ICAD INC
Form 10-K
March 29, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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

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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.

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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 , expe estimate , anticipate , likely , seek , would , could , may , consider , confident and similar expressions ide 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.

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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

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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

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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.

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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.

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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.

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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

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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.

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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

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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

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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

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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.

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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.

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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.

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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

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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.

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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.

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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.

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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

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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.

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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.

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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

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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.

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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

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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

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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.

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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

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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.

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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.

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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.

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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.

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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

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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

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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.

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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.

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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

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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

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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.

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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.

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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.

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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:

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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

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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

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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.

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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:

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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,