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

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

iCAD Inc (ICAD-NASDAQ)

ICAD: Tomo Seeing "Strong Demand". Plug Pulled on Unprofitable Skin Subscription Biz

Based on average EV/S and P/S multiples of five comparable companies, iCAD is valued at approximately $7.00/share.

Current Price (04/02/18)	$3.21
Valuation	**$7.00**

OUTLOOK

Detection product sales, up 100% yoy, turned in the best quarter since Q3 2011 (when ICAD was still direct-selling MRI software). While Q4 is typically ICAD's strongest, the apparent accelerating adoption of the 'legacy' 2D and first-gen 3D tomo (GE-only) applications is obviously encouraging, particularly given the near-term launch of ICAD's next-gen software. This version '2.0', which is compatible with all OEM systems and received a warm welcome during its recent introduction at ECR, will massively expand the size of ICAD's tomo target markets – initial contribution from which could come as soon as Q1 '18 and more meaningful impact in 2H.
Relative to Therapy - despite recent increased growth in the number of sites treating for NMSC, in January ICAD decided to pull the plug on the Xoft subscription business. The good news is that management expects the elimination of the NMSC-subscription business to meaningfully improve Therapy margins and decrease cash burn. Meanwhile, potential opportunities in the (relatively much higher volume) NMSC-capital segment as well as in IORT breast and gyn, means that the value of the Therapy business might be the greatest in years.

SUMMARY DATA

52-Week High	**$6.07**
52-Week Low	**$2.93**
One-Year Return (%)	**-35.97**
Beta	**1.44**
Average Daily Volume (sh)	**36,925**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$53**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**21**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-5.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Blend**
Industry	**Comp-Software**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	6791 A	6409 A	7000 A	7902 A	28102 A
2018	6971 E	7506 E	7532 E	8581 E	30590 E
2019					40100 E
2020					50096 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.18 A	-$0.16 A	-$0.14 A	-$0.26 A	-$0.87 A
2018	-$0.14 E	-$0.10 E	-$0.09 E	-$0.06 E	-$0.39 E
2019					-$0.19 E
2020					$0.04 E

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

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Q4 2017 Results: Tomo Seeing "Strong Demand". Plug Pulled on Unprofitable Skin Subscription Biz …

iCAD reported financial results for their fourth quarter ending December 31st. Revenue, particularly in the Detection segment, continued to impress with very strong sales of the tomo (2D and 3D) products pushing total revenue up by 14% yoy. Detection product sales, up 100% yoy (pro-forma for ex-MRI), turned in the best quarter since Q3 2011 (when ICAD was still direct-selling MRI software) and crushed our number by 25%. While Q4 is typically ICAD's strongest, the apparent accelerating adoption of the 'legacy' 2D and first-gen 3D tomo (GE-only) applications is obviously encouraging, particularly given the near-term launch of ICAD's next-gen software. This version '2.0', which is compatible with all OEM systems and received a warm welcome during its recent introduction at ECR, will massively expand the size of ICAD's tomo target markets – initial contribution from which could come as soon as Q1 '18.

While almost everything seems to be going nearly to-plan for the Detection segment, the story is much different with Therapy, particularly the skin business – and particularly the skin subscription business. Despite recent increased growth in the number of sites treating for NMSC, in January ICAD decided to pull the plug on the Xoft subscription business. Noting that growth in the number of active sites lost steam after peaking in Q3 and lack of sufficient treatment volumes (necessary to cover costs, much less to generate profit), the decision was made to shutter the business – to be clear, the Xoft capital-customer segment not only remains intact but, per comments on the Q4 call, was responsible for ~80% of treatment volume in 2017.

But, as a whole, the Therapy business has struggled to gain sustainable traction since ICAD's acquisition of Xoft/Axxent in December 2010 (for $12.9M and $5.0M in contingent considerations) and of DermEbx/Radion (for $12.6M) in July 2014. Mostly related to adverse change in NMSC-treatment reimbursement policy and rates, since the end of 2014 ICAD has written down more than $34M in Xoft-related goodwill and intangible assets. Over the same period, the Therapy segment generated $41M in revenue and incurred aggregate operating losses (excluding the impairment charges) of $17M.

But, hopefully the worst in now in the past. The good news is that management expects the elimination of the NMSC-subscription business to meaningfully improve Therapy margins and decrease cash burn. Meanwhile, potential opportunities in the (relatively much higher volume) NMSC-capital segment as well as in IORT breast and gyn, means that the value of the Therapy business might be the greatest that it has been in years.

Total Revenue: $7.9M (vs. $7.4M estimate) up 14% yoy, up 13% sequentially

While on a GAAP basis revenue was up 14% yoy, on an apples-to-apples basis, results were even stronger. As a reminder, the company's MRI assets were sold in Q1 2017. Stripping out MRI revenue, which contributed approximately $400k in the prior-year period, means revenue from comparable operations grew 22% from Q4 2016. All of the Q4 growth (both yoy and sequential) was driven by the Detection segment and largely reflective of strong adoption of the tomo products. Meanwhile, Therapy revenue was down 4% yoy and flat from Q3.

For the full-year, total revenue was $28.1M, up 7% and +15% on an ex-MRI basis. Detection accounted for 80% of the $3.6M (ex-MRI) revenue growth in 2017, with all of that related to growth in Detection product sales – again, related to ramping adoption of the company's tomo products.

Relative to segment-specific profitability, Detection generated operating income of $2.1M and $6.4M in Q4 and full-year 2017 while Therapy incurred operating losses (excluding impairment charges of $2.0M in Q4 and $6.7M for the full-year) of $2.5M and $8.4M in the same periods.

Cancer Detection (Q4): $5.2M (vs. $4.7M estimate): +26% (+40% organic) yoy, +21% sequentially

While ICAD does not report specifics in terms of unit or license sales, indications are that the recent tomo launches in both the U.S. and Europe have been gaining traction. While this was anecdotally supported with Detection revenue growth of 23% in Q3, we think it is even more substantiated with the Q4 numbers. And with management's comments on the call – including that Detection revenue benefitted from "particularly strong demand for 2D and 3D" tomo software, we think we are finally seeing the potential that these products have to drive long-term revenue growth.

Q4 is typically the strongest for ICAD's Detection segment, so while we could see some variability through Q1 '18, we continue to think the tomo-related revenue curve steepens in 2018. In fact, there are several reasons to believe that ICAD's Detection segment has very substantial upside from the current numbers – most of which relates to technology evolution and ICAD's leading position in reading software. Management again indicated on the call that

much of the current demand is still coming from 2D. But, clearly the future is in 3D, the shift towards which has been incremental but one we think is likely to gain momentum - similar to the shift from film to digital mammography.

Rates of adoption of new 3D capable machines has been somewhat slow-going – perhaps related to budget resets and/or lack of widespread insurance coverage for tomo (both of which can be an impediments to hospitals committing to the technology). But, with new budgets and building awareness of the benefits of 3D vs. 2D (such as lower recall rates), adoption should increase. Reading 3D images is more time consuming, however, which will drive demand for ICAD's software. Insurers who do not already reimburse for tomo will likely soon have little choice but to do so, which should help alleviate any ROI-related concerns at the provider level. And, finally, providers will leverage tomo as competitive differentiation, prompting other hospitals to follow suit and also adopt the technology. GE and the other imaging manufacturers have been actively promoting at the customer level and management noted on the Q4 call that their direct sales team also had a strong quarter closing sales. While much of the volume is still for the 2D product (even for new machines that are capable of both 2D and 3D), we expect current headwinds to adoption of 3D tomo to dissipate over time.

With approximately two-thirds of the U.S. market still yet to adopt tomosynthesis, significant upside remains. GE's plan is to sequentially grow shipments of their Pristina machine each quarter and they have been actively promoting why their technology is superior to other manufacturers'. GE notes that customer surveys indicate that 83% of patients had a better experience getting a mammography with their Pristina machine as compared to competitors' and also touts lower 3D radiation dose as competitive differentiation. Indications are that GE has been increasing sequential sales.

And while we expect to see sequential growth of ICAD's GE-only tomo product, their next-generation software (version 2.0) offers a much greater opportunity for the company. This product is not only expected to reduce reading time but also further improve on accuracy to the point where radiologists will only need to read abnormal exams. This combination could prove of significant value in reducing reading time and, potentially, reduce staffing needs thereby helping to lower related costs. It also can be used on all manufacturers machines, which significantly increases the size of ICAD's target market. ICAD has previously mentioned that preliminary testing has shown much higher performance then they had initially anticipated. Competitive performance could be key relative to maximizing market share among the various manufacturers' installed bases.

Clearly encouraging in that regard was feedback of version 2.0 at ECR in late-Feb / early-March. Version 2.0 received CE Mark in February and was showcased not only by ICAD but also in GE's and Siemens' booths. Feedback, including that of some KOL's, was "incredibly positive". Management indicated that initial meaningful sales of 2.0 may not happen until around Q3 '18 – as system manufacturers (i.e. GE, Siemens, Hologic, etc) finalize interface work. Meanwhile, with the U.S. reader study completed, ICAD hopes to file for FDA clearance of 2.0 in the coming weeks – if all goes perfectly, U.S launch might happen in late-2018 (although we think U.S. launch is much more likely a 2019 event).

Given the industry shift from 2D to 3D and wider breadth of machines that this second-gen product has availability for (~75% of tomo systems are non-GE machines) and its enhanced features, introduction of this could result in another, and potentially much steeper, new wave of Detection segment growth.

Cancer Therapy (Q4): $2.7M (vs. $2.7M estimate): -4% yoy, +0% sequentially

For the full-year, Therapy revenue was $9.8M, up 6% from $9.2M in 2016. Growth was largely evenly split between products and services/supplies in 2017.

For Q4, Therapy product sales were $650k, representing four controllers – all of which were sold OUS. Service/supplies revenue was $2.0M. ICAD noted that they are seeing strong IORT-related growth OUS – indicating both breast and gyn applications are seeing meaningful demand. As we noted in a prior update, we think capital system sales may be able to do slightly better than treading water going forward, particularly as the Xoft system expands into additional geographies. This should soon include China where ICAD's IORT balloon applicators recently received CFDA approval. This follows prior approval of the console in that country.

Unfortunately, our prediction that service/supplies revenue would benefit from aggregate NMSC utilization as well as an increase in the subscription customer base (and number of 'active' sites), was not particularly prescient. While based on prior recent trends indicating improved subscription-utilization as well as re-activating of subscription sites, clearly both lost enough steam that ICAD felt it prudent to pull the plug. As noted, Therapy has

been a loser for ICAD and, given what appears to not have been nearly as significant turn-around in NMSC volumes (at least from the subscription side) as hoped-for, the decision to shut down the subscriber business was (in hindsight) already long-in-the-tooth. ICAD will eat about $200k of severance charges (in Q1) as a result of reducing headcount by 21. But with capital customers accounting for ~80% of treatment volumes, and presumably (at least marginally) profitable, we would hope to see Therapy do much better for the full-year 2018 then the $8.4M operating loss it turned in during 2017.

And as we have noted in the recent past, lack of significant capital console sales continues to raise the question regarding a "sufficient" level of reimbursement - particularly given that these are customers that would have significant capital at risk. But, the other side of that coin is that having capital at-risk is a motivator to generate volume – something that ICAD indicated was largely lacking with subscription customers. 2018 may provide a much clearer picture of the health of the NMSC treatment segment.

We still remain optimistic longer term on NMSC given clinical outcomes supporting use of eBx. Clinical data continues to show excellent outcomes including superior cosmetic results and patient satisfaction as compared to surgery, which should help support the quest for favorable insurance reimbursement. Most recently, ICAD was busy at ASTRO 2017, presenting data from their NMSC matched-pairs study (n=369) which showed similar cancer recurrence rates at more than 3 years follow-up between eBx and Mohs surgery (i.e. standard therapy). Additionally, cosmetic outcomes were as good or better among the eBx cohort as compared to Mohs. Another ASTRO presentation, relating to the treatment of peri-ocular NMSC, showed treatment with Xoft was associated with a 99% control rate at 2 years follow-up among patients (n=86) with basal cell carcinoma and squamous cell carcinoma of the eyelid.

Relative to IORT, balloon volumes grew 13% in 2017 (1,809 vs 1,596), which included relatively robust OUS growth. Internationally, balloon volumes were up 36%. OUS growth has been a focus and catalyzed by expansion into additional countries. That could be further stoked with entry into China. As noted, regulatory approval of Xoft and the IORT balloon applicators was just obtained in China. The relatively enormous population, combined with the convenience of radiation therapy at the time of surgery with eBx (versus traditional radiation which requires multiple trips back following lumpectomy), are reasons why ICAD believes China could represent another significant market for Xoft.

ICAD also recently launched an applicator for cervical cancer (GYN) which represents another potential area of growth - early indications suggest growing international demand in this application.

We think the U.S. holds opportunity for future growth, particularly with additional clinical data supporting the benefits of IORT over traditional radiation regimens. ICAD's ExBRT (Safety and Efficacy Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft Axxent eBx System at the Time of Breast Conservation Surgery for Early-Stage Breast Cancer) study recently completed enrollment. So far 1,200 patients have been treated with a median follow-up of just over 19 months. Following analysis, ICAD will look to have the data published (possibly later in 2018). The study is being conducted at 20+ sites in the U.S. and Canada and is evaluating safety, efficacy, cosmetic outcomes and quality of life of patients for 10 years post-treatment.

Also adding to the evidence supporting the use of IORT instead of traditional EBRT was a study that was recently published in *Cost Effectiveness and Resource Allocation.* The study (see our Appendix) demonstrated that IORT is associated with a longer quality of life, lower overall cost and higher monetary benefit as compared with external beam radiation therapy among patients with early-stage breast cancer.

Model / Valuation

Model Updates
With shuttering of the subscription business, on the Therapy side we have revenue falling 9% from in 2018 and will be particularly interested to see how the services/supplies revenue line trends given the relationship to the fundamental health of the ever-important NMSC subscription business. We have also made upward revisions to gross margin, reflective of relief of subscription-related downward pressure.

Meanwhile, we have Detection revenue growing 18% in 2018 – this could prove conservative but we are assuming a moderate sequential decline from Q4 ’17 to Q1 ’18 on some seasonality but then revenue to gain more traction in with 2.0 roll-out in Europe. Longer-term, we continue to model additional contribution from 3D tomo on technology-evolution adoption drivers and as aforementioned headwinds dissipate. into 2019, facilitated by launch of the next-gen product.

Valuation
We value iCAD based on competitor price/sales (P/S) and enterprise value /sales (EV/S) multiples. Using analyst's revenue estimates for the years 2018 and 2019, we calculated P/S and EV/S ratios from imaging (HOLX) as well as surgical (VAR, ISR, EKTAF, SRTS) companies. These companies currently trade at an average P/S-2018 of 3.3x and P/S-2019 of 2.8x and average EV/S-2018 of 3.4x and EV/S-2019 of 2.9x.

Based on the average of the EV/S and P/S multiples iCAD is valued approximately $7.00/share.

FINANCIAL MODEL

iCAD Inc.

	2017 A	Q1E	Q2E	Q3E	Q4E	2018 E	2019 E	2020 E
Cancer Detection	$18,310.0	$4,701.0	$5,205.6	$5,384.8	$6,340.3	$21,631.7	$29,397.5	$38,106.4
YOY Growth	6.9%	4.7%	23.0%	23.9%	20.9%	18.1%	35.9%	29.6%
% of total revenue	65.2%	67.4%	69.4%	71.5%	73.9%	70.7%	73.3%	76.1%
Therapy	$9,792.0	$2,270.0	$2,300.0	$2,147.0	$2,241.0	$8,958.0	$10,702.0	$11,990.0
YOY Growth	6.4%	-1.4%	5.6%	-19.1%	-15.7%	-8.5%	19.5%	12.0%
% of total revenue	34.8%	32.6%	30.6%	28.5%	26.1%	29.3%	26.7%	23.9%
Total Revenues	$28,102.0	$6,971.0	$7,505.6	$7,531.8	$8,581.3	$30,589.7	$40,099.5	$50,096.4
YOY Growth	6.7%	2.7%	17.1%	7.6%	8.6%	8.9%	31.1%	24.9%
Cost of Revenues	$9,926.0	$1,960.2	$2,004.9	$1,963.4	$2,181.3	$8,109.9	$10,173.1	$12,150.7
Gross Income	$18,176.0	$5,010.8	$5,500.7	$5,568.3	$6,400.0	$22,479.8	$29,926.3	$37,945.7
Gross Margin	64.7%	71.9%	73.3%	73.9%	74.6%	73.5%	74.6%	75.7%
R&D	$9,327.0	$2,420.0	$2,255.0	$2,388.0	$2,401.0	$9,464.0	$9,857.0	$10,556.0
% R&D	33.2%	34.7%	30.0%	31.7%	28.0%	30.9%	24.6%	21.1%
Selling & Mktg	$10,503.0	$2,662.9	$2,566.9	$2,470.4	$2,874.7	$10,575.0	$12,912.0	$14,477.9
% Sell&Mktg	37.4%	38.2%	34.2%	32.8%	33.5%	34.6%	32.2%	28.9%
G&A	$8,329.0	$2,133.0	$2,215.0	$2,178.0	$2,068.0	$8,594.0	$10,158.0	$11,845.0
% G&A	29.6%	30.6%	29.5%	28.9%	24.1%	28.1%	25.3%	23.6%
Operating Income	($16,676.0)	($2,205.1)	($1,536.3)	($1,468.1)	($943.7)	($6,153.2)	($3,000.7)	$1,066.8
Operating Margin	-59.3%	-31.6%	-20.5%	-19.5%	-11.0%	-20.1%	-7.5%	2.1%
Other income	$2,526.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other income, net	$2,402.0	($75.5)	($75.5)	($109.3)	($109.3)	($369.5)	($367.0)	($370.0)
Pre-Tax Income	($14,274.0)	($2,280.6)	($1,611.8)	($1,577.3)	($1,053.0)	($6,522.7)	($3,367.7)	$696.8
Taxes	($18.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	0.1%	0.8%	0.8%	0.8%	0.8%	0.0%	0.0%	0.0%
Net Income	($14,256.0)	($2,280.6)	($1,611.8)	($1,577.3)	($1,053.0)	($6,522.7)	($3,367.7)	$696.8
YOY Growth	-41.2%	-399.0%	38.7%	77.2%	75.1%	-54.2%	48.4%	120.7%
Net Margin	-50.7%	-32.7%	-21.5%	-20.9%	-12.3%	-21.3%	-8.4%	1.4%
EPS	($0.87)	($0.14)	($0.10)	($0.09)	($0.06)	($0.39)	($0.19)	$0.04
YOY Growth	-38.0%	-386.5%	39.7%	77.5%	75.4%	-55.0%	51.8%	120.2%
Pro-forma adjustments	$6,693.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pro-forma EPS	($0.62)	($0.14)	($0.10)	($0.09)	($0.06)	($0.39)	($0.19)	$0.04
Diluted Shares O/S	16,343	16,550	16,580	16,625	16,700	16,614	17,800	18,250

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APPENDIX

Decision-Tree Analysis of Published Studies Indicates IORT Superior To EBRT in QoL, Cost:

A study which was recently published in *Cost Effectiveness and Resource Allocation* (a peer-reviewed online publication "aimed at health economists, health services researchers, and policy-makers with an interest in enhancing the flow and transfer of knowledge relating to efficiency in the health sector") demonstrated that IORT is associated with a longer quality of life, lower overall cost and higher monetary benefit as compared with external beam radiation therapy among patients with early-stage breast cancer.

The study, *Lifetime cost-effectiveness analysis of intraoperative radiation therapy versus external beam radiation therapy for early stage breast cancer*[1], incorporated data from previously published peer-reviewed studies of IORT and EBRT into a Markov decision tree. Key inputs into the model (for both IORT and EBRT tree branches) included life expectancy, amount of radiation exposure and related complications, probability of acute and long-term complications, probability of recurrent cancer, probability of death due to cancer, probability of death due to other causes, cost of each treatment (including cost of treating potential complications and cancer recurrence) as well as several quality of life measures including those related to complications (associated with each therapy, radiation exposure or other factors) and cancer recurrence.

Results showed that IORT was not only less costly than (up to 6-weeks of) EBRT, but that it was also associated with a greater number of 'quality adjusted life years' or QALYs (i.e. a commonly used measure of both quality and length of life). This also meant that the 'net monetary benefit' favored IORT as compared to EBRT.

In terms of cost, which included cost of not only the individual breast cancer treatments, but also that related potential complications, estimated lifetime cost of IORT was $53,179, while EBRT lifetime cost was $63,828. The higher cost of EBRT largely relates to greater risk of radiation-exposure complications (such as major coronary events and development of other solid cancers) and the related cost to treat these.

In terms of QALY, the analysis showed that IORT was associated with QALY of 17.86, while EBRT was 17.06. Greater risk of radiation-related complications associated with EBRT were, again, the major factors that favored IORT.

Finally, cost and QALY were used to calculate what the authors called '**net monetary benefit**' (NMB), which was used to determine which treatment modality was the most cost effective over a lifetime. NMB is calculated as: (amount a person is willing to pay per QALY x QALYs) – lifetime costs. The authors assumed a person is willing to pay $50k per QALY, which is based on its use in prior clinical studies spanning more than decade. NMB for the two treatment modalities was:

IORT: ($50,000 x 17.86) - $53,179 = $839,821
EBRT: ($50,000 x 17.06) - $63,828 = $789,172

In other words, assuming that a patient with early-stage breast cancer values each QALY at $50k and will choose between either EBRT or IORT, this study indicates that they would benefit (on average) by $50,649 (i.e. $839,921 - $789,172) over their lifetime by choosing IORT.

While previous studies have shown that IORT is more cost-effective than EBRT, **this is the only study that evaluates QALY, cost and net monetary benefit of the two modalities over the lifetime of patients**. Authors of this study note that the difference is important given that the higher radiation doses of EBRT are associated with long-term complications, particularly major cardiac events due to a larger area of the chest being exposed to radiation (and at higher doses versus IORT). As noted, these cardiac-related complications are largely the reason why IORT results in a lifetime NMB which is superior to that of EBRT.

The authors also note that the cost-advantage of IORT is also a benefit to the overall healthcare system. Another advantage of IORT versus EBRT is that the former is performed in one session while the latter requires the patient to return for several radiation treatments – which means less disruptions to patients' lives, lower transportation burdens and, potentially, faster recovery of those patients which choose IORT. In fact, ICAD's management has pointed to these advantages as potentially helping to facilitate uptake in not only the U.S. but certain overseas markets as well. For example, IORT therapy's lower treatment burden could be attractive to patients living in rural

[1] Patel et al. Cost Eff Resour Alloc (2017) 15:22 DOI 10.1186/s12962-017-0084-5

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areas of China (where ICAD's Axxent system and balloon applicators recently received regulatory clearance) which have to travel long distances to access radiation therapy.

Our comments:
While ICAD's IORT breast cancer therapy segment growth (particularly as it relates to the U.S.) has been less substantial than other areas, as we have noted in our coverage of the company, we have and continue to believe that key to fueling greater adoption and utilization of IORT lies with additional clinical data favoring its use over that of traditional radiation therapy (i.e. EBRT). This study, along with ICAD's ongoing 1,000-patient ExBRT (Safety and Efficacy Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft Axxent eBx System at the Time of Breast Conservation Surgery for Early-Stage Breast Cancer) study, should help in that regard.

HISTORICAL STOCK CHART



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