

ICAD INC  
Form 10-K  
February 27, 2013  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2012

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 1-9341

**iCAD, INC.**

(Exact name of registrant as specified in its charter)

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

**02-0377419**  
(I.R.S. Employer  
Identification No.)

**98 Spit Brook Road, Suite 100, Nashua, New Hampshire**  
( Address of principal executive offices)

**03062**  
( Zip Code)

Registrant's telephone number, including area code: **(603) 882-5200**

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

Title of Class	Name of each exchange on which registered
Common Stock, \$.01 par value	The Nasdaq Stock Market LLC

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

**None**

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

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

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

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

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

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

Large Accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing price for the registrant's Common Stock on June 29, 2012 was \$20,227,150. Shares of voting stock held by each officer and director and by each person who, as of June 29, 2012, 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.

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As of February 20, 2013, the registrant had 10,813,080 shares of Common Stock outstanding.

Documents Incorporated by Reference: Certain portions of the registrant's definitive Proxy Statement for its 2013 Annual Meeting of Stockholders are incorporated by reference into Items 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

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

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

## **PART I**

### **Item 1. Business.** **General**

iCAD is an industry-leading provider of advanced image analysis, workflow solutions and radiation therapy for the early identification and treatment of cancer.

The Company has grown primarily through acquisitions including Qualia Computing Inc, and its subsidiaries, including CADx Systems, Inc, 3TP LLC d/b/a CAD Sciences, Inc. ( CAD Sciences ) and its subsidiary Xoft, Inc. ( Xoft ) to become a broad player in the oncology market. Its industry-leading solutions include advanced image analysis and workflow solutions that enable healthcare professionals to better serve patients by identifying pathologies and pinpointing the most prevalent cancers earlier, a comprehensive range of high-performance, upgradeable Computer-Aided Detection ( CAD ) systems and workflow solutions for mammography, Magnetic Resonance Imaging ( MRI ) and Computed Tomography ( CT ), and an isotope-free cancer treatment platform technology.

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

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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 U.S. Food and Drug Administration ( 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.

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.

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 eBx system ( eBx 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.

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

The iCAD website is [www.icadmed.com](http://www.icadmed.com). 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

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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 San Jose, California. The San Jose, California facility is also the design, and manufacturing facility for a portion of the Company's Xoft products.

## **Strategy**

iCAD is evolving from a business focused on image analysis for the early detection of cancers to a broader player in the oncology market. The Company's belief is that early detection in combination with earlier targeted intervention provides patients and care providers with the best tools available to achieve better clinical outcomes resulting in a market demand that will drive market adoption for iCAD's solutions. The Company intends to provide customers with a broader portfolio of oncology solutions that address four key stages of the cancer care cycle: detection, diagnosis, treatment and monitoring.

The acquisition of Xoft in 2010 was a transformative event for the Company. The Xoft Axxent eBx system is a disruptive radiation oncology treatment solution with significant cost, mobility, and treatment time advantages over its competitors. While the primary application of this system today is localized breast cancer treatment using a ten to fifteen minute IORT protocol, the Xoft eBx system platform can be used to treat a wide and growing array of additional cancers, including gynecological and non-melanoma skin cancers.

The Company believes that the Xoft eBx system is uniquely well positioned to offer a differentiated treatment alternative for the approximately 110,000 annual new cases of early stage breast cancer in the US. The Xoft eBx system does not require a shielded environment and is relatively small in size, which means that it can easily be transported for use in virtually any clinical setting (including the operating room where IORT is delivered) under radiation oncology supervision. The Xoft System may also be used for APBI, which can be delivered twice daily for five days. Along with the growing body of clinical evidence in support of breast IORT, there is considerable economic momentum behind the Xoft eBx system for IORT as the Centers for Medicare and Medicaid Services ( CMS ) recently enacted significantly more favorable hospital and physician reimbursement effective January 1, 2013.

The Company views the additional Xoft eBx system platform indications as important opportunities in both the U.S. and international markets. Basal and Squamous Cell Carcinoma are two of the most prevalent types of skin cancer in the US. The Xoft eBx system, which utilizes an isotope-free miniaturized x-ray radiation source, enables radiation oncologists and dermatologists to collaborate in offering their patients a non-surgical treatment option that is particularly appropriate for certain challenging lesion locations on the ear, face, and neck. The

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Xoft eBX system is also marketed for gynecological cancers including endometrial cancer and in 2013 the Company intends to launch a new application for the treatment of cervical cancer. Vaginal cancer is the fourth most common cancer affecting women in the US and cervical cancer incidence rates outside of the US are very high due to inadequate penetration of screening modalities. The Company believes an additional strategic growth opportunity exists in the application of the Xoft eBX system for the treatment of other cancers beyond breast cancer in the IORT setting including integration with minimally invasive surgical techniques and systems.

The Company intends to address the detection and diagnosis stages of the cancer care cycle through continued extension of its image analysis and clinical decision support solutions for mammography, 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 virtual CTC exams.

The Company believes that MR image analysis for prostate imaging continues to represent a growth opportunity. Nearly one in six men over age 40 becomes 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. 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.

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### **Existing Markets**

Radiation therapy is the medical use of ionizing radiation, generally as part of cancer treatment to control or kill malignant cells. Radiation therapy may be curative in a number of types of cancer if the cancer cells are localized to one area of the body. It may also be used as part of curative therapy to prevent tumor recurrence after surgery to remove a primary malignant tumor (for example, early stages of breast cancer). The clinical goal in radiation oncology is to deliver the highest radiation dose possible directly to the tumor to kill the cancer cells while minimizing radiation exposure to healthy tissue surrounding the tumor in order to limit complications and side effects. Global incidence rates of new cancer cases are rising, primarily due to aging populations and changing lifestyle habits. However, survival rates are also improving as a result of earlier detection and enhanced treatment options. The global number of new cancer cases diagnosed is projected to increase from 13 million in 2008 to greater than 21 million in 2030, according to the International Agency for Research on Cancer.

The three main segments of radiation therapy are external beam radiation therapy ( EBRT ), brachytherapy or sealed source radiation therapy, and systemic radioisotope therapy or unsealed source radiotherapy. The differences relate to the position of the radiation source; external is outside the body, brachytherapy uses sealed radioactive sources placed precisely in the treatment area, and systemic radioisotopes are given by infusion or oral ingestion. Brachytherapy uses temporary or permanent placement of radioactive sources. Conventional EBRT typically involves multiple treatments of a tumor in up to fifty radiation sessions (fractions). In the case of brachytherapy, radiation of healthy tissues further away from the sources is reduced. In addition, if the patient moves or if there is any tumor movement within the body during treatment, the radiation source(s) retain their correct position in relation to the tumor. These aspects of brachytherapy offer advantages over EBRT in that it is able to direct high doses of radiation to the size and shape of the cancerous area while sparing healthy tissue and organs. Brachytherapy is commonly used as an effective treatment for endometrial, cervical, prostate, breast, and skin cancer, and can also be used to treat tumors in many other body sites. Electronic Brachytherapy is a type of radiotherapy that utilizes a miniaturized high dose rate X-ray source to apply radiation directly to the cancerous site. The Xofig<sup>®</sup> system is a proprietary electronic brachytherapy platform designed to deliver isotope-free (non-radioactive) radiation treatment in virtually any clinical setting without the limitations of radionuclides.

The process for delivering radiation therapy principally involves a radiation oncologist, a medical physicist responsible for planning the treatment and performing appropriate quality assurance procedures and, in certain instances, other related physicians depending upon the type of cancer e.g. a breast surgeon for breast cancer, a gynecologist for endometrial or cervical cancer.

Breast cancer is a primary market for the use of radiation therapy. Globally, the incidence rate for breast cancer reached 1.4 million new cases annually in 2008, according to the American Cancer Society 2012 Facts and Figures. Treatment options have progressed significantly over



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the past several years from mastectomy to breast conserving surgery which typically includes lumpectomy followed by a course of radiation therapy. Techniques for the delivery of radiotherapy associated with breast conserving surgery have evolved from focusing on 5-7 weeks of EBRT to APBI which reduces the protocol to 10 fractions over 5 days to IORT which delivers a complete dose of radiation during surgery for appropriately selected patients. This trend toward hypo-fractionation reflects market demand for more cost-efficient, flexible, and less resource intensive treatment options that also offer significant patient access advantages. Electronic Brachytherapy, due to its isotope-free energy source and thus minimal shielding requirements, is particularly well suited to IORT.

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 2012. 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's healthcare 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 8,660 facilities (with approximately 12,500 mammography systems) were certified to provide mammography screening in 2012. Historically, these centers have used conventional film-based medical imaging technologies to capture and analyze breast images. Of the 8,660 certified facilities, to date approximately 89% 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.

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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 cancer-related deaths among women in the European Union ( EU ). The number of expected breast cancer cases based on the 2007 report was 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 one out of every 10 women in the EU is expected to develop breast cancer at some point in her life. As a result, most countries in Western Europe have or are planning to implement mammography screening programs resulting in an expected increase in the number of mammograms performed in the coming years.

## **Market Size and Share**

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

In its 2010 report, Thomson Reuters estimates, national outpatient MRI procedure volumes grew 2.4% between 2008 and 2010. Frost and Sullivan predicted the use of MRI in the management of breast cancer volumes will heighten to 3 million by 2014. More than 6,000 MRI systems could be used for breast MRI procedures today. Merge Healthcare, Inc. (formerly Confirma, Inc. acquired by Merge Healthcare in September 2009) and Invivo Corporation have been and currently remain the market leaders in breast MR image analysis.

In addition, IMV, a market research company, 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**

### **Radiation Therapy: Electronic Brachytherapy**

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.

The Xofig eBx system utilizes a miniaturized high dose rate yet low energy X-ray source to apply radiation directly to the cancerous site. The goal is to direct the radiation dose to the size and shape of the cancerous area while sparing healthy tissue and organs. The Xofig technology delivers clinical dose rates similar to traditional radio-active systems. However, because of the electronic nature of the Xofig technology, the dose fall off is much faster, thus lowering the

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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 Xofigo 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 Xofigo 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 Xofigo. 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. In December 2012, Dr. Vaidya presented five-year follow up data on the TARGIT-A trial at a forum in conjunction with the San Antonio Breast Cancer Symposium. The updated results of the trial demonstrated that local recurrence rates in the TARGIT (IORT) group were within the non-inferiority boundary when compared to the results in the group who received external beam radiation therapy and that mortality rates from other causes than breast cancer were lower in the TARGIT (IORT) group.

Importantly, the reimbursement landscape for IORT improved substantially in 2011 and 2012. The American Medical Association (AMA) established category 1 CPT codes for IORT based on strong clinical evidence and a clear economic advantage relative to alternative treatment options including external beam radiotherapy. Following this significant development, in October 2012 the Centers for Medicaid and Medicare Services unpackaged the IORT treatment delivery code and assigned it to a payment value associated with stereotactic radiosurgery. These codes and payment values became effective beginning January 2013.

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Other markets for the use of electronic brachytherapy include non-melanoma skin cancers, gynecological cancers and other areas where either primary tumors occur or metastatic lesions require treatment. Squamous cell and basal cell carcinoma are the two main types of skin cancers appropriate for treatment with electronic brachytherapy. With more than 1 million new cases in the U.S. each year, basal cell carcinoma is the most common type of skin cancer. The squamous cell variation is the second most prevalent type with approximately 250,000 new cases per year in the U.S. Appropriately selected patients with either type may be eligible for treatment with electronic brachytherapy especially those lesions in difficult to treat locations such as the ear, nose, and neck. In October 2012, Dr. Ajay Bhatnagar presented a study at the annual meeting of the American Society for Radiation Oncology (ASTRO) utilizing the Xofig<sup>®</sup> system for non-melanoma skin cancer. With a mean follow-up of 11 months but as long as 38 months after treatment Dr. Bhatnagar reported no recurrences among 122 patients who had 171 lesions.

Gynecological cancers are also appropriate for treatment with electronic brachytherapy. There are approximately 50,000 new cases of endometrial cancer each year in the U.S. and nearly 300,000 new cases worldwide. Cervical cancer is highly prevalent in the developing world and there are 75,000 new cases per year in China alone. Additionally, electronic brachytherapy is appropriate for use in other IORT clinical settings where surgical resection is unable to completely eliminate all cancer cells. In the U.S. and International settings, IORT for pelvic, gastrointestinal, abdominal, spinal, and soft tissue sarcoma applications remains a potential market given the minimal shielding requirements associated with this treatment modality. The growth of minimally invasive surgery, estimated to be 30-40% of all surgical procedures currently in the U.S., is expected to accelerate the adoption of compatible eBx systems.

### **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 IMV that over 85.3 million CT procedures were performed in 2011 in the U.S. alone with an installed base of approximately 13,775 scanners at 8,500 locations. 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 present 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 2013. It is the second leading cause of cancer deaths in spite of being highly preventable with early

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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, 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 picture archiving and communication system (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*. In addition, bills were introduced into both the US House of Representatives (HR4165) and US Senate (S2265) in March 2012 that would require that CTC screening be reimbursed by Medicare and Medicaid.

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### **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 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 a urologist under the assistance of a portable ultrasound system. Anywhere

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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.

**Products and Product Development**

The table below presents the revenue and percentage of revenue attributable to the Company's products and services, in 2012, 2011 and 2010 (in thousands):

	For the year ended December 31,					
	2012	%	2011	%	2010	%
Digital & MRI CAD revenue	\$ 8,379	29.6%	\$ 13,256	46.3%	\$ 15,392	62.6%
Electronic brachytherapy	8,130	28.8%	3,711	13.0%		0.0%
Film based revenue	1,467	5.2%	2,361	8.2%	3,335	13.6%
Service & supplies revenue	10,299	36.4%	9,324	32.5%	5,848	23.8%
Total revenue	\$ 28,275		\$ 28,652		\$ 24,575	

The revenues above exclude the results of Xoft for the year ended December 31, 2010 as the acquisition did not take place until December 30, 2010.

**Table of Contents*****Electronic Brachytherapy products:******Electronic Brachytherapy (eBx ) Treatment for Breast Cancer*****Axxent® eBx**

The portable Axxent eBx system uses isotope-free miniaturized X-ray tube technology to deliver therapy directly to cancer sites with minimal radiation exposure to surrounding healthy tissue. The Axxent eBx system is FDA-cleared for the treatment of early stage breast cancer, endometrial cancer and skin cancer, as well as for the treatment of other cancers or conditions where radiation therapy is indicated, including IORT. The Company offers FDA-cleared applicators for the utilization of the Axxent eBx system including breast applicators for IORT and APBI in the treatment of breast cancer, vaginal applicators for the treatment of endometrial cancer, and skin applicators for the treatment of non-melanoma skin cancers. The single-use breast IORT and APBI applicators are offered in a variety of sizes based on clinical need. The endometrial and skin applicators are reusable and are manufactured in various sizes based on the anatomical requirements of the patient. The Company also provides the 50kV isotope-free energy source, a comprehensive service warranty program, and various accessories such as the Axxent eBx Rigid Shield for internal IORT shielding. The 50kV energy source is sold either as an annual contract customized to individual customer volume/usage requirements or on a single unit basis.

The Company has recently made several enhancements to the Axxent eBx system controller including a new software interface enabling enhanced system functionality and an upgraded high voltage connection improving system performance. The Company has recently submitted a 510k application to the FDA for a new applicator for use in the treatment of cervical cancer. This new applicator would further expand the Company's product portfolio in the gynecological cancer market and enable customers to offer comprehensive electronic brachytherapy solutions to their patients in need of gynecological radiation therapy. Cervical cancer is a particularly large market opportunity outside of the United States, particularly in areas of the world where screening for cancer of the cervix is less prevalent. Current customers of the Axxent eBx system include university research and community hospitals, private and governmental institutions, doctors' offices, cancer care clinics, and veterinary facilities in the United States, Europe and Asia.

***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.



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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.

In June 2012, iCAD introduced its next generation of mammography CAD products, PowerLook Advanced Mammography Platform® (AMP). The technology expands on iCAD's SecondLook platform and is the CAD platform upon which all future breast imaging CAD offerings from iCAD will be built. PowerLook AMP incorporates both the SecondLook Digital and SecondLook Premier CAD algorithms. PowerLook AMP's CAD metrics offer industry-leading tissue and lesion characteristics to support the breast imager's workflow. In addition, PowerLook AMP is the first product of its kind to integrate Matakina's Volpara Volumetric Breast Density assessment software that aids radiologists by standardizing their approach to breast density assessment. The system's modular design gives radiologists the freedom to choose the products and functionality they need today and in the future. Included with PowerLook AMP is a multi-vendor CAD server that allows hospitals and imaging facilities to connect up to four mammography acquisition devices regardless of vendor. This reduces the need for separate CAD servers while lowering hardware and service costs. iCAD's PowerLook AMP also provides the most powerful flexible DICOM connectivity solution enabling universal compatibility with leading PACS and Review Workstations. Additional modules are expected to be released and integrated into PowerLook AMP in the future.

### **PowerLook Advanced Mammography Platform**

PowerLook AMP is designed to function with leading digital mammography systems (FFDM and computed radiography) including systems sold by GE Healthcare, Siemens Medical Systems, Fuji Medical Systems, Hologic, Inc., Sectra Medical Systems, Philips, IMS Giotto, Agfa Corporation, and Planmed. iCAD believes it has strong development partnerships with imaging providers. The algorithms in PowerLook AMP products have been optimized for each digital imaging provider based upon characteristics of their unique detectors. PowerLook AMP incorporates both the SecondLook Digital and SecondLook Premier CAD algorithms. The Company's SecondLook Premier CAD solution was tailored for GE Healthcare and Siemens Medical Systems upon initial release of their systems for Europe.

PowerLook AMP is a computer server residing on a customer's network that receives patient studies from the imaging modality, performs CAD analysis and sends the CAD results to PACS

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and/or review workstations. Workflow and efficiency are critical in digital imaging environments therefore iCAD has developed flexible, powerful DICOM integration capabilities that enable PowerLook AMP to integrate 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.

### ***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®, 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.

### ***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*

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*Colonography in a Multireader, Multicase Trial* demonstrated that reader sensitivity improved 5.5% for patients with both small and large polyps with use of CAD. Use of CAD reduced specificity of readers by 2.5%. The clinical relevance of this CAD program was improved reader performance while maintaining high reader specificity. Throughout 2012, iCAD continued to globally distribute the VeraLook product with advanced visualization reading workstations manufactured by Vital Images, a Toshiba Medical System Group Company, TeraRecon, Inc, and Viatronix, Inc.

### ***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 radiology information systems ( RIS ). Specialized image compression techniques reduce file sizes up to 80%, minimizing long-term storage requirements.

### **Sales and Marketing**

iCAD, through its Xoft subsidiary, markets the eBx system in the United States and select countries worldwide. The Company has substantially expanded its installed base of eBx systems in the US and has established initial installations in Western Europe and Taiwan. 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. The system offers a distinct competitive advantage in that it is a highly mobile unit with minimal shielding requirements that can easily be moved from room to room within a single healthcare institution or be transported from facility to facility given its relatively compact form factor. Breast IORT is a strategic focus of the Company due to the significant clinical /lifestyle benefits to the patient and economic advantages to the facility. The additional clinical applications including skin and gynecological cancers as well as its potential to scale in the future to address other indications for use highlight the Xoft eBx system' s unique platform flexibility.

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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, ISORT, Milan Breast, 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.

The Company further supports breast IORT through its recent launch of the ExBRT Study – a post-market clinical trial designed to enroll 1,000 patients at up to 50 sites. The study will enable facilities interested in treating early stage breast cancer patients with the Xoft eBx system to participate in a common clinical protocol and follow enrolled patients for up to 10 years. The ExBRT Study is led by a prestigious and diverse group of leading brachytherapy and breast care physicians including breast surgeons, radiation oncologists, pathologists, and medical physicists from leading US breast cancer care institutions.

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 Health, Inc.

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 advanced 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, where industry leaders discuss the future of CAD in these modalities.

## **Competition**

The Company's existing eBx products face competition primarily from one company, Carl Zeiss Meditec, Inc., ( Zeiss ) a multinational company, where eBx products are only one of that company's many products. Zeiss manufactures and sells eBx products for the use of intraoperative radiation therapy. Recently, Zeiss has expanded their product portfolio to include additional anatomical areas beyond breast IORT. Zeiss now offers a range of radiation therapy applicators for use in various applications including spine, the gastrointestinal tract, skin, and endometrial cancers. Zeiss has an established base of breast IORT installations in Europe where the majority of the TARGIT-A trial clinical sites are located. Europe is also the focus of their clinical research and approvals in the various new applications previously listed. IntraOp/Mobetron is an additional competitor in the high dose rate ( HDR ) 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. New market opportunities including expansion of the gynecological product portfolio and other IORT applications beyond breast IORT will bring new competitive dynamics to the Company's efforts.

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Larger, more diversified radiation therapy companies offering a wide variety of clinical solutions for HDR brachytherapy including Varian Medical Systems, Elekta, and Nucletron compete in these areas. These multi-national firms offer broad product portfolios including a full range of HDR brachytherapy afterloaders and applicators as well as traditional radiation therapy solutions including linear accelerators, treatment planning solutions, and workflow management capabilities.

The Company currently faces direct competition in its 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. 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.

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,

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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 Axxent® 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 San Jose, CA facility. Xoft operations consist of manufacturing, engineering, administration, purchasing, planning and scheduling, service repairs, quality assurance, inventory management, and warehousing. Once the product has shipped, it is 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

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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.

## **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.

The Company has many patents covering its CAD and eBx technologies expiring between 2018 and 2028. These patents help the Company maintain a proprietary position in its markets. Additionally, the Company has a number of patent applications pending domestically, some of which have been also filed internationally, and 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 tomosynthesis, CAD for CT colonography and lung and CAD for MRI breast and prostate, as well as Xofig's current and future eBx technologies and products. The Company has also secured a non-exclusive patent license from the National Institute of Health which relates broadly to CAD in colonography, a non-exclusive patent license from Cytac/Hologic which relates to balloon applicators for breast brachytherapy, a non-exclusive license from Yeda Research which relates to the 3TP method for the detection of cancer and a non-exclusive license from Zeiss which relates to brachytherapy. The Company believes it has all the necessary licenses from third parties for software and other technologies in its products, however we do not know if current or future patent applications will issue with the full scope of the claims sought, if at all, or whether any patents issued will be challenged or invalidated.

## **Sources and Availability of Materials**

The Company depends upon a limited number of suppliers and manufacturers for its products, and certain components in its products may be available from a sole or limited number of suppliers. The Company's products are generally either manufactured and assembled for it by a sole manufacturer, by a limited number of manufacturers or assembled by it from supplies it obtains from a limited number of suppliers. Critical components required to manufacture these products, whether by outside manufacturers or directly, may be available from a sole or limited number of component suppliers. The Company generally does not have long-term arrangements with any of its manufacturers or suppliers. The loss of a sole or key manufacturer or supplier would impair 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.

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### **Major Customers**

The Company's two major customers over the past three years were GE Healthcare and Fuji Medical Systems. GE Healthcare accounted for \$4.5 million in 2012, \$6.8 million in 2011 and \$9.3 million in 2010 or 16%, 24%, and 38% of the Company's revenues, respectively. Fuji Medical Systems accounted for \$2.3 million in 2012, \$3.2 million in 2011 and \$3.1 million in 2010 or 8%, 11% and 13% of the Company's revenues, respectively.

### **Engineering and Product Development**

The Company spent \$7.8 million, \$10.8 million, and \$6.6 million on research and development activities during the years ended December 2012, 2011 and 2010, respectively. Research and development expenses for 2012 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, 2013, the Company had 101 employees, all of which are full time employees, with 30 involved in sales and marketing, 29 in research and development, 31 in service, manufacturing, technical support and operations functions, and 11 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 increased to approximately \$2.9 million or 10% of sales in 2012 as compared to \$1.8 million or 6% of total sales in 2011 and \$4.0 million or 16% of total sales in 2010.

The Company's principal concentration of export sales is in Europe, which accounted for 74% of the Company's export sales in 2012, 67% of the Company's export sales in 2011 and 77% of



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export sales in 2010. France accounted for approximately 28% in 2012, 16% in 2011 and 55% in 2010 of the total export sales. In addition approximately 27% and 10% of export sales in 2012 were to the United Kingdom and Canada, respectively.

### **Foreign Regulations**

International sales of the Company's products are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. Obtaining and maintaining foreign regulatory approvals is an expensive and time consuming process. The Company cannot be certain that it will be able to obtain the necessary regulatory approvals timely or at all in any foreign country in which it plans to market its CAD products and the Axxent eBx system, and if it fails to receive and maintain such approvals, its ability to generate revenue may be significantly diminished.

### **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 2012 and there can be no assurance that we will be able to achieve and sustain future profitability.**

We have incurred significant losses since our inception. We incurred a net loss of \$9.4 million in fiscal 2012 and have an accumulated deficit of \$136.4 million at December 31, 2012. We may not be able to achieve profitability.

#### **A limited number of customers account for a significant portion of our total revenue. The loss of a principal customer could seriously hurt our business.**

Our principal sales distribution channel for our digital products is through our OEM partners. Our digital product revenue accounted for 26% and 41% of our total revenue for the years ended December 31, 2012 and 2011, respectively. In 2012 we had two major customers, GE Healthcare and Fuji Medical Systems, with 16% and 8% of our revenue, 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 revenue. The loss of our relationships with principal customers or a decline in sales to principal customers could materially adversely affect our business and operating results.

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**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 an impairment of \$26.8 million on our goodwill. Under current accounting guidelines, we must assess, at least annually and potentially more frequently, whether the value of our goodwill of \$21.1 million and our other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings which could materially adversely affect our reported results of operations in future periods.

**We may not be able to obtain regulatory approval for any of the other products that we may consider developing.**

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

**Our products 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.

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

Sales of our products in certain countries outside of the U.S. are also subject to extensive regulatory approvals. Obtaining and maintaining foreign regulatory approvals is an expensive and time consuming process. We cannot be certain that we will be able to obtain the necessary regulatory approvals timely or at all in any foreign country in which we plan to market our CAD products and Axxent eBx systems, and if we fail to receive such approvals, our ability to generate revenue may be significantly diminished.

### **Our products may be recalled even after we have received FDA or other governmental approval or clearance.**

If the safety or efficacy of any of our products is called into question, the FDA and similar governmental authorities in other countries may require us to recall our products, even if our product received approval or clearance by the FDA or a similar governmental body. Such a recall would divert the focus of our management and our financial resources and could materially and adversely affect our reputation with customers and our financial condition and results of operations.

### **Our quarterly and annual operating and financial results and our gross margins are likely to fluctuate significantly in future periods.**

Our quarterly and annual operating and financial results are difficult to predict and may fluctuate significantly from period to period. Our revenue and results of operations may fluctuate as a result of a variety of factors that are outside of our control including, but not limited to, general economic conditions, the timing of orders from our OEM partners, our OEM partners ability to manufacture and ship their digital mammography systems, our timely receipt by the FDA for the clearance to market our products, our ability to timely engage other OEM partners for the sale of our products, the timing of product enhancements and new product introductions by us or our competitors, the pricing of our products, changes in customers' budgets, competitive conditions and the possible deferral of revenue under our revenue recognition policies.

### **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;

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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.

**Sales and market acceptance of our products is dependent upon the coverage and reimbursement decisions made by third-party payors. The failure of third-party payors to provide appropriate levels of coverage and reimbursement for the use of our products and treatments facilitated by our products could harm our business and prospects.**

Sales and market acceptance of our medical products and the treatments facilitated by our products in the United States and other countries is dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. Market acceptance of our products and treatments has and will continue to depend upon our customers' ability to obtain an appropriate level of coverage for, and reimbursement from third-party payors for, these products and treatments. In the U.S., CMS establishes coverage and reimbursement policies for healthcare providers treating Medicare and Medicaid beneficiaries. Under current CMS policies, varying reimbursement levels have been established for our products and treatments. Coverage policies for Medicare patients may vary by regional Medicare carriers in the absence of a national coverage determination and reimbursement rates for treatments may vary based on the geographic price index. Coverage and reimbursement policies and rates applicable to patients with private insurance are dependent upon individual private

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payor decisions which may not follow the policies and rates established by CMS. The use of our products and treatments outside the United States is similarly affected by coverage and reimbursement policies adopted by foreign governments and private insurance carriers.

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

The successful commercialization of our newly developed products and treatments and newly introduced enhancements to our existing products and treatments are subject to numerous risks, both known and unknown, including:

uncertainty of the development of a market for such product or treatment;

trends relating to, or the introduction or existence of, competing products, technologies or alternative treatments or therapies that may be more effective, safer or easier to use than our products, technologies, treatments or therapies;

the perceptions of our products or treatments as compared to other products and treatments;

recommendation and support for the use of our products or treatments by influential customers, such as hospitals, radiological practices, breast surgeons and radiation oncologists and treatment centers;

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

competition, including the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks; and

other technological developments.

Often, the development of a significant market for a product or treatment will depend upon the establishment of a reimbursement code or an advantageous reimbursement level for use of the product or treatment. Moreover, even if addressed, such reimbursement codes or levels frequently are not established until after a product or treatment is developed and commercially introduced, which can delay the successful commercialization of a product or treatment.

If we are unable to successfully commercialize and create a significant market for our newly developed products and treatments and newly introduced enhancements to our existing products and treatments our business and prospects could be harmed.

### **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, 2012 and will continue to do so for future fiscal periods. Although we believe that we currently have adequate internal

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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 revenue.**

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

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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. There is a risk that our patent applications will not result in granted patents or that granted patents will not provide significant protection for our products and technology. Unauthorized third parties may infringe our intellectual property rights, or copy or reverse engineer portions of our technology. Our competitors may independently develop similar technology that our patents do not cover. In addition, because patent applications in the U.S. are not generally publicly disclosed until eighteen months after the application is filed, applications may have been filed by third parties that relate to our technology. Moreover, there is a risk that foreign intellectual property laws will not protect our intellectual property rights to the same extent as intellectual property laws in the U.S. The rights provided by a patent are finite in time. Over the coming years, certain patents relating to current products will expire in the U.S. and abroad thus allowing third parties to utilize certain of our technologies. In the absence of significant patent protection, we may be vulnerable to competitors who attempt to copy our products, processes or technology

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.**

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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



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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.**

Our revenue from sales outside of the United States are increasing, representing approximately 10% of our revenue for 2012. We are subject to the risks inherent in conducting business across national boundaries, any one of which could adversely impact our business. In addition to currency fluctuations, these risks include, among other things: economic downturns; changes in or interpretations of local law, governmental policy or regulation; restrictions on the transfer of funds into or out of the country; varying tax systems; and government protectionism. One or more of the foregoing factors could impair our current or future operations and, as a result, harm our overall business.

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

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

### **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.

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

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

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

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

### **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

### **Item 2. Properties.**

The Company's executive offices are leased pursuant to a five-year lease (the "Lease") that commenced on December 15, 2006, and renewed on January 1, 2012, consisting of approximately 11,000 square feet of office space located at 98 Spit Brook Road, Suite 100 in Nashua, New Hampshire

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(the Premises ). The Lease renewal provided for an annual base rent of \$181,764 during 2012; \$187,272 for 2013; \$192,780 for 2014; \$198,288 for 2015 and \$203,796 for 2016. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the Premises. The Company also has the right to extend the term of the Lease for an additional five year period at the then current market rent rate (but not less than the last annual rent paid by the Company).

The Company leases 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.

The Company leases a facility consisting of approximately 24,350 square feet of office, manufacturing and warehousing space located at 101 Nicholson Lane, San Jose, CA. The operating lease commenced September 2012 and provides for an annual base rent of \$248,376, for the first year \$260,064, for the second year \$271,752, for the third year \$283,440 for the fourth year and \$295,140 for the fifth year, with all amounts payable in equal monthly installments. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the facility.

In addition to the foregoing leases relating to its principal properties, the Company also has a lease for an additional facility in Nashua, New Hampshire used for product repairs, manufacturing and warehousing.

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),

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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. On April 11, 2012, the above-referenced cases were consolidated for all purposes, excluding trial. On May 2, 2012, plaintiffs filed a master consolidated complaint, with the same case number as the original filed complaint. On August 2, 2012, plaintiffs filed fictitious name amendments adding defendants, Mel Silverstein, M.D., Peter Chen, M.D., Lisa Guerrero, M.D., Ralph Mackintosh, Ph.D., Robert Dillman, M.D., and Jack Cox. On September 14, 2012, an additional Jane Doe plaintiff and John Doe spouse filed a complaint in the Orange County Superior Court (Docket No. 30-2012-00598740-CU-PL-CXC) with identical allegations as plaintiffs above against the same original defendants. On October 17, 2012, plaintiff John Doe No. 11 dismissed his complaint, with prejudice, as to all defendants. On November 26, 2012, plaintiffs filed an additional fictitious name amendment adding defendant, American Ceramic Technology, Inc. On January 15, 2013, plaintiffs filed a dismissal, with prejudice, as to defendant, Mel Silverstein, M.D., only. It is alleged that each Jane Doe plaintiff 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 was 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 our preliminary analysis, we plan to vigorously defend the lawsuits, however a loss is reasonably possible. Accordingly, since the amount of the potential damages in the event of an adverse result is not reasonably estimable, we are unable to estimate a range of loss and no expense has been recorded with respect to the contingent liability associated with this matter.

**Item 4. Mine Safety Disclosures.**

Not applicable.

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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 2012 and 2011.

Fiscal year ended December 31, 2012	High	Low
First Quarter	\$ 3.45	\$ 2.25
Second Quarter	2.90	2.10
Third Quarter	2.99	1.75
Fourth Quarter	5.12	1.85

Fiscal year ended December 31, 2011		
First Quarter	\$ 7.55	\$ 5.20
Second Quarter	6.90	4.90
Third Quarter	5.75	2.00
Fourth Quarter	4.00	2.10

As of February 5, 2013, there were 348 holders of record of the Company's common stock. In addition, the Company believes that there are in excess of 5,286 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, 2012.

*Issuer's Purchases of Equity Securities.* For the majority of restricted stock units granted, the number of shares issued on the date that the restricted stock units vest is net of the minimum statutory tax withholding requirements that we pay in cash to the appropriate taxing authorities on behalf of our employees. For the three months ended December 31, 2012 there were 211 shares of our common stock that were repurchased to cover employee income tax withholding obligations in connection with the vesting of restricted stock units under our equity incentive plans.

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Month of purchase	Total number of shares purchased (1)	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum dollar value of shares that may yet be purchased under the plans or programs
October 1 - October 31, 2012		\$	\$	\$
November 1 - November 30, 2012	211	\$ 2.73	\$	\$
December 1 - December 31, 2012		\$	\$	\$
Total	211	\$ 2.73	\$	\$

**Item 6. Selected Financial Data.**

Not applicable.

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

#### **Overview**

iCAD is an industry-leading provider of advanced image analysis, workflow solutions and radiation therapy for the early identification and treatment of cancer.

The Company has grown primarily through acquisitions to become a broad player in the oncology market. Its industry-leading solutions include advanced image analysis and workflow solutions that enable healthcare professionals to better serve patients by identifying pathologies and pinpointing the most prevalent cancers earlier, a comprehensive range of high-performance, upgradeable Computer-Aided Detection (CAD) systems and workflow solutions for mammography, Magnetic Resonance Imaging (MRI) and Computed Tomography CT, and the Xofig eBx system, an isotope-free cancer treatment platform technology.

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

During fiscal year 2012, revenue from the Xofig eBx system and service and supplies revenue have offset the decline in revenue from MRI and CAD systems. The shift in revenue is primarily due to the market growth in cancer therapy, the related supplies and the conversion of CAD product revenue from a perpetual sale to a subscription based sale. The Company expects the product mix to change as the market for cancer therapy continues to grow.

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

#### **Critical Accounting Policies**

The Company's discussion and analysis of its financial condition, results of operations, and cash flows are based on its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates these estimates, including those related to revenue recognition, allowance for doubtful accounts, inventory valuation and obsolescence, intangible assets, goodwill, warrants, income taxes, contingencies and litigation.

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Additionally, the Company uses assumptions and estimates in calculations to determine stock-based compensation and the value of warrants. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company's critical accounting policies include:

Revenue recognition;

Allowance for doubtful accounts;

Inventory;

Valuation of long-lived and intangible assets;

Goodwill;

Warrants

Stock based compensation;

Income taxes.

### **Revenue Recognition**

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

The Company recognizes revenue from the sale of its digital, film-based CAD and eBx products and services in accordance with Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements* ( ASU 2009-13 ) and ASC Update No. 2009-14, *Certain Arrangements That Contain Software Elements* (Update No. 2009-14). ( ASU 2009-14 ). Revenue for the sale of certain CAD products is recognized in accordance with ASC 840 ( *Leases* ) ( ASC 840 ). For multiple element arrangements, revenue is allocated to all deliverables based on their relative selling prices. In such circumstances, a hierarchy is used to determine the selling price to be used for allocating revenue to deliverables as follows: (i) vendor-specific objective evidence of fair value ( VSOE ), (ii) third-party evidence of selling price ( TPE ), and (iii) best estimate of the selling price ( BESP ). VSOE generally exists only when the deliverable is sold separately and is the price actually charged for that deliverable. The process for determining 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.

The Company primarily uses customer purchase orders that are subject to the Company's terms and conditions or, in the case of an Original Equipment Manufacturer ( OEM ) are governed by distribution agreements. In accordance with our distribution agreements, the OEM does not have a right of return, and title and risk of loss passes to the OEM upon shipment. The Company





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generally ships Free On Board shipping point and uses shipping documents and third-party proof of delivery to verify delivery and transfer of title. In addition, the Company assesses whether collection is probable by considering a number of factors, including past transaction history with the customer and the creditworthiness of the customer, as obtained from third party credit references.

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

The Company has determined that iCAD's Digital, MRI and film based sales generally follow the guidance of FASB ASC Topic 605 Revenue Recognition (ASC 605) as the software has been considered essential to the functionality of the product per the guidance of ASU 2009-14. Typically, the responsibility for the installation process lies with the OEM partner. On occasion, when iCAD is responsible for product installation, the installation element is considered a separate unit of accounting because the delivered product has stand-alone value to the customer. In these instances, the Company allocates the 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 BEP. In prior years (prior to ASU 2009-13), the Company recognized the element on the residual method.

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

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

### **Allowance for Doubtful Accounts**

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

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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, 2012 is adequate.

### **Inventory**

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

### **Long Lived Assets**

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 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 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 with a reasonable control premium (Market Approach) as the best evidence of fair value (market capitalization is calculated using the quoted closing share price of the Company's common stock multiplied by the number of common shares outstanding). The Company tests goodwill for impairment by comparing its market capitalization using the Market Approach to its carrying value at the same date as the basis to determine if a potential impairment exists. The Company also evaluates goodwill using a discounted cash flow analysis (the Income Approach) to corroborate the Market Approach at its annual impairment testing date of October 1.

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;

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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.

### **Warrants**

In January 2012, the Company entered into several agreements with Deerfield Management, a healthcare investment fund (Deerfield), which included the issuance of warrants to purchase up to 550,000 shares of common stock at an exercise price of \$3.50 per share, of which 450,000 shares of the Company's common stock became immediately exercisable. An additional 100,000 shares of common stock will become exercisable if the Company elects to extend the debt as described in the agreements. The Company accounts for the warrants as debt in accordance with ASC 480 *Distinguishing Liabilities from Equity*. On a quarterly basis the Company evaluates the fair value of Warrants using a binomial lattice model. Inputs into the binomial lattice method include expected volatility, interest rate, and probabilities of a voluntary exercise of the warrants as well as the probability of major transaction (i.e. company sale). The inputs to determine the value of the warrants in the binomial lattice model require significant accounting judgment and estimates.

### **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

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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, 2012 and 2011 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 revalues 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, 2012 compared to Year Ended December 31, 2011**

*Revenue.* Revenue for the year ended December 31, 2012 was \$28.3 million compared with revenue of \$28.7 million for the year ended December 31, 2011, a decrease of \$377,000 or 1.3%. eBx revenue increased \$4.4 million, service and supplies revenue increased \$1.0 million which offset the decline in digital and MRI CAD revenue of \$4.9 million and the decline of film based revenue of \$0.9 million.

The table below presents the components of revenue for 2012 and 2011:

	2012	For the year ended December 31,		
		2011	Change	% Change
Digital & MRI CAD revenue	\$ 8,379	\$ 13,256	\$ (4,877)	(36.8%)
Electronic brachytherapy	8,130	3,711	4,419	119.1%
Film based revenue	1,467	2,361	(894)	(37.9%)
Service & supplies revenue	10,299	9,324	975	10.5%
Total revenue	\$ 28,275	\$ 28,652	\$ (377)	(1.3%)

eBx revenue increased 119.1% to \$8.1 million for the year ended December 31, 2012 from \$3.7 million in the year ended December 31, 2011. We believe the increase in demand for eBx systems resulted from increased awareness, additional clinical trial data and an increase in reimbursement rates for customers treating patients.

The Company's digital and MRI CAD revenue for the year ended December 31, 2012 decreased \$4.9 million or 36.8%, to \$8.4 million compared to \$13.3 million for the year ended December 31,

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2011. The decrease in digital and MRI CAD revenue was due primarily to a decrease in digital revenue of \$4.6 million which was driven by decreases in demand for digital CAD systems primarily from our OEM customers, a decrease of approximately \$0.5 million in MRI CAD revenue which was offset by an increase in colon revenue of approximately \$0.2 million.

Revenue from iCAD's film based products for the year ended December 31, 2012 decreased 37.9% to \$1.5 million compared to \$2.4 million in 2011. The decline in revenue from film-based products and accessories was the result of the decreasing market for film based products as most customers have transitioned to digital technologies.

Service and supply revenue for the year ended December 31, 2012 increased 10.5% to \$10.3 million compared to \$9.3 million in 2011. The increase in the Company's service and supplies revenue was due primarily to approximately \$0.7 million of service revenue related to service and supplies for Xoft, which reflects the increased use of supplies as customers treatment volumes increase. CAD service and supplies revenue increased \$0.3 million primarily due to customization work completed on our MRI products, increased service contract revenue on the Company's growing installed base of CAD products offset by a decline in analog service contracts.

*Gross Margin.* Gross margin was 70.8% for the year ended December 31, 2012 compared to 69.9% for the year ended December 31, 2011. Gross margin increased slightly despite the reduction in revenue and gross margin percent increased slightly by 0.9%. The reduction in cost of revenue resulted primarily from a reduction in the cost of service due to ongoing expense reductions during 2012. Cost of revenue and gross margin for 2012 and 2011 were as follows (in thousands):

	2012	For the year ended December 31,		
		2011	Change	% Change
Products	\$ 4,834	\$ 4,788	\$ 46	1.0%
Service and supplies	2,479	2,906	(427)	(14.7%)
Amortization	931	931		0.0%
Total cost of revenue	8,244	8,625	(381)	(4.4%)
Gross margin	\$ 20,031	\$ 20,027	\$ 4	0.0%
Gross margin %	70.8%	69.9%		

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

Operating expenses for 2012 and 2011 are as follows (in thousands):

	2012	For the year ended December 31, 2011	Change	% Change
Operating expenses:				
Engineering and product development	\$ 7,769	\$ 10,791	\$ (3,022)	(28.0%)
Marketing and sales	10,708	13,684	(2,976)	(21.7%)
General and administrative	6,966	9,999	(3,033)	(30.3%)
Contingent consideration		(4,900)	4,900	(100.0%)
Goodwill impairment		26,828	(26,828)	(100.0%)
Loss on indemnification asset		741	(741)	(100.0%)
Total operating expenses	\$ 25,443	\$ 57,143	\$ (31,700)	(55.5%)

*Engineering and Product Development.* Engineering and product development costs for the year ended December 31, 2012 decreased by \$3.0 million or 28.0%, from \$10.8 million in 2011 to \$7.8 million in 2012. The decrease in engineering and product development costs was primarily due to an approximately \$1.1 million reduction in salary expense and a \$1.8 million reduction in consulting and professional services expenses. The decrease in salary expense was due to a decrease in headcount, and the decrease in consulting and professional services expense was due to product development activities that were completed during 2011.

*Marketing and Sales.* Marketing and sales expense for the year ended December 31, 2012 decreased by \$3.0 million or 21.7%, from \$13.7 million in 2011 to \$10.7 million in 2012. The decrease in marketing and sales expense was primarily due to the decrease of approximately \$2.8 million reduction in salary and commission expense reflecting the reduction in commercial headcount.

*General and Administrative.* General and administrative expenses for the year ended December 31, 2012 decreased by \$3.0 million or 30.3%, from \$10.0 million in 2011 to \$6.9 million in 2012. The reduction in general and administrative expenses was primarily due to a \$1.4 million reduction in legal expenses resulting from litigation settled during 2011, a reduction in consulting and professional services of \$0.6 million, a reduction of rent and facilities expense of \$0.5 million and a reduction in salaries of \$0.3 million.

*Contingent Consideration.* The gain of \$4.9 million during the year ended December 31, 2011 represents a reduction of contingent consideration resulting from the acquisition of Xoft. The Company is required to determine the fair value of the contingent 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. As of December 31, 2012, it remains unlikely that the revenue thresholds would be met, and accordingly the fair value remains at \$0.

*Goodwill Impairment.* During the quarter ended September 30, 2011, the Company recorded an impairment of goodwill of approximately \$26.8 million. There were no impairment charges during 2012.

*Loss on indemnification asset.* In connection with the settlement of the litigation with Zeiss, the Company recorded, retrospectively, an indemnification asset as a purchase price adjustment as of

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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.

*Other Income and Expense*

	For the year ended December 31,			
	2012	2011	Change	Change %
Interest expense	\$ (3,415)	\$ (422)	(2,993)	709.2%
Loss from change in fair value of warrants	(539)		(539)	0.0%
Interest income	35	27	8	29.6%
	\$ (3,919)	\$ (395)	\$ (3,524)	892.2%

The Company recorded \$3.4 million of interest expense in 2012 as compared to \$422,000 of interest expense during the year ended December 31, 2011. Interest expense in 2012 represents approximately \$3.0 million associated with the Deerfield financing and \$0.4 million related to the accretion of the settlement liabilities with Zeiss and Hologic. Interest expense in 2011 represents the accretion of the settlement liabilities with Zeiss and Hologic.

The warrants were issued in connection with the financing closed in January 2012 and are recorded at fair value using the binomial lattice method. The loss from the change in the fair value of the warrant in 2012 was due primarily to the increase in the stock price of the Company from the date of issuance to December 31, 2012.

**Year Ended December 31, 2011 compared to Year 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 revenue resulting from the acquisition of Xofig of \$3.7 million and a \$3.5 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:

	For the year ended December 31,			
	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	3,711		3,711	
Service & supplies revenue	9,324	5,848	3,476	59.4%
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



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decrease in digital revenue 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 revenue. The increase of MRI CAD revenue was 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. Revenue 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 59.4% to \$9.3 million compared to \$5.8 million in 2010. The increase in the Company's service and supply revenue was primarily due to approximately \$2.2 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):

	For the year ended December 31,			
	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 %	69.9%	80.1%		

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

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

	2011	2010	Change	% Change
<b>Operating expenses:</b>				
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	9,999	9,889	110	1.1%
Contingent consideration	(4,900)		(4,900)	
Goodwill impairment	26,828		26,828	
Loss on indemnification asset	741		741	
<b>Total operating expenses</b>	<b>\$ 57,143</b>	<b>\$ 26,235</b>	<b>\$ 30,908</b>	<b>117.8%</b>

*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 \$0.1 million or 1.1%, from \$9.9 million in 2010 to \$10.0 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 \$2.7 million. The decrease of \$2.7 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.

*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.

*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.

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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.

*Other Income/Expense:*

	For the year ended December 31,			
	2011	2010	Change	Change %
Interest expense	\$ (422)	\$	(422)	100.0%
Interest income	27	73	(46)	(63.0)%
Other income		275	(275)	(100.0)%
	\$ (395)	\$ 348	\$ (743)	(213.5)%

Interest expense in 2011 of \$422,000 represents primarily \$156,000 related to the accretion of the Hologic settlement liability and approximately \$266,000 related to the accretion of the Zeiss settlement liability. Interest income decreased due to the decrease of cash balances during the year. Other income for the year ended December 31, 2010 represents a gain on a sale of a patent.

**Liquidity and Capital Resources**

The Company believes that the \$13.9 million cash balance as of December 31, 2012, and projected cash balances from operations are sufficient to sustain operations through at least the next 12 months. The Company's ability to generate cash adequate to meet its future capital requirements will depend primarily on operating cash flow. If sales or cash collections are reduced from current expectations, or if expenses and cash requirements are increased, the Company may require additional financing, although there are no guarantees that the Company will be able to obtain the financing if necessary. The Company will continue to closely monitor its liquidity and the capital and credit markets.

The Company had working capital of \$6.9 million at December 31, 2012. The ratio of current assets to current liabilities at December 31, 2012 and 2011 was 1.5 and 0.9, respectively. The increase in working capital is due to the cash generated from the debt financing arrangement of approximately \$14.3 million which was funded in January 2012, offset by cash used for operations.

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Net cash used for operating activities for the year ended December 31, 2012 decreased by \$5.9 million from \$4.2 million compared to net cash used for operations of \$10.1 million for 2011. The reduction in cash used for operating activities during the year ended December 31, 2012 was due primarily to the reduction in net loss from \$37.6 million in 2011 to \$9.4 million in 2012, which net of adjustments was \$10.4 million in 2011 versus \$3.5 million in 2012. During 2012 the Company used cash due to changes in operating assets and liabilities of approximately \$0.7 million, an increase of cash used of approximately \$1.0 million. The change in operating assets and liabilities is due primarily to reductions of accounts payable and accrued expenses from 2011 which included payment of legal costs and settlement obligations related to Zeiss. Accounts receivable grew by approximately \$0.9 million in 2012, as several large eBx system orders were at the end of the quarter. Deferred revenue grew \$0.8 million, reflecting an increase in service and supplies agreements related to sales of eBx systems and Powerlook AMP. Prepaid expenses and other current assets increased \$0.5 million due primarily to prepaid financing costs related to the debt financing arrangement.

The net cash used for investing activities for the year ended December 31, 2012 was \$0.7 million. The cash used for investing activities in 2012 was primarily for purchases of fixed assets of \$0.7 million.

Net cash provided by financing activities for the year ended December 31, 2012 was \$14.3 million, which was due to the proceeds from the debt financing closed in January, 2012

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

Contractual Obligations	Total	Payments due by period			
		Less than 1 year	1-3 years	3-5 years	5+ years
Lease Obligations	\$ 2,210	\$ 516	\$ 949	\$ 745	\$
Royalty Obligations	3,250	\$ 775	\$ 1,050	1,050	375
Notes Payable	20,144	\$ 1,363	\$ 6,313	12,468	
Other Commitments	2,000	1,591	409		
<b>Total Contractual Obligations</b>	<b>\$ 27,604</b>	<b>\$ 4,245</b>	<b>\$ 8,721</b>	<b>\$ 14,263</b>	<b>\$ 375</b>

**Lease Obligations:**

As of December 31, 2012, 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

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\$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.

The Company leases a facility in San Jose California under a noncancelable operating lease which commenced in September, 2012. The facility has office, manufacturing and warehousing space. The operating lease provides for an annual base rent of \$248,376, for the first year \$260,064, for the second year \$271,752, for the third year \$283,440 for the fourth year and \$295,140 for the fifth year with all amounts payable in equal monthly installments. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the facility.

In addition to the foregoing leases relating to its principal properties, the Company also has a lease for an additional facility in Nashua, New Hampshire used for product repairs, manufacturing and warehousing.

### **Royalty Obligations:**

As a result of the acquisition of Xoft, the Company recorded a royalty obligation pursuant to a settlement agreement entered into between Xoft and Hologic, in August 2007. Xoft received a nonexclusive, irrevocable, perpetual, worldwide license, including the right to sublicense certain Hologic patents, and a non-compete covenant as well as an agreement not to seek further damages with respect to the alleged patent violations. In return the Company has a remaining obligation to pay a minimum annual royalty payment of \$250,000 payable through 2016. In addition to the minimum annual royalty payments, the litigation settlement agreement with Hologic also provided for payment of royalties based upon a specified percentage of future net sales on any products that practice the licensed rights. The estimated fair value of the patent license and non-compete covenant is \$100,000 and is being amortized over the estimated remaining useful life of approximately four years. In addition, a liability has been recorded within accrued expenses and long-term settlement cost for future payment and for future minimum royalty obligations totaling \$0.

During December, 2011, the Company settled the litigation with Zeiss. The Company determined that this settlement should be recorded as a measurement period adjustment and accordingly recorded the present value of the litigation to the opening balance sheet of Xoft. The present value of the liability was estimated at approximately \$1.8 million as of December 31, 2012. The Company has a remaining obligation to pay \$0.5 million in June 2013, \$0.5 million in June 2015 and \$0.5 million in June 2017, for a total of \$1.5 million.

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### Notes Payable:

In connection with the \$15.0 million note dated December 2011 and funded in January 2012, the Company is obligated to pay quarterly interest payments on the outstanding balance at 5.75%. In addition the Company is obligated to repay 25% of the principal amount of the note 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.

In addition to the contractual obligations related to the interest payments from Notes Payable, the Company is obligated under a revenue purchase agreement discussed in Note 3 of the accompanying financial statements, to pay 4.25% of revenue up to \$25 million, 2.75% of annual revenue from \$25 million to \$50 million and 1.0% of annual revenue 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. Notes Payable includes the minimum annual payment related to the revenue purchase agreement.

### Other Commitments:

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

### **Effect of New Accounting Pronouncements**

In February 2013, the FASB issued Accounting Standards Update ( ASU ) 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, an amendment to FASB ASC Topic 220. The update requires disclosure of amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present either on the face of the statement of operations or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required to be reclassified to net income in its entirety in the same reporting period. For amounts not reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional detail about those amounts. This ASU is effective prospectively for the Company for annual and interim periods beginning January 1, 2013. The Company will comply with the disclosure requirements of this ASU for the quarter ending March 31, 2013, and does not expect the disclosure to have a material impact.

### **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.

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

See Financial Statements and Schedule attached hereto.

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

Not Applicable

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

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

The Company, under the supervision and with the participation of its management, including its principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures as of the end of the period covered by this annual report on Form 10-K. Based on this evaluation, the principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of December 31, 2012.

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

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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, 2012 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, 2012, 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.



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**Item 9B. Other Information.**

Not applicable.

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

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

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

<b>Name</b>	<b>Age</b>	<b>Position with iCAD</b>	<b>Director/Officer Since</b>
Dr. Lawrence Howard	60	Chairman of the Board, and Director	2006
Kenneth Ferry	59	President, Chief Executive Officer, and Director	2006
Kevin Burns	42	Executive Vice President of Finance, Chief Financial Officer and Treasurer and Secretary	2011
Jonathan Go	50	Senior Vice President of Research and Development	2006
Stacey Stevens	45	Senior Vice President of Marketing and Strategy	2006
Rachel Brem, MD	54	Director	2004
Anthony Ecock	51	Director	2008
Michael Klein	59	Director	2010
Steven Rappaport	64	Director	2006
Somu Subramaniam	58	Director	2010
Elliot Sussman, MD	61	Director	2002

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.

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*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 and healthcare industries. Most recently, Mr. Burns served as senior vice president and chief financial officer at AMICAS, Inc., a publicly traded image and information management solutions company. During his tenure at AMICAS, from November 2004 to May 2010, Mr. Burns led significant revenue and profit growth and culminating in a successful sale of the company. Prior to joining AMICAS, Mr. Burns worked in finance and corporate planning at NMS Communications, a public telecom equipment company in the wireless applications and infrastructure market, from November 2003 to November 2004. Previously, Mr. Burns was the director of corporate development at Demantra, Inc. and has also held senior management positions in finance, accounting and corporate development at MAPICS, Inc. and Marcam Corporation, both public software companies. Mr. Burns earned both a Bachelor of Science degree in Finance and an MBA degree from Babson College.

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*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.

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

*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* is a General Partner with the private equity investment firm, Welsh, Carson, Anderson & Stowe (WCAS), which he joined in 2007. He has 26 years of experience in the healthcare field with 8 years in senior management positions at leading healthcare technology companies. At WCAS, Mr. Ecock leads the Resources Group, a team responsible for helping its 30 portfolio companies identify and implement initiatives to increase growth, earnings and cash flow. Before joining WCAS, he served as Vice

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President and General Manager of GE Healthcare's Enterprise Sales organization from 2003 to 2007. From 1999 to 2003, he served as Senior Vice President and Global General Manager of Hewlett Packard's, then Agilent's and finally Philips' Patient Monitoring divisions. Mr. Ecock spent his early career at the consulting firm of Bain & Company, where he was a Partner in the healthcare and technology practices and Program Director for Consultant Training. We believe Mr. Ecock's qualifications to serve on our Board of Directors include his financial expertise and his years of experience in the healthcare and technology markets.

*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.

*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.

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*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.

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

### **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

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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, 2012, 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, 2012. The response to this item will be contained in our proxy statement for our 2013 annual meeting of stockholders under the captions Executive Compensation, Compensation of Directors, Compensation Committee Interlocks and Insider Participation, and Compensation Committee Report, and is incorporated herein by reference.

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

The response to this item will be contained in our proxy statement for our 2013 annual meeting of stockholders in part under the caption Stock Ownership of Certain Beneficial Owners and Management and in part below.

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

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2012.

Plan Category:	Number of securities to be issued upon exercise of outstanding options, and rights	Weighted-average exercise price of outstanding options, and rights	Number of securities remaining available for issuance under equity compensation plans, excluding securities reflected in column (a))
Equity compensation plans approved by security holders:	1,332,882	\$ 4.65	249,013
Equity compensation plans not approved by security holders (1):	102,063	\$ 6.02	-0-
<b>Total</b>	<b>1,434,945</b>	<b>\$ 4.75</b>	<b>249,013</b>

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

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

The response to this item is contained in our proxy statement for our 2013 annual meeting of stockholders under the captions Certain Relationships and Related Transactions, Corporate Governance Matters Director Independence and Compensation Committee Report, and is incorporated herein by reference.

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

The response to this item is contained in our proxy statement for our 2013 annual meeting of stockholders under the caption Ratification of Appointment of Independent Registered Public Accounting Firm, and is incorporated herein by reference.



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**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 68.
- ii. Financial Statement Schedule - See Index on page 68. 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 August 15, 2012.

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- 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].

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- 10(h) Lease Agreement dated December 6, 2006 between the Registrant and Gregory D. Stoye and John J. Flatley, Trustees of the 1993 Flatley Family Trust, of Nashua, NH [incorporated by reference to Exhibit 10(mm) to the Registrant's Report on Form 10-K for the year ended December 31, 2006].
- 10(i) 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(j) 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(k) Form of Restricted Stock Agreement under the Registrant's 2007 Stock Incentive Plan. [incorporated by reference to Exhibit 10(vv) to the Registrant's Report on Form 10-K for the year ended December 31, 2009].\*
- 10(l) Employment Agreement entered into as of September 25, 2012 between the Registrant and Kenneth Ferry [incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on September 26, 2012] \*
- 10(m) 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(n) 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(o) Employment Agreement dated April 26, 2011 between the Registrant and Kevin C. Burns [incorporated by reference to Exhibit 10.2 of the Registrant's report on Form 8-K filed with the SEC on April 27, 2011].
- 10(p) 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].\*

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- 10(q) Facility Agreement including form of Promissory note, dated as of December 29, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited [incorporated by reference to Exhibit 10.1 of the Registrant's report on Form 8-K filed with the SEC on January 3, 2012].
  
- 10(r) 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(s) 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(t) 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(u) Settlement Agreement, dated as of December 22, 2011, by and among the Company, Carl Zeiss Meditec, AG and Carl Zeiss Meditec, Inc. [incorporated by reference to Exhibit 10(y) to the Registrant's Report on Form 10-K for the year ended December 31, 2012]
  
- 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.

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31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101 The following materials formatted in XBRL (eXtensible Business Reporting Language); (i) Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011, (ii) Consolidated Statements of Operations for the twelve months ended December 31, 2011 and 2011 and 2010, (iii) Consolidated Statements of Cash Flows for the twelve months ended December 31, 2012 and 2011 and 2010, 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.

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**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: February 27, 2013

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	February 27, 2013
/s/ Kenneth Ferry Kenneth Ferry	President, Chief Executive Officer Director (Principal Executive Officer)	February 27, 2013
/s/ Kevin C. Burns Kevin C. Burns	Executive Vice President of Finance, Chief Financial Officer, Treasurer (Principal Financial and Accounting Officer)	February 27, 2013
/s/ Rachel Brem Rachel Brem, M.D.	Director	February 27, 2013
/s/ Anthony Ecock Anthony Ecock	Director	February 27, 2013
/s/ Michael Klein Michael Klein	Director	February 27, 2013
/s/ Steven Rappaport Steven Rappaport	Director	February 27, 2013
/s/ Somu Subramaniam Somu Subramaniam	Director	February 27, 2013
/s/ Elliot Sussman Elliot Sussman, M.D.	Director	February 27, 2013

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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, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Boston, Massachusetts

February 27, 2013



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

	December 31, 2012	December 31, 2011
	(in thousands except share and per share data)	
<u>Assets</u>		
Current assets:		
Cash and cash equivalents	\$ 13,948	\$ 4,576
Trade accounts receivable, net of allowance for doubtful accounts of \$48 in 2012 and \$54 in 2011	4,980	4,003
Inventory, net	2,119	2,040
Prepaid expenses and other current assets	486	490
Total current assets	21,533	11,109
Property and equipment:		
Equipment	4,422	3,958
Leasehold improvements	108	527
Furniture and fixtures	283	286
Marketing assets	297	297
	5,110	5,068
Less accumulated depreciation and amortization	3,627	3,184
Net property and equipment	1,483	1,884
Other assets:		
Other assets	638	595
Intangible assets, net of accumulated amortization of \$10,744 in 2012 and \$8,840 in 2011	15,230	17,064
Goodwill	21,109	21,109
Total other assets	36,977	38,768
Total assets	\$ 59,993	\$ 51,761
<u>Liabilities and Stockholders' Equity</u>		
Current liabilities:		
Accounts payable	\$ 1,940	\$ 1,198
Accrued expenses	4,142	5,521
Interest payable	499	
Warrant liability	1,538	
Deferred revenue	6,520	5,765
Total current liabilities	14,639	12,484
Other long-term liabilities	68	141
Deferred revenue, long-term portion	1,502	1,446
Settlement costs, long-term	1,273	1,635
Notes payable	14,846	

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Total liabilities	32,328	15,706
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 10,993,933 in 2012 and 10,950,902 in 2011; outstanding 10,808,102 in 2012 and 10,765,071 in 2011		
	110	110
Additional paid-in capital	165,416	164,432
Accumulated deficit	(136,446)	(127,072)
Treasury stock at cost 185,831 in 2012 and 2011	(1,415)	(1,415)
Total stockholders' equity	27,665	36,055
Total liabilities and stockholders' equity	\$ 59,993	\$ 51,761

*See accompanying notes to consolidated financial statements.*

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

	<b>For the Years Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
	(in thousands except per share data)		
<b>Revenue:</b>			
Products	\$ 17,976	\$ 19,328	\$ 18,727
Service and supplies	10,299	9,324	5,848
<b>Total revenue</b>	<b>28,275</b>	<b>28,652</b>	<b>24,575</b>
<b>Cost of Revenue:</b>			
Products	4,834	4,788	2,396
Service and supplies	2,479	2,906	2,486
Amortization	931	931	
<b>Total cost of revenue</b>	<b>8,244</b>	<b>8,625</b>	<b>4,882</b>
<b>Gross profit</b>	<b>20,031</b>	<b>20,027</b>	<b>19,693</b>
<b>Operating expenses:</b>			
Engineering and product development	7,769	10,791	6,596
Marketing and sales	10,708	13,684	9,750
General and administrative	6,966	9,999	9,889
Contingent consideration		(4,900)	
Goodwill impairment		26,828	
Loss on indemnification asset		741	
<b>Total operating expenses</b>	<b>25,443</b>	<b>57,143</b>	<b>26,235</b>
<b>Loss from operations</b>	<b>(5,412)</b>	<b>(37,116)</b>	<b>(6,542)</b>
<b>Other income (expense):</b>			
Interest expense	(3,415)	(422)	
Loss from change in fair value of warrant liability	(539)		
Interest income	35	27	73
Other income			275
<b>Other (expense) income, net</b>	<b>(3,919)</b>	<b>(395)</b>	<b>348</b>
<b>Loss before income tax expense</b>	<b>(9,331)</b>	<b>(37,511)</b>	<b>(6,194)</b>
<b>Income tax expense</b>	<b>43</b>	<b>76</b>	<b>30</b>
<b>Net loss and comprehensive loss</b>	<b>\$ (9,374)</b>	<b>\$ (37,587)</b>	<b>\$ (6,224)</b>
<b>Net loss per share:</b>			
Basic	\$ (0.87)	\$ (3.45)	\$ (0.68)
Diluted	\$ (0.87)	\$ (3.45)	\$ (0.68)
<b>Weighted average number of shares used in computing loss per share:</b>			
Basic	10,796	10,910	9,166
Diluted	10,796	10,910	9,166

*See accompanying notes to consolidated financial statements.*

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

(in thousands except shares)

	Common Stock Number of Shares Issued	Par Value	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Stockholders Equity
Balance at December 31, 2009	9,149,347	\$ 91	\$ 150,429	\$ (83,261)	\$ (950)	\$ 66,309
Issuance of common stock relative to vesting of restricted stock, net of 10,614 shares forfeited for tax obligations	57,702	1	(89)			(88)
Merger consideration (Note 2)	1,669,700	17	11,680			11,697
Stock-based compensation			1,516			1,516
Net loss				(6,224)		(6,224)
Balance at December 31, 2010	10,876,749	109	163,536	(89,485)	(950)	73,210
Issuance of common stock relative to vesting of restricted stock, net of 11,468 shares forfeited for tax obligations	59,153	1	(68)			(67)
Issuance of common stock pursuant to stock option plans	15,000		60			60
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	10,950,902	110	164,432	(127,072)	(1,415)	36,055
Issuance of common stock relative to vesting of restricted stock, net of 4,789 shares forfeited for tax obligations	43,031	0	(12)			(12)
Stock-based compensation			996			996
Net loss				(9,374)		(9,374)
Balance at December 31, 2012	10,993,933	\$ 110	\$ 165,416	\$ (136,446)	\$ (1,415)	\$ 27,665

*See accompanying notes to consolidated financial statements.*

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

	<b>For the Years Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
	(in thousands)		
Cash flow from operating activities:			
Net loss	\$ (9,374)	\$ (37,587)	\$ (6,224)
Adjustments to reconcile net loss to net cash (used for) provided by operating activities:			
Depreciation	891	1,077	476
Amortization	1,904	2,094	1,167
Gain on sale of patent			(275)
Goodwill impairment		26,828	
Loss on disposal of assets	174	21	
Loss on indemnification asset		741	
Loss from change in fair value of warrant liability	539		
Stock-based compensation expense	996	904	1,516
Amortization of debt discount and debt costs	1,012		
Interest on settlement obligations	388	422	
Fair value of contingent consideration		(4,900)	
Changes in operating assets and liabilities, net of acquisition:			
Accounts receivable	(976)	(614)	1,914
Inventory	(79)	1,449	278
Prepaid and other current assets	469	248	78
Accounts payable	815	(1,375)	125
Accrued expenses	(1,775)	(713)	446
Deferred revenue	812	1,263	706
Total adjustments	5,170	27,445	6,431
Net cash (used for) provided by operating activities	(4,204)	(10,142)	207
Cash flow from investing activities:			
Additions to patents, technology and other	(70)	(13)	(28)
Additions to property and equipment	(665)	(263)	(322)
Proceeds from sale of patent			275
Acquisition of Xoft, net of cash acquired			(24)
Net cash used for investing activities	(735)	(276)	(99)
Cash flow from financing activities:			
Issuance of common stock for cash		60	
Taxes paid related to restricted stock issuance	(14)	(67)	(87)
Payment for Xoft		(1,268)	
Proceeds from debt financing, net	14,325		
Net cash (used for) provided by financing activities	14,311	(1,275)	(87)
Increase (decrease) in cash and equivalents	9,372	(11,693)	21
Cash and equivalents, beginning of year	4,576	16,269	16,248

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Cash and equivalents, end of year	\$ 13,948	\$ 4,576	\$ 16,269
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### Supplemental disclosure of cash flow information:

Interest paid	\$ 1,516	\$	\$ 2
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Taxes paid	\$ 55	\$ 40	\$ 89
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### Non-cash items from investing and financing activities:

Fair market value of iCAD common stock issued to acquire Xoft, Inc. and accrued cash consideration	\$	\$	\$ 12,668
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Return of common stock from escrow related to acquisition of Xoft in 2011 and CAD Sciences in 2008.	\$	\$ 465	\$
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*See accompanying notes to consolidated financial statements.*

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**iCAD, INC. AND SUBSIDIARY**

**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 an industry-leading provider of advanced image analysis, workflow solutions and radiation therapy for the early identification and treatment of cancer.

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

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

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

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

Certain prior period amounts presented in the consolidated financial statements have been reclassified to conform to current period presentation as follows: Revenue of approximately \$460,000 for the year ended December 31, 2011 previously classified as Product revenue has been reclassified as Service and supplies revenue.



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

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Xoft, Inc.. All 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, 2012 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, 2012 approximated \$13.1 million.

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

Financial instruments consist of cash and equivalents, accounts receivable accounts payable, notes payable and warrants. The carrying amounts of the financial instruments, approximated fair value as of December 31, 2012 and 2011.

### **(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 based on historical experience, in its overall allowance for doubtful accounts. An amount would be written off against the allowance

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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, 2012 and 2011 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, 2012 and 2011 respectively inventories consisted of the following (in thousands):

	<b>As of December 31,</b>	
	<b>2012</b>	<b>2011</b>
Raw materials	\$ 878	\$ 643
Work in process	47	23
Finished Goods	1,194	1,374
Inventory	\$ 2,119	\$ 2,040

**(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, 2012, 2011 or 2010.

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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 2012 and 2011 are as follows (in thousands):

For the years ended December 31,	2012	2011	Weighted average useful life
<b>Gross Carrying Amount</b>			
Patents and licenses	\$ 693	\$ 623	5 years
Technology	25,033	25,033	10 years
Tradenname	248	248	10 years
<b>Total amortizable intangible assets</b>	<b>25,974</b>	<b>25,904</b>	
<b>Accumulated Amortization</b>			
Patents and licenses	\$ 433	\$ 409	
Technology	10,088	8,233	
Tradenname	223	198	
<b>Total accumulated amortization</b>	<b>10,744</b>	<b>8,840</b>	
<b>Total amortizable intangible assets, net</b>	<b>\$ 15,230</b>	<b>\$ 17,064</b>	

Amortization expense related to intangible assets was approximately \$1,904, \$2,094 and \$1,167 for the years ended December 31, 2012, 2011, and 2010, respectively. Estimated remaining amortization of the Company's intangible assets is as follows (in thousands):

For the years ended December 31:	Estimated amortization expense
2013	\$ 1,712
2014	1,456
2015	1,454
2016	1,447
2017	1,426
Thereafter	7,735
	<b>\$ 15,230</b>

**(i) Goodwill**

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



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The Company measures the fair value of its reporting unit by comparing its market capitalization calculated based on the quoted closing share price of the Company's common stock, using a reasonable control premium, multiplied by the number of shares outstanding at each reporting period (the Market Approach). If the fair value of the reporting unit is less than carrying value based on the above measure, the Company will then embark upon a Step 1 approach to determine the fair value of the reporting unit using a discounted cash flow (Income Approach). On an interim basis the Company may also use a discounted cash flow analysis to corroborate the control premium to provide greater assurance that the Market Approach is reflective of fair value. The Company has consistently applied a control premium from period to period, and the premium is supported by industry transaction data of premiums potential acquirers would pay to gain control of the Company.

The Company assesses the potential impairment of goodwill on an annual basis or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. 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.

At October 1, 2012 (the date of the last annual impairment assessment), fair value, using the Market Approach exceeded fair value by approximately \$0.1 million. The Company also assessed fair value using an Income Approach which was approximately \$39.2 million and exceeded carrying value by approximately \$8.8 million. Accordingly, the Company did not evaluate goodwill using the second step (Step 2) of the goodwill impairment test as fair value exceeded carrying value. At December 31, 2012, with a reasonable control premium, fair value using the Market Approach was approximately \$67.3 million which exceeded carrying value by approximately \$39.6 million.

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 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.

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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.

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, 2011 and 2012 are as follows (in thousands):

<b>Balance as of December 31, 2010</b>	<b>\$ 45,969</b>
Purchase accounting adjustments	1,968
Impairment	(26,828)
<b>Balance as of December 31, 2011</b>	<b>21,109</b>
<b>Balance as of December 31, 2012</b>	<b>\$ 21,109</b>

The Company recorded purchase accounting adjustments considered to be measurement period adjustments, related to the acquisition of Xoft in 2010, which had an immaterial effect on the December 31, 2010 balance sheet. Accordingly, the adjustments were recorded during 2011.

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### **(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 estimated life of the supply agreement.

The Company recognizes revenue from the sale of its digital, film-based CAD and electronic brachytherapy products and services in accordance with Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements* ( ASU 2009-13 ) and ASC Update No. 2009-14, *Certain Arrangements That Contain Software Elements* (Update No. 2009-14). ( ASU 2009-14 ). Revenue for the sale of certain CAD products is recognized in accordance with ASC 840 ( *Leases* ) ( ASC 840 ). Revenue related to arrangements services was recognized in accordance with FASB ASC Topic 605-35 *Revenue Recognition Construction Type and Production Type Contracts* ( ASC 605-35 ). For multiple element arrangements, revenue is allocated to all deliverables based on their relative selling prices. In such circumstances, a hierarchy is used to determine the selling price to be used for allocating revenue to deliverables as follows: (i) vendor-specific objective evidence of fair value ( VSOE ), (ii) third-party evidence of selling price ( TPE ), and (iii) best estimate of the selling price ( BEP ). VSOE generally exists only when the deliverable is sold separately and is the price actually charged for that deliverable. The process for determining BEP for deliverables without VSOE or TPE considers multiple factors including relative selling prices; competitive prices in the marketplace, and management judgment, however, these may vary depending upon the unique facts and circumstances related to each deliverable.

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

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

The Company has determined that iCAD's Digital, MRI and film based sales generally follow the guidance of FASB ASC Topic 605 *Revenue Recognition* (ASC 605 ) as the software has been considered essential to the functionality of the product per the

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guidance of ASU 2009-14. Typically, the responsibility for the installation process lies with the OEM partner. On occasion, when iCAD is responsible for product installation, the installation element is considered a separate unit of accounting because the delivered product has stand-alone value to the customer. In these instances, the Company allocates the 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.

Sales of the Company's electronic brachytherapy product typically include a controller, accessories, and service and source agreements. The Company allocates revenue to the deliverables in the arrangement based on the BESP in accordance with ASU 2009-13. Product revenue is generally recognized when the product has been delivered and service and source revenue is typically recognized over the life of the service and source agreement.

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

**(k) Cost of Revenue**

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

**(l) Warranty Costs**

The Company provides for the estimated cost of standard product warranty against defects in material and workmanship based on historical warranty trends, including in the volume and cost of product returns during the warranty period. Warranty provisions and claims for the years ended December 31, 2012, 2011 and 2010, were as follows:

Warranty costs: (000 \$)			
	2012	2011	2010
Beginning balance	\$ 89	\$ 86	\$ 91
Warranty provision	37	107	11
Usage	(90)	(104)	(16)
Ending balance	\$ 36	\$ 89	\$ 86



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The warranty costs above include long-term warranty obligations of \$10,000, \$13,000 and \$15,000 for the years ended December 31, 2012, 2011 and 2010, 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, 2012, 2011 and 2010 was approximately \$762,000, \$938,000 and \$666,000 respectively.

### (o) Net Loss per Common Share

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

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

	2012	2011	2010
Net loss available to common shareholders	\$ (9,374)	\$ (37,587)	\$ (6,224)
Basic shares used in the calculation of earnings per share	10,796	10,910	9,166
Effect of dilutive securities:			
Stock options			
Restricted stock			
Diluted shares used in the calculation of earnings per share	10,796	10,910	9,166
Net loss per share :			
Basic	\$ (0.87)	\$ (3.45)	\$ (0.68)
Diluted	\$ (0.87)	\$ (3.45)	\$ (0.68)

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

	2012	2011	2010
Common stock options	1,434,945	1,080,722	1,058,705
Warrants	550,000		
Restricted Stock	67,075	122,795	153,215
	<b>2,052,020</b>	<b>1,203,517</b>	<b>1,211,920</b>



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

**(p) Income Taxes**

The Company follows the liability method under ASC Topic 740, *Income Taxes*, (ASC 740). The primary objectives of accounting for taxes under ASC 740 are to (a) recognize the amount of tax payable for the current year and (b) recognize the amount of deferred tax liability or asset for the future tax consequences of events that have been reflected in the Company's financial statements or tax returns. The Company has provided a full valuation allowance against its deferred tax assets at December 31, 2012 and 2011, as it is more likely than not that the deferred tax asset will not be realized. Any subsequent changes in the valuation allowance will be recorded through operations in the provision (benefit) for income taxes.

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

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.

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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**

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

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

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

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value measurement. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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

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

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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. At December 31, 2012 and 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.

In connection with the financing as further described in Note 3 to the Consolidated Financial Statements, the Company issued 550,000 Warrants to purchase shares of common stock at an exercise price of \$3.50 per share. The value of the warrants was determined using a binomial lattice model and the value is based on significant inputs not observable in the market including the probability of exercise and the probability of a major transaction. The significant assumptions underlying the value of the warrants are as follows:

	January 6, 2012	December 31, 2012
<b><u>Warrants</u></b>		
Exercise price	\$ 3.50	\$ 3.50
Volatility	80.4%	82.4%
Equivalent term (years)	6.00	5.00
Risk-free interest rate	1.4%	0.8%

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

**Fair value measurements using: (000's) as of December 31, 2012**

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Money market accounts	\$ 12,336	\$	\$	\$ 12,336
<b>Total Assets</b>	\$ 12,336	\$	\$	\$ 12,336
<b>Liabilities</b>				
Contingent Consideration	\$	\$	\$	\$
Warrants			1,538	1,538
<b>Total Liabilities</b>	\$	\$	\$ 1,538	\$ 1,538

**Fair value measurements using: (000's) as of December 31, 2011**

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Money market accounts	\$ 4,452	\$	\$	\$ 4,452
<b>Total Assets</b>	\$ 4,452	\$	\$	\$ 4,452
<b>Liabilities</b>				
Contingent Consideration	\$	\$	\$	\$
<b>Total Liabilities</b>	\$	\$	\$	\$

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

<b>Contingent Consideration</b>	<b>Amount</b>
Balance as of December 31, 2010	\$ 5,000
Measurement period adjustment	(100)
Mark to market	(4,900)

Balance as of December 31, 2011

<b>Balance as of December 31, 2012</b>	<b>\$</b>
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<b>Warrants</b>	<b>Amount</b>
Balance as of December 31, 2011	\$
Value at issuance	999

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Loss from change in fair value of warrant	539
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<b>Balance as of December 31, 2012</b>	<b>\$ 1,538</b>
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### *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, 2012.

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### **(s) Recently Issued Accounting Standards**

In February 2013, the FASB issued Accounting Standards Update ( ASU ) 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, an amendment to FASB ASC Topic 220. The update requires disclosure of amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present either on the face of the statement of operations or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required to be reclassified to net income in its entirety in the same reporting period. For amounts not reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional detail about those amounts. This ASU is effective prospectively for the Company for annual and interim periods beginning January 1, 2013. The Company will comply with the disclosure requirements of this ASU for the quarter ending March 31, 2013 and expects the disclosure to have an immaterial impact.

### **(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 1,669,700 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 \$7.00, 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 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



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\$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 acquisition the Company recorded \$4.9 million of contingent consideration, however the Company does not expect to reach these thresholds, and accordingly at December 31, 2012, there is no liability recorded for the earn-out consideration.

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 (collectively Zeiss), which was partially indemnified under the Xoft merger agreement.

In connection with the settlement, the Company determined the settlement was a measurement period adjustment and recorded, retrospectively, approximately \$1.6 million as the fair value of the settlement liability, an indemnification asset of approximately \$1.3 million 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 escrow 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, as of December 31, 2012 and 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):

	Amount
Current and other assets	\$ 5,956
Long-term assets	\$ 15,751
Goodwill	4,422
Current liabilities	(5,196)
Long-term liabilities	(3,154)
 Purchase price	 \$ 17,779

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

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.

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, however a loss is reasonably possible. Accordingly, since the amount of the potential damages in the event of an adverse result is not reasonably estimable, we are unable to estimate a range of loss and no expense 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 revenue 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 450,000 shares of common stock at an exercise price of \$3.50 per share and (ii) a second Warrant (the B Warrant ) to purchase an additional 100,000 shares of common stock at a exercise price of \$3.50 per share, which may become exercisable if certain conditions are met, as described below. Collectively, these

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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.

**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 will exercise its option 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 paid the Company \$4,107,900, in the form of an original issue discount from the \$15.0 million Facility agreement, in exchange for the Purchasers' right to receive a percentage of the Company's revenue. 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 revenue for such quarter and the applicable quarterly minimum, which is \$125,000 per quarter. In the final quarter of each calendar year

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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 revenue 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 revenue payments through 2017. The applicable percentage for the calendar years 2012, 2013 and 2014 are 4.25% of revenue up to \$25 million in annual revenue for the calendar year, 2.75% of revenue from \$25 million in annual revenue up to \$50 million in annual revenue for such calendar year and 1.0% of revenue in excess of \$50 million in annual revenue for such calendar year. The applicable percentage for the calendar years 2015, 2016, and, if applicable, 2017, are 4.25% of revenue up to \$25 million in annual revenue for such calendar year, 2.25% of revenue from \$25 million up to \$50 million in annual revenue for such calendar year and 1.0% of revenue in excess of \$50 million in annual revenue 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 550,000 shares of common stock at an exercise price of \$3.50 per share (the Warrants). On the Funding Date, the Warrants to purchase 450,000 shares of the Company's common stock became immediately exercisable. If the Company extends the maturity date of the Facility Agreement, the 100,000 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

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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.

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's outstanding 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.

The Company has determined that the Facility Agreement will be accounted for as debt pursuant to ASC 470, *Debt* (ASC 470). The Facility Agreement had an original issue discount of approximately \$4.1 million which was assigned to the Revenue Purchase Agreement and an additional value allocated to the warrants of approximately \$1.0 million. The original issue discount is being accreted to the \$15.0 million face value of the Note on the effective interest method with an effective interest rate of 17.35% based on the discount of approximately \$5.1 million.

The original issue discount of approximately \$4.1 million was assigned to the Revenue Purchase Agreement. Under this agreement, the Company is obligated to pay 4.25% of revenue up to \$25 million, 2.75% of annual revenue from \$25 million to \$50 million

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during 2012, 2013 and 2014, and 2.25% of annual revenue during 2015, 2016 and if the Facility Agreement is extended, in 2017, and 1.0% of annual revenue in excess of \$50 million. The proceeds of the Revenue Purchase Agreement will be capitalized as debt in accordance with ASC 470-10-25, *Sales of Future Revenues or Various Other Measures of Income*. Expected revenue related payments under this agreement are included as interest expense in the period incurred. The repayment of the \$4.1 million original issue discount capitalized as debt will be amortized as a reduction of interest expense over the term of the arrangement. The effective amortization rate of the repayment is approximately 28.8% which is calculated based on the expected cash outflows over the term of the arrangement.

The overall effective interest rate of the financing arrangement, which excludes future changes in the fair value of the warrants, is currently estimated to be approximately 19%.

The Company determined the Warrants should be classified as debt in accordance with ASC 480, *Distinguishing Liabilities from Equity*, as the Warrants contain a feature whereby the Company could be required to redeem the Warrants for cash upon the occurrence of a major transaction, as defined in the Warrants. The value of the Warrants was determined using a binomial lattice model as the provisions in the Warrant could not be valued using the Black-Scholes model. The Warrant is being valued at fair value at each reporting period with changes in fair value recorded in the consolidated statement of operations.

The Company has determined that the B Warrant does not have any value as of the Funding Date, as the B Warrant is exercisable upon the Company's election to extend the Facility Agreement. The Company does not plan to extend the Facility Agreement at this time. If the Company determines it will extend the Facility Agreement, the value of the B Warrant will be determined using the binomial lattice model at such time.

The following amounts are included in the consolidated balance sheet as of December 31, 2012 related to the Facility and Revenue Purchase agreements:

Principal Amount of Facility Agreement	\$ 15,000
Unamortized discount	(4,196)
Carrying amount of Facility Agreement	10,804
Revenue Purchase Agreement	4,042
Notes payable total	\$ 14,846

The following amounts comprise interest expense included in our consolidated statement of operations for the twelve months ended December 31, 2012:

	December 31, 2012
Cash interest expense	\$ 2,015
Non-cash amortization of debt discount	845
Amortization of debt costs	167
Amortization of settlement obligations	388
Total interest expense	\$ 3,415

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Cash interest expense represents the amount of interest expected to be paid in cash under the agreements, which represents the interest of 5.75% on the Facility Agreement and the expected cash payments on the Revenue Purchase Agreement for the period. Non-cash amortization is the amortization of the discount on the Facility Agreement. The amortization of debt costs represents the costs incurred with the financing, which is primarily the facility fee and the finder's fee which has been capitalized and is expensed using the effective interest method. The amortization of the settlement obligations represent the interest associated with the settlement agreements for both Zeiss and Hologic, Inc.( Hologic ).

**(4) Accrued Expenses**

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

	2012	2011
Accrued salary and related expenses	\$ 2,112	\$ 2,249
Accrued accounts payable	528	1,001
Accrued professional fees	303	357
Accrued short term settlement costs	721	1,241
Other accrued expenses	425	302
Deferred rent	53	371
	\$ 4,142	\$ 5,521

**(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 240,000 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

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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, 2012, 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 100,000 shares of the Company's common stock. The purchase price of each share for which an option is granted is determined by the Board of Directors or the Committee appointed by the Board of Directors provided that the purchase price of each share for which an incentive option is granted cannot be less than the fair market value of the Company's common stock on the date of grant, except for options granted to 10% stockholders for whom the exercise price cannot be less than 110% of the market price. Incentive options granted to date under the 2002 Plan vest 100% over periods extending from six months to five years from the date of grant and expire no later than ten years after the date of grant, except for 10% holders whose options expire not later than five years after the date of grant. Non-qualifying options granted under the 2002 Plan are generally exercisable over a ten year period, vesting 1/3 each on the first, second, and third anniversaries of the date of grant. At December 31, 2012, there were no further options available for grant under the 2002 Plan.

**The 2004 Stock Incentive Plan ( The 2004 Plan )**.

The 2004 Plan was adopted by the Company's stockholders in June 2004. The 2004 Plan provides for the grant of any or all of the following types of awards: (a) stock options, (b) restricted stock, (c) deferred stock and (d) other stock-based awards. The 2004 Plan provides for the granting of non-qualifying and incentive stock options to employees and other persons to purchase up to an aggregate of 200,000 shares of the Company's common stock. The purchase price of each share for which an option is granted is determined by the Board of Directors or the Committee appointed by the Board of Directors provided that the purchase price of each share for which an option is granted cannot be less than the fair market value of the Company's common stock on the date of grant, except for incentive options granted to 10% stockholders for whom the exercise price cannot be less than 110% of the market price. Incentive options granted under the 2004 Plan generally vest 100% over periods extending from the date of grant to five years from the date of grant and expire not later than ten years after the date of grant, except for 10% holders whose options expire not later than five years after the date of grant. Non-qualifying



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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, 2012 there were 27,612 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 120,000 shares of the Company's common stock. The purchase price of each share for which an option is granted is determined by the Board of Directors or the Committee appointed by the Board of Directors provided that the purchase price of each share for which an option is granted cannot be less than the fair market value of the Company's common stock on the date of grant, except for incentive options granted to 10% stockholders for whom the exercise price cannot be less than 110% of the market price. Incentive options granted under the 2005 Plan generally vest 100% over periods extending from the date of grant to three years from the date of grant and expire not later than five years after the date of grant, except for 10% stockholders whose options expire not later than five years after the date of grant. Non-qualifying options granted under the 2005 Plan are generally exercisable over a ten year period, vesting 1/3 each on the first, second, and third anniversaries of the date of grant. At December 31, 2012, there were 1,906 shares available for issuance under the 2005 Plan.

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

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

The 2007 Plan provides that it will be administered by the Company's Board of Directors ( 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.

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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, 2012, there were 10,864 shares available for issuance under the 2007 Plan.

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

The 2012 Plan was adopted by the Company's stockholders in May 2012. The 2012 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 2012 Plan, (i) the 2012 Plan provides for a total of 600,000 shares of the Company's common stock to be available for distribution pursuant to the 2012 Plan, and (ii) the maximum number of shares of the Company's common stock with respect to which stock options, restricted stock, deferred stock, or other stock-based awards may be granted to any participant under the 2012 Plan during any calendar year or part of a year may not exceed 100,000 shares.

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

The administrator will generally have the authority to administer the 2012 Plan, determine participants who will be granted awards under the 2012 Plan, the size and types of awards, the terms and conditions of awards and the form and content of the award agreements representing awards. Awards under the 2012 Plan may be granted to employees, directors, consultants and advisors of the Company and its subsidiaries. However, only employees of the Company and its subsidiaries will be eligible to receive options that are designated as incentive stock options.

With respect to options granted under the 2012 Plan, the exercise price must be at least 100% (110% in the case of an incentive stock option granted to a 10% stockholder) of the fair market value of the common stock subject to the award, determined as of the date of grant. Restricted stock awards are shares of common stock that are awarded subject to the satisfaction of the terms and conditions established by the administrator. In general, awards that do not require exercise may be made in exchange for such lawful consideration, including services, as determined by the administrator. At December 31, 2012, there were 208,630 shares available for issuance under the 2012 Plan.

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

	Option Shares	Price range per share	Weighted Average
Outstanding, January 1, 2010	1,031,824	\$4.00-\$26.40	\$ 12.50
Granted	64,380	\$7.00-\$9.75	\$ 7.80
Exercised			\$ 0.00
Forfeited	(37,500)	\$7.50-\$24.40	\$ 11.35
Outstanding, December 31, 2010	1,058,705	\$4.00-\$26.40	\$ 12.25
Granted	631,357	\$2.75-\$7.10	\$ 5.35
Exercised	(15,000)	\$4.00	\$ 4.00
Forfeited	(594,339)	\$3.00-\$24.40	\$ 9.60
Outstanding, December 31, 2011	1,080,722	\$2.75-\$26.40	\$ 9.75
Granted	693,601	\$2.00-\$3.70	\$ 2.43
Exercised			\$ 0.00
Forfeited	(339,978)	\$2.85-\$24.40	\$ 15.95
Outstanding, December 31, 2012	1,434,345	\$2.00-\$26.40	\$ 4.75

Exercisable at year-end	Option Shares	Price range per share	Weighted average exercise price
2010	1,018,476	\$4.00-\$26.40	\$ 12.35
2011	679,716	\$2.80-\$26.40	\$ 12.40
2012	485,553	\$2.00-\$26.40	\$ 7.06

Available for future grants at December 31, 2012 from all plans: 249,012

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

	Years Ended December 31,		
	2012	2011	2010
Cost of revenue	\$ 15	\$ 14	\$ 14
Engineering and product development	178	172	138
Marketing and sales	242	224	367
General and administrative expense	561	494	997
	<b>\$ 996</b>	<b>\$ 904</b>	<b>\$ 1,516</b>

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As of December 31, 2012, there was \$1.3 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 1.14 years.

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

	Years Ended December 31,		
	2012	2011	2010
Average risk-free interest rate	0.98%	2.51%	1.94%
Expected dividend yield	None	None	None
Expected life	3.5 years	3.5 years	3.5 years
Expected volatility	65.9% to 68.9%	67.0% to 69.3%	69.4%
Weighted average exercise price	\$ 2.43	\$ 5.35	\$ 7.80
Weighted average fair value	\$ 1.17	\$ 2.65	\$ 3.30

The Company's 2012, 2011 and 2010, 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, 2012, 2011 and 2010 was \$1.8 million, \$2,050 and \$91,523, respectively. The aggregate intrinsic value of the options exercisable at December 31, 2012, 2011 and 2010 was \$0.3 million, \$250 and \$85,790, respectively. The aggregate intrinsic value of stock options exercised during 2012, 2011 and 2010 was \$0, \$24,088 and \$0, respectively. The Company used the market price of \$4.79, \$2.85 and \$6.75 per share at December 31, 2012, 2011 and 2010, 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, 2012, there were 67,075 unvested restricted stock awards outstanding. A summary of restricted stock activity for all stock option plans is as follows:

	Years Ended December 31,		
	2012	2011	2010
Beginning outstanding balance	122,795	153,215	118,431
Granted		62,000	108,100
Vested	(43,387)	(59,153)	(57,702)
Forfeited	(12,333)	(33,267)	(15,614)
Ending outstanding balance	<b>67,075</b>	<b>122,795</b>	<b>153,215</b>

The aggregate intrinsic value of restricted stock outstanding at December 31, 2012, 2011 and 2010 was \$0.3 million, \$0.3 million, and \$1.0 million, respectively. The aggregate

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intrinsic value of restricted stock vested during 2012, 2011 and 2010 was \$0.2 million, \$0.2 million and \$0.4 million, respectively. The Company used the market price of \$4.79, \$2.85 and \$6.75 per share at December 31, 2012, 2011 and 2010, respectively, to determine the aggregate intrinsic values.

**(6) Income Taxes**

The components of income tax expense for the years ended December 31, 2012, 2011 and 2010 are as follows:

	2012	2011	2010
Current provision (benefit):			
Federal	\$	\$	\$
State	43	76	30
	\$ 43	\$ 76	\$ 30

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, 2012, 2011 and 2010 is as follows:

	2012	2011	2010
Federal statutory rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit	4.0%	1.8%	0.0%
Net state impact of deferred rate change	0.1%	0.2%	0.0%
Stock compensation expense	(1.8%)	(0.4%)	0.0%
Goodwill impairment	0.0%	(24.3%)	0.0%
Contingent consideration	0.0%	4.4%	0.0%
Other permanent differences	(2.4%)	(0.5%)	3.2%
Change in valuation allowance	(34.4%)	(15.6%)	(37.3%)
Other	0.0%	0.4%	0.1%
Effective income tax	(0.5%)	0.0%	0.0%

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.

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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):

	2012	2011
Inventory (Section 263A)	\$ 298	\$ 320
Inventory reserves	182	262
Receivable reserves	52	77
Other accruals	1,159	2,525
Deferred revenue	897	205
Accumulated depreciation/amortization	179	138
Stock options	1,808	1,646
Developed technology	(3,915)	(4,268)
Tax credits	1,698	1,297
NOL carryforward	34,288	31,786
Net deferred tax assets	36,646	33,988
Valuation allowance	(36,646)	(33,988)
	\$	\$

The valuation allowance as of December 31, 2012 and 2011 totaled approximately \$36.6 million and \$34.0 million 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, 2012, the Company has net operating loss carryforwards totaling approximately \$96.0 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, 2012, 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, 2012 and 2011.

The Company currently has approximately \$17.0 million (including approximately \$9.0 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 2032. 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 \$1.7 million. The Company currently has approximately \$3.5 million (including approximately \$1.8 million that relate to Xoft, Inc.) in tax credit carryforwards that are subject to limitations. The tax credits related to Xoft have been fully reserved for and as a result no deferred tax asset has been recorded. The credits expire in various years through 2032.

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.

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As of December 31, 2012 and 2011, 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, 2012, 2011 and 2010. 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, 2012 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, electronic brachytherapy equipment and other medical equipment, and to foreign distributors of mammography and electronic brachytherapy equipment. Export sales to a single country did not exceed 10% of total revenue in any year. Total export sales were approximately \$2.9 million or 10% of revenue in 2012 as compared to \$1.8 million or 6% of total revenue in 2011 and \$4.0 million or 16% of total revenue in 2010.

As of December 31, 2012 and 2011, the Company had outstanding receivables of \$0.8 million and \$0.1 million, respectively, from distributors of its products who are located outside of the U.S.

**(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 \$4.5 million in 2012, \$6.8 million in

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2011 and \$9.3 million in 2010 or 16%, 24%, and 38% of the Company's revenue, respectively, with accounts receivable balances of \$0.6 and \$0.2 million at December 31, 2012 and 2011, respectively. Fuji Medical Systems accounted for \$2.3 million in 2012, \$3.2 million in 2011 and \$3.1 million in 2010 or 8%, 11% and 13% of the Company's revenue, respectively, with accounts receivable balances of \$0.3 million and \$0.2 million at December 31, 2012 and 2011, respectively.

### **(8) Commitments and Contingencies**

#### **(a) Lease Obligations**

As of December 31, 2012, 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.

The Company leases a facility in San Jose California under a noncancelable operating lease which commenced in September, 2012. The facility has office, manufacturing and warehousing space. The operating lease provides for an annual base rent of \$248,376, for the first year \$260,064, for the second year \$271,752, for the third year \$283,440 for the fourth year and \$295,140 for the fifth year with all amounts payable in equal monthly installments. Additionally, the Company is required to pay its proportionate share of the building and real estate tax expenses and obtain insurance for the facility.

In addition to the foregoing leases relating to its principal properties, the Company also has a lease for an additional facility in Nashua, New Hampshire used for product repairs, manufacturing and warehousing.

Rent expense for all leases for the years ended December 31, 2012, 2011 and 2010 was \$799,000, \$957,000 and \$656,000, net of sublease income of \$0, \$0, and \$200,046, respectively.



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Future minimum rental payments due under these agreements as of December 31, 2012 are as follows (in thousands):

Fiscal Year	Operating Leases
2013	\$ 516
2014	476
2015	473
2016	490
2017	255
	\$ 2,210

**(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 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, 2012.

**(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, 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

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\$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 four years. In addition, a liability has been recorded within accrued expenses and long-term settlement cost for future payment and for future minimum royalty obligations totaling \$0.

During December, 2011, the Company settled the litigation with Zeiss. The Company determined that this settlement should be recorded as a measurement period adjustment and accordingly recorded the present value of the litigation to the opening balance sheet of Xoft. The present value of the liability was estimated at approximately \$1.8 million as of December 31, 2012. The Company has a remaining obligation to pay \$0.5 million in June 2013, \$0.5 million in June 2015 and \$0.5 million in June 2017, for a total of \$1.5 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 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

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Superior Court (Docket No. 30-2012-00538423-CU-PL-CXC) with identical allegations against the same defendants. On April 11, 2012, the above-referenced cases were consolidated for all purposes, excluding trial. On May 2, 2012, plaintiffs filed a master consolidated complaint, with the same case number as the original filed complaint. On August 2, 2012, plaintiffs filed fictitious name amendments adding defendants, Mel Silverstein, M.D., Peter Chen, M.D., Lisa Guerrero, M.D., Ralph Mackintosh, Ph.D., Robert Dillman, M.D., and Jack Cox. On September 14, 2012, an additional Jane Doe plaintiff and John Doe spouse filed a complaint in the Orange County Superior Court (Docket No. 30-2012-00598740-CU-PL-CXC) with identical allegations as plaintiffs above against the same original defendants. On October 17, 2012, plaintiff John Doe No. 11 dismissed his complaint, with prejudice, as to all defendants. On November 26, 2012, plaintiffs filed an additional fictitious name amendment adding defendant, American Ceramic Technology, Inc. On January 15, 2013, plaintiffs filed a dismissal, with prejudice, as to defendant, Mel Silverstein, M.D., only. It is alleged that each Jane Doe plaintiff 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 was 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 our preliminary analysis, we plan to vigorously defend the lawsuits, however a loss is reasonably possible. Accordingly, since the amount of the potential damages in the event of an adverse result is not reasonably estimable, we are unable to estimate a range of loss and no expense has been recorded with respect to the contingent liability associated with this matter.

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

	Net sales	Gross profit	Net loss	Loss per share available to common stockholders	Weighted average number of shares outstanding
<b>2012</b>					
First quarter	\$ 6,343	\$ 4,427	\$ (2,264)	(\$ 0.21)	10,776
Second quarter	5,931	4,169	(2,943)	(\$ 0.27)	10,794
Third quarter	8,183	5,882	(1,465)	(\$ 0.14)	10,805
Fourth quarter	7,818	5,553	(2,702)	(\$ 0.25)	10,808
<b>2011</b>					
First quarter	\$ 7,344	\$ 5,132	\$ (4,312)	(\$ 0.40)	10,873
Second quarter	6,646	4,503	(5,411)	(\$ 0.50)	10,910
Third quarter	8,052	5,889	(25,637)	(\$ 2.35)	10,936
Fourth quarter	6,610	4,503	(2,227)	(\$ 0.20)	10,918