

ICAD INC  
Form 10-K  
March 11, 2016  
Table of Contents

**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, 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**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**02-0377419**  
**(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:**

<b>Title of Class</b>	<b>Name of each exchange on which registered</b>
<b>Common Stock, \$.01 par value</b>	<b>The NASDAQ Stock Market LLC</b>

**Securities registered pursuant to Section 12 (g) of the Act:**

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirement for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically 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  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 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   
Non-accelerated filer  (do not check if a smaller reporting company) Smaller reporting company   
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, 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.

---

**Table of Contents**

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

Certain information included in this annual report on Form 10-K that are not historical facts contain forward looking statements that involve a number of known and unknown risks, uncertainties and other factors that could cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievement expressed or implied by such forward looking statements. These risks and uncertainties include, but are not limited to, the Company's ability to defend itself in litigation matters, to achieve business and strategic objectives, the risks of uncertainty of patent protection, the impact of supply and manufacturing constraints or difficulties, uncertainty of future sales levels, protection of patents and other proprietary rights, the impact of supply and manufacturing constraints or difficulties, product market acceptance, possible technological obsolescence of products, increased competition, litigation and/or government regulation, changes in Medicare reimbursement policies, risks relating to our existing and future debt obligations, competitive factors, the effects of a decline in the economy or markets served by the Company and other risks detailed in this report and in the Company's other filings with the United States Securities and Exchange Commission (SEC). The words believe, demonstrate, intend, expect, estimate, anticipate, likely, seek and similar expressions identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date the statement was made. Unless the context otherwise requires, the terms iCAD, Company, we, our registrant, and us means iCAD 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](http://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.

## **Table of Contents**

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

## **Table of Contents**

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.

---

**Table of Contents**

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

**Table of Contents**

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.



**Table of Contents**

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	%
<b>Detection:</b>						
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%
<b>Therapy:</b>						
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.



## **Table of Contents**

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.

---

**Table of Contents**

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

---

**Table of Contents**

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 Xofig 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

---

**Table of Contents**

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,

## **Table of Contents**

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.

---

**Table of Contents**

*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,



## **Table of Contents**

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.

**Table of Contents**

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 Xofig 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

## **Table of Contents**

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 Axser® 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

**Table of Contents**

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.

## **Table of Contents**

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.

## **Table of Contents**

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 Cytoc/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.

## **Table of Contents**

### **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.



**Table of Contents**

**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

---

**Table of Contents**

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.

**Table of Contents**

**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 principal customer could seriously hurt our business.**

Our principal sales distribution channel for our digital products is through our OEM partners which accounted for 25% of our total revenue in 2015, with one major customer, GE Healthcare at 10% of our revenue. In addition six customers accounted for 29% of our total revenue, which includes both OEM partners and direct customers. 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. 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;

the availability and extent of data demonstrating the clinical efficacy of our products or treatments;

**Table of Contents**

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 a reimbursement code or an appropriate reimbursement level for use of the product or treatment. Moreover, even if addressed, such reimbursement codes or 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. In September 2011, we recorded an impairment of \$26.8 million on our goodwill, and in June 2015, we recorded an additional impairment of \$14.0 million on our goodwill. Under current accounting guidelines, we must assess, at least annually and potentially more frequently, whether the value of our goodwill of \$14.2 million at December 31, 2015 and our other intangible assets has 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.**

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 state to state and it is difficult to ensure our business complies with evolving laws in all states. In addition, we believe that our business will continue to be subject to increasing regulation, the scope and effect of which we cannot predict. Federal and state legislatures and 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.

---

**Table of Contents**

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 management 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 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 government-sponsored health care programs such as Medicare and Medicaid.**

Our operations, including our arrangements with healthcare providers, are subject to extensive federal and state government regulation and are subject to audits, inquiries and investigations from government agencies from time to time. Those laws may have related rules and regulations that are subject to interpretation and may not provide definitive guidance as to their application to our operations, including our arrangements with physicians and professional corporations.

We believe we are in substantial compliance with these laws, rules and regulations based upon what we believe are reasonable and defensible interpretations of these laws, rules and regulations. However, 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 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, the 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 as to 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.

---

**Table of Contents**

**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.

***Anti-Kickback Statutes***

The federal Anti-Kickback Statute prohibits persons from knowingly or willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce:

the referral of an individual for a service or product for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare program; or

purchasing, ordering, arranging for, or recommending the ordering of, any service or product for which payment may be made by a government-sponsored healthcare program.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The statutory penalties for violating the Anti-Kickback Statute include imprisonment for up to five years and criminal fines of up to \$25,000 per violation. In addition, through application of other laws, conduct that violates the Anti-Kickback Statute can also give rise to False Claims Act lawsuits, civil monetary penalties and possible exclusion from Medicare and Medicaid and other federal healthcare programs. In addition to the Federal Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states, these anti-kickback laws apply not only to payment made by a government health care program but also with respect to other payers, including commercial insurance companies.

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.

---

**Table of Contents*****Our relationships with healthcare providers and our marketing practices are subject to the federal Anti-Kickback Statute and similar state laws.***

We are subject to the federal Anti-Kickback Statute, which prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, the referral of business or ordering of services paid for by Medicare or other federal programs. Remuneration has been broadly interpreted to mean anything of value, including, for example, gifts, discounts, credit arrangements, and in-kind goods or services, as well as cash. Certain federal courts have held that the Anti-Kickback Statute can be violated if one purpose of a payment is to induce referrals. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Violations of the Anti-Kickback Statute can result in imprisonment, civil or criminal fines or exclusion from Medicare and other governmental programs. Many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any payor, not only the Medicare and Medicaid programs. 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. The False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam 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 payor and not merely a federal healthcare program.

Although we have attempted to structure our marketing initiatives and business relationships to comply with the Anti-Kickback Statute, we cannot assure you that we will not have to defend against alleged violations from private or public entities or that the Office of Inspector General or other authorities will not find that our marketing practices and relationships violate the 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***

The 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.



---

**Table of Contents**

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.

In February 2016, President Obama released the Administration's proposed fiscal 2017 budget for the Department of Health and Human Services, which once again recommends the exclusion of anatomic pathology, advanced diagnostic imaging and therapy services, including physical therapy and radiation therapy, from the in-office ancillary services exception to Stark law self-referral restrictions. The in-office ancillary services exception currently allows physicians to provide certain designated health services within the confines of their office without violating the Stark prohibition of self-referrals if certain conditions are met. If adopted, the recommended changes in the budget would eliminate this exception, which could result in a reduction in the provision of certain radiation therapy services by physicians, and could impact our arrangements to provide services and equipment to physicians and professional corporations. The elimination of the in-office ancillary services exception for radiation therapy could require us to modify our contractual arrangements with physicians and professional corporations, which could increase our operating costs, and we could also lose contracts or our revenues could decrease under existing contracts.

***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.***

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.

We have financial relationships with physicians in the form of equipment leases and services arrangements. While we believe our arrangements with physicians are in material compliance with applicable laws and regulations, government authorities might take a contrary position or prohibited referrals may occur. Further, because we cannot be certain that we will have knowledge of all physicians who may hold an indirect ownership interest, referrals from any such physicians may cause us to violate these laws and regulations.

## **Table of Contents**

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.

### ***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 be made, a false statement to obtain payment from the federal government. 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. Congress strengthened the False Claims Act in amendments contained in the Fraud Enforcement and Recovery Act of 2009 (Pub.L. 111-21). 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.

### ***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

---

**Table of Contents**

Medicare, Medicaid, commercial health insurers and managed care companies. However, our business will 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 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, or was used for an unapproved indication. They may also pay an inadequate amount for the procedure which could cause healthcare providers to use a lower cost competitor's device or perform a medical procedure without our device.

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

a covered benefit under its health plan;

appropriate and medically necessary for the specific indication;

cost effective; and

neither experimental nor investigational.

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.

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 our Therapy segment as a result of the reimbursement uncertainty. Revenues for the year ended December 31, 2015 were negatively impacted as a result of the uncertainty. For a further discussion, please Management's Discussion and Analysis of Financial Condition and Results of Operations.

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.

**The adoption of healthcare reform in the United States may adversely affect our business and/or results of operations.**

---

**Table of Contents**

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 for 2016 and 2017. We are unable to predict whether the postponement will be continued beyond 2017. 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.

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

Our CAD systems for the computer aided detection of cancer and Axxent eBx systems are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act. In addition, our manufacturing operations are subject to FDA regulation and we are also subject to FDA regulations covering labeling, adverse event reporting, and the FDA's general prohibition against promoting products for unapproved or off-label uses.

Our failure to fully comply with applicable regulations could result in the issuance of warning letters, non-approvals, suspensions of existing approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution. Moreover, unanticipated changes in existing regulatory requirements or adoption of new requirements could increase our application, 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.

---

**Table of Contents**

**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 require us to recall our products, 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 may be subject to criminal or civil sanctions if we fail to comply with privacy 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 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.

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. If we or any of our subcontractors experience a breach of the privacy or security of patient information, the breach reporting requirements and the liability for business associates under HIPAA could result in substantial financial liability and reputational harm.

Federal and state consumer laws are being applied increasingly by the Federal Trade Commission (FTC) 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

## **Table of Contents**

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.

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

Our services involve the storage and transmission of customers' proprietary information and patient information, including health, financial, payment and other personal or confidential information. We rely on proprietary and commercially available systems, software, tools and monitoring, as well as other processes, to provide security for processing, transmission and storage of such information. Because of the sensitivity of this information and due to requirements under applicable laws and regulations, the effectiveness of such security efforts is very important. If our security measures are breached or fail as a result of third-party action, employee error, malfeasance or otherwise, someone may be able to obtain unauthorized access to customer or patient data. Improper activities by third-parties, advances in computer and software capabilities and encryption technology, new tools and discoveries and other events or developments may facilitate or result in a compromise or breach of our computer systems. Techniques used to obtain unauthorized access or to sabotage systems change frequently and generally are not recognized until launched against a target, and we may be unable to anticipate these techniques or fail to implement adequate preventive measures. Our security measures may not be effective in preventing such unauthorized access. If a breach of our security occurs, we could face damages for contract breach, penalties for violation of applicable laws or regulations, possible lawsuits by individuals affected by the breach and significant remediation costs and efforts to prevent future occurrences. In addition, whether there is an actual or a perceived breach of our security, the market perception of the effectiveness of our security measures could be harmed and we could lose current or potential customers.

### **Our recent acquisitions involve risks.**

We have recently completed acquisitions and we may make acquisitions in the future. Such transactions involve numerous risks, including possible adverse effects on our operating results or the market price of our common stock. Some of the potential risks involved with acquisitions are the following:

difficulty in realizing anticipated financial or strategic benefits of such acquisition;

diversion of capital and potential dilution of stockholder ownership;

the risks related to increased indebtedness, as well as the risk such financing will not be available on satisfactory terms or at all;

diversion of management's attention and other resources from current operations, including potential strain on financial and managerial controls and reporting systems and procedures;

management of employee relations across facilities;

difficulties in the assimilation of different corporate cultures and practices, as well as in the assimilation and retention of broad and geographically dispersed personnel and operations;



**Table of Contents**

difficulties and unanticipated expenses related to the integration of departments, systems (including accounting systems), technologies, books and records, procedures and controls (including internal accounting controls, procedures and policies), as well as in maintaining uniform standards, including environmental management systems;

assumption of known and unknown liabilities, some of which may be difficult or impossible to quantify;

inability to realize cost savings, sales increases or other benefits that we anticipate from such acquisitions, either as to amount or in the expected time frame;

non-cash impairment charges or other accounting charges relating to the acquired assets; and

maintaining strong relationships with our and our acquired companies' customers after the acquisitions. If our integration efforts are not successful, we may not be able to maintain the levels of revenues, earnings or operating efficiency that we and the acquired companies achieved or might achieve separately.

**Our acquisitions may not result in the benefits and revenue growth we expect.**

We are in the process of integrating companies that we acquired and 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.**

The markets for many products we sell are subject to changing technology, new product introductions and product enhancements, and evolving industry standards. The introduction or enhancement of products embodying new technology or the emergence of new industry



## **Table of Contents**

standards could render our existing products obsolete or result in short product life cycles or our inability to sell our products without offering a significant discount. Accordingly, our ability to compete is in part dependent on our ability to continually offer enhanced and improved products.

If we are unable to successfully introduce new technology solutions or services or fail to keep pace with advances in technology, our business, financial condition and results of operations will be adversely affected.

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 would suffer. Because the healthcare information technology market is constantly evolving, our existing Radion technology may become obsolete and fail to meet the requirements of current and potential customers. Our success will depend, in part, on our ability to continue to enhance our existing technology solutions and services, develop new technology that addresses the increasingly sophisticated and varied needs of our customers, and respond to technological advances and emerging industry standards and practices on a timely and cost-effective basis. The development of our proprietary technology entails significant technical and business risks. We may not be successful in developing, using, marketing, selling, or maintaining new technologies effectively or adapting our proprietary Radion 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. A failure by us 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.**

## **Table of Contents**

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. In addition, our competitors may achieve patent protection, regulatory approval, or product commercialization that would limit our ability to compete with them. These and other competitive pressures could have a material adverse effect on our business.

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

We rely on third-parties who provide access to data centers. Our information technologies and systems are vulnerable to damage or interruption from various causes, including (i) acts of God and other natural disasters, war and acts of terrorism and (ii) power losses, computer systems failures, internet and telecommunications or data network failures, operator error, losses of and corruption of data and similar events. We conduct business continuity planning according 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.**

Complex software, such as our Radion software, often contains defects or errors, some of which may remain undetected for a period of time. It is possible that such errors may be found after the introduction of new software or enhancements to existing software. We continually introduce new solutions and enhancements to our solutions, and, despite testing by us, it is possible that errors may occur in our software. If we detect any errors before we introduce a solution, we might have to delay deployment for an extended period of time while we address the problem. If we do not discover software errors that affect our new or current solutions or enhancements until

**Table of Contents**

after they are deployed, we would need to provide enhancements to correct such errors. Errors in our software could result in:

harm to our reputation;

lost sales;

delays in commercial releases;

product liability claims;

delays in or loss of market acceptance of our solutions;

license terminations or renegotiations;

unexpected expenses and diversion of resources to remedy errors; and

privacy and security vulnerabilities.

Furthermore, our customers might use our software together with products from other companies or those that they have developed internally. As a result, when problems occur, it might be difficult to identify the source of the problem. Even when our software does not cause these problems, the existence of these errors might cause us to incur significant costs, divert the attention of our technical personnel from our solution development efforts; impact our reputation and cause significant customer relations problems.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, 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, 2015 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 future material changes to our internal controls over financial reporting will 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 of the Sarbanes-Oxley Act of 2002 could adversely affect investor confidence and, as a result, our stock price.**

We are required to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ( Section 404 ). Although we 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.**

## **Table of Contents**

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 6% of our revenue for 2015. 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; restrictions on the transfer of funds into or out of the country; varying tax systems; and government protectionism. One or more of the foregoing factors could impair our current or future operations and, as a result, harm our overall business.

### **The market price of our common stock has been, and may continue to be, volatile which could reduce the market price of our common stock.**

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

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

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

**Table of Contents**

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. If holders of options or warrants choose to exercise their securities and sell shares of common stock issued upon the exercise 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 that are exercisable into a significant number of shares of our common stock. Should existing holders of options exercise their securities into shares of our common stock, it may cause significant dilution of equity interests of existing holders of our common stock and reduce the market price of shares of our common stock.

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

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

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

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

**Item 1B. Unresolved Staff Comments.**

Not applicable



**Table of Contents**

**Item 2. Properties.**

The Company's executive offices are leased pursuant to a five-year lease (the "Lease") that commenced on December 15, 2006, and renewed on January 1, 2012, 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 Lease renewal provided for an annual base rent of \$198,288 in 2015 and \$203,796 for 2016. 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 also has the right to extend the term of the Lease for an additional five year period at the then current market rent rate (but not less than the last annual rent paid by the Company).

The Company leases a facility consisting of approximately 24,350 square feet of office, manufacturing and warehousing space located at 101 Nicholson Lane, San Jose, CA. The operating lease commenced September 2012 with a current annual payment of, \$271,752 from October 2014 through September 2015, \$283,440 through September 2016 and \$295,140 through September 2017, 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.**

The Company is 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.

**Table of Contents****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 2015 and 2014.

Fiscal year ended December 31, 2015	High	Low
First Quarter	\$ 11.14	\$ 7.61
Second Quarter	10.86	3.22
Third Quarter	4.69	2.95
Fourth Quarter	5.41	2.96
 Fiscal year ended December 31, 2014		
First Quarter	\$ 14.11	\$ 9.02
Second Quarter	9.64	5.94
Third Quarter	11.40	6.42
Fourth Quarter	11.63	8.05

As of February 20, 2016, there were 264 holders of record of the Company's common stock. In addition, the Company believes that there are in excess of 3,700 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. There are no non-statutory restrictions on 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, 2015.

*Issuer's Purchases of Equity Securities.* For the majority of restricted stock units granted, 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 did not have any repurchases of securities in the quarter ended December 31, 2015.

**Table of Contents****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.

**Selected Statement of Operations Data**

	<b>Year Ended December 31,</b>				
	<b>2015</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>
Total Revenue	\$ 41,554	\$ 43,924	\$ 33,067	\$ 28,275	\$ 28,652
Gross margin	29,350	31,227	23,085	20,031	20,027
Gross margin %	70.6%	71.1%	69.8%	70.8%	69.9%
Total operating expenses	59,429	30,412	24,861	25,443	57,143
Income (loss) from operations	(30,079)	815	(1,776)	(5,412)	(37,116)
Other (expense) income, net	(2,352)	(1,671)	(5,706)	(3,919)	(395)
Net loss	\$ (32,447)	\$ (1,009)	\$ (7,608)	\$ (9,374)	\$ (37,587)
Net income (loss) per share					
Basic	\$ (2.07)	\$ (0.07)	\$ (0.70)	\$ (0.87)	\$ (3.45)
Diluted	\$ (2.07)	\$ (0.07)	\$ (0.70)	\$ (0.87)	\$ (3.45)
Weighted average shares outstanding					
Basic	15,686	14,096	10,842	10,796	10,910
Diluted	15,686	14,096	10,842	10,796	10,910

**Selected Balance Sheet Data**

	<b>As of December 31,</b>				
	<b>2015</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>
Cash and cash equivalents	\$ 15,280	\$ 32,220	\$ 11,880	\$ 13,948	\$ 4,576
Total current assets	27,767	44,616	22,043	21,533	11,109
Total assets	48,640	93,770	58,916	59,993	51,761
Total current liabilities	14,279	22,049	22,452	14,639	12,484
Long term deferred revenue	1,079	1,525	1,726	1,502	1,446
Notes and lease payable, long term	86	6,622	12,005	14,846	
Stockholders' equity	\$ 32,746	\$ 62,779	\$ 21,377	\$ 27,665	\$ 36,055

---

**Table of Contents**

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

**Overview**

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 segments – Cancer Detection ( Detection ) and Cancer Therapy ( Therapy ).

The Company has grown primarily through acquisitions to become a broad player in the oncology market.

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

The Company intends to continue the extension of its superior image analysis and clinical decision support solutions for mammography, MRI and CT imaging. iCAD believes that advances in digital imaging techniques should bolster its efforts to develop additional commercially viable CAD/advanced image analysis and workflow products.

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

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 twelve months 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.

## **Table of Contents**

As the Company has noted in its 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 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 condensed consolidated financial statements for additional discussion).

On April 29, 2015, pursuant to the terms of the Asset Purchase Agreement with VuComp, the Company purchased VuComp's M-Vu Breast Density product for \$1,700,000 in cash.

In January 2016, the Company acquired the VuCOMP cancer detection portfolio, including the M-Vu<sup>®</sup> computer aided detection (CAD) technology platform.

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.

## **Critical Accounting Policies**

The Company's discussion and analysis of its financial condition, results of operations, and cash flows are based on its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates these estimates, including those related to revenue recognition, allowance for doubtful accounts, inventory valuation and obsolescence, intangible assets, goodwill, warrants, income taxes, contingencies and litigation. Additionally, the Company uses assumptions and estimates in calculations to determine stock-based compensation and the value of warrants. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company's critical accounting policies include:

Revenue recognition;

Allowance for doubtful accounts;

Inventory;

Valuation of long-lived and intangible assets;

44

**Table of Contents**

Goodwill;

Warrants

Stock based compensation; and

Income taxes.

**Revenue Recognition**

The Company recognizes revenue primarily from the sale of products and from the sale of services and supplies. Revenue is recognized when delivery has occurred, persuasive evidence of an arrangement exists, fees are fixed or determinable and collectability of the related receivable is probable. For product revenue, delivery has occurred upon shipment provided title and risk of loss have passed to the customer. Services and supplies revenue are considered to be delivered as the services are performed or over the estimated life of the supply agreement.

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

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

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

## **Table of Contents**

The Company has determined that iCAD's digital and film based sales generally follow the guidance of FASB ASC Topic 605 Revenue Recognition (ASC 605) as the software has been considered essential to the functionality of the product per the guidance of ASU 2009-14. Typically, the responsibility for the installation process lies with the OEM partner. On occasion, when iCAD is responsible for product installation, the installation element is considered a separate unit of accounting because the delivered product has stand-alone value to the customer. In these instances, the Company allocates revenue to the deliverables based on the framework established within ASU 2009-13. Therefore, the installation and training revenue is recognized as the services are performed according to the BEP of the element. Revenue from the digital and film based equipment, when there is installation, is recognized based on the relative selling price allocation of the BEP, when delivered.

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

The Company recognizes post contract customer support revenue together with the initial licensing fee for certain MRI products in accordance with ASC 985-605-25-71.

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

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

## **Allowance for Doubtful Accounts**

The Company's policy is to maintain allowances for estimated losses from the inability of its customers to make required payments. Credit limits are established through a process of reviewing the financial results, stability and payment history of each customer. Where appropriate, the Company obtains credit rating reports and financial statements of customers



---

## **Table of Contents**

when determining or modifying credit limits. The Company's senior management reviews accounts receivable on a periodic basis to determine if any receivables may potentially be uncollectible. The Company includes any accounts receivable balances that it determines may likely be uncollectible, along with a general reserve for estimated probable losses based on historical experience, in its overall allowance for doubtful accounts. An amount would be written off against the allowance after all attempts to collect the receivable had failed. Based on the information available to the Company, it believes the allowance for doubtful accounts as of December 31, 2015 is adequate.

## **Inventory**

Inventory is valued at the lower of cost or market value, with cost determined by the first-in, first-out method. The Company regularly reviews inventory quantities on hand and records a provision for excess and/or obsolete inventory primarily based upon historical usage of its inventory as well as other factors.

## **Long Lived Assets**

In accordance with FASB ASC Topic 360, *Property, Plant and Equipment*, (ASC 360), the Company assesses long-lived assets for impairment if events and circumstances indicate it is more likely than not that the fair value of the asset group is less than the carrying value of the asset group.

ASC 360-10-35 uses *events and circumstances* criteria to determine when, if at all, an asset (or asset group) is evaluated for recoverability. Thus, there is no set interval or frequency for recoverability evaluation. In accordance with ASC 360-10-35-21 the following factors are examples of events or changes in circumstances that indicate the carrying amount of an asset (asset group) may not be recoverable and thus is to be evaluated for recoverability.

A significant decrease in the market price of a long-lived asset (asset group);

A significant adverse change in the extent or manner in which a long-lived asset (asset group) is being used or in its physical condition;

A significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset (asset group), including an adverse action or assessment by a regulator;

An accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of a long-lived asset (asset group);

A current period operating or cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with the use of a long-lived asset (asset group).

As a result of external factors and general uncertainty related to reimbursement for the treatment of NMSC, the Company evaluated the long-lived assets of the Therapy segment and reviewed them for potential impairment. The Company determined the *Asset Group* to be the assets of the Therapy segment, which the Company considered to be the lowest level for which the identifiable cash flows were largely independent of the cash flows of other assets and

liabilities.

---

**Table of Contents**

In accordance with ASC 360-10-35-17, if the carrying amount of an asset or asset group (in use or under development) is evaluated and found not to be fully recoverable (the carrying amount exceeds the estimated gross, undiscounted cash flows from use and disposition), then an impairment loss must be recognized. The impairment loss is measured as the excess of the carrying amount over the assets (or asset group's) fair value.

In connection with the preparation of the financial statements for the second quarter ended June 30, 2015, the Company completed its analysis pursuant to ASC 360-10-35-17 and determined that the carrying value of the Asset Group was approximately \$36.8 million, which exceeded the undiscounted cash flows by approximately \$2.8 million. Accordingly the Company completed the Step 2 analysis to determine the fair value of the Asset Group. The Company recorded long-lived asset impairment charges of approximately \$13.4 million in the second quarter ended June 30, 2015 and as a result the long lived assets in the Asset Group were recorded at their current fair values.

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

Intangible assets subject to amortization consist primarily of patents, technology intangibles, trade names, customer relationships and distribution agreements purchased in the Company's previous acquisitions. These assets are amortized on a straight-line basis or the pattern of economic benefit over their estimated useful lives of 5 to 10 years.

**Goodwill**

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

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

significant underperformance relative to historical or projected future operating results;

significant changes in the manner or use of the assets or the strategy for the Company's overall business;

**Table of Contents**

significant negative industry or economic trends;

significant decline in the Company's stock price for a sustained period; and

a decline in the Company's market capitalization below net book value.

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

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

As a result of external factors and general uncertainty related to reimbursement for non-melanoma skin cancer and in conjunction with the long-lived asset impairment testing, the Company performed an impairment assessment of the Therapy reporting unit as of June 30, 2015. As a result the Company recorded a goodwill impairment charge of \$14.0 million during the quarter ended June 30, 2015.

The implied fair value of the Therapy reporting unit was determined in the same manner as the manner in which the amount of goodwill recognized in a business combination is determined. The excess of the fair value of the reporting unit over the amounts assigned to its assets and liabilities is the implied amount of goodwill. The Company identified the intangible assets that were valued during this process, including technology, customer relationships, trade-names, and the Company's workforce. The allocation process was performed only for purposes of testing goodwill for impairment.

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

## **Table of Contents**

The Company uses internal forecasts to estimate future cash flows and includes an estimate of long-term future growth rates based on the most recent views of the long-term forecast for the reporting unit. Accordingly, actual results can differ from those assumed in the forecasts. The discount rate of approximately 17% is derived from a capital asset pricing model and analyzing published rates for industries relevant to the reporting unit to estimate the cost of equity financing. The Company uses discount rates that are commensurate with the risks and uncertainty inherent in the respective businesses and in the internally developed forecasts.

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

The Step 2 test resulted in an approximate fair value of goodwill of \$5.7 million which resulted in a goodwill impairment loss of \$14.0 million.

The Company performed the annual impairment assessment at October 1, 2015 and compared the fair value of each of reporting unit to its carrying value as of this date. Fair value of each reporting unit exceeded the carry value by approximately 584% for the Detection reporting unit and 144% for the Therapy reporting unit. The carrying values of the reporting units were determined based on an allocation of our assets and liabilities through specific allocation of certain assets and liabilities, to the reporting units and an apportionment of the remaining net assets based on the relative size of the reporting units' revenues and operating expenses compared to the Company as a whole. The determination of reporting units also requires management judgment.

The Company determined the fair values for each reporting unit using a weighting of the income approach and the market approach. For purposes of the income approach, fair value is determined based on the present value of estimated future cash flows, discounted at an appropriate risk adjusted rate. The Company uses internal forecasts to estimate future cash flows and includes estimates of long-term future growth rates based on our most recent views of the long-term forecast for each segment. Accordingly, actual results can differ from those assumed in our forecasts. The discount rate of approximately 17% is derived from a capital asset pricing model and analyzing published rates for industries relevant to our reporting units to estimate the cost of equity financing. The Company uses discount rates that are commensurate with the risks and uncertainty inherent in the respective businesses and in our internally developed forecasts.

In the market approach, the Company uses a valuation technique in which values are derived based on market prices of publicly traded companies with similar operating characteristics and industries. A market approach allows for comparison to actual market transactions and multiples. It can be somewhat limited in its application because the population of potential comparable publicly-traded companies can be limited due to differing characteristics of the comparative business and ours, as well as the fact that market data may not be available for divisions within larger conglomerates or non-public subsidiaries that could otherwise qualify as comparable, and the specific circumstances surrounding a market transaction (e.g., synergies between the parties, terms and conditions of the transaction, etc.) may be different or irrelevant with respect to our business.

---

**Table of Contents**

The Company corroborated the total fair values of the reporting units using a market capitalization approach; however, this approach cannot be used to determine the fair value of each reporting unit value. The blend of the income approach and market approach is more closely aligned to our business profile, including markets served and products available. In addition, required rates of return, along with uncertainties inherent in the forecast of future cash flows, are reflected in the selection of the discount rate. Equally important, under the blended approach, reasonably likely scenarios and associated sensitivities can be developed for alternative future states that may not be reflected in an observable market price. The Company assesses each valuation methodology based upon the relevance and availability of the data at the time the valuation is performed and weight the methodologies appropriately.

**Warrants**

In January 2012, the Company entered into several agreements with Deerfield Management, a healthcare investment fund ( Deerfield ), which included a debt facility agreement and the issuance of warrants (the Warrants ) to purchase up to 550,000 shares of common stock at an exercise price of \$3.50 per share, of which 450,000 shares of the Company s common stock became immediately exercisable. On April 30, 2014, Deerfield exercised the Warrants, for an aggregate purchase price of \$1,575,000, and the Company issued 450,000 shares of common stock. The Warrant obligation was fully satisfied following that exercise. The additional 100,000 shares of common stock that would have become exercisable if the Company extended the debt were cancelled.

**Stock-Based Compensation**

The Company maintains stock-based incentive plans, under which it provides stock incentives to employees, directors and contractors. The Company grants to employees, directors and contractors, options to purchase common stock at an exercise price equal to the market value of the stock at the date of grant. The Company may grant restricted stock to employees and directors. The underlying shares of the restricted stock grant are not issued until the shares vest, and compensation expense is based on the stock price of the shares at the time of grant. The Company follows ASC 718, *Compensation - Stock Compensation* , ( ASC 718 ), for all stock-based compensation.

The Company uses the Black-Scholes option pricing model to value stock options which requires extensive use of accounting judgment and financial estimates, including estimates of the expected term participants will retain their vested stock options before exercising them, the estimated volatility of its common stock price over the expected term, and the number of options that will be forfeited prior to the completion of their vesting requirements. Fair value of restricted stock is determined based on the stock price of the underlying option on the date of the grant. Application of alternative assumptions could produce significantly different estimates of the fair value of stock-based compensation and consequently, the related amounts recognized in the Consolidated Statements of Operations.

**Table of Contents**

**Income Taxes**

The Company follows the liability method under ASC 740, Income Taxes (ASC 740). The primary objectives of accounting for taxes under ASC 740 are to (a) recognize the amount of tax payable for the current year and (b) recognize the amount of deferred tax liability or asset for the future tax consequences of events that have been reflected in the Company's financial statements or tax returns. The Company has provided a full valuation allowance against its deferred tax assets at December 31, 2015 and 2014 as it is more likely than not that the deferred tax asset will not be realized.

ASC 740-10 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC 740-10 also provides guidance on de-recognition, classification, interest and penalties, disclosure and transition.

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

**Year Ended December 31, 2015 compared to Year Ended December 31, 2014**

*Revenue.* Revenue for the year ended December 31, 2015 was \$41.6 million compared with revenue of \$43.9 million for the year ended December 31, 2014, a decrease of \$2.4 million or 5.4%. Therapy revenue decreased \$3.0 million and Detection revenue increased \$0.6 million.

**Table of Contents**

The table below presents the components of revenue for 2015 and 2014:

	<b>For the year ended December 31,</b>			
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>% Change</b>
<b>Detection revenue</b>				
Product revenue	\$ 11,226	\$ 10,082	\$ 1,144	11.3%
Service and supplies revenue	8,017	8,522	(505)	(5.9)%
Subtotal	19,243	18,604	639	3.4%
<b>Therapy revenue</b>				
Product revenue	2,972	8,601	(5,629)	(65.4)%
Service and supplies revenue	19,339	16,719	2,620	15.7%
Subtotal	22,311	25,320	(3,009)	(11.9)%
<b>Total revenue</b>	<b>\$ 41,554</b>	<b>\$ 43,924</b>	<b>\$ (2,370)</b>	<b>(5.4)%</b>

Detection revenues increased by \$0.6 million from \$18.6 million for the year ended December 31, 2014 to \$19.2 million for the year ended December 31, 2015. Detection product revenue increased by \$1.1 million and Detection service revenue decreased \$0.5 million. The increase in Detection product revenue is primarily due to a \$0.7 million increase in digital CAD systems and a \$0.7 million increase in MRI products, offset by a \$0.3 million decrease in film based products. The increase in digital CAD and MRI products are driven by increases in demand primarily from our OEM customers. The decline in revenue from film-based products and accessories was the result of the decreasing market for film based products as most customers have transitioned to digital technologies. Detection service and supplies revenue decreased \$0.5 million primarily due to the decline in customers with analog and digital service contracts.

Therapy revenue decreased 11.9% or \$3.0 million to \$22.3 million for the year ended December 31, 2015 from \$25.3 million in the year ended December 31, 2014. The decrease in Therapy revenue was driven by a decrease in Therapy product revenue of \$5.6 million offset by an increase in Therapy service and supplies revenue of \$2.6 million.

The decrease in Therapy product revenue for the year ended December 31, 2015 is primarily due to the negative impact of customer reaction to the uncertainty of reimbursement rates for NSMC in the United States. Product revenue from the sale of our Axxent eBx systems can vary significantly due to an increase or decrease in the number of units sold which can cause a significant fluctuation in product revenue in the period.

The increase in Therapy service and supplies revenue of \$2.6 million for the year ended December 31, 2015 is due primarily to the impact of the acquisition of the assets of Radion and DermEbx, which contributed \$7.8 million of revenue from the acquisition date through December 31, 2014. Therapy service revenue in the first six months of 2015 was approximately \$13.4 million as compared to \$4.6 million in the first six months of 2014. The Company acquired DermEbx and Radion in July 2014, and the growth in revenue from the acquisition is reflected in the first six months of 2015. Therapy service revenue in the last six months of 2015 was \$5.9 million as compared to \$12.2 million for the last six months of 2014. The decrease in





**Table of Contents**

Therapy service and supplies revenue in 2015 is due primarily to a decrease in the services related to electronic brachytherapy the treatment of NMSC as a result of the reimbursement uncertainty for this procedure in the United States.

*Gross Profit.* Gross profit was \$29.4 million for the year ended December 31, 2015 compared to \$31.2 million for the year ended December 31, 2014, a decrease of \$1.9 million, Therapy gross profit decreased \$2.6 million from \$16.0 million in the year ended December 31, 2014 to \$13.3 million in the year ended December 31, 2015. Detection gross profit increased \$0.7 million from \$15.3 million in the year ended December 31, 2014 to \$16.0 million in the year ended December 31, 2015. The decrease in Therapy gross profit was due primarily to the decrease in Therapy revenue. Detection gross profit increased due primarily to the increase in Detection product sales, which have higher gross profits than Detection service revenues.

Gross profit percent was 70.6% for the year ended December 31, 2015 compared to 71.1% for the year ended December 31, 2014. Gross profit percent decreased slightly by 0.5%, due primarily to the decrease in Therapy product margins. Gross profit will fluctuate due to the costs related to manufacturing, amortization and the impact of product mix in each segment. Cost of revenue and gross profit for 2015 and 2014 were as follows (in thousands):

	<b>For the year ended December 31,</b>			
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>% Change</b>
Products	\$ 3,130	\$ 4,912	\$ (1,782)	(36.3%)
Service and supplies	7,357	6,000	1,357	22.6%
Amortization and depreciation	1,717	1,785	(68)	(3.8%)
Total cost of revenue	12,204	12,697	(493)	(3.9%)
Gross profit	\$ 29,350	\$ 31,227	\$ (1,877)	(6.0%)
Gross profit %	70.6%	71.1%		
	<b>For the year ended December 31,</b>			
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>% Change</b>
Detection gross profit	\$ 16,019	\$ 15,276	\$ 743	4.9%
Therapy gross profit	13,331	15,951	(2,620)	(16.4%)
Gross profit	29,350	31,227	(1,877)	(6.0%)

**Table of Contents***Operating Expenses:*

Operating expenses for 2015 and 2014 are as follows (in thousands):

	<b>For the year ended December 31,</b>			
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>% Change</b>
<b>Operating expenses:</b>				
Engineering and product development	\$ 9,163	\$ 8,159	\$ 1,004	12.3%
Marketing and sales	12,404	12,468	(64)	(0.5%)
General and administrative	8,788	8,044	744	9.2%
Amortization and depreciation	1,631	1,741	(110)	(6.3%)
Goodwill and long-lived asset impairment	27,443		27,443	
<b>Total operating expenses</b>	<b>\$ 59,429</b>	<b>\$ 30,412</b>	<b>\$ 29,017</b>	<b>95.4%</b>

*Engineering and Product Development.* Engineering and product development costs for the year ended December 31, 2015 increased by \$1.0 million or 12.3%, from \$8.2 million in 2014 to \$9.2 million in 2015. Therapy engineering and product development costs increased by approximately \$0.6 million and Detection increased by \$0.4 million. Ongoing clinical trial, consulting and research expenses in the Therapy segment increased by approximately \$0.4 million, and personnel expenses increased approximately \$0.2 million. The primary increase in the Detection segment is clinical trial expenses of approximately \$0.7 million offset by decreases in legal and other expenses of approximately \$0.3 million. The Company continues to invest in research and development to develop clinical evidence for the Therapy segment and ongoing development to support tomosynthesis in the Detection segment.

*Marketing and Sales.* Marketing and sales expense for the year ended December 31, 2015 decreased by \$64,000 or 0.5%, from \$12.5 million in 2014 to \$12.4 million in 2015. Therapy marketing and sales expenses decreased approximately \$0.3 million offset by an increase of \$0.2 million in the Detection segment. The decrease in Therapy marketing and sales expense was due primarily to a decrease in personnel expenses. The increase in the Detection segment is primarily due to increases in personnel expense.

*General and Administrative.* General and administrative expenses for the year ended December 31, 2015 increased by \$0.7 million or 9.2%, from \$8.0 million in 2014 to \$8.8 million in 2015. The increase in general and administrative expenses was primarily due to increases in stock compensation costs, insurance costs and bad debt expense.

*Amortization and Depreciation.* Amortization and depreciation decreased by \$0.1 million from \$1.7 million to \$1.6 million. In June 2015, the Company impaired intangible assets of the Therapy reporting unit and recorded amortization expense based on the revised values of the assets; as a result amortization and depreciation for the intangibles decreased.

*Goodwill and long-lived asset impairment.* 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 and recorded an impairment charge of \$14.0 million related to goodwill and an impairment charge of \$13.4 related to long-lived assets for a total of \$27.4 million.



**Table of Contents***Other Income and Expense*

	<b>For the year ended December 31,</b>			
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>Change %</b>
Interest expense	\$ (650)	\$ (2,640)	1,990	(75.4)%
Gain (loss) from change in fair value of warrant liability		1,835	(1,835)	(100.0)%
Loss from extinguishment of debt	(1,723)	(903)	(820)	90.8%
Interest income	21	37	(16)	(43.2)%
	\$ (2,352)	\$ (1,671)	\$ (681)	40.8%
Income tax expense	\$ 16	\$ 153	(137)	(89.5)%

*Interest Expense* The Company recorded \$0.7 million of interest expense in 2015 as compared with \$2.6 million of interest expense during the year ended December 31, 2014. The reduction in interest expense is due primarily to the reduction in interest related to the Deerfield facility agreement that was terminated on March 31, 2015.

*Gain from change in fair value of warrants* The gain from the change in the fair value of the warrant in 2014 was due primarily to the decrease in the Company's stock price when the fair value of the warrant was calculated in April 2014. In April 2014, Deerfield exercised the warrants and paid the Company \$1.6 million.

*Loss from extinguishment of debt.* The loss of \$1.7 million for the year ended December 31, 2015 represents the loss associated with the payoff of the Deerfield facility agreement, which was terminated on March 31, 2015. The Company paid \$11.25 million which represented the entire obligation. The loss on extinguishment represents the unamortized discount on the Facility agreement, and the write-off of the deferred debt costs. The Facility Agreement was to mature on December 29, 2016 and was able to be repaid at the Company's option without penalty or premium. The loss of \$0.9 million from the extinguishment of debt for the year ended December 31, 2014 represents the loss associated with the payoff of the Deerfield revenue purchase agreement, which was terminated in April 2014.

*Interest income.* Interest income of \$21,000 and \$37,000 for the years ended December 31, 2015, and 2014, respectively, reflects income earned from our money market accounts.

*Tax benefit (expense).* The Company recorded tax expense of \$16,000 as compared to \$153,000 for the years ended December 31, 2015, and 2014, respectively. For the year ended December 31, 2015, the Company recorded a tax benefit due primarily to a deferred tax liability of approximately \$79,000, offset by tax expense of approximately \$95,000. The deferred tax liability was the result of tax amortizable goodwill that was recognized due to the impairment of goodwill. Tax expense in 2015 and 2014 relates primarily to state non-income and franchise based taxes.

**Year Ended December 31, 2014 compared to Year Ended December 31, 2013**

*Revenue.* Revenue for the year ended December 31, 2014 was \$43.9 million compared with revenue of \$33.1 million for the year ended December 31, 2013, an increase of \$10.9 million or 32.8%. Therapy revenue increased \$9.2 million and Detection revenue increased \$1.7 million.



**Table of Contents**

The table below presents the components of revenue for 2014 and 2013:

	<b>For the year ended December 31,</b>			
	<b>2014</b>	<b>2013</b>	<b>Change</b>	<b>% Change</b>
<b>Detection revenue</b>				
Product revenue	\$ 10,082	\$ 8,491	\$ 1,591	18.7%
Service and supplies revenue	8,522	8,414	108	1.3%
Subtotal	18,604	16,905	1,699	10.1%
<b>Therapy revenue</b>				
Product revenue	8,601	10,045	(1,444)	(14.4)%
Service and supplies revenue	16,719	6,117	10,602	173.3%
Subtotal	25,320	16,162	9,158	56.7%
<b>Total revenue</b>	<b>\$ 43,924</b>	<b>\$ 33,067</b>	<b>\$ 10,857</b>	<b>32.8%</b>

Detection revenues increased by \$1.7 million from \$16.9 million for the year ended December 31, 2013 to \$18.6 million for the year ended December 31, 2014. Detection product revenue increased by \$1.6 million and Detection service revenue increased \$0.1 million. The increase in Detection product revenue was primarily due to a \$0.3 million increase in digital CAD systems and a \$1.5 million increase in MRI products, offset by a \$0.2 million decrease in film based products. The increase in digital CAD and MRI products are driven by increases in demand primarily from our OEM customers. The decline in revenue from film-based products and accessories was the result of the decreasing market for film based products as most customers have transitioned to digital technologies. Detection service and supplies revenue increased \$0.1 million primarily due to an increase in the number of customers with a CAD service contract, offset by a decline in customer with analog service contracts.

Therapy revenue increased 56.7% or \$9.2 million to \$25.3 million for the year ended December 31, 2014 from \$16.2 million in the year ended December 31, 2013. The increase in Therapy revenue was driven by an increase in Therapy service and supplies revenue of \$10.6 million offset by a decrease in Therapy product revenue of \$1.4 million. The growth of Therapy service and supplies revenue was due to the growing installed base of customers and expanded service offerings available to dermatology customers.

The decrease in Therapy product revenue for the year ended December 31, 2014 was due primarily to a decrease in the average selling price of the Xoft eBx systems sold, as compared to fiscal year ended December 31, 2013. Applicators, which are typically sold with the Xoft eBx system accounted for a decrease of approximately \$0.1 million. We expect that sales of the Xoft eBx system will continue to fluctuate.

**Table of Contents**

The increase in Therapy service and supplies revenue of \$10.6 million for the year ended December 31, 2014 was due primarily to the impact of the acquisition of the assets of Radion and DermEbx, which contributed \$7.8 million of revenue from the acquisition date thru December 31, 2014. Service and supplies revenue has increased and was expected to increase due to the growing installed base of customers and expanded service offerings available to dermatology customers.

*Gross Profit.* Gross profit was \$31.2 million for the year ended December 31, 2014 compared to \$23.1 million for the year ended December 31, 2013, an increase of \$8.1 million, Therapy gross profit increased \$6.4 million from \$9.5 million in the year ended December 31, 2013 to \$15.9 million in the year ended December 31, 2014. Detection gross profit increased \$1.7 million from \$13.6 million in the year ended December 31, 2013 to \$15.3 million in the year ended December 31, 2014. The increase in Therapy gross profit was due primarily to the increase in Therapy service revenue which has a higher profit than Therapy product revenue. Detection gross profit increased due primarily to the increase in Detection product sales, which have higher gross profits than Detection service revenues.

Gross profit percent was 71.1% for the year ended December 31, 2014 compared to 69.8% for the year ended December 31, 2013. Gross profit percent increased slightly by 1.3%, due primarily to the increase in higher profit service revenue. Gross profit will fluctuate due to the costs related to manufacturing, amortization and the impact of product mix in each segment. Cost of revenue and gross profit for 2014 and 2013 were as follows (in thousands):

	<b>For the year ended December 31,</b>			
	<b>2014</b>	<b>2013</b>	<b>Change</b>	<b>% Change</b>
Products	\$ 4,912	\$ 4,668	\$ 244	5.2%
Service and supplies	6,000	4,009	1,991	49.7%
Amortization and depreciation	1,785	1,305	480	36.8%
Total cost of revenue	12,697	9,982	2,715	27.2%
Gross profit	\$ 31,227	\$ 23,085	\$ 8,142	35.3%
Gross profit %	71.1%	69.8%		

	<b>For the year ended December 31,</b>			
	<b>2014</b>	<b>2013</b>	<b>Change</b>	<b>% Change</b>
Detection gross profit	\$ 15,276	\$ 13,576	\$ 1,700	12.5%
Therapy gross profit	15,951	9,509	6,442	67.7%
Gross profit	31,227	23,085	8,142	35.3%



**Table of Contents***Operating Expenses:*

Operating expenses for 2014 and 2013 are as follows (in thousands):

	<b>For the year ended December 31,</b>			
	<b>2014</b>	<b>2013</b>	<b>Change</b>	<b>% Change</b>
Operating expenses:				
Engineering and product development	\$ 8,159	\$ 7,043	\$ 1,116	15.8%
Marketing and sales	12,468	10,328	2,140	20.7%
General and administrative	8,044	6,365	1,679	26.4%
Amortization and depreciation	1,741	1,125	616	54.8%
 Total operating expenses	 \$ 30,412	 \$ 24,861	 \$ 5,551	 22.3%

*Engineering and Product Development.* Engineering and product development costs for the year ended December 31, 2014 increased by \$1.1 million or 15.8%, from \$7.0 million in 2013 to \$8.2 million in 2014. Therapy engineering and product development costs increased by approximately \$0.7 million and Detection increased by \$0.4 million. Clinical trial and research expenses in the Therapy segment increased by approximately \$0.5 million, and legal, consulting and salaries and wages were the primary drivers of the increase in the Detection segment. The Company continues to invest in research and development to develop clinical evidence for the Therapy segment and development to support tomosynthesis in the Detection segment.

*Marketing and Sales.* Marketing and sales expense for the year ended December 31, 2014 increased by \$2.1 million or 20.7%, from \$10.3 million in 2013 to \$12.5 million in 2014. Therapy marketing and sales expenses increased approximately \$3.1 million offset by a decrease of \$0.9 million in the Detection segment. The increase in Therapy marketing and sales expense was due primarily to an increase in personnel, travel, education and trade show expenses, with the acquisition of the assets of DermEbx and Radion driving the increase in personnel expenses. The decrease in the Detection segment was primarily due to decreases in personnel expense. The Company expects investments in Marketing and Sales to continue primarily in the Therapy segment to drive awareness through ongoing education programs and presence at trade shows.

*General and Administrative.* General and administrative expenses for the year ended December 31, 2014 increased by \$1.7 million or 26.4%, from \$6.4 million in 2013 to \$8.0 million in 2014. The increase in general and administrative expenses was primarily due to \$0.5 million of expense related to the acquisition and additional legal and audit costs.

*Amortization and Depreciation.* Amortization and depreciation increased by \$0.6 million from \$1.1 million for the year ended December 31, 2013 to \$1.7 million for the year ended December 31, 2014. The primary driver of the increase was the additional intangible assets as a result of the acquisition of the assets of DermEbx and Radion.

**Table of Contents***Other Income and Expense*

	<b>For the year ended December 31,</b>			
	2014	2013	Change	Change %
Interest expense	\$ (2,640)	\$ (3,277)	637	(19.4)%
Gain (loss) from change in fair value of warrant liability	1,835	(2,448)	4,283	(175.0)%
Loss from extinguishment of debt	(903)		(903)	100.0%
Interest income	37	19	18	94.7%
	<b>\$ (1,671)</b>	<b>\$ (5,706)</b>	<b>\$ 4,035</b>	<b>(70.7)%</b>
Income tax expense	\$ 153	\$ 126	27	21.4%

The Company recorded \$2.6 million of interest expense in 2014 as compared with \$3.3 million of interest expense during the year ended December 31, 2013. In April 2014, the Company terminated the Revenue Purchase Agreement with Deerfield, and as a result interest expense decreased as compared to 2013. The Company also recorded a loss from the extinguishment of the Revenue Purchase Agreement of approximately \$0.9 million. Interest expense related to the Deerfield financing was \$2.4 million for the year ended December 31, 2014 as compared to \$3.0 million for the year ended December 31, 2013.

The gain from the change in the fair value of the warrant in 2014 was due primarily to the decrease in the stock price of the Company when it was valued in April 2014 as compared to the price at December 2013. In April 2014, Deerfield exercised the warrants and paid the Company \$1.6 million.

**Segment Analysis**

The Company operates in and reports results for two segments: Cancer Detection and Cancer Therapy. Segment operating income (loss) includes Cost of Sales, Engineering and Product Development and Marketing and Sales and depreciation and amortization for the respective segment. Adjusted EBITDA is a Non-GAAP measure and excludes Stock Compensation, Depreciation and Amortization expense in the department of the respective segment. The Company does not allocate General and Administrative and depreciation and amortization expense included in General and Administrative expenses, as well as Other Income and Expense to a segment, and accordingly those are included as reconciling items to the Loss before income tax. These non-GAAP metrics may be inconsistent with similar measures presented by other companies and should only be used in conjunction with our results reported according to U.S. GAAP. Any financial measure other than those prepared in accordance with U.S. GAAP should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with U.S. GAAP. Management considers these non-GAAP financial measures to be an important indicator of the Company's operational strength and performance of its business and a good measure of its historical operating trends, in particular the extent to which ongoing operations impact the Company's overall financial performance. A summary of Segment revenues, segment operating income

**Table of Contents**

(loss) and segment adjusted EBITDA for each of the fiscal years ended December 31, 2015, 2014 and 2013, respectively are below:

	Year Ended December 31,		
	2015	2014	2013
<b>Segment revenues:</b>			
Detection	\$ 19,243	\$ 18,604	\$ 16,905
Therapy	22,311	25,320	16,162
Total Revenue	\$ 41,554	\$ 43,924	\$ 33,067
<b>Segment gross profit:</b>			
Detection	\$ 16,019	\$ 15,276	\$ 13,576
Therapy	13,331	15,951	9,509
Segment gross profit	\$ 29,350	\$ 31,227	\$ 23,085
<b>Segment operating income (loss):</b>			
Detection	\$ 7,233	\$ 7,231	\$ 5,016
Therapy	(28,405)	1,868	(52)
Segment operating income (loss)	\$ (21,172)	\$ 9,099	\$ 4,964
General, administrative, depreciation and amortization expense			
	\$ (8,907)	\$ (8,284)	\$ (6,740)
Interest expense	(650)	(2,640)	(3,277)
Gain (loss) on fair value of warrant		1,835	(2,448)
Other income	21	37	19
Loss on debt extinguishment	(1,723)	(903)	
Loss before income tax	\$ (32,431)	\$ (856)	\$ (7,482)
<b>Segment adjusted EBITDA:</b>			
Detection segment operating income	\$ 7,233	\$ 7,231	\$ 5,016
Stock compensation	430	352	383
Depreciation	220	188	175
Amortization	532	515	517
Restructuring	182		
Detection adjusted EBITDA	\$ 8,597	\$ 8,286	\$ 6,091
Therapy segment operating income (loss)	\$ (28,405)	\$ 1,868	\$ (52)
Stock compensation	465	178	139
Depreciation	1,142	844	424

Edgar Filing: ICAD INC - Form 10-K

Amortization	1,213	1,739	939
Restructuring	405		
Goodwill and long-lived asset impairment	27,443		

Therapy adjusted EBITDA	\$ 2,263	\$ 4,629	\$ 1,450
-------------------------	----------	----------	----------

Detection segment operating income improved from \$5.0 million for the year ended December 31, 2013 to \$7.2 million for the year ended December 31, 2014, and remained flat at \$7.2 million

---

**Table of Contents**

for the year ended December 31, 2015. The increase in segment operating income for the year ended December 31, 2014 as compared to the year ended December 31, 2013 was primarily the result of the increase in revenue from \$16.9 million to \$18.6 million and reductions in operating expenses from \$8.6 million and \$8.0 million in the periods ended December 31, 2013 and 2014, respectively. Detection operating expenses increased slightly for the year ended December 31, 2015 to approximately \$8.8 million. Detection gross profit improved from approximately \$13.6 million or 80% of revenue for the year ended December 31, 2013 to \$15.3 million or 82% of revenue for the year ended December 31, 2014 to \$16.0 million or 83% of revenue for the year ended December 31, 2015, which is the result of increases in revenue as well as changes in product mix. Detection segment adjusted EBITDA increased due primarily to the reduction in segment operating expenses, and the improvement in gross margin.

Therapy segment operating income improved from a loss of \$52,000 for the year ended December 31, 2013 to income of \$1.9 million for the period ended December 31, 2014, and decreased to a loss of \$28.4 million for the year ended December 31, 2015. The increase in Therapy operating income between the years ended December 31, 2014 and December 31, 2013 was due primarily to the increase in Therapy revenues. The increase in Therapy operating income between the year ended December 31, 2014 and December 31, 2013 is due to the increase in Therapy revenue, driven by the acquisition of the assets of DermEbx and Radion, which increased revenue by \$7.9 million from the closing date of the transactions on July 15, 2014 to December 31, 2014. The operating loss of \$28.4 million for the year ended December 31, 2015 is due primarily to the impairment loss of \$27.4 million and the reduction in revenue from \$25.3 million for the year ended December 31, 2014 to \$22.3 million for the year ended December 31, 2015. Therapy gross profit improved from approximately \$9.5 million or 59% of revenue for the year ended December 31, 2013 to \$16.0 million or 63% of revenue for the year ended December 31, 2014 to \$13.3 million or 60% of revenue for the year ended December 31, 2015. The increase in gross profit for the year ended December 31, 2014 as compared to the year ended December 31, 2013 is due primarily to the increase in revenue. Revenue from the acquisition of the assets of DermEbx and Radion was primarily service revenue which has a higher gross margin than product revenue. Therapy gross profit decreased to \$13.3 million for the year ended December 31, 2015 from \$15.9 million in the year ended December 31, 2014 due primarily to the reduction in revenue. Total operating expenses were \$9.6 million, \$14.1 million and \$14.2 million in the periods ending December 31, 2013, 2014 and 2015, respectively. The increase in Therapy operating expense for the period ended December 31, 2014 is due to the acquisition of the assets of DermEbx and Radion and increased investments in the Therapy segment. The increase in Therapy segment adjusted EBITDA for the year ended December 31, 2014 as compared to the year ended December 31, 2013 is due primarily to the increase in segment revenues. Therapy segment adjusted EBITDA decreased to \$2.3 million for the year ended December 31, 2015 from \$4.6 million for the year ended December 31, 2014, which is due primarily to the reduction in revenue and gross profit.

**Liquidity and Capital Resources**

The Company believes that its cash and cash equivalents balance of \$15.3 million as of December 31, 2015, and projected cash balances are sufficient to sustain operations through at least the next 12 months. The Company's ability to generate cash adequate to meet its future

**Table of Contents**

capital requirements will depend primarily on operating cash flow. If sales or cash collections are reduced from current expectations, or if expenses and cash requirements are increased, the Company may require additional financing, although there are no guarantees that the Company will be able to obtain the financing if necessary. The Company will continue to closely monitor its liquidity and the capital and credit markets.

The Company had working capital of \$13.5 million at December 31, 2015. The ratio of current assets to current liabilities at December 31, 2015 and 2014 was 1.94 and 2.02, respectively. The decrease in working capital is due primarily to the decrease in cash. In April 2015, the Company paid \$11.25 million to repay borrowings under the Deerfield facility agreement in full.

Net cash used for operating activities for the year ended December 31, 2015 was \$1.9 million compared to net cash provided by operations of \$3.2 million for 2014. The decrease in cash for operating activities during the year ended December 31, 2015 was due primarily to increases in inventory, and decreases in accrued expenses and deferred revenue, offset by a decrease in accounts receivable, which generates cash. During 2015 the Company used cash due to changes in operating assets and liabilities of approximately \$5.1 million, an increase of cash used of approximately \$3.8 million. We expect that changes in accounts receivable and deferred revenue will continue to be the significant driver of changes in cash used in or provided by operations.

The net cash used for investing activities for the year ended December 31, 2015 was \$2.7 million. The cash used for investing activities in 2015 was primarily for the acquisition VuComp M-Vu Breast Density product of \$1.7 million and purchases of fixed assets of \$1.0 million.

Net cash used for financing activities for the year ended December 31, 2015 was \$12.4 million. The net cash used for financing activities represents primarily the repayment of the Deerfield Facility Agreement of \$11.3 million during 2015 and \$1.4 million for capital leases, offset by cash received of approximately \$0.4 million from stock option exercises. The cash provided by financing activities of \$21.9 million for the year ended December 31, 2014 includes the underwritten offering in March 2014 of 2.76 million shares at approximately \$11.00 per share, with net proceeds of \$28.2 million after deducting offering expenses and underwriting discounts.

**Table of Contents**

The following table summarizes as of December 31, 2015, for the periods presented, the Company's future estimated cash payments under existing contractual obligations, and the financing obligations as noted below (in thousands).

<b>Contractual Obligations</b>	<b>Total</b>	<b>Payments due by period</b>			
		<b>Less than 1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>5+ years</b>
Operating Lease Obligations	\$ 822	\$ 524	\$ 298	\$	\$
Capital Lease Obligations	1,055	969	86		
Royalty Obligations	1,425	525	550	50	300
Other Commitments	1,349	1,349			
<b>Total Contractual Obligations</b>	<b>\$ 4,651</b>	<b>\$ 3,367</b>	<b>\$ 934</b>	<b>\$ 50</b>	<b>\$ 300</b>

**Lease Obligations:**

As of December 31, 2015, the Company had three lease obligations related to its facilities.

The Company's executive offices are located in Nashua, New Hampshire and are leased pursuant to a five-year lease (the "Lease") that commenced on December 15, 2006, and renewed on January 1, 2012 (the "Premises"). The Lease renewal provided for annual base rent of \$181,764 for the first year; \$187,272 for the second year; \$192,780 for the third year; \$198,288 for the fourth year and \$203,796 for the fifth year. 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 also has the right to extend the term of the Lease for an additional five year period at the then current market rent rate (but not less than the last annual rent paid by the Company).

The Company leases a facility in San Jose, California under a non-cancelable operating lease which commenced in September, 2012. The facility has office, manufacturing and warehousing space. The operating lease provides for an annual base rent of \$248,376 for the first year, \$260,064 for the second year, \$271,752 for the third year, \$283,440 for the fourth year and \$295,140 for the fifth year 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.

**Royalty Obligations:**

As a result of the acquisition of Xoft, the Company recorded a royalty obligation pursuant to a settlement agreement entered into between Xoft and Hologic, in August 2007. Xoft received a nonexclusive, irrevocable, perpetual, worldwide license, including the right to sublicense certain Hologic patents, and a non-compete covenant as well as an agreement not to seek further damages with respect to the alleged patent violations. In return the Company has a remaining obligation to pay a minimum annual royalty payment of \$250,000 payable through 2016. In addition to the

**Table of Contents**

minimum annual royalty payments, the litigation settlement agreement with Hologic also provided for payment of royalties based upon a specified percentage of future net sales on any products that practice the licensed rights. The estimated fair value of the patent license and non-compete covenant is \$100,000 and is being amortized over the estimated remaining useful life of approximately four years. In addition, a liability has been recorded within accrued expenses and long-term settlement cost for future payment and for future minimum royalty obligations totaling \$0.4 million.

In December, 2011, the Company settled patent litigation with Zeiss. The Company determined that this settlement should be recorded as a measurement period adjustment and accordingly recorded the present value of the litigation to the opening balance sheet of Xoft. The present value of the liability is approximately \$0.4 million as of December 31, 2015. The Company has a remaining obligation to pay \$0.5 million in June 2017.

The Company was granted a non-exclusive license from Yeda Research which relates to the 3TP method for the detection of cancer and has a minimum obligation of \$25,000 annually through 2032 for a total of approximately \$0.4 million.

**Notes Payable:**

In December, 2011, the Company entered into several agreements pursuant to which Deerfield agreed to provide \$15 million of debt. During October 2014, the Company elected to prepay the first principal payment of \$3.75 million which was originally due on the third anniversary of the date of the facility agreement in December 2014. The Company paid the remaining outstanding obligation of \$11.25 million on March 31, 2015.

**Capital Lease Obligations:**

The Company entered into a capital lease agreement for the purchase of certain equipment in August 2013 for approximately \$409,000 at a rate of 3.99%. Under the guidance of ASC Topic 840, *Leases*, the Company determined that the lease was a capital lease as it contained a bargain purchase option wherein the Company has the option to buy the equipment for \$1 at the end of the lease term. Accordingly, the equipment has been capitalized and a liability was recorded. The Company has a remaining balance of \$95,000 as of December 31, 2015. The equipment cost of \$409,000 was reflected as property and equipment in the balance sheet and will be being depreciated over its useful life.

In connection with the acquisition of DermEbx and Radion, the Company assumed two separate equipment lease obligations with payments totaling approximately \$2.6 million thru May, 2017. The leases were determined to be capital leases and accordingly the equipment was capitalized and a liability of \$2.5 million was recorded. As of December 31, 2015, the outstanding liability for the acquired equipment leases was approximately \$1.0 million.



---

**Table of Contents****Other Commitments:**

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

**Effect of New Accounting Pronouncements**

In May 2014, the FASB issued Accounting Standards Update ( ASU ) 2014-09 *Revenue from Contracts with Customers* ( ASU 2014-09 ), which amends ASC 605 *Revenue Recognition* and creates a new Topic 606 *Revenue from Contracts with Customers*. This update provides guidance on how an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Upon initial application, the provisions of this update are required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this update recognized at the date of initial application. This update also expands the disclosure requirements surrounding revenue recorded from contracts with customers. In August 2015, the FASB issued ASU 2015-14 *Deferral of the Effective Date* . The amendments in this Update defer the effective date of Update 2014-09 for all entities by one year. Public business entities, certain not-for-profit entities, and certain employee benefit plans should apply the guidance in Update 2014-09 to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We are currently evaluating the effect of this update on our financial statements and have not yet determined the method of initial application we will use.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes* ( ASU 2015-17 ), which simplifies the presentation of deferred income taxes. ASU 2015-17 requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for fiscal years beginning after December 15, 2016 (and interim periods within those fiscal years) with early adoption permitted. ASU 2015-17 may be either applied prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented. We have elected to early adopt ASU 2015-17 prospectively in the fourth quarter of 2015. There was no impact on our results of operations as a result of the adoption of ASU 2015-17.

In September 2015, the FASB issued ASU No. 2015-16: *Simplifying the Accounting for Measurement-Period Adjustments*, which eliminates the requirement for an acquirer in a business combination to account for measurement-period adjustments retrospectively. Under the ASU, acquirers must recognize measurement-period adjustments in the period in which they determine the amounts, including the effect on earnings of any amounts they would have recorded in previous periods if the accounting had been completed at the acquisition date. The acquirer still must disclose the amounts and reasons for adjustments to the provisional amounts. The acquirer also must disclose, by line item, the amount of the adjustment reflected in the current-period income statement that would have been recognized in previous periods if the adjustment to provisional amounts had been recognized as of the acquisition date. Alternatively, an acquirer may present those amounts separately on the face of the income statement. The ASU

---

**Table of Contents**

does not change the criteria for determining whether an adjustment qualifies as a measurement-period adjustment and does not change the length of the measurement period. The ASU results in differences between US GAAP and IFRS, which are currently aligned on this topic. The ASU is effective for public business entities for fiscal years beginning after 15 December 2015, and interim periods within those fiscal years. Early adoption is permitted for any interim and annual financial statements that have not yet been issued.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The standard establishes a right-of-use ( ROU ) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. We are currently evaluating the impact of our pending adoption of the new standard on our consolidated financial statements.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk.**

We believe we are not subject to material foreign currency exchange rate fluctuations, as most of our sales and expenses are domestic and therefore are denominated in the U.S. dollar. We do not hold derivative securities and have not entered into contracts embedded with derivative instruments, such as foreign currency and interest rate swaps, options, forwards, futures, collars, and warrants, either to hedge existing risks or for speculative purposes.

**Item 8. Financial Statements and Supplementary Data.**

See Financial Statements and Schedule attached hereto.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

Not Applicable.

**Item 9A. Controls and Procedures.**

**(a) Evaluation of Disclosure Controls and Procedures.**

The Company, under the supervision and with the participation of its management, including its principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures as of the end of the period covered by this annual report on Form 10-K. Based on this evaluation, the principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of December 31, 2015.

**Table of Contents**

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. The Company conducts periodic evaluations to enhance, where necessary its procedures and controls.

**(b) Management's Annual Report on Internal Control Over Financial Reporting.**

The Company, under the supervision and with the participation of its management, including its principal executive officer and principal financial officer, is responsible for the preparation and integrity of the Company's Consolidated Financial Statements, establishing and maintaining adequate internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) for the Company and all related information appearing in this Annual Report on Form 10-K.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Based on its assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

**(c) Changes in Internal Control Over Financial Reporting.**

The Company's principal executive officer and principal financial officer conducted an evaluation of the Company's internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) to determine whether any changes in internal control over financial reporting occurred during the quarter ended December 31, 2015, that have materially affected or which are reasonably likely to materially affect internal control over financial reporting. Based on that evaluation there has been no such change during such period.

**Table of Contents**

**Item 9B. Other Information.**

The Company's 2016 Annual Meeting of Stockholders (the 2016 Annual Meeting) has been scheduled for May 4, 2016. Because the date of the 2016 Annual Meeting is more than 30 days before the anniversary date of the Company's 2015 Annual Meeting of Stockholders, in accordance with Rule 14a-5(f) under the Exchange Act, the Company is informing stockholders of the change. For stockholders who wished to present a proposal to be considered for inclusion in our proxy statement for the 2016 Annual Meeting, pursuant to Rule 14a-8 under the Exchange Act, the proposal must have been received by our Corporate Secretary no later than January 5, 2016. With respect to the notification deadline for a stockholder who wishes to nominate candidates for director or propose other business for consideration at the 2016 Annual Meeting, our bylaws provide that the notice of such nomination or proposal must be delivered to our Corporate Secretary at our principal executive offices no later than the close of business on the 10<sup>th</sup> day following the date of filing this Annual Report on Form 10-K with the SEC.

**Table of Contents****PART III****Item 10. Directors, Executive Officers and Corporate Governance.**

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

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

<b>Name</b>	<b>Age</b>	<b>Position with iCAD</b>	<b>Director/Officer Since</b>
Dr. Lawrence Howard	63	Chairman of the Board, and Director	2006
Rachel Brem, MD	57	Director	2004
Anthony Ecock	54	Director	2008
Robert Goodman, MD	75	Director	2014
Steven Rappaport	67	Director	2006
Andy Sassine	51	Director	2015
Somu Subramaniam	61	Director	2010
Elliot Sussman, MD	64	Director	2002
Kenneth Ferry	62	Chief Executive Officer, and Director	2006
Kevin Burns	45	President, Chief Operating Officer, Chief Financial Officer, Treasurer and Secretary	2011
Stacey Stevens	48	Executive Vice President of Marketing and Strategy	2006

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

Upon the recommendation of the Company's Nominating and Corporate Governance Committee, the Board of Directors fixed the size of the Company's Board at nine directors.

*Dr. Lawrence Howard* was appointed Chairman of the Board in 2007 and has been a director of the Company since November 2006. Dr. Howard has been, since March 1997, a

**Table of Contents**

general partner of Hudson Ventures, L.P. (formerly known as Hudson Partners, L.P.), a limited partnership that is the general partner of Hudson Venture Partners, L.P. ( HVP ), a limited partnership that is qualified as a small business investment company. Since March 1997, Dr. Howard has also been a managing member of Hudson Management Associates LLC, a limited liability company that provides management services to HVP. Since November 2000, Dr. Howard has been a General Partner of Hudson Venture Partners II, and a limited partner of Hudson Venture II, L.P. We believe Dr. Howard's qualifications to serve on our Board of Directors include his financial expertise and his understanding of our products and market.

*Dr. Rachel Brem* is currently the Professor and Vice Chairman in the Department of Radiology at The George Washington University Medical Center and Associate Director of the George Washington Cancer Institute. Dr. Brem has been at the George Washington University since 2000. From 1991 to 1999 Dr. Brem was at the Johns Hopkins Medical Institution where she introduced image guided minimally invasive surgery and previously was the Director of Breast Imaging. Dr. Brem is a nationally and internationally recognized expert in new technologies for the improved diagnosis of breast cancer and has published over 80 manuscripts. We believe Dr. Brem's qualifications to serve on our Board of Directors include her expertise in the medical field specifically the diagnosis of breast cancer as well as her understanding of our products and market.

*Anthony Ecock* is a General Partner with the private equity investment firm of Welsh, Carson, Anderson & Stowe ( WCAS ), which he joined in 2007. He has over 25 years of experience in the healthcare field with eight years in senior management positions at leading healthcare technology companies. At WCAS, Mr. Ecock leads the Resources Group, a team responsible for helping its 30 portfolio companies identify and implement initiatives to increase growth, earnings and cash flow. Before joining WCAS, he served as Vice President and General Manager of GE Healthcare's Enterprise Sales organization from 2003 to 2007. From 1999 to 2003, he served as Senior Vice President and Global General Manager of Hewlett Packard's, then Agilent's and finally Philips' Patient Monitoring divisions. Mr. Ecock spent his early career at the consulting firm of Bain & Company, where he was a Partner in the healthcare and technology practices and Program Director for Consultant Training. We believe Mr. Ecock's qualifications to serve on our Board of Directors include his financial expertise and his years of experience in the healthcare and technology markets.

*Dr. Robert Goodman* is a radiation oncologist who oversees all aspects of care at Jersey City Radiation Oncology. Dr. Goodman has served with Jersey City Radiation Oncology since 2001. Prior to joining Jersey City Radiation Oncology, from 1998-2011, Dr. Goodman served as the chair of Radiation Oncology at St. Barnabas Medical Center. From 1977 to 1990, Dr. Goodman served as the Pancoast Professor and Chair of the Department of Radiation Oncology at the University of Pennsylvania. Dr. Goodman also has served as Acting Executive Director of the Hospital of the University of Pennsylvania. He has published extensively in the oncology literature in highly respected peer-reviewed journals and has co-authored a textbook on breast cancer. We believe Dr. Goodman's qualifications to serve on our Board of Directors include his extensive clinical background and his business leadership experience.

---

**Table of Contents**

*Steven Rappaport* has been a partner of RZ Capital, LLC since July 2002, a private investment firm that also provides administrative services for a limited number of clients. From March 1995 to July 2002, Mr. Rappaport was Director, President and Principal of Loanet, Inc., an online real-time accounting service used by brokers and institutions to support domestic and international securities borrowing and lending activities. Loanet, Inc. was acquired by SunGard Data Systems in May 2001. From March 1992 to December 1994, Mr. Rappaport was Executive Vice President of Metallurg, Inc. ( Metallurg ), a producer and seller of high quality specialty metals and alloys, and President of Metallurg's subsidiary, Shieldalloy Corporation. He served as Director of Metallurg from 1985 to 1998. From March 1987 to March 1992, Mr. Rappaport was Director, Executive Vice President and Secretary of Telerate, Inc. ( Telerate ), an electronic distributor of financial information. Telerate was acquired by Dow Jones over a number of years commencing in 1985 and culminating in January 1990, when it became a wholly-owned subsidiary. Mr. Rappaport practiced corporate and tax law at the New York law firm of Hartman & Craven from August 1974 to March 1987. He became a partner in the firm in 1979. Mr. Rappaport is currently serving as an independent director of a number of open and closed end American Stock Exchange funds of which Credit Suisse serves as the investment adviser and a number of closed end mutual funds of which Aberdeen Investment Trust serves as the adviser. In addition, Mr. Rappaport serves as a director of several privately owned businesses and a few not for profit organizations. We believe Mr. Rappaport's qualifications to serve on our Board of Directors include his extensive financial and legal expertise combined with his experience as an executive officer, partner and director.

*Andy Sassine* has served on the board of directors of three private companies: Gemphire Therapeutics, Inc., an early-stage cardiovascular drug company formed by a licensing agreement with Pfizer Inc., Freedom Meditech, Inc., a medical device company focused on the development and commercialization of first-to-market non-invasive ophthalmic medical devices that can screen for diabetes up to six years prior to the onset of the disease; and ComHear Inc., a digital audio software and device company, where he is also the chairman of the board. Mr. Sassine previously served on the board of Acorn Energy, Inc. Mr. Sassine has served on the Fidelity Investments Board of Directors since February 25, 2013. Mr. Sassine served in various positions at Fidelity Investments from 1999 to 2012, including, most recently as Portfolio Manager. Between 2004 and 2011, he managed the Fidelity Small Cap Stock Fund, the Fidelity International Small Cap Opportunities Fund and the Fidelity Advisor International Small Cap Opportunities Fund. Mr. Sassine joined Fidelity as a high yield research analyst covering the Telecommunications, Satellite, Technology, Defense and Aerospace, and Restaurant Industries and in 2001, joined the international group as a research analyst covering small and mid-cap international stocks. Prior to joining Fidelity, he served as a vice president in the Acquisition Finance Group at Fleet National Bank. Mr. Sassine has been a member of the Henry B. Tippie College of Business, University of Iowa Board of Advisors since 2009 and served on the Board of Trustees at the Clarke Schools for Hearing and Speech between 2009 and 2014. Mr. Sassine earned a Bachelor of Arts degree at the University of Iowa in 1987 and an MBA from the Wharton School at the University of Pennsylvania in 1993. We believe Mr. Sassine's extensive knowledge and experience as a fund manager and board member of other companies of a similar size to our company qualifies him to serve as a member of our Board of Directors.

**Table of Contents**

*Somu Subramaniam* is currently a Managing Partner and co-founder of New Science Ventures, a New York-based venture capital firm that invests in both early and late stage companies, using novel scientific approaches to address significant unmet needs and create order of magnitude improvements in performance. Mr. Subramaniam serves on several Boards of companies managed in New Science Venture's portfolio, including Achronix Semiconductor Corporation, RF Arrays, Inc., Lightwire, Inc., Silicon Storage Technology, Inc., MagSil Corporation, Trellis BioScience, Inc., and BioScale, Inc. Prior to starting New Science Ventures in 2004, Mr. Subramaniam was a Director at McKinsey & Co. and at various times led their Strategy Practice, Technology Practice and Healthcare Practice. While at McKinsey, he advised leading multinational companies in the pharmaceuticals, medical devices, biotechnology, photonics, software and semiconductor industries. He was also a member of McKinsey's Investment Committee. We believe Mr. Subramaniam's qualifications to serve on our Board include his extensive financial and legal expertise combined with his experience as an executive officer, partner and director.

*Dr. Elliot Sussman* is currently a Chairman of The Villages Health and Professor of Medicine at the University of South Florida College of Medicine. From 1993 to 2010, Dr. Sussman served as President and Chief Executive Officer of Lehigh Valley Health Network. Dr. Sussman served as a Fellow in General Medicine and a Robert Wood Johnson Clinical Scholar at the University of Pennsylvania, and trained as a resident at the Hospital of the University of Pennsylvania. Dr. Sussman is a director and the Chairperson of the compensation committee of the Board of Directors of Universal Health Realty Income Trust, a public company involved in real estate investment trust primarily engaged in investing in healthcare and human service-related facilities. We believe Dr. Sussman's qualifications to serve on our Board include his experience as a Chief Executive Officer of a leading healthcare network, combined with his medical background and his understanding of our products and market.

*Kenneth Ferry* has served as the Company's Chief Executive Officer since May 2006. He has over 25 years of experience in the healthcare technology field, with more than 10 years' experience in senior management positions. Prior to joining the Company, from October 2003 to May 2006, Mr. Ferry was Senior Vice President and General Manager for the Global Patient Monitoring business for Philips Medical Systems, a leader in the medical imaging and patient monitoring systems business. In this role he was responsible for Research & Development, Marketing, Business Development, Supply Chain and Manufacturing, Quality and Regulatory, Finance and Human Resources. From September 2001 to October 2003, Mr. Ferry served as a Senior Vice President in the North America Field Organization of Philips Medical Systems. From 1983 to 2001, Mr. Ferry served in a number of management positions with Hewlett Packard Company, a global provider of products, technologies, software solutions and services to individual consumers and businesses and Agilent Technologies, Inc., a provider of core bio-analytical and electronic measurement solutions to the communications, electronics, life sciences and chemical analysis industries. We believe Mr. Ferry's qualifications to serve on our Board of Directors include his global executive leadership skills and significant experience as an executive in the healthcare industry.



---

**Table of Contents**

*Kevin C. Burns* is the Company's President, Chief Operating Officer, and Chief Financial Officer. Mr. Burns previously served as the Company's Executive Vice President of Finance and Chief Financial Officer and Treasurer from April 2011 to November 2013 when Mr. Burns was named to his role as Chief Operating Officer. Mr. Burns was named President in February 2014. Mr. Burns has approximately twenty years of professional experience in finance primarily in the technology and healthcare industries. Most recently, Mr. Burns served as senior vice president and chief financial officer at AMICAS, Inc., a publicly traded image and information management solutions company. During his tenure at AMICAS, from November 2004 to May 2010, Mr. Burns led significant revenue and profit growth and culminating in a successful sale of the company. Prior to joining AMICAS, Mr. Burns worked in finance and corporate planning at NMS Communications, a public telecom equipment company in the wireless applications and infrastructure market, from November 2003 to November 2004. Previously, Mr. Burns was the director of corporate development at Demantra, Inc. and has also held senior management positions in finance, accounting and corporate development at MAPICS, Inc. and Marcam Corporation, both public software companies. Mr. Burns earned both a Bachelor of Science degree in Finance and an MBA degree from Babson College.

*Stacey Stevens* is now the Company's Executive Vice president, Marketing and Strategy. Ms. Stevens previously served as the Company's Senior Vice President of Marketing and Strategy from June 2006 to February 2016. Prior to joining iCAD, Ms. Stevens experience included a variety of sales, business development, and marketing management positions with Philips Medical Systems, Agilent Technologies, Inc. and Hewlett Packard's Healthcare Solutions Group (which was acquired in 2001 by Philips Medical Systems). From February 2005 until joining the Company she was Vice President, Marketing Planning at Philips Medical Systems, where she was responsible for the leadership of all global marketing planning functions for Philips' Healthcare Business. From 2003 to January 2005, she was Vice President of Marketing for the Cardiac and Monitoring Systems Business Unit of Philips where she was responsible for all marketing and certain direct sales activities for the America's Field Operation. Prior to that, Ms. Stevens held several key marketing management positions in the Ultrasound Business Unit of Hewlett-Packard/Agilent and Philips Medical Systems. Ms. Stevens earned a Bachelor of Arts Degree in Political Science from the University of New Hampshire, and an MBA from Boston University's Graduate School of Management.

**Audit Committee and Audit Committee Financial Expert**

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

**Table of Contents**

**Section 16(a) Beneficial Ownership Reporting Compliance**

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

Based solely on our review of copies of such forms received by us, we believe that during the year ended December 31, 2015, all filing requirements applicable to all of our officers, directors, and greater than 10% beneficial stockholders were timely complied with.

**Code of Ethics**

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

iCAD, Inc.

98 Spit Brook Road, Suite 100

Nashua, NH 03062

Attention: Corporate Secretary

**Item 11. Executive Compensation.**

The Company will furnish to the Securities and Exchange Commission a definitive proxy statement not later than 120 days after the end of the fiscal year ended December 31, 2015. The response to this item will be contained in our proxy statement for our 2016 annual meeting of stockholders under the captions Executive Compensation, Compensation of Directors, Compensation Committee Interlocks and Insider Participation, and Compensation Committee Report, and is incorporated herein by reference.

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

The response to this item will be contained in our proxy statement for our 2016 annual meeting of stockholders in part under the caption Stock Ownership of Certain Beneficial Owners and Management and in part below.

**Table of Contents****Equity Compensation Plans**

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2015.

Plan Category:	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for issuance under equity compensation plans excluding securities reflected in column (a)
Equity compensation plans approved by security holders:	1,471,998	\$ 5.01	71,530
Equity compensation plans not approved by security holders (1):	100,000	\$ 5.60	-0-
<b>Total</b>	<b>1,571,998</b>	<b>\$ 5.05</b>	<b>71,530</b>

(1) Represents the aggregate number of shares of common stock issuable upon exercise of individual arrangements with non-plan option holders. See Note 5 of Notes to our consolidated financial statements for a description of our Stock Option and Stock Incentive Plans and certain information regarding the terms of the non-plan options.

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

The response to this item is contained in our proxy statement for our 2016 annual meeting of stockholders under the captions Certain Relationships and Related Transactions, Corporate Governance Matters Director Independence and Compensation Committee Report, and is incorporated herein by reference.

**Item 14. Principal Accounting Fees and Services.**

The response to this item is contained in our proxy statement for our 2016 annual meeting of stockholders under the caption Ratification of Appointment of Independent Registered Public Accounting Firm, and is incorporated herein by reference.

---

**Table of Contents**

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

a) The following documents are filed as part of this Annual Report on Form 10-K:

- i. Financial Statements - See Index on page 84.
- ii. Financial Statement Schedule - See Index on page 84. All other schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are not applicable and, therefore, have been omitted.
- iii. Exhibits - the following documents are filed as exhibits to this Annual Report on Form 10-K:
  - 2(a) Plan and Agreement of Merger dated February 15, 2002, by and among the Registrant, ISSI Acquisition Corp. and Intelligent Systems Software, Inc., Maha Sallam, Kevin Woods and W. Kip Speyer. [incorporated by reference to Annex A of the Company's proxy statement/prospectus dated May 24, 2002 contained in the Registrant's Registration Statement on Form S-4, File No. 333-86454].
  - 2(b) Amended and Restated Plan and Agreement of Merger dated as of December 15, 2003 among the Registrant, Qualia Computing, Inc., Qualia Acquisition Corp., Steven K. Rogers, Thomas E. Shoup and James Corbett [incorporated by reference to Exhibit 2(a) to the Registrant's Current Report on Form 8-K for the event dated December 31, 2003].
  - 2(c) Asset Purchase Agreement as of dated June 20, 2008 between the Registrant and 3TP LLC dba CAD Sciences [incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K for the event dated July 18, 2008]. \*\*
  - 2(d) Agreement and Plan of Merger dated December 15, 2010 by and among the Registrant, XAC, Inc., Xoft, Inc. and Jeffrey Bird as representative of the Xoft, Inc.'s stockholders [incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K for the event dated December 30, 2010]. \*\*
  - 2(e) Asset Purchase Agreement by and between iCAD, Inc. and Radion, Inc., dated as of July 15, 2014. [incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K for the event dated July 15, 2014]. \*\*

---

**Table of Contents**

- 2(f) Asset Purchase Agreement by and between iCAD, Inc. and DermEbx, a series of Radion Capital Partners, LLC, dated as of July 15, 2014. [incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K for the event dated July 15, 2014]. \*\*
- 3(a) Certificate of Incorporation of the Registrant as amended through June 16, 2015 [incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 6, 2015].
- 3(b) Amended and Restated By-laws of the Registrant [incorporated by reference to Exhibit 3 (b) to the Registrant's Report on Form 10-K for the year ended December 31, 2007].
- 4.1(a) Form of Warrant issued on January 9, 2012 [incorporated by reference to Exhibit 4.1 of the Registrant's report on Form 8-K filed with the SEC on January 3, 2012].
- 4.2(b) Form of B Warrant issued on January 9, 2012 [incorporated by reference to Exhibit 4.2 of the Registrant's report on Form 8-K filed with the SEC on January 3, 2012].
- 4.3(c) Registration Rights Agreement, dated as of December 29, 2011 [incorporated by reference to Exhibit 4.3 of the Registrant's report on Form 8-K filed with the SEC on January 3, 2012].
- 10(a) 2002 Stock Option Plan [incorporated by reference to Annex F to the Registrant's Registration Statement on Form S-4 (File No. 333-86454)].\*
- 10(b) 2004 Stock Incentive Plan [incorporated by reference to Exhibit B to the Registrant's definitive proxy statement on Schedule 14A filed with the SEC on May 28, 2004].\*
- 10(c) Form of Option Agreement under the Registrant's 2002 Stock Option Plan [incorporated by reference to Exhibit 10.2 to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2004].\*
- 10(d) Form of Option Agreement under the Registrant's 2004 Stock Incentive Plan [incorporated by reference to Exhibit 10.3 to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2004].\*

---

**Table of Contents**

- 10(e) 2005 Stock Incentive Plan [incorporated by reference to Exhibit 10.1 to the Registrant's report on Form 8-K filed with the SEC on June 28, 2005].\*
- 10(f) Form of Option Agreement under the Registrant's 2005 Stock Incentive Plan [incorporated by reference to Exhibit 10.2 to the Registrant's report on Form 8-K filed with the SEC on June 28, 2005].\*
- 10(g) Form of Indemnification Agreement with each of the Registrant's directors and officers [incorporated by reference to Exhibit 10.6 of Registrant's Quarterly report on Form 10-Q for the quarter ended June 30, 2006].
- 10(h) Form of Indemnification Agreement with each of the Registrant's directors and officers [incorporated by reference to Exhibit 10.1 of Registrant's Quarterly report on Form 10-Q for the quarter ended September 30, 2014].
- 10(i) Lease Agreement dated December 6, 2006 between the Registrant and Gregory D. Stoye and John J. Flatley, Trustees of the 1993 Flatley Family Trust, of Nashua, NH [incorporated by reference to Exhibit 10(mm) to the Registrant's Report on Form 10-K for the year ended December 31, 2006].
- 10(j) 2007 Stock Incentive Plan, as amended [incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed with the SEC on June 16, 2009]. \*
- 10(k) Form of Option Agreement under the Registrant's 2007 Stock Incentive Plan. [incorporated by reference to Exhibit 10(vv) to the Registrant's Report on Form 10-K for the year ended December 31, 2009]\*
- 10(l) Form of Restricted Stock Agreement under the Registrant's 2007 Stock Incentive Plan. [incorporated by reference to Exhibit 10(vv) to the Registrant's Report on Form 10-K for the year ended December 31, 2009].\*
- 10(m) Employment Agreement entered into as of September 25, 2012 between the Registrant and Kenneth Ferry [incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on September 26, 2012] \*

---

**Table of Contents**

- 10(n) Employment Agreement entered into as of June 1, 2008 between the Registrant and Stacey Stevens [incorporated by reference to Exhibit 10.8 of the Registrant's report on Form 10-Q filed with the SEC on August 8, 2008]. \*
- 10(o) Employment Agreement dated as of June 1, 2008 between the Registrant and Jonathan Go [incorporated by reference to Exhibit 10.9 of the Registrant's report on Form 10-Q filed with the SEC on August 8, 2008]. \*
- 10(p) Employment Agreement dated April 26, 2011 between the Registrant and Kevin C. Burns [incorporated by reference to Exhibit 10.2 of the Registrant's report on Form 8-K filed with the SEC on April 27, 2011].
- 10(q) Option Agreement dated April 26, 2011 between the Registrant and Kevin C. Burns [incorporated by reference to Exhibit 10.3 of the Registrant's report on Form 8-K filed with the SEC on April 27, 2011].\*
- 10(r) Facility Agreement including form of Promissory note, dated as of December 29, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited [incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on January 3, 2012].
- 10(s) Form of Security Agreement by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited [incorporated by reference to Exhibit 10.2 of the Registrant's report on Form 8-K filed with the SEC on January 3, 2012].
- 10(t) Form of Security Agreement by and among Xoft, Inc., Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited [incorporated by reference to Exhibit 10.3 of the Registrant's report on Form 8-K filed with the SEC on January 3, 2012].
- 10(u) Revenue Purchase Agreement, dated as of December 29, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL [incorporated by reference to Exhibit 10.4 of the Registrant's report on Form 8-K filed with the SEC on January 3, 2012].

**Table of Contents**

10(v)	Revenue Purchase Termination and Amendment of Facility Agreement, dated as of April 28, 2014, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL [incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 10-Q filed with the SEC on May 14, 2014].
10(w)	Settlement Agreement, dated as of December 22, 2011, by and among the Company, Carl Zeiss Meditec, AG and Carl Zeiss Meditec, Inc. [incorporated by reference to Exhibit 10(y) to the Registrant's Report on Form 10-K for the year ended December 31, 2012]
10(x)	Amendment No. 1 to the Employment Agreement dated April 26, 2011 between the Registrant and Kevin C. Burns [incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on November 25, 2013].*
10(y)	Amendment No. 2 to the Employment Agreement dated April 26, 2011 between the Registrant and Kevin C. Burns [incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on February 11, 2015].*
10(z)	Change in Control Bonus Agreement dated October 29, 2015 between the Registrant and Ken Ferry [incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 4, 2015].*
10(aa)	Change in Control Bonus Agreement dated October 29, 2015 between the Registrant and Kevin Burns [incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 4, 2015].*
10(bb)	Change in Control Bonus Agreement dated October 29, 2015 between the Registrant and Stacey Stevens [incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 4, 2015].*
21	Subsidiaries
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials formatted in XBRL (eXtensible Business Reporting Language); (i) Consolidated Balance Sheets as of



**Table of Contents**

December 31, 2015 and December 31, 2014, (ii) Consolidated Statements of Operations for the twelve months ended December 31, 2015 and 2014 and 2013, (iii) Consolidated Statements of Cash Flows for the twelve months ended December 31, 2015 and 2014 and 2013, and (iv) Notes to Consolidated Financial Statements.

- \* Denotes a management compensation plan or arrangement.
- \*\* The Registrant has omitted certain schedules and exhibits pursuant to Item 601(b)(2) of Regulation S-K and shall furnish supplementally to the SEC copies any of the omitted schedules and exhibits upon request by the SEC.

(b) Exhibits - See (a) iii above.

(c) Financial Statement Schedule - See (a) ii above.

Table of ContentsSIGNATURES

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

iCAD, INC.

Date: March 11, 2016

By: /s/ Kenneth Ferry  
Kenneth Ferry  
Chief Executive Officer, Director

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

Signature	Title	Date
/s/ Lawrence Howard Dr. Lawrence Howard	Chairman of the Board, Director	March 11, 2016
/s/ Kenneth Ferry Kenneth Ferry	Chief Executive Officer Director (Principal Executive Officer)	March 11, 2016
/s/ Kevin C. Burns Kevin C. Burns	President Chief Operating Officer, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 11, 2016
/s/ Rachel Brem Rachel Brem, M.D.	Director	March 11, 2016
/s/ Anthony Ecock Anthony Ecock	Director	March 11, 2016
/s/ Robert Goodman Robert Goodman, M.D.	Director	March 11, 2016
/s/ Steven Rappaport Steven Rappaport	Director	March 11, 2016

Edgar Filing: ICAD INC - Form 10-K

/s/ Andy Sassine	Director	March 11, 2016
Andy Sassine		
/s/ Somu Subramaniam	Director	March 11, 2016
Somu Subramaniam		
/s/ Elliot Sussman	Director	March 11, 2016
Elliot Sussman, M.D.		

**Table of Contents**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	85
<u>Consolidated Balance Sheets</u> <u>As of December 31, 2015 and 2014</u>	86
<u>Consolidated Statements of Operations</u> <u>For the years ended December 31, 2015, 2014 and 2013</u>	87
<u>Consolidated Statements of Stockholders' Equity</u> <u>For the years ended December 31, 2015, 2014 and 2013</u>	88
<u>Consolidated Statements of Cash Flows</u> <u>For the years ended December 31, 2015, 2014 and 2013</u>	89
<u>Notes to Consolidated Financial Statements</u>	90-123

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of iCAD, Inc.,

Nashua, New Hampshire

We have audited the accompanying consolidated balance sheets of iCAD, Inc. and subsidiaries (the Company) as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of iCAD, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Boston, Massachusetts

March 11, 2016

Table of Contents**iCAD, INC. AND SUBSIDIARIES****Consolidated Balance Sheets**

	<b>December 31, 2015</b>	<b>December 31, 2014</b>
	(in thousands except shares and per share data)	
<u>Assets</u>		
Current assets:		
Cash and cash equivalents	\$ 15,280	\$ 32,220
Trade accounts receivable, net of allowance for doubtful accounts of \$236 in 2015 and \$203 in 2014	7,488	9,642
Inventory, net	4,315	2,214
Prepaid expenses and other current assets	684	540
<b>Total current assets</b>	<b>27,767</b>	<b>44,616</b>
Property and equipment:		
Equipment	7,049	8,430
Leasehold improvements	62	62
Furniture and fixtures	295	293
Marketing assets	376	331
	7,782	9,116
Less accumulated depreciation and amortization	5,475	4,861
<b>Net property and equipment</b>	<b>2,307</b>	<b>4,255</b>
Other assets:		
Other assets	94	132
Intangible assets, net of accumulated amortization of \$10,896 in 2015 and \$14,738 in 2014	4,274	17,504
Goodwill	14,198	27,263
<b>Total other assets</b>	<b>18,566</b>	<b>44,899</b>
<b>Total assets</b>	<b>\$ 48,640</b>	<b>\$ 93,770</b>
<u>Liabilities and Stockholders Equity</u>		
Current liabilities:		
Accounts payable	\$ 1,593	\$ 2,151
Accrued expenses	4,220	5,554
Interest payable		180
Notes and capital lease payable, short-term portion	969	5,044
Deferred revenue	7,497	9,120

Edgar Filing: ICAD INC - Form 10-K

Total current liabilities	14,279	22,049
Other long-term liabilities	29	51
Deferred revenue, long-term portion	1,079	1,525
Settlement costs, long-term portion	421	744
Capital lease - long-term portion	86	1,020
Notes payable, long-term portion		5,602
Total liabilities	15,894	30,991
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$ .01 par value: authorized 1,000,000 shares; none issued.		
Common stock, \$ .01 par value: authorized 30,000,000 shares; issued 15,923,349 in 2015 and 15,732,177 in 2014; outstanding 15,737,518 in 2015 and 15,546,346 in 2014		
	159	157
Additional paid-in capital	211,512	209,100
Accumulated deficit	(177,510)	(145,063)
Treasury stock at cost, 185,831 shares in 2015 and 2014	(1,415)	(1,415)
Total stockholders' equity	32,746	62,779
Total liabilities and stockholders' equity	\$ 48,640	\$ 93,770

*See accompanying notes to consolidated financial statements.*

**Table of Contents****iCAD, INC. AND SUBSIDIARIES****Consolidated Statements of Operations**

	<b>For the Years Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
	(in thousands except per share data)		
<b>Revenue:</b>			
Products	\$ 14,198	\$ 18,683	\$ 18,536
Service and supplies	27,356	25,241	14,531
<b>Total revenue</b>	<b>41,554</b>	<b>43,924</b>	<b>33,067</b>
<b>Cost of Revenue:</b>			
Products	3,130	4,912	4,668
Service and supplies	7,357	6,000	4,009
Amortization and depreciation	1,717	1,785	1,305
<b>Total cost of revenue</b>	<b>12,204</b>	<b>12,697</b>	<b>9,982</b>
<b>Gross profit</b>	<b>29,350</b>	<b>31,227</b>	<b>23,085</b>
<b>Operating expenses:</b>			
Engineering and product development	9,163	8,159	7,043
Marketing and sales	12,404	12,468	10,328
General and administrative	8,788	8,044	6,365
Amortization and depreciation	1,631	1,741	1,125
Goodwill and long-lived asset impairment	27,443		
<b>Total operating expenses</b>	<b>59,429</b>	<b>30,412</b>	<b>24,861</b>
<b>Income (loss) from operations</b>	<b>(30,079)</b>	<b>815</b>	<b>(1,776)</b>
<b>Other (expense) income:</b>			
Interest expense	(650)	(2,640)	(3,277)
Gain (loss) from change in fair value of warrant liability		1,835	(2,448)
Loss from extinguishment of debt	(1,723)	(903)	
Interest income	21	37	19
<b>Other expense, net</b>	<b>(2,352)</b>	<b>(1,671)</b>	<b>(5,706)</b>
<b>Loss before income tax expense</b>	<b>(32,431)</b>	<b>(856)</b>	<b>(7,482)</b>
<b>Income tax expense</b>	<b>16</b>	<b>153</b>	<b>126</b>
<b>Net loss and comprehensive loss</b>	<b>\$ (32,447)</b>	<b>\$ (1,009)</b>	<b>\$ (7,608)</b>



## Net loss per share:

Basic	\$ (2.07)	\$ (0.07)	\$ (0.70)
Diluted	\$ (2.07)	\$ (0.07)	\$ (0.70)

## Weighted average number of shares used in computing loss per share:

Basic	15,686	14,096	10,842
Diluted	15,686	14,096	10,842

*See accompanying notes to consolidated financial statements.*

**Table of Contents****iCAD, INC. AND SUBSIDIARIES****Consolidated Statements of Stockholders Equity**

(in thousands except shares)

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Treasury</b>	<b>Stockholders</b>
	<b>Number of</b>	<b>Par Value</b>	<b>Paid-in</b>	<b>Deficit</b>	<b>Stock</b>	<b>Equity</b>
	<b>Shares Issued</b>		<b>Capital</b>			
Balance at December 31, 2012	10,993,933	110	165,416	(136,446)	(1,415)	27,665
Issuance of common stock relative to vesting of restricted stock, net of 5,249 shares forfeited for tax obligations	41,759		(28)			(28)
Issuance of common stock pursuant to stock option plans	48,427	1	145			146
Stock-based compensation			1,202			1,202
Net loss				(7,608)		(7,608)
Balance at December 31, 2013	11,084,119	111	166,735	(144,054)	(1,415)	21,377
Issuance of common stock relative to vesting of restricted stock, net of 9,904 shares forfeited for tax obligations	75,530	1	(111)			(110)
Issuance of common stock for warrants exercised	450,000	4	3,722			3,726
Issuance of stock for acquisitions	1,200,000	12	8,544			8,556
Issuance of common stock pursuant to stock option plans	162,528	1	707			708
Sale of common stock	2,760,000	28	28,186			28,214
Stock-based compensation			1,318			1,318
Net loss				(1,009)		(1,009)
Balance at December 31, 2014	15,732,177	\$ 157	\$ 209,100	\$ (145,063)	\$ (1,415)	\$ 62,779
Issuance of common stock relative to vesting of restricted stock, net of 13,058 shares forfeited for tax obligations	111,700	1	(88)			(87)
Issuance of common stock pursuant to stock option plans	79,472	1	365			366
Stock-based compensation			2,135			2,135
Net loss				(32,447)		(32,447)

Balance at December 31, 2015	15,923,349	\$	159	\$	211,512	\$	(177,510)	\$	(1,415)	\$	32,746
------------------------------	------------	----	-----	----	---------	----	-----------	----	---------	----	--------

*See accompanying notes to consolidated financial statements.*

**Table of Contents****iCAD, INC. AND SUBSIDIARIES****Consolidated Statements of Cash Flows**

	<b>For the Years Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
	(in thousands)		
<b>Cash flow from operating activities:</b>			
Net loss	\$ (32,447)	\$ (1,009)	\$ (7,608)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:			
Amortization	1,768	2,270	1,724
Depreciation	1,580	1,256	706
Bad debt provision	383	167	35
Stock-based compensation expense	2,135	1,318	1,202
Amortization of debt discount and debt costs	341	1,246	856
Goodwill and long-lived asset impairment	27,443		
Interest on settlement obligations	146	206	266
Loss (gain) from change in fair value of warrant liability		(1,835)	2,448
Loss on disposal of assets	125		53
Loss on extinguishment of debt	1,723	903	
Changes in operating assets and liabilities, net of acquisition:			
Accounts receivable	1,772	(840)	(2,678)
Inventory	(1,987)	(323)	228
Prepaid and other assets	(197)	11	(126)
Accounts payable	(557)	150	60
Accrued expenses	(2,060)	296	(609)
Deferred revenue	(2,068)	(612)	2,010
<b>Total adjustments</b>	<b>30,547</b>	<b>4,213</b>	<b>6,175</b>
<b>Net cash (used for) provided by operating activities</b>	<b>(1,900)</b>	<b>3,204</b>	<b>(1,433)</b>
<b>Cash flow from investing activities:</b>			
Additions to patents, technology and other	(40)	(50)	(168)
Additions to property and equipment	(932)	(1,214)	(539)
Acquisition of Radion Inc, and DermEbx		(3,482)	
Acquisition of VuComp M-Vu Breast Density	(1,700)		
<b>Net cash used for investing activities</b>	<b>(2,672)</b>	<b>(4,746)</b>	<b>(707)</b>
<b>Cash flow from financing activities:</b>			
Issuance of common stock for cash, net		28,214	
Stock option exercises	366	708	146
Warrant exercise		1,575	

Edgar Filing: ICAD INC - Form 10-K

Taxes paid related to restricted stock issuance	(87)	(110)	(28)
Principal payments of capital lease obligations	(1,397)	(655)	(46)
Principal repayment of debt financing, net	(11,250)	(7,850)	
Net cash (used for) provided by financing activities	(12,368)	21,882	72
Increase (decrease) in cash and equivalents	(16,940)	20,340	(2,068)
Cash and equivalents, beginning of year	32,220	11,880	13,948
Cash and equivalents, end of year	\$ 15,280	\$ 32,220	\$ 11,880
Supplemental disclosure of cash flow information:			
Interest paid	\$ 558	\$ 1,637	\$ 2,163
Taxes paid	\$ 128	\$ 157	\$ 78
Equipment purchased under capital lease	\$	\$	\$ 409
Non-cash items from investing and financing activities:			
Settlement of warrant liability with purchase of common stock	\$	2,151	
Issuance of common stock related to acquisition of Radion, Inc and DermEbx	\$	8,556	

*See accompanying notes to consolidated financial statements.*

---

**Table of Contents**

**iCAD, INC. AND SUBSIDIARIES**

Notes to Consolidated Financial Statements

**(1) Summary of Significant Accounting Policies**

**(a) Nature of Operations and Use of Estimates**

iCAD, Inc. and subsidiaries (the Company or iCAD ) is a provider of advanced image analysis, workflow solutions and radiation therapy for the early identification and treatment of cancer.

The Company has grown primarily through acquisitions to become a broad player in the oncology market. Its solutions include advanced image analysis and workflow solutions that enable healthcare professionals to better serve patients by identifying pathologies and pinpointing the most prevalent cancers earlier, a comprehensive range of high-performance, upgradeable Computer-Aided Detection (CAD) systems and workflow solutions for mammography, MRI and CT, and the Xofigo system which is an isotope-free cancer treatment platform technology. CAD is reimbursable in the U.S. under federal and most third-party insurance programs.

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

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

The Company operates in two segments: Cancer Detection ( Detection ) and Cancer Therapy ( Therapy ). The Detection segment consists of advanced image analysis and workflow products, and the Therapy segment consists of radiation therapy products. The Company sells its products throughout the world through its direct sales organization as well as through various OEM partners, distributors and resellers. See Note 7 for segment, major customer and geographical information.

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported

## **Table of Contents**

amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. It is reasonably possible that changes may occur in the near term that would affect management's estimates with respect to assets and liabilities.

### **(b) Principles of Consolidation**

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

### **(c) Cash and cash equivalents**

The Company defines cash and cash equivalents as all bank accounts, money market funds, deposits and other money market instruments with original maturities of 90 days or less, which are unrestricted as to withdrawal. Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. Insurance coverage is \$250,000 per depositor at each financial institution, and the Company's non-interest bearing cash balances exceed federally insured limits. Interest-bearing amounts on deposit in excess of federally insured limits at December 31, 2015 approximated \$14.5 million.

### **(d) Financial instruments**

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, and notes payable. Due to their short term nature and market rates of interest, the carrying amounts of the financial instruments approximated fair value as of December 31, 2015 and 2014.

### **(e) Accounts Receivable and Allowance for Doubtful Accounts**

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

The Company's policy is to maintain allowances for estimated losses from the inability of its customers to make required payments. The Company's senior management reviews accounts receivable on a periodic basis to determine if any receivables may potentially be uncollectible. The Company includes any accounts receivable balances that it determines may likely be uncollectible, along with a general reserve for estimated probable losses based on historical experience, in its overall allowance for doubtful accounts. An amount would be written off against the allowance after all attempts to collect the receivable had failed. Based on the information available, the Company believes the allowance for doubtful accounts as of December 31, 2015 and 2014 is adequate.

**Table of Contents**

The following table summarizes the allowance for doubtful accounts for the three years ended December 31, 2015 (in thousands):

	<b>2015</b>	<b>2014</b>	<b>2013</b>
Balance at beginning of period	\$ 203	\$ 73	\$ 48
Additions charged to costs and expenses	383	167	35
Reductions	(350)	(37)	(10)
Balance at end of period	\$ 236	\$ 203	\$ 73

**(f) Inventory**

Inventory is valued at the lower of cost or market value, with cost determined by the first-in, first-out method. The Company regularly reviews inventory quantities on hand and records an allowance for excess and/or obsolete inventory primarily based upon the estimated usage of its inventory as well as other factors. At December 31, 2015 and 2014, inventories consisted of the following (in thousands):

	<b>As of</b>	
	<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>
Raw materials	\$ 2,900	\$ 955
Work in process	154	54
Finished Goods	1,261	1,205
Inventory	\$ 4,315	\$ 2,214

**(g) Property and Equipment**

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets or the remaining lease term, if shorter, for leasehold improvements (see below).

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

**(h) Long Lived Assets**

In accordance with FASB ASC Topic 360, *Property, Plant and Equipment*, (ASC 360), the Company assesses long-lived assets for impairment if events and circumstances indicate it is more likely than not that the fair value of the asset group is less than the carrying value of the asset group.





**Table of Contents**

ASC 360-10-35 uses events and circumstances criteria to determine when, if at all, an asset (or asset group) is evaluated for recoverability. Thus, there is no set interval or frequency for recoverability evaluation. In accordance with ASC 360-10-35-21, the following factors are examples of events or changes in circumstances that indicate the carrying amount of an asset (asset group) may not be recoverable and thus is to be evaluated for recoverability.

A significant decrease in the market price of a long-lived asset (asset group);

A significant adverse change in the extent or manner in which a long-lived asset (asset group) is being used or in its physical condition;

A significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset (asset group), including an adverse action or assessment by a regulator;

An accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of a long-lived asset (asset group);

A current period operating or cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with the use of a long-lived asset (asset group).

As a result of external factors and general uncertainty related to reimbursement for the treatment of non-melanoma skin cancer, the Company evaluated the long-lived assets of the Therapy segment and reviewed them for potential impairment. The Company determined the Asset Group to be the assets of the Therapy segment, which the Company considered to be the lowest level for which the identifiable cash flows were largely independent of the cash flows of other assets and liabilities.

In accordance with ASC 360-10-35-17, if the carrying amount of an asset or asset group (in use or under development) is evaluated and found not to be fully recoverable (the carrying amount exceeds the estimated gross, undiscounted cash flows from use and disposition), then an impairment loss must be recognized. The impairment loss is measured as the excess of the carrying amount over the asset's (or asset group's) fair value.

In connection with the preparation of the financial statements for the second quarter ended June 30, 2015, the Company completed its analysis pursuant to ASC 360-10-35-17 and determined that the carrying value of the Asset Group was approximately \$36.8 million, which exceeded the undiscounted cash flows by approximately \$2.8 million. Accordingly the Company completed the Step 2 analysis to determine the fair value of the asset group. The Company recorded long-lived asset impairment charges of approximately \$13.4 million in the second quarter ended June 30, 2015 and as a result the long lived assets in the Asset Group were recorded at their current fair values.

**Table of Contents**

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

Intangible assets subject to amortization consist primarily of patents, technology, customer relationships and trade names purchased in the Company's previous acquisitions. These assets, which include assets from the acquisition of the assets of VuComp, DermEbx and Radion and the acquisition of Xoft, Inc., are amortized on a straight-line basis consistent with the pattern of economic benefit over their estimated useful lives of 5 to 15 years. A summary of intangible assets for 2015 and 2014 are as follows (in thousands):

	2015	2014	Weighted average useful life
<b>Gross Carrying Amount</b>			
Patents and licenses	\$ 579	\$ 767	5 years
Technology	14,075	25,639	10 years
Customer relationships	268	5,548	7 years
Tradename	248	288	10 years
<b>Total amortizable intangible assets</b>	<b>15,170</b>	<b>32,242</b>	
<b>Accumulated Amortization</b>			
Patents and licenses	\$ 451	\$ 517	
Technology	9,996	13,076	
Customer relationships	201	896	
Tradename	248	249	
<b>Total accumulated amortization</b>	<b>10,896</b>	<b>14,738</b>	
<b>Total amortizable intangible assets, net</b>	<b>\$ 4,274</b>	<b>\$ 17,504</b>	

**Table of Contents**

Amortization expense related to intangible assets was approximately \$1,768, \$2,270 and \$1,724 for the years ended December 31, 2015, 2014, and 2013, respectively. Estimated remaining amortization of the Company's intangible assets is as follows (in thousands):

<b>For the years ended</b>	<b>Estimated amortization expense</b>
<b>December 31:</b>	
2016	\$ 920
2017	897
2018	676
2019	392
2020	324
Thereafter	1,065
	<b>\$ 4,274</b>

**(i) Goodwill**

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

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

significant underperformance relative to historical or projected future operating results;

significant changes in the manner or use of the assets or the strategy for the Company's overall business;

significant negative industry or economic trends;

significant decline in the Company's stock price for a sustained period; and

a decline in the Company's market capitalization below net book value.

The Company would record an impairment charge if such an assessment were to indicate that the fair value of a reporting unit was less than the carrying value. In evaluating potential impairments outside of the annual measurement date, judgment is required in determining whether an event has occurred that may impair the value of goodwill or intangible assets. The Company utilizes either discounted cash flow models or other valuation models, such as comparative transactions and market multiples, to determine the fair value of reporting units. The Company makes assumptions about future cash flows, future operating plans, discount rates, comparable companies, market multiples,

purchase price premiums and other factors in those models. Different assumptions and judgment determinations could yield different conclusions that would result in an impairment charge to income in the period that such change or determination was made.

As a result of external factors and general uncertainty related to reimbursement for non-melanoma skin cancer and in conjunction with the long-lived asset impairment testing, the Company performed an impairment assessment of the Therapy reporting unit as of June 30, 2015. As a result the Company recorded a goodwill impairment charge of \$14.0 million during the quarter ended June 30, 2015.

## Table of Contents

The implied fair value of the Therapy reporting unit was determined in the same manner as the manner in which the amount of goodwill recognized in a business combination is determined. The excess of the fair value of the reporting unit over the amounts assigned to its assets and liabilities is the implied amount of goodwill. The Company identified the intangible assets that were valued during this process, including technology, customer relationships and trade-names. The allocation process was performed only for purposes of testing goodwill for impairment.

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

The Company uses internal forecasts to estimate future cash flows and includes an estimate of long-term future growth rates based on the most recent views of the long-term forecast for the reporting unit. Accordingly, actual results can differ from those assumed in the forecasts. The discount rate of approximately 17% is derived from a capital asset pricing model and analyzing published rates for industries relevant to the reporting unit to estimate the cost of equity financing. The Company uses discount rates that are commensurate with the risks and uncertainty inherent in the respective businesses and in the internally developed forecasts.

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

The Step 2 test resulted in an approximate fair value of goodwill of \$5.7 million which resulted in a goodwill impairment loss of \$14.0 million.

As discussed in Note 3, the Company acquired VuComp's M-V<sup>®</sup> Breast Density product for \$1.7 million. The product will be integrated into the Company's Powerlook AMP system, which is a component of the Detection reporting unit. The Company determined that the acquisition was a business combination and accordingly recorded goodwill of \$0.8 million.

The Company performed an annual impairment assessment at October 1, 2015 and compared the fair value of each reporting unit to its carrying value as of this date. The fair value of each reporting unit exceeded the carrying value by approximately 584% for

**Table of Contents**

the Detection reporting unit and 144% for the Therapy reporting unit. The carrying values of the reporting units were determined based on an allocation of our assets and liabilities through specific allocation of certain assets and liabilities to the reporting units and an apportionment of the remaining net assets based on the relative size of the reporting units' revenues and operating expenses compared to the Company as a whole. The determination of reporting units also requires management judgment.

The Company determined the fair values for each reporting unit using a weighting of the income approach and the market approach. For purposes of the income approach, fair value is determined based on the present value of estimated future cash flows, discounted at an appropriate risk adjusted rate. The Company used internal forecasts to estimate future cash flows and includes an estimate of long-term future growth rates based on the most recent views of the long-term forecast for each segment. Accordingly, actual results can differ from those assumed in the forecasts. The discount rate of approximately 17% is derived from a capital asset pricing model and analyzing published rates for industries relevant to the reporting units to estimate the cost of equity financing. The Company uses discount rates that are commensurate with the risks and uncertainty inherent in the respective businesses and in the internally developed forecasts.

In the market approach, the Company uses a valuation technique in which values are derived based on market prices of publicly traded companies with similar operating characteristics and industries. A market approach allows for comparison to actual market transactions and multiples. It can be somewhat limited in its application because the population of potential comparable publicly-traded companies can be limited due to differing characteristics of the comparative business and ours, as well as market data may not be available for divisions within larger conglomerates or non-public subsidiaries that could otherwise qualify as comparable, and the specific circumstances surrounding a market transaction (e.g., synergies between the parties, terms and conditions of the transaction, etc.) may be different or irrelevant with respect to the business.

The Company corroborated the total fair values of the reporting units using a market capitalization approach; however, this approach cannot be used to determine the fair value of each reporting unit value. The blend of the income approach and market approach is more closely aligned to the business profile of the Company, including markets served and products available. In addition, required rates of return, along with uncertainties inherent in the forecast of future cash flows, are reflected in the selection of the discount rate. In addition, under the blended approach, reasonably likely scenarios and associated sensitivities can be developed for alternative future states that may not be reflected in an observable market price. The Company will assess each valuation methodology based upon the relevance and availability of the data at the time the valuation is performed and weight the methodologies appropriately.

**Table of Contents**

A rollforward of goodwill activity by reportable segment is as follows:

	Detection	Therapy	Total
Accumulated Goodwill	\$	\$	\$ 47,937
Accumulated impairment			(26,828)
Fair value allocation	7,663	13,446	
Balance at December 31, 2013	7,663	13,446	21,109
Acquisition of DermEbx and Radion		6,154	6,154
Balance at December 31, 2014	7,663	19,600	27,263
Acquisition measurement period adjustments		116	116
Acquisition of VuComp	800		800
Impairment		(13,981)	(13,981)
Balance at December 31, 2015	\$ 8,463	\$ 5,735	\$ 14,198
Accumulated Goodwill	800	6,270	55,007
Fair value allocation	7,663	13,446	
Accumulated impairment		(13,981)	(40,809)
Balance at December 31, 2015	\$ 8,463	\$ 5,735	\$ 14,198

**(j) Revenue Recognition**

The Company recognizes revenue primarily from the sale of products, services and supplies. Revenue is recognized when delivery has occurred, persuasive evidence of an arrangement exists, fees are fixed or determinable and collectability of the related receivable is probable. For product revenue, delivery has occurred upon shipment provided title and risk of loss have passed to the customer. Services and supplies revenue are considered to be delivered as the services are performed or over the estimated life of the supply agreement.

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



circumstances related to each deliverable.

## **Table of Contents**

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

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

The Company has determined that iCAD's digital and film based sales generally follow the guidance of FASB ASC Topic 605 *Revenue Recognition* ( ASC 605 ) as the software has been considered essential to the functionality of the product per the guidance of ASU 2009-14. Typically, the responsibility for the installation process lies with the OEM partner. On occasion, when iCAD is responsible for product installation, the installation element is considered a separate unit of accounting because the delivered product has stand-alone value to the customer. In these instances, the Company allocates the revenue to the deliverables based on the framework established within ASU 2009-13. Therefore, the installation and training revenue is recognized as the services are performed according to the BEP of the element. Revenue from the digital and film based equipment when there is installation, is recognized based on the relative selling price allocation of the BEP, when delivered.

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

The Company recognizes post contract customer support revenue together with the initial licensing fee for certain MRI products in accordance with 985-605-25-71.

Sales of the Company's Therapy segment products typically include a controller, accessories, source agreements and services. The Company allocates revenue to the deliverables in the arrangement based on the BEP in accordance with ASU 2009-13. Product revenue is generally recognized when the product has been delivered and service

**Table of Contents**

and/or supplies revenue is typically recognized over the life of the service and/or supplies. The Company includes in service and supplies revenue the following: the sale of physics and management services, the lease of electronic brachytherapy equipment, development fees, supplies and the right to use the Company's AxxentHub software. Physics and management services revenue and development fees are considered to be delivered as the services are performed or over the estimated life of the agreement. The Company typically bills items monthly over the life of the agreement except for development fees, which are generally billed in advance or over a 12 month period and the fee for treatment supplies which is generally billed in advance.

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

**(k) Cost of Revenue**

Cost of revenue consists of the costs of products purchased for resale, cost relating to service including costs of service contracts to maintain equipment after the warranty period, inbound freight and duty, manufacturing, warehousing, material movement, inspection, scrap, rework, depreciation and in-house product warranty repairs, amortization of acquired technology and medical device tax.

**(l) Warranty Costs**

The Company provides for the estimated cost of standard product warranty against defects in material and workmanship based on historical warranty trends, including the cost of product returns during the warranty period. Warranty provisions and claims for the years ended December 31, 2015, 2014 and 2013, were as follows (in thousands):

	2015	2014	2013
Beginning accrual balance	\$ 14	\$ 25	\$ 36
Warranty provision	54	58	96
Usage	(49)	(69)	(107)
Ending accrual balance	\$ 19	\$ 14	\$ 25

The warranty accrual above includes long-term warranty obligations of \$2,000, \$5,000 and \$8,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

**(m) Engineering and Product Development Costs**

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

**Table of Contents****(n) Advertising Costs**

The Company expenses advertising costs as incurred. Advertising expense for the years ended December 31, 2015, 2014 and 2013 was approximately \$950,000, \$882,000 and \$639,000 respectively.

**(o) Net Loss per Common Share**

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

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

	<b>2015</b>	<b>2014</b>	<b>2013</b>
Net loss available to common shareholders	\$ (32,447)	\$ (1,009)	\$ (7,608)
Basic shares used in the calculation of earnings per share	15,686	14,096	10,842
Effect of dilutive securities:			
Stock options			
Restricted stock			
Diluted shares used in the calculation of earnings per share	15,686	14,096	10,842
Net loss per share:			
Basic	\$ (2.07)	\$ (0.07)	\$ (0.70)
Diluted	\$ (2.07)	\$ (0.07)	\$ (0.70)

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

	<b>2015</b>	<b>2014</b>	<b>2013</b>
Common stock options	1,571,998	1,417,887	1,334,955
Warrants			550,000
Restricted Stock	516,396	309,317	216,250
	<b>2,088,394</b>	<b>1,727,204</b>	<b>2,101,205</b>

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



**Table of Contents**

**(p) Income Taxes**

The Company follows the liability method under ASC Topic 740, *Income Taxes*, (ASC 740). The primary objectives of accounting for taxes under ASC 740 are to (a) recognize the amount of tax payable for the current year and (b) recognize the amount of deferred tax liability or asset for the future tax consequences of events that have been reflected in the Company's financial statements or tax returns. The Company has provided a full valuation allowance against its deferred tax assets at December 31, 2015 and 2014, as it is more likely than not that the deferred tax asset will not be realized. Any subsequent changes in the valuation allowance will be recorded through operations in the provision (benefit) for income taxes.

ASC 740-10 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC 740-10 also provides guidance on de-recognition, classification, interest and penalties, disclosure and transition.

**(q) Stock-Based Compensation**

The Company maintains stock-based incentive plans, under which it provides stock incentives to employees, directors and contractors. The Company may grant to employees, directors and contractors, options to purchase common stock at an exercise price equal to the market value of the stock at the date of grant. The Company may grant restricted stock to employees and directors. The underlying shares of the restricted stock grant are not issued until the shares vest, and compensation expense is based on the stock price of the shares at the time of grant. The Company follows FASB ASC Topic 718, *Compensation - Stock Compensation* (ASC 718), for all stock-based compensation. Under this application, the Company is required to record compensation expense over the vesting period for all awards granted.

The Company uses the Black-Scholes option pricing model to value stock options which requires extensive use of accounting judgment and financial estimates, including estimates of the expected term participants will retain their vested stock options before exercising them, the estimated volatility of its common stock price over the expected term, the risk free rate, expected dividend yield, and the number of options that will be forfeited prior to the completion of their vesting requirements. Fair value of restricted stock is determined based on the stock price of the underlying option on the date of the grant. Application of alternative assumptions could produce significantly different estimates of the fair value of stock-based compensation and consequently, the related amounts recognized in the Consolidated Statements of Operations.

---

**Table of Contents**

**(r) Fair Value Measurements**

The Company follows the provisions of FASB ASC Topic 820, Fair Value Measurement and Disclosures (ASC 820). This topic defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value

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

The Company's assets that are measured at fair value on a recurring basis relate to the Company's money market accounts. The Company's liabilities that are measured at fair value on a recurring basis relate to contingent consideration resulting from the acquisition of Xoft and the warrants issued in connection with the financing arrangement.

The money market funds are included in cash and cash equivalents in the accompanying balance sheet, and are considered a level 1 investment as they are valued at quoted market prices in active markets.

In connection with the financing as further described in Note 3, the Company issued 550,000 warrants to Deerfield in December 2011. On April 30, 2014, Deerfield exercised 450,000 warrants for an aggregate purchase price of \$1,575,000, and the Company issued 450,000 shares of common stock and cancelled the remaining 100,000 warrants issued to Deerfield, since these 100,000 warrants were exercisable only in the event the Company extended the last debt payment for an additional year. The warrant obligation was fully satisfied following that exercise. The liability for the warrants associated with the debt was valued using the binomial lattice-based valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. The warrant was valued at \$2,151,000 as of April 30, 2014 immediately prior to exercise which included a gain of \$699,000. Significant assumptions in valuing the warrant liability as of April 30, 2014 were as follows.

Edgar Filing: ICAD INC - Form 10-K

Warrants	April 30, 2014
Exercise price	\$ 3.50
Volatility	40.8%
Equivalent term (years)	
Risk-free interest rate	0.1%



**Table of Contents**

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

**Fair value measurements using: (000 s) as of December 31, 2015**

	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Money market accounts	\$ 13,577	\$	\$	\$ 13,577
<b>Total Assets</b>	\$ 13,577	\$	\$	\$ 13,577

**Fair value measurements using: (000 s) as of December 31, 2014**

	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Money market accounts	\$ 26,530	\$	\$	\$ 26,530
<b>Total Assets</b>	\$ 26,530	\$	\$	\$ 26,530

The following table provides a summary of changes in the fair value of the warrants during the period are as follows (in thousands):

<b>Warrants</b>	<b>Amount</b>
Balance as of December 31, 2012	\$ 1,538
Loss from change in fair value of warrant	2,448
<b>Balance as of December 31, 2013</b>	<b>3,986</b>
Gain from change in fair value of warrant	(1,835)
Warrant exercise	(2,151)
<b>Balance as of December 31, 2014</b>	<b>\$</b>

*Items Measured at Fair Value on a Nonrecurring Basis*

Certain assets, including long-lived assets and goodwill, are measured at fair value on a nonrecurring basis. These assets are recognized at fair value when they are deemed to be

---

**Table of Contents**

impaired. The Company recorded a \$27.4 million impairment consisting of \$14.0 million related to goodwill and \$13.4 million related to long-lived assets as discussed in Note (h) and Note (i) and re-measured long-lived assets and goodwill of the Therapy reporting unit at fair value as of the impairment date as noted in the following table. The fair values of long-lived assets and goodwill were measured using Level 3 inputs.

**(s) Recently Issued Accounting Standards**

In May 2014, the FASB issued Accounting Standards Update ( ASU ) 2014-09 *Revenue from Contracts with Customers* ( ASU 2014-09 ), which amends ASC 605 *Revenue Recognition* and creates a new Topic 606 *Revenue from Contracts with Customers*. This update provides guidance on how an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Upon initial application, the provisions of this update are required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this update recognized at the date of initial application. This update also expands the disclosure requirements surrounding revenue recorded from contracts with customers. In August 2015, the FASB issued ASU 2015-14 *Deferral of the Effective Date*. The amendments in this Update defer the effective date of Update 2014-09 for all entities by one year. Public business entities, certain not-for-profit entities, and certain employee benefit plans should apply the guidance in Update 2014-09 to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We are currently evaluating the effect of this update on our financial statements and have not yet determined the method of initial application we will use.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes* ( ASU 2015-17 ), which simplifies the presentation of deferred income taxes. ASU 2015-17 requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for fiscal years beginning after December 15, 2016 (and interim periods within those fiscal years) with early adoption permitted. ASU 2015-17 may be either applied prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented. We have elected to early adopt ASU 2015-17 prospectively in the fourth quarter of 2015. There was no impact on our results of operations as a result of the adoption of ASU 2015-17.

In September 2015, the FASB issued ASU No. 2015-16: *Simplifying the Accounting for Measurement-Period Adjustments*, which eliminates the requirement for an acquirer in a business combination to account for measurement-period adjustments retrospectively. Under the ASU, acquirers must recognize measurement-period adjustments in the period in which they determine the amounts, including the effect on earnings of any amounts they would have recorded in previous periods if the accounting had been completed at the acquisition date. The acquirer still must disclose the amounts and reasons for adjustments to the provisional amounts. The acquirer also must disclose, by line item, the amount of the adjustment reflected in the current-period income statement that would have been recognized in previous periods if the adjustment to provisional amounts had been recognized as of the acquisition date. Alternatively, an acquirer may present those amounts separately on the face of the income statement. The ASU does not change the criteria for determining whether an adjustment qualifies as a measurement-period adjustment and does not change the length of the measurement period. The ASU results in differences between US GAAP and IFRS, which are currently aligned on this topic. The ASU is effective for public business entities for fiscal years beginning after 15 December 2015, and interim periods within those fiscal years. Early adoption is permitted for any interim and annual financial statements that have not yet been issued.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The standard establishes a right-of-use ( ROU ) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. We are currently evaluating the impact of our pending adoption of the new standard on our consolidated financial statements.

#### (t) Subsequent event

In April 2015, iCAD entered into an asset purchase agreement (the April 2015 APA ) with VuCOMP, Inc. ( VuCOMP ) to purchase certain assets related to VuCOMP s M-Vu Breast Density product. In December 2015, iCAD entered into negotiations to purchase VuCOMP s remaining assets and in the course of iCAD s due diligence investigation, VuCOMP disclosed that it had previously entered into a license agreement pursuant to which it issued an irrevocable, royalty-free worldwide license to a third party. On December 24, 2015, iCAD notified VuCOMP of a claim under the April 2015 APA based on the disclosure of the third party license agreement, which iCAD believed constituted a breach of VuCOMP s representation as to its exclusive ownership of its intellectual property. In January 2016, VuCOMP obtained an amendment to the third party license agreement providing that the third party would not use the intellectual property in the breast density assessment field of use (except that after five years, the third party may use the intellectual property in the breast density assessment field of use in the country of India). On January 12, 2016, iCAD entered into an asset purchase agreement for an immaterial amount with VuCOMP to purchase VuCOMP s remaining assets and in connection with such purchase, provided VuCOMP with a release of the aforementioned claim.

## (2) Acquisitions

### *Acquisition of VuComp M-Vu Breast Density Assets:*

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

The amount allocated to the acquired assets was estimated primarily through the use of discounted cash flow valuation techniques. Appraisal assumptions utilized under this method include a forecast of estimated future net cash flows, as well as discounting the future net cash flows to their present value. The acquired technology is being amortized over the estimated useful life of approximately eight years and nine months from the closing of the transaction. The following is a summary of the preliminary allocation of the total purchase price based on the estimated fair values as of the date of the acquisition and the amortizable life:

	Amount	Estimated Amortizable Life
Developed Technology	900	8 years 9 months

Goodwill 800

Purchase price \$ 1,700

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

---

**Table of Contents***DermEbx and Radion:*

On July 15, 2014, the Company entered into two Asset Purchase Agreements, one with Radion, Inc. ( Radion ) the other with DermEbx, a series of Radion Capital Partners LLC ( DermEbx ) (the Radion/DermEbx Acquisition ). Pursuant to the Asset Purchase Agreement with DermEbx, the Company purchased substantially all of the assets of DermEbx, including all of DermEbx 's intellectual property and customer contracts. The Company paid the following consideration to DermEbx: (i) \$1,600,000 in cash and (ii) 600,000 restricted shares of the Company 's common stock, \$0.01 par value per share. The 600,000 restricted shares were subject to the following provisions; 25% was locked up until the date that was two trading days after the Company announced its fourth quarter 2014 earnings, which occurred on March 2, 2015; 30% of the shares were to be locked up for a period of 24 months from the date of the agreement; and 30% of the shares were to be locked up for a period of 36 months from the date of the agreement. In addition, the Company delivered the remaining 15%, or 90,000, of the restricted shares to US Bank, N.A., as escrow agent, which were to be held in escrow for a period of 18 months pursuant to the terms of an escrow agreement. The 90,000 escrow shares acted as the source of payment for the indemnification of the Company by DermEbx under the DermEbx Asset Purchase Agreement. On October 7, 2015, the Company and each of Radion and DermEbx entered into a working capital settlement agreement pursuant to which the restrictions on the shares were lifted, the escrow shares were released from escrow and the parties agreed to settle all amounts owed under the Asset Purchase Agreements.

Pursuant to the terms of the Asset Purchase Agreement with Radion, the Company purchased substantially all of the assets of Radion, including all of Radion 's intellectual property and customer contracts. The Company paid the following consideration to Radion: (i) \$2,382,000 in cash which included \$182,000 payoff of an existing note payable and (ii) the issuance to Radion of 600,000 restricted shares of the Company 's common stock. The 600,000 restricted shares were subject to the following provisions; 25% of the shares were locked up until the date that was two trading days after the Company announces its fourth quarter 2014 earnings, which occurred on March 2, 2015; 30% of the shares shall be locked up for a period of 24 months from the date of the agreement; and 30% of the shares were to be locked up for a period of 36 months from the date of the agreement. In addition the Company delivered the remaining 15% or 90,000 of the restricted shares to US Bank, N.A., as escrow agent, which were to be held in escrow for a period of 18 months pursuant to the terms of an escrow agreement. The 90,000 escrow shares acted as the source of payment for the indemnification of the Company by Radion under the Radion Asset Purchase Agreement. On October 7, 2015, the Company and each of Radion and DermEbx entered into a working capital settlement agreement pursuant to which the restrictions on the shares were lifted, the escrow shares were released from escrow and the parties agreed to settle all amounts owed under the Asset Purchase Agreements.

Prior to the Radion DermEbx Acquisition in July 2014, the Sellers represented one of the Company 's significant customers in the Therapy segment. The Company recognized approximately \$0.5 million of Therapy service revenue, for a total of \$2.1 million related to Sellers, in the six months ended June 30, 2014, and these amounts are included in the results for the year ended December 31, 2014.

**Table of Contents**

The amounts allocated to purchased and developed software, customer relationships, trade names, employee non-compete agreements and backlog were estimated primarily through the use of discounted cash flow valuation techniques. Appraisal assumptions utilized under these methods include a forecast of estimated future net cash flows, as well as discounting the future net cash flows to their present value. Acquired intangible assets are being amortized over the estimated useful lives as set forth in the following table. The following is a summary of the allocation of the total purchase price based on the estimated fair values of the assets acquired and liabilities assumed as of the date of the acquisition and the amortizable lives of the intangible assets:

	Amount	Estimated Amortizable Life
Current assets	\$ 3,457	
Property and equipment	2,625	3 7 Years
Identifiable intangible assets	6,050	5 10 Years
Goodwill	6,154	
Current liabilities	(4,316)	
Long-term liabilities	(2,114)	
Purchase price	\$ 11,856	

The goodwill of \$6.2 million is deductible for income tax purposes.

**(3) Financing Arrangements**

In December, 2011, the Company entered into several agreements with entities affiliated with Deerfield Management, a healthcare investment fund ( Deerfield ), pursuant to which Deerfield agreed to provide \$15 million in funding to the Company. The agreements consist of a Facility Agreement (the Facility Agreement ), a Revenue Purchase Agreement (the Revenue Purchase Agreement ) and the issuance of warrants to purchase up to 550,000 shares of the Company s common stock at an exercise price of \$3.50 (the Warrants ).

On April 30, 2014, the Company agreed to pay Deerfield \$4.1 million to terminate the Revenue Purchase Agreement, which eliminated the ability to extend the last debt payment for an additional year and eliminated the payment obligation for 2017 under the Revenue Purchase Agreement. The Company recorded a loss of \$0.9 million in connection with termination of the Revenue Purchase Agreement. In addition, Deerfield exercised their Warrants, for an aggregate purchase price of \$1,575,000, and the Company issued 450,000 shares of common stock to Deerfield, pursuant to the terms of

**Table of Contents**

the Warrants. The Warrants to purchase an additional 100,000 shares of common stock were cancelled, since these Warrants were exercisable only in the event the Company extended the last debt payment for an additional year.

On March 31, 2015, the Company repaid in full the aggregate amount outstanding under the Deerfield Facility Agreement. The Facility Agreement was to mature on December 29, 2016 and was able to be repaid prior to the maturity date at the Company's option without penalty or premium. The Company used cash on hand to pay the \$11.25 million outstanding principal amount due under the Facility Agreement and approximately \$162,000 in accrued and unpaid interest on such principal amount.

The Company recorded a loss on the extinguishment of debt of approximately \$1.7 million at the termination date in the quarter ended March 31, 2015.

The following amounts are included in the consolidated balance sheet as of December 31, 2014 related to the Facility Agreement:

	December 31, 2014	
Principal Amount of Facility Agreement	\$	15,000
Unamortized discount		(1,898)
Principal repayment		(3,750)
Carrying amount of Facility Agreement		9,352
Less current portion of Facility Agreement		(3,750)
Notes payable long-term portion	\$	5,602

The following amounts are included in interest expense in our consolidated statement of operations for the years ended December 31, 2015 and 2014:

	December 31, 2015		December 31, 2014	
Cash interest expense	\$	163	\$	1,189
Non-cash amortization of debt discount		254		1,053
Amortization of debt costs		13		110
Amortization of settlement obligations		146		206
Interest expense capital lease		74		82
Total interest expense	\$	650	\$	2,640

Cash interest expense represents the amount of interest expected to be paid in cash under the agreements, which represents the interest of 5.75% on the Facility Agreement that was terminated in March 2015 and the cash payments on the Revenue Purchase Agreement that was terminated in April 2014. Non-cash amortization is the amortization of the discount on the Facility Agreement. The amortization of debt costs represents the costs incurred with the financing, which is primarily the facility fee and the finder's fee which had been capitalized and was expensed using the effective interest method. The facility fee and finders fee amortization was written off with the termination of the





**Table of Contents**

Facility Agreement and is included in the loss on extinguishment of debt. The amortization of the settlement obligations represent the interest associated with the settlement agreements for both Zeiss and Hologic, Inc.( Hologic ), see Note 8(f) to our Consolidated Financial Statements.

**(4) Accrued Expenses**

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

	2015	2014
Accrued salary and related expenses	\$ 1,765	\$ 2,518
Accrued accounts payable	1,518	1,589
Accrued professional fees	425	414
Accrued short term settlement costs	418	698
Other accrued expenses	52	287
Deferred rent	42	48
	\$ 4,220	\$ 5,554

**(5) Stockholders Equity****(a) Stock Options**

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

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

The 2002 Plan was adopted by the Company's stockholders in June 2002. The 2002 Plan provides for the granting of non-qualifying and incentive stock options to employees and other persons to purchase up to an aggregate of 100,000 shares of the Company's common stock. The purchase price of each share for which an option is granted is determined by the Board of Directors or the Committee appointed by the Board of Directors provided that the purchase price of each share for which an incentive option is granted cannot be less than the fair market value of the Company's common stock on the date of grant, except for options granted to 10% stockholders for whom the exercise price cannot be less than 110% of the market price. Incentive options granted to date under the 2002 Plan vest 100% over periods extending from six months to five years from the date of grant and expire no later than ten years after the date of grant, except for 10% holders whose options expire not later than five years after the date of grant. Non-qualifying options granted under the 2002 Plan are generally exercisable over a ten year period, vesting 1/3 each on the first, second, and third anniversaries of the date of grant. At December 31, 2015, there are no further options available for grant under the 2002 Plan.

---

**Table of Contents****The 2004 Stock Incentive Plan (the 2004 Plan )**.

The 2004 Plan was adopted by the Company's stockholders in June 2004. The 2004 Plan provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. The 2004 Plan provides for the granting of non-qualifying and incentive stock options to employees and other persons to purchase up to an aggregate of 200,000 shares of the Company's common stock. The purchase price of each share for which an option is granted is determined by the Board of Directors or the Committee appointed by the Board of Directors provided that the purchase price of each share for which an option is granted cannot be less than the fair market value of the Company's common stock on the date of grant, except for incentive options granted to 10% stockholders for whom the exercise price cannot be less than 110% of the market price. Incentive options granted under the 2004 Plan generally vest 100% over periods extending from the date of grant to five years from the date of grant and expire not later than ten years after the date of grant, except for 10% holders whose options expire not later than five years after the date of grant. Non-qualifying options granted under the 2004 Plan are generally exercisable over a ten year period, vesting 1/3 each on the first, second, and third anniversaries of the date of grant. At December 31, 2015, there are no further shares available for grant under the 2004 Plan.

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

The 2005 Plan was adopted by the Company's stockholders in June 2005. The 2005 Plan provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. The 2005 Plan provides for the granting of non-qualifying and incentive stock options to employees and other persons to purchase up to an aggregate of 120,000 shares of the Company's common stock. The purchase price of each share for which an option is granted is determined by the Board of Directors or the Committee appointed by the Board of Directors provided that the purchase price of each share for which an option is granted cannot be less than the fair market value of the Company's common stock on the date of grant, except for incentive options granted to 10% stockholders for whom the exercise price cannot be less than 110% of the market price. Incentive options granted under the 2005 Plan generally vest 100% over periods extending from the date of grant to three years from the date of grant and expire not later than five years after the date of grant, except for 10% stockholders whose options expire not later than five years after the date of grant. Non-qualifying options granted under the 2005 Plan are generally exercisable over a ten year period, vesting 1/3 each on the first, second, and third anniversaries of the date of grant. At December 31, 2015, there are no further options available for grant under the 2005 Plan.

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

The 2007 Plan was adopted by the Company's stockholders in July 2007 and amended in June 2009. The 2007 Plan provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. Awards may be granted singly, in combination, or in tandem. Subject to anti-dilution

---

**Table of Contents**

adjustments as provided in the 2007 Plan, (i) the 2007 Plan provides for a total of 1,050,000 shares of the Company's common stock to be available for distribution pursuant to the 2007 Plan, and (ii) the maximum number of shares of the Company's common stock with respect to which stock options, restricted stock, deferred stock, or other stock-based awards may be granted to any participant under the 2007 Plan during any calendar year or part of a year may not exceed 160,000 shares.

The 2007 Plan provides that it will be administered by the Company's Board of Directors ( Board ) or a committee of two or more members of the Board appointed by the Board.

The administrator will generally have the authority to administer the 2007 Plan, determine participants who will be granted awards under the 2007 Plan, the size and types of awards, the terms and conditions of awards and the form and content of the award agreements representing awards. Awards under the 2007 Plan may be granted to employees, directors, consultants and advisors of the Company and its subsidiaries. However, only employees of the Company and its subsidiaries will be eligible to receive options that are designated as incentive stock options.

With respect to options granted under the 2007 Plan, the exercise price must be at least 100% (110% in the case of an incentive stock option granted to a 10% stockholder) of the fair market value of the common stock subject to the award, determined as of the date of grant. Restricted stock awards are shares of common stock that are awarded subject to the satisfaction of the terms and conditions established by the administrator. In general, awards that do not require exercise may be made in exchange for such lawful consideration, including services, as determined by the administrator. At December 31, 2015, there were 63,188 shares available for issuance under the 2007 Plan.

**The 2012 Stock Incentive Plan (the 2012 Plan )**

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

The 2012 Plan provides that it will be administered by the Company's Board of Directors ( Board ) or a committee of two or more members of the Board appointed by the Board.

The administrator will generally have the authority to administer the 2012 Plan, determine participants who will be granted awards under the 2012 Plan, the size and types of awards, the terms and conditions of awards and the form and content of the award agreements representing awards. Awards under the 2012 Plan may be granted to employees, directors,

**Table of Contents**

consultants and advisors of the Company and its subsidiaries. However, only employees of the Company and its subsidiaries will be eligible to receive options that are designated as incentive stock options.

With respect to options granted under the 2012 Plan, the exercise price must be at least 100% (110% in the case of an incentive stock option granted to a 10% stockholder) of the fair market value of the common stock subject to the award, determined as of the date of grant. Restricted stock awards are shares of common stock that are awarded subject to the satisfaction of the terms and conditions established by the administrator. In general, awards that do not require exercise may be made in exchange for such lawful consideration, including services, as determined by the administrator. At December 31, 2015, there were 8,342 shares available for issuance under the 2012 Plan.

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding, January 1, 2013	1,434,945	\$ 4.75	
Granted	46,537	\$ 5.42	
Exercised	(48,427)	\$ 3.00	
Forfeited	(98,100)	\$ 11.62	
Outstanding, December 31, 2013	1,334,955	\$ 4.75	
Granted	281,043	\$ 8.08	
Exercised	(162,528)	\$ 4.36	
Forfeited	(35,583)	\$ 13.62	
Outstanding, December 31, 2014	1,417,887	\$ 4.34	
Granted	363,239	\$ 6.58	
Exercised	(79,472)	\$ 4.60	
Forfeited	(129,656)	\$ 7.38	
Outstanding, December 31, 2015	1,571,998	\$ 5.05	6.6 years
Exercisable at December 31, 2013	743,910	\$ 5.09	
Exercisable at December 31, 2014	955,210	\$ 4.43	
Exercisable at December 31, 2015	1,087,725	\$ 4.33	5.6 years

**Table of Contents**

Available for future grants at December 31, 2015 from all plans: 71,530

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

	<b>Years Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Cost of revenue	\$ 14	\$ 13	\$ 21
Engineering and product development	223	165	228
Marketing and sales	659	353	273
General and administrative expense	1,239	787	680
	<b>\$ 2,135</b>	<b>\$ 1,318</b>	<b>\$ 1,202</b>

As of December 31, 2015, there was \$3.8 million of total unrecognized compensation costs related to unvested options and restricted stock. That cost is expected to be recognized over a weighted average period of 1.10 years.

Options granted under the stock incentive plans were valued utilizing the Black-Scholes model using the following assumptions and had the following fair values:

	<b>Years Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Average risk-free interest rate	0.97%	0.85%	0.53%
Expected dividend yield	None	None	None
Expected life	3.5 years	3.5 years	3.5 years
Expected volatility	60.5% to 75.2%	64.2% to 69.4%	57.6% to 68.9%
Weighted average exercise price	\$6.58	\$8.09	\$5.42
Weighted average fair value	\$3.17	\$3.84	\$2.35

The Company's 2015, 2014 and 2013, average expected volatility and average expected life is based on the average of the Company's historical information. The risk-free rate is based on the rate of U.S. Treasury zero-coupon issues with a remaining term equal to the expected life of option grants. The Company has paid no dividends on its common stock in the past and does not anticipate paying any dividends in the future.

The aggregate intrinsic value of options outstanding at December 31, 2015, 2014 and 2013 was \$1.9 million, \$6.3 million and \$10.0 million, respectively. The aggregate intrinsic value of the options exercisable at December 31, 2015, 2014 and 2013 was \$1.6 million, \$4.6 million and \$5.1 million, respectively. The aggregate intrinsic value of stock options exercised during 2015, 2014 and 2013 was \$0.3 million, \$1.0 million and \$0.5 million, respectively. The Company used the closing market price of \$5.17, \$9.17 and \$11.66 per share at December 31, 2015, 2014 and 2013, respectively, to determine the aggregate intrinsic values of options outstanding and exercisable.

**Table of Contents****(b) Restricted Stock**

The Company's restricted stock awards typically vest in either one year or three equal annual installments with the first installment vesting one year from grant date. A summary of restricted stock activity for all equity incentive plans is as follows:

	<b>Years Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Beginning outstanding balance	309,317	216,250	67,075
Granted	352,666	180,500	196,250
Vested	(124,758)	(85,434)	(47,008)
Forfeited	(20,829)	(1,999)	(67)
<b>Ending outstanding balance</b>	<b>516,396</b>	<b>309,317</b>	<b>216,250</b>

The aggregate intrinsic value of restricted stock outstanding at December 31, 2015, 2014 and 2013 was \$2.7 million, \$2.8 million, and \$2.5 million, respectively. The aggregate intrinsic value of restricted stock vested during 2015, 2014 and 2013 was \$0.6 million, \$0.8 million and \$0.5 million, respectively. The Company used the closing market price of \$5.17, \$9.17 and \$11.66 per share at December 31, 2015, 2014 and 2013, respectively, to determine the aggregate intrinsic values.

**(6) Income Taxes**

The components of income tax expense for the years ended December 31, 2015, 2014 and 2013 are as follows (in thousands):

	2015	2014	2013
<b>Current provision (benefit):</b>			
Federal		\$ (44)	\$
State	95	118	126
	\$ 95	\$ 74	\$ 126
<b>Deferred provision:</b>			
Federal	\$ (65)	\$ 65	\$
State	(14)	14	
	\$ (79)	\$ 79	\$
<b>Total</b>	<b>\$ 16</b>	<b>\$ 153</b>	<b>\$ 126</b>



**Table of Contents**

A summary of the differences between the Company's effective income tax rate and the Federal statutory income tax rate for the years ended December 31, 2015, 2014 and 2013 is as follows:

	2015	2014	2013
Federal statutory rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit	2.5%	5.5%	2.3%
Net state impact of deferred rate change	(0.1%)	13.0%	0.1%
Stock compensation expense	(10.7%)	(9.6%)	(2.0%)
Tax amortization on goodwill	0.2%	(9.0%)	0.0%
Loss on warrant	0.0%	71.6%	0.0%
Other permanent differences	(0.1%)	(1.1%)	(11.7%)
Change in valuation allowance	(26.6%)	(222.6%)	(27.6%)
Tax credits	0.9%	100.8%	3.3%
Effective income tax	0.1%	(17.4%)	(1.6%)

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

Deferred income taxes reflect the impact of temporary differences between the amount of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations. The Company has fully reserved the net deferred tax assets, as it is more likely than not that the deferred tax assets will not be utilized. Deferred tax assets (liabilities) are composed of the following at December 31 (in thousands):

	2015	2014
Inventory (Section 263A)	\$ 588	\$ 191
Inventory reserves	106	106
Receivable reserves	159	197
Other accruals	591	887
Deferred revenue	367	1,142
Accumulated depreciation/amortization	417	65
Stock options	2,529	2,252
Developed technology	3,554	(2,941)
Tax credits	2,765	3,054
NOL carryforward	36,706	34,690
Net deferred tax assets	47,782	39,643
Valuation allowance	(47,782)	(39,643)
Goodwill tax amortization		(79)
Deferred tax liability	\$	\$ (79)



The increase in net deferred tax assets and corresponding valuation allowance is primarily attributable to additional research and development credits and differences in amortization periods on the Company's intangible assets.

---

**Table of Contents**

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes ( ASU 2015-17 ), which simplifies the presentation of deferred income taxes. ASU 2015-17 requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for fiscal years beginning after December 15, 2016 (and interim periods within those fiscal years) with early adoption permitted. ASU 2015-17 may be either applied prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented. We have elected to early adopt ASU 2015-17 prospectively in the fourth quarter of 2015. There was no impact on our results of operations as a result of the adoption of ASU 2015-17.

As of December 31, 2015, the Company has net operating loss carryforwards totaling approximately \$100.9 million expiring between 2018 and 2035. A portion of the total net operating loss carryforwards amounting to approximately \$25.3 million relate to the acquisition of Xoft, Inc. As of December 31, 2015, the Company has provided a valuation allowance for its net operating loss carryforwards due to the uncertainty of the Company's ability to generate sufficient taxable income in future years to obtain the benefit from the utilization of the net operating loss carryforwards. In the event of a deemed change in control, an annual limitation imposed on the utilization of the net operating losses may result in the expiration of all or a portion of the net operating loss carryforwards. There were no net operating losses utilized for the years ended December 31, 2015 and 2014.

The Company currently has approximately \$13.8 million (including approximately \$9.5 million that relate to Xoft, Inc.) in net operating losses that are subject to limitations, of which approximately \$2.0 million (including approximately \$473,000 that relates to Xoft, Inc.) can be used annually through 2035. The Company has available tax credit carryforwards (adjusted to reflect provisions of the Tax Reform Act of 1986) to offset future income tax liabilities totaling approximately \$2.8 million. The tax credits related to Xoft have been fully reserved for and as a result no deferred tax asset has been recorded. The credits expire in various years through 2035.

ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

As of December 31, 2015 and 2014, the Company had no unrecognized tax benefits and no adjustments to liabilities or operations were required under ASC 740-10. The Company's practice was and continues to be to recognize interest and penalty expenses related to uncertain tax positions in income tax expense, which was zero for the years ended December 31, 2015, 2014 and 2013. The Company files United States federal and various state income tax returns. Generally, the Company's three preceding tax years remain subject to examination by federal and state taxing authorities. The Company completed an examination by the Internal Revenue Service with respect to the 2008 tax year in January 2011, which resulted in no changes to the tax return originally filed. The Company is not under examination by any other federal or state jurisdiction for any tax year.

**Table of Contents**

The Company does not anticipate that it is reasonably possible that unrecognized tax benefits as of December 31, 2015 will significantly change within the next 12 months.

**(7) Segment Reporting, Geographical Information and Major Customers**

**(a) Segment Reporting**

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

The Company's CODM is the Chief Executive Officer ( CEO ). Each reportable segment generates revenue from the sale of medical equipment and related services and/or sale of supplies. The Company has determined there are two segments: Cancer Detection ( Detection ) and Cancer Therapy ( Therapy ).

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

We do not track our assets by operating segment and our CODM does not use asset information by segment to allocate resources or make operating decisions.

**Table of Contents**

Segment revenues, gross profit, segment operating income or loss, and a reconciliation of segment operating income or loss to GAAP loss before income tax is as follows (in thousands, including prior periods which have been presented for consistency):

	Year Ended December 31,		
	2015	2014	2013
<b>Segment revenues:</b>			
Detection	\$ 19,243	\$ 18,604	\$ 16,905
Therapy	22,311	25,320	16,162
Total Revenue	\$ 41,554	\$ 43,924	\$ 33,067
<b>Segment gross profit:</b>			
Detection	\$ 16,019	\$ 15,276	\$ 13,576
Therapy	13,331	15,951	9,509
Segment gross profit	\$ 29,350	\$ 31,227	\$ 23,085
<b>Segment operating income (loss):</b>			
Detection	\$ 7,233	\$ 7,231	\$ 5,016
Therapy	(28,405)	1,868	(52)
Segment operating income	\$ (21,172)	\$ 9,099	\$ 4,964
General, administrative, depreciation and amortization expense			
	\$ (8,907)	\$ (8,284)	\$ (6,740)
Interest expense	(650)	(2,640)	(3,277)
Gain (loss) on fair value of warrant		1,835	(2,448)
Other income	21	37	19
Loss on debt extinguishment	(1,723)	(903)	
Loss before income tax	\$ (32,431)	\$ (856)	\$ (7,482)

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

<b>Detection depreciation and amortization</b>			
Depreciation	220	188	175
Amortization	532	515	517
<b>Therapy depreciation and amortization</b>			
Depreciation	1,142	844	424
Amortization	1,213	1,739	939

**(b) Geographic Information**

The Company's sales are made to customers, distributors and dealers of mammography, electronic brachytherapy equipment and other medical equipment, and to foreign distributors of mammography and electronic brachytherapy equipment. Export sales to a single country did not exceed 10% of total revenue in any year. Total export sales were approximately \$2.3 million or 6% of total revenue in 2015, \$1.8 million or 4% of total revenue in 2014 and \$1.9 million or 6% of total revenue in 2013.

---

**Table of Contents**

As of December 31, 2015 and 2014, the Company had outstanding receivables of \$0.5 million and \$0.3 million, respectively, from distributors and customers of its products who are located outside of the U.S.

**(c) Major Customers**

The Company had one major customer, GE Healthcare, with revenues of approximately \$4.1 million in 2015, \$4.1 million in 2014, and \$3.7 million in 2013 or 10%, 9%, and 11% of total revenue, respectively. Cancer detection products are also sold through OEM partners, including GE Healthcare, Fuji Medical Systems, Siemens Medical and In vivo. These four OEM partners composed approximately 53% of Detection revenues and 25% of revenue overall.

OEM partners represented \$2.2 million or 28% of outstanding receivables as of December 31, 2015, with GE Healthcare accounting for \$1.2 million or 15% of this amount. The two largest Cancer Therapy customers composed \$0.8 million or 10% of outstanding receivables as of December 31, 2015. These six customers in total represented \$3.0 million or 38% of outstanding receivables as of December 31, 2015.

**(8) Commitments and Contingencies**

**(a) Lease Obligations**

As of December 31, 2015, the Company had three lease obligations related to its facilities.

The Company's executive offices are located in Nashua, New Hampshire and are leased pursuant to a five-year lease (the "Lease") that commenced on December 15, 2006, and renewed on January 1, 2012 (the "Premises"). The Lease renewal provided for annual base rent of \$181,764 for the first year; \$187,272 for the second year; \$192,780 for the third year; \$198,288 for the fourth year and \$203,796 for the fifth year. 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 also has the right to extend the term of the Lease for an additional five year period at the then current market rent rate (but not less than the last annual rent paid by the Company).

The Company leases a facility in San Jose California under a non-cancelable operating lease which commenced in September, 2012. The facility has approximately 24,250 square feet of office, manufacturing and warehousing space. The operating lease provides for an annual base rent of \$248,376, increasing to \$260,064 in October 2013, \$271,752 beginning October 2014, \$283,440 beginning October 2015 and \$295,140 beginning October 2016 through September 2017, with all amounts payable in equal monthly installments, with the right to extend the lease for an additional 3 year period. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the facility.

**Table of Contents**

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.

Rent expense for all leases for the years ended December 31, 2015, 2014 and 2013 was \$663,000, \$643,000 and \$697,000, respectively.

Future minimum rental payments due under these agreements as of December 31, 2015 are as follows (in thousands):

Fiscal Year	Operating Leases
2016	524
2017	289
2018	9
	\$ 822

**(b) Capital lease obligations**

The Company entered into a capital lease agreement for the purchase of certain equipment in August 2013 for approximately \$409,000 at a rate of 3.99%. Under the guidance of ASC Topic 840, *Leases* the Company determined that the lease was a capital lease as it contained a bargain purchase option wherein the Company has the option to buy the equipment for \$1 at the end of the lease term. Accordingly, the equipment has been capitalized and a liability has been recorded. The equipment cost of \$409,000 is reflected as property and equipment in the balance sheet and will be depreciated over its useful life. As of December 31, 2015, the remaining obligation is \$0.1 million.

In connection with the Acquisition, the Company assumed two separate equipment lease obligations with payments totaling approximately \$2.6 million through May, 2017. The leases were determined to be capital leases and accordingly the equipment was capitalized and a liability of \$2.5 million was recorded. As of December 31, 2015, the outstanding liability for the acquired equipment leases was approximately \$1.0 million.

**Table of Contents**

Future minimum lease payments under all outstanding capital leases are as follows (in thousands):

Fiscal Year	Capital Leases
2016	1,039
2017	89
subtotal minimum lease obligation	1,128
less interest	(73)
Total, net	1,055
less current portion	(969)
long term portion	\$ 86

*Related Party Lease:*

Kamal Gogineni is an employee of one of the Company's subsidiaries and a shareholder of the Company's common stock. Additionally, Mr. Gogineni is a shareholder of Radion Capital Partners ( RCP ). RCP was the lessor under a lease between RCP and DermEbx (the Lease ). In connection with the Company's acquisition of assets of Radion and DermEbx that closed in July 2014, one of the assets and obligations that the Company acquired was the Lease. Pursuant to the Lease, the Company is obligated to pay a total of \$0.5 million and the liability is included in the minimum lease payments above, with remaining annual payments of \$396,000 in 2016 and \$76,000 in 2017.

**(c) Other Commitments**

The Company has non-cancelable purchase orders with three key suppliers executed in the normal course of business that total approximately \$1.0 million. In connection with our employee savings plans, our matching contribution for 2015 was approximately \$0.5 million in cash. Our matching contribution for 2016 is estimated to be approximately \$0.5 million in cash.

**(d) Employment Agreements**

The Company has entered into employment agreements with certain key executives. The employment agreements provide for minimum annual salaries and performance-based annual bonus compensation as defined in their respective agreements. In addition, the employment agreements provide that if employment is terminated without cause, the executive will receive an amount equal to their respective base salary then in effect for the greater of the remainder of the original term of employment or, for Mr. Ferry, a period of two years from the date of termination, for Mr. Burns, a period of eighteen months from the date of termination and for all other executives a period of one year from the date of termination, in each case, plus the pro rata portion of any annual bonus earned in any employment year through the date of termination.



---

**Table of Contents****(e) Foreign Tax Claim**

In July 2007, a dissolved former Canadian subsidiary of the Company, CADx Medical Systems Inc. ( CADx Medical ), received a tax re-assessment of approximately \$6,800,000 from the Canada Revenue Agency ( CRA ) resulting from CRA 's audit of CADx Medical 's Canadian federal tax return for the year ended December 31, 2002. In February 2010, the CRA reviewed the matter and reduced the tax re-assessment to approximately \$703,000, excluding interest and penalties. The CRA has the right to pursue the matter until July 2017. The Company believes that it is not liable for the re-assessment against CADx Medical and continues to defend this position. As the Company believes that a probability of a loss is remote, no accrual was recorded as of December 31, 2015.

**(f) Royalty Obligations**

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

During December, 2011, the Company settled litigation with Zeiss and as of December 31, 2015, has a remaining obligation to pay \$0.5 million in June 2017. The present value of the liability is estimated at approximately \$0.4 million as of December 31, 2015.

The Company was granted a non-exclusive license from Yeda Research which relates to the 3TP method for the detection of cancer and has a minimum obligation of \$25,000 annually through 2032 for a total of approximately \$0.4 million.

**(g) Litigation**

The Company is 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.

**Table of Contents****(9) Quarterly Financial Data** (in thousands, except per share data, and unaudited)

	<b>Net sales</b>	<b>Gross profit</b>	<b>Net income (loss)</b>	<b>Income (loss) per share</b>
<b>2015</b>				
First quarter	\$ 13,220	\$ 9,362	\$ (1,857)	(\$ 0.12)
Second quarter	11,143	7,878	\$ (27,786)*	(\$ 1.77)
Third quarter	9,582	6,821	\$ (402)	(\$ 0.03)
Fourth quarter	7,609	5,289	\$ (2,402)	(\$ 0.15)
<b>2014</b>				
First quarter	\$ 8,520	\$ 5,934	\$ (190)	(\$ 0.02)
Second quarter	9,667	6,830	\$ (997)	(\$ 0.07)
Third quarter	12,572	9,167	\$ 274	\$ 0.02
Fourth quarter	13,165	9,296	\$ (96)	(\$ 0.01)

(\*) - includes goodwill and long-lived asset impairment of \$27.4 million