ICAD INC Form 10-K March 09, 2012

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

# **FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2011

OR

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

For the transition period from

Commission file number 1-9341

to

iCAD, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

02-0377419 (I.R.S. Employer

incorporation or organization)

Identification No.)

98 Spit Brook Road, Suite 100,

Nashua, New Hampshire 03062 (Address of principal executive offices) (Zip Code) Registrant s telephone number, including area code: (603) 882-5200

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

**Title of Class**Common Stock, \$.01 par value

Name of each exchange on which registered The Nasdaq Stock Market LLC

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO ".

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large Accelerated filer "Accelerated filer Accelerated filer Accelerated filer Son-accelerated filer (do not check if a smaller reporting company) Smaller reporting company x Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No x

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing price for the registrant's Common Stock on June 30, 2011 was \$46,735,512. Shares of voting stock held by each officer and director and by each person who, as of June 30, 2011, 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 5, 2012, the registrant had 53,944,755 shares of Common Stock outstanding.

Documents Incorporated by Reference: Certain portions of the registrant s definitive Proxy Statement for its 2012 Annual Meeting of Stockholders are incorporated by reference into Items 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

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

Certain information included in this annual report on Form 10-K that are not historical facts contain forward looking statements that involve a number of known and unknown risks, uncertainties and other factors that could cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievement expressed or implied by such forward looking statements. These risks and uncertainties include, but are not limited to, the Company's ability to defend itself in litigation matters, to achieve business and strategic objectives, the risks of uncertainty of patent protection, the impact of supply and manufacturing constraints or difficulties, uncertainty of future sales levels, protection of patents and other proprietary rights, the impact of supply and manufacturing constraints or difficulties, product market acceptance, possible technological obsolescence of products, increased competition, litigation and/or government regulation, changes in Medicare reimbursement policies, risks relating to our existing and future debt obligations, competitive factors, the effects of a decline in the economy or markets served by the Company and other risks detailed in this report and in the Company's other filings with the United States Securities and Exchange Commission (SEC). The words believe, demonstrate, intend, expect, estimate, anticipate, like 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 registra and us means iCAD, Inc. and any consolidated subsidiaries.

#### PART I

# <u>Item 1</u>. <u>Business</u>. General

iCAD was founded in 1984 as Howtek, Inc. ( Howtek ). In June 2002, the Company acquired Intelligent Systems Software, Inc. ( ISSI ), a privately held company based in Florida and in December 2003, the Company acquired Qualia Computing, Inc. ( Qualia ), a privately held company based in Ohio, and its subsidiaries, including CADx Systems, Inc. (together CADx ). ISSI and Qualia Computing offered Computer-Aided Detection ( CAD ) for breast cancer detection. These acquisitions brought together two of the three companies with clearance by the United States Food and Drug Administration ( FDA ) to market CAD solutions for breast cancer in the United States.

Since that time the Company has established itself as an industry-leading provider of CAD solutions for mammography. iCAD offers a comprehensive range of high-performance upgradeable products for use with mammography, including digital radiography, computed radiography and film-based mammography. These solutions enable radiologists to better serve patients by identifying pathologies and pinpointing cancers. Early detection of cancer is a key to better prognosis, less invasive treatment and lower treatment costs, and higher survival rates. Performed as an adjunct to a mammography screening, CAD quickly became a standard of care

in breast cancer detection, helping radiologists improve clinical outcomes while enhancing workflow. Since iCAD received FDA clearance for its first breast cancer detection product in January 2002, more than 4,000 iCAD systems have been placed in healthcare sites worldwide.

In July 2008, iCAD expanded its portfolio of products with the acquisition of substantially all of the assets of 3TP LLC, dba CAD Sciences ( CAD Sciences ). The technology acquired is a pharmacokinetic based CAD technology that aids in the interpretation of contrast enhanced Magnetic Resonance Imaging ( MRI ) images. This acquisition extended iCAD s position beyond mammography CAD and provided the Company with a portfolio of advanced image analysis and workflow solutions for the early detection of some of the most prevalent cancers using digital mammography, MRI and Computed Tomography ( CT ). iCAD believes that advances in MRI and CT are creating opportunities in the medical imaging sector. There is also significant synergy regarding customer call points, providing the iCAD sales team with additional products to sell.

iCAD is also applying its patented detection technology and algorithms to the development of CAD solutions for use with virtual colonoscopy or CT Colonography ( CTC ) to improve the detection of colonic polyps. The Company s pattern recognition and image analysis expertise are readily applicable to colonic polyp detection and the Company has developed a CTC CAD solution. The Company completed clinical testing of its CTC CAD product in the first quarter of 2009 and in August 2010 became the first CAD technology product to receive FDA clearance for use with CTC.

On December 30, 2010, the Company acquired Xoft, Inc. ( Xoft ), a privately held company based in California. The Company acquired 100% of the outstanding stock of Xoft in exchange for 8,348,501 shares of the Company s common stock and approximately \$1,183,000 in cash, for total consideration at closing of approximately \$12,879,000 based on a per share value of \$1.40, the average of the closing sale price of the Company s common stock over the thirty trading days immediately preceding the closing date and the closing price on the closing date. The Company s Consolidated Statement of Operations does not include the financial results of Xoft for the periods ended December 31, 2010 and 2009.

The acquisition of Xoft brought an isotope-free cancer treatment platform technology to the Company's product line. Xoft designs, develops, manufactures, markets and sells electronic brachytherapy (eBx) products for the treatment of breast, endometrial and skin cancer, and for the treatment of other cancers or conditions where radiation therapy is indicated, and is used in a broad range of clinical settings. The portable Axxent System which delivers electronically controlled radiation therapy directly to cancer sites with minimal radiation exposure to surrounding healthy tissue is FDA-cleared. Electronic Brachytherapy is a type of brachytherapy that utilizes a miniaturized high dose rate 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, sparing healthy tissue and organs. The Xoft technology delivers similar clinical dose rates to traditional radioactive systems. Electronic Brachytherapy can be delivered during an operative procedure and may be used for Accelerated Partial Breast Irradiation (APBI) which delivers the full course of radiation over a course of five days. This technology enables radiation oncology departments in hospitals, clinics and physician offices to perform traditional radiotherapy

treatments and provide advanced treatments such as Intraoperative Radiation Therapy (IORT). Current customers of the Xoft eBx system include university research and community hospitals, private and governmental institutions, doctors offices, cancer care clinics, and veterinary facilities.

Today, the Company is an industry-leading provider of advanced image analysis and workflow solutions that enable healthcare professionals to better serve patients by identifying pathologies and pinpointing the most prevalent cancers earlier. iCAD offers 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 believes that the acquisition of Xoft will transform the Company into a broader player in the oncology market.

The iCAD website is <a href="www.icadmed.com">www.icadmed.com</a>. At 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. 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.

The Company is headquartered in Nashua, New Hampshire with research and development ( R&D ) centers located in Fairborn, Ohio and Sunnyvale, California. The Sunnyvale, California facility is also the design, and manufacturing facility for a portion of the Company s Xoft products.

#### Strategy

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.

The Company is currently applying its patented detection technology, pharmacokinetics, and algorithms to products used to detect disease states where pattern recognition, image analysis, and clinical efficiency play a pivotal role. For breast imaging, the Company is developing CAD solutions for tomosynthesis (3-D mammography) and a next-generation of breast MR image analysis workstations to help radiologists find cancer earlier and more efficiently. The Company believes that CAD for tomosynthesis has the potential to help radiologists better detect cancer and manage the workflow issues created by large 3D tomosynthesis datasets. The pharmacokinetics or second generation kinetics technology complements iCAD s core competency in morphology (anatomy) based CAD solutions providing a platform for iCAD to produce next-generation MRI products delivering both kinetics and morphology technology in a single CAD solution. For colorectal cancer screening, iCAD has developed a CAD solution to help radiologists detect colonic polyps during their review of CTC exams.

The Company believes that MR image analysis for prostate imaging is an emerging growth opportunity. Nearly one in six men over age 40 is afflicted with prostate cancer in the U.S. and 10% of those cases are expected to be fatal. Current standards for detecting prostate cancer are considered, by many medical professionals, to be antiquated and subject to accuracy issues. The current Prostate Specific Antigen blood test has a false negative rate approaching 15%, while only approximately 12% of men with abnormal tests actually have cancer. Biopsies miss at least 20% of all malignancies and underestimate the disease aggressiveness in up to 30% of men. Scientific evidence is growing that advanced imaging technologies will improve early detection, eliminate unnecessary procedures, and provide accurate image guidance for biopsies.

The Company is also exploring the role of MR image analysis in treatment planning and the early monitoring of cancer treatment. Radiosurgical planning and delivery systems can be used to create a customized radiation dose distribution tailored to focus the highest regions of dose on the areas within the prostate where cancer is most heavily involved and to deliver the dose pattern with sub-millimeter accuracy and precision. The Company's technology delivers an imaging method for mapping these tumor-bearing regions. As part of a collaborative research effort, the direct three-dimensional computerized integration of these complementary technologies shows promise in delivering customized treatment plans, to more exactly and safely treat the specific cancer involvement pattern of each individual prostate cancer. Today, monitoring of therapy is solely based on tumor size and the response is assessed after the fact, often resulting in patients and payers having to deal with ineffective treatment. The Company believes that an early-stage therapy monitoring solution that is simple and widely available could result in more effective cancer treatment plans.

While the Company continues to pursue growth opportunities in its CAD markets, it also continues to assess strategic opportunities for incremental growth beyond CAD. The Company is transforming itself from a business focused on image analysis for the early detection of cancers to a broader player in the oncology market and embarked on this strategy with the acquisition of Xoft at the end of 2010. The Company s belief is 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.

#### **Existing Markets and Market Opportunities**

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.

Approximately 39 million mammograms were performed in the U.S. in 2010. 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 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. CAD as an adjunct to mammography screening is reimbursable in the U.S. under federal and most third party insurance programs. This reimbursement provides economic support for the acquisition of CAD products by women shealthcare providers. Market growth has also been driven in recent years by the introduction of full field digital mammography (FFDM) systems.

In the U.S., approximately 8,620 facilities (with approximately 12,300 mammography systems) were certified to provide mammography screening in 2010. Historically, these centers have used conventional film-based medical imaging technologies to capture and analyze breast images. Of the 8,620 certified facilities, to date approximately 82% have acquired FFDM systems. A FFDM system generates a digital image eliminating film used in conventional mammography.

While a double reading protocol is currently advocated as a standard of care in most European countries this is not the standard protocol in the United States. Double reading requires substantially more resources, which are often not available due to the shortage of mammographers. In view of the frequency of missed cancers and of the lack of resources for double reading as a standard of care, CAD in combination with review by a single radiologist is an alternative to double reading of mammography and may further reduce breast cancer mortality.

Based on the report published by Frost and Sullivan entitled 2007 European Women s Healthcare Imaging Markets , breast cancer is one of the most prevalent forms of cancer and it is also responsible for the most number of cancer-related deaths among women in the European Union (EU). The number of expected cancer cases is expected to continue to rise as the incidence of cancer increases steeply with age and life expectancy. According to the European Parliamentary Group on Breast Cancer, they expect approximately 269,000 new breast cancer cases will be reported and over 87,000 deaths per year. On average 1 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.

#### **Market Size and Share**

GlobalData projects the full-field digital mammography sector will grow at a compound annual growth rate of 8% and reach \$1.3 billion in 2017.

Frost and Sullivan and IMV, a market research company, both reported historical increases and foresee continuing growth in breast MRI exams as published in their 2008 reports. Frost and Sullivan predicts the use of MRI in the management of breast cancer volumes will heighten to 3 million by 2014. More than 5,000 MRI systems could be used for breast MRI procedures today. Merge Healthcare, Inc. (formerly Confirma, Inc. acquired in September 2009) and Invivo Corporation have been and currently remain the market leaders in breast MR image analysis.

In addition, IMV estimated that 1.1 million patients were treated with radiation therapy in 2009. According to the same study, the top indication treated was breast MRI procedures at 24% of all procedures. U.S. sales of brachytherapy products were \$240 million in 2008 and are expected to increase to \$1,979 million by 2016 as estimated by the market research firm Bio-tech Systems, Inc.

#### **New Market Opportunities**

#### Computed Tomography Applications and Colonic Polyp Detection

CT is a well-established and widely used imaging technology that has evolved rapidly over the last few years. CT equipment 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. The use of multi-detectors in CT equipment has progressed in just a few years from 4 slices to 8, 16, 64 slices and beyond, resulting in vastly improved image quality. The image quality improvements resulting from the increased number of slices per procedure and greatly increased imaging speeds have expanded the use of CT imaging in both the number of procedures performed as well as the applications for which it is utilized. It was estimated by Frost and Sullivan that over 72 million CT procedures would be performed in 2011 in the U.S. alone with an installed base of approximately 6,000 machines. While the increased number of cross sectional slices provides important and 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 presents it with opportunities to provide automated image analysis and clinical decision support solutions.

According to data from the American Cancer Society, it is estimated that over 51,000 Americans will die from colorectal cancer and 143,000 people will be diagnosed with colon cancer in 2012. It is the second leading cause of cancer deaths in spite of being highly preventable with early identification and removal of colorectal polyps. Several techniques including optical colonoscopy, which involves visualizing the inside of the colon with a specialized scope, exist for the early identification of polyps. More than 116 million Americans are age 50 and older, the recommended age for colorectal cancer screening. However, this technique remains highly underutilized with less than half of this population being tested. This reluctance can be directly linked to patients—general discomfort with the invasive nature of this screening procedure.

Abundant research has been performed and CT techniques have evolved over more than a decade, to the point where CTC, as it is performed today, has demonstrated itself as a valid and highly effective screening tool for colorectal cancer. ACRIN s large multi-center National CT Colonography Trial of a screening population published in the September 18<sup>th</sup>, 2008 issue of the *New England Journal of Medicine* demonstrated that CTC is highly accurate for the detection of intermediate and large polyps and that the accuracy of CTC is similar to colonoscopy. In March

of 2008, new consensus guidelines for screening for colorectal cancer ( CRC ) were jointly issued by the American Cancer Society ( ACS ), the American College of Radiology (ACR), and the U.S. Multi-Society Task Force on CRC. The guidelines include recommendations for the use of CTC for CRC screening. Most surveys of patients that have had both traditional colonoscopy and CTC have also shown greater patient preference for CTC with most patients preferring continued CTC surveillance over traditional colonoscopic surveillance. The Company believes that the ACRIN Study coupled with the 2008 consensus guidelines for screening for CRC are likely to increase the utilization of CTC.

CTC is a less invasive technique than traditional colonoscopy for imaging the colon. CTC is performed with standard CT imaging of the abdomen while the colon is distended after subjecting the patient to a colon cleansing regimen. Specialized software from third party display workstation and PACS vendors is then used to reconstruct and visualize the internal surface of the colon and review the CT slices. 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 anticipates that CAD will become an important adjunct to CTC.

Three insurance procedure codes for CTC were approved and became effective January 1, 2010. The codes include: 74263 Screening CTC without contrast, 74261 Diagnostic CTC without contrast, and 74262 Diagnostic CTC with contrast. While screening CTC is not covered by Medicare, coverage continues to increase with approximately half of the U.S. states providing coverage for CTC screening and some of the private payers currently covering CTC screening include: CIGNA, Anthem BCBS (15 states), Kaiser Permanente, Carefirst BCBS, Healthlink, Horizon BCBS (NJ), Oxford Health Plans, Independence BC (PA), Physicians Plus of WI, BCBS Delaware, WPS Health Insurance (WI), BCBS AR, United Healthcare, UniCare, BCBS N.C., and BCBS Texas, BCBS Wellmark

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

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

MRI is an excellent tool to detect breast cancer as well as prostate cancer. While MRI is a more expensive option than traditional mammography, it enables physicians to view tumors which may have been missed during routine screenings. The first breast MRI product received FDA clearance in 1991 for use as an adjunct to mammography. The ACS published new guidelines in the March/April 2007 *CA: A Cancer Journal of Clinicians*, recommending that women at high risk for breast cancer augment their annual mammogram with an annual breast MRI. The guidelines recommended MRI scans for women with a lifetime risk of breast cancer of 20%-25%

or greater, including women with a strong family history of breast or ovarian cancer and women who were treated for Hodgkin s disease. The ACR and SBI endorsed these recommendations in their recommendations published in the Journal of the American College of Radiology 2010;7:18-27.

The Prostate Specific Antigen (PSA) in conjunction with digital rectal examination (DRE) and pathologic information from biopsies are what urologists and radiation oncologists have traditionally used to determine the extent and expected behavior of prostate cancer, which may affect 1 out of 6 men over the course of their lifetime. While commonly used, and recommended by the American Urological Association, PSA tests can be unreliable and potentially misleading.

Accurate staging of the disease is one of the biggest challenges with prostate cancer. Of the 230,000 men who are diagnosed with prostate cancer every year in the U.S., most have slow-growing tumors that likely will not lead to death or require invasive treatment, though the diagnosis does cause patient anxiety and requires close monitoring.

Those men who are diagnosed with a non-aggressive cancer are typically periodically monitored through repeat PSA, DRE and, at times, biopsies. This monitoring is referred to as watchful waiting or active surveillance. The goal of this watchful waiting is to monitor the indolent cancer and catch it at an early stage before it progresses to a more aggressive state. This will theoretically allow patients better treatment options, but because the current tests have their faults by the time the disease has been identified, treatment options may be limited to a prostatectomy. This radical procedure creates numerous morbidities such as impotence, incontinence as well as psychological issues. Advanced imaging tools such as MRI, may play an important role in this population to allow earlier detection and allow more choices for treatment options.

With advanced diagnostic imaging tools, physicians can more accurately stage the severity of the prostate cancer and minimize a patient s exposure to unnecessary and painful biopsies. Prostate biopsies are typically done following an elevated PSA, suspicious DRE, or both. These biopsies are usually performed by an urologist under the assistance of a portable ultrasound system. Anywhere from a dozen to 30 or more samples are taken from the prostate. More than 1.2 million men have transrectal ultrasound (TRUS) biopsies each year in the U.S. and less than 15 percent come back positive for cancer. This translates into roughly \$2 billion in cost to the healthcare system, not to mention the psychological implications for patients worried they may have a deadly form of the disease.

Without an optimal visual picture of the prostate and surrounding area, biopsy exams are essentially conducted blindly. This can result in cancerous lesions being missed and other sections of the prostate unnecessarily oversampled. Oversampling causes the patient pain and can even lead to impotence or incontinence.

Historically, imaging the prostate has presented a challenge because of the vascularity of the organ coupled with its location deep within the abdominal/pelvic cavity. Now other options are available that can provide more accurate imaging of the prostate gland, including MRI with dynamic contrast enhancement (DCE). Similar to MRI for breast cancer, prostate DCE MRI provides a more thorough diagnostic assessment, and improved staging of the disease. A necessary component to this technology is CAD which uses advanced algorithms to assist radiologists in determining malignant versus benign tumors and to pinpoint tumor location and size.

In the future, MRI imaging may have an expanded role in the management of prostate cancer patients, particularly for management strategies involving active surveillance. As more men consider—watchful waiting—or delaying active treatment of their cancer, advances in imaging will help make these decisions easier, based more on solid science than on the assumption that a man—s prostate cancer is slow growing.

#### Radiation Therapy: Electronic Brachytherapy (eBx ) for Breast Cancer Treatment

The Company believes that radiation therapy is an important tool in the fight against cancer. When radiation interacts with a cell it alters the cell s DNA (or genetic make-up) and its ability to reproduce, which ultimately leads to cell death. eBx is a form of radiation therapy that is delivered directly at the location of the tumor and targets and kills cancer cells.

eBx is a type of brachytherapy that 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 technology delivers clinical dose rates similar to traditional radio-active 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 prescription area. Given this rapid dose fall off, there is no need for a leaded vault as compared to traditional radiation therapy, enabling the eBx system to be transported to different locations within the same facility or between multiple facilities.

Electronic Brachytherapy can be delivered during an operative procedure 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 Intraoperative Radiation Therapy (IORT). Current customers of the Xoft eBx system include university research and community hospitals, private and governmental institutions, doctors offices, cancer care clinics, and veterinary facilities.

Of the approximately 261,000 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 70% of early stage breast cancers qualify as candidates for treatment with electronic brachytherapy. Currently about 80% of early stage breast cancer patients that are treated with radiation therapy follow a 5-7 week daily protocol of traditional external beam radiation and 20% are treated with a 5-day protocol using brachytherapy.

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 in the recent past for most women

included a day procedure for a lumpectomy and 5-7 weeks daily for 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 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.

#### **Products and Product Development**

The table below presents the revenue and percentage of revenue attributable to the Company s products and services, in 2011, 2010 and 2009 (in thousands):

	Sep	otember 30, For the	September 30, year ended Decembe	September 30, per 31,		September 30,		eptember 30,	September 30,	
		2011	%		2010	%		2009	%	
Digital & MRI CAD										
revenue	\$	13,256	46.3%	\$	15,392	62.6%	\$	18,290	65.1%	
Film based revenue		2,361	8.2%		3,335	13.6%		5,795	20.6%	
Electronic										
brachytherapy		4,170	14.6%			0.0%			0.0%	
Service & supply										
revenue		8,865	30.9%		5,848	23.8%		4,024	14.3%	
Total revenue	\$	28,652		\$	24,575		\$	28,109		

The revenues above exclude the results of Xoft for the years ended December 31, 2010 and 2009.

## Digital and MRI 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 and film-based mammography systems. iCAD s SecondLook systems are based on sophisticated patented algorithms that analyze the data; automatically identifying and marking suspicious regions in the images. The system 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.

The Company launched and began shipments of its next generation SecondLook Digital CAD, SecondLook® Premier\* to Europe in December of 2010. SecondLook Premier was developed to provide breast imagers with the most advanced and customizable digital mammography CAD

system providing improved cancer detection through increased sensitivity, reduced false positives and robust clinical decision support tools. Built on an all-digital dataset, the technology expands on the SecondLook® platform and provides, what the Company believes to be, the richest set of clinical decision support tools. Its CAD metrics provide automated measurements of mammographic characteristics for every case and each CAD detection and CAD iNSIGHT provides the rationale for each CAD detection. The Company initiated a reader study in 2011 to obtain the clinical data that will be used to prepare their regulatory submission for SecondLook Premier to the FDA. iCAD continues to develop CAD products for additional digital imaging (FFDM and computed radiography) providers. Developmental work continues with PACS companies and iCAD is focused on developing new, more efficient ways of integrating CAD into PACS review workstations to create a streamlined workflow for mammography and potentially other specialties.

#### SecondLook Digital

SecondLook Digital (SLD) 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. iCAD believes it has strong development partnerships with imaging providers. The algorithms in SecondLook Digital products have been optimized for each digital imaging provider based upon characteristics of their unique detectors. The Company s SecondLook Premier CAD solution was tailored for GE Healthcare and Siemens Medical Systems upon initial release of their systems for Europe.

SecondLook Digital 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 SecondLook Digital to integrate seamlessly with leading 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.

During 2010, the Company also introduced and expanded shipments of its SecondLook Digital Multivendor Solution (MVS) to address U.S. customers as well as the European and Canadian markets. The MVS solution enables hospitals and imaging facilities to process cases from multiple digital mammography vendors using a single server and incremental software licenses. This reduces the hardware required resulting in a lower overall cost to the facility, including the consolidation of support to a single unit and service contract. In 2011, the Company entered into a distribution agreement with Carestream Health, Inc. to distribute its MVS globally.

Advanced Image Analysis and Workflow Solutions in MRI Imaging Breast and Prostate

## SpectraLook, VividLook, OmniLook

iCAD offers a suite of FDA cleared dynamic contrast enhanced (DCE) MRI analysis solutions for breast, prostate, and other organs.

Each of three modules, SpectraLook for breast, VividLook for prostate, and OmniLook for other organs, deliver objective, consistent quantitative analysis of DCE MR images. The 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.

iCAD s algorithm uniquely uses all data available from an MR study, resulting in more consistent analysis across magnets and contrast agents.

#### VersaVue Enterprise

VersaVue Enterprise is a review and reporting solution built on read-anywhere thin client architecture. Used in conjunction with SpectraLook, VividLook, or OmniLook modules, it provides visual and quantitative depictions of the movement of contrast agent through a lesion. Colorized overlays draw the attention of the reading radiologist to suspicious areas within the organ being imaged, aiding in the analysis of large MRI datasets. The combination of quantitative and qualitative information reveals characteristics of tumor physiology, and can aid in detecting and localizing cancer as well as supporting treatment planning and monitoring of the lesion over time.

PrecisionPoint<sup>®</sup>, iCAD s interventional planning solution, provides radiologists with an automatic calculation of the location and depth of a targeted region of interest making breast biopsies easier, faster, and more reliable.

In 2011, the Company entered into a distribution agreement with Hitachi Medical Systems to distribute its SpectraLook and PrecisionPoint software. The Company also entered into a distribution agreement with Carestream Health, Inc. to globally distribute its entire suite of MR image analysis workstation software, including SpectraLook, VividLook, OmniLook, VersaVue, and PrecisionPoint.

#### 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. In 2011, the Company entered into a distribution agreement with Vital Images, a Toshiba Medical System Group Company, to globally distribute its VeraLook product.

#### Film based products

## Products for Converting Mammography Films to Digital Images

#### TotalLook MammoAdvantage

The TotalLook MammoAdvantage ( TLMA ) system is iCAD s second generation mammography specific digitizer. TLMA provides a comprehensive film-to-digital solution making it easier for facilities to transition from film to digital mammography. The product converts prior mammography films to digital images delivering high resolution digitized images to meet the critical specifications required for conversion of prior films. The TLMA s unique configurable image resolution settings enable the digitized and newly acquired digital images to be displayed at the same time. In moving to one review workstation for comparative review, users experience improvements in workflow, productivity and reduced discomfort associated with switching between a light box and a computer screen to view images. Results from a study (*Full Field Digital Mammography Interpretation with Prior Analog versus Prior Digitized Analog Mammograms: Time for Interpretation*) presented at the 2009 RSNA meeting demonstrated a 30% reduction in time for image interpretation with digitized analog mammograms.

The TLMA provides flexible DICOM connectivity for seamless integration with leading review workstations, PACS and RIS systems. Specialized image compression techniques reduce file sizes up to 80%, minimizing long-term storage requirements.

#### Electronic Brachytherapy products:

#### Electronic Brachytherapy (eBx ) Treatment for Breast Cancer

#### Axxent® eBx

The acquisition of Xoft brings the Axxent eBx system to the Company s product offerings. The portable Axxent system uses isotope-free miniaturized X-ray tube technology to deliver therapy directly to cancer sites with minimal radiation exposure to surrounding healthy tissue. Axxent is FDA-cleared for the treatment of early stage breast cancer, endometrial cancer and skin cancer, as well as for the treatment of other cancers or conditions where radiation therapy is indicated, including Intraoperative Radiation Therapy (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, and skin applicators for the treatment of non-melanoma skin cancers. The applicators are offered in a variety of sizes based on clinical need. 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. Current customers of the Xoft eBx system include university research and community hospitals, private and governmental institutions, doctors offices, cancer care clinics, and veterinary facilities.

#### Sales and Marketing

iCAD s 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.

The Company s 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. In 2011, the Company continued to build upon its positioning of advance image analysis and clinical decision support solutions for mammography, MRI and CTC. 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, including at the RSNA meeting in December 2011, where industry leaders discussed the future of CAD in these modalities.

In 2011, iCAD continued to invest in a series of educational initiatives and advocacy efforts to advance the use of MRI technologies in the diagnosis and management of prostate and other cancers. Decisions in Medical Imaging was a series of live webinars focused on how MRI combined with an advanced quantitative image analysis solution can support improved cancer management. The seminars, which have been archived as part of an eLearning library, provide clinicians with an understanding of how DCE MRI supports improved patient care throughout the cancer care cycle.

iCAD, through its Xoft subsidiary, markets the Axxent eBx system in the United States and select countries worldwide, primarily in Europe. Xoft s direct 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. 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. The Axxent eBx system offers a distinct competitive advantage given its overall flexibility in terms of portability, minimal shielding requirement, and ability to treat various types of cancers.

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, AAPM, ESTRO and ASTRO on an annual basis. At select industry conferences and at independent venues the Company provides specific additional eBx professional education programs and product demonstrations in the form of symposia.

#### Competition

The Company currently faces direct competition in its CAD business from Hologic, Inc. and imaging equipment manufacturers such as GE Healthcare, Siemens Medical, and Philips Medical Systems. Other medical imaging equipment manufacturers have explored the possibility of introducing their own versions of CAD and comparative reading products into the market, but thus far have not had a significant impact in the market. The Company believes that current regulatory requirements present a significant barrier to entry into this market.

Merge Healthcare, Inc. (which acquired Confirma, Inc. in September 2009) and InVivo Corporation (Philips) are the market leaders in breast MR image analysis. Both companies also offer prostate MR image analysis solutions following iCAD s lead in entering this market in the U.S. The Company believes that its market leadership in mammography CAD and prostate education provides it with a competitive advantage with the breast and prostate imaging communities.

The Company s CT Colon solution faces competition from the traditional imaging CT equipment manufacturers, 3D Rendering and Analysis firms, as well as from emerging CAD companies. Siemens Medical, GE Healthcare, and Philips Medical Systems currently offer or are in the process of developing polyp detection products. The Company expects that these companies will offer a colonic polyp detection solution as an advanced feature of their image management and display products typically sold with their CT equipment. Medicsight has a commercial product available in the United States, Europe, and Asia. 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.

The Company s eBx products face competition primarily from one company, Carl Zeiss, Inc., a multinational company, where eBx products are only one of that company s many products. Carl Zeiss Inc. manufactures and sells eBx products for the use of intraoperative radiation therapy. The Company believes the main focus of the Carl Zeiss company is Breast IORT and they have to-date not positioned their product as a traditional Brachytherapy system for use in multi-fraction accelerated partial breast irradiation, skin or endometrial applications. IntraOp/Mobetron is an additional competitor in the HDR (high dose rate) brachytherapy market. IntraOp/Mobetron provides a brachytherapy solution for IORT but due to this company s isotope-based technology their system requires a vaulted facility.

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 they 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 we manufacture and distribute 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 for it by a contract manufacturer of medical devices. The Company s manufacturing efforts are generally limited to 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 taken direct from the end customer by iCAD, the product is installed by iCAD personnel at the customer site.

iCAD s Professional Services staff is comprised 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 Axxeft Controller is manufactured and assembled for it by a contract manufacturer. Its electronic brachytherapy miniaturized X-ray source, which is used to deliver radiation directly to the cancerous site, is manufactured in the Company s Sunnyvale, 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 installed by Xoft personnel at the customer site.

Xoft s Field Service and Customer Service staff is comprised of a team of trained and specialized individuals providing comprehensive product support on a pre-sales and post-sales basis. The Field Service staff 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 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.

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.

On February 3, 2011, the Company in cooperation with the FDA, voluntarily recalled its Axxent Flexishield Mini which was acquired as part of its acquisition of Xoft in December 2010. The voluntary recall was prompted after the Company was notified in January 2011 of the presence of microscopic particles found in certain patients—breasts during post-surgery follow up imaging exams, which were later determined to be tungsten and alleged to be originating from the Axxent Flexishield Mini, an optional accessory device to the Company s Axxent Electronic Brachytherapy system. The Company has developed the Flexishield Rigid, which is a replacement for the Flexishield Mini and the new product has received FDA clearance. On June 9' 2011, the Company received notification from the FDA that the recall was complete and that the FDA considered the recall terminated at that time.

#### **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.

Currently, the Company has 57 U.S. and 4 foreign issued 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 28 patent applications pending domestically, some of which have been also filed internationally, and it 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 CT colonography and lung and CAD for MRI breast and prostate, as well as Xoft s current and future eBx technologies and products. In June 2006, the Company secured a non-exclusive patent license from the National Institute of Health which relates broadly to CAD in colonography. In August 2007, Xoft secured a non-exclusive patent license from Cytyc/Hologic which relates to balloon applicators for breast brachytherapy. The Company believes it has all the necessary licenses from third parties for software and other technologies in its products.

#### 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 its 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 s two major customers over the past three years were GE Healthcare and Fuji Medical Systems. GE Healthcare accounted for \$6.8 million in 2011, \$9.3 million in 2010 and \$8.8 million in 2009 or 24%, 38%, and 31% of the Company s revenues, respectively. Fuji Medical Systems accounted for \$3.2 million in 2011, \$3.1 million in 2010 and \$4.8 million in 2009 or 11%, 13% and 17% of the Company s revenues, respectively.

#### **Engineering and Product Development**

The Company spent \$10.8 million, \$6.6 million, and \$7.2 million on research and development activities during the years ended December 2011, 2010 and 2009, respectively. The research and development expenses for 2011 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, 2012, the Company had 110 employees, all of which are full time employees, with 35 involved in sales and marketing, 36 in research and development, 25 in service, manufacturing, technical support and operations functions, and 13 in administrative functions. None of the Company s employees are represented by labor organizations. 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) and competitive position of the Company.

#### **Financial Geographic Information**

The Company markets its products for digital mammography in the U.S. through its direct regional sales organization as well as through its OEM partners, including GE Healthcare, Fuji Medical Systems and Siemens Medical. Outside the U.S. the Company markets its products for digital mammography generally through its OEM partners, GE Healthcare, Siemens Medical,

Agfa Corporation, Sectra Medical Systems, Planmed Oy, Fuji Medical Systems and IMS Giotto. Total export sales decreased to approximately \$1.8 million or 6% of sales in 2011 as compared to \$4.0 million or 16% of total sales in 2010 and \$3.7 million or 13% of total sales in 2009.

The Company s principal concentration of export sales is in Europe, which accounted for 67% of the Company s export sales in 2011, 77% of export sales in 2010, and 64% of export sales in 2009. Of these sales 16% in 2011, 55% in 2010 and 36% in 2009 were in France, and in 2011, an additional 21% were in Germany. The balance of the export sales in 2011 were primarily into Canada and Asia.

#### **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.

#### **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 2011 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 \$37.6 million during the fiscal year ended December 31, 2011. We may not be able to achieve profitability.

A limited number of customers account for a significant portion of our total revenues. 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. Our digital product revenue accounted for 41% and 55% of our total revenue for the years ended December 31, 2011 and 2010, respectively. In 2011 we had two major customers, GE Healthcare and Fuji Medical Systems, with 24% and 11% of our revenues, respectively. A limited number of major customers have in the past and may continue in the future to account for a significant portion of our revenues. 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.

Our business is dependent upon future market growth of full field digital mammography systems and digital computer aided detection products 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 full field digital mammography systems and digital computer aided detection products as well as advanced image analysis and workflow solutions for use with MRI and CT and to the market growth of electronic brachytherapy 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.

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 a significant impairment on our goodwill. Under current accounting guidelines, we must assess, at least annually and potentially more frequently, whether the value of goodwill and 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.

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 only for our currently offered CAD products. Before we are able to commercialize any other product, we must obtain regulatory approvals for each indicated use for that product. The process for satisfying these regulatory requirements is lengthy and costly and will require us to comply with complex standards for research and development, clinical trials, testing, manufacturing, quality control, labeling, and promotion of products.

#### Our products 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 CAD 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.

# During 2011, we recalled the Axxent Flexishield Mini and our other products may be recalled even after we have received FDA or other governmental approval or clearance.

On February 3, 2011, the Company in cooperation with the FDA, voluntarily recalled its Axxent Flexishield Mini. The voluntary recall was prompted after the Company was notified in January 2011 of the presence of microscopic particles found in certain patients—breasts during post-surgery follow up imaging exams, which were later determined to be tungsten and alleged to be originating from the Axxent Flexishield Mini, an optional accessory device to the Company—s Axxent Electronic Brachytherapy system. On June 92011, the Company received notification from the FDA that the recall was complete and that the FDA considered the recall terminated at that time. We cannot assure you that the recall will not adversely affect our ability to market our Axxent eBx system due to, market perception or otherwise

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.

# 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 revenues 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.

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

In connection with a Facility Agreement entered into on December 29, 2011, we incurred \$15,000,000 principal amount of long-term debt. Our debt obligations:

could impair our liquidity;

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

require us to dedicate a substantial portion of our cash flow to payments on our debt obligations, which reduces the availability of our cash flow to fund working capital, capital expenditures and other corporate requirements;

impose restrictions on our ability to incur indebtedness, other than permitted indebtedness, and could impede us from obtaining additional financing in the future for working capital, capital expenditures, acquisitions and general corporate purposes;

impose restrictions on us with respect to the use of our available cash, including in connection with future acquisitions;

require us to maintain at least \$5,000,000 of cash and cash equivalents as of the last day of each calendar quarter;

make us more vulnerable in the event of a downturn in our business prospects and could limit our flexibility to plan for, or react to, changes in our licensing markets; and

could place us at a competitive disadvantage when compared to our competitors who have less debt.

We have pledged substantially all of our assets to secure our obligations under the Facility Agreement. In the event that we were to fail in the future to make any required payment under agreements governing our indebtedness or fail to comply with the financial and operating covenants contained in those agreements, we would be in default regarding that indebtedness. A debt default would enable the lenders to foreclose on the assets securing such debt and could significantly diminish the market value and marketability of our common stock and could result in the acceleration of the payment obligations under all or a portion of our consolidated indebtedness.

#### Changes in or non-reimbursement of procedures by Medicare or other third-party payers may adversely affect our business.

In the U.S., Medicare and a number of commercial third-party payers provide reimbursements for the use of CAD in connection with mammography screening and diagnostics. In the future, however, these reimbursements may be unavailable, reduced or inadequate due to changes in applicable legislation or regulations, changes in attitudes toward the use of mammograms for broad screening to detect breast cancer or due to changes in the reimbursement policies of third-party payers. As a result, healthcare providers may be unwilling to purchase our CAD products or any of our future products, which could significantly harm our business, financial condition and operating results.

There is no guaranty that any of the products which we are developing or are contemplating developing will become eligible for reimbursements or health insurance coverage at favorable rates or even at all or maintain eligibility.

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the medical device industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the U.S. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on reimbursement, which could negatively affect market acceptance of our products. Members of the U.S. Congress and some state legislatures are seeking to overturn at least portions of the legislation and we expect they will continue to review and assess this legislation and possibly alternative health care reform proposals. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

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, 2011 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.

Our business is subject to The Health Insurance Portability and Accountability Act of 1996, or HIPAA, and changes to or violations of these regulations could negatively impact our revenues.

HIPAA mandates, among other things, the adoption of standards to enhance the efficiency and simplify the administration of the nation s healthcare system. HIPAA requires the U.S. Department of Health and Human Services to adopt standards for electronic transactions and code sets for basic healthcare transactions such as payment, eligibility and remittance advices, or transaction standards, privacy of individually identifiable health information, or privacy standards, security of individually identifiable health information, or security standards, electronic signatures, as well as unique identifiers for providers, employers, health plans and individuals and enforcement. Final regulations have been issued by DHHS for the privacy standards, certain of the transaction standards and security standards.

As a covered entity, we are required to comply in our operations with these standards and are subject to significant civil and criminal penalties for failure to do so. In addition, in connection with providing services to customers that also are healthcare providers, we are required to provide satisfactory written assurances to those customers that we will provide those services in accordance with the privacy standards and security standards. HIPAA has and will require significant and costly changes for us and others in the healthcare industry. Compliance with the privacy standards became mandatory in April 2003 and compliance with the security standards became mandatory in April 2005.

Like other businesses subject to HIPAA regulations, we cannot fully predict the total financial or other impact of these regulations on us. The costs associated with our ongoing compliance could be substantial, which could negatively impact our profitability.

#### 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 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.

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 would 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 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.

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 were 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 have been named as a defendant in an action alleging personal injury resulting from gross negligence and product liability by patients that were treated with the Axxent eBx system that incorporated the Axxent Flexishield Mini, and we may be exposed to additional significant product liability for which we may not have sufficient insurance coverage or be able to procure sufficient insurance coverage.

The Company is a defendant in multiple suits brought in Orange County Superior Court by plaintiffs who allege personal injury resulting from gross negligence and product liability relating to their treatment with the Axxent Electronic Brachytherapy System that incorporated the Axxent Flexishield Mini. These suits are discussed in more detail in Item 3 of this Form 10-K and in Note 8(e) to the Consolidated Financial Statements filed with this Form 10-K.

Because of the preliminary nature of these complaints we are unable to evaluate the merits of the claims, however based upon its preliminary analysis, we plan to vigorously defend the law suit.

There can be no assurances that we will be able to defend or settle these claims on favorable terms or that additional claims will not be made by other patients treated with the Axxent Flexishield Mini.

Our product liability and general liability insurance coverage may not be adequate for us to avoid or limit our liability exposure in the pending action or in future 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. In any event, the pending and any future product liability claims could be costly to defend and/or costly to resolve and could harm our reputation and business.

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

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

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

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

We operate in highly competitive and rapidly changing markets that contain competitive products available from nationally and internationally recognized companies. Many of these competitors have significantly greater financial, technical and human resources than us and are well established. In addition, some companies have developed or may develop technologies or products that could compete with the products we manufacture and distribute or that would render our products obsolete or noncompetitive. 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.

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

We derive some of our revenues from sales outside of the United States. 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.

# We do not anticipate paying cash dividends on our common stock.

We have not paid cash dividends on our common stock in the past, and we do not intend to do so in the foreseeable future. Any payment of dividends will be in the sole discretion of our Board of Directors.

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.

Future sales of shares of our common stock may cause the prevailing market price of our shares to decrease and could harm our ability to raise additional capital.

We have previously issued a substantial number of shares of common stock, which are eligible for resale under Rule 144 of the Securities Act of 1933, as amended, and may become freely tradable. In addition, shares of our common stock issued upon conversion of our convertible debt are also eligible for sale under Rule 144. We have also registered shares that are issuable upon the exercise of options. If holders of options choose to exercise their options and sell shares of common stock in the public market, or if holders of currently restricted common stock or common stock issued upon conversion of convertible debt 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. The sale of shares of common stock issued upon the exercise of our securities could also dilute the holdings of our existing stockholders.

We face the potential delisting of our common stock from the Nasdaq Global Market as a result of failure to comply with the minimum bid price requirement. If we are unable to meet this requirement or to transfer our listing to the Nasdaq Capital Market, we could be required to list our common stock in the over-the-counter market, which could make obtaining future financing more difficult.

Companies listed on The NASDAQ Stock Market ( NASDAQ ) are subject to delisting for, among other things, failure to maintain a minimum closing bid price per share of \$1.00 for 30 consecutive business days. On September 9, 2011, we received a letter from NASDAQ indicating that for the last 30 consecutive business days, the bid price of our common shares closed below the minimum \$1.00 per share requirement pursuant to NASDAQ Listing Rule 5450(a)(1) for continued inclusion on The NASDAQ Global Market. In accordance with NASDAQ Listing Rule 5810(c)(3)(A), we had an initial grace period of 180 calendar days, or until March 7, 2012, to regain compliance with the minimum bid price requirement. NASDAQ has granted us an extension until September 4, 2012 to regain compliance. We cannot be sure that our share price will comply with the requirements for continued listing of our common shares on The NASDAQ Global Market in the future. If our common shares lose their status on The NASDAQ Global Market and we are not successful in obtaining a listing on The NASDAQ Capital Market, our common shares would likely trade in the over-the-counter market.

If our shares were to trade in the over-the-counter market, selling our common shares could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and security analysts—coverage of us may be reduced. In addition, in the event our common shares are delisted, broker-dealers have certain regulatory burdens imposed upon them, which may discourage broker-dealers from effecting transactions in our common shares, further limiting the liquidity of our common shares. These factors could result in lower prices and larger spreads in the bid and ask prices for common shares.

Such delisting from The NASDAQ Global Market and continued or further declines in our share price and market value could also greatly impair our ability to raise additional necessary capital through equity or debt financing, and could significantly increase the ownership dilution to shareholders caused by our issuing equity in financing or other transactions.

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.

We could be exposed to unknown pre-existing liabilities of Xoft, which could cause us to incur substantial financial obligations and harm our business.

In connection with the acquisition, we may have assumed liabilities of Xoft of which we are not aware and may have little or no recourse against Xoft with respect thereto. To date, we have voluntarily recalled Xoft s Axxent Flexishield Mini and have been named in an action alleging personal injury resulting from general negligence and product liability seeking unlimited damages by two plaintiffs, one of whom was a patient at a hospital who was treated with the Axxent eBx system that incorporated the Axxent Flexshield Mini. If we were to discover that

there were intentional misrepresentations made to us by Xoft, or its representatives as to these or other matters, we would explore all possible legal remedies to compensate us for any loss, including our rights to indemnification under the merger agreement that we entered into with Xoft upon the closing of the Xoft acquisition. However, there is no assurance that in such case legal remedies would be available or collectible. If such unknown liabilities exist and we are not fully indemnified for any loss that we incur as a result thereof, we could incur substantial financial obligations, which could negatively impact our financial condition and harm our business.

#### Acquisition-related accounting impairment and amortization charges may delay and reduce our post-acquisition profitability.

Our acquisition of Xoft has been accounted for under the purchase method of accounting. Accordingly, under generally accepted accounting principles, the acquired assets and assumed liabilities of Xoft have been recorded on our books post-acquisition at their fair values at the date the acquisition was completed. Any excess of the value of the consideration paid by us at the date the acquisition was completed over the fair value of the identifiable tangible and finite-lived intangible assets of Xoft is treated as excess of purchase price over the fair value of net assets acquired (commonly known as goodwill). Under current accounting standards, finite-lived intangible assets will be amortized to expense over their estimated useful lives, which will reduce our post-acquisition profitability over several years. In addition, goodwill will be tested on an annual basis for impairment, which may result in non-cash accounting impairment charges.

# Item 1B. Unresolved Staff Comments.

Not applicable

#### <u>Item 2.</u> <u>Properties.</u>

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 \$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 approximately 3,492 square feet of office space located at the 675/Fairborn Commerce Center, 1160 Dayton Yellow Springs Road, Suite 21, in Fairborn Ohio. The Ohio Lease provides for a three (3) year and three (3) month term, which commenced on January 1, 2011 for approximately \$43,650 per year, with all amounts payable in equal monthly installments. The Ohio Lease provides the Company with the option to renew the lease for an additional three (3) year period. The monthly payments for the renewal term, if any, will be substantially similar to the payments referred to above.

As a result of its acquisition of Xoft on December 30, 2010, the Company leases a facility and certain office equipment under a noncancelable operating lease which expires in January and February 2013, respectively. The facility consists of approximately 41,000 square feet of office, manufacturing and warehousing space located at 345 Potrero Avenue, Sunnyvale, CA. The operating lease provides for annual minimum lease payment of \$885,000 in 2012 and \$76,000 in 2013 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. Given local market conditions the Sunnyvale lease is at a rate above market rate. The Company has a liability recorded of approximately \$402,000 at December 31, 2011 to reflect the off-market value of the rent.

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.

On February 18, 2011, in the Orange County Superior Court (Docket No. 30-2011-00451816-CU-PL-CXC), named plaintiffs Jane Doe and John Doe filed a complaint against Xoft, the Company, and Hoag Memorial Hospital Presbyterian asserting causes of action for general negligence, breach of warranty, and strict liability and seeking unlimited damages in excess of \$25,000. On March 2, 2011, the Company received a Statement of Damages specifying that the damages being sought aggregated an amount of at least approximately \$14.5 million. On April 6, 2011, plaintiffs Jane Doe and John Doe amended their complaint alleging only medical malpractice against Hoag Memorial Hospital Presbyterian. On April 8, 2011, another complaint was filed in the Orange County Superior Court (Docket No. 30-2011-00465448-CU-MM-CXC) on behalf of four additional Jane Doe plaintiffs and two John Doe spouses with identical allegations against the same defendants. One John Doe spouse from this group of plaintiffs was later dismissed on August 18, 2011. On April 19, 2011, a sixth Jane Doe plaintiff filed an identical complaint in the Orange County Superior Court (Docket No. 30-2011-00468687-CU-MM-CXC), and on May 4, 2011, a seventh Jane Doe plaintiff and John Doe spouse filed another complaint in the Orange County Superior Court (Docket No. 30-2011-00473120-CU-PO-CXC), again with identical allegations against the same defendants. On July 12, 2011, an eighth Jane Doe plaintiff and John Doe spouse filed a complaint in the Orange County Superior Court (Docket No. 30-2011-00491068-CU-PL-CXC), and on July 14, 2011, a ninth Jane Doe plaintiff and John Doe spouse filed another complaint in the Orange County Superior Court (Docket No. 30-2011-00491497-CU-PL-CXC), each with identical allegations as the previously filed complaints. On August 18, 2011, these two groups of Jane Doe plaintiffs and John Doe spouses amended their complaints to correct certain deficiencies. Additionally on August 18, 2011, a tenth Jane Doe plaintiff and two additional John Doe spouses filed a complaint in the Orange County Superior Court (Docket No. 30-2011-501448-CU-PL-CXC), again with identical allegations against the same defendants. On January 18, 2012, three additional Jane Doe plaintiffs and one additional John Doe spouse filed a complaint in the Orange County Superior Court (Docket No. 30-2012-00538423-CU-PL-CXC) with identical allegations against the same defendants.

It is alleged that each plaintiff Jane Doe was a patient who was treated with the Axxent Electronic Brachytherapy System that incorporated the Axxent Flexishield Mini. The Company believes that all of the Jane Doe plaintiffs were part of the group of 29 patients treated using the Axxent Flexishield Mini as part of a clinical trial. The Axxent Flexishield Mini is the subject of a voluntary recall. Because of the preliminary nature of the complaints, the Company is unable to evaluate the merits of the claims; however, based upon its preliminary analysis, it plans to vigorously defend the lawsuits. Accordingly, since the amount of the potential damages in the event of an adverse result is not reasonably estimable, no expense or purchase price adjustment has been recorded with respect to the contingent liability associated with this matter.

# <u>Item 4.</u> <u>Mine Safety Disclosures.</u>

Not applicable.

#### PART II

#### Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The Company s common stock is traded on the NASDAQ Global Market under the symbol ICAD . The following table sets forth the range of high and low sale prices for each quarterly period during 2011 and 2010.

	Septe	September 30, High		September 30, Low	
	H				
Fiscal year ended					
<u>December 31, 2011</u>					
First Quarter	\$	1.51	\$	1.04	
Second Quarter		1.38		0.98	
Third Quarter		1.15		0.40	
Fourth Quarter		0.80		0.42	
Fiscal year ended					
<u>December 31, 2010</u>					
First Quarter	\$	1.95	\$	1.35	
Second Quarter		2.23		1.28	
Third Quarter		2.44		1.46	
Fourth Quarter		1.76		1.26	

As of February 28, 2012 there were 381 holders of record of the Company's common stock. In addition, the Company believes that there are in excess of 5,250 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, 2011.

# Item 6. Selected Financial Data.

Not applicable.

# <u>Item 7.</u> <u>Management s Discussion and Analysis of Financial Condition and Results of Operations.</u> Results of Operations

#### Overview

iCAD is an industry-leading provider of advanced image analysis and workflow solutions that enable radiologists and other healthcare professionals to better serve patients by identifying pathologies and pinpointing cancer earlier. iCAD offers a comprehensive range of high-performance, expandable Computer-Aided Detection (CAD) systems and workflow solutions for mammography (film-based, digital radiography (DR) and computed radiography (CR), Magnetic Resonance Imaging (MRI), and Computed Tomography (CT)). iCAD is solutions aid in the early detection of the most prevalent cancers including breast, prostate and colon cancer. Early detection of cancer is the key to better prognosis, less invasive and lower treatment costs, and higher survival rates. Performed as an adjunct to mammography screening, CAD has quickly become the standard of care in breast cancer detection, helping radiologists improve clinical outcomes while enhancing workflow. Computer-enhanced breast and prostate MRI analysis streamlines case interpretation workflow and generates more robust information for more effective patient treatment. CAD for mammography screening is also reimbursable in the U.S. under federal and most third-party insurance programs. Since receiving approval from the FDA for the Company is first breast cancer detection product in January 2002, over 4,000 of iCAD is CAD systems have been placed in mammography practices worldwide. iCAD is the only independent company offering CAD solutions for the early detection of breast cancer.

The Company s CAD systems include proprietary algorithm and other technology together with standard computer and display equipment. CAD systems for the film-based analog mammography market also include a radiographic film digitizer, either manufactured by the Company or others for the digitization of film-based medical images.

The Company is applying its core competencies in pattern recognition and algorithm development in disease detection to its future product development efforts. Its focus is on the development and marketing of cancer detection products for disease states where there are established or emerging protocols for screening as a standard of care. iCAD continues to pursue development or acquisition of products for select disease states that demonstrate one or more of the following: it is clinically proven that screening has a significant positive impact on patient outcomes, where there is an opportunity to lower health care costs, where screening is non-invasive or minimally invasive and where public awareness is high. The Company also intends to pursue opportunities beyond CAD through possible strategic acquisitions as part of its growth strategy, and as such the Company continues to actively evaluate strategic opportunities in the oncology market that could leverage its opportunities for growth beyond its historic core markets.

iCAD has applied its patented detection technology and algorithms to the development of CAD solutions for use with virtual colonoscopy or CT Colonography (CTC) to improve the detection of colonic polyps. The Company s pattern recognition and image analysis expertise are readily applicable to colonic polyp detection and the Company has developed a CTC CAD solution.

CTC is a technology that has evolved rapidly in recent years. Based on the results of the National CT Colonography trial, the Company expects that the market for virtual colonoscopy will grow along with the procedures for early detection of colon cancer. This trial demonstrated that CTC is highly accurate for the detection of intermediate and large polyps and that the accuracy of CTC is similar to a colonoscopy. CTC is emerging as an alternative imaging procedure for evaluation of the colon. The Company has developed and commenced marketing Veralook, a product for computer aided detection of polyps in the colon using CTC and completed the clinical testing of its CTC CAD product in the first quarter of 2009. The Company filed a 510(k) application with the FDA in May 2009 seeking FDA clearance to market Veralook in the U.S and received FDA clearance in August, 2010. Colorectal cancer has been shown to be highly preventable with early detection and removal of polyps.

In July 2008, the Company acquired pharmaco-kinetic based CAD products that aid in the interpretation of contrast enhanced MRI images of the breast and prostate and began marketing these products in the fourth quarter of 2008. The interpretation of MRI exams also benefits from advanced image analysis and clinical decision support tools. MRI is an excellent tool to detect breast cancer as well as prostate cancer. While MRI is a more expensive option than traditional mammography, it enables physicians to view tumors which may have been missed during routine screenings. MRI uses magnets and radio waves instead of x-rays to produce very detailed, cross-sectional images of the body, and can be used to look specifically at those areas.

The acquisition of Xoft, on December 30, 2010, brought an isotope-free cancer treatment platform technology to the Company s product line. Xoft designs, develops, manufactures, markets and sells electronic brachytherapy (eBx) products for the treatment of breast and other cancers, used in a broad range of clinical settings. The portable Axxent System which delivers electronically controlled radiation therapy directly to cancer sites with minimal radiation exposure to surrounding healthy tissue is FDA-cleared. Electronic Brachytherapy (eBx) is a type of brachytherapy that utilizes a miniaturized high dose rate 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, sparing healthy tissue and organs. The Xoft technology delivers similar clinical dose rates to traditional radio-active systems. Electronic Brachytherapy can be delivered during an operative procedure 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 provide advanced treatments such as Intra-Operative Radiation Therapy (IORT). Current customers for the Xoft eBx system include university research and community hospitals, private and governmental institutions, doctors offices, cancer care clinics and veterinary facilities.

#### **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, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates these estimates,

including those related to accounts receivable allowance, inventory valuation and obsolescence, intangible assets, income taxes, warranty obligations, contingencies and litigation. Additionally, the Company uses assumptions and estimates in calculations to determine stock-based compensation. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company s critical accounting policies include:

Revenue recognition;
Allowance for doubtful accounts;
Inventory;
Valuation of long-lived and intangible assets;
Goodwill;
Stock based compensation;
Income taxes.  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 is probable. For product revenue delivery has occurred upon shipment, provided title and risk of loss has passed to the customer. Services and supplies revenue are considered to be delivered as the services are performed or over the estimate life of the supply agreement.

The Company recognizes revenue from the sale of certain of its MRI CAD products and services in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 985-605, (Software, Revenue Recognition) (ASC 985-605).

The Company recognizes revenue from the sale of its digital, film-based CAD and electronic brachytherapy products and services in accordance with ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements ( ASU 2009-13 ). In accordance with the guidance of ASU 2009-13, fair value as the measurement criteria is replaced with the term selling price and establishes a hierarchy for determining the selling price of a deliverable. ASU 2009-13 also eliminates the use of the residual value method for determining the allocation of arrangement consideration. For multi-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 ( BESP ). VSOE generally exists only when the deliverable is sold separately and is the price actually charged for that deliverable. The process for determining a BESP 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. Sales of the Company s

electronic brachytherapy product typically include several devices, accessories, service and supply. The Company generally allocates revenue to the deliverables in the arrangement based on the BESP. Revenue is recognized when the product has been delivered, and service and supply revenue is recognized over the life of the service and supply agreement.

For most of iCAD s Digital, MRI and film based sales, the responsibility for the installation process lies with its Original Equipment Manufacturer (OEM) partners, GE Healthcare, Siemens Medical and others. 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 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 VSOE of the element. Revenue from the Digital, MRI and film based equipment when there is installation is recognized based on the relative selling price allocation of the BESP. In prior years (prior to ASU 2009-13), the Company recognized the element on the residual method. The adoption of ASU 2009-13 did not have a material effect on the financial condition or results of operations of the Company.

The Company uses customer purchase orders that include all terms of the arrangement and in the case of OEM customers are also supported by distribution agreements. In accordance with the distribution agreement, the OEM customers do not have a right of return, and title and risk of loss passes to the OEM customer 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 reasonably assured 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 revenues are 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 defers revenue from the sale of extended service contracts related to future periods and recognizes revenue on a straight-line basis in accordance with FASB ASC Topic 605-20, Services . The Company provides for estimated warranty costs on original product warranties at the time of sale.

The Company also adopted ASC Update No. 2009-14, Certain Arrangements That Contain Software Elements (Update No. 2009-14). This Update amended the scope of ASC Subtopic No. 985-605, Revenue Recognition, to exclude tangible products that include software and non-software components that function together to deliver the product sessential functionality. The adoption of this standard did not have a material effect on the Company s financial condition or results of operations.

#### Allowance for Doubtful Accounts

The Company s policy is to maintain allowances for estimated losses from the inability of its customers to make required payments. Credit limits are established through a process of reviewing the financial results, stability and payment history of each customer. Where appropriate, the Company obtains credit rating reports and financial statements of customers when determining or modifying credit limits. The Company s senior management reviews accounts receivable on a periodic basis to determine if any receivables may potentially be uncollectible. The Company includes any accounts receivable balances that it determines may likely be uncollectible, along with a general reserve for estimated probable losses based on historical experience, in its overall allowance for doubtful accounts. An amount would be written off against the allowance after all attempts to collect the receivable had failed. Based on the information available to the Company, it believes the allowance for doubtful accounts as of December 31, 2011 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 estimated usage of its inventory as well as other factors.

#### **Long Lived Assets**

Long-lived assets, other than goodwill, are evaluated for impairment when events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows from the use of these assets. When any such impairment exists, the related assets are written down to fair value. 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, which include assets acquired from Xoft, Inc., 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.

The Company s goodwill arose in connection with its acquisitions in June 2002, December 2003 and December 2010. The Company operates in one segment and one reporting unit since operations are supported by one central staff and the results of operations are evaluated as one business unit. In general the Company s medical device products are similar in nature based on production, distribution, services provided and regulatory requirements. The Company uses market capitalization as the best evidence of fair value (market capitalization is calculated using the quoted closing share price of the Company s common stock at its annual impairment testing

date of October 1, multiplied by the number of common shares outstanding) of the Company. The Company tests goodwill for impairment by comparing its market capitalization (fair value) to its carrying value. The fair value of the Company is compared to the carrying amount at the same date as the basis to determine if a potential impairment exists.

The Company assesses the potential impairment of goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable and at least annually. 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.

During the quarter ended September 30, 2011, as a result of the sustained decline in the market capitalization of the Company, an interim Step 1 analysis was completed. The interim Step 1 test resulted in the determination that the carrying value of equity exceeded the fair value of equity, thus requiring the Company to measure the amount of any goodwill impairment by performing the second step of the impairment test. The Company corroborated the Step 1 analysis using an income approach.

The second step (defined as Step 2 ) of the goodwill impairment test, used to measure the amount of impairment loss, compares the implied fair value of reporting unit goodwill with the carrying amount of that goodwill. The guidance in FASB ASC 350 Intangibles Goodwill and Other was used to estimate the implied fair value of goodwill. The guidance provides that If the carrying amount of the Company's goodwill exceeds the implied fair value of that goodwill, an impairment loss shall be recognized in an amount equal to that excess. The loss recognized cannot exceed the carrying amount of goodwill. After a goodwill impairment loss is recognized, the adjusted carrying amount of goodwill shall be its new accounting basis.

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

The Company determined the value of the select assets utilizing the income approach. 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.

Other significant assumptions include terminal value margin rates, future capital expenditures, and changes in future working capital requirements. The Company also compared and reconciled the overall fair value to the Company s market capitalization. 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 Company s single reporting unit.

On December 22, 2011, the Company agreed to a settlement related to the litigation with Carl Zeiss Meditec Inc. and Carl Zeiss Surgical GmbH (see Note 2). The Company determined that this settlement should be recorded as a measurement period adjustment and accordingly recorded the present value of the litigation, retrospectively to the opening balance sheet of Xoft. As a result, goodwill increased from approximately \$45.7 million as of December 31, 2010 to \$46.0 million as of December 31, 2010.

During the quarter ended, September 30, 2011, the Company recorded an impairment loss of approximately \$26.8 million. However, as a result of recording a measurement period adjustment, the fair value of goodwill was reevaluated. The Step 2 test resulted in determining the fair value of goodwill of \$21.1 million which resulted in an additional impairment loss of \$78,000.

Additional, purchase accounting adjustments, considered to be measurement period adjustments, were recorded in the six months subsequent to the acquisition of Xoft and consisted primarily of a \$1.5 million decrease of the acquired patent asset, a decrease of \$500,000 in the acquired technology asset, a decrease in the fair value estimate of the royalty obligation of \$200,000 and a decrease of \$100,000 related to contingent consideration and an increase of approximately \$300,000 related to unrecorded liabilities. These measurement period adjustments had no effect on the Company s operations and results and had an immaterial effect on the December 31, 2010 balance sheet. Accordingly, the adjustments were recorded during 2011, and considered in the impairment analysis during the third quarter of 2011.

The changes in the carrying amount of goodwill for the year ended December 31, 2011, are as follows:

	Septe	ember 30,
Twelve months ended	December 31, 2011	
Balance as of December 31, 2010	\$	45,969
Purchase accounting adjustments		1,968
Impairment		(26,828)
•		
Balance as of December 31, 2011	\$	21,109

No goodwill impairment loss was recorded in 2010. For 2011 and 2010 the Company performed the annual step one fair value comparison as of October 1, 2011 and October 1, 2010. At October 1, 2010, the Company s market capitalization (or market capitalization with a reasonable control premium) exceeded its carrying value. At October 1, 2011, the Company s market

capitalization with a reasonable control premium was less than the carrying value of goodwill. However, the Company completed a goodwill impairment analysis as of September 30, 2011, and concluded that the October 1, 2011 step one fair value comparison was consistent with the results on September 30, 2011. At December 31, 2011 and 2010 the Company s market capitalization (or market capitalization with a reasonable control premium) exceeded its carrying value.

#### **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, restricted stock and/or options to purchase common stock at an option price equal to the market value of the stock at the date of grant. The Company follows FASB ASC Topic 718, Compensation Stock Compensation , (ASC 718), for all stock-based compensation.

The Company uses the Black-Scholes option pricing model 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. Application of alternative assumptions could produce significantly different estimates of the fair value of stock-based compensation and consequently, the related amounts recognized in the Consolidated Statements of Operations.

#### **Income Taxes**

The Company follows the liability method under FASB 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, 2011 and 2010 as it is more likely than not that the deferred tax asset will not be realized.

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

In addition, uncertain tax positions and tax related valuation allowances assumed in connection with a business combination are initially estimated as of the acquisition date and the Company revaluates these items quarterly, with any adjustments to preliminary estimates being recorded to goodwill, provided that the Company is within the measurement period (which may be up to one year from the acquisition date) and continues to collect information in order to determine their

estimated values. Subsequent to the measurement period or final determination of the tax allowance s or contingency s estimated value, changes to these uncertain tax positions and tax related valuation allowances may affect the provision for income taxes presented in the Company s statement of operations.

## Year Ended December 31, 2011 compared to Year Ended December 31, 2010

The Consolidated Statement of Operations does not include the financial results of Xoft for the period ended December 31, 2010.

*Revenue*. Revenue for the year ended December 31, 2011 was \$28.7 million compared with revenue of \$24.6 million for the year ended December 31, 2010, an increase of \$4.1 million or 16.6%. The increase in revenue was due primarily to the increase in Electronic Brachytherapy revenues resulting from the acquisition of Xoft of \$4.2 million and a \$3.0 million increase in service and supply revenue offset by a decrease in digital and MRI CAD and film-based revenue.

The table below presents the components of revenue for 2011 and 2010:

	Sep	tember 30,	tember 30, the year ende		otember 30, mber 31,	September 30,
		2011	2010	(	Change	% Change
Digital & MRI CAD revenue	\$	13,256	\$ 15,392	\$	(2,136)	(13.9%)
Film based revenue		2,361	3,335		(974)	(29.2%)
Electronic brachytherapy		4,170			4,170	
Service & supply revenue		8,865	5,848		3,017	51.6%
Total revenue	\$	28,652	\$ 24,575	\$	4,077	16.6%

The Company s digital and MRI CAD revenue for the year ended December 31, 2011 decreased \$2.1 million or 13.9%, to \$13.3 million compared to revenue of \$15.4 million for the year ended December 31, 2010. The decrease in digital and MRI CAD revenue was due primarily to a decrease in digital revenues of \$2.7 million which was driven by decreases in the international demand for the digital CAD systems, offset by an increase of approximately \$0.6 million in MRI CAD revenues. The increase of MRI CAD revenues is due largely to growing market adoption of this product.

Revenue from iCAD s film based products for the year ended December 31, 2011 decreased 29.2% to \$2.4 million compared to \$3.3 million in 2010. The TotalLook MammoAdvantage product is used for digitizing film based prior mammography exams for comparative reading and is sold to further optimize workflow in a digital mammography environment. The TotalLook MammoAdvantage product is typically sold as customers are preparing transition to digital mammography. Revenues from film-based products and accessories continues to decline as the marketplace continues to transition to digital technologies.

Service and supply revenue for the year ended December 31, 2011 increased 51.6% to \$8.9 million compared to \$5.8 million in 2010. The increase in the Company s service and supply revenue is due primarily to approximately \$1.7 million of service revenue related to the acquisition of Xoft and \$1.3 million due to increased service contract revenue on the Company s growing installed base of CAD products as customers migrate from warranty to service contracts, and to renewed service contract agreements.

Gross Margin. Gross margin decreased to 69.9% for the year ended December 31, 2011 compared to 80.1% for the year ended December 31, 2010. The decline in gross margin is attributable to the increase of amortization related to acquired technology, the mix of products, specifically for the electronic brachytherapy product, which has lower margins than the CAD products, and increased costs related to the fixed cost of our Xoft manufacturing operation. The Company has reclassified on the statement of operations for the twelve months ended December 31, 2010, the cost of product installation, training, customer support and certain warranty repair costs of approximately \$1.74 million that were previously included in sales and marketing expenses to cost of revenue to conform to current period classifications. Cost of revenue and gross margin for 2011 and 2010 are as follows (in thousands):

	Sep	otember 30,	•	ptember 30, or the year end	ptember 30, cember 31,	September 30,
		2011		2010	Change	% Change
Products	\$	4,788	\$	2,396	\$ 2,392	99.8%
Service and supplies		2,906		2,486	420	16.9%
Amortization		931			931	
Total cost of revenue		8,625		4,882	3,743	76.7%
Gross margin	\$	20,027	\$	19,693	\$ 334	1.7%
Gross margin % Operating Expenses:		69.9%		80.1%		

Operating expenses for 2011and 2010 are as follows (in thousands):

	Sep	tember 30,	otember 30, or the year end	 ptember 30, ember 31,	September 30,
		2011	2010	Change	% Change
Operating expenses:				_	
Engineering and product development	\$	10,791	\$ 6,596	\$ 4,195	63.6%
Marketing and sales		13,684	9,750	3,934	40.3%
General and administrative		10,075	9,919	156	1.6%
Contingent consideration		(4,900)		(4,900)	
Goodwill impairment		26,828		26,828	
Loss on indemnification asset		741		741	
Total operating expenses	\$	57,219	\$ 26,265	\$ 30,954	117.9%

Engineering and Product Development. Engineering and product development costs for the year ended December 31, 2011 increased by \$4.2 million or 63.6%, from \$6.6 million in 2010 to \$10.8 million in 2011. The increase in engineering and product development costs was primarily due to an approximate \$3.6 million increase as a result of the acquisition of Xoft, and an increase of approximately \$0.6 million due primarily to costs of clinical trials of approximately \$0.7 million, offset by various expense reductions.

Marketing and Sales. Marketing and sales expense for the year ended December 31, 2011 increased by \$3.9 million or 40.3%, from \$9.8 million in 2010 to \$13.7 million in 2011. The increase in marketing and sales expense was primarily due to the increase of approximately \$5.1 million related to the acquisition of Xoft, offset by a decrease in expenses of approximately \$1.2 million. The decrease in expenses is due primarily to a reduction in headcount which reduced salary, fringe benefits and commissions approximately \$0.5 million, a decrease in subcontract services of approximately \$0.4 million, a reduction in stock compensation of approximately \$0.2 million and the remainder of \$0.1 million in miscellaneous expenses.

General and Administrative. General and administrative expenses for the year ended December 31, 2011 increased by \$0.2 million or 1.6%, from \$9.9 million in 2010 to \$10.1 million in 2011. The increase in general and administrative expense during 2011 was due primarily to an increase of \$2.8 million of general and administrative expenses that were not included in the 2010 results related to Xoft offset by a decrease of \$2.6 million. The decrease of \$2.6 million is due primarily to a \$3.2 million decrease related to transactions costs associated with a potential acquisition and the acquisition of Xoft, incurred in 2010, offset by an increase in severance costs of approximately \$0.5 million and the remainder of \$0.1 million increase in other expenses.

Contingent Consideration: The Company recorded a gain of \$4.9 million during the year ended December 31, 2011. The Contingent consideration resulted from the acquisition of Xoft, and the Company is required to determine the fair value of the consideration at each reporting period. The Company determined that the revenue thresholds to achieve the consideration were unlikely to be met, and therefore, reduced the fair value of contingent consideration to \$0.0 million.

Goodwill Impairment: During the quarter ended September 30, 2011, the Company recorded an impairment of goodwill of approximately \$26.8 million. The Company determined that a triggering event had occurred and as a result performed a Step 2 impairment analysis. In December 2011, the Company agreed to settle outstanding litigation with Carl Zeiss Meditec. The litigation settlement was recorded retrospectively as a measurement period adjustment and an additional amount was recorded to goodwill. The Company evaluated the additional goodwill in the impairment analysis, and as a result recorded an additional \$78,000 impairment as of the third quarter of 2011, for a total impairment of \$26.8 million.

Loss on indemnification asset:. In connection with the settlement of the litigation with Carl Zeiss Meditec, the Company recorded, retrospectively, an indemnification asset as a purchase price adjustment as of December 31, 2010. The fair value of the indemnification asset was determined to be the value of the underlying shares in escrow at the date of acquisition. Subsequent changes in the value of the shares were recorded as an approximate \$0.7 million loss on the indemnification asset during the year ended December 31, 2011. The respective quarterly amounts were recorded retrospectively during the year ended December 31, 2011.

Interest Income/Expense. Interest income for the year ended December 31, 2011 decreased by \$49,000, from \$73,000 in 2010 to \$24,000 in 2011. The decrease in interest income is due primarily to lower cash balances which reduced the interest earned from the Company s money market accounts. Interest expense in 2011 of \$419,000 represents approximately \$153,000 related to the accretion of the Hologic settlement liability and approximately \$266,000 related to the accretion of the Zeiss settlement liability.

#### Year Ended December 31, 2010 compared to Year Ended December 31, 2009

The Consolidated Statement of Operations does not include the financial results of Xoft for the fiscal years ended December 31, 2010 and December 31, 2009.

*Revenue*. Revenue for the year ended December 31, 2010 was \$24.6 million compared with revenue of \$28.1 million for the year ended December 31, 2009, for a decrease of \$3.5 million or 12.6%. The decrease in revenue was due primarily to the decrease in digital and MRI CAD and film-based revenue partially offset by an increase in service and supply revenue.

The table below presents the revenue attributable to different products and services, in 2010 and 2009 (in thousands):

	Sep	tember 30,	Sep	tember 30,	Sep	tember 30,	September 30,
			For	the year ende	d Decei	nber 31,	
		2010		2009	(	Change	% Change
Digital & MRI CAD revenue	\$	15,392	\$	18,289	\$	(2,897)	(15.8%)
Film based revenue		3,335		5,796		(2,461)	(42.5%)
Service & supply revenue		5,848		4,024		1,824	45.3%
Total revenue	\$	24,575	\$	28,109	\$	(3,534)	(12.6%)

The Company s digital and MRI CAD revenue for the year ended December 31, 2010 decreased \$2.9 million or 15.8%, to \$15.4 million compared to revenue of \$18.3 million for the year ended December 31, 2009. The decrease in digital and MRI CAD revenue was largely the result of a combination of having a key OEM customer out of the market awaiting FDA approval of their new digital mammography system, and to the weakened economy as well as to continued budget constraints in healthcare capital spending.

Revenue from iCAD s film based products for the year ended December 31, 2010 decreased 42.5% to \$3.3 million compared to \$5.8 million in 2009. This decrease can be attributed to the softer demand for full field digital mammography systems which affected sales of TotalLook MammoAdvantage, current economic conditions and constraints in healthcare capital spending. The majority of film-based revenue is derived from sales of the Company s TotalLook MammoAdvantage. The TotalLook MammoAdvantage product is used for digitizing film based prior mammography exams for comparative reading and is sold to further optimize workflow in a digital mammography environment. The TotalLook MammoAdvantage product is typically sold as customers are preparing to transition to digital mammography. In addition, as expected the demand for film-based products and accessories continues to decline as the marketplace continued to transition to digital technologies.

Service and supply revenue for the year ended December 31, 2010 increased 45.3% to \$5.8 million compared to \$4.0 million in 2009. The increase in the Company s service and supply revenue is due primarily to increased service contract revenue on the Company s growing installed base of products as customers migrate from warranty to service contracts, and to renewed service contract agreements. Service contract revenue represented 93% and 91% of the Company s total service and supply revenue for 2010 and 2009, respectively.

Gross Margin. Gross margin increased to 80.1% for the year ended December 31, 2010 compared to 77.6% for the year ended December 31, 2009. The increase in gross margin is primarily attributable to component cost reductions, the realization of some average selling price increases, and lower repair costs related to service contracts on a growing installed base of products. The Company has reclassified \$1.74 million and \$1.68 million on the statement of operations for the twelve months ended December 31, 2010 and 2009, respectively, the cost of product installation, training, customer support and certain warranty repair costs that were previously included in sales and marketing expenses to cost of revenue to conform to current period classifications. Cost of revenue and gross margin for 2010 and 2009 are as follows (in thousands):

	Sept	ember 30,	eptember 30, or the year ende	eptember 30, cember 31,	September 30,
		2010	2009	Change	% Change
Products	\$	2,396	\$ 3,905	\$ (1,509)	(38.6%)
Service and supplies		2,486	2,395	91	3.8%
Total cost of revenue		4,882	6,300	(1,418)	(22.5%)
Gross profit	\$	19,693	\$ 21,809	\$ (2,116)	(9.7%)
Gross profit %		80.1%	77.6%		
Operating Expenses:					

Operating expenses for 2010 and 2009 are as follows (in thousands):

	Sept	tember 30,	Sep	tember 30,	Sep	otember 30,	September 30,
			For	the year ende	d Decer	nber 31,	
		2010		2009	(	Change	% Change
Operating expenses:							
Engineering and product development	\$	6,596	\$	7,217	\$	(621)	(8.6%)
Marketing and sales		9,750		9,360		390	4.2%
General and administrative		9,919		7,354		2,565	34.9%
Total operating expenses	\$	26,265	\$	23,931	\$	2,334	9.8%

*Engineering and Product Development.* Engineering and product development costs for the year ended December 31, 2010 decreased by \$0.6 million or 8.6%, from \$7.2 million in 2009 to \$6.6 million in 2010. The decrease in engineering and product development costs was primarily due to decreases of \$0.5 million in stock-based and other compensation related expenses resulting

primarily from staff reductions, and in subcontracting services of \$0.4 million, principally relating to the licensing and clinical trial costs for the Company s CT Colon product which was completed in the first quarter of 2009. In addition, during 2010, the Company recorded decreases in legal costs of \$0.1 million, in rent expense of \$62,000 and in depreciation and various other expenses totaling \$92,000. These decreases were partially offset by increases in consulting expenses of \$0.2 million, subcontracting services of \$0.4 million and licensing and data collection expenses of \$11,000, principally relating to new product development.

Marketing and Sales. Marketing and sales expense for the year ended December 31, 2010 increased by \$0.4 million or 4.2%, from \$9.4 million in 2009 to \$9.8 million in 2010. The increase in marketing and sales expense was primarily due to the increase in consulting and subcontracting expenses of \$0.4 million, principally relating to a strategy consulting project initiated by the Company. In addition, during 2010, the Company recorded an increase in compensation related expenses for existing employees of \$0.2 million., These increases were partially offset by decreases in depreciation and freight totaling \$0.2 million.

General and Administrative. General and administrative expenses for the year ended December 31, 2010 increased by \$2.5 million or 34.9%, from \$7.4 million in 2009 to \$9.9 million in 2010. The increase in general and administrative expense during 2010 was due primarily to an increase in legal and professional fees of \$3.0 million associated with the acquisition of Xoft and a potential acquisition that was not consummated, as well as increases in compensation related expenses of \$0.2 million, and in various administrative expenses totaling \$0.1 million. These increases were partially offset by a decrease in stock based compensation expense of \$0.4 million, principally due to the completion of the three year vesting period on the awards of restricted stock and stock options that were granted to the executive officers of the Company in July 2007. In addition, during 2010 the Company recorded decreases in general legal costs, consulting and subcontracting services, depreciation, taxes and insurance cost totaling \$0.3 million.

*Other Income:* During the second quarter of 2010 the Company received a one-time payment of \$0.3 million related to the sale of a non-core patent that was acquired as part of the Qualia Computing, Inc. acquisition in 2003. The patent is for technology that is outside of the medical device industry and unrelated to the Company s core business.

*Interest Income/Expense*. Net interest income for the year ended December 31, 2010 decreased by \$37,000, from \$110,000 in 2009 to \$73,000 in 2010. The decrease in interest income is due primarily to the reduction of the interest rate earned from the Company s money market accounts.

#### **Liquidity and Capital Resources**

The Company believes that the proceeds of its debt financing signed on December 29, 2011 and funded on January 9, 2012, its current liquidity and capital resources are sufficient to sustain operations through at least the next 12 months, primarily due to cash on hand and projected cash balances from operations. The Company's ability to generate cash adequate to meet its future

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

On December 30, 2010, the Company completed the acquisition of Xoft, acquiring 100% of the outstanding stock of Xoft in exchange for 8,348,501 shares of the Company s common stock and approximately \$1.2 million in cash, for a total consideration at closing of approximately \$12.9 million based on a per share value of \$1.40, the closing price of the Company s common stock on the closing date. The Company also paid certain transaction expenses of Xoft totaling approximately \$1.0 million which is included in the Company s statement of operations.

The Company had a working capital deficit of \$1.4 million as current liabilities exceeded current assets at December 31, 2011. The ratio of current assets to current liabilities at December 31, 2011 and 2010 was 0.9 and 1.8, respectively. The decrease in working capital is due to the cash used for the Company s acquisition of Xoft and the increase in operating expenses as a result of the acquisition. On December 29, 2011, the Company entered into a debt financing arrangement in the amount of \$15.0 million, which was funded on January 9, 2012.

Net cash used for operating activities for the year ended December 31, 2011 was \$10.1 million compared to net cash provided by operations of \$0.2 million for 2010. The cash used for operating activities during the year ended December 31, 2011 was due primarily to operating losses of \$37.6 million, offset by \$27.2 million of non-cash expenses included in net loss. The cash provided by operating activities for the year ended December 31, 2010 resulted from decreases in accounts receivable of \$1.9 million, inventory of \$0.2 million, prepaid and other current assets of \$78,000, accounts payable and accrued expenses of \$0.5 million and deferred revenue of \$0.7 million, plus non-cash items including depreciation and amortization totaling \$1.6 million and stock-based compensation of \$1.5 million, which were partially offset by the net loss of \$6.2 million, and the gain on the sale of a patent of \$0.3 million.

The net cash used for investing activities for the year ended December 31, 2011 was \$1.5 million. The cash used for investing activities in 2011 was primarily due to cash paid related to the acquisition of Xoft of approximately \$1.3 million and purchases of fixed assets of \$0.2 million. Cash used for investing activities for the year ended December 31, 2010 was \$99,000 which consisted of proceeds from the sale of a patent of \$0.3 million offset by additions to patents, technology and other assets of \$28,000 and additions to property and equipment of \$0.3 million and \$24,000 related to the acquisition of Xoft.

Net cash used for financing activities for the year ended December 31, 2011 was \$7,000, which consisted of taxes paid related to the issuance of restricted stock. Cash used for financing activities for the year ended December 31, 2010 was \$87,000 relating to taxes paid with respect to the issuance of restricted stock.

The following table summarizes as of December 31, 2011, for the periods presented, the Company s future estimated cash payments under existing contractual obligations, and the financing obligation funded during 2012 as noted below (in thousands).

	Sept	ember 30,	•			otember 30, s due by period		ptember 30,	Septem	ber 30,
<b>Contractual Obligations</b>	,	Total		ess than 1 year	1	-3 years	;	3-5 years	5+ ye	ears
Lease Obligations	\$	2,065	\$	1,143	\$	718	\$	204	\$	
Royalty Obligations		3,750	\$	1,250	\$	1,750	\$	750		
Notes Payable		21,381	\$	1,022	\$	11,426	\$	8,933		
Other Commitments		879		879						
Total Contractual Obligations	\$	28,075	\$	4,294	\$	13,894	\$	9,887	\$	

See Note 8 to our financial statements for a description of our obligations.

In addition to the contractual obligations related to the interest payments from Notes Payable, the Company is obligated under the revenue purchase agreement discussed in Note 3 of the accompanying financial statements, to pay 4.25% of revenues up to \$25 million, 2.75% of annual revenues from \$25 million to \$50 million and 1.0% of annual revenues in excess of \$50 million. Included in the above amounts are the minimum annual payments under the revenue purchase agreement of \$125,000 per quarter payable in arrears. The Company is unable to estimate the variable contractual payments related to the revenue purchase agreement, and accordingly only the minimum annual payments have been included.

## **Effect of New Accounting Pronouncements**

In May 2011, the FASB issued Accounting Standards Update No. 2011-04, "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards" (Topic 820) Fair Value Measurement (ASU 2011-04), to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for level 3 fair value measurements. ASU 2011-04 is effective for fiscal years and interim periods within those years, beginning after December 15, 2011. The Company does not expect the adoption to have a material impact on its financial statements.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05). ASU 2011-05 increases the prominence of other comprehensive income in financial statements. Under ASU 2011-05, companies will have the option to present the components of net income and comprehensive income in either one or two consecutive financial statements. ASU 2011-05 eliminates the option to present other comprehensive income in the statement of changes in equity and is applied retrospectively. For public companies, ASU 2011-05 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company does not expect the adoption to have a material impact on its financial statements.

In September 2011, the FASB issued Accounting Standards Update No. 2011-08, Intangibles Goodwill and Other (Topic 350) Testing Goodwill for Impairment (ASU 2011-08), to allow entities to use a qualitative approach to test goodwill for impairment. ASU 2011-08 permits an entity to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, it is necessary to perform the currently prescribed two-step goodwill impairment test. Otherwise, the two-step goodwill impairment test is not required. ASU 2011-08 is effective for fiscal years beginning after December 15, 2011, however early adoption is permitted. The Company does not expect this to have a material impact on its financial statements.

In December 2011, the FASB issued Accounting Standards Update No. 2011-12: Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 ("ASU 2011-12"). The Update defers the specific requirement to present items that are reclassified from accumulated other comprehensive income to net income separately with their respective components of net income and other comprehensive income. As part of this update, the FASB did not defer the requirement to report comprehensive income either in a single continuous statement or in two separate but consecutive financial statements. ASU 2011-12 is effective for annual periods beginning after December 15, 2011.

#### 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.

#### <u>Item 8.</u> <u>Financial Statements and Supplementary Data.</u>

See Financial Statements and Schedule attached hereto.

<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.</u>

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, 2011.

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.

The Company employed the Internal Control-Integrated Framework founded by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of the Company s internal control over financial reporting. Management of the Company has assessed the Company s internal control over financial reporting to be effective as of December 31, 2011 based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of the Company s registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by the Company s registered public accounting firm pursuant to SEC rules that permit the Company to provide only management s report in this Annual Report on Form 10-K.

## (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, 2011, that have materially affected or which are reasonably likely to materially affect internal control over financial reporting. Based on that evaluation there has been no such change during such period.

# Item 9B. Other Information. Not applicable.

#### **PART III**

#### Item 10. Directors, Executive Officers and Corporate Governance.

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

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

Director/Officer

Name	Age	Position with iCAD	Since
Dr. Lawrence Howard	59	Chairman of the Board, and Director	2006
Kenneth Ferry	58	President, Chief Executive Officer, and Director	2006
Kevin Burns		Executive Vice President of Finance, Chief Financial	2011
	41	Officer and Treasurer and Secretary	
Jonathan Go	49	Senior Vice President of Research and Development	2006
Rachel Brem, MD	53	Director	2004
Anthony Ecock	50	Director	2008
Steven Rappaport	63	Director	2006
Elliot Sussman, MD	60	Director	2002
Michael Klein	58	Director	2010
Somu Subramaniam	57	Director	2010

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 eight 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 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. He was a founder and has been since November 1987, and continues to be, a director of Presstek, Inc. (Presstek), a public company which has developed proprietary imaging and consumables technologies for the printing and graphic arts industries, and served in various officer positions at Presstek from October 1987 to June 1993, lastly as its Chief Executive Officer. 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.

Kenneth Ferry has served as the Company s President and 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.

Kevin C. Burns has served as the Company s Executive Vice President of Finance and Chief Financial Officer and Treasurer since April 2011. Mr. Burns has approximately twenty years of professional experience in finance primarily in the technology industry. 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 effected a successful sale of the company. Prior to joining AMICAS, Mr. Burns was responsible for 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.

Jonathan Go has served as the Company s Senior Vice President of Research and Development since October 2006. Mr. Go brings more than twenty years of software development experience in the medical industry to his position with the Company. From February 1998 to May 2006, Mr. Go served as Vice President of Engineering at Merge eMed Inc., a provider of Radiology Information System and Picture Archiving and Communication Systems solutions for imaging centers, specialty practices and hospitals. At Merge eMed, Mr. Go was responsible for software development, product management, testing, system integration and technical support for all of eMed's products. From July 1986 to January 1998, Mr. Go held various development roles at Cedara Software Corp. in Toronto culminating as Director of Engineering. Cedara Software is focused on the development of custom engineered software applications and development tools for medical imaging manufacturers. At Cedara Mr. Go built the workstation program, developing multiple specialty workstations that have been adopted by a large number of partners. Mr. Go earned a Bachelor of Science in Electrical Engineering from the University of Michigan and a Master s of Science in Electrical Engineering and Biomedical Engineering from the University of Michigan.

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 John 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 has been Senior Operating Executive with the private equity investment firm, Welsh, Carson, Anderson & Stowe (WCAS), since 2007. Mr. Ecock has over 9 years of experience in the healthcare technology field and with more than 15 years in senior management positions. At WCAS, Mr. Ecock is responsible for helping portfolio companies identify and implement growth, as well as earnings improvement opportunities. Before joining WCAS, he served as Vice President and General Manager of GE Healthcare s Enterprise Sales organization, a unit of the General Electric Company, from 2003 to 2007. From 1999 to 2003 he served as

Senior Vice President and Global General Manager of the Hewlett Packard Company. Mr. Ecock spent most of his career at the consulting firm of Bain & Company, where he was a Partner, Practice Leader for Information Technology and Global Program Director for Consultant Training. We believe Mr. Ecock squalifications to serve on our Board of Directors include his financial expertise and his years of experience in the healthcare market.

Steven Rappaport has been a partner of RZ Capital, LLC a private investment firm that also provides administrative services for a limited number of clients since July 2002. 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 Presstek and 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.

Dr. Elliot Sussman is currently a 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.

Michael Klein was President and CEO of Xoft, Inc, a position he held since 2005 until the sale of Xoft to iCAD, Inc. in December 2010. Mr. Klein led the development, approval and commercialization of Xoft s non-radioactive x-ray technology for radiation therapy. The Xoft platform offering is used to treat breast, vaginal and skin cancers. Prior to joining Xoft, from 2000 to 2004, Mr. Klein served as Chairman, President and CEO of R2 Technology, Inc., a breast and lung cancer computer aided detection company. From 1997 to 2000 he served as

General Manager of Varian Medical Systems' Oncology Group where he managed businesses ranging from \$25 million to \$250 million. Mr. Klein has also served on the Board of Sanarus Medical, a breast biopsy and cryo-ablation company focused on the treatment of fibro adenomas. He received his MBA degree from the New York Institute of Technology and completed his post-graduate Executive Education Studies at Harvard University and Babson College. In 2008, Mr. Klein received the R&D Magazine Top 100 Award on behalf of Xoft, where honors were awarded for the 100 most technologically significant new products of 2008. A similar award was received in 2008 from Frost & Sullivan. We believe Mr. Klein s qualifications to serve on our Board include his experience as the former Chief Executive Officer of Xoft, as well as his industry and product knowledge.

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. Mr. Subramaniam received his undergraduate degree (B.Tech) from the Indian Institute of Technology and his M.B.A. from Harvard Business School. We believe Mr. Subramaniam s qualifications to serve on our Board include his experience in healthcare and medical devices, his financial expertise, as well as his market and product knowledge.

#### **Audit Committee and Audit Committee Financial Expert**

Our Board of Directors maintains an Audit Committee which is comprised 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.

#### 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, 2011, 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, 2011. The response to this item will be contained in our proxy statement for our 2012 annual meeting of stockholders under the captions Executive Compensation, 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 2012 annual meeting of stockholders in part under the caption Stock Ownership of Certain Beneficial Owners and Management and in part below.

#### **Equity Compensation Plans**

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2011.

	September 30,	September 30,	September 30, Number of securities
	Number of securities to be issued upon exercise of	Weighted-average exercise price of outstanding options	issuance under equity compensation plans (excluding
	outstanding options, warrants	warrants and	securities reflected in column
Plan Category:	and rights	rights	(a))
Equity compensation plans approved by security holders:	4,230,796	\$ 1.81	862,574
Equity compensation plans not approved by security holders (1):	1,172,815	\$ 2.46	-0-
Total	5,403,611	\$ 1.95	862,574

(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.

## <u>Item 13.</u> <u>Certain Relationships and Related Transactions, and Director Independence.</u>

The response to this item is contained in our proxy statement for our 2012 annual meeting of stockholders under the captions Certain Relationships and Related Transactions, Corporate Governance Matters Director Independence and Compensation Committee Report, and is incorporated herein by reference.

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

The response to this item will be contained in our proxy statement for our 2012 annual meeting of stockholders under the caption Ratification of Appointment of Independent Registered Public Accounting Firm, and is incorporated herein by reference.

#### PART IV

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

- a) The following documents are filed as part of this Annual Report on Form 10-K:
- i. Financial Statements See Index on page xx.
- ii. Financial Statement Schedule See Index on page xx. All other schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are not applicable and, therefore, have been omitted.
- iii. Exhibits the following documents are filed as exhibits to this Annual Report on Form 10-K:
- 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]. \*\*
- 3(a) Certificate of Incorporation of the Registrant as amended through July 18, 2007 [incorporated by reference to Exhibit 3(i) to the Registrant's Quarterly report on Form 10-Q for the quarter ended June 30, 2007].

- 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].\*
- 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) Option Agreement dated April 19, 2006 between the Registrant and Kenneth Ferry [incorporated by reference to Exhibit 10.5 of the Registrant s Quarterly report on Form 10-Q for the quarter ended September 30, 2006].\*
- 10(i) Option Agreement dated April 19, 2006 between the Registrant and Stacey Stevens [incorporated by reference to Exhibit 10.7 of the Registrant s Quarterly report on Form 10-Q for the quarter ended September 30, 2006].\*
- 10(j) Lease Agreement dated December 6, 2006 between the Registrant and Gregory D. Stoyle and John J. Flatley, Trustees of the 1993 Flatley Family Trust, of Nashua, NH [incorporated by reference to Exhibit 10(mm) to the Registrant s Report on Form 10-K for the year ended December 31, 2006].
- 10(k) Option Agreement dated November 3, 2006 between the Registrant and Jonathan Go [incorporated by reference to Exhibit 10(oo) to the Registrant s Report on Form 10-K for the year ended December 31, 2006].\*
- 10(1) 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(m) 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(n) Form of Restricted Stock Agreement under the Registrant s 2007 Stock Incentive Plan [incorporated by reference to Exhibit 10(ww) to the Registrant s Report on Form 10-K for the year ended December 31, 2009] \*.
- Employment Agreement entered into as of June 1, 2008 between the Registrant and Kenneth Ferry [incorporated by reference to Exhibit 10.5 of the Registrant s report on Form 10-Q filed with the SEC on August 8, 2008] \*
- 10(p) 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(q) 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(r) Separation Agreement dated April 27, 2011 between the Registrant and Darlene M. Deptula- Hicks [incorporated by reference to Exhibit 10.1 of the Registrant s report on Form 8-K filed with the SEC on April 27, 2011].
- 10(s) 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].
- 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(u) Facility Agreement, 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(v) 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(w) 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(x) 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].
- 10(y) Settlement Agreement, dated as of December 22, 2011, by and among the Company, Carl Zeiss Meditec, AG and Carl Zeiss Meditec, Inc.

- 21 Subsidiary
- 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.
- The following materials formatted in XBRL (eXtensible Business Reporting Language); (i) Consolidated Balance Sheets as of December 31, 2011 and December 31, 2010, (ii) Consolidated Statements of Operations for the twelve months ended December 31, 2011 and 2010 and 2009 and (iii) Consolidated Statements of Cash Flows for the twelve months ended December 31, 2011 and 2010 and 2009, 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.
- \*\*\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

## **SIGNATURES**

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

Date: March 8, 2012

By: /s/ Kenneth Ferry Kenneth Ferry

President, 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 8, 2012
/s/ Kenneth Ferry Kenneth Ferry	President, Chief Executive Officer, Director (Principal Executive Officer)	March 8, 2012
/s/ Kevin C. Burns Kevin C. Burns	Executive Vice President of Finance, Chief Financial Officer, Treasurer (Principal Financial and Accounting Officer)	March 8, 2012
/s/ Rachel Brem Rachel Brem, M.D.	Director	March 8, 2012
/s/ Anthony Ecock Anthony Ecock	Director	March 8, 2012
/s/ Michael Klein Michael Klein	Director	March 8, 2012
/s/ Steven Rappaport Steven Rappaport	Director	March 8, 2012
/s/ Somu Subramaniam Somu Subramaniam	Director	March 8, 2012
/s/ Elliot Sussman Elliot Sussman, M.D.	Director	March 8, 2012

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#### 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 subsidiary (the Company) as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2011. 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 controls 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 subsidiary as of December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Boston, Massachusetts

March 8, 2012

# iCAD, INC. AND SUBSIDIARY

## **Consolidated Balance Sheets**

Assets	Dec	sember 30, cember 31, 2011 asands except sh	De	otember 30, ecember 31, 2010 per share data)
Current assets:				
Cash and cash equivalents	\$	4,576	\$	16,269
Trade accounts receivable, net of allowance for doubtful accounts of \$54 in 2011 and \$50 in 2010	Ψ	4,003	Ψ	3,389
Inventory, net		2,040		3,489
Prepaid expenses and other current assets		490		581
		490		
Indemnification asset				1,283
Total current assets		11,109		25,011
Property and equipment:				
Equipment		3,958		4,436
Leasehold improvements		527		539
Furniture and fixtures		286		355
Marketing assets		297		297
		5,068		5,626
Less accumulated depreciation and amortization		3,184		2,852
Less accumulated depreciation and amortization		3,104		2,632
Net property and equipment		1,884		2,774
Other assets:				
Deposits		595		675
Intangible assets, net of accumulated amortization of \$8,840 in 2011 and \$6,746 in 2010		17,064		21,165
Goodwill		21,109		45,969
Total other assets		38,768		67,809
Total assets	\$	51,761	\$	95,594
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable	\$	1,198	\$	2,500
Accrued expenses	-	5,150	-	5,521
Deferred rent		371		381
Deferred revenue		5,765		4,906
Total current liabilities		12,484		13,308
_				
Long-term warranty expense		13		15
Long-term deferred rent		57		402
Long-term recall cost		71		
Long-term deferred revenue		1,446		961
Long-term settlement costs		1,635		2,698
Contingent consideration liability				5,000
Total liabilities		15,706		22,384

#### Commitments and contingencies (Notes 3 and 8) Stockholders equity: Preferred stock, \$ .01 par value: authorized 1,000,000 shares; none issued. Common stock, \$.01 par value: authorized 85,000,000 shares; issued 54,754,510 in 2011 and 54,383,747 in 2010; outstanding 53,825,355 in 2011 and 54,315,871 in 2010547 544 Additional paid-in capital 163,995 163,101 Accumulated deficit (127,072)(89,485) Treasury stock at cost 929,155 in 2011 and 67,876 in 2010 (950) (1,415)Total stockholders equity 36,055 73,210

See accompanying notes to consolidated financial statements.

Total liabilities and stockholders equity

\$

51,761

\$

95,594

# ${\bf iCAD, INC. \, AND \, SUBSIDIARY}$

## **Consolidated Statements of Operations**

	Se	September 30, September 30, September 30, September 31, September 31, September 31, September 31, September 31, September 31, September 30, Se				
			sands e	except per sha	re dat	2009 a)
Revenue:		(				
Products	\$	19,787	\$	18,727	\$	24,085
Service and supplies		8,865		5,848		4,024
Total revenue		28,652		24,575		28,109
Cost of Revenue:						
Products		4,788		2,396		3,905
Service and supplies		2,906		2,486		2,395
Amortization		931		,		,
Total cost of revenue		8,625		4,882		6,300
Gross profit		20,027		19,693		21,809
Operating expenses:						
Engineering and product development		10,791		6,596		7,217
Marketing and sales		13,684		9,750		9,360
General and administrative		10,075		9,919		7,354
Contingent consideration		(4,900)				
Goodwill impairment		26,828				
Loss on indemnification asset		741				
Total operating expenses		57,219		26,265		23,931
Loss from operations		(37,192)		(6,572)		(2,122)
Other income (expense):						
Other income (expense).				275		
Interest income		24		73		119
Interest expense		(419)		73		(9)
interest expense		(419)				(9)
Other income (expense), net		(395)		348		110
Loss before income tax benefit		(37,587)		(6,224)		(2,012)
Income tax benefit						(44)
Net loss	\$	(37,587)	\$	(6,224)	\$	(1,968)
Net loss per share:						
Basic	\$	(0.69)	\$	(0.14)	\$	(0.04)
Diluted	\$	(0.69)	\$	(0.14)	\$	(0.04)

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Weighted average number of shares used in computing loss per share:			
Basic	54,548	45,828	45,512
Diluted	54,548	45,828	45,512

See accompanying notes to consolidated financial statements.

## ${\bf iCAD, INC. \, AND \, SUBSIDIARY}$

## Consolidated Statements of Stockholders Equity

(in thousands except shares)

	September 30, Commo		tember 30, k	eptember 30, Additional	September 30	, s	eptember 30,	Sej	otember 30,
	Number of Shares Issued	Pa	ar Value	Paid-in Capital	Accumulated Deficit		Treasury Stock		ockholders Equity
Balance at December 31, 2008	45,411,384	\$	454	\$ 148,082	\$ (81,29	3) \$	(950)	\$	66,293
Issuance of common stock pursuant to stock option plans	47,161			23					23
Issuance of common stock relative to vesting of restricted stock, net of 18,619 shares forfeited for									
tax obligations	292,147		3	(25)					(22)
Return of common stock relative to the asset acquisition	(3,956)			(11)					11
Stock-based compensation				1,994					1,994
Net loss					(1,96	8)			(1,968)
Balance at December 31, 2009	45,746,736		457	150,063	(83,26	1)	(950)		66,309
Issuance of common stock relative to vesting of restricted stock, net of 53,072 shares forfeited for									
tax obligations	288,510		3	(91)					(88)
Merger consideration (Note 2)	8,348,501		84	11,613					11,697
Stock-based compensation				1,516					1,516
Net loss					(6,22	4)			(6,224)
Balance at December 31, 2010	54,383,747		544	163,101	(89,48.	5)	(950)		73,210
Issuance of common stock relative to vesting of restricted stock, net of 57,340 shares forfeited for									
tax obligations	295,763		3	(70)					(67)
Issuance of common stock pursuant to stock option	75,000			60					60

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## plans

Shares added to treasury pursuant to litigation settlement					(465)	(465)
Stock-based compensation			904			904
Net loss				(37,587)		(37,587)
Balance at December 31, 2011	54,754,510	\$ 547	\$ 163,995	\$ (127,072)	\$ (1,415) \$	36,055

See accompanying notes to consolidated financial statements.

## **Consolidated Statements of Cash Flows**

	-	mber 30, For the 011	September 3 Years Ended D 2010 (in thousand	ecember	September 30, · 31, 2009
Cash flow from operating activities:	ф	(27.507)	Φ (6.2	<b>3.</b> 4)	(1.060)
Net loss	\$	(37,587)	\$ (6,2	24) \$	(1,968)
Adjustments to reconcile net loss to net cash (used for) provided by operating					
activities:		1.077	4	76	751
Depreciation		1,077		76	751
Amortization		2,094	1,1		1,170
Gain on sale of patent		26,929	(2	75)	
Goodwill impairment		26,828			
Loss on disposal of assets		21 741			
Loss on indemnification asset			1 5	1.6	1.004
Stock-based compensation expense		904	1,5	16	1,994
Interest on royalty obligation		422			
Fair value of contingent consideration		(4,900)			
Changes in operating assets and liabilities, net of acquisition:		(614)	1.0	1.4	070
Accounts receivable		(614)	1,9		878
Inventory Prepaid and other current assets		1,449 248		78 78	354 58
				78 25	(824)
Accounts payable		(1,375)		23 46	
Accrued expenses Deferred revenue		(713)		46 06	(530) 1,559
Deferred revenue		1,263	/	00	1,339
Total adjustments		27,445	6,4	31	5,410
Net cash (used for) provided by operating activities		(10,142)	2	07	3,442
Cash flow from investing activities:		(40)		• 0)	(120)
Additions to patents, technology and other		(13)		28)	(138)
Additions to property and equipment		(263)		22)	(173)
Proceeds from sale of patent				75	
Acquisition of Xoft, net of cash acquired			(	24)	
Net cash used for investing activities		(276)	(	99)	(311)
Cash flow from financing activities:					
Issuance of common stock for cash		60			23
Payment for Xoft		(1,268)			
Taxes paid related to restricted stock issuance		(67)	(	87)	(22)
Net cash (used for) provided by financing activities		(1,275)	(	87)	1
Increase (decrease) in cash and equivalents		(11,693)		21	3,132
Cash and equivalents, beginning of year		16,269	16,2		13,116
Cash and equivalents, end of year	\$	4,576	\$ 16,2	69 \$	16,248

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Supplemental disclosure of cash flow information:						
Interest paid	\$		\$	2	\$	9
Taxes paid	\$	40	\$	89	\$	95
Tunes para	Ψ	10	Ψ	0)	Ψ	,,,
Non-cash items from investing and financing activities:						
Fair market value of iCAD common stock issued to acquire Xoft, Inc. and accrued						
cash consideration	\$		2	12,668	\$	
cash consideration	Ψ		Ψ	12,000	Ψ	
D. C 1.C. 1.1. '.'.' CV.C.' 2011 1CAD						
Return of common stock from escrow related to acquisition of Xoft in 2011 and CAD			_		_	
Sciences in 2008.	\$	465	\$		\$	11

 $See\ accompanying\ notes\ to\ consolidated\ financial\ statements.$ 

Notes to Consolidated Financial Statements

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

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

iCAD, Inc. and subsidiary (the Company or iCAD ) is a provider of Computer Aided Detection ( CAD ) solutions that enable radiologists and other healthcare professionals to better serve patients by identifying pathologies and pinpointing cancer earlier. CAD is performed as an adjunct to certain medical screening procedures. CAD is reimbursable in the U.S. under federal and most third-party insurance programs. In July 2008, through the asset acquisition of 3TP LLC dba CAD Sciences ( CAD Sciences ), the Company acquired pharmaco-kinetic based CAD products that aid in the interpretation of contrast enhanced MRI images of the breast and prostate. iCAD has also developed CAD solutions for use with virtual colonoscopy to improve the detection of colonic polyps while delivering improved workflow for the radiologists, and higher quality patient care.

In addition, the acquisition of Xoft, Inc. (Xoft) on December 30, 2010, brought an isotope-free cancer treatment platform technology to the Company s product line. In this acquisition, the Company acquired electronic brachytherapy (eBx) products for the treatment of breast, endometrial, skin and other cancers, used in a broad range of clinical settings. The portable Axxent System which delivers electronically controlled radiation therapy directly to cancer sites with minimal radiation exposure to surrounding healthy tissue is FDA-cleared. This technology enables radiation oncology departments in hospitals, clinics and physician offices to perform traditional radiotherapy treatments and offer advanced treatments such as Intra-Operative Radiation Therapy (IORT). Customers include university research and community hospitals, private and governmental institutions, doctors offices,, cancer care clinics and veterinary facilities. iCAD, Inc and Xoft, Inc are collectively referred to herein as the Company or iCAD.

The Company considers itself a single reportable business segment. 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 geographical and major customer information.

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

Notes to Consolidated Financial Statements (continued)

#### (b) Principles of Consolidation

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

#### (c) Cash and cash equivalents

For purposes of reporting cash flows, the Company defines cash and cash equivalents as all bank transaction 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. All of the Company s non-interest bearing cash balances were fully insured at December 31, 2011 due to a temporary federal program in effect from December 31, 2010 through December 31, 2012. Under the program, there is no limit to the amount of insurance for eligible accounts. Beginning in 2013, insurance coverage will revert to \$250,000 per depositor at each financial institution, and the Company s non-interest bearing cash balances may again exceed federally insured limits. Interest-bearing amounts on deposit in excess of federally insured limits at December 31, 2011 approximated \$4.2 million.

#### (d) Financial instruments

The carrying amounts of financial instruments, including cash and equivalents, accounts receivable and accounts payable, approximated fair value as of December 31, 2011 and 2010 due to their short-term nature.

#### (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. Credit limits are established through a process of reviewing the financial history and stability of each customer. Where appropriate, the Company obtains credit rating reports and financial statements of customers when determining or modifying credit limits. The Company s senior management reviews accounts receivable on a periodic basis to determine if any receivables may potentially be uncollectible. The Company includes any accounts receivable balances that it determines may likely be uncollectible, along with a general reserve for estimated probable losses

Notes to Consolidated Financial Statements (continued)

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, 2011 and 2010 is adequate.

#### (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, 2011 and 2010 respectively inventories consisted of the following (in thousands):

	Septemb A	er 30, s of Dece	-	otember 30, 31,
	2011			2010
Raw materials	\$	643	\$	2,018
Work in process		23		
Finished Goods		1,374		1,471
Inventory	\$	2,040	\$	3,489

#### (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 various classes of assets (ranging from 3 to 5 years) or the remaining lease term, whichever is shorter for leasehold improvements.

#### (h) Long Lived Assets

Long-lived assets, other than goodwill, are evaluated for impairment when events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows from the use of these assets. When any such impairment exists, the related assets are written down to fair value. The Company did not record any impairment losses in the years ended December 31, 2011, 2010 or 2009. Intangible assets subject to amortization consist primarily of patents, technology, trade name, customer relationships and distribution agreements purchased in the Company s previous acquisitions. These assets, which include assets acquired from Xoft, Inc., are amortized on a straight-line basis or the pattern of economic benefit over their estimated useful lives of 5 to 10 years. A summary of intangible assets for 2011 and 2010 are as follows (in thousands):

Notes to Consolidated Financial Statements (continued)

	September 30,			ptember 30,	September 30, Weighted average
		2011		2010	useful life
For the years ended December 31,					
Gross Carrying Amount					
Patents and licenses	\$	623	\$	2,129	5 years
Technology		25,033		25,533	10 years
Tradename		248		248	10 years
Total amortizable intangible assets		25,904		27,910	
Accumulated Amortization					
Patents and licenses	\$	409	\$	391	
Technology		8,233		6,181	
Tradename		198		173	
Total accumulated amortization		8,840		6,745	
Total amortizable intangible assets, net	\$	17,064	\$	21,165	

Amortization expense related to intangible assets was approximately \$2,094, \$1,167 and \$1,170 for the years ended December 31, 2011, 2010, and 2009, respectively. Estimated remaining amortization of the Company s intangible assets is as follows (in thousands):

For the years ended December 31:	I an	eptember 30, Estimated nortization expense
2012	\$	1,899
2013		1,701
2014		1,445
2015		1,443
2016		1,437
Future years		9,139
	\$	17,064

## (i) 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.

Notes to Consolidated Financial Statements (continued)

The Company s goodwill arose in connection with its acquisitions in June 2002, December 2003 and December 2010. The Company operates in one segment and one reporting unit since operations are supported by one central staff and the results of operations are evaluated as one business unit. In general, the Company s medical device products are similar in nature based on production, distribution, services provided and regulatory requirements. The Company uses market capitalization as the best evidence of fair value (market capitalization is calculated using the quoted closing share price of the Company s common stock at its annual impairment testing date of October 1, multiplied by the number of common shares outstanding) of the Company. The Company tests goodwill for impairment by comparing its market capitalization (fair value) to its carrying value. The fair value of the Company is compared to the carrying amount at the same date as the basis to determine if a potential impairment exists.

The Company assesses the potential impairment of goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable, or at least annually. Factors management 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 our overall business;

significant negative industry or economic trends;

significant decline in our stock price for a sustained period; and

a sustained decline in our market capitalization below net book value.

During the quarter ended September 30, 2011, as a result of the sustained decline in the market capitalization of the Company, an interim first step (Step 1) analysis was completed. The interim Step 1 test resulted in the determination that the carrying value of equity exceeded the fair value of equity, thus requiring the Company to measure the amount of any goodwill impairment by performing the second step of the impairment test. The Company corroborated the Step 1 value using an income approach.

The second step ( Step 2 ) of the goodwill impairment test, used to measure the amount of impairment loss, compares the implied fair value of reporting unit goodwill with the carrying amount of that goodwill.

The implied fair value of goodwill 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 single reporting unit over the amounts assigned to its assets and liabilities is the implied amount of goodwill. The Company identified several intangible assets that were valued during this process, including technology, customer relationships, trade names, non-compete agreements, and the Company s workforce. The allocation process was performed only for purposes of testing goodwill for impairment.

Notes to Consolidated Financial Statements (continued)

The Company determined the value of the select assets utilizing the income approach. 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.

Other significant assumptions include terminal value margin rates, future capital expenditures, and changes in future working capital requirements. The Company also compared and reconciled the overall fair value to the Company s market capitalization. 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 Company s single reporting unit.

The Step 2 test resulted in determining the fair value of goodwill of \$21,109 which resulted in an impairment loss of \$26,828.

The changes in the carrying amount of goodwill for the years ended December 31, 2010 and 2011, are as follows (in thousands):

	Sep	otember 30,
Balance as of December 31, 2009	\$	43,515
Xoft acquistion		2,174
Retrospective adjustments		280
Balance as of December 31, 2010		45,969
Purchase accounting adjustments		1,968
Impairment		(26,828)
Balance as of December 31, 2011	\$	21,109

Purchase accounting adjustments, considered to be measurement period adjustments, were recorded in the six months subsequent to the acquisition and consisted primarily of a \$1.5 million decrease of the acquired patent asset, a decrease of \$500,000 in the acquired technology asset, a decrease in the fair value estimate of the royalty obligation of \$200,000 a decrease of \$100,000 related to contingent consideration and an increase of approximately \$300,000 related to unrecorded liabilities. The measurement period adjustments had no effect on the Company s operations and results and had an immaterial effect on the December 31, 2010 balance sheet. Accordingly, the adjustments were recorded during 2011.

No goodwill impairment loss was recorded in 2010 or 2009. For 2011 and 2010 the Company performed the annual step one fair value comparison as of October 1, 2011 and October 1, 2010. At October 1, 2010, the Company s market capitalization (or market capitalization with a reasonable control premium) exceeded its carrying value. At October 1, 2011, the Company s market capitalization with a reasonable control premium was less than the carrying value of goodwill. However, the Company completed a goodwill impairment analysis as of September 30, 2011, and concluded that the October 1, 2011 step one fair value comparison was consistent with the results at September 30, 2011. At December 31, 2011 and 2010, the Company s market capitalization (or market capitalization with a reasonable control premium) exceeded its carrying value.

Notes to Consolidated Financial Statements (continued)

#### (j) 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 is probable. For product revenue delivery has occurred upon shipment, provided title and risk of loss has passed to the customer. Services and supplies revenue are considered to be delivered as the services are performed or over the estimate life of the supply agreement.

The Company recognizes revenue from the sale of certain of its MRI CAD products and services in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 985-605, (Software, Revenue Recognition) (ASC 985-605).

The Company recognizes revenue from the sale of its digital, film-based CAD and electronic brachytherapy products and services in accordance with ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements ( ASU 2009-13 ). In accordance with the guidance of ASU 2009-13, fair value as the measurement criteria is replaced with the term selling price and establishes a hierarchy for determining the selling price of a deliverable. ASU 2009-13 also eliminates the use of the residual value method for determining the allocation of arrangement consideration. For multi-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 ( BESP ). VSOE generally exists only when the deliverable is sold separately and is the price actually charged for that deliverable. The process for determining a BESP 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. Sales of the electronic brachytherapy product typically include several devices, accessories, service and supply. The Company generally allocates revenue to the deliverables in the arrangement based on the BESP. Revenue is recognized when the product has been delivered, and service and supply revenue is recognized over the life of the service and supply agreement.

For most of iCAD s Digital, MRI and film based sales, the responsibility for the installation process lies with its Original Equipment Manufacturer (OEM) partners, including GE Healthcare, Siemens Medical and others. On occasion, when iCAD is responsible for product installation, the installation element is considered a separate unit

Notes to Consolidated Financial Statements (continued)

of accounting because the delivered product has stand alone value to the customer. In these instances, the Company allocates 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 VSOE of the element. Revenue from the Digital, MRI and film based equipment when there is installation is recognized based on the relative selling price allocation of the BESP. In prior years (prior to ASU 2009-13), the Company recognized the element on the residual method. The adoption of ASU 2009-13 did not have a material effect on the financial condition or results of operations of the Company.

The Company uses customer purchase orders that include all terms of the arrangement and in the case of OEM customers are also supported by distribution agreements. In accordance with the distribution agreement, the OEM customers do not have a right of return, and title and risk of loss passes to the OEM customer 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 reasonably assured 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 revenues are 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 defers revenue from the sale of extended service contracts related to future periods and recognizes revenue on a straight-line basis in accordance with FASB ASC Topic 605-20, Services . The Company provides for estimated warranty costs on original product warranties at the time of sale.

The Company also adopted ASC Update No. 2009-14, Certain Arrangements That Contain Software Elements (Update No. 2009-14). This Update amended the scope of ASC Subtopic No. 985-605, Revenue Recognition, to exclude tangible products that include software and non-software components that function together to deliver the product s essential functionality. The adoption of this standard did not have a material effect on the Company s financial condition or results of operations.

Notes to Consolidated Financial Statements (continued)

#### (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. The Company has reclassified on the statements of operations the cost of product installation, training, customer support and certain warranty repair costs of approximately \$1.74 million and \$1.67 million in the years ended December 31, 2010 and 2009, respectively, that were previously included in sales and marketing expenses to cost of revenue to conform to current period classifications.

#### (I) 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 in the volume and cost of product returns during the warranty period. Warranty provisions and claims for the years ended December 31, 2011, 2010 and 2009, were as follows:

Warranty costs: (000 s)	nber 30, 11	tember 30, 2010	Sep	tember 30, 2009
Beginning balance	\$ 86	\$ 91	\$	147
Warranty provision	107	11		12
Usage	(104)	(16)		(68)
Ending balance	\$ 89	\$ 86	\$	91

The warranty costs above include long-term warranty obligations of \$13,000, \$15,000 and \$23,000 for the years ended December 31, 2011, 2010 and 2009, 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.

### (n) Advertising Costs

The Company expenses advertising costs as incurred. Advertising expense for the years ended December 31, 2011, 2010 and 2009 was approximately \$938,000, \$666,000 and \$724,000 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.

Notes to Consolidated Financial Statements (continued)

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

	Sep	tember 30, 2011	S	eptember 30, 2010	Se	ptember 30, 2009
Net loss available to common shareholders	\$	(37,587)	\$	(6,224)	\$	(1,968)
Basic shares used in the calculation of earnings per share		54,548		45,828		45,512
Effect of dilutive securities:						
Stock options						
Restricted stock						
Diluted shares used in the calculation of earnings per share		54,548		45,828		45,512
Net loss per share :						
Basic	\$	(0.69)	\$	(0.14)	\$	(0.04)
Diluted	\$	(0.69)	\$	(0.14)	\$	(0.04)

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

	September 30,	September 30,	September 30,
	2011	2010	2009
Common stock options	5,403,611	5,293,524	5,159,122

The calculation of basic loss per share for 2011, 2010 and 2009 does not include 613,976, 766,075 and 592,155 shares, respectively, of restricted common stock issued to executive officers and employees of the Company as they are subject to time-based vesting. These potential shares were excluded from the computation of basic loss per share as these shares are not considered outstanding until vested.

#### (p) Income Taxes

The Company follows the liability method under ASC Topic 740, Income Taxes , (ASC 740). The primary objectives of accounting for taxes under ASC 740 are to (a) recognize the amount of tax payable for the current year and (b) recognize the amount of deferred tax liability or asset for the future tax consequences of events that have been reflected in the Company s financial statements or tax returns. The Company has provided a full valuation allowance against its deferred tax assets at December 31, 2011 and 2010, 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.

Notes to Consolidated Financial Statements (continued)

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 assumed in connection with a business combination are initially estimated as of the acquisition date and the Company evaluates 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 changes to these uncertain tax positions may affect the provision for income taxes presented in the Company s statement of operations.

#### (q) 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, restricted stock and/or options to purchase common stock at an option price equal to the market value of the stock at the date 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 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. Application of alternative assumptions could produce significantly different estimates of the fair value of stock-based compensation and consequently, the related amounts recognized in the Consolidated Statements of Operations.

#### (r) Fair Value Measurements

On January 1, 2008, the Company adopted 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

Notes to Consolidated Financial Statements (continued)

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 and an indemnification asset resulting from the acquisition of Xoft completed on December 30, 2010. The Company s liabilities that are measured at fair value on a recurring basis relate to contingent consideration resulting from the acquisition of Xoft.

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. The fair value measurement for the indemnification asset is based on the value of the underlying iCAD stock and the cash in escrow. The fair value is considered a level 1 input as the stock price is a quoted price in an active market. The indemnification asset was recorded as a retrospective measurement period adjustment, as a result of the settlement of the litigation with Carl Zeiss Meditec, Inc and Carl Zeiss Surgical, GmbH.

The fair value measurement for the contingent consideration liability is valued using Level 3 inputs. The Company recorded a contingent consideration liability of \$5.0 million based upon the estimated fair value of the additional earn-out potential for the sellers that is tied to cumulative net revenue of Xoft products from January 1, 2011 through December 31, 2013, payable January, 2014. During the quarter ended March 31, 2011, the Company recorded a measurement period adjustment of \$100,000 and reduced the value of the contingent consideration to \$4.9 million. The Company determines the fair value of the contingent consideration liability based on a probability-weighted approach derived from earn-out criteria estimates and a probability assessment with respect to the likelihood of achieving the various earnout criteria. Accordingly, the value of contingent consideration is evaluated each quarter. During the quarter ended June 30,

Notes to Consolidated Financial Statements (continued)

2011, the Company reduced the value of contingent consideration to \$3.8 million as a result of lower expectations of Xoft product revenue. In the quarter ended September 30, 2011, the Company evaluated the revenue expectations of Xoft products and determined that the thresholds were unlikely to be met, and therefore reduced the value of the contingent consideration to \$0.0 million. The measurement is based upon significant inputs not observable in the market. Subsequent changes in the value of this liability will be recorded in the statement of operations.

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

	s	eptember 30, Fair value Level 1		eptember 30, S urements using: (000 Level 2		September 30, l, 2011 Total
Assets						
Money market accounts Indemnification asset	\$	4,452	\$	\$		4,452
Total Assets					\$	
	\$	4,452	\$	\$		4,452
Liabilities						
Contingent Consideration	\$		\$	\$	\$	
		value m	easur	Fair ements using: (000 s) Level 2	as of December 31, 2	2010 Total
Assets						
Money market accounts Indemnification asset	\$	15,151 1,283	\$	\$	\$	15,151 1,283
Total Assets	\$	16,434	\$	\$	\$	16,434
Liabilities Continuent Consideration	¢		¢	¢	5,000 P	5,000
Contingent Consideration	\$		\$	\$	5,000 \$	5,000

Notes to Consolidated Financial Statements (continued)

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

	•	ember 30, mount
Balance as of December 31, 2009	\$	
Contingent consideration liability established at acquistion		5,000
Balance as of December 31, 2010		5,000
Measurement period adjustment		(100)
Mark to market		(4,900)
Balance as of December 31, 2011	\$	

As noted above, the Company recorded an additional \$4.9 million reduction in the fair value of the contingent consideration as a gain in the consolidated statement of operations during the year ended December 31, 2011.

Items Measured at Fair Value on a Nonrecurring Basis

Certain assets, including our goodwill, are measured at fair value on a nonrecurring basis. These assets are recognized at fair value when they are deemed to be impaired. We recorded an estimated impairment charge for goodwill of \$26.8 million during the year ended December 31, 2011. We did not consider any other assets to be impaired during the twelve months ended December 31, 2011.

Notes to Consolidated Financial Statements (continued)

#### (s) Recently Issued Accounting Standards

In May 2011, the FASB issued Accounting Standards Update No. 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (Topic 820) Fair Value Measurement (ASU 2011-04), to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for level 3 fair value measurements. ASU 2011-04 is effective for fiscal years and interim periods within those years, beginning after December 15, 2011. The Company does not expect the adoption to have a material impact on its financial statements.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05). ASU 2011-05 increases the prominence of other comprehensive income in financial statements. Under ASU 2011-05, companies will have the option to present the components of net income and comprehensive income in either one or two consecutive financial statements. ASU 2011-05 eliminates the option to present other comprehensive income in the statement of changes in equity and is applied retrospectively. For public companies, ASU 2011-05 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company does not expect the adoption to have a material impact on its financial statements.

In December 2011, the FASB issued Accounting Standards Update No. 2011-12: Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 ("ASU 2011-12"). The Update defers the specific requirement to present items that are reclassified from accumulated other comprehensive income to net income separately with their respective components of net income and other comprehensive income. As part of this update, the FASB did not defer the requirement to report comprehensive income either in a single continuous statement or in two separate but consecutive financial statements. ASU 2011-12 is effective for annual periods beginning after December 15, 2011.

In September 2011, the FASB issued Accounting Standards Update No. 2011-08, Intangibles Goodwill and Other (Topic 350) Testing Goodwill for Impairment (ASU 2011-08), to allow entities to use a qualitative approach to test goodwill for impairment. ASU 2011-08 permits an entity to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, it is necessary to perform the currently prescribed two-step goodwill impairment test. Otherwise, the two-step goodwill impairment test is not required. ASU 2011-08 is effective for fiscal years beginning after December 15, 2011, however early adoption is permitted. The Company does not expect this to have a material impact on its financial statements.

Notes to Consolidated Financial Statements (continued)

#### (2) Acquisition of Xoft

On December 30, 2010, the Company completed its acquisition of Xoft, a privately held company based in California. Xoft designs, develops, manufactures, markets and sells electronic brachytherapy (eBx) products for the treatment of breast and other cancers, used in a broad range of clinical settings. The acquisition was made pursuant to an Agreement and Plan of Merger dated December 15, 2010, by and between the Company, XAC, Inc., a wholly-owned subsidiary of the Company ( Merger Sub ), Xoft and Jeffrey Bird as the representative of the stockholders of Xoft ( Merger Agreement ). Upon the closing, Xoft was merged with and into the Merger Sub with the Merger Sub surviving the merger (the Merger ).

The Company acquired 100% of the outstanding stock of Xoft in exchange for 8,348,501 shares of the Company s common stock and approximately \$1.2 million in cash, for a total consideration at closing of approximately \$12.9 million based on a per share value of \$1.40, the closing price of the Company s common stock on the closing date. The Company also paid certain transaction expenses of Xoft totaling approximately \$1.0 million which were accrued as of December 31, 2010 and paid in January 2011.

The Company deemed the 8,348,501 shares of common stock issuable to the former stockholders of Xoft, Inc pursuant to the Merger Agreement to be issued and outstanding as of December 31, 2010 for accounting purposes, although none of these shares were issued by the Company s transfer agent until 2011.

Under the Merger Agreement, there is an additional earn-out potential for the sellers that is tied to cumulative net revenue of Xoft products over the three years from the closing, payable at the end of that period. The threshold for earn-out consideration begins at \$50,000,000 of cumulative revenue of Xoft Products (as defined in the Merger Agreement) over the three year period immediately following the closing. The targeted earn-out consideration of \$20,000,000 will occur at \$76,000,000 of cumulative revenue of Xoft Products and the maximum earn-out consideration of \$40,000,000 would be achieved at \$104,000,000 of cumulative revenue of Xoft Products over the three year period.

At closing, 10% of the cash amount and 10% of the amount of the Company s common stock comprising the merger consideration was placed in escrow. The escrow was to remain for a period of 15 months following the closing of the merger to Secure post closing indemnification obligations of Xoft Stockholders.

On December 22, 2011, the Company agreed to settle an outstanding litigation with Carl Zeiss Meditec Inc. and Carl Zeiss Surgical GmbH, which was partially indemnified under the Xoft Merger Agreement.

Notes to Consolidated Financial Statements (continued)

In connection with the settlement of the outstanding litigation the Company determined the settlement was a measurement period adjustment recorded, retrospectively, approximately \$1.6 million as the fair value of the settlement liability, an indemnification asset of approximately \$1.3 million as a purchase price adjustment to reflect the value of the escrow shares and cash as of the date of acquisition and approximately \$0.3 million of additional goodwill. The fair value of the indemnification asset was recorded based on the value of the underlying stock at the date of acquisition. Subsequent changes in the value of the stock and the fair value of the indemnification asset were recorded as a loss on the asset of approximately \$0.7 million in the consolidated statement of operations through the settlement on December 22, 2011. The indemnification asset was extinguished upon recovery of the cash and escrow shares on December 23, 2011, and the shares were recorded to treasury stock.

The purchase price of \$17.8 million, which includes \$12.9 million of merger consideration and \$4.9 million of contingent consideration, has been allocated to net assets acquired based upon the estimated fair value of those assets. As discussed in Note 1(r), the Company has determined that the fair value of the contingent consideration is \$0.0 million, as of December 31, 2011. The change in fair value of approximately \$4.9 million has been included in the consolidated statement of operations for the twelve months ended December 31, 2011.

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 (amounts in thousands):

	•	tember 30, mount	September 30, Estimated Amortizable Life
Current assets	\$	5,313	
Property and equipment		1,951	3 7 Years
Identifiable intangible assets		13,700	15 Years
Patent license		100	6 Years
Other assets		643	
Goodwill		4,422	
Current liabilities		(5,196)	
Long-term liabilities		(3,154)	
Purchase price	\$	17,779	

The goodwill of \$4.4 million is not deductible for income tax purposes.

Notes to Consolidated Financial Statements (continued)

The Company s Consolidated Statement of Operations does not include the financial results of Xoft for the periods ended December 31, 2010 and 2009.

The unaudited proforma operating results for the Company, assuming the acquisition of Xoft occurred as of January 1, 2009 are as follows:

	Sep	tember 30,	Sep	tember 30,
Year ended December 31,		2010		2009 .
Revenue	\$	30,298	\$	34,016
Loss from operations	\$	(16,104)		(22,213)
Net loss	\$	(16,325)		(22,942)
Net loss per share:				
Basic and diluted	\$	(0.30)	\$	(0.43)

On February 3, 2011, the Company in cooperation with the FDA, voluntarily recalled its Axxent Flexishield Mini acquired as part of its acquisition of Xoft in December 2010. The voluntary recall was prompted after the Company was notified in January 2011 of the presence of microscopic particles found in certain patients—breasts during post-surgery follow up imaging exams, which were later determined to be tungsten and alleged to be originating from the Axxent Flexishield Mini, an optional accessory device to the Company s Axxent Electronic Brachytherapy system. On June 9' 2011, the Company received notification from the FDA that the recall was complete and that the FDA considered the recall terminated at that time. The Company expensed approximately \$128,000 for the year ended December 31, 2011 in connection with the recall.

As discussed in Note 8(e) to the Consolidated Financial Statements, the Company is a defendant in multiple suits brought in Orange County Superior Court by plaintiffs who allege personal injury resulting from gross negligence and product liability relating to their treatment with the Axxent Electronic Brachytherapy System that incorporated the Axxent Flexishield Mini.

Notes to Consolidated Financial Statements (continued)

The Company believes that all of the Jane Doe plaintiffs were part of the group of 29 patients treated using the Axxent Flexishield Mini as part of a clinical trial. The Axxent Flexishield Mini was the subject of a voluntary recall. Because of the preliminary nature of the complaints, the Company is unable to evaluate the merits of the claims; however, based upon its preliminary analysis, it plans to vigorously defend the lawsuits. Accordingly, since the amount of the potential damages in the event of an adverse result is not reasonably estimable, no expense or purchase price adjustment has been recorded with respect to the contingent liability associated with this matter.

#### (3) Financing Arrangements

On December 29, 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. Pursuant to the terms of a Facility Agreement, dated as of December 29, 2011 (the Facility Agreement ), on January 9, 2012 (the Funding Date ), the Company issued to Deerfield promissory notes in the aggregate principal amount of \$15 million (the Notes ). Under a Revenue Purchase Agreement, dated as of December 29, 2011 (the Revenue Purchase Agreement ), the Company agreed to pay Deerfield a portion of the Company s revenues until the maturity date of the Notes, whether or not the Notes are outstanding through that date. On the Funding Date, the Company issued to Deerfield (i) six-year warrants to purchase up to 2,250,000 shares of common stock at an exercise price of \$0.70 per share and (ii) a second Warrant (the B Warrant ) to purchase an additional 500,000 shares of common stock at a exercise price of \$0.70 per share, which may become exercisable if certain conditions are met, as described below. Collectively, these transactions are referred to as the Transactions. In January, 2012, the Company received net proceeds of \$14,325,000 from the Transactions, representing \$15,000,000 of gross proceeds, less a \$225,000 facility fee and a \$450,000 finders fee before deducting other expenses of the Transactions.

Notes to Consolidated Financial Statements (continued)

#### **Facility Agreement**

Under the terms of the Facility Agreement, the Company issued the Notes in the aggregate principal amount of \$15 million. The Notes bear interest at an annual rate of 5.75%. The maturity date of the Notes is the fifth anniversary of the date of the Facility Agreement, unless the Company notifies the lenders prior to the fourth anniversary of the date of the Facility Agreement that the Company would like to extend the maturity date for another year, in which case the maturity date will be the sixth anniversary of the date of the Facility Agreement. The Company must pay 25% of the original principal amount of the Notes on each of the third and fourth anniversaries of the date of the Facility Agreement and 50% of such principal amount on the fifth anniversary of the date of the Facility Agreement. If, however, the final payment date is extended to the sixth anniversary of the date of the Facility Agreement, then the Company must pay 25% of the principal amount on each of the fifth and sixth anniversaries of the date of the Facility Agreement. There is no penalty for prepayment and the Notes are due on the earlier of the final payment date or an event of default. Deerfield has the option to require the Company to repay the Notes if the Company completes a major transaction, which includes, but is not limited to, a merger or sale of the Company.

#### **Security Agreement**

In connection with the Facility Agreement, on the Funding Date, Deerfield and each of the Company and Xoft,, a wholly owned subsidiary of the Company, entered into Security Agreements on the Funding Date (the Security Agreements), pursuant to which each of the Company and Xoft has granted to Deerfield a security interest in substantially all of their respective assets, including their respective intellectual property, accounts, receivables, equipment, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing.

#### **Revenue Purchase Agreement**

In connection with the Facility Agreement, the Company entered into a Revenue Purchase Agreement with Deerfield Private Design Fund II, L.P. and Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL (these entities collectively referred to as the Purchasers). Pursuant to the Revenue Purchase Agreement, the Purchasers will pay to the Company \$4,107,900 in exchange for the Purchasers right to receive a percentage of the Company s revenues. For the first three quarters of each fiscal year during the term of the Revenue Purchase Agreement, the Company must pay to the Purchasers the greater of the applicable percentage of revenues for such quarter and the applicable quarterly minimum, which is \$125,000 per quarter. In the final quarter of each calendar year during the term of the Revenue Purchase Agreement, the Company must pay to the Purchasers the amount equal to the difference between the greater of the applicable percentage of revenues for the applicable calendar year and the applicable annual minimum of \$500,000 minus the aggregate revenue participation payments the Company made for the first three quarters of the applicable year. If the Company extends the maturity date of the Facility Agreement, then the Company must pay the Purchasers the

Notes to Consolidated Financial Statements (continued)

revenue payments through 2017. The applicable percentage for the calendar years 2012, 2013 and 2014 are 4.25% of revenues up to \$25 million in annual revenues for the calendar year, 2.75% of revenues from \$25 million in annual revenues up to \$50 million in annual revenues for such calendar year and 1.0% of revenues in excess of \$50 million in annual revenues for such calendar year. The applicable percentage for the calendar years 2015, 2016, and, if applicable, 2017, are 4.25% of revenues up to \$25 million in annual revenues for such calendar year, 2.25% of revenues from \$25 million up to \$50 million in annual revenues for such calendar year and 1.0% of revenues in excess of \$50 million in annual revenues for such calendar year. Additionally, if the Company sells assets in excess of \$500,000 in the aggregate during the term of the Revenue Purchase Agreement, the proceeds of which are not recorded as revenue in accordance with generally accepted accounting principles, the Company must pay the Purchasers certain percentages of the gross proceeds of any such asset sale. The percentage of any such payment varies with the total amount of the gross proceeds and when the asset sale takes place.

#### Warrant to Purchase Common Stock and Registration Rights Agreement

In connection with the Transactions, on the Funding Date, the Company issued to Deerfield six-year warrants to purchase an aggregate of 2,750,000 shares of common stock at an exercise price of \$0.70 per share (the Warrants ). On the Funding Date, the Warrants to purchase 2.250,000 shares of the Company s common stock became immediately exercisable. If the Company extends the maturity date of the Facility Agreement, the 500,000 shares of common stock underlying the B Warrants will become exercisable. The B Warrants will become exercisable on the first business day following the four year anniversary of the date of the Facility Agreement. The B Warrants shall otherwise have the same terms, including exercise price and expiration date, as the Warrants. The exercise price may be paid, at the election of the holder, in cash, by a reduction of the principal amount of the holder s Note outstanding under the Facility Agreement or, pursuant to certain cashless exercise provisions. If the Company declares and pays dividends or makes other distributions to the holders of its common stock, the holders of the Warrants are entitled to receive the dividends or distributions as if the holders had exercised the Warrants and held common stock. All Warrants issued under the Facility Agreement expire on the six year anniversary of the Funding Date and contain certain limitations that prevent the holder from acquiring shares upon exercise of a Warrant that would result in the number of shares beneficially owned by it to exceed 9.985% of the total number of shares of the Company s common stock then issued and outstanding. Upon certain change of control transactions, or upon certain events of default (as defined in the Warrants), each holder has the right to net exercise the Warrants for an amount of shares of the Company s common stock equal to the Black-Scholes value of the shares issuable under the terms of the Warrants divided by 95% of the closing price of the Company s common stock on the day immediately prior to the consummation of such change of control or event of default, as applicable. In certain circumstances where a Warrant or portion of a Warrant is not net exercised in connection with a change of control or event of default, the holder will be paid an amount in cash equal to the Black-Scholes value of such portion of the Warrant not treated as a net exercise.

Notes to Consolidated Financial Statements (continued)

In connection with the Transactions, the Company entered into a registration rights agreement with Deerfield, pursuant to which the Company agreed to register for resale all of the shares issuable under the Warrants upon exercise or otherwise, including the B Warrants. The Company is required to use its commercially reasonable best efforts to have the registration statement declared effective as soon as practicable (but in no event later than sixty (60) days after the Funding Date). The Company completed the registration statement and it was declared effective on January 20, 2012.

The Company is required to file additional registration statements to register the resale of any shares underlying warrants which are not included in the registration statement. The Company s registration obligations terminate on the earlier of (i) the date on which all of the shares of common stock covered by an applicable registration statement have been sold and (ii) the date on which all of such shares (in the opinion of counsel to Deerfield) may be immediately sold to the public (other than pursuant to a Cash Exercise (as defined in the Warrants)) without registration or restriction (including without limitation as to volume by each holder thereof) under the Securities Act.

The maximum number of shares of common stock the Company may issue under the Transactions may not exceed 19.9% of the Company soutstanding stock immediately prior to the Transactions.

The sale of the Warrants was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended (the Securities Act). The Warrants and the securities to be issued upon exercise of the Warrants have not been registered under the Securities Act or state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements.

#### (4) Accrued Expenses

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

	September 30, 2011	Se	ptember 30, 2010
Accrued salary and related expenses	\$ 2,249	\$	2,446
Accrued accounts payable	1,001		2,218
Accrued professional fees	357		449
Accrued short term settlement costs	1,241		237
Other accrued expenses	302		171
	\$ 5.150	\$	5,521

Notes to Consolidated Financial Statements (continued)

# (5) Stockholders Equity(a) Stock Options

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

#### The 2001 Stock Option Plan ( The 2001 Plan ).

The 2001 Plan was adopted by the Company's stockholders in August 2001. The 2001 Plan provides for the granting of non-qualifying and incentive stock options to employees and other persons to purchase up to an aggregate of 1,200,000 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 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 2001 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 shall expire not later than five years after the date of grant. Non-qualifying options granted under the 2001 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, 2011, there are no further options available for grant under this plan.

#### 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 500,000 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, 2011, there were 38,999 options available for issuance under the 2002 Plan.

Notes to Consolidated Financial Statements (continued)

#### 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 1,000,000 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, 2011 there were 26,561 shares available for issuance 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 600,000 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, 2011, there were 262.140 shares available for issuance under the 2005 Plan.

Notes to Consolidated Financial Statements (continued)

#### The 2007 Stock Incentive Plan ( The 2007 Plan ).

The 2007 Plan was adopted by the Company s stockholders in July 2007 and amended in June 2009. The 2007 Plan provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. Awards may be granted singly, in combination, or in tandem. Subject to anti-dilution adjustments as provided in the 2007 Plan, (i) the 2007 Plan provides for a total of 5,250,000 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 800,000 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, 2011, there were 534,874 shares available for issuance under the 2007 Plan.

Notes to Consolidated Financial Statements (continued)

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

	September 30, Option Shares	September 30, Price range per share	Ŵ	ember 30, eighted verage
Outstanding, January 1, 2009	5,158,726	\$0.80-\$5.28	\$	2.55
Granted	291,896	\$0.86-\$2.03	\$	1.32
Exercised	(80,249)	\$0.80-\$1.45	\$	0.85
Forfeited	(211,251)	\$0.81-\$4.88	\$	2.84
Outstanding, December 31, 2009	5,159,122	\$0.80-\$5.28	\$	2.50
Granted	321,902	\$1.40-\$1.95	\$	1.56
Exercised			\$	0.00
Forfeited	(187,500)	\$1.50-\$4.88	\$	2.27
Outstanding, December 31, 2010	5,293,524	\$0.80-\$5.28	\$	2.45
Granted	3,156,783	\$0.55-\$1.42	\$	1.07
Exercised	(75,000)	\$0.80	\$	0.80
Forfeited	(2,971,696)	\$0.60-\$4.88	\$	1.92
Outstanding, December 31, 2011	5,403,611	\$0.55-\$5.28	\$	1.95

	September 30,	September 30,	September 30,
Exercisable at	Option	Price range per	Weighted average
year-end	Shares	share	exercise price
2009	4,631,324	\$0.80-\$5.28	\$ 2.42
2010	5,092,379	\$0.80-\$5.28	\$ 2.47
2011	3,398,580	\$0.56-\$5.28	\$ 2.48

Available for future grants at December 31, 2011 from all plans: 862,574

The weighted-average remaining contractual life of stock options outstanding for all plans at December 31, 2011 was 1.23 years.

The Company s stock-based compensation expense by categories is as follows (amounts in thousands):

	September 30, September Years Ended De		ptember 30, ded December	cember 31,		
	2	011		2010		2009
Cost of revenue	\$	14	\$	14	\$	43
Engineering and product development		172		138		250
Marketing and sales		224		367		327
General and administrative expense		494		997		1,374
	\$	904	\$	1,516	\$	1,994

Notes to Consolidated Financial Statements (continued)

As of December 31, 2011, there was \$1.5 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 1.23 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:

	September 30,	September 30,	September 30,			
	Yea	Years Ended December 31,				
	2011	2011 2010				
Average risk-free interest rate	2.51%	1.94%	2.03%			
Expected dividend yield	None	None	None			
Expected life	3.5 years	3.5 years	3.5 years			
Expected volatility	67.0% to 69.3%	69.4%	63.5%			
Weighted average exercise price	\$ 1.07	\$ 1.56	\$ 1.32			
Weighted average fair value	\$ 0.53	\$ 0.66	\$ 0.49			

The Company s 2011, 2010 and 2009, 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 aggregate intrinsic value of options outstanding at December 31, 2011, 2010 and 2009 was \$2,050, \$91,523 and \$145,798, respectively. The aggregate intrinsic value of the options exercisable at December 31, 2011, 2010 and 2009 was \$250, \$85,790 and \$132,799, respectively. The aggregate intrinsic value of stock options exercised during 2011, 2010 and 2009 was \$24,088, \$0 and \$53,484, respectively. The Company used the market price of \$0.57, \$1.35 and \$1.52 per share at December 31, 2011, 2010 and 2009, respectively, to determine the aggregate intrinsic values.

#### (b) Restricted Stock

The Company s restricted stock awards vest in three equal annual installments with the first installment vesting one year from grant date. At December 31, 2011, there were 613,976 unvested restricted stock awards outstanding. A summary of restricted stock activity for all stock option plans is as follows:

## **Restricted Stock**

	September 30, Year	September 30, rs Ended December	September 30, 31,
	2011	2010	2009
Beginning outstanding balance	766,075	592,155	814,753
Granted	310,000	540,500	100,000
Vested	(295,763)	(288,510)	(292,147)
Forfeited	(166,336)	(78,070)	(30,451)
		, , ,	
Ending outstanding balance	613,976	766,075	592,155

Notes to Consolidated Financial Statements (continued)

The aggregate intrinsic value of restricted stock outstanding at December 31, 2011, 2010 and 2009 was \$349,966, \$1,034,201, and \$900,076, respectively. The aggregate intrinsic value of restricted stock vested during 2011, 2010 and 2009 was \$168,585, \$389,489 and \$444,063, respectively. The Company used the market price of \$0.57, \$1.35 and \$1.52 per share at December 31, 2011, 2010 and 2009, respectively, to determine the aggregate intrinsic values.

#### (6) Income Taxes

The significant components of income tax expense for the years ended December 31, 2011, 2010 and 2009 are as follows:

	September 30, 2011	September 30, 2010	Sep	otember 30, 2009
Current provision (benefit):				
Federal	\$	\$	\$	(55,968)
State				12,398
	\$	\$	\$	(43,570)

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, 2011, 2010 and 2009 is as follows:

	September 30, 2011	September 30, 2010	September 30, 2009
Federal statutory rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit	1.8%	0.0%	(0.4%)
Net state impact of deferred rate change	0.2%		
Stock compensation expense	(0.4%)		
Goodwill impairment	(24.3%)		
Contingent consideration	4.4%		
Other permanent differences	(0.5%)	3.2%	3.8%
Change in valuation allowance	(15.6%)	(37.3%)	(27.8%)
Other	0.4%	0.1%	(7.5%)
Effective income tax	0.0%	0.0%	2.2%

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 comprised of the following at December 31 (in thousands):

Notes to Consolidated Financial Statements (continued)

	September 30, 2011		September 30, 2010	
Inventory (Section 263A)	\$	320	\$	314
Inventory reserves		262		288
Receivable reserves		77		51
Other accruals		2,525		1,353
Deferred revenue		205		562
Accumulated depreciation/amortization		138		(22)
Stock options		1,646		1,625
Developed technology		(4,268)		(5,680)
Tax credits		1,297		1,170
NOL carryforward		31,786		30,475
Net deferred tax assets		33,986		30,136
Valuation allowance		(33,986)		(30,136)
	\$		\$	

The valuation allowance as of December 31, 2011 and 2010 totaled approximately \$33,986 and \$30,136 respectively. The increase in net deferred tax asset and corresponding valuation allowance is primarily attributable to the additional net operating losses created in the current year.

As of December 31, 2011, the Company has net operating loss carryforwards totaling approximately \$89 million expiring between 2016 and 2031. A portion of the total net operating loss carryforwards amounting to approximately \$9.5 million relate to the acquisition of Xoft, Inc. As of December 31, 2011, 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, 2010 and December 31, 2011.

The Company currently has approximately \$18 million (including approximately \$9 million that relate to Xoft, Inc.) in net operating losses that are subject to limitations, of which approximately \$2 million (including approximately \$473,000 that relate to Xoft, Inc.) can be used annually through 2031. 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 \$1.3 million. The amount of tax credits available for utilization may be subject to limitations based upon changes in ownership of the Company. The credits expire in various years through 2031.

Notes to Consolidated Financial Statements (continued)

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, 2011 and 2010, 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, 2011, 2010 and 2009. The Company files United States federal and various state income tax returns. Generally, the Company s three preceding tax years remain subject to examination by federal and state taxing authorities. The Company completed an examination by the Internal Revenue Service with respect to the 2008 tax year in January 2011, which resulted in no changes to the tax return originally filed. The Company is not under examination by any other federal or state jurisdiction for any tax year.

The Company does not anticipate that it is reasonably possible that unrecognized tax benefits as of December 31, 2011 will significantly change within the next 12 months.

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

## (a) Segment Reporting

The Company follows FASB ASC 280-10, Segment Reporting , which establishes standards for reporting information about operating segments. Operating segments are defined as components of a company about which the chief operating decision maker evaluates regularly in deciding how to allocate resources and in assessing performance. The Company s chief operating decision maker is the Chief Executive Officer. The Company operates in one segment and as one reporting unit for all years presented since operations are supported by one central staff and the results of operations are evaluated as one business unit.

#### (b) Geographic Information

The Company's sales are made to distributors and dealers of mammography and other medical equipment, and to foreign distributors of mammography medical equipment. Total export sales were approximately \$1.8 million or 6% of sales in 2011 as compared to \$4.0 million or 16% of total sales in 2010 and \$3.7 million or 13% of total sales in 2009.

As of December 31, 2011 and 2010, the Company had outstanding receivables of \$0.1 million and \$1.1 million, respectively, from distributors of its products who are located outside of the U.S.

Notes to Consolidated Financial Statements (continued)

#### (c) Major Customers

The Company s two major customers over the past three years were GE Healthcare and Fuji Medical Systems. GE Healthcare accounted for \$6.8 million in 2011, \$9.3 million in 2010 and \$8.8 million in 2009 or 24%, 38%, and 31% of the Company s revenues, respectively, with accounts receivable balances of \$0.2 and \$0.7 million at December 31, 2011 and 2010, respectively. Fuji Medical Systems accounted for \$3.2 million in 2011, \$3.1 million in 2010 and \$4.8 million in 2009 or 11%, 13% and 17% of the Company s revenues, respectively, with accounts receivable balances of \$0.2 million at both December 31, 2011 and 2010.

#### (8) Commitments and Contingencies

#### (a) Lease Obligations

As of December 31, 2010, the Company had four 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 office space located in Fairborn Ohio. The Ohio Lease provides for a three (3) year and three (3) month term, which commenced on January 1, 2011 for approximately \$43,650 per year, with all amounts payable in equal monthly installments. The Ohio Lease provides the Company with the option to renew the lease for an additional three (3) year period. The monthly payments for the renewal term, if any, will be substantially similar to the payments referred to above.

As a result of its acquisition of Xoft on December 30, 2010, the Company leases a facility and certain office equipment under a noncancelable operating lease which expires in January and February 2013, respectively. The facility has office, manufacturing and warehousing space located in Sunnyvale, CA. The operating lease provides for annual minimum lease payment of \$885,000 in 2012 and \$76,000 in 2013 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. Given local market conditions the Sunnyvale lease is at a rate above market rate. The Company has a liability recorded of approximately \$402,000 as of December 31, 2011 to reflect the off-market value of the rent.

Notes to Consolidated Financial Statements (continued)

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.

Rent expense for all leases for the years ended December 31, 2011, 2010 and 2009 was \$957,000, \$656,000 and \$718,000, net of sublease income of \$0, \$200,046, and \$197,594, respectively.

Future minimum rental payments due under these agreements as of December 31, 2011 are as follows (in thousands):

Fiscal Year	S	September 30, Operating Leases	
2012	\$	1,143	
2013		315	
2014		204	
2015		199	
2016		204	
	\$	2,065	

## (b) 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 and for all other executives a period of one year from the date of termination plus the pro rata portion of any annual bonus earned in any employment year through the date of termination.

## (c) 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

Notes to Consolidated Financial Statements (continued)

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 no accrual was recorded as of December 31, 2011.

#### (d) Royalty Obligation

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, Inc.( 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 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 six 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 \$1,047,000.

On December 22, 2011, the Company agreed to a settlement related to the litigation with Carl Zeiss Meditec Inc. and Carl Zeiss Surgical GmbH. 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 was estimated at approximately \$1.6 million and \$1.8 million as of December 31, 2010 and 2011, respectively. The Company is obligated to pay \$1.0 million in payments throughout 2012, and an additional \$0.5 million in June 2013, \$0.5 million in June 2015 and \$0.5 million in June 2017, for a total of \$2.5 million.

## (e) Litigation

On February 18, 2011, in the Orange County Superior Court (Docket No. 30-2011-00451816-CU-PL-CXC), named plaintiffs Jane Doe and John Doe filed a complaint against Xoft, the Company, and Hoag Memorial Hospital Presbyterian asserting causes of action for general negligence, breach of warranty, and strict liability and seeking unlimited damages in excess of \$25,000. On March 2, 2011, the Company received a Statement of Damages—specifying that the damages being sought aggregated an amount of at least approximately \$14.5 million. On April 6, 2011, plaintiffs Jane Doe and John Doe amended their complaint alleging only medical malpractice against Hoag Memorial Hospital Presbyterian. On April 8, 2011, another complaint was filed in the Orange County Superior Court (Docket No. 30-2011-00465448-CU-MM-CXC) on behalf of four additional Jane Doe plaintiffs and two John Doe spouses with identical allegations against the same defendants. One John Doe spouse from this group of plaintiffs was later

Notes to Consolidated Financial Statements (continued)

dismissed on August 18, 2011. On April 19, 2011, a sixth Jane Doe plaintiff filed an identical complaint in the Orange County Superior Court (Docket No. 30-2011-00468687-CU-MM-CXC), and on May 4, 2011, a seventh Jane Doe plaintiff and John Doe spouse filed another complaint in the Orange County Superior Court (Docket No. 30-2011-00473120-CU-PO-CXC), again with identical allegations against the same defendants. On July 12, 2011, an eighth Jane Doe plaintiff and John Doe spouse filed a complaint in the Orange County Superior Court (Docket No. 30-2011-00491068-CU-PL-CXC), and on July 14, 2011, a ninth Jane Doe plaintiff and John Doe spouse filed another complaint in the Orange County Superior Court (Docket No. 30-2011-00491497-CU-PL-CXC), each with identical allegations as the previously filed complaints. On August 18, 2011, these two groups of Jane Doe plaintiffs and John Doe spouses amended their complaints to correct certain deficiencies. Additionally on August 18, 2011, a tenth Jane Doe plaintiff and two additional John Doe spouses filed a complaint in the Orange County Superior Court (Docket No. 30-2011-501448-CU-PL-CXC), again with identical allegations against the same defendants. On January 18, 2012, three additional Jane Doe plaintiffs and one additional John Doe spouse filed a complaint in the Orange County Superior Court (Docket No. 30-2012-00538423-CU-PL-CXC) with identical allegations against the same defendants.

It is alleged that each plaintiff Jane Doe was a patient who was treated with the Axxent Electronic Brachytherapy System that incorporated the Axxent Flexishield Mini. The Company believes that all of the Jane Doe plaintiffs were part of the group of 29 patients treated using the Axxent Flexishield Mini as part of a clinical trial. The Axxent Flexishield Mini is the subject of a voluntary recall. Because of the preliminary nature of this complaint, the Company is unable to evaluate the merits of the claims; however, based upon its preliminary analysis, we plan to vigorously defend the lawsuits. Accordingly, since the amount of the potential damages in the event of an adverse result is not reasonably estimable, no expense or purchase price adjustment has been recorded with respect to the contingent liability associated with this matter.

Notes to Consolidated Financial Statements (continued)

#### 9) Quarterly Financial Data (unaudited in thousands, except per share data)

	September 30,  Net sales		September 30,  Gross profit		September 30,  Net		September 30, Loss per share available to to common stockholders		September 30,  Weighted average number of shares outstanding	
<u>2011</u>										
First quarter	\$	7,344	\$	5,132	\$	(4,312)	\$	(0.08)	54,366	
Second quarter		6,646		4,503		(5,411)	\$	(0.10)	54,550	
Third quarter		8,052		5,889		(25,637)	\$	(0.47)	54,681	
Fourth quarter		6,610		4,503		(2,227)	\$	(0.04)	54,591	
<u>2010</u>										
First quarter	\$	6,520	\$	5,238	\$	(1,185)	\$	(0.03)	45,686	
Second quarter		6,097		4,950		(735)	\$	(0.02)	45,737	
Third quarter		5,587		4,456		(1,392)	\$	(0.03)	45,922	
Fourth quarter		6,371		5,049		(2,912)	\$	(0.06)	45,962	

Quarterly results for the first, second and third quarters of 2011 do not agree with the Company's Form 10Q's as filed due to retrospective adjustments related to the settlement of litigation with Carl Zeiss, Meditec, Inc and Carl Zeiss Surgical, GmbH., as described in Note 2. The impact of the retrospective adjustments increased net loss by \$111,000, \$318,000 and \$654,000 for the quarters ended March 31, June 30, and September 30, 2011, respectively. The quarterly adjustments are due to approximately \$78,000 of additional goodwill impairment recorded during the quarter ended September 30, 2011, a loss of \$43,000, \$250,000, and \$508,000, for the quarters ended March 31, June 30, and September 30, 2011, respectively, related to losses on the indemnification asset, and \$68,000, for each of the quarters ended March 31, June 30, and September 30, 2011, respectively, related to the accretion of the settlement obligation.