ICAD INC
Form 10-K
March 11, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

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 x

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 x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x 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. x

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

Large Accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨ (do not check if a smaller reporting company)	Smaller reporting company	x

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

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, 2015 was $47,316,443. Shares of voting stock held by each officer and director and by each person who, as of June 30, 2015, may be deemed to have beneficially owned more than 10% of the outstanding voting stock have been excluded. This determination of affiliate status is not necessarily a conclusive determination of affiliate status for any other purpose.

As of March 7, 2016, the registrant had 15,893,231 shares of Common Stock outstanding.

Documents Incorporated by Reference: Certain portions of the registrant s definitive Proxy Statement for its 2016 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 and similar expressions identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date the statement was made. Unless the context otherwise requires, the terms iCAD , Company , we , our registrant , and us means iC and any consolidated subsidiaries.

PART I

Item 1. Business.

General

iCAD is an industry-leading provider of advanced image analysis, workflow solutions and radiation therapy for the early identification and treatment of cancer. The Company reports in two operating segments, Cancer Detection (Detection) and Cancer Therapy (Therapy). The Company was incorporated in 1984 as Howtek, Inc. under the laws of the state of Delaware. In 2002 the Company changed its name to iCAD and changed its ticker symbol to ICAD.

The iCAD website is www.icadmed.com. On this website the following documents are available at no charge: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), as soon as reasonably practicable after the Company electronically files such material with, or furnishes it to, the SEC. Our SEC filings are also available on the SEC s website at http://www.sec.gov. Alternatively, you may access any document we have filed by visiting the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The information on the website listed above, is not and should not be considered part of this annual report on Form 10-K and is not incorporated by reference in this document.

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

Company Overview and Strategy

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 believes that early detection, together with earlier targeted intervention, provides patients and healthcare providers with the best tools available to achieve better clinical outcomes resulting in market demand that will drive adoption of iCAD s solutions. The Company s strategy is to provide customers with a broad portfolio of oncology solutions that address four key stages of the cancer care cycle: detection, diagnosis, treatment and monitoring.

Cancer Therapy:

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. One of the differences relate to the position of the radiation source; external is outside the body, brachytherapy uses sealed radioactive sources placed precisely in the treatment area, and systemic radioisotopes are given by infusion or oral ingestion. Brachytherapy uses temporary or permanent placement of radioactive sources. Conventional EBRT typically involves multiple treatments of a tumor in up to 50 radiation sessions (fractions). In the case of brachytherapy, radiation of healthy tissues further away from the sources is reduced. In addition, if the patient moves or if there is any tumor movement within the body during treatment, the radiation source(s) retain their correct position in relation to the tumor. These aspects of brachytherapy offer advantages over EBRT in that brachytherapy is able to 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

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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. The Xoft eBx system (eBx 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 process for delivering radiation therapy typically includes a radiation oncologist, a medical physicist responsible for planning the treatment and performing appropriate quality assurance procedures and, in certain instances, other specialty physicians depending upon the type of cancer e.g. a breast surgeon for breast cancer, a dermatologist for skin cancer, a gynecologist for endometrial or cervical cancer.

The Company s Xoft eBx 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 eBx 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.

There are approximately 300,000 new cases of breast cancer in the United States each year. The Company believes that the Xoft eBx system is uniquely well positioned to offer a differentiated treatment alternative for the approximately 111,000 of these 300,000 annual new cases of early stage breast cancer in the U.S. where patients fit the clinical criteria to make this treatment a viable alternative to conventional radiation treatments. The Xoft eBx system does not require a shielded environment and is relatively small in size, which means that it can easily be transported for use in virtually any clinical setting (including the operating room where IORT is delivered) under radiation oncology supervision. The Xoft System may also be used for Accelerated Partial Breast Irradiation (APBI), which can be delivered twice daily for five days. There is a growing body of clinical evidence in support of breast IORT and category I Current Procedural Terminology (CPT) codes have been in place for several years, providing reimbursement for the hospital, radiation oncologist, and surgeon for performing the IORT treatment.

Basal and Squamous Cell Carcinoma are two of the most prevalent types of NMSC in the U.S., with more than 3.5 million cases being diagnosed annually. The Xoft eBx system enables radiation oncologists and dermatologists to collaborate in offering their patients a non-surgical treatment option that is particularly appropriate for certain challenging lesion locations on the ear, face, scalp, neck and extremities. In July 2014, iCAD s acquisition of the assets of DermEbx (a leading electronic brachytherapy services and technology provider) and Radion, Inc. (a cloud-based oncology collaboration software solution) further enhanced Xoft s ability to provide comprehensive skin cancer treatment solutions to the dermatology market. The acquisitions expanded the Company s Xoft eBx skin offering to include all the necessary components to enable dermatologists and radiation oncologists to develop, launch and expand their electronic brachytherapy programs for the treatment of NMSC. These acquisitions also expanded the Xoft offerings to include physics support, billing support, assistance with radiation oncology provider selection, as well as the Axxent Hub web-based software platform that enables centers to improve patient safety, conduct treatment planning, enhance and monitor workflow, and improve communication between clinical specialties.

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In May 2015 the Company announced that one of the regional Medicare Administrative Contractors instructed physicians to report CPT code (17999) rather than the established CPT code (0182T) for electronic brachytherapy for treatment of NMSC. This announcement resulted in a significant disruption in the Therapy segment as a result of the reimbursement uncertainty. Revenues for the year ended December 31, 2015 were also negatively impacted as a result of the uncertainty. In addition, the Company implemented expense reductions in response to the general uncertainty with respect to reimbursement levels. The Company has been proactively addressing the situation in its dialogue with the regional provider and Centers for Medicare and Medicaid Services (CMS) and implemented a strategy to target a new skin-specific level III reimbursement code for skin eBx in the U.S.; However, there is no assurance that payment rates under this code will be adequate and there remains insufficient clarification to fully assess the long-term impact on our business.

As the Company has noted in the risk factors the Company s business can be affected by coverage 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 customers are willing to pay for those products in a particular jurisdiction. The change in CPT codes for the Company s electronic brachytherapy treatment of NMSC had a negative impact on the Company s revenues for the year ended December 31, 2015.

In connection with the preparation of the financial statements for the second quarter ended June 30, 2015, the Company evaluated the Therapy reporting unit for both long-lived asset and goodwill impairment. As a result of this assessment, the Company recorded material impairment charges in the Therapy reporting unit (see Note h and Note i to the consolidated financial statements included herein for additional discussion).

The Company views additional Xoft eBx system platform indications as important opportunities in both the U.S. and international markets. The Xoft eBx system is also marketed for gynecological cancers including endometrial and cervical cancer. In 2013 the Company received FDA clearance for a new application for the treatment of cervical cancer and launched a new applicator to treat cervical cancer in late 2015. Vaginal cancer is the fourth most common cancer affecting women worldwide and cervical cancer incidence rates outside of the U.S. are very high due to inadequate penetration of screening modalities. The Company believes an additional strategic growth opportunity exists in the application of the Xoft eBx system for the treatment of other cancers beyond breast cancer in the IORT setting including integration with minimally invasive surgical techniques and systems.

Cancer Detection:

Approximately 40 million mammograms were performed in the U.S. in 2015. 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. More than half of the cancers missed are due to observational errors. CAD, when used in conjunction with mammography, has been proven to help reduce the risk of these observational

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errors by as much as 20%. Earlier cancer detection typically leads to more effective, less invasive, and less costly treatment options which ultimately should translate into improved patient survival rates.

The Company intends to address the detection and diagnosis stages of the cancer care cycle through continued extension of its image analysis and clinical decision support solutions for mammography, breast tomosynthesis, MRI and CT imaging. iCAD believes that advances in digital imaging techniques should bolster its efforts to develop additional commercially viable CAD, advanced image analysis and workflow products. CAD for breast tomosynthesis is a growth area which the Company believes will provide additional benefits for early breast cancer detection. The Company believes that CAD for tomosynthesis has the potential to help radiologists better detect cancer and manage the workflow efficiency issues created by large 3D datasets. The Company completed development of a tomosynthesis CAD and workflow tool in 2015 and expects to launch this product in the European market in early 2016. Pending FDA approval, the Company expects to begin marketing the product in conjunction with its OEM partners beginning in the second half of 2016.

The Company believes that the CAD solution for breast tomosynthesis may represent a significant growth opportunity over the next three to five years. With over 12,000 installation opportunities for tomosynthesis systems in the U.S., there is a significant future opportunity for CAD solutions for tomosynthesis. 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.

In the U.S., approximately 8,470 facilities (with approximately 15,230 mammography systems) were certified to provide mammography screening in 2015. The majority of these centers are using 2D digital mammography (FFDM) systems and we believe approximately 20% of the market has converted to 3D mammography or tomosynthesis.

With several European countries currently exploring the advantages of radiologists reading digital mammograms with CAD, the Company believes there is growth opportunity for mammography CAD in the international markets both from the analog to digital conversion and as more countries accept the use of radiologists using CAD, rather than two radiologists having to read each case. Based on the report published by the European Commission in April 2012, breast cancer is one of the most prevalent forms of cancer and it is also responsible for the most cancer-related deaths among women in the European Union (EU). The number of expected breast cancer cases based on the 2012 report was expected to continue to rise as the incidence of cancer increases steeply with age and life expectancy. On average one out of every 10 women in the EU is expected to develop breast cancer at some point in her life. As a result, most countries in Western Europe have or are planning to implement mammography screening programs resulting in an expected increase in the number of mammograms performed in the coming years.

Although sales of CAD with 2D mammography in Europe have been historically lower than in the U.S., the Company believes sales of its CAD for tomosynthesis will be adopted with a higher attachment rate in Europe than previously due to workflow and reading time reduction that we believe solution will offer.

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Revenue:

The table below presents the revenue and percentage of revenue attributable to the Company s products and services, in 2015, 2014 and 2013 (in thousands):

	For the year ended December 31,					
	2015	%	2014	%	2013	%
Detection:						
Digital & MRI CAD revenue	$ 11,216	27.0%	$ 9,765	22.2%	$ 7,930	24.0%
Film based revenue	10	0.0%	317	0.7%	561	1.7%
Service	8,017	19.3%	8,522	19.4%	8,414	25.4%
Detection revenue	19,243	46.3%	18,604	42.4%	16,905	51.1%
Therapy:						
Product	2,972	7.2%	8,601	19.6%	10,045	30.4%
Service	19,339	46.5%	16,719	38.1%	6,117	18.5%
Therapy revenue	22,311	53.7%	25,320	57.6%	16,162	48.9%
Total revenue	$ 41,554	100.0%	$ 43,924	100.0%	$ 33,067	100.0%

Cancer Therapy Segment Overview and Products

The Xoft eBx system utilizes a miniaturized high dose rate yet 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 Xoft eBx 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 much faster, thus lowering the radiation exposure outside of the prescribed area. Given this rapid dose fall off, there is no need for a lead vault as compared to traditional isotope based radiation therapy, enabling the Xoft eBx system to be transported to different locations within the same facility or between multiple facilities.

IORT Electronic Brachytherapy can be delivered during an operative procedure, in as little as eight minutes, and may be used as a primary or secondary modality over a course of days. This technology enables radiation oncology departments in hospitals, clinics and physician offices to perform traditional radiotherapy treatments and offer advanced treatments such as IORT. Current customers of the Xoft eBx system include university research and community hospitals, private and governmental institutions, doctors offices, cancer care clinics, veterinary facilities, and strategic partnerships with radiation oncology service providers that enable the supervised delivery of the technology in dermatologist offices.

Of the approximately 300,000 women who are diagnosed with breast cancer every year in the U.S., the majority, or 60% are diagnosed with early stage breast cancer. About 60% of early stage breast cancers qualify as candidates for treatment with eBx. Currently, a majority of early stage breast cancer patients who are treated with radiation therapy follow a 5-7 week daily protocol of traditional external beam radiation while a small portion are treated with a 5-day protocol using brachytherapy.

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Breast cancer is a relatively common disease and is often treatable by surgery, followed by radiotherapy with an additional therapy such as chemotherapy and/or hormonal therapy. Early detection has led to earlier diagnosis with small, early stage diseases that can be removed by local excision rather than a complete mastectomy. Microscopic cancerous cells can be present and easily managed with the application of radiotherapy. The protocol for many years for most women included a day procedure for a lumpectomy and 5-7 weeks of daily radiation. IORT allows the physician to treat the remaining breast tissue in the operating room while the patient is still under anesthesia, eliminating the need for 5-7 weeks of daily traditional radiation therapy. In the last few years, in Europe and in the U.S., shorter treatment protocols of external beam radiation therapy hypo-fractionated to as few as three weeks have emerged as alternatives.

In a scientific paper presented at the 2010 ASCO Meeting, Dr. Jayant Vaidya of the University College London, UK, concluded that in the 2,200 patient multinational clinical trial (TARGIT-A trial) IORT, generated with 50 kV electronic brachytherapy, is equivalent to conventional external beam radiotherapy. In December 2012, Dr. Vaidya presented five-year follow up data on the TARGIT-A trial at a forum in conjunction with the San Antonio Breast Cancer Symposium. Following this presentation, in November 2013 the Lancet online published the five-year update results of the TARGIT-A trial. The updated results of the trial demonstrated that local recurrence rates in the TARGIT (IORT) group were within the non-inferiority boundary when compared to the results in the group who received external beam radiation therapy and that mortality rates from other causes than breast cancer were lower in the TARGIT (IORT) group. In addition, the data revealed that at five years, the local recurrence rate in patients who were treated with IORT concurrent with lumpectomy was 2.3% compared with the recurrence rate for patients who received traditional external beam radiation therapy which was 1.3%. Given the study had a non-inferiority boundary of 2.5%, the study revealed that IORT is a non-inferior treatment relative to external beam radiation therapy for patients who meet the established clinical criteria.

The reimbursement for IORT has improved from 2011 when the American Medical Association (AMA) established category 1 CPT codes for IORT based on clinical evidence. These codes and payment values became effective beginning January 2013. In 2014, CMS raised the payment value for the IORT treatment delivery code by 27% and overall IORT reimbursement increased. In 2016, CMS has enacted payment rates similar to rates in 2015.

Non-melanoma skin cancer is considered an epidemic in the U.S. with over 3.5 million cases diagnosed annually. 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 over 15,000 NMSC lesions. Additionally, the Xoft System is the only electronic brachytherapy system with peer reviewed published clinical data.

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In 2015, electronic brachytherapy for the treatment for NMSC continued to be reimbursed under a Category III CPT code. Twenty-one states had positive coverage policies in place for Medicare patients who are suitable candidates for NMSC using electronic brachytherapy. Reimbursement is provided through a Category III electronic brachytherapy treatment delivery CPT code along with other Category I medical physics and treatment-planning CPT codes as determined by medical necessity. In 2015, new Category III reimbursement CPT codes for multi-fraction electronic brachytherapy applications for skin, breast and gynecological cancers were approved by the American Medical Association (AMA) and became active as of January 2016. Coverage policies and payment values associated with the new CPT codes will be determined by the regional U.S. Medicare Administrative Contractors.

Gynecological cancers are also appropriate for treatment with electronic brachytherapy. There are approximately 50,000 new cases of endometrial cancer each year in the U.S. and nearly 300,000 new cases worldwide. 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, 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.

Electronic Brachytherapy products:

Electronic Brachytherapy (eBx) Treatment for Breast Cancer

Axxent® eBx

The portable Axxent eBx system uses isotope-free miniaturized X-ray tube technology to deliver therapy directly to cancer sites with minimal radiation exposure to surrounding healthy tissue. The Axxent eBx system is FDA-cleared for the treatment of early stage breast cancer, endometrial cancer, cervical cancer, and skin cancer, as well as for the treatment of other cancers or conditions where radiation therapy is indicated, including IORT. The Company offers FDA-cleared applicators for the utilization of the Axxent eBx system including breast applicators for IORT and APBI in the treatment of breast cancer, vaginal applicators for the treatment of endometrial cancer, cervical applicators for the treatment of cervical cancer, and skin applicators for the treatment of non-melanoma skin cancers. The 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 Company also provides the 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 as an annual contract customized to individual customer volume/usage requirements.

The Company has made several enhancements to the Axxent eBx system controller including a new software interface enabling enhanced system functionality and an upgraded high voltage connection improving system performance. In 2014, the Company developed and launched a new Axxent SPX Controller which includes an optimized skin treatment arm customized for

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compatibility in confined patient treatment rooms in physician office-based facilities. This controller complements the Axxent MPX Controller which is designed for multi-application use. In early 2013 the Company received FDA clearance for a new applicator for use in the treatment of cervical cancer and launched this product in the U.S and International markets in 2015. This new applicator further expands the Company s product portfolio in the gynecological cancer market and enables customers to offer comprehensive electronic brachytherapy solutions to their patients in need of gynecological radiation therapy. Current customers of the Xoft eBx system include university research and community hospitals, private and governmental institutions, doctors offices, cancer care clinics, and veterinary facilities in the United States, Europe and Asia.

Cancer Detection Segment Overview and Products

Mammography CAD systems use sophisticated algorithms to analyze image data and mark suspicious areas in the image that may indicate cancer. The locations of the abnormalities are marked in a manner that allows the reader of the image to reference the same areas in the original mammogram for further review. The use of CAD aids in the detection of potential abnormalities for the radiologist to review. After initially reviewing the case films or digital images, a radiologist reviews the CAD results and subsequently re-examines suspicious areas that warrant a second look before making a final interpretation of the study. The radiologist determines if a clinically significant abnormality exists and whether further diagnostic evaluation is warranted. As a medical imaging tool, CAD is most prevalent as an adjunct to mammography given the documented success of CAD for detecting breast cancer.

Digital Mammography CAD products:

Advanced Image Analysis and Workflow Solutions in Breast Imaging (Mammography)

iCAD develops and markets a comprehensive range of high-performance CAD solutions for digital mammography systems. iCAD s SecondLook Digital CAD is based on sophisticated patented algorithms that analyze the data, automatically identifying and marking suspicious regions in the images. The CAD provides the radiologist with a second look which helps the radiologist detect actionable missed cancers earlier than screening mammography alone. SecondLook detects and identifies suspicious masses and micro-calcifications utilizing image processing, pattern recognition and artificial intelligence techniques. Knowledge from thousands of mammography images are incorporated in these algorithms enabling the product to distinguish between characteristics of cancerous and normal tissue. The result is earlier detection of hard-to-find cancers, improved workflow for radiologists, and higher quality patient care.

In June 2012, iCAD introduced its next generation of mammography CAD products, PowerLook Advanced Mammography Platform® (AMP). The technology expands on iCAD s SecondLook platform and is the CAD platform upon which all future breast imaging CAD offerings from iCAD will be built. PowerLook AMP incorporates both the SecondLook Digital and the next-generation SecondLook Premier CAD algorithms. PowerLook AMP s CAD metrics offer industry-leading tissue and lesion characteristics to support the breast imager s workflow. In addition, PowerLook AMP is the first product of its kind to integrate a breast density software

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package which aids radiologists by standardizing their approach to breast density assessment. The Company acquired the breast density solution from VuComp in April 2015 and subsequently released it to market under the product name iReveal. Twenty-four states now mandate reporting of a breast density score as part of the annual mammogram, iReveal provides a consistent and standardized reporting tool to assist with this process.

Included with PowerLook AMP is a multi-vendor CAD server that allows hospitals and imaging facilities to connect up to four mammography acquisition devices regardless of vendor. This reduces the need for separate CAD servers while lowering hardware and service costs. iCAD s PowerLook AMP also provides a powerful flexible DICOM connectivity solution enabling universal compatibility with leading PACS and Review Workstations. Additional modules are expected to be released and integrated into PowerLook AMP in the future.

PowerLook Advanced Mammography Platform

PowerLook AMP is designed to function with leading digital mammography systems (FFDM and computed radiography) including systems sold by GE Healthcare, Siemens Medical Systems, Fuji Medical Systems, Hologic, Inc., Sectra Medical Systems, Philips, IMS Giotto, Agfa Corporation, and Planmed. The algorithms in PowerLook AMP products have been optimized for each digital imaging provider based upon characteristics of their unique detectors.

PowerLook AMP is a computer server residing on a customer s network that receives patient studies from the imaging modality, performs CAD analysis and sends the CAD results to PACS and/or review workstations. Workflow and efficiency are critical in digital imaging environments therefore iCAD has developed flexible, powerful DICOM integration capabilities that enable PowerLook AMP to integrate with leading picture archiving and communication systems (PACS) archives and review workstations from multiple providers. iCAD has worked with its OEM partners to ensure CAD results are integrated and easily viewed using each review workstation s graphical user interface. To further improve efficiency and clinical efficacy, the most urgent or important patient studies can be prioritized and analyzed with CAD first.

Magnetic Resonance Imaging (MRI)

In July 2012, iCAD entered into a strategic partnership agreement with Invivo Corp., a subsidiary of Philips Healthcare. With this agreement, iCAD began developing the DynaCAD product software for breast and prostate MR image analysis workstations to help radiologists find cancer earlier and more efficiently. Invivo sells the DynaCAD product both directly and through the Philips global distribution network. In August, 2015, Invivo exercised a contractual right to a perpetual paid up license in exchange for a payment of approximately $2.0 million.

DynaCAD offers a suite of FDA-cleared dynamic contrast enhanced (DCE) MRI analysis solutions for breast, prostate, and other organs. Each of the three modules delivers objective, consistent quantitative analysis of DCE MR images. The DynaCAD software automates the process of drawing regions of interest, minimizing potential errors inherent in manual processes. Once a region of interest has been identified, a sophisticated algorithm analyzes changes in the MR signal in the tissue to help clinicians discern biological processes taking place in malignant versus benign tumors. The DynaCAD algorithm uses all data available from an MR study,

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resulting in more consistent analysis across magnets and contrast agents. Also available within DynaCAD is a breast interventional and prostate interventional module which allows for MRI guided biopsies of the breast and prostate to be performed, respectively.

Breast Tomosynthesis

Breast Tomosynthesis was introduced in the United States in 2010 by Hologic, Inc. GE received approval for their tomosynthesis system in August 2014, and Siemens approval followed in April 2015. 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 along with lower radiation dose per examination when compared to mammography. Clinical studies indicate that diagnostic 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%.

CAD technology 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 CAD solution for tomosynthesis to aid radiologists in their review of breast tomosynthesis as a means of improving lesion detection and reducing the time to read the large tomosynthesis datasets.

Computed Tomography Applications and Colonic Polyp Detection

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, there has been an expanded use of CT imaging 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. 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.

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Advanced Image Analysis and Workflow Solutions in CT Colonography

VeraLook

iCAD introduced a CAD solution, VeraLook, in August 2010 following FDA clearance of the product. This solution is designed to support detection of colonic polyps in conjunction with CTC. iCAD believes that CAD for CTC is a natural extension of iCAD s core competencies in image analysis and image processing. The system works in conjunction with third party display workstations and PACS vendors. Field testing of the product was initiated in 2008 and iCAD conducted a multi-reader clinical study of iCAD s CT Colon CAD product, for use with CTC. Results of the Company s clinical study, *Impact of Computer-Aided Detection for CT Colonography in a Multireader, Multicase Trial* demonstrated that reader sensitivity improved 5.5% for patients with both small and large polyps with use of CAD. Use of CAD reduced specificity of readers by 2.5%. The clinical relevance of this CAD program was improved reader performance while maintaining high reader specificity. Throughout 2015, iCAD distributed the VeraLook product with advanced visualization reading workstations manufactured by Vital Images, a Toshiba Medical System Group Company. In Q4 2014, iCAD received CFDA (China Food and Drug Administration) approval to sell VeraLook in China.

Sales and Marketing

iCAD, through its Xoft subsidiary, markets the eBx system in the United States and select countries worldwide. The Company has expanded its installed base of eBx systems in the U.S. and has established initial installations in a number of countries located in Europe and Asia. Xoft has signed distribution agreements in Russia and China and is actively exploring market entry in India, Australia, New Zealand, Turkey, Saudi Arabia, Israel and Eastern Europe. Xoft s direct U.S. sales force sells the system on the basis of its clinical effectiveness as a platform high dose rate, low energy radiation therapy solution for hospitals, ambulatory care centers and free standing radiation oncology facilities and other office-based uses, e.g. dermatology clinical practices. The eBx system offers a distinct competitive advantage in that it is a highly mobile unit with minimal shielding requirements that can easily be moved from room to room within a single healthcare institution or be transported from facility to facility given its relatively compact form factor.

Breast IORT is a strategic focus of the Company due to the significant clinical /lifestyle benefits to the patient and economic advantages to the facility. NMSC is an additional strategic priority given the high incidence rate of the disease and the benefits of the Xoft eBx system in this clinical indication. Based on the additional clinical applications including gynecological cancers, other IORT applications (in addition to breast IORT), as well as its potential to scale in the future to address other indications for use, the Company believes the Xoft eBx system offers unique flexibility and opportunities for growth.

Core to the Company s eBx market development strategy is a comprehensive medical education program. Xoft actively participates in several key industry scientific conferences in the United States and Europe including but not limited to ACRO, Miami Breast, ASBS, ABS, ACS, SSO, AAPM, ESTRO, ISIORT, Milan Breast, AAD, and ASTRO on an annual basis. More recently,

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Xoft has participated in key dermatology conferences in the U.S. including AAD, Fall and Winter Dermatology Conferences, ASDS, and ACMS. At select industry conferences and at independent venues, the Company provides specific additional eBx professional education programs and product demonstrations in the form of live symposia in U.S. markets. The Company expanded its medical education program in 2015 to include breast IORT and NMSC educational webinars in both CME and non-CME formats to broaden physician awareness of the Xoft System and eBx technology in the U.S.

The Company further supports breast IORT through its ongoing ExBRT Clinical a post-market clinical trial designed to enroll 1,000 patients at up to 50 sites. The study enables facilities interested in treating early stage breast cancer patients with the Xoft eBx system to participate in a common clinical protocol and follow enrolled patients for up to ten years. The Company believes that 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. From its inception in 2012 through February 2016, the ExBRT study has enrolled more than 700 patients at more than 20 facilities in the U.S. and Europe. Initial clinical results from the ExBRT study are expected to be presented at key breast cancer medical conferences in 2016.

iCAD s mammography products are sold through its direct regional sales organization in the U.S. as well as through its OEM partners, including GE Healthcare, Fuji Medical Systems, Siemens Medical, Philips Healthcare, Agfa Corporation, Sectra Medical Systems, Planmed, Fuji Medical Systems, IMS Giotto, and Carestream Health, Inc. iCAD s MRI products are distributed through Invivo and Philips globally. The VeraLook CTC CAD product is primarily distributed by Vital Images.

The Company s cancer detection products are marketed on the basis of their clinical superiority and their ability to help radiologists detect more cancers earlier, while seamlessly integrating into the clinical workflow of the radiologist. As part of its sales and marketing efforts, iCAD has developed and executed a variety of public relations and local outreach programs with numerous iCAD customers. Additional investments are being made in cultivating relationships with the leaders in breast, colon, and prostate CAD at national trade shows, where industry leaders discuss the future of CAD in these modalities.

Competition

The Company s existing eBx products face competition in breast IORT primarily from one company: Carl Zeiss Meditec, Inc., (Zeiss) a multinational company, where eBx products are only one of that company s many products. Zeiss manufactures and sells eBx products for the delivery of IORT. Zeiss has expanded their product portfolio to include additional anatomical areas beyond breast IORT. Zeiss now offers a range of radiation therapy applicators for use in various applications including spine, the gastrointestinal tract, skin, and endometrial cancers. Zeiss has an established base of breast IORT installations in Europe where the majority of the TARGIT-A trial clinical sites are located. IntraOp Medical is an additional competitor in the high dose rate (HDR) radiation therapy market.

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The Company s NMSC products face numerous competitors utilizing a variety of technologies. Surface Radiation Therapy (SRT) systems, including Sensus Healthcare, directly compete with the Xoft System in this market in which Dermatologists and Radiation Oncologists seek mobile, efficient, non-surgical treatment options. In late 2013, Elekta received clearance for its electronic brachytherapy system Esteya for use in the treatment of NMSC. This system utilizes a low energy 69.5 kV source and a range of surface applicators in a small footprint system profile. Clinical experience with the Esteya system remains limited as of early 2016. Other competitors in the NMSC market include surgery (excision, Mohs surgery, and destruction). Mohs surgery remains the primary treatment option for dermatologists in the majority of NMSC cases. Traditional radiation therapy including external beam radiation therapy is also a treatment modality used to treat NMSC patients.

New market opportunities including expansion of the gynecological product portfolio and other IORT applications beyond breast IORT will bring new competitive dynamics to the Company s efforts. Larger, more diversified radiation therapy companies offering a wide variety of clinical solutions for HDR brachytherapy including Varian Medical Systems and Elekta compete in these areas. These multi-national firms offer broad product portfolios including a full range of HDR brachytherapy afterloaders and applicators as well as traditional radiation therapy solutions including linear accelerators, treatment planning solutions, and workflow management capabilities.

The Company currently faces direct competition in its cancer detection business from Hologic, Inc., and Parascript. The Company believes that its market leadership in mammography CAD and strong relationships with its strategic partners will provide it with a competitive advantage in the mammography CAD market.

Merge Healthcare, Inc. and Invivo Corporation (Philips) are the market leaders in breast MR image analysis. The Company believes that its market leadership in mammography CAD and its strategic partnership with Invivo Corporation, provide the Company with a competitive advantage in the breast and prostate imaging markets.

The Company s CT Colon solution faces competition from the traditional imaging CT equipment manufacturers and emerging CAD companies. Siemens Medical, GE Healthcare, and Philips Medical Systems currently offer polyp detection products outside the U.S. Siemens Medical received FDA clearance for CT Polyp 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. The Company believes that current regulatory requirements present a significant barrier to entry into this market and that its market leadership in mammography CAD provides it with a competitive advantage within the CT Colonography community.

iCAD 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

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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.

Manufacturing and Professional Services

The Company s CAD products are manufactured and assembled by the Company. In addition, the Company conducts purchasing and supply chain management, planning/scheduling, manufacturing engineering, service repairs, quality assurance, inventory management, and warehousing. Once the product has shipped, it is usually installed by one of the Company s OEM partners at the customer site. When a product sale is made directly to the end customer by iCAD, the product is generally installed by iCAD personnel at the customer site.

iCAD s professional services staff is composed of a team of trained and specialized individuals providing comprehensive product support on a pre-sales and post-sales basis. This includes pre-sale product demonstrations, product installations, applications training, and call center management (or technical support). The support center is the single point of contact for the customer, providing remote diagnostics, troubleshooting, training, and service dispatch. Service repair efforts are generally performed at the customer site by third party service organizations or in the Company s repair depot by the Company s repair technicians.

Xoft s portable Axxent® Controller is manufactured and assembled for Xoft by contract manufacturers. Xoft s electronic brachytherapy miniaturized X-ray source, which is used to deliver radiation directly to the cancerous site, is manufactured in the Company s San Jose, CA facility. Xoft operations consist of manufacturing, engineering, administration, purchasing, planning and scheduling, service repairs, quality assurance, inventory management, and warehousing. Once the product has shipped, it is typically installed by Xoft personnel at the customer site.

Xoft s field service and customer service staff is composed of a team of trained and specialized individuals providing comprehensive product support, physics support, radiation therapists and billing support on a pre-sales and post-sales basis. The field service staff also provides product installations, maintenance, training and service repair efforts generally performed at the customer site. The customer service staff provides pre-sale product demonstrations, customer support, troubleshooting, service dispatch and call center management.

Government Regulation

The Company s systems are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act with potentially significant costs for compliance. The FDA s regulations govern, among other things, product development, product testing, product labeling, product storage, pre-market clearance or approval, advertising and promotion, and sales and distribution. The Company s devices are also subject to FDA clearance or approval before

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they can be marketed in the U.S. and may be subject to additional regulatory approvals before they can be marketed outside the U.S. There is no guarantee that future products or product modifications will receive the necessary approvals.

The FDA s Quality System Regulations require that the Company s operations follow extensive design, testing, control, documentation and other quality assurance procedures during the manufacturing process. The Company is subject to FDA regulations covering labeling regulations and adverse event reporting including the FDA s general prohibition of promoting products for unapproved or off-label uses.

The Company s manufacturing facilities are subject to periodic inspections by the FDA and corresponding state agencies. Compliance with extensive international regulatory requirements is also required. Failure to fully comply with applicable regulations could result in the Company receiving warning letters, non-approvals, suspensions of existing approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

We are also subject to a variety of federal, state and foreign laws which broadly relate to our interactions with healthcare practitioners and other participants in the healthcare system, including, among others, the following:

- anti-kickback, false claims, physician self-referral, and anti-bribery laws, such as the Foreign Corrupt Practices Act, or FCPA, the UK s Bribery Act 2010, or the UK Anti-Bribery Act;

- state law and regulation regarding fee splitting and other relationships between health care providers and non-professional entities, including companies providing management and reimbursement services;

- laws regulating the privacy and security of personally identifiable information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Health Information Technology for Economic and Clinical Health Act, or HITECH Act; and

- healthcare reform laws, such as the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, which we refer to together as PPACA, which include new regulatory mandates and other measures designed to constrain medical costs, as well as stringent new reporting requirements of financial relationships between device manufacturers and physicians and teaching hospitals.

In addition, we are subject to numerous federal, state, foreign and local laws relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances, among others. 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 its products in certain countries outside of the U.S., the Company must obtain and maintain regulatory approvals and comply with the regulations of each specific country. These regulations, including the requirements for approvals, and the time required for regulatory review vary by country.

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

The federal and state governments of the United States establish guidelines and pay reimbursements to hospitals and free-standing clinics for diagnostic examinations and therapeutic procedures under Medicare at the federal level and Medicaid at the state level. Private insurers often establish payment levels and policies based on reimbursement rates and guidelines established by the government.

The federal government reviews and adjusts coverage policies and reimbursement levels periodically and also consider 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.

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 of patients medical expenses by government healthcare programs, private insurers or other healthcare payors.

The provisions of the Affordable Care Act went into effect in 2012. We are continuing to evaluate the Affordable Care Act and its 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. Other elements of this legislation, including comparative effectiveness research, an independent payment advisory board, payment system reforms (including shared savings pilots) and other provisions, could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business, including the demand and availability of our products, the reimbursement available for our products from governmental and third-party payors, and reduced medical procedure volumes.

In May 2015 the Company announced that one of the regional Medicare Administrative Contractors instructed physicians to report CPT code (17999) rather than the established CPT code (0182T) for electronic brachytherapy for treatment of NMSC. This announcement resulted in a significant disruption in the Therapy segment as a result of the reimbursement uncertainty. Revenues for the year ended December 31, 2015 were also negatively impacted as a result of the uncertainty. In addition, the Company implemented expense reductions in response to the general uncertainty with respect to reimbursement levels. The Company has been proactively addressing the situation in its dialogue with the regional provider and Centers for Medicare and Medicaid Services (CMS) and implemented a strategy to target a new skin-specific level III reimbursement code for skin eBx in the U.S.; However, there is no assurance that payment rates under this code will be adequate and there remains insufficient clarification to fully assess the long-term impact on our business.

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 our products and technologies.

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The Company has many patents covering its CAD and eBx technologies expiring between 2018 and 2028. 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 CAD and digitizer technologies and products, including CAD 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, a non-exclusive license from Yeda Research which relates to the 3TP method for the detection of cancer 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, we do not know if 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 for it by a sole manufacturer, by 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. The loss of a sole or key manufacturer or supplier would impair the Company s ability to deliver products to customers in a timely manner and would adversely affect its sales and operating results. The Company s business would be harmed if any of its manufacturers or suppliers could not meet its quality and performance specifications and quantity and delivery requirements.

Major Customers

The Company operates in two segments: Cancer Detection (Detection) and Cancer Therapy (Therapy). The Company markets its products for digital mammography, MRI, and cancer therapy systems through its direct regional sales organization. Cancer detection products are also sold through OEM partners, including GE Healthcare, Fuji Medical Systems, Siemens Medical and Invivo. OEM partners generated approximately 53% of detection revenues and 25% of revenue overall. GE Healthcare was the largest single customer with approximately $4.1 million in 2015, $4.1 million in 2014, and $3.7 million in 2013 or 10%, 9%, and 11% of total revenues, respectively.

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Engineering and Product Development

The Company spent $9.8 million, $8.8 million, and $7.7 million on research and development activities during the years ended December 31, 2015, 2014 and 2013, 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 February 2016, the Company had 108 employees, of whom 105 are full time employees, with 24 involved in sales and marketing, 23 in research and development, 48 in service, manufacturing, technical support and operations functions, and 13 in administrative functions. None of the Company s employees is represented by a labor organization. The Company considers its relations with employees to be good.

Environmental Protection

Compliance with federal, state and local provisions which have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, has not had a material effect upon the capital expenditures, earnings (losses) or competitive position of the Company.

Financial Geographic Information

The Company s primary market is in the United States through its direct sales force and OEM partners. Export sales are typically through OEM and channel partners. Total export sales represented approximately $2.3 million or 6% of revenue in 2015 as compared to $1.8 million or 4% of revenue in 2014 and $1.9 million or 6% of total revenue in 2013.

The Company s principal concentration of export sales is in Europe, which accounted for 55% of the Company s revenue from export sales in 2015, 40% of the Company s revenue from export sales in 2014 and 65% of the Company s revenue from export sales in 2013. Bulgaria accounted for approximately 26% of export sales in 2015 and France accounted for approximately 21% in 2015, 17% in 2014 and 23% in 2013 of the total revenues from export sales. In addition approximately 9% and 11% of revenues from export sales in 2015 were to the United Kingdom and Canada, respectively.

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 it will be able to obtain the necessary regulatory approvals timely or at all in any foreign country in which it plans to market its CAD products and the Axxent eBx system, and if it fails to receive and maintain such approvals, its ability to generate revenue may be significantly diminished.

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Product Liability Insurance

The Company believes that it maintains appropriate product liability insurance with respect to its products. The Company cannot be certain that with respect to its current or future products, such insurance coverage will continue to be available on terms acceptable to the Company or that such coverage will be adequate for liabilities that may actually be incurred.

Item 1A. Risk Factors.

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

We have incurred significant losses from inception through 2015 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 $32.4 million in fiscal 2015 and have an accumulated deficit of $177.5 million at December 31, 2015. 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. There is a risk that our patent applications will not result in granted patents or that granted patents will not provide significant protection for our products and technology. Unauthorized third parties may infringe our intellectual property rights, or copy or reverse engineer portions of our technology. Our competitors may independently develop similar technology that our patents do not cover. 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. Over the coming years, certain patents relating to current products will expire in the U.S. and abroad thus allowing third parties to utilize certain of our technologies. In the absence of significant patent protection, we may be vulnerable to competitors who attempt to copy our products, processes or technology

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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, to the extent that any of our intellectual property and proprietary rights was ever deemed to violate the proprietary rights of others in any litigation or proceeding or as a result of any claim, we may be prevented from using them, which could cause a termination of our ability to sell our products. Litigation could also result in a judgment or monetary damages being levied against us.

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 payors. The failure of third-party payors to provide appropriate levels of coverage and reimbursement for the use of our products and treatments facilitated by our products could harm our business and prospects.

Sales and market acceptance of our medical products and the treatments facilitated by our products in the United States and other countries is dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. Market acceptance of our products and treatments has and will continue to depend upon our customers ability to obtain an appropriate level of coverage for, and reimbursement from third-party payors for, these products and treatments. In the U.S., 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 may vary based on the geographic price index. Coverage and reimbursement policies and rates applicable to patients with private insurance are dependent upon individual private payor 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 private insurance carriers. We cannot provide assurance that government or private third-party payors will continue to reimburse for our products or services using the existing codes, nor can we provide assurance that the payment rates will be adequate. If providers and physicians are unable to obtain reimbursement for our products or services at cost-effective levels, this could have a material adverse effect on our business and operations. In addition, in the event that the current coding and/or payment methodology for these products or services changes, this could have a material adverse effect on our business and business operations.

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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 to 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 cost 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