenses	$ 571	$ 556	5 years
Technology	8,257	8,257	10 years
Customer relationships	272	292	7 years
Tradename	259	259	10 years
Total amortizable intangible assets	9,359	9,364	
Accumulated Amortization			
Patents and licenses	$ 511	$ 503	
Technology	6,958	6,610	
Customer relationships	81	61	
Tradename	259	259	
Total accumulated amortization	7,809	7,433	
Total amortizable intangible assets, net	$1,550	$1,931	

Amortization expense related to intangible assets was approximately $383,000, $494,000 and $983,000 for the years ended December 31, 2018, 2017, and 2016, respectively. Estimated remaining amortization of the Company's intangible assets is as follows (in thousands):

For the years ended December 31:	Estimated amortization expense
2019	$ 422
2020	304
2021	226
2022	297
2023	100
Thereafter	201
	$ 1,550

(j) Revenue Recognition

Revenue Recognition Upon Adoption of ASC 606

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. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605.

We 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 our 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.

The cumulative effect of the changes made to the Company's consolidated balance sheet for the adoption of Topic 606 were as follows (in thousands):

Selected Balance Sheet	Balance at December 31, 2017	Adjustments Due to ASU 2014-09	Balance at January 1, 2018
Assets			
Prepaid expenses and other current assets	$ 1,100	$ 147	$ 1,247
Liabilities			
Deferred revenue	—	408	408
Contract liabilities	5,910	(369)	5,541
Stockholders' equity			
Accumulated deficit	(201,865)	108	(201,973)

In accordance with the requirements of the new standard, the disclosure of the impact of the adoption on our consolidated balance sheet and statement of operations was as follows (in thousands):

	As of December 31, 2018		
Selected Balance Sheet	As Reported	Balances without Adoption of ASC 606	Effect of Change Increase (Decrease)
Assets			
Prepaid expenses and other current assets	$ 1,045	$ 763	$ (282)
Liabilities			
Accrued expenses	5,060	5,060	—
Deferred revenue	287	287	—
Contract liabilities	5,209	5,209	—
Deferred tax	3	2	(1)
Stockholders' equity			
Accumulated deficit	(210,774)	(211,056)	(282)

The impact to revenues as a result of applying Topic 606 for the year ended December 31, 2018 was an increase of $116,000 (table in thousands).

Selected Statement of Operations	Year ended December 31, 2018		
	As Reported	Balances without Adoption of ASC 606	Effect of Change Increase (Decrease)
Revenue			
Products	$ 13,111	$ 12,944	$ 167
Service and supplies	12,510	12,561	(51)
Cost of revenue			
Products	2,161	2,161	—
Service and supplies	3,627	3,627	—
Operating expenses			
Marketing and sales	8,693	8,975	(282)
Interest expense	(504)	(504)	—
Other income	110	110	—
Tax benefit (expense)	42	42	—
Net loss	(9,017)	(9,415)	(398)

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 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. 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 our revenues disaggregated by major good or service line, timing of revenue recognition and sales channel, reconciled to our reportable segments (in thousands).

	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

	Year ended December 31, 2017(1)		
	Reportable Segments		
	Detection	Therapy	Total
Major Goods/Service Lines			
Products	$ 11,650	$ 4,763	$ 16,413
Service contracts	5,687	1,482	7,169
Supply and source usage agreements	—	1,956	1,956
Professional services	—	254	254
Other	388	1,337	1,725
	$ 17,725	$ 9,792	$ 27,517
Timing of Revenue Recognition			
Goods transferred at a point in time	11,684	5,266	$ 16,814
Services transferred over time	6,041	4,526	10,703
	$ 17,725	$ 9,792	$ 27,517
Sales Channels			
Direct sales force	$ 7,787	$ 8,354	$ 16,141
OEM partners	9,938	—	9,938
Channel partners	—	1,438	1,438
	$ 17,725	$ 9,792	$ 27,517
Total Revenue			
Revenue from contracts with customers	$ 17,725	$ 9,792	$ 27,517
Revenue from lease components	585	—	585
	$ 18,310	$ 9,792	$ 28,102

(1) As noted above, prior period amounts have not been adjusted under the modified retrospective method.

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. As lease contracts are not within the scope of Topic 606, the Company accounts for the lease components of these arrangements in accordance with ASC 840 and the remaining consideration is allocated to the other performance obligations identified in accordance with Topic 606. The

consideration allocated to the lease component is 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, is recognized on a straight-line basis over the term of the agreement. The service contracts range from 12 months to 48 months. The Company typically receives payment at the inception of the contract and recognizes revenue on a straight-line basis over the term of the agreement.

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

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

Other. Other revenue consists primarily of miscellaneous products and services. The Company transfers control and recognizes a sale when the installation services are performed or when the Company ships the product from our 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 we sell 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, and contract assets are a component of prepaid and other current assets. The following table provides information about receivables, contract assets, and contract liabilities from contracts with customers (in thousands).

	Balance at December 31, 2018
Receivables, which are included in 'Trade accounts receivable'	$ 6,252
Contract assets, which are included in "Prepaid and other current assets"	19
Contract liabilities, which are included in "Deferred revenue"	5,209

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 opening balance of accounts receivable from contracts with customers, net of allowance for doubtful accounts, was $8.5 million as of January 1, 2018. As of December 31, 2018, accounts receivable, net of allowance for doubtful accounts, was $6.3 million.

The Company records a contract asset for unbilled revenue when the Company's performance is in excess of amounts billed or billable. The Company has classified the contract asset balance as a component of prepaid expenses and other current assets as of January 1, 2018 and December 31, 2018. The opening balance of contract assets was $166,000 as of January 1, 2018. As of December 31, 2018, the contract asset balance was $19,000.

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 we have been paid in advance and earn the revenue when we transfer control of the product or service. Deferred revenue from contracts with customers is included in deferred revenue in the consolidated balance sheets. Deferred revenue on the consolidated balance sheet also includes $369,000 and $287,000 at December 31, 2017 and December 31, 2018, respectively of amounts associated with service contracts accounted for under Topic 840. The balance of deferred revenue at December 31, 2017 and December 31, 2018 is as follows (in thousands):

December 31, 2017	Contract liabilities	Lease revenue	Total
Short term	$ 5,044	$ 360	$ 5,404
Long term	497	9	506
Total	$ 5,541	$ 369	$ 5,910

December 31, 2018	Contract liabilities	Lease revenue	Total
Short term	$ 4,885	$ 280	$ 5,165
Long term	324	7	331
Total	$ 5,209	$ 287	$ 5,496

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

	Year Ended December 31, 2018
Balance at beginning of period	$ 5,541
Adoption adjustment	39
Deferral of revenue	9,993
Recognition of deferred revenue	(10,364)
Balance at end of period	$ 5,209

We expect to recognize approximately $4.9 million of the deferred amount in 2019, $0.2 million in 2020, and $0.1 million thereafter.

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

We recognize 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. We have determined that certain commissions programs meet the requirements to be capitalized. The opening balance of capitalized costs to obtain a contract was $117,000 as of January 1, 2018. As of December 31, 2018, the balance of capitalized costs to obtain a contract was $282,000. The Company has classified the capitalized costs to obtain a contract as a component of prepaid expenses and other current assets as of January 1, 2018 and December 31, 2018.

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

	Year Ended December 31, 2018
Balance at beginning of period	$ 117
Deferral of costs to obtain a contract	368
Recognition of costs to obtain a contract	(203)
Balance at end of period	$ 282

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 we recognize revenue at the amount to which we have the right to invoice for services performed.

Revenue Recognition Prior to the Adoption of ASC 606

The Company's reporting periods prior to the adoption of ASC 606 and the year ended December 31, 2018 are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605.

Under Topic 605, revenue was recognized when delivery occurred, persuasive evidence of an arrangement existed, fees were fixed or determinable and collectability of the related receivable was probable. For product revenue, delivery was considered to occur

upon shipment provided title and risk of loss had passed to the customer. Services and supplies revenue was considered to be delivered as the services were performed or over the estimated life of the supply agreement. Revenue from the sale of certain CAD products was recognized in accordance with ASC 840, which continues to be the case under Topic 606. In addition, revenue from certain CAD products was recognized in accordance with ASC 985-605, which has now been superseded by Topic 606. For multiple element arrangements, revenue was allocated to all deliverables based on their relative selling prices. In such circumstances, a hierarchy was used to determine the selling price to be used for allocating revenue to deliverables as follows: (i) vendor-specific objective evidence of fair value ("VSOE"), (ii) third-party evidence of selling price ("TPE") and (iii) best estimate of the selling price ("BESP"). VSOE generally existed only when the deliverable was sold separately and was the price actually charged for that deliverable. The process for determining BESP for deliverables without VSOE or TPE considered multiple factors depending upon the unique facts and circumstances related to each deliverable including relative selling prices, competitive prices in the marketplace and management judgment.

The Company historically determined that iCAD's digital and film based sales generally followed the guidance of ASC 605 as the software was considered essential to the functionality of the product per the guidance of ASU 2009-14. Typically, the responsibility for the installation process lies with the OEM partner. On occasion, when iCAD was responsible for product installation, the installation element was considered a separate unit of accounting because the delivered product had standalone value to the customer. In these instances, the Company allocated the revenue to the deliverables based on the framework established within ASU 2009-13. Therefore, the installation and training revenue was recognized as the services were performed according to the BESP of the element. Revenue from the digital and film based equipment when there was installation was recognized based on the relative selling price allocation of the BESP, when delivered.

Revenue from certain CAD products was recognized in accordance with ASC 985-605. Sales of this product include training, and the Company had established VSOE for this element. Product revenue was determined based on the residual value in the arrangement and was recognized when delivered. Revenue for training was deferred and recognized when the training had been completed. For multiple element arrangements, the Company allocated revenue to the deliverables in the arrangement based on the BESP in accordance with ASU 2009-13. Product revenue was generally recognized when the product had been delivered and service and/or supplies revenue was typically recognized over the life of the service and/or supplies agreement. Physics and management services revenue and development fees were considered to be delivered as the services were performed or over the estimated life of the agreement. The Company deferred revenue from the sale of certain service contracts and recognized the related revenue on a straight-line basis in accordance with ASC 605-20, "Services."

(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. Included in cost of revenue for the year ended December 31, 2016 is a credit of $491,000 related to a refund of the Medical Device Excise Tax ("MDET"). The MDET refund of $491,000 for the year ended December 31, 2016 related to refunds of the MDET for the periods from April 2013 to December 2015. The MDET refund was not material to the year ended December 31, 2016 or to any prior period and as such no prior periods were restated. There have been no MDET refunds received by the Company subsequent to the year ended December 31, 2016.

(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, 2018, 2017 and 2016, were as follows (in thousands):

	2018	2017	2016
Beginning accrual balance	$ 10	$ 11	$ 19
Warranty provision	19	49	47
Usage	(17)	(50)	(55)
Ending accrual balance	$ 12	$ 10	$ 11

(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, 2018, 2017 and 2016 was approximately $811,000, $990,000 and $955,000 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):

	2018	2017	2016
Net loss available to common shareholders	$ (9,017)	$(14,256)	$(10,099)
Basic shares used in the calculation of earnings per share	16,685	16,343	15,932
Effect of dilutive securities:			
Stock options	—	—	—
Restricted stock	—	—	—
Diluted shares used in the calculation of earnings per share	16,685	16,343	15,932
Net loss per share :			
Basic	$ (0.54)	$ (0.87)	$ (0.63)
Diluted	$ (0.54)	$ (0.87)	$ (0.63)

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:

	2018	2017	2016
Common stock options	1,983,477	1,465,115	1,425,348
Restricted Stock	423,202	415,147	511,398
Convertible Debentures	1,742,500	—	—
	4,149,179	**1,880,262**	**1,936,746**

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, 2018 and 2017, 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 follows FASB ASC Topic 718, "*Compensation – Stock Compensation*" ("ASC 718"), 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. The Company granted performance based restricted stock during 2016 based on the achievement of certain revenue targets. Compensation cost for performance based restricted stock 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.

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, and 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, and are considered a Level 3 measurement due to the utilization of significant unobservable inputs in their valuation. See Note 4(b) 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:

Fair Value Measurements (000's) as of December 31, 2018	Level 1	Level 2	Level 3	Total
Assets				
Money market accounts	$12,134	$ —	$ —	$12,134
Total Assets	$12,134	$ —	$ —	$12,134
Liabilities				
Convertible debentures	$ —	$ —	$6,970	$ 6,970
Total Liabilities	$ —	$ —	$6,970	$ 6,970

Fair Value Measurements (000's) as of December 31, 2017	Level 1	Level 2	Level 3	Total
Assets				
Money market accounts	$8,853	$ —	$ —	$8,853
Total Assets	$8,853	$ —	$ —	$8,853

The following is a roll forward of the Company's Level 3 instruments for the year ended December 31, 2018:

	Convertible Debentures
Balance, December 20, 2018	$ —
Issuances	6,970
Fair value adjustments	—
Balance, December 31, 2018	$ 6,970

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. In 2017, the Company recorded a $6.7 million impairment consisting of $5.7 million related to goodwill and $1.0 million related to long-lived and other assets. The fair values of long-lived assets and goodwill were measured using Level 3 inputs. There were no items measured at fair value on a nonrecurring basis as of or during the year ended December 31, 2018.

(s) Recently Issued and Recently Adopted Accounting Standards

Recently Adopted Accounting Standards

On January 1, 2018, the Company adopted the new accounting standard ASC 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. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605. See Note 1 for details of the impact of the Company's adoption of Topic 606 and the updated accounting policies related to revenue recognition.

On January 1, 2018, the Company adopted FASB issued ASU 2016-01, “Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities” (“ASU 2016-01”), to update certain aspects of recognition, measurement, presentation and disclosure of financial instruments and applies to all entities that hold financial assets or owe financial liabilities. As a result of the adoption, the Company will be required to present the portion of the change in fair value of its financial liabilities measured using the fair value option that relates to changes in the Company’s own credit risk as a component of other comprehensive income, rather than as a component of the change in fair value in current earnings. The Company did not have any financial instruments outstanding that would be impacted by ASU 2016-01 prior to the fourth quarter of 2018. The Company elected to account for the Convertible Debentures issued in December 2018 using the fair value option and considered the impact of ASU 2016-01 as part of that decision. The adoption of this standard did not have a material impact on the Company’s financial statements for the year ended December 31, 2018.

On January 1, 2018, the Company adopted FASB ASU 2017-09, “Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting” (“ASU 2017-09”). ASU 2017-09 specifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The adoption of this standard did not have a material impact on the Company’s financial statements for the year ended December 31, 2018.

On January 1, 2018, the Company adopted FASB ASU 2016-15, “Statement of Cash Flows (Topic 230)” (“ASU 2016-15”). This update is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The update requires cash payments for debt prepayment or debt extinguishment costs to be classified as cash outflows for financing activities. It also requires cash payments made soon after an acquisition’s consummation date (approximately three months or less) to be classified as cash outflows for investing activities. Payments made thereafter should be classified as cash outflows for financing activities up to the amount of the original contingent consideration liability. Payments made in excess of the amount of the original contingent consideration liability should be classified as cash outflows for operating activities. The adoption of ASU 2016-15 did not have a material impact on the consolidated financial statements.

On January 1, 2018, the Company adopted FASB ASU 2016-18, “Restricted Cash” (“ASU 2016-18”), which requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The amendments in this update should be applied using a retrospective transition method to each period presented. The adoption of this standard will change the presentation of the Company’s statement of cash flows to include restricted cash balances with the non-restricted cash balances. The adoption of ASU 2016-18 did not otherwise have a material impact on the consolidated financial statements.

Recently Issued Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized over the term of the lease based on an effective interest method for a finance lease or on a straight line basis for an operating lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases unless it has elected as an accounting policy not to apply the recognition requirements under the new standard for leases with a term of 12 months or less (short-term leases). The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases.

For public companies, Topic 842 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period. The effective date for us is January 1, 2019. An entity may adopt the guidance either (1) retrospectively to each prior reporting period presented in the financial statements with a cumulative-effect adjustment recognized at the beginning of the earliest comparative period presented or (2) retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment. The Company will adopt the guidance retrospectively at the beginning of the period of adoption, January 1, 2019, through a cumulative-effect adjustment, and will not apply the new standard to comparative periods presented.

The new standard provides a number of practical expedients. Upon adoption, the Company will elect the transition package of practical expedients permitted within the new standard, which among other things, allows the carryforward of the historical lease classification. Further, upon implementation of the new guidance, the Company will elect the practical expedients for lessees to combine lease and non-lease components for all asset classes and adopt an accounting policy to not recognize right-of-use assets and lease liabilities for short-term leases for all asset classes. The Company will not elect the practical expedients to use hindsight in determining the lease term and assessing impairment of right-of-use assets. The Company intends to elect the practical expedients provided to lessors, including, in certain circumstances, to not separate nonlease components (which are accounted for under Topic 606) from the associated lease component, and to adopt an accounting policy to exclude sales and related taxes from consideration in the contract.

ASC 842 will impact the Company’s consolidated financial statements as the Company has operating lease arrangements for which it is the lessee. The Company has substantially identified a complete population of leases, including any embedded leases. Based on the Company’s portfolio of leases as of December 31, 2018, we estimate the

impact of the adoption to be an increase in lease-related assets and liabilities of approximately $1.0 million on the Company's consolidated balance sheet with no material impact on the results of operations, equity or cash flows. In addition, upon electing the practical expedient to combine lease and non-lease components under ASC 842, the Company does not expect the changes to lessor accounting to impact the amount or timing of revenue recognition, but will result in revenue to be recognized under ASC 606 because the nonlease component will be the predominant component in the arrangement. The Company has implemented new business processes and developed the appropriate controls related to the disclosures and accounting for leasing arrangements.

In July 2017, the FASB issued ASU 2017-11, "Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815): (Part I.) Accounting for Certain Financial Instruments with Down Round Features, and (Part II.) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception" ("ASU 2017-11"). Among other provisions, ASU 2017-11 requires that when determining whether certain financial instruments should be classified as liabilities or equity instruments, an entity should not consider a down round feature. ASU 2017-11 also recharacterizes as a scope exception the indefinite deferral available to private companies with mandatorily redeemable financial instrument and certain noncontrolling interests, which does not have an accounting effect but addresses navigational concerns within the FASB Accounting Standards Codification. The provisions of the ASU related to down round features are effective for the Company for the fiscal year and interim periods therein beginning January 1, 2019. The Company does not currently expect that the adoption of ASU 2017-11 will have a material impact on its consolidated financial statements.

(t) Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

On March 15, 2019, the Company and Silicon Valley Bank entered into the Fourth Loan Modification Agreement related to the Company's Loan and Security Agreement. The modification revises certain covenants such that the Company must maintain minimum consolidated revenues of $11.4 million, $11.6 million, $13.0 million and $14.5 million during the trailing six month periods ending on March 31, 2019, June 30, 2019, September 30, 2019 and December 31, 2019, respectively, as well as adjusted EBITDA levels of $(3.5 million), $(4.0 million), $(4.0 million) and $(2.0 million) during the trailing six month periods ending on March 31, 2019, June 30, 2019, September 30, 2019 and December 31, 2019, respectively. In addition, the Company and Silicon Valley Bank will be required to negotiate the covenants for the 2020 and 2021 fiscal years, with a failure to agree to such covenants by specified dates in the agreement leading to an acceleration of the Initial Term Loan maturity date to either April 30, 2020 or April 31, 2021, respectively.

(2) Acquisitions

Acquisition of VuComp Cancer detection portfolio

On January 13, 2016, the Company completed the acquisition of the VuCOMP cancer detection portfolio, including the M-Vu computer aided detection (CAD) technology platform. The acquisition includes an extensive library of related clinical data, VuCOMP's key personnel and the customer base that existed at closing of the transaction. The acquisition of the key personnel and clinical data is expected to contribute to the ongoing development of the Company's CAD technology which will be used for future cancer detection research and patents. As the Company considered this to be a business combination, the assets were valued in accordance with ASC Topic 805, "Business Combinations" ("ASC 805").

As noted below, the Company acquired VuComp's M-Vu Breast Density product in April 2015. In connection with the diligence of the January 2016 acquisition, VuComp disclosed that it had previously entered into a license agreement pursuant to which it issued an irrevocable, royalty-free worldwide license to a third party. On December 24, 2015, iCAD notified VuComp of a claim under the April 2015 asset purchase agreement based on the disclosure of the third party license agreement, which iCAD believed constituted a breach of VuComp's representation as to its exclusive ownership of its intellectual property at the time of the April 2015 transaction. In connection with the purchase of the VuComp cancer detection portfolio, the Company provided a release of the aforementioned claim. The Company determined that this claim was a component of the purchase price. The Company determined the value of litigation settlement as the excess of the fair value of the business acquired over the cash consideration paid. As a result the Company recorded a gain on litigation settlement of $249,000 in the first quarter of 2016, which is a component of the purchase price as noted below:

	Amount (000's)
Cash	$ 6
Acquisition litigation settlement	249
Purchase price	$ 255

The amount allocated to the acquired assets was estimated primarily through the use of discounted cash flow valuation techniques. Appraisal assumptions utilized under this method include a forecast of estimated future net cash flows, as well as discounting the

future net cash flows to their present value. The following is a summary of the allocation of the total purchase price based on the estimated fair values as of the date of the acquisition and the amortizable life:

	Amount (000's)	Estimated amortizable life
Current assets	$ 84	
Property and equipment	65	3 Years
Identifiable intangible assets	699	1-10 Years
Goodwill	293	
Current liabilities	(280)	
Long-term liabilities	(606)	
Purchase price	$ 255	

The assets obtained in the acquisition of VuComp's M-Vu Cancer detection portfolio (including the M-Vu breast density product) and the anticipated future revenues are included in the Detection segment and, accordingly, the goodwill resulting from the purchase price allocation is included in goodwill of the Detection segment. The Company has tax basis in the goodwill that resulted from the VuComp acquisition of $293,000 which is amortized over a 15 year period.

Acquisition of VuComp M-Vu Breast Density Assets:

On April 29, 2015, pursuant to the terms of the Asset Purchase Agreement with VuComp, the Company purchased VuComp's M-Vu Breast Density asset for $1,700,000 in cash. The Company considered the acquisition to be an acquisition of a business as the Company acquired the Breast Density product and certain customer liabilities which were considered to be an integrated set of activities at acquisition. Under the terms of the agreement, the Company acquired the breast density intellectual property product, which has been integrated with the Company's PowerLook Advanced Mammography Platform (AMP). PowerLook AMP is a modular solution designed to provide advanced tools for breast disease detection and analysis, including CAD for tomosynthesis. As the Company considered this to be a business combination, the assets were valued in accordance with ASC Topic 805, "*Business Combinations*" ("ASC 805").

The amount allocated to the acquired assets was estimated primarily through the use of discounted cash flow valuation techniques. Appraisal assumptions utilized under this method include a forecast of estimated future net cash flows, as well as discounting the future net cash flows to their present value. The acquired technology is being amortized over the estimated useful life of approximately eight years and nine months from the

closing of the transaction. The following is a summary of the allocation of the total purchase price based on the estimated fair values as of the date of the acquisition and the amortizable life (in thousands):

	Amount	Estimated Amortizable Life
Developed Technology	$ 900	8 years 9 months
Goodwill	800	
Purchase price	$1,700	

The assets obtained in the acquisition of VuComp's M-Vu Breast Density product and the anticipated future revenues are included in the Detection segment and, accordingly, the goodwill resulting from the purchase price allocation is included in goodwill of the Detection segment. The goodwill is deductible for income tax purposes.

(3) Sale of MRI Assets

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. The holdback reserve of $350,000 has been recorded as an asset in other assets and will be paid to the Company within eighteen months from the closing date, less any amounts, if any, due and payable or reserved under the indemnification provisions in the Asset Purchase agreement. See Note 9(g) *Litigation*.

The Company determined the sale constituted the sale of a business in accordance with ASC 805. The Company performed an evaluation to determine if the sale constituted discontinued operations and concluded that the sale did not represent a major strategic shift, and accordingly it was not considered to be discontinued operations. In connection with the transaction, the Company allocated $394,000 of goodwill which was a component of the gain on the sale. The allocation was based on the fair value of the assets sold relative to the fair value of the Detection reporting unit as of the date of the agreement, based on the guidance from ASC 350-20-40-3.

The value of the net assets sold is as follows (in thousands):

Assets	
Accounts Receivable	$ 116
Intangible assets	810
Allocated Goodwill	394
Total Assets	$1,320
Liabilities	
Deferred Revenue	$ 746
Total Liabilities	$ 746
Net Assets Sold	$ 574

In connection with the sale the Company agreed to provide certain transition services to Invivo. The fair value of the transition services were determined based on the cost to provide plus a reasonable profit margin and have been recognized as revenue over the term of approximately ninety days from the closing date. The Company recorded a gain of $2.5 million as of January 30, 2017. The components of the gain on the sale are as follows (in thousands):

Gain on Sale	
Cash received	$2,850
Holdback reserve	350
Fair value of transition services	(118)
Net Assets sold	(574)
Total	$2,508

(4) Financing Arrangements

(a) Loan and Security Agreement

On August 7, 2017, the Company entered into a Loan and Security Agreement, which has been modified by the First Loan Modification Agreement dated as of March 22, 2018, the Second Loan Modification Agreement dated as of August 13, 2018, and the Third Loan Modification Agreement dated as of December 20, 2018 (collectively, the "Loan Agreement") with Silicon Valley Bank (the "Bank") that provided an initial term loan facility (amounts borrowed thereunder, the "Initial Term Loan") of $6.0 million and a $4.0 million revolving line of credit (amounts borrowed thereunder, the "Revolving Loans"). The Company also has the option to borrow an additional $3.0 million term loan under the Loan Agreement (amounts borrowed thereunder, the "Subsequent Term Loan" and together with the Initial Term Loan, the "Term Loan"), subject to meeting a Detection revenue minimum of at least $21.5 million for a trailing twelve month period ending on or prior to June 30, 2019.

The Company began repayment of the Initial Term Loan on March 1, 2019, with 30 equal monthly installments of principal, based on the amended terms of the Loan Agreement. The maturity date of the Initial Term Loan is August 1, 2021.

The Company will be required to begin repayment of the Subsequent Term Loan, if drawn, on October 1, 2019 and make 23 equal monthly installments of principal, as determined by the Third Loan Modification Agreement. The maturity date of the Subsequent Term Loan is August 1, 2021.

The maturity date of the Revolving Loans is March 1, 2022. However, the maturity date will become April 30, 2020 or April 30, 2021 if (after the Fourth Loan Modification Agreement, see Note 1(t) *Subsequent Events*), on or before March 15, 2020 or 2021, as applicable, the Company does not agree in writing to the Detection revenue and adjusted EBITDA covenant levels proposed by the Bank with respect to the upcoming 2020 or 2021 calendar year.

The outstanding Revolving Loans will accrue interest at a floating per annum rate equal to 1.50% above the prime rate for periods when the ratio of the Company's unrestricted cash to the Company's outstanding liabilities to the Bank, plus the amount of the Company's total liabilities that mature within one year is at least 1.25 to 1.0. At all other times, the interest rate shall be 0.50% above the prime rate. The outstanding Term Loans will accrue interest at a floating per annum rate equal to the prime rate.

If the Revolving Loans are paid in full and the Loan Agreement is terminated prior to the maturity date, then the Company will pay to the Bank a termination fee in an amount equal to two percent (2.0%) of the maximum revolving line of credit. If the Company prepays the Term Loans prior to the maturity date, then the Company will pay to the Bank an amount equal to 1.0% to 3.0% of the Term Loans, depending on when such Term Loans are repaid. In addition, the Loan Agreement requires the Company to pay a final payment of 8.5% of the Term Loans (which was increased by the Second Loan Modification Agreement from 8.0%) upon the earliest of the repayment of the Term Loans, the termination of the Loan Agreement and the maturity date. The Company is accruing such payment as additional interest expense. As of December 31, 2018, the accrued final payment is approximately $162,000 and is a component of the outstanding loan balance.

The Loan Agreement, as amended, required the Company to maintain minimum Detection revenues during the trailing six month period ending on December 31, 2018 of $8.75 million, and adjusted EBITDA during the trailing six month period ending on December 31, 2018 of $1.00. On December 21, 2018, the Bank agreed to waive the covenants for the six month trailing period ended December 31, 2018. Although the Bank has agreed to revise the covenants in prior periods, there is no guarantee that the Bank would be willing to revise the covenants in future periods.

Obligations to the Bank under the Loan Agreement or otherwise are secured by a first priority security interest in substantially all of the assets, including intellectual property, accounts receivable, equipment, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing, of each of the Company and Xoft, Inc. and Xoft Solutions LLC, wholly-owned subsidiaries of the Company.

In connection with the Loan Agreement, the Company incurred approximately $74,000 of closing costs. In accordance with ASC Topic 835, "Interest," the closing costs have been deducted from the carrying value of the debt and will be amortized through August 1, 2021, the maturity date of the Initial Term Loan.

The Company has evaluated the accounting impact of each of the modifications noted above, and as all have occurred within a 12 month period, each successive modification has been combined and compared to the terms of the original Loan Agreement. The Company has determined that modifications occurring at each modification date above are modifications of the Loan Agreement for accounting purposes. As such, the Company has capitalized any closing costs paid to the Bank as part of the modifications and has expensed any third party costs incurred. The additional closing costs and the unamortized initial closing costs are being amortized over the remaining term of the modified Initial Term Loan.

The current repayment schedule for the Initial Term Loan is based on repayment beginning on March 1, 2019. The carrying value of the Term Loans (net of debt issuance costs) as of December 31, 2018 and 2017 is as follows (in thousands):

	December 31, 2018	December 31, 2017
Principal Amount of Term Loan	$ 6,000	$ 6,000
Unamortized closing costs	(58)	(64)
Accrued final payment	163	—
Carrying amount of Term Loan	6,105	5,936
Less current portion of Term Loan	(1,851)	(817)
Notes payable long-term portion	$ 4,254	$ 5,119

(b) Convertible Debentures

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

The Company will pay interest to the Investors on the outstanding principal amount of the Convertible Debentures at the rate of 5.0% per annum, payable semi-annually on December 21st and June 21st, beginning on June 21, 2019, as well as on each conversion date (as to that principal amount then being converted) and on the maturity date. The Convertible Debentures mature on December 21, 2021.

At any time prior to the maturity date, the Convertible Debentures are convertible into shares of the Company's common stock at a conversion price of $4.00 per share, at the Investor's option, subject to certain anti-dilution adjustments. The Convertible Debentures contain a cap of shares to be issued upon the conversion of the Convertible Debentures at 19.99% of the issued and outstanding shares of the Company's Common Stock on December 21, 2018, unless shareholder approval of such issuance has been obtained. Upon the satisfaction of certain conditions, the Company has the right to cause the Investors to convert all or part of the then outstanding principal amount of the Convertible Debentures (a "Forced Conversion"). In connection with such Forced Conversion, the Company will be required to pay accrued but unpaid interest, an interest make whole amount determined based on the timing of the Forced Conversion and interest payments made to that date, liquidated damages and other amounts owing to the Investors under the Convertible Debentures. The conversion price in both the optional conversion and Forced Conversion provisions is subject to adjustment due to certain 'down-round' dilutive issuances as well for typical anti-dilutive actions, such as stock splits and stock dividends.

The Investors also have the right to require the Company to repurchase the Convertible Debentures, at a repurchase price that would be at least 115% of the then outstanding principal, plus any accrued but unpaid interest, upon the occurrence of an event of default, as defined in the SPA. The Convertible Debentures will also accrue interest upon an event of default at a rate of the lesser of 10.0% or the maximum permitted by law.

The Convertible Debentures also include certain liquidate damages provisions, whereby the Company will be required to compensate the Investors for certain contingent events, such as the failure to timely deliver conversion shares of common stock, failure to timely pay any accrued interest when due and failure to timely report public information.

The Convertible Debentures are unsecured and structurally subordinated to the Company's existing indebtedness. In connection with the issuance of the Convertible Debentures, all of the Company's subsidiaries entered into a Subsidiary Guarantee, dated as of December 20, 2018, for the benefit of the Investors, pursuant to which all the subsidiaries guaranteed the Company's payments under the Convertible Debentures.

In connection with the issuance, on December 20, 2018, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Investors, pursuant to which the Company agreed to file a registration statement with the Securities and Exchange Commission ("SEC") to register the resale of shares of common stock underlying the Convertible Debentures on or prior to January 31, 2019. The Company filed the Registration Rights Agreement with the SEC on January 31, 2019.

Certain Investors in the Convertible Debentures include directors and employees of the Company. These related parties purchased approximately 10% of the principal value of the Convertible Debentures, or $670,000. The Convertible Debentures issued to the related parties have substantially the same rights and provisions as the unrelated third party investors, with the exception of certain terms where the related parties received less favorable terms than the unrelated third parties (such as with determination of the make whole conversion rate, as defined in the SPA; or limits on the impact of potential 'down-round' adjustments to the conversion price).

In connection with the issuance of the Convertible Debentures, the Company incurred approximately $503,000 in issuance costs related to placement agent fees and third party legal fees.

The Company initially evaluated the required accounting for the Convertible Debentures under ASC Topic 470, "*Debt*" ("ASC 470"), ASC Topic 480, "*Distinguishing Liabilities from Equity*" ("ASC 480") and ASC Topic 815, "*Derivatives and Hedging*" ("ASC 815"). The Company determined that the Convertible Debentures contained multiple embedded derivative features that would be required to be bifurcated and accounted for as a combined derivative liability at fair value, with subsequent changes in fair value being recorded in current earnings in the respective periods. As a result of this assessment, the Company elected to make a one-time, irrevocable election to utilize the fair value option allowed under ASC Topic 825, "*Financial Instruments*." Under the fair value option election, the Company will 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 believes that the election of the fair value option will allow for a more meaningful representation of the total fair value of its obligation under the Convertible Debentures and allow for a better understanding of how changes in the external market environment and valuation assumptions impact such fair value, when compared to recording the Convertible Debentures and fair value of the bifurcated embedded derivatives separately under the guidance of ASC 470 and ASC 815.

In accordance the Company's election of the fair value option, the Company expensed the approximately $503,000 in issuance costs incurred related to the Convertible Debentures during the year ended December 31, 2018.

Fair Value Measurements Related to the Convertible Debentures

The Company utilized a Monte Carlo simulation model to estimate the fair value of the Convertible Debentures as of their issuance date and as of December 31, 2018. The simulation model is designed to capture the potential settlement features of the Convertible Debentures (the embedded features described above), in conjunction with simulated changes in the Company's stock price and the probability of certain events occurring. The simulation utilizes 100,000 trials or simulations to determine the estimated fair value.

The simulation utilizes the assumptions that if the Company is able to exercise its Forced Conversion right (if the requirements to do so are met), that it will do so in 100% of such scenarios. Additionally, if an event of default occurs during the simulated trial (based on the Company's probability of default), the Investors will opt to redeem the Convertible Debentures in 100% of such scenarios. If neither event occurs during a simulated trial, the simulation assumes that the Investor will hold the Convertible Debentures until the maturity date. The value of the cash flows associated with each potential settlement are 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 notes that the key inputs to the simulation model that were utilized to estimate the fair value of the Convertible Debentures included:

Input	December 21, 2018	December 31, 2018
Company's stock price	$ 3.68	$ 3.70
Conversion price	$ 4.00	$ 4.00
Remaining term (years)	3.00	2.97
Equity volatility	54.00%	54.00%
Risk free rate	2.58%	2.46%
Probability of default event	0.75%	0.81%
Utilization of Forced Conversion (if available)	100.00%	100.00%
Exercise of Default Redemption (if available)	100.00%	100.00%
Effective discount rate	21.90%	21.90%

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 1 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 December 21, 2018 and December 31, 2018 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.

As of the issuance date of the Convertible Debentures (December 21, 2018) and December 31, 2018, the fair value and principal value of the Convertible Debentures was:

Convertible Debentures	December 21, 2018	December 31, 2018
Fair value, in accordance with fair value option	$ 6,970	$ 6,970
Principal value outstanding	$ 6,970	$ 6,970

The Company did not record any gains or losses from the change in fair value of the Convertible Debentures between their issuance date and December 31, 2018. See also additional fair value disclosures related to the Convertible Debentures in Note 1(r) above.

(c) Principal and Interest Payments Related to Financing Arrangements

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

Fiscal Year	Amount Due
2019	$ 2,624
2020	2,895
2021	9,454
Total	$ 14,972

The following amounts are included in interest expense in our consolidated statement of operations for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	December 31, 2018	December 31, 2017	December 31, 2016
Cash interest expense, notes payable	$ 299	$ 98	$ —
Cash interest expense, convertible debentures	9	—	—
Amortization of debt costs	29	9	—
Accrual of notes payable final payment	163	—	—
Amortization of settlement obligations	—	26	82
Interest expense capital lease	4	1	70
Capital lease - fair value amortization	—	(10)	(89)
Total interest expense	$ 504	$ 124	$ 63

Cash interest expense, notes payable, represents the cash interest paid monthly on the term loan. Cash interest expense, convertible debentures represents cash interest accrued in connection with the convertible debt closed in December 2018. Interest payments are due to the holders in June and December of each year. The amortization of debt costs represents the closing costs incurred with the Loan Agreement, which have been capitalized and expensed using the effective interest method. The amortization of the settlement obligations represents the interest associated with the settlement agreement for Zeiss. See Note 9(f) to our Consolidated Financial Statements.

(5) Accrued Expenses

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

	2018	2017
Accrued salary and related expenses	$1,811	$1,388
Accrued accounts payable	2,329	2,523
Accrued professional fees	737	418
Other accrued expenses	91	70
Deferred rent	92	76
	$5,060	$4,475

(6) Stockholders' Equity

(a) Stock Options

The Company has six stock option or stock incentive plans, which are described as follows:

The 2002 Stock Option Plan (the "2002 Plan").

The 2002 Plan was adopted by the Company's stockholders in June 2002. The 2002 Plan provides for the granting of non-qualifying and incentive stock options to employees and other persons to purchase up to an aggregate of 100,000 shares of the Company's common stock. The purchase price of each share for which an option is granted is determined by the Board of Directors or the Committee appointed by the Board of Directors provided that the purchase price of each share for which an incentive option is granted cannot be less than the fair market value of the Company's common stock on the

date of grant, except for options granted to 10% stockholders for whom the exercise price cannot be less than 110% of the market price. Incentive options granted to date under the 2002 Plan vest 100% over periods extending from six months to five years from the date of grant and expire no later than ten years after the date of grant, except for 10% holders whose options expire not later than five years after the date of grant. Non-qualifying options granted under the 2002 Plan are generally exercisable over a ten year period, vesting 1/3 each on the first, second, and third anniversaries of the date of grant. At December 31, 2018, there are no further options available for grant under the 2002 Plan.

The 2004 Stock Incentive Plan (the "2004 Plan").

The 2004 Plan was adopted by the Company's stockholders in June 2004. The 2004 Plan provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. The 2004 Plan provides for the granting of non-qualifying and incentive stock options to employees and other persons to purchase up to an aggregate of 200,000 shares of the Company's common stock. The purchase price of each share for which an option is granted is determined by the Board of Directors or the Committee appointed by the Board of Directors provided that the purchase price of each share for which an option is granted cannot be less than the fair market value of the Company's common stock on the date of grant, except for incentive options granted to 10% stockholders for whom the exercise price cannot be less than 110% of the market price. Incentive options granted under the 2004 Plan generally vest 100% over periods extending from the date of grant to five years from the date of grant and expire not later than ten years after the date of grant, except for 10% holders whose options expire not later than five years after the date of grant. Non-qualifying options granted under the 2004 Plan are generally exercisable over a ten year period, vesting 1/3 each on the first, second, and third anniversaries of the date of grant. At December 31, 2018, there are no further shares available for grant under the 2004 Plan.

The 2005 Stock Incentive Plan (the "2005 Plan").

The 2005 Plan was adopted by the Company's stockholders in June 2005. The 2005 Plan provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. The 2005 Plan provides for the granting of non-qualifying and incentive stock options to employees and other persons to purchase up to an aggregate of 120,000 shares of the Company's common stock. The purchase price of each share for which an option is granted is determined by the Board of Directors or the Committee appointed by the Board of Directors provided that the purchase price of each share for which an option is granted cannot be less than the fair market value of the Company's common stock on the date of grant, except for incentive options granted to 10% stockholders for whom the exercise price cannot be less than 110% of the market price. Incentive options granted under the 2005 Plan generally vest 100% over periods extending from the date of grant to three years from the date of grant and expire not later than five years after the date of grant, except for 10% stockholders whose options expire not later than five years after the date of grant. Non-qualifying options granted under the 2005 Plan are generally exercisable

over a ten year period, vesting 1/3 each on the first, second, and third anniversaries of the date of grant. At December 31, 2018, there are no further shares available for grant under the 2005 Plan.

The 2007 Stock Incentive Plan (the "2007 Plan").

The 2007 Plan was adopted by the Company's stockholders in July 2007 and amended in June 2009. The 2007 Plan provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. Awards may be granted singly, in combination, or in tandem. Subject to anti-dilution adjustments as provided in the 2007 Plan, (i) the 2007 Plan provides for a total of 1,050,000 shares of the Company's common stock to be available for distribution pursuant to the 2007 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 2007 Plan during any calendar year or part of a year may not exceed 160,000 shares.

The 2007 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 2007 Plan, determine participants who will be granted awards under the 2007 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 2007 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 2007 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, 2018, there are no further shares available for grant under the 2007 Plan.

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, 2018, there were 99,215 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, 2018, there were 866,504 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, January 1, 2016	1,571,998	$ 5.05	
Granted	127,500	$ 5.46	
Exercised	(75,583)	$ 2.62	
Forfeited	(198,567)	$ 6.19	
Outstanding, December 31, 2016	1,425,348	$ 5.05	
Granted	200,813	$ 4.14	
Exercised	(36,530)	$ 2.18	
Forfeited	(124,516)	$ 4.71	
Outstanding, December 31, 2017	1,465,115	$ 5.03	
Granted	888,263	$ 2.95	
Exercised	(139,556)	$ 2.27	
Forfeited	(230,345)	$ 5.41	
Outstanding, December 31, 2018	1,983,477	$ 4.25	4.4 years
Exercisable at December 31, 2016	1,054,211	$ 4.71	
Exercisable at December 31, 2017	1,301,651	$ 4.95	
Exercisable at December 31, 2018	1,296,439	$ 4.90	4.1 years

There were 965,719 shares available for future grants from all plans at December 31, 2018.

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

	Years Ended December 31,		
	2018	2017	2016
Cost of revenue	$ 4	$ 5	$ 6
Engineering and product development	399	715	329
Marketing and sales	190	1,003	677
General and administrative expense	912	1,933	1,295
	$1,505	**$3,656**	**$2,307**

As of December 31, 2018, there was $1.8 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:

	Years Ended December 31,		
	2018	2017	2016
Average risk-free interest rate	2.65%	1.61%	0.98%
Expected dividend yield	None	None	None
Expected life	3.5 years	3.5 years	3.5 years
Expected volatility	50.4% to 61.6%	64.2% to 72.0%	68.5% to 75.3%
Weighted average exercise price	$2.96	$4.14	$5.46
Weighted average fair value	$1.23	$1.99	$2.66

The Company's 2018, 2017 and 2016 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:

	Years Ended December 31,		
	2018	2017	2016
Outstanding	$1,021	$ 449	$ 409
Exercisable	499	442	409
Exercised	224	79	201
Company's stock price at December 31	$ 3.70	$3.44	$3.24

(b) 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 granted a total of 162,500 shares of performance based restricted stock during

2016 with performance measured on meeting a revenue target based on growth for fiscal year 2017 and vesting in three equal installments with the first installment vesting upon measurement of the goal. In addition, a maximum of 108,333 additional shares are available to be earned based on exceeding the revenue goal. The revenue target was partially exceeded and 189,583 shares were granted with initial vesting of 63,194 at the grant date in April 2018, and 63,194 vesting on the second and third anniversary of the initial vesting. The Company granted an additional 144,500 shares with time based vesting and 45,356 shares with immediate vesting in the year ended December 31, 2018.

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

	Years Ended December 31,		
	2018	2017	2016
Beginning outstanding balance	415,147	511,398	516,396
Granted	379,439	394,599	345,778
Vested	(322,388)	(469,434)	(289,030)
Forfeited	(48,996)	(21,416)	(61,746)
Ending outstanding balance	**423,202**	**415,147**	**511,398**

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,		
	2018	2017	2016
Outstanding	$1,566	$1,428	$1,657
Vested	1,193	1,615	936
Company's stock price at December 31	$ 3.70	$ 3.44	$ 3.24

(7) Income Taxes

The components of income tax expense for the years ended December 31, 2018, 2017 and 2016 are as follows (in thousands):

	2018	2017	2016
Current provision (benefit):			
Federal	$—	$—	$—
State	54	(26)	69
	$ 54	$ (26)	$ 69
Deferred provision:			
Federal	$ (10)	$ 7	$ 6
State	(2)	1	1
	$ (12)	$ 8	$ 7
Total	$ 42	$ (18)	$ 76

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, 2018, 2017 and 2016 is as follows:

	2018	2017	2016
Federal statutory rate	21.0%	34.0%	34.0%
State income taxes, net of federal benefit	3.6%	1.4%	2.8%
Net state impact of deferred rate change	0.6%	(0.3%)	0.2%
Stock compensation expense	(1.1%)	(1.9%)	(3.2%)
Tax amortization on goodwill	0.1%	(0.1%)	(0.1%)
Goodwill impairment	0.0%	(13.7%)	0.0%
Other permanent differences	(0.5%)	(0.4%)	(0.4%)
Change in valuation allowance	(27.6%)	97.4%	(37.3%)
Tax credits	3.1%	1.5%	3.2%
Federal Rate Change	0.0%	(133.5%)	0.0%
Accrual to TR	0.3%	(0.7%)	0.0%
Increase Xoft NOLs under 382 Study	0.0%	16.2%	0.0%
Effective income tax	(0.5%)	(0.1%)	(0.8%)

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

Deferred income taxes reflect the impact of "temporary differences" between the amount of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations. The Company has fully reserved the 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 (in thousands):

	2018	2017
Inventory (Section 263A)	$ 239	$ 287
Inventory reserves	270	305
Receivable reserves	45	27
Other accruals	88	224
Deferred revenue	85	129
Accumulated depreciation/amortization	138	320
Stock options	1,879	1,901
Developed technology	2,031	2,201
Tax credits	3,364	3,130
NOL carryforward	32,074	31,113
Net deferred tax assets	40,213	39,637
Valuation allowance	(40,213)	(39,637)
Goodwill tax amortization	(3)	(14)
Deferred tax liability	$ (3)	$ (14)

The increase in the net deferred tax assets and corresponding valuation allowance during the year ended December 31, 2018 is primarily attributable to additional net operating losses and additional research and development credits. The decrease in the net deferred tax assets and corresponding valuation allowance during the year ended December 31, 2017 is related primarily to the decrease in corporate tax rate from 34% to 21% starting on January 1, 2018. The Company completed an asset acquisition in January 2016 which resulted in $293,307 of goodwill. For book purposes, the goodwill was classified as an indefinite lived asset and tested for impairment each year. For tax, the Company is allowed amortization expense over a 15-year life. Prior to 2018, due to the indefinite life of the asset for book purposes, the Company could not assume there would be a deferred tax assets available to offset the liability in future years. This created a tax expense equal to the tax effected amount of tax amortization, or $7,434 in 2017. Beginning January 1, 2018, federal net operating losses generated after December 31, 2017 will be carried forward indefinitely and able to offset up to 80% of taxable income. As the deferred tax asset generated relating to federal net operating losses for 2018 has an indefinite carryforward period, it can be used to offset the deferred tax liability related to tax amortizable goodwill. This created a tax benefit in 2018 as the Company reversed 80% of the historical deferred tax liability resulting in a benefit of $11,761.

As of December 31, 2018, Company has federal net operating loss carryforwards totaling approximately $134.9 million. The federal net operating loss carryforwards of $127.7 million will expire at various dates from 2019 to 2037. Approximately $7.2 million of the federal net operating losses can be carried forward indefinitely. A portion of the total net operating loss carryforwards amounting to approximately $56.7 million relate to the acquisition of Xoft, Inc. As of December 31, 2018, 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, 2018 or 2017.

The Company currently has approximately $7.9 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 $3.4 million. The tax credits related to Xoft have been fully reserved for and as a result no deferred tax asset has been recorded. The credits expire in various years through 2038.

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, 2018 and 2017, 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, 2018, 2017 and 2016. The Company files United States federal and various state income tax returns. Generally, the Company's three preceding tax years remain subject to examination by federal and state taxing authorities. The Company completed an examination by the Internal Revenue Service with respect to the 2008 tax year in January 2011, which resulted in no changes to the tax return originally filed. 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, 2018 will significantly change within the next 12 months.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act ("TCJA") tax reform legislation. This legislation makes significant change in U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from the current rate of 34% down to 21% starting on January 1, 2018. As a result of the enacted law, the Company was required to revalue deferred tax assets and liabilities at the 21%. This revaluation resulted in a provision of $19.1 million to income tax expense in continuing operations and a corresponding reduction in the valuation allowance. As a result, there was no impact to the Company's income statement as a result of reduction in tax rates. The other provisions of the TCJA did not have a material impact on our consolidated financial statements.

In December 2017, the SEC staff issued SAB 118 to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of TCJA. The Company did not record any adjustments in the year ended December 31, 2018 to provisional amounts that were material to its financial statements. As of December 31, 2018, the Company's accounting treatment is complete.

(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 ("CEO"). 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: Cancer Detection ("Detection") and Cancer Therapy ("Therapy").

The Detection segment consists of our advanced image analysis and workflow products, and the Therapy segment consists of our radiation therapy ("Axxent") products, and related services. The primary factors used by our 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 ("Adjusted EBITDA") of each segment. Included in segment operating income are stock compensation, amortization of technology and depreciation expense. There are no intersegment revenues.

We do not track our assets by operating segment and our 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, including prior periods which have been presented for consistency):

	Year Ended December 31,		
	2018	2017	2016
Segment revenues:			
Detection	$16,864	$ 18,310	$ 17,133
Therapy	8,757	9,792	9,205
Total Revenue	$25,621	$ 28,102	$ 26,338
Segment gross profit:			
Detection	$14,709	$ 16,218	$ 15,113
Therapy	4,721	1,958	3,405
Segment gross profit	$19,430	$ 18,176	$ 18,518
Segment operating income (loss):			
Detection	$ 3,412	$ 6,401	$ 5,694
Therapy	(2,373)	(15,102)	(7,752)
Segment operating income (loss)	$ 1,039	$ (8,701)	$ (2,058)
General, administrative, depreciation and amortization expense	$ (9,169)	$ (7,975)	$ (7,912)
Interest expense	(504)	(124)	(63)
Financing costs	(451)	—	—
Gain on sale of MRI assets	—	2,508	—
Other income	110	18	10
Loss on debt extinguishment	—	—	—
Loss before income tax	$ (8,975)	$(14,274)	$(10,023)

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

	Year Ended December 31,		
	2018	2017	2016
Detection depreciation and amortization			
Depreciation	$106	$172	$223
Amortization	248	246	696
Therapy depreciation and amortization			
Depreciation	$177	$768	$970
Amortization	129	222	252

(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 $3.2 million or 12% of total revenue in 2018, $3.9 million or 14% of total revenue in 2017 and $2.3 million or 9% of total revenue in 2016.

As of December 31, 2018 and 2017, the Company had outstanding receivables of $1.1 million and $2.1 million, respectively, from distributors and customers of its products who are located outside of the U.S.

(c) Major Customers

The Company had one major customer, GE Healthcare, with revenues of approximately $6.1 million in 2018, $7.1 million in 2017, and $3.9 million in 2016 or 24%, 25%, and 15% of total revenue, respectively. Cancer detection products are also sold through OEM partners, including GE Healthcare, Fuji Medical Systems, Siemens Medical and Vital Images and Invivo. For the year ended December 31, 2018, these five OEM partners composed approximately 50% of Detection revenues and 33% of revenue overall. OEM partners composed 55% of Detection revenues and 39% of revenue overall for the year ended December 31, 2017 and 47% of Detection revenues and 30% of revenue overall for the year ended December 31, 2016.

OEM partners represented $2.5 million or 37% of outstanding receivables as of December 31, 2018, with GE Healthcare accounting for $1.6 million or 25% of this amount. The three largest Cancer Therapy customers composed $0.8 million or 12% of outstanding receivables as of December 31, 2018. These eight customers in total represented $3.3 million or 50% of outstanding receivables as of December 31, 2018.

(9) Commitments and Contingencies

(a) Lease Obligations

As of December 31, 2018, the Company had three lease obligations related to its facilities. The Company's executive offices are leased pursuant to a five-year operating lease (the "Lease") that commenced on December 15, 2006, with renewals in January 2012 and August 2016, of office space located at 98 Spit Brook Road, Suite 100 in Nashua, New Hampshire (the "Premises"). The August 2016 renewal provides for an annual base rent of $184,518 for the period from March 2017 to February 2020. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the Premises.

The Company leases a facility in San Jose, California under a non-cancelable operating lease which commenced in September 2012, with annual payments of $295,140 through September 2017, and all amounts payable in equal monthly installments. In September 2016, the Company extended this lease for the period from October 2017 to March 2020, with annual payments of $540,588 from October 2017 to September 2018, $558,120 from October 2018 to September 2019 and $286,368 for the period from October 2019 to March 2020, with all amounts payable in equal monthly installments. 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 an operating lease for an additional facility in Nashua, New Hampshire used for product repairs, manufacturing and warehousing.

Rent expense for all leases for the years ended December 31, 2018, 2017 and 2016 was $896,000, $899,000 and $745,000, respectively.

Future minimum rental payments due under these agreements as of December 31, 2018 are as follows (in thousands):

Fiscal Year	Operating Leases
2019	$ 781
2020	183
	$ 964

(b) Capital lease obligations

In August, 2017, the Company assumed an equipment lease obligation with payments totaling $50,000. The leases were determined to be capital leases and accordingly the equipment was capitalized and a liability of $42,000 was recorded. The equipment will be depreciated over the expected life of 3 years. The remaining minimum lease payments are as follows (in thousands):

Fiscal Year	Capital Lease
2019	$ 17
2020	13
subtotal minimum lease obligation	30
less interest	(4)
Total, net	26
less current portion	11
long term portion	$ 15

(c) Other Commitments

The Company has non-cancelable purchase orders with key suppliers executed in the normal course of business that total approximately $2.0 million. In connection with the Company's employee savings plans, the matching contribution for 2018 was approximately $0.5 million in cash. The matching contribution for 2019 is estimated to be approximately $0.5 million in cash.

(d) Employment Agreements

The Company has entered into employment agreements with certain key 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 the greater of the remainder of the original term of employment or, for Mr. Ferry, a period of two years from the date of termination, for Mr. Christopher and Ms. Stevens, a period of eighteen months from the date of termination, 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, 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 will be paid monthly beginning in May 2019.

On December 27, 2018, the Company announced that Mr. Christopher would be resigning from his position as Chief Financial Officer of the Company, effective January 11, 2019. There were no termination benefits associated with Mr. Christopher's resignation.

(e) Foreign Tax Claim

In July 2007, a dissolved former Canadian subsidiary of the Company, CADx Medical Systems Inc. ("CADx Medical"), received a tax re-assessment of approximately $6,800,000 from the Canada Revenue Agency ("CRA") resulting from CRA's audit of CADx Medical's Canadian federal tax return for the year ended December 31, 2002. In February 2010, the CRA reviewed the matter and reduced the tax re-assessment to approximately $703,000, excluding interest and penalties. The CRA has the right to pursue the matter until July 2020. The Company believes that it is not liable for the re-assessment against CADx Medical and continues to defend this position. As the Company believes that a probability of a loss is remote, no accrual was recorded as of December 31, 2018.

(f) 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.

(g) 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 we 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 our 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, referred to in this Section as the Agreement, with Invivo Corporation, referred to in this Section as 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.

On September 5, 2018, third-party Yeda Research and Development Company Ltd., referred to in this Section as Yeda, filed a 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 Agreement. In the Complaint, Yeda asserts 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. The Company is awaiting a decision from the Court. To the extent that the Complaint is not dismissed in its entirety, the Company will vigorously defend against the claims asserted by Yeda. The amount of the loss, if any, cannot be reasonably estimated at this time. Any amounts owed by the Company in connection with its indemnification obligations to Invivo related to this action may reduce the $350,000 holdback under the Asset Purchase Agreement.

(10) Quarterly Financial Data (in thousands, except per share data, and unaudited)

2018	Net sales	Gross profit	Net loss	Income (loss) per share	Weighted average number of shares outstanding
First quarter	$ 6,313	$ 4,498	$(3,281)	($ 0.20)	16,583
Second quarter	6,162	4,784	$(1,027)	($ 0.06)	16,664
Third quarter	6,192	4,738	$(1,365)	($ 0.08)	16,700
Fourth quarter	6,954	5,410	$(3,344)	($ 0.20)	16,774
2017					
First quarter	$ 6,791	$ 4,689	$ (457)	($ 0.03)	16,135
Second quarter	6,409	4,503	$(2,631)	($ 0.16)	16,310
Third quarter	7,000	4,643	$(6,933)	($ 0.42)	16,424
Fourth quarter	7,902	4,341	$(4,235)	($ 0.26)	16,501

EXHIBIT 21

Subsidiaries of iCAD, Inc.

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

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8, (No. 333-201874, 333-187660, 33-72534, No. 333-99973, No. 333-119509, No. 333-139023, No. 333-144671 No. 333-161959 and No. 333-211656), and Registration Statements on Forms S-3, (No. 333-169716, 333-176777 and 333-178952) of iCAD, Inc. and subsidiaries, of our report dated March 29, 2019, relating to the consolidated financial statements which appears in this Annual Report on Form10-K.

/s/ BDO USA, LLP

Boston, Massachusetts
March 29, 2019

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, 2018 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; and

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 29, 2019

/s/ Michael Klein

Michael Klein
Chief Executive Officer and Director

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, 2018 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; and

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 29, 2019

/s/ R. Scott Areglado

R. Scott Areglado
Interim Chief Financial Officer, Vice President and Corporate Controller

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, 2018 (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:

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

Date: March 29, 2019

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, 2018 (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:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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
Interim Chief Financial Officer, Vice President and
Corporate Controller

Date: March 29, 2019