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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

Zacks Small-Cap Research

www.zacks.com 111 North Canal Street, Chicago, IL 60606

Icad Inc (ICAD-NASDAQ)

ICAD: Q3 Results Beat on Revenue, GM, Expenses, EPS.

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	07/29/2011
Current Price (10/28/11)	$0.71
Target Price	**$1.30**

OUTLOOK

iCAD's December 2010 acquisition of Xoft expands their capabilities beyond just a leader in cancer image analysis to also being a provider of novel cancer therapy.
The inclusion of Xoft should offset declining imaging-related revenue and is already providing iCAD with incremental revenue growth. Medicare reimbursement for IORT (Xoft's sweet-spot) is expected to be available in January 2012 and be the catalyst to ramp Xoft's revenue.
We think image-related revenue could begin to rebound in 2012 as well as a result of new product launches, recent favorable regulatory changes, broader reimbursement and new agreements with OEM partners. Street's over-reaction to Q2 results created an attractive entry point. Shares remain cheap. We are maintaining our Outperform rating and $1.30/share price target.

SUMMARY DATA

52-Week High	**$1.55**
52-Week Low	**$0.40**
One-Year Return (%)	**-51.54**
Beta	**1.40**
Average Daily Volume (sh)	**61,221**
Shares Outstanding (mil)	**55**
Market Capitalization ($mil)	**$39**
Short Interest Ratio (days)	**1.27**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**14**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**4.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**Small-Value**
Industry	**Comp-Software**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	6,520 A	6,097 A	5,586 A	6,371 A	24,575 A
2011	7,344 A	6,646 A	8,052 A	8,495 E	30,537 E
2012					38,461 E
2013					57,680 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.02 A	-$0.02 A	-$0.03 A	-$0.07 A	-$0.14 A
2011	-$0.08 A	-$0.11 A	-$0.04 A	-$0.05 E	-$0.28 E
2012					-$0.18 E
2013					-$0.09 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Q3 RESULTS

iCAD announced financial results for the third quarter ending September 30, 2011 on October 27th. Similar to the prior quarter, revenue again came in well ahead of our estimate. However, unlike Q2 where a slightly softer than anticipated gross margin and higher than modeled operating expenses more than offset the beat on the top-line (resulting in lower than estimated EPS), Q3's results were better than our numbers in all three categories (i.e. - revenue, gross margin and operating expenses). The result was a big beat on EPS (adjusted for one-time items) in Q3.

Revenue
Revenue of $8.05MM was up 44% y-o-y and 15% better than our $7.0MM estimate, the difference mostly a result of Digital & MRI CAD revenue coming in over $600k ahead of our number.

- **Products revenue:** $5.76MM actual vs. $4.9MM estimate

  - Digital & MRI CAD revenue was $3.79MM, up 15% y-o-y and significantly better than our $3.18MM estimate (implying -4.0% growth). MRI CAD sales continue to be relatively strong in the U.S. but remain soft overseas. Management noted on the call that mammography CAD sales benefitted from a strong introduction of their SecondLook multi-vendor product. iCAD does not break out sales of MRI CAD versus that for mammography, although management has indicated in the past that the majority of revenue from this category comes from mammography. Growth in iCAD's mammography CAD sales have historically closely tracked that of new digital mammography systems (as reported by FDA's MQSA data - see our graph in this report) - which management noted continued to be the case through the first nine months of 2011.

  - Film-based revenue was $616k, down 18% but better than our $500k estimate

  - Electronic brachytherapy (Axxent) devices revenue came in at $1,347k, ahead of our $1,200k estimate. Management noted that they sold several systems during the quarter including overseas. As we have indicated in the past, the assignment of CPT codes should be a further catalyst to increasing the placement rate. The American Medical Association assigned CPT codes for IORT in early October. Reimbursement payment amounts are expected to be assigned any day now.

- **Services / supplies revenue**: Came in at $2.3MM ($441k Axxent-related, $1,857k CAD-related), up 51% y-o-y and ahead of our $2.1MM ($576k Axxent-related, $1,576k CAD-related) estimate

EPS
Q3 EPS on a GAAP basis was ($0.46) but, stripping out one-time items, came in at ($0.04), compared to our ($0.08) estimate. The $0.04 positive difference between actual adjusted EPS and our estimate was split between better than modeled revenue ($0.016), gross margin ($0.005), and significantly lower operating expenses ($0.023).

It is worth noting that gross margin, at 73.1% in Q3, was particularly strong (GM was 69.9% in Q1 and 67.8% in Q2) and significantly wider than where we had it modeled (69.8%). We have since increased our GM estimate for Q4 from 69.4% to 71.7% - which could still prove conservative as this implies full-year GM of 70.8%, slightly below the low-end of management's GM guidance of 71% - 73%. We have also adjusted our future operating expense estimates as a result of iCAD trimming expenses quicker and deeper than we had earlier anticipated. Operating expenses were almost $1.5MM less than where we had them modeled in Q3 and fell about $2.8MM (excluding a severance charge) from Q2 - which is a testament to management delivering on their previously announced cost-cutting initiatives.

The non-recurring, non-cash items in Q3 included a $26.8MM charge for goodwill impairment (related to the drop in iCAD's stock price during Q3) and a $3.8MM gain reversing the liability iCAD had been carrying as an estimate for potential earn-outs payable to Xoft which is contingent on iCAD hitting minimum pre-determined sales of Axxent and related consumables.

Guidance
Management reiterated revenue guidance of $30MM - $32MM for 2011. Gross margin guidance is 71% - 73%.

Prior to Q3 results we were modeling 2011 revenue of $29.7MM. We now look for revenue of $30.5MM. We moved our 2011 non-GAAP (adjusted for one-time items) EPS estimate from ($0.34) prior to Q3 results to our current ($0.28). Our 2011 GAAP EPS estimate moved from ($0.33) to ($0.68).

We have also made some slight adjustments to our later years EPS estimates, mostly reflecting our updated view on operating expenses (which we have moderately trimmed) and gross margins (which have increased very slightly).

BUSINESS UPDATE

SecondLook Premier: "Reader study" completed during Q3. Management expects FDA filing by the middle of November and hopes to have the product in the U.S. market by late in the first half of 2012 - this is commensurate with our previous expectations. SecondLook is already available in Europe, Canada and China.

CPT I Code: AMA assigned CPT codes for Intraoperative Radiation Therapy in early October. The codes, 77424 and 77469, will be active January 1, 2012. Reimbursement amounts under these codes are expected to be announced by November 1st. If all goes well, the level of reimbursement (i.e. - relative value) will incentivize (or at least does not dis-incentivize) radiation oncologists to use IORT instead of EBRT or APBI for those patients where it is appropriate. Assuming that turns out to be the case, this should be a significant catalyst to increasing demand for Axxent.

BUSINESS

Already established as a leading provider of advanced image analysis for mammography, MRI and CT, iCAD, Inc's. (iCAD) December 2010 purchase of Xoft, Inc. (Xoft) expanded their capabilities beyond just cancer detection/diagnosis and into cancer therapy. Management expects the acquisition to be a catalyst in transforming iCAD from "a leader in image analysis" to a company with "a broader portfolio of oncology solutions that provide *targeted* analysis, therapy and monitoring throughout the cancer cycle." Management looks for 2011 to be the front-end of this transformation and believes the company is now well positioned for long-term growth.

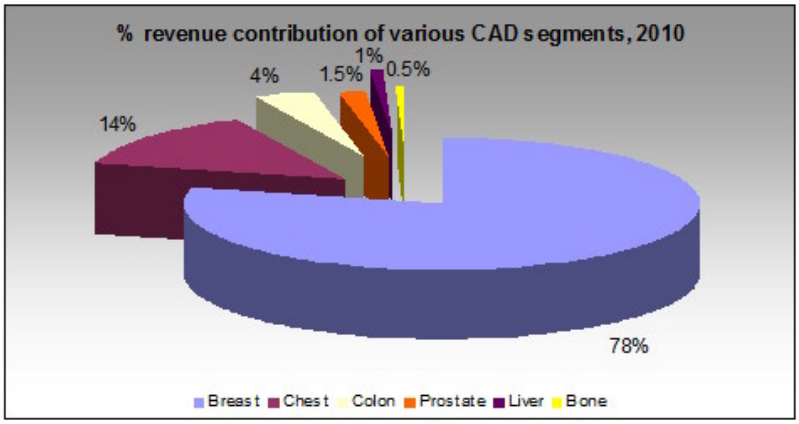
iCAD is the world's largest independent Computer-Aided Detection (CAD) company. The company's CAD imaging systems are used as an adjunct to mammography (digital radiography, computed radiography and film-based) screening to provide earlier detection of cancer and improve patient outcomes. iCAD has placed approximately 4,100 systems since receiving FDA clearance of its first breast cancer detection product in January 2002. The company continues to look to broaden its image analysis capabilities and in August 2010 its CAD technology became the first of its kind to receive FDA clearance for use with virtual colonoscopy in the detection of colonic polyps. In July 2008 iCAD acquired CAD technology for use with Magnetic Resonance Imaging (MRI) which extended its reach into budding areas of interest in cancer detection including breast and prostate MRI.

Xoft develops and sells the Axxent System, an electronic brachytherapy (eBx™) device used primarily for the treatment of breast cancer. iCAD closed on its $12.9 million acquisition of Xoft on December 30, 2010, marking iCAD's initial foray into cancer therapy. The acquisition will bolt on roughly $7MM - $8MM in additional annual revenue in 2011 but this is expected to ramp after intraoperative radiation therapy (IORT), Axxent's sweet-spot, gains widespread insurance reimbursement (reimbursement should be available by January 2012). eBx directs high dose radiation to the cancerous site while sparing healthy surrounding tissue. An isotope-free technology delivered in minutes during (and/or after) breast cancer surgery, eBx affords a safe, low cost and mobile alternative to traditional radiation therapy with no compromise in efficacy with the added benefit of significantly shorter treatment times. Along with breast cancer, the Axxent System is FDA cleared for the treatment of other cancers including endometrial (gynecological) and skin cancers.

iCAD is headquartered in Nashua, NH and has an R&D facility in Fairborn, OH. iCAD will maintain Xoft's operations in Sunnyvale, CA and retain the majority of the acquired company's employees. As of March 15, 2011 iCAD had 146 employees which included 49 that came with Xoft.

MARKETS: COMPUTER AIDED DETECTION

CAD has become an established supplement to mammography and is just recently making headway into detection of other cancers including lung, colon and prostate. According to an independent report by market research firm Frost and Sullivan, the CAD market is expected to grow at approximately 16% over the next several years with breast CAD "expected to grow at a steady rate for the immediate future." The report also notes that growth of each specific CAD market (i.e. - breast, prostate, etc) is highly dependent on growth of the corresponding modality (i.e. - growth in colon CAD is dependent on growth in virtual colonoscopy). Our "Markets" discussion related to iCAD's CAD products therefore touches on recent developments in both the specific CAD applications as well as the associated modalities.



SOURCE: Frost & Sullivan

❖ BREAST CANCER

iCAD's CAD products can be used with all mammography technology platforms including film-based and digital. The digital platform, called Full Field Digital Mammography (FFDM), was approved by the FDA in 2000 and has quickly become the dominant technology in mammography with approximately 78% of certified mammography facilities now using FFDM. It is estimated that 90% of new digital mammography systems sold in the U.S. include CAD. Despite CAD's deep penetration of digital mammography, there should be continued growth opportunities for iCAD from the 22% of the market that has yet to switch to digital mammography, a growing systems replacement market and growth in international markets.

iCAD also provides software that is compatible with breast MRI, which has recently gained acceptance as an adjunct to mammography and has shown significant progress in the detection of breast cancer.

...Mammography and CAD

Mammography, which uses low-dose amplitude x-rays to examine the breast, remains the dominant method of breast cancer detection with roughly 39 million mammograms performed in the U.S. during 2010. Despite being the most effective method for breast cancer detection, mammography fails to detect as much as 20% of all breast cancers. In order to reduce the risk of these errors, mammography is often used in conjunction with CAD, which has shown to shrink false negatives (missed cancer) by as much as 20% compared to mammography alone. The additional cancers detected by CAD are typically early stage and small and therefore can be easily missed by a physician examining a mammogram.

Studies have also shown that, on average, mammography has a false-positive (identifies benign mass as cancerous) rate of 7% - 15%. While CAD can increase the sensitivity (i.e. - reduce false-positives), some studies

have indicated that this may come with a compromise to specificity (i.e. - increase false-negatives). There is also some debate whether the higher sensitivity afforded by CAD actually results in an increase to the survival rate as these early-stage, small tumors might be found at the next mammography screening and still be at a curable stage. While debate over CAD specificity and utility afforded by its increased sensitivity is still alive, it has not been pervasive enough to stall demand for CAD.

In fact a study done by researchers at Thomas Jefferson University in Philadelphia found that mammography CAD utilization grew 91% from 2004 to 2008. The report, which was published in the October 2010 issue of the Journal of American College of Radiology, noted that, "Although there remains debate over the efficacy of CAD, it is apparent that radiologists are increasingly utilizing this technology and that it is becoming standard practice in breast cancer diagnosis." The study, using information from Medicare databases, found that CAD was used in 74% of mammography exams in 2008, up from just 39% in 2004.

In Europe "double-reading" is standard practice and CAD is used in only 25% - 30% of all mammogram readings. Double-reading involves two physicians reading the same mammogram. While this has shown to be effective in reducing errors relative to single reading, it is resource intensive (i.e. - requires 2 highly trained professionals), more expensive and may not be practical due to a shortage of mammographers. Results of a large trial, announced in 2008, showed that the accuracy of CAD in conjunction with a single mammography reading was almost identical to that of double reading. Of 227 cancers found in 31,000 women, CAD found only one fewer than the 199 cancers found with double reading. Also noteworthy is that sensitivity was almost identical (87.7% for double reading, 87.2% for CAD) between the two cohorts. Results of this study were published in the New England Journal of Medicine and have been one of the catalysts in driving greater interest in and demand for CAD for breast cancer detection.

Innovation geared towards increasing the predictive power of mammography has also focused on changes in breast density. Mammography sensitivity can suffer depending on the density of the breast and studies have shown that women with denser breasts are more susceptible to breast cancer. As a result certain states have begun mandating that breast density be reported along with mammogram results. In May 2011 iCAD announced an agreement with Matakina, which makes Volpara Volumetric Breast Density assessment software, whereby iCAD will integrate the software into their CAD systems.

....Mammography Screening Guidelines

In 2009 the U.S. Preventive Services Task Force issued new recommended guidelines for breast cancer screening of asymptomatic women. USPSTF, an independent panel of experts in prevention and evidence-based medicine, recommended that women begin having mammograms at age 50 as opposed to at age 40, the prior recommended starting age. The change reflects the relatively low risk of breast cancer in younger women coupled with the risk associated with radiation exposure (although miniscule) from mammography.

Despite the change to USPSTF guidelines, influential organizations such as the American Cancer Society, the National Cancer Institute and the American College of Radiology continue to recommend mammogram screening every one to two years beginning at age 40. A study done by the National Institute of Health which examined what impact USPSTF's guideline change had to physicians' recommendations relative to breast cancer screening found that virtually all primary care physicians continue to recommend mammography to their patients aged 40 and older. This suggests that the USPSTF guideline change has had little to no meaningful impact on the number of mammography screenings - an obvious benefit to iCAD.

....Breast MRI

In 2007 the American Cancer Society approved breast MRI as an alternative to mammography for patients at high risk of breast cancer. Breast MRI involves scanning the breast before and after the injection of a contrast agent. The before and after images are then compared for areas with increased blood flow, which are highlighted by the contrast agent. These areas may be indicative of cancer.

Breast MRI studies have demonstrated higher sensitivity than mammography and can check multiple tumor locations, determine the effect of chemotherapy, verify the integrity of breast implants and analyze tumor growth in dense tissue. However, breast MRI suffers from relatively low specificity (i.e. - high rate of false positives) which, along with a higher cost than mammography, has confined its use mostly to high-risk patients (i.e. - as a confirmatory diagnostic and not for screening). Unlike mammography which is used both as a screening and diagnostic tool, breast MRI is largely only used for diagnosis.

A study done by Frost & Sullivan, published in June 2011, notes that these factors have resulted in breast MRI "experiencing a slow growth which is proportional to its market adoption rate." The report indicates breast MRI is

used in only about 10% of breast cancer screenings. Despite the lackluster growth of breast MRI to-date, the authors believe the introduction of low-cost MRI machines and efficient reimbursement patterns coupled with advantages of breast MRI such as high sensitivity "will lead to increased penetration rates of the breast MRI industry."

CAD is used with breast MRI to facilitate more efficient and rapid interpretation of the results as well as to more accurately determine the sizes and locations of cancers. A single exam using breast MRI generates more than 1,000 images which can make analysis and interpretation difficult and time consuming. CAD simplifies this, increasing throughput and accuracy which should be a catalyst for its use with breast MRI.

It is estimated that approximately 65% of breast MRI systems in the U.S. currently utilize CAD. The 35% of the market yet to be tapped, along with breast MRI procedure volumes expected to substantially increase over the next few years should bode well for demand for iCAD's CAD MRI products. The international market, especially Europe where the penetration of breast MRI is substantially less than in the U.S., should also offer opportunities for growth.

....Reimbursement for Mammography and Breast MRI

The Centers for Medicare and Medicaid Services (CMS) covers one **mammography** screening for women aged 35 - 40 and screening on an annual basis over the age of 40. Diagnostic mammography is also covered when an individual shows symptoms of breast cancer or is otherwise at high risk of the disease. CAD is also covered with both screening and diagnostic mammographies as an add-on. Mammography with CAD is also widely reimbursed by private payers.

CMS's national coverage policy for **breast MRI** states that MRI scans may be covered as diagnostic services if reasonable and necessary, and if performed on an FDA-approved model of MRI equipment. Local Medicare contractors have discretion over whether they will cover diagnostic breast MRI. As a general rule, CMS does not cover breast MRI for screening procedures. While there is no separate billing code for CAD with breast MRI (as there is for CAD with mammography), billing for breast MRI can be bundled into related services. Some private payers reimburse for breast MRI while others do not.

❖ COLON CANCER

....CT Colonography (CTC)

While breast cancer is iCAD's largest target market, the company has been expanding into other diagnostic and therapeutic categories. In August 2010 iCAD gained FDA clearance of VeraLook, a CAD product for use with virtual colonoscopy (CT Colonography or CTC) to improve the detection of colonic polyps.

Despite colon cancer being the second most deadly form of cancer in the U.S., only about 50% of the eligible population is screened for it. This is alarmingly low considering that colon cancer has a five-year survival rate of 90% if detected early. CTC screens for colonic polyps, a marker for colon cancer. A large clinical study published in the New England Journal of Medicine in 2008 showed that CTC is as effective as conventional optical colonoscopy in screening for cancer and precancerous polyps. CTC, when used with CAD, has shown to increase the detection rate of colonic polyps.

In March 2008 the American Cancer Society, the American College of Radiology and the U.S. Multi-Society Task Force on CRC (colorectal cancer) issued new consensus guidelines for colon cancer screening which included recommendations for use of CTC for CRC screening.

Despite the lack of widespread insurance reimbursement for CTC, procedural volumes have been increasing rapidly. According to a study in the April 2011 issue of the Journal of the American College of Radiology, diagnostic CTC procedures increased 195% (from 3,660 to 10,802) from 2005 to 2008. The majority of hospitals using CTC have been utilizing it as an alternative for frail, elderly patients and those with failed optical colonoscopies. The study noted that hospitals that have chosen not to use CTC, cited the lack of reimbursement as the primary reason. According to the study's lead author, growth in CTC procedural volume is expected to continue to be robust as insurance coverage continues to expand. Dr. Richard Duszak notes, "Given its recent technological and clinical maturation, the expansion of CTC across the country is not unexpected. Although regional variation exists, coverage for diagnostic CTC continues to expand across the country, setting the stage for expanded patient access. Medicare coverage of screening CTC could spark wider access to this potentially life-saving exam and help raise what have traditionally been low colorectal cancer screening rates."

....Reimbursement for CTC

A large and widely reported study called ACRIN 6664 showed CTC could detect 90% of asymptomatic patients with colonic polyps compared to optical colonoscopy. Results of the 2,531-patient study were published in the New England Journal of Medicine in 2008 and were expected to be the catalyst to CTC gaining reimbursement from Medicare. Despite the compelling results, in 2009 the Centers for Medicare & Medicaid Services (CMS) denied reimbursement for screening with CTC as statistical analysis of the data was not powered specifically for the Medicare (i.e. - older) population. A re-evaluation of the data to break out results specific to the Medicare population is currently underway. The expectation is that following the analysis, the data will again be submitted for publication and then to CMS for reimbursement consideration - possibly within the next 12 months.

While CTC is not currently covered by Medicare, some state programs and private insurers will reimburse for CTC screening. Coverage continues to grow and if, and when, Medicare coverage comes on-line, CTC procedural volume will almost certainly ramp very rapidly. Dr. Perry Pickhardt, co-author of the JACR study, notes, " "We've published findings specific to the Medicare population, and more research is forthcoming addressing the objections raised about CT colonography. There's no reason CMS shouldn't cover CT colonography. It's better, faster, safer and cheaper than optical colonoscopy." Dr. Abraham Dachman (author of a study that we cite below) appears to agree. In the June 2011 edition of RSNA Radiological Society of North America Dr. Dachman notes, "CT colonography has passed every litmus test conceivable. Within five years, it should be a—if not the—frontline screening test for colorectal cancer."

Medicare reimbursement would mean CTC would often be used in place of optical colonoscopy, instead of only when optical colonoscopy fails - as is largely the case today. This should be a significant catalyst to growth of iCAD's virtual colonoscopy CAD products.

....CTC and CAD

CTC, when used with CAD, has shown to increase the detection rate of colonic polyps. A study published in the September 2010 issue of Radiology showed that 13 of 19 radiologists demonstrated higher accuracy in interpreting CTC images with the use of CAD. Dr. Abraham Dachman, lead author of the study, noted, "CAD use resulted in a significant improvement in overall reader performance per polyp and per patient".

There is an estimated 11k OEM imaging workstations in use with 3D colon applications. iCAD currently has agreements with three manufacturers (Vital Images, TeraRecon, and Viatronix) that account for about 4k of these units. iCAD is pursuing agreements with GE and Philips which account for almost 5k units.

❖ PROSTATE CANCER

VividLook is iCAD's image analysis software for prostate dynamic contrast enhanced (DCE) MRI.

...PSA Fraught With Error

Prostate cancer afflicts about one in six men over the age of 40 in the U.S. While only about 10% of cases are fatal, early diagnosis is key to increasing survivability. Despite often being fraught with error, the most common test for prostate cancer is the Prostate Specific Antigen (PSA). PSA is highly prone to both false-positives (~ 80% of positive tests are false positive) and false-negatives (~ 15% of negative tests are false negative).

The FDA has approved the PSA test for annual screening of prostate cancer in men aged 50 and older. This does not necessarily mean that there is much confidence in the test however. In fact the USPSTF "found insufficient evidence to recommend either for or against screening" using PSA. Following a positive PSA result, a biopsy may be ordered to determine whether cancer is present. Prostate biopsies, however, are not always accurate and can miss 20% or more cancer cases. Biopsies are also highly invasive and costly.

iCAD is looking to capitalize on the antiquated nature of prostate cancer diagnosis through its VividLook software. Prostate MRI's were virtually non-existent prior to the introduction of VivivLook due to the extreme difficulty in interpreting the result (i.e. - the area is filled with veins and arteries and the contrast agent makes the whole area glow). VividLook allows physicians to more easily discern the suspicious-looking areas. While prostate MRI's are currently not commonplace, if over time they are proven to be effective in eliminating unnecessary biopsies in

patients with a rising PSA, iCAD would be a direct beneficiary. Educating the healthcare community and the general public about the advantages of prostate MRI will likely be one of the keys to expanding the use of prostate MRI.

Another factor that may be hindering uptake of prostate MRI is the relatively low level of reimbursement from Medicare. In a 2010 edition of *Advance for Imaging & Radiation Oncology*, Dr. A. Joseph Borelli, President and Medical Director of MRI at Belfair LLC and Chair of the MRI Accreditation Committee American College of Radiology, notes that "low reimbursement (~ $500) is probably the greatest factor limiting widespread implementation of prostate MRI." Dr. Borelli indicates that recent technological advancements in prostate MRI, including the addition of CAD should reduce the cost of each prostate MRI procedure, making it economically feasible for healthcare facilities which should increase prostate MRI volume in the future.

....Reimbursement for Prostate MRI
Similar to breast MRI, Medicare may reimburse for prostate MRI as a diagnostic procedure if it is deemed reasonable and necessary, and if performed on an FDA-approved model of MRI equipment. Some private payers reimburse for prostate MRI while others do not. There are no assigned codes for CAD with prostate MRI and reimbursement for CAD prostate MRI can be spotty.

MARKETS: RADIATION THERAPY

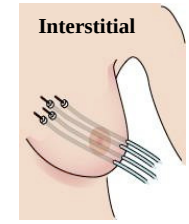
iCAD's December 2010 purchase of Xoft expanded their capabilities beyond just cancer detection/diagnosis and into cancer therapy. Xoft's electronic brachytherapy (eBx) device called Axxent kills cancer cells through high-dose radiation applied directly to the cancerous site. The device is ideally suited for localized (i.e.- early stage or non-metastasized) cancers and is being initially marketed for breast cancer treatment through IORT.

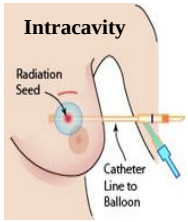
Approximately 261k women are diagnosed with breast cancer in the U.S. every year. The majority (~ 160k) of these women are candidates for radiation therapy following lumpectomy surgery. Radiation therapy is used to kill any cancer cells that may remain after the tumor has been removed from the breast. Of the women that qualify for radiation therapy, about 110k meet certain criteria that make them candidates for treatment with brachytherapy (traditional brachytherapy or eBx). Despite qualifying for brachytherapy, about 80% (88k) of these 110k women choose to undergo the much more burdensome external beam radiation therapy (EBRT) which requires daily treatment for 5 - 7 weeks compared to the other 20% who choose brachytherapy (5 day outpatient treatment time). The expectation is that the benefits afforded by eBx relative to traditional brachytherapy will compel more brachytherapy-appropriate breast cancer patients to undergo IORT via eBx instead of either APBI or EBRT. Therefore the current U.S. target market for eBx is not just the ~ 22k women that choose brachytherapy each year but instead the 110k women that qualify for brachytherapy each year.

....External Beam Radiation (EBRT)
External beam is the most common form of radiation therapy. As the name implies, an external beam of radiation is pointed at a particular part of the body. As opposed to brachytherapy, where the radiation source is inside the body, external beam delivers radiation to the tumor from outside of the body. Megavoltage X-rays are used to kill the cancer cells. One of the drawbacks of external beam is that since the radiation is delivered from outside the body and is less targeted, these x-rays can also damage healthy tissue. Another significant disadvantage is the relatively long treatment time associated with EBRT. Typical treatment protocol with EBRT is daily treatment for 5 - 7 weeks (~ 30 - 40 treatments).

....Traditional Brachytherapy
Brachytherapy is also known as internal radiotherapy and involves the placement of a high-dose radiation source directly next to the cancerous area, thereby sparing healthy tissue from damage. It is used either alone or in conjunction with external beam radiation and typically for the treatment of cancers of the cervix, prostate, breast and skin.

In addition to less radiation exposure to healthy tissue, brachytherapy has other advantages relative to EBRT. Brachytherapy can be completed in significantly less time than EBRT through a method called Accelerated Partial Breast Irradiation (APBI). APBI is completed over 5 days on an outpatient basis. In addition, due to the lower treatment burden, brachytherapy is typically significantly more cost effective than EBRT.





SOURCE: about.com

With breast cancer, traditional brachytherapy is delivered one of two ways; interstitial or intracavity. Interstitial involves the placement of multiple plastic catheters in the breast tissue which are positioned to allow targeting of radiation to the treatment area while sparing the surrounding breast tissue. The catheters are connected to an "afterloader", which delivers the radiation to the treatment area. Intracavity involves the placement of a single catheter into the breast cavity left after the removal of the tumor (lumpectomy). The catheter can be placed at the time of the lumpectomy or postoperatively. Through the catheter a balloon is then inflated in the cavity. The catheter is then connected to an afterloader which delivers the radiation dose through the catheter and into the balloon.

A drawback of traditional brachytherapy (relative to eBx) is that the radiation source must be secured in a shielded vault and requires the physician and staff to leave the treatment room during delivery of radiation so as to eliminate any risk of exposure.

....eBx

Xoft's eBx technology allows the radiation dose to fall off much faster compared to traditional brachytherapy and lowers the radiation exposure outside of the treatment area. The rapid radiation dose fall-off means a shielded room is unnecessary. This not only reduces the cost to the healthcare provider (and ultimately the patient), it also allows portability of the device. Portability and reduced shielding requirements are also of significant benefit in developing countries where treatment facilities consist largely of small, widely disbursed and rudimentary clinics.

eBx is a form of intracavity brachytherapy that can be delivered either during surgery or through a 5-day outpatient protocol (APBI). If administered during surgery (i.e. - intraoperative radiation therapy or IORT), the eBx procedure takes only about 15 minutes. This is probably the most significant benefit of eBx compared to traditional brachytherapy, which can not be administered during surgery without a shielded operating room.

...Market Opportunity

eBx launched in 2008 with FDA clearance for breast cancer treatment. Since then it has received FDA clearance for endometrial and skin cancer as well as IORT. iCAD pegs the annual U.S. market opportunity for eBx at about 2 million procedures (skin 1.6MM, non-breast IORT 164k, breast 110k, and 37k gynecological). The low-hanging fruit will almost certainly be in IORT breast cancer. iCAD estimates demand for breast IORT alone could represent a total market worth $200MM in system sales and another $200MM in recurring revenue over the next five years.

iCAD also expects to pursue other indications including cancers of the lung, head/neck, bone, colon, and brain.

....Reimbursement for IORT

Reimbursement for IORT breast brachytherapy is currently very limited which has constrained its use. This is about to change, however. In October 2011 the American Medical Association (AMA) assigned Category I Current Procedural Terminology (CPT I) codes (77424 and 77469) for IORT brachytherapy. The codes will be active January 1, 2012. A CPT I code assigns a relative value for the amount that CMS will reimburse for radiation via IORT - assignment of the relative value is expected to come by November 1, 2011. If all goes well, the level of reimbursement (i.e. - relative value) will incentivize (or at least does not dis-incentivize) radiation oncologists to use IORT instead of EBRT or APBI for those patients where it is appropriate. Assuming that turns out to be the case, this should be a significant catalyst to increasing demand for Axxent.

Support for establishing reimbursement for IORT in breast cancer comes from a large (n = 2,232 women) phase III clinical trial called **TARGIT** (TARGeted Intraoperative radioTherapy). TARGIT compared the effectiveness and safety of IORT to whole breast radiotherapy. Four-year follow-up data, which was published in *The Lancet* in June 2010 showed that IORT was as effective as standard breast radiotherapy in reducing the risk of cancer recurrence after lumpectomy. Five-year follow-up data, which is often considered a minimum study duration by physicians before they will consider adopting a new technology, should be available in the near future. Publication of the five-year data, assuming it continues to support use of IORT, could be another catalyst in the adoption of IORT and interest in Axxent.

PRODUCTS

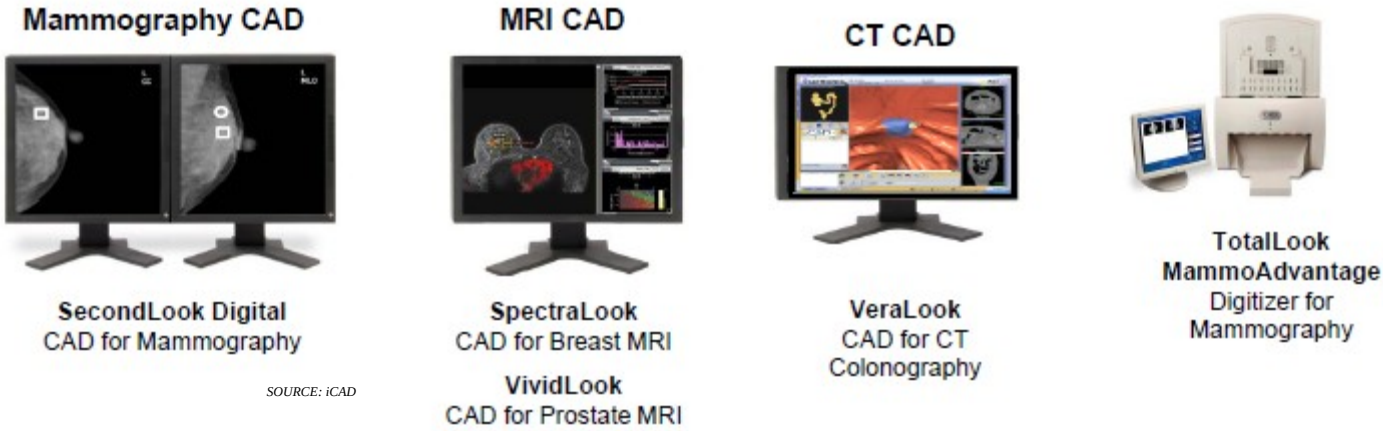
PRODUCTS: COMPUTER AIDED DETECTION

iCAD's CAD products include proprietary algorithm and other technology together with standard computer and display equipment. The systems are not stand-alone imagers but instead are used with leading OEM mammography systems from GE Healthcare, Siemens Medical Systems, Fuji Medical Systems, Hologic, IMS Giotto, Sectra, Agfa Healthcare, Planmed and Philips. Connectivity is made through Digital Imaging and Communications (DICOM), an industry standard for interoperability of medical imaging equipment. iCAD works with each of its OEM partners to ensure seamless integration between the systems. iCAD's intellectual property is protected by 22 CAD-related patents and 20 additional patents are currently in process.

iCAD sells their CAD products in the U.S. through a direct sales force as well as through their OEM partners. iCAD supplements its sales efforts through presentations at industry conferences, events and trade shows. Sales of iCAD's digital CAD products are highly correlated to sales of new digital mammography imagers. While growth of both were robust through 2008 as customers switched from film-based to digital-based systems, this has since slowed as most hospitals and clinics have now switched to digital systems (~ 78% penetration).

However, iCAD expects the U.S. market for its digital CAD products to begin to rebound as a result of the FDA recently making it easier for FFDM manufacturers to gain approval of digital mammography systems. In November 2010 the FDA reclassified FFDM systems from class III (requiring approval through the lengthy PMA process) to class II (requiring the much less stringent and shorter 510(k) clearance). iCAD, along with other industry participants, expect this FDA action to spark new entrants to the OEM digital mammography space which should, in-turn, spark greater demand iCAD's CAD mammography products. Several OEM's, including GE, Philips, Carestream Health, Fuji and Siemens and Hologic are all in various stages of bringing new digital mammography systems to market and this FDA decision will likely significantly reduce the time to market for at least some of these products - another clear benefit for iCAD. iCAD also expects to launch its next-generation CAD mammography system in the U.S. in 2012 which could provide a significant boost to the company's digital CAD revenue.

While the U.S. market accounts for the majority (~ 84% in 2010) of iCAD's revenue, the company has recently made greater headway into international markets. iCAD believes international markets could hold opportunities for significant growth and in Q4 2010 began hiring a direct sales force in parts of Europe to supplement sales through OEM channels. iCAD believes there's growth opportunities in Europe for breast MRI CAD, SecondLook Premier, CTC CAD (VeraLook) and Axxent. iCAD will also look to further penetrate Asian markets and in May 2011 received regulatory approval for SecondLook Digital in China which allows the system to be sold with GE's digital mammography system in that country.



SOURCE: iCAD

❖ MAMMOGRAPHY

SecondLook

SecondLook is iCAD's flagship series of mammography CAD products. The SecondLook line includes **SecondLook Digital**, **SecondLook Premier** and **SecondLook Multi-Vendor**. The systems analyze data through patented algorithms which compare the image in question to thousands of mammography images incorporated into the algorithms. This enables SecondLook to distinguish between cancerous and normal tissue and mark suspicious-looking areas in the mammography image. This affords earlier detection of cancer that may be missed if the radiologist were to rely on mammography alone. iCAD's SecondLook systems have been found to be able to detect up to 72% of the cancers that mammograms missed (validated through biopsy), an average of 15 months earlier.

- **Digital-based systems:** SecondLook Digital, SecondLook Premier and SecondLook Multi-Vendor are iCAD's digital-based CAD mammography systems.

    - **SecondLook Premier** is iCAD's next generation mammography CAD product which was specifically tailored for GE Healthcare and Siemens Medical Systems. It launched in Canada and Europe in early 2011. iCAD wrapped up their "Reader study" in Q3 2011 which will be used as support of an FDA filing - which is expected by mid-November. If all goes well, SecondLook Premier could be in the U.S. market by mid-2012. Upon U.S. approval iCAD will target the ~4k first generation CAD systems to upgrade to Premier. The 12% growth in iCAD's "Digital / MRI CAD" revenue that we model for 2012 is largely based on the assumption that Premier sales ramp very rapidly following U.S. regulatory approval.

    - **SecondLook Multi-Vendor** is compatible with digital mammography systems manufactured by GE, Siemens, Agfa, Planmed, Sectra, Fuji, Hologic, Giotto, and Philips using a single server for all input devices. This eliminates the need to purchase a separate server for each manufacturer's system. Management noted on the Q3 2011 call that sales of the multi-vendor product were particularly strong.

TotalLook MammoAdvantage

iCAD's TotalLook MammoAdvantage encompasses their film-based business. TotalLook converts prior mammography films over to digital images. Customers that purchase TotalLook are typically in the process of switching their equipment and facilities from film-based to digital. The product provides high resolution digitized images, meeting required conversion specifications. Conversion is popular with customers who are switching to digital-based mammography and need prior film-based images to be compatible with digital imagers for ease of comparison between newly acquired digital images and the film-to-digital converted images. TotalLook represents the vast majority of iCAD's film-based revenue which has fallen precipitously since 2009, reflecting the aforementioned industry shift from film to digital based imaging systems.

❖ MRI ANALYSIS

SpectraLook, VividLook, OmniLook

iCAD's SpectraLook and VividLook are used for DCI MRI of the breast and prostate, respectively. OmniLook is used for DCI MRI for other organs. All three help identify areas of interest and then through an algorithm analyze changes in the magnetic resonance signal in the tissue to help clinicians to discern biological processes taking place in malignant versus benign tumors.

iCAD believes there is opportunity for SpectraLook, especially in Europe where breast MRI is still a significant growth category and with fewer competitors relative to the U.S.

iCAD, through presentations and other educational programs, has been touting the benefits of prostate MRI with VividLook which they hope will eventually spark greater demand of the product. VividLook should also benefit if and when more favorable reimbursement comes online.

❖ CT COLONOGRAPHY

VeraLook

Indicated for use as a second-read, VeraLook uses algorithms to detect and highlight potential polyps. VeraLook gained FDA clearance in August 2010, becoming the first CAD software cleared by the FDA for CTC. iCAD has shown through a clinical study that VeraLook increased reader sensitivity by 5.5% over CTC alone. While specificity decreased by 2.5%, overall reader performance was improved with the use of VeraLook.

VeraLook is compatible with all CT system manufacturers including Viatronix, Tera recon and Vital Images and can be used with both 2D and 3D images. During Q1 2011 iCAD entered a commercial agreement with Vital Images (part of Toshiba Medical Systems Group) to provide VeraLook on their CTC applications all over the world. Vital Images is the leading provider of advanced visualization and analysis solutions for healthcare providers. The roll-out of VeraLook with Vital Images' systems commenced in June 2011. iCAD is also in the process of pursuing agreements with other manufacturers including GE and Philips which could materialize sometime in 2012. iCAD expects VeraLook sales to benefit from increased interest from the healthcare community in virtual colonoscopy especially as further studies are published validating its benefits. The company noted that they hope to capitalize on the positive feedback that they received from potential customers following a presentation at the European Congress of Radiology in 2010. VeraLook should also benefit as reimbursement for virtual colonoscopy becomes more widespread.

PRODUCTS: AXXENT eBx

Xoft Acquisition

In December 2010 iCAD acquired Xoft for $12.9 million. The purchase was paid for with a combination of iCAD common stock (8.35MM shares @ $1.40/share) and cash ($1.18MM). iCAD also paid about $1MM in transaction expenses of Xoft. The sellers are also eligible to receive "earn-outs" based on sales of Xoft products over the three year period following close of the transaction. Earn-outs are payable beginning with a minimum of $50MM of sales of Xoft products. $20MM in earn-outs will be paid on $76MM in Xoft sales and the maximum of $40MM in earn-outs will be achieved at $104MM in Xoft revenue.

Prior to the Xoft acquisition iCAD was solely involved in cancer detection and diagnostics. The company's rationale for buying Xoft was to broaden their capabilities to include treatment and leverage both businesses' technologies over a larger customer base. The expectation is that iCAD can cross-sell their CAD product line to Axxent customers and vice-versa. The Axxent System is FDA cleared for breast, endometrial and skin cancers as well as IORT. While Xoft has already placed several systems for the treatment of skin and endometrial cancers, breast cancer clearly represents the biggest near-term opportunity.

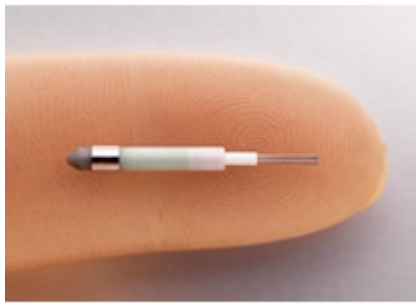
Axxent is sold through a very small direct sales force in the U.S. and through third-party distributors in Europe. In July 2010 Xoft also signed an agreement with Premier, Inc. a large group purchasing organization which gives Premier's large network of U.S. hospitals and other healthcare customers preferred pricing for Axxent. iCAD expects to incrementally add head count to the Axxent U.S. sales force now that CPT I codes have been assigned.

Axxent eBx System

The Axxent System consists of a controller which provides power to the X-ray source and controls the radiation, a proprietary miniaturized x-ray source and a variety of disposable applicators. iCAD has noted in conference calls and presentations that the controller sells for between $225k and $300k and the x-ray sources sell for around $5k each or $80k for a one-year contract (based on 3 procedures per week). Each x-ray source can be used for approximately 10 IORT procedures. Single-use disposable applicators are priced at around $1.5k each. In addition Xoft / iCAD offer annual service and maintenance agreements for approximately $25k.

Axxent Controller **Axxent HDR X-ray Source** **Axxent Balloon Applicator**







SOURCE: iCAD

The Axxent System competes with traditional brachytherapy but, as we noted earlier, has certain advantages such as not requiring a shielded vault and is portable. Xoft offers a vehicle to transport up to three Axxent Systems from one location to another, allowing patients that may forego treatment due to transportation limitations to receive radiation therapy.

Axxent for Breast Cancer (IORT / APBI)

Radiation treatment with Axxent for breast cancer is accomplished either through IORT or APBI. While APBI has a significantly lower treatment burden compared to EBRT (5 days versus 5 -7 weeks), it is not nearly as convenient and patient-friendly as IORT. IORT, which uses a higher single dose of radiation compared to each dose delivered during APBI, can be completed in 15 minutes during the lumpectomy surgery. Important is that traditional brachytherapy, which Axxent competes directly against, can not be performed through IORT due to radiation exposure risk. And, as we noted earlier, the main advantage of APBI with eBx (Axxent) compared to APBI with traditional brachytherapy is that eBx does not require a shielded room (which also makes it portable).

IORT (intraoperative radiation therapy) delivers a concentrated beam of radiation to cancerous tumors or the tumor bed while they are exposed during lumpectomy surgery. After the surgeon removes the tumor from the breast, he places a shield over the chest wall to protect the ribs, lungs and heart from radiation. An Axxent balloon applicator is then inserted into the tumor cavity through a small incision in the side of the breast. The size of the tumor cavity determines the size of the balloon used as the balloon must fit snugly in order to maximize contact with any remaining cancer tissue. A small shield is then draped over the operative field in order to reduce radiation transmission to the patient and hospital staff. The balloon catheter, which is passed through a hole in the shield, is attached to the controller, a radiation source inserted into the balloon via the catheter and radiation therapy is initiated. The surgeon and staff can remain in the room as the radiation is delivered. After the radiation is delivered, the balloon is removed and the incision closed. The radiation therapy is completed within about 15 minutes and the entire procedure (lumpectomy and radiation therapy) takes about two hours.

Balloon applicator inserted during IORT **Balloon catheter passed through shield**





SOURCE: World Journal of Surgical Oncology

The procedure for **APBI** (accelerated partial breast irradiation) is similar to that for IORT with the major difference being APBI uses a lower radiation dose per treatment and treatment is performed over several days versus just a few minutes during surgery with IORT. With APBI, radiation is delivered on an outpatient basis twice per day for five days. The portion of the balloon catheter that remains outside of the body is connected to the Axxent controller. After draping the breast with a shield, the radiation source is passed into the balloon via the catheter. Radiation is delivered for about 10 minutes after which the x-ray source is turned off and removed through the catheter. Following the final treatment (i.e. - the fifth day), the balloon is deflated and removed.

Flexishield Recall

iCAD / Xoft had also been offering customers a flexible radiation shield called Axxent Flexishield Mini to protect surrounding areas from radiation during IORT procedures. In early February 2011, in cooperation with the FDA, iCAD voluntarily recalled the shield after tungsten was found in the breasts of women who had undergone IORT when the shield was used. iCAD believes approximately 30 women were treated with the use of the Axxent Flexishield Mini - the vast majority of whom were enrolled in an IORT study at Hoag Memorial Hospital Presbyterian, the protocol of which mandated use of this specific shield.

Shortly after the recall was announced iCAD (along with Hoag) was served with a lawsuit alleging personal injury from negligence and product liability. The plaintiff in this lawsuit is seeking approximately $14.5 million. Additional lawsuits could be forthcoming.

While it seems to be unclear what the effects of long-term exposure to tungsten might be, an FDA spokeswoman noted that the agency's toxicologists had found no evidence that the tungsten was toxic. And despite iCAD having product liability insurance (and potentially pursuing indemnification claims against Xoft), it remains highly uncertain what, if any, impact these lawsuits will have on iCAD's future. As such, we believe it is prudent for investors in iCAD to consider these lawsuits as a material risk until and unless future developments suggest a favorable outcome to iCAD is likely.

<u>iCAD's FY 2010 10-K (filed 3/30/11) includes the following related to the recall and lawsuit:</u>
Because of the preliminary nature of this complaint we are unable to evaluate the merits of the claims, however based upon its preliminary analysis, we plan to vigorously defend the law suit.

We recently acquired the Axxent Electronic Brachytherapy System and Axxent Flexishield Mini as part of our acquisition of Xoft in December 2010. Since the initial commercial sale of the Axxent Flexishield Mini in August 2009, this accessory has been sold on a very limited basis. We are in the process of indentifying a replacement for this accessory, and we do not anticipate a material impact on revenues resulting from this recall. We are also evaluating possible indemnification claims against Xoft as well as insurance coverage. There can be no assurances that we will be able to defend or settle this claim on favorable terms or that additional claims will not be made by other patients treated with the Axxent Flexishield Mini.

If available at all, product liability insurance for the medical device industry generally is expensive. 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. 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.

...New Shield Receives FDA Clearance

Management indicated on the Q1 2011 conference call that Flexishield recall had stunted sales of Axxent and related consumables. Potential customers were hesitant to buy the system until a replacement shield was available. iCAD received FDA clearance for its new shield, called Rigid Shield, on July 22, 2011. The new shield is made of stainless steel instead of tungsten. With the new shield now available, Axxent sales should no longer be hindered by this issue.

COMPETITION

Hologic, Inc., a company with a $5 billion market capitalization and annual revenues of $1.7 billion, is an industry leader in technologies serving women's health including breast cancer diagnosis and treatment. Hologic represents the most significant competition to iCAD's CAD products. Hologic manufactures and sells digital and film mammography systems as well as CAD systems for mammography (digital and film) and MRI. Hologic has integrated their CAD systems into their line of imaging instruments and also offers their CAD products to OEM imaging manufacturers. Hologic's *ImageChecker CAD* was the first FDA approved mammography CAD system and holds a market leading position in CAD.

Merge Healthcare, Inc. manufactures and sells MRI CAD systems for breast, liver and prostate cancer. Merge describes *CADstream*, their lead MRI CAD product, as "the most complete, fully-featured MRI-CAD system available, optimized for fast, easy, reliable and integrated analysis and interpretation of studies." Merge also notes that *CADstream* was named the standard of care in MRI-CAD by Frost & Sullivan. Invivo Corp. also manufactures and sells MRI CAD systems for breast and prostate cancer. They recently launched a new breast MRI CAD product.

The most direct competition to the Axxent System is from Carl Zeiss Meditec AG, a German-based medical technology company with about EUR 754 million in annual revenue. Carl Zeiss manufactures and sells an electronic brachytherapy system called *INTRABEAM* for breast IORT as well as treatment of spine metastases. The company notes that *INTRABEAM* has been in clinical use since 1997 and is indicated for IORT of all solid tumors. Similar to with Axxent, INTRABEAM can be operated without the use of a shielded room. Carl Zeiss also mentions INTRABEAM is portable and can "be conveniently transported to where it is needed." One potential drawback of INTRABEAM compared to Axxent is that INTRABEAM is not indicated for breast cancer via APBI nor for other indications. While IORT breast cancer is clearly the sweet-spot for eBx systems, unlike INTRABEAM, Axxent is also approved for use in APBI as well as gynecological and skin cancers - providing more flexibility and potentially ancillary sources of revenue for hospitals and radiologists.

Carl Zeiss' INTRABEAM eBx system



SOURCE: www.zeiss.com

There are also various manufacturers of traditional brachytherapy systems such as Hologic, Varian, Huiheng Medical, and Nucletron Oldelft. These traditional systems do not have the advantages of eBx systems such as the low shielding requirements and breast radiation treatment via IORT. As IORT for breast cancer is where the bulk of the opportunity for Axxent lies, we would classify traditional brachytherapy systems as indirect competition.

FINANCIALS

Cash Position

As of their most recent reporting period (9/30/2011) iCAD had $5.3MM in cash and equivalents, down from $7.7MM at the end of Q2. The company has no preferred stock or debt outstanding. In Q3 2011 iCAD reversed the liability it had been carrying related to an estimate of potential earn-outs to Xoft which is contingent on iCAD hitting minimum pre-determined sales of Axxent and related consumables.

iCAD's cash (out)flow from operating activities has significantly improved over the last three quarters, the result of significant cost-cutting efforts. Cash used in operations was $3.7 million in Q1 2011, $3.5MM in Q2 and only $2.4MM in Q3.

At the most recent quarter's cash burn rate iCAD has about 6 months worth of cash on hand. The level of cash burn should come down, however, especially with a longer-term view as a result of expected acceleration in Xoft-related sales.

It is possible that iCAD could achieve cash flow break-even within the next 6 - 12 months and avoid needing to raise additional operating cash. However, our model maintains the assumption that iCAD looks to raise additional financing by the early part of 2012. While we have no insight into the likely source of additional financing, for simplicity our model incorporates an assumption that it comes from common stock issuance.

Revenue

iCAD breaks out revenue into two categories; products and service/supplies. Product revenue is further broken out into Digital & MRI CAD and Film-based CAD (beginning Q1 2011 Xoft revenue is also itemized by product and services revenue).

...Saturation of Digital Mammography Hurts Product Revenue Growth

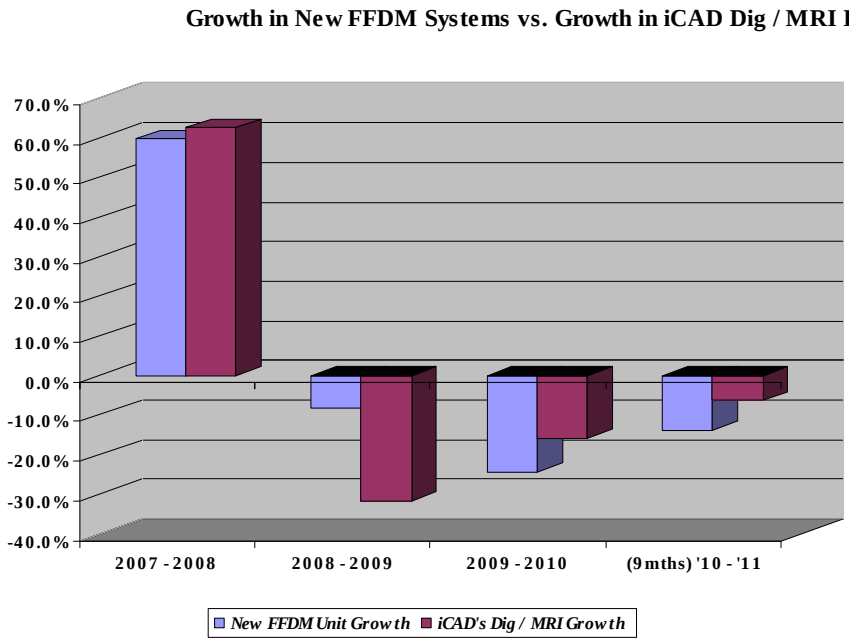
iCAD saw its product revenue grow from $10.3MM in 2006 to $26.7MM in 2009, largely as a result of an influx of new digital CAD mammography sales from the industry shifting from film-based to digital imagers. iCAD's product sales growth stalled in early 2009 and has fallen almost every quarter since Q2 2009 as digital imaging became more saturated and fewer digital imagers were being sold. Digital / MRI CAD revenue peaked at $26.7MM in 2009 and fell to $15.4MM in 2010.

iCAD's film-based business, which is driven by customers converting their film images to digital, experienced a similar slide in sales as digital imagers became more commonplace than film. iCAD's film-based revenue peaked at $7.4MM in 2008. It fell to $5.8MM in 2009 and $3.3MM in 2010.

...Service / Supplies Revenue Holding Up

Service and supplies revenue mostly represents extended service warranties on iCAD's products. As iCAD's products largely consist of sophisticated software, most customers will opt for these extended warranties. Service / Supplies revenue has held up relatively well, growing from $3.3MM in 2008 to $4.0MM in 2009 to $5.8MM in 2010.

iCAD's product revenue growth has been highly correlated to growth in new digital mammography systems



SOURCE of FFDM Systems: www.fda.gov.

OUTLOOK

Digital & MRI CAD

Digital & MRI CAD accounted for 82% of product revenue and 63% of total revenue in 2010. While iCAD does not disclose the percentage of Digital & MRI CAD revenue that comes from digital CAD (i.e. - mammography CAD), management has indicated that it represents the vast majority. Therefore, especially in the near-term, sales of iCAD's mammography CAD products will have the greatest influence on growth in Digital & MRI CAD revenue. Sales in international markets, which can be somewhat choppy, accounted for approximately 16% of total revenue in 2010.

Despite film-based systems still accounting ~ 22% of all mammography instruments in the U.S., we expect Digital & MRI CAD revenue to continue to struggle in the near-term as a result of the continued slowing pace of film-to-digital conversions. Mammography CAD sales in iCAD's international markets was also soft in the first nine months of 2011 despite the roll-out of SecondLook Premier in Canada and Europe during Q1. Economic softness hampered international mammography CAD sales which is expected to continue through at least the end of 2011. Management recently indicated that sales of MRI CAD has been very strong as a result of new product launches in late 2010. While MRI CAD should continue to show strength through the remainder of 2011 from the roll-out of new OEM agreements and the continued benefit of recent product enhancements, due to the relatively small contribution to overall revenue, growth in this segment will likely not be enough to offset declining mammography CAD sales.

We model a rebound in Digital & MRI CAD sales growth beginning in 2012 due to a combination of factors. The declassification of digital mammography from PMA to 510(k) that happened in late 2010 has sparked a resurgence in activity from several OEM's, a number of which are in various stages of bringing new digital mammography systems to market. The major catalyst to Digital / MRI growth in 2012 should be the launch of SecondLook in the U.S. - if all goes well a 510(k) filing will happen later this year and the product will hit the U.S. market by mid-2012. And finally, CAD for CTC, breast MRI and prostate MRI could all see an uptick in demand. CTC (VeraLook) should benefit from the recent agreement with Vital Images and new potential deals with GE and Philips materializing in 2012. Re-evaluation of the ACRIN study should be completed and published and potentially lead to eventual Medicare reimbursement - if that happens iCAD's CTC CAD sales could ramp quickly. Prostate MRI (VividLook), while still struggling to gain acceptance despite proven benefits against PSA, may experience slow but steady growth. iCAD has seen some success in terms of sales of VividLook through education about the benefits of prostate MRI CAD which should continue to be the case in 2012. Breast MRI (SpectraLook), which remains a significant growth category in Europe, could reverse the recent slide in international sales, especially with strengthening in world economies.

Film-based CAD

Film-based accounted for 18% of product revenue and 14% of total revenue in 2010. We model film-based sales to continue to decline going forward as a direct result of the slowing conversion rate of film to digital mammography.

Xoft

Xoft revenue was approximately $5.5MM in 2010 (prior to iCAD's acquisition). Xoft product revenue, which includes sales of the Axxent controller, in Q1 2011, the first full quarter under iCAD, was $960k. Xoft service and supplies revenue, which includes sales of the x-ray source, disposables and extended warranties, was $360k. iCAD/Xoft announced the recall of the FlexiShield in early February 2011. The recall softened Axxent sales in Q2, which fell to $760k (plus $407k in related services and supplies) as customers had been hesitant to buy the system until a replacement shield is available. The new shield received FDA clearance in late July and helped jump-start Axxent sales - pushing revenue to $1,347k in Q3 (plus $441k in related services and supplies).

We model total (Axxent controller and supplies/services) Xoft sales of $7.5MM in 2011. Going into 2012 we think Xoft sales could begin to show a significantly greater rate of growth, predicated on the assumption that CPT I code reimbursement amount is favorable. This also assumes that there are no significant lingering hangovers from the shield recall. Our Xoft-related revenue forecasts assume Axxent's penetration of the brachytherapy-appropriate breast cancer market (currently ~ 110k annual procedures) is approximately 4% by year-end 2012, 10% in 2013 and 15% in 2014, the market grows at 2% per year and 3 procedures per unit per week. Our model also includes only marginal revenue contribution from Xoft for indications other than breast cancer (i.e. - skin, endometrial, veterinary, etc.) as we currently view these as more ancillary applications.

Revenue and EPS Estimates

Management's revenue guidance as of 5/3/2011 for 2011 was $32MM - $35MM. This was revised lower from $34MM - $38MM following the recall of FlexiShield. Management again revised guidance lower with the announcement of Q2 earnings to $30MM - $32MM - this guidance was affirmed with the release of Q3 earnings.

Prior to Q3 results we were modeling 2011 revenue of $29.7MM. We now look for revenue of $30.6MM. We moved our 2011 non-GAAP (adjusted for one-time items) EPS estimate from ($0.34) prior to Q3 results to our current ($0.28). Our 2011 GAAP EPS estimate moved from ($0.33) to ($0.68).

We have also made some slight adjustments to our later years EPS estimates, mostly reflecting our updated view on operating expenses (which we have moderately trimmed) and gross margins (which have increased very slightly). We look for revenue to grow to $38.4MM in 2012 and $83.5MM in 2014. We now model EPS of ($0.18) in 2012 and approximately break-even EPS in 2014.

VALUATION / RECOMMENDATION

As we model iCAD to post negative income and EPS through 2014, valuation using a P/E multiple is not appropriate. Instead we value iCAD using competitor price/sales (P/S) and enterprise value/sales (EV/S) multiples. Using analyst's revenue estimates for the years 2011 and 2012, we calculated P/S and EV/S ratios from imaging (HOLX, MRGE) as well as surgical (VAR, ARAY, ISR) companies. The five companies currently trade at an average P/S-2011 of 2.6x, P/S-2012 of 1.9x, EV/S-2011 of 2.7x and EV/S-2012 of 2.1x.

Our 2011 and 2012 revenue estimates for iCAD are $30.5MM and $38.5MM. On the basis of the comp ratios above, iCAD's stock is valued at between $1.37 (using P/S-2011) and $1.75 (using EV/S-2012). While we would normally feel it appropriate to just use the average of the two (~ $1.60), as noted earlier in the report, we believe the potential liability related to FlexiShield lawsuits introduces material risk and this should be factored into the valuation. To account for this risk we think it is appropriate to handicap the valuation by 20%, which values iCAD at approximately $1.30/share. If future developments suggest a favorable outcome to iCAD related to FlexiShield liability is likely, we think it may be appropriate to reduce or eliminate this valuation discount.

As it is now we value iCAD at $1.30/share. The stock, trading at around $0.71, remains significantly undervalued in our opinion. As such, we are maintaining our Outperform rating.

Management Profiles

Kenneth Ferry - President and Chief Executive Officer

As Chief Executive Officer of iCAD, Kenneth M. Ferry brings two decades of extensive experience in the management and leadership of healthcare technology organizations, with more than a decade of direct responsibility to the organizations' P&L. He was most recently Senior Vice President and General Manager for the Global Patient Monitoring business for Philips Medical Systems, the market leader in a $2.5 billion industry. In this role he was responsible for Research & Development, Marketing, Business Development, Supply Chain and Manufacturing, Quality and Regulatory, Finance and Human Resources. Since 2001, Mr. Ferry was also a Senior Vice President for the parent company, Philips Electronics Medical Systems Division. From 1983 to 2001, Mr. Ferry served in a number of management positions with Hewlett Packard and Agilent Technologies. As a Vice President and General Manager in the Hewlett Packard / Agilent Technologies Healthcare Solutions Group, he was one of the key executives responsible for the sale of Agilent's Medical Solutions Group to Philips in August 2001. Prior to this, beginning in 1997, he served as Vice President and General Manager of North American Field Operations for Hewlett Packard and Agilent Technologies. He was responsible for sales, service, and marketing for Patient Monitoring, Cardiac Ultrasound, Defibrillation, Diagnostic EKG and Information Technology solutions. In addition to his role as Chief Executive Officer, Ferry also serves as a member of iCAD's Board of Directors. Ferry is a graduate of the Boston College School of Management in Newton, Massachusetts.

Kevin Burns - Executive Vice President of Finance and Chief Financial Officer

Mr. Burns most recently served as Senior Vice President and Chief Financial Officer of AMICAS, Inc., a publicly-traded provider of image and information management solutions to the healthcare industry. Under his leadership, AMICAS delivered significant revenue and profit growth culminating in the successful sale of the company to Merge Healthcare, Inc. His prior experience includes several senior level finance positions primarily with publicly-traded technology companies including NMS Communications Corporation, MAPICS, Inc. and Marcam Corporation. Mr. Burns received his MBA in Finance and Global Management and Bachelor of Science in Finance from Babson College in Wellesley, MA.

Stacey Stevens - Senior Vice President of Marketing and Strategy

Stacey Stevens holds the position of Senior Vice President of Marketing and Strategy for iCAD. In previous roles she has served in a variety of sales, business development, and marketing management positions with Philips Medical Systems, Agilent Technologies and Hewlett Packard's Healthcare Solutions Group (which was acquired in 2001 by Philips Medical Systems). She most recently held the position of 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 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, 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.

Jeffrey Barnes - Executive Vice President, Global Commercial Operations

Jeffrey H. Barnes brings more than 17 years of healthcare sales and marketing management experience to his role as Executive Vice President, Global Commercial Operations at iCAD. Prior to joining iCAD, Barnes has held a variety of sales and marketing management positions for Philips Medical Systems and Hewlett-Packard's Healthcare Solutions Group (which was acquired in 2001 by Philips Medical Systems). In his most recent position as Vice President-Sales and National Sales Manager for Cardiac Resuscitation Solutions at Philips Medical Systems, Barnes was responsible for sales and service operations at Philips' market-leading defibrillation field organization, resulting in an increase in sales of more than 60% between 2003 and 2005. Barnes also served as Vice President of Marketing, Americas, for the Cardiac and Monitoring Systems unit of Hewlett-Packard and Philips Medical Systems where he was responsible for all marketing activities and certain direct sales activities for the North and South American field operation. In this role, Barnes led a team of more than 110 employees, including 10 marketing managers. Barnes experience also includes the position of Marketing Director for Hewlett-Packard's Ultrasound operation in Europe, Middle East and Africa. Barnes earned a Bachelor of Arts Degree in Economics from St. Lawrence University and an MBA Degree from New York University's Leonard N. Stern School of Business.

Jonathan Go - Senior Vice President of Research and Development

Jonathan Go brings more than twenty years of software development experience in the medical industry to his position as Senior Vice President of Research and Development at iCAD. Prior to joining iCAD, Go served as Vice President of Engineering at Merge eMed, a provider of RIS/PACS solutions for imaging centers, specialty practices and hospitals. At Merge eMed, Go was responsible for software development, product management, testing, system integration and technical support for all of eMed's products. Before joining Merge eMed, Go was Director of Engineering at Cedara Software in Toronto. Cedara Software is focused on the development of custom engineered software applications and development tools for the medical imaging OEMs. At Cedara, Go built the workstation program, developing multiple specialty workstations that have been adopted by a large number of OEM partners. Go earned a Bachelor of Science in Electrical Engineering from the University of Michigan and a Masters of Science in Electrical Engineering and Biomedical Engineering from the University of Michigan.

FINANCIAL MODEL

iCAD Inc.

	2010 A	Q1A	Q2A	Q3A	Q4E	2011 E	2012 E	2013 E	2014 E
Digital & MRI CAD revenue	$15,392	$3,763	$3,197	$3,791	$3,190	$13,941	$15,600	$17,725	$19,780
YOY Growth	*-15.8%*	*-9.7%*	*-19.9%*	*14.5%*	*-18.7%*	*-9.4%*	*11.9%*	*13.6%*	*11.6%*
Film-based revenue	$3,335	$517	$537	$616	$500	$2,170	$1,675	$1,510	$1,397
YOY Growth	*-42.5%*	*-50.6%*	*-25.9%*	*-17.7%*	*-38.7%*	*-34.9%*	*-34.4%*	*-27.8%*	*-23.3%*
Electronic brachytherapy	-	$960	$760	$1,347	$2,100	$5,167	$7,756	$12,022	$16,535
YOY Growth	-	-	-	-	-	-	*27.6%*	*24.1%*	*14.0%*
Products	$18,726.6	$5,240.0	$4,494.0	$5,754.0	$5,790.0	$21,278.0	$25,031.4	$31,257.4	$37,712.1
YOY Growth	*-22.2%*	*0.6%*	*-4.7%*	*41.7%*	*22.2%*	*13.6%*	*17.6%*	*24.9%*	*20.7%*
Xoft	-	$360	$407	$441	$1,155	$2,363	$6,520	$18,729	$37,304
YOY Growth	-	-	-	-	-	-	*83.8%*	*85.3%*	*44.8%*
Legacy iCAD	$5,848	$1,744	$1,745	$1,857	$1,550	$6,896	$6,910	$7,694	$8,471
YOY Growth	*45.3%*	*33.2%*	*26.4%*	*21.6%*	*-5.0%*	*17.9%*	*0.2%*	*11.3%*	*10.1%*
Service and Supplies	$5,848.4	$2,104.0	$2,152.0	$2,298.0	$2,704.8	$9,258.8	$13,429.6	$26,422.8	$45,775.1
YOY Growth	*45.3%*	*60.7%*	*55.8%*	*50.5%*	*65.8%*	*58.3%*	*45.0%*	*96.8%*	*73.2%*
Total Revenues	$24,575.0	$7,344.0	$6,646.0	$8,052.0	$8,494.8	$30,536.8	$38,461.0	$57,680.2	$83,487.3
YOY Growth	*-12.6%*	*12.6%*	*9.0%*	*44.1%*	*33.3%*	*24.3%*	*25.9%*	*50.0%*	*44.7%*
Cost of products	$2,395.9	$1,207.0	$1,140.0	$1,280.0	$1,360.7	$4,987.7	$6,321.7	$8,032.4	$9,701.7
Products margin	*87.2%*	*77.0%*	*74.6%*	*77.8%*	*76.5%*	*76.6%*	*74.7%*	*74.3%*	*74.3%*
Cost of service/ supplies	$750.8	$772.0	$769.0	$650.0	$811.4	$3,002.4	$5,108.2	$8,412.2	$12,197.6
Service / supplies margin	*87.2%*	*63.3%*	*64.3%*	*71.7%*	*70.0%*	*67.6%*	*62.0%*	*68.2%*	*73.4%*
Amortization	$0.0	$233.0	$233.0	$233.0	$233.0	$932.0	$932.0	$932.0	$932.0
Cost of Revenues	$3,146.7	$2,212.0	$2,142.0	$2,163.0	$2,405.1	$8,922.1	$12,362.0	$17,376.6	$22,831.3
Gross Income	$21,428.4	$5,132.0	$4,504.0	$5,889.0	$6,089.7	$21,614.7	$26,099.0	$40,303.6	$60,655.9
Gross Margin	*87.2%*	*69.9%*	*67.8%*	*73.1%*	*71.7%*	*70.8%*	*67.9%*	*69.9%*	*72.7%*
R&D	$6,596.1	$2,776.0	$3,304.0	$2,630.0	$2,712.0	$11,422.0	$11,310.0	$11,980.0	$14,020.0
% R&D	*26.8%*	*37.8%*	*49.7%*	*32.7%*	*31.9%*	*37.4%*	*29.4%*	*20.8%*	*16.8%*
Selling & Mktg	$11,485.1	$3,727.0	$3,945.0	$3,108.0	$3,567.8	$14,347.8	$15,384.4	$20,764.9	$28,385.7
% Sell&Mktg	*46.7%*	*50.7%*	*59.4%*	*38.6%*	*42.0%*	*47.0%*	*40.0%*	*36.0%*	*34.0%*
G&A	$9,919.4	$2,804.0	$3,412.0	$2,147.0	$2,590.0	$10,953.0	$11,538.3	$14,420.1	$18,367.2
% G&A	*40.4%*	*38.2%*	*51.3%*	*26.7%*	*30.5%*	*35.9%*	*30.0%*	*25.0%*	*22.0%*
Contingent Consideration	$0.0	$0.0	($1,100.0)	($3,800.0)	$0.0	($4,900.0)	$0.0	$0.0	$0.0
Goodwill Impairment	$0.0	$0.0	$0.0	$26,750.0	$0.0	$26,750.0	$0.0	$0.0	$0.0
Operating Income	($6,572.2)	($4,175.0)	($5,057.0)	($24,946.0)	($2,780.1)	($36,958.1)	($12,133.7)	($6,861.4)	($116.9)
Operating Margin	*-26.7%*	*-56.8%*	*-76.1%*	*-309.8%*	*-32.7%*	*-121.0%*	*-31.5%*	*-11.9%*	*-0.1%*
Other income	$275.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest income, net	$73.3	($26.0)	($36.0)	($37.0)	($35.0)	($134.0)	($150.0)	($150.0)	($150.0)
Pre-Tax Income	($6,224.0)	($4,201.0)	($5,093.0)	($24,983.0)	($2,815.1)	($37,092.1)	($12,283.7)	($7,011.4)	($266.9)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*N/A*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($6,224.0)	($4,201.0)	($5,093.0)	($24,983.0)	($2,815.1)	($37,092.1)	($12,283.7)	($7,011.4)	($266.9)
YOY Growth	*-216.3%*	*-460.1%*	*-591.9%*	*-1694.0%*	*15.8%*	*-496.0%*	*66.9%*	*42.9%*	*96.2%*
Net Margin	*-25.3%*	*-57.2%*	*-76.6%*	*-310.3%*	*-33.1%*	*-121.5%*	*-31.9%*	*-12.2%*	*-0.3%*
EPS	($0.14)	($0.08)	($0.09)	($0.46)	($0.05)	($0.68)	($0.18)	($0.09)	($0.00)
YOY Growth	*-214.1%*	*-370.6%*	*-480.1%*	*-1406.6%*	*29.3%*	*-400.4%*	*73.4%*	*50.2%*	*96.2%*
Pro-forma adjustments	$0.0	$0.0	($1,100.0)	$22,950.0	$0.0	$21,850.0	$0.0	$0.0	$0.0
Pro-forma EPS	($0.14)	($0.08)	($0.11)	($0.04)	($0.05)	($0.28)	($0.18)	($0.09)	($0.00)

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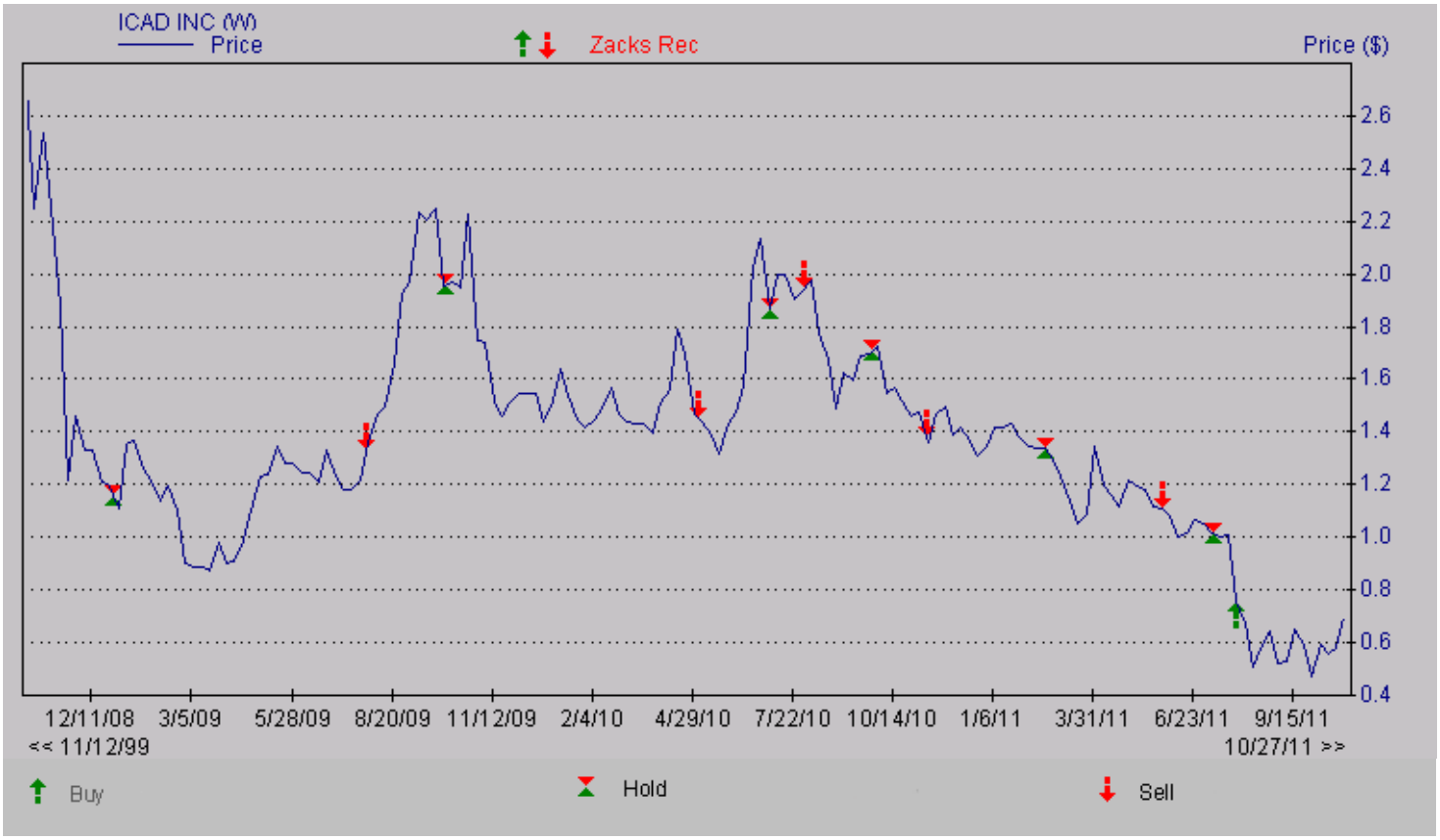
Diluted Shares O/S	45,828	54,366	54,550	54,681	54,720	54,579	68,000	78,000	78,000

Brian Marckx, CFA

HISTORICAL ZACKS RECOMMENDATIONS



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