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iCAD Inc (ICAD-NASDAQ)

ICAD: *Confident of FDA Approval of Tomo 2.0 (i.e. ProFound AI). New/Interim CEO Looks Like Perfect Fit for ICAD*

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

Current Price (11/27/18)	$3.25
Valuation	**$7.00**

OUTLOOK

It didn't take long to find out that axing the cash and resource-intensive NSMC therapy subscription business was a good move. So, while tomo sales have been disappointing, with PMA approval of 2.0 anticipated any day now, we continue to think revenue and the rest of the income statement show dramatic improvement next year. And in the meantime, with the boat anchor cut loose, expense base trimmed and incremental growth coming from breast IORT, we think ICAD should finish the year in a much more favorable position than where they started it. As the share price has yet to reflect their improved prospects, we think this presents an attractive entry and/or position-addition opportunity.
At the urging of the board, Ken Ferry stepped down as CEO in early November. Michael Klein took the reins as interim CEO and also assumed the Executive Chairmanship. Based on his background and experience, it appears ICAD is in good hands. With relevant and significant experience in executive roles at companies focused on CAD and minimally-invasive cancer therapy, Michael Klein's background appears to be as perfect a fit for ICAD as could be hoped for.
Tomo 2.0 Reader Study presented at RSNA. FDA approval appears to be likely in the very near term. Much of our 2019 revenue growth hinges on it.

SUMMARY DATA

52-Week High	**$4.10**
52-Week Low	**$2.42**
One-Year Return (%)	**-18.09**
Beta	**0.80**
Average Daily Volume (sh)	**58,501**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$54**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**16**
Insider Ownership (%)	**10**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-10.1**
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	6313 A	6162 A	6192 A	6549 A	25216 E
2019					33089 E
2020					45303 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	-$0.20 A	-$0.06 A	-$0.08 A	-$0.08 E	-$0.42 E
2019					-$0.22 E
2020					$0.03 E

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

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Q3 2018 Results: *ICAD Confident of FDA Approval of Tomo 2.0 (i.e. ProFound AI). New CEO Looks Like Perfect Fit…*

iCAD reported financial results for their third quarter ending September 30th. Both top and bottom lines were just about dead-on with our respective estimates although there were some moderate differences as it relates to sources of revenue. Specifically, Detection product revenue missed our number by about 9% which was largely offset by slightly stronger than anticipated Therapy revenue (both product and services/supplies).

As we noted in recent prior updates, it didn't take long to find out that axing the cash and resource-intensive NSMC therapy subscription business was a good move. So, while total revenue slid nearly 12% yoy, or $808k, operating loss improved by 44%, or $993k, in Q3 (all comparisons exclude a $2.1M gain on asset sale in Q1'17 and $4.7M goodwill impairment in Q3'17). Meanwhile, cash used in operating activities fell by $1.5M (or ~$600k ex-changes in working capital) over the same period.

YTD revenue is down 8% through Q3 yet operating loss improved by 32%, or $2.5M. Cash used in operating activities was $859k less through the first nine months of 2018 as compared to the same period in 2017. However, excluding working capital, cash used in operating activities actually increased by about $650k – but, that can be explained by a ~$1M jump in R&D expense in Q1 related to development of tomo 2.0 (i.e. the anticipated major driver of the topline beginning in early 2019).

So, while tomo sales have been disappointing to-date, with PMA approval of 2.0 anticipated any day now, we continue to think revenue and the rest of the income statement show dramatic improvement next year. And in the meantime, with the boat anchor cut loose, expense base trimmed and incremental growth coming from breast IORT, we think ICAD should finish the year in a much more favorable position than where they started it. As the share price has yet to reflect their improved prospects, we think this presents an attractive entry and/or position-addition opportunity.

Change in CEO, ICAD is in good hands…

ICAD will also be going into next year with a major change in leadership. At the urging of (at least some members of) the board, Ken Ferry stepped down as CEO in early November. Michael Klein took the reins as interim CEO and also assumed the Executive Chairmanship. While it is not yet clear how long Mr. Klein will serve in these positions, based on his background and experience, it appears ICAD is in good hands. With relevant and significant experience in executive roles at companies focused on CAD and minimally-invasive cancer therapy, Michael Klein's background appears to be as perfect a fit for ICAD as could be hoped for.

Prior to his most recent role as CEO of Inflection Point Consulting, Mr. Klein was CEO of SonaCare Medical, LLC (2011 – 2014), which designs and manufactures minimally invasive high intensity focused ultrasound (HIFU) ablation systems (including Sonablate for the treatment of prostate cancer). He initially became affiliated with ICAD in December 2004, when the company acquired Xoft, Inc. (and the Axxent system). Klein was the President and CEO of Xoft over the prior six years. Before that he held similar roles at R2 Technology, Inc. (2000 – 2004) a designer and marketer of breast and lung cancer CAD products which was acquired by Hologic in 2006 for $220M, or approximately 5x revenue. Per Hologic's press release announcing closing of the acquisition, R2 Technology "pioneered the use of CAD for mammography in 1998 when the ImageChecker system became the first CAD system approved by the FDA for screening mammography. The ImageChecker CAD system was also the first system approved for use with digital mammography." Also, comforting, are Klein's comments on the Q3 call that along with his deep breadth of product and commercial knowledge, that he is very familiar with working with FDA and with the reimbursement side of the businesses.

Q3 Total Revenue: $6.2M (vs. $6.4M estimate) down 12% yoy, flat sequentially

While yoy total revenue fell 12% in Q3 and fell 8% YTD, excluding contribution from MRI and subscription-Therapy from the prior year period, total revenue (on a current-operations basis) was **down just 5% for the quarter and was flat through the first nine months of 2018.**

As a reminder, the MRI assets were sold in January '17 and contributed ~$0.4M through the first three quarters of that year. Per the 10-Qs, Therapy revenue from subscription NMSC contributed ~$0.3M, $40k and $62k in Q1, Q2 and Q3'18 (~$400k YTD), respectively, compared to ~$0.4M, $0.6M and $0.6M (~$1.7M YTD) in the prior year periods.

Cancer Detection: $4.0M (vs $4.2M E) down 10% yoy, flat sequentially

Detection continues to lag our expectations. Excluding MRI, Detection revenue fell ~$900k, or 7% through the first nine months of 2018. Given that we had expected to see more obvious accelerating adoption of tomo by now, Detection continues to disappoint. Q3 Detection revenue is essentially flat from both Q1 and Q2 of this year – with product revenue between $2.3M and $2.4M and service/supplies revenue of $1.5M in each of the last three quarters. And, it appears the similarities between don't end there, as GE's lack of sufficient sales effort was cited as a major reason for the lackluster Detection performance in each quarter.

We estimate that GE accounts for ~70% - 75% of ICADs OEM Detection revenue. OEM partners (which also includes Fuji and Siemens and, will include others following FDA clearance of tomo 2.0) contribute ~50% of total Detection revenue. OEM revenue fell 40% yoy to $1.5M in Q3 and fell 21% yoy to $5.3M YTD (through Q3). Meanwhile, Detection revenue from ICAD's direct sales force, which also accounts for ~50% of total Detection revenue, increased 31% yoy to $2.3M in Q3 and was up 5% yoy to $6.2M YTD (through Q3).

This is a significant change from what we saw through the first half of the year. Through 1H'18, OEM and direct Detection sales were down 10% and 7%, respectively. The updated numbers, through Q3, do appear to very much align with management's comments that while growth is emanating from their own efforts, that it is indeed sorely lacking from GE's.

While we continue to model a significant uptick in sequential growth of Detection product sales into Q4, most of that relates to assumed typical seasonal late-year strength. But, given the continued softer-than-modeled results, we have made some additional (although relatively minor) downward adjustments to our Detection product sales in the early part of 2019. But while the initial roll-out in Europe has been much less climactic than we had hoped for, we do continue believe FDA approval of 2.0 has the potential to create a halo effect and help catalyze sales and accelerate OUS attachment rates. And, as we had noted in a prior update, we are also encouraged that ICAD appears committed to penetrating the European market and growing their distribution footprint in key markets, including Germany and France. ICAD noted that initial interest of 2.0 in Europe, including from KOL's, has been very positive.

FDA PMA approval could be imminent…

The U.S. market is where the majority of the opportunity lies. And, we still like the big-picture view. 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. 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.

Awareness of the benefits of artificial intelligence, in general, is gaining traction – and will almost certainly increase momentum going forward and spur adoption. A recent example is research from the University of Pittsburgh published in October in Clinical Cancer Research (*Deep Learning to Distinguish Recalled but Benign Mammography Images in Breast Cancer Screening*) which showed AI reduced unnecessary recalls from screening mammography exams.

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.

Eventual release and potential publishing of the U.S. reader study (which was used to support the 2.0 PMA filing) could also help facilitate adoption. Results were compelling and unprecedented – showing an 8% increase in accurately detecting cancer (i.e. 8.0% increase in sensitivity), 6.9% reduction in the number of false positives (i.e. 6.9% increase in specificity) and 52.7% reduction in reading time (as compared to reading without 2.0). The fact that the study showed a simultaneous increase in both sensitivity and specificity, combined with the magnitude of improvement (for context, a 5% increase in detection is considered clinically meaningful) and massive reduction in

reading time, is rather extraordinary and should be a very persuasive marketing message as to why radiologists should adopt the tool.

The study results were presented at the RSNA Annual Meeting this week. ICAD also unveiled the formal name for their next-gen 3D tomo product, officially now known as ProFound AI. The fact that the product was featured at RSNA – which (given the effort and expense of travel, booth set-up, marketing materials, etc,) undoubtedly consumed a not-insignificant amount of resources and capital – seems to indicate ICAD is confident in gaining PMA approval. ICAD has also been making other operational preparations – which also seem to speak about their confidence of getting FDA approval. That includes increasing the size of their U.S. sales force and rolling out new awareness-based initiatives.

In terms of background and current status of the PMA application….ICAD filed Version 2.0 PMA submission to FDA in late-May and in ~mid-August received follow-up questions from the agency. Relative to the scope of the questions, management noted on the Q2 call (Aug 14th) that they did not cause serious concerns, that they anticipated responding to them in approximately two weeks (~end of Aug) and "feel confident" that they will have U.S. marketing approval later this year.

They provided an update on the Q3 call on November 13th noting that they received a letter from FDA on October 25th which requested (what management described as) mostly minor clarifications and additions – and which elicited no significant concerns. They then had a teleconference with FDA approximately one week later which management noted went "extremely well". The following few days there was additional back-and-forth and on November 6th ICAD formally responded to additional questions. Per the Q3 call (as it relates to the Nov 6th response), ICAD "submitted responses to a list of questions included in our recent letter from the FDA last week. The letter did not outline issues or questions that caused us any serious concerns. Rather they were clarifying in nature." Management noted that they had discussions with FDA subsequent to that formal response and they **"remain highly confident that our new AI product for tomo could be cleared in the fourth quarter of this year."** Management further mentioned that they are **"very, very confident that we're in the very final stages of this approval."**

As we had been (and continue to) modeling U.S. launch in early 2019, we have made no related changes to our projections. 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, U.S. introduction of this should result in an accelerated growth curve of the Detection segment.

ICAD's digital breast density software (version 3.4) for tomosynthesis, which received FDA clearance in August, provides another growth opportunity and, perhaps just as importantly, adds what is increasingly becoming must-have functionality. Growth has been spurred by increasing awareness of the false negative risk on mammography of dense breasts. That has resulted in more and more states (currently 36 states and increasing) mandating that patients must be notified of their breast density.

Cancer Therapy: $2.3M (vs. $2.2M estimate): -15% yoy, +4% sequentially

Therapy product sales were $699k, slightly ahead of our $650k estimate. Therapy services/supplies was $1.57M, about 3% better than our $1.52M number. Total Therapy revenue was down 6% YTD through Q3 ($6.7M) but, considering the subscription divestiture, has held up very well and the recent results highlight how much of a drag the skin subscription business was on the segment and ICAD as a whole.

Subscription NMSC contributed ~$0.3M, $40k and $62k in Q1, Q2 and Q3 (~$0.4M YTD) of this year, respectively, compared to ~$0.4M, $0.6M and $0.6M (~$1.7M YTD) in the prior year periods. So, excluding skin-subscription, Therapy revenue grew 7% yoy in Q3 and 17% YTD through Q3. OUS IORT revenue has been a major catalyst in the past and continues to be. More surprising is that U.S. IORT has recently showed glimpses of growth. Through Q3 balloon volumes are up 10% worldwide.

Given the size of China and India and their ever-increasing prosperity, these countries may represent significant growth opportunities. 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's IORT balloon applicators recently received CFDA approval. This follows prior approval of the console in that country. ICAD noted on the Q3 call that they will be installing the first systems in China in Q4 of this year. Meanwhile, Xoft received approval from India's Atomic Energy Board in late-August 2018 and the first Xoft system was placed in that country at Omega Hospitals Hyderabad in Q3.

ICAD notes that they continue to see growing international demand in several newer applications – including brain, rectal and prostate. This is in addition to breast and gyn, which have already witnessed meaningful demand. ICAD will continue their international expansion strategy and expects to soon enter Saudi Arabia, Egypt, Colombia and Africa.

With more data supporting the benefits of IORT versus traditional radiation therapy, we continue to think adoption in the U.S. market could soon begin to accelerate. *Intraoperative Radiation Therapy (IORT): A Series of 1000 Tumors*, a study of 984 breast cancer patients which received IORT breast cancer therapy (between June 2010 and August 2017), was published in Annals of Surgical Oncology in July 2018. Results to-date showed local recurrence rates (i.e. primary endpoint) at median follow-up of 36-months which are comparable to that of the landmark prospective TARGIT-A and ELIOT trials.

Results of 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 were presented at ASTRO 2018 in San Antonio in late-October. Results through (median follow-up of) two years showed less than 1% of patients had cancer regrowth or developed new cancer in the other breast. Moreover, treatment was well tolerated and mean treatment time was just 10.5 minutes. Results of the study, which enrolled 1,201 patients at 28 U.S. and international sites, are expected to be submitted for publication in the near term.

And, data with a mean follow-up of 55 months further supporting the low recurrence rates of IORT, was published in October 2018 in The American Journal of Surgery (*Application of 21-gene recurrence score results and ASTRO suitability criteria in breast cancer patients treated with intraoperative radiation therapy (IORT)*). Specifically, the study showed recurrence rates at 55 months (i.e. 4.6 years) among patients treated with IORT and (standard of care) adjuvant medical therapy (such as chemotherapy and endocrine therapy) were comparable to referenced recurrence rates in TARGIT-A. The study included 184 breast cancer patients (from Nv 2011 to Jan 2016).

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.

Relative to NMSC, ICAD has recently noted that they are detailing to cancer centers, as well as their legacy focus on dermatology practices. We expect they will continue to pick their spots as dictated by areas with favorable reimbursement. Michael Klein's experience could be an asset in this regard.

Given shedding of the subscription-related cost base, we think any topline growth in the NMSC business should be incremental (relative to 2017) to profitability. And, 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. At ASTRO 2017 ICAD presented 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.

Gross margin, OpEx and Cash flow

Divesting the NMSC subscription business has dramatically improved gross margin, operating loss and cash flow. Gross margin was 76.5% and an average of 75.1% in Q3 and through the first nine months of 2018, respectively. This compares to 66.3% and 68.5% in the prior year periods. For an even more exact comparison, if we eliminate the amortization portion of COGS (to eliminate differences related to the write down of assets in 2017), gross margin still shows significant improvement. On that basis, gross margin was 78.1% in Q3 and 76.7% YTD'18, which compares to 70.1% and 72.7% in the prior year.

Operating loss improved to $1.3M and $5.3M in Q3 and YTD through Q3'18 from $2.2M and $7.8M in the 2017 periods. This is despite revenue falling 12% and 8% over those respective periods. Meanwhile, cash used in operating activities fell by $1.5M (or ~$600k ex-changes in working capital) in Q3. Cash used in operating activities was $859k less through the first nine months of 2018 as compared to the same period in 2017. However, excluding working capital, cash used in operating activities actually increased by about $650k – but, that can be explained by

a ~$1M jump in R&D expense in Q1 related to development of tomo 2.0 (i.e. the anticipated major driver of the topline beginning in early 2019).

Model / Valuation

Model Updates
With shuttering of the subscription business, on the Therapy side we have revenue falling 10% in 2018. We 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 also continue to model incremental improvement in gross margin through the remainder of 2018 and into 2019.

With a slower than expected start, we now have Detection falling 10% (ex-MRI) in 2018 but continue to expect growth to steepen late in the year (with greater contribution of 2.0 in Europe and typical seasonal strength in Q4) and going into 2019 (as ProFound AI enters the U.S.) We have ProFound AI U.S. launch occurring in 2019, which represents much of the catalyst to our ~44% Detection revenue growth in that year. Longer-term, we continue to model additional contribution from 3D tomo on technology-evolution adoption drivers and dissipation of aforementioned headwinds.

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 2019 and 2020, 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-2019 of 3.2x and P/S-2020 of 2.8x and average EV/S-2019 of 3.2x and EV/S-2020 of 2.9x.

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

FINANCIAL MODEL

iCAD Inc.

	2017 A	Q1A	Q2A	Q3A	Q4E	2018 E	2019 E	2020 E
Cancer Detection	$18,310.0	$4,011.0	$3,990.0	$3,927.0	$4,276.6	$16,204.6	$23,388.6	$34,341.8
YOY Growth	6.9%	-10.6%	-5.7%	-9.6%	-18.4%	-11.5%	44.3%	46.8%
% of total revenue	65.2%	63.5%	64.8%	63.4%	65.3%	64.3%	70.7%	75.8%
Therapy	$9,792.0	$2,302.0	$2,172.0	$2,265.0	$2,272.0	$9,011.0	$9,700.0	$10,961.0
YOY Growth	6.4%	0.0%	-0.3%	-14.7%	-14.5%	-8.0%	7.6%	13.0%
% of total revenue	34.8%	36.5%	35.2%	36.6%	34.7%	35.7%	29.3%	24.2%
Total Revenues	$28,102.0	$6,313.0	$6,162.0	$6,192.0	$6,548.6	$25,215.6	$33,088.6	$45,302.8
YOY Growth	6.7%	-7.0%	-3.9%	-11.5%	-17.1%	-10.3%	31.2%	36.9%
Cost of Revenues	$9,926.0	$1,815.0	$1,378.0	$1,454.0	$1,480.2	$6,127.2	$7,210.6	$9,420.8
Gross Income	$18,176.0	$4,498.0	$4,784.0	$4,738.0	$5,068.4	$19,088.4	$25,878.0	$35,882.1
Gross Margin	64.7%	71.2%	77.6%	76.5%	77.4%	75.7%	78.2%	79.2%
R&D	$9,327.0	$3,339.0	$2,057.0	$2,035.0	$2,062.0	$9,493.0	$9,551.0	$10,596.0
% R&D	33.2%	52.9%	33.4%	32.9%	31.5%	37.6%	28.9%	23.4%
Selling & Mktg	$10,503.0	$2,166.0	$2,006.0	$2,100.0	$2,193.8	$8,465.8	$10,257.5	$13,137.8
% Sell&Mktg	37.4%	34.3%	32.6%	33.9%	33.5%	33.6%	31.0%	29.0%
G&A	$8,329.0	$2,141.0	$1,660.0	$1,852.0	$2,068.0	$7,721.0	$9,419.0	$11,221.0
% G&A	29.6%	33.9%	26.9%	29.9%	31.6%	30.6%	28.5%	24.8%
Goodwill Impairment	$6,693.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($16,676.0)	($3,148.0)	($939.0)	($1,249.0)	($1,255.4)	($6,591.4)	($3,349.5)	$927.3
Operating Margin	-59.3%	-49.9%	-15.2%	-20.2%	-19.2%	-26.1%	-10.1%	2.0%
Other income	$2,526.0	$22.0	$29.0	$28.0	$0.0	$79.0	$0.0	$0.0
Other income, net	$2,402.0	($120.0)	($84.0)	($90.0)	($113.0)	($407.0)	($466.0)	($370.0)
Pre-Tax Income	($14,274.0)	($3,268.0)	($1,023.0)	($1,339.0)	($1,368.4)	($6,998.4)	($3,815.5)	$557.3
Taxes	($18.0)	$13.0	$4.0	$26.0	$6.84	$49.8	$53.4	$79.1
Tax Rate	0.1%	-0.4%	-0.4%	-1.9%	-0.5%	-0.7%	-1.4%	14.2%
Net Income	($14,256.0)	($3,281.0)	($1,027.0)	($1,365.0)	($1,375.2)	($7,048.2)	($3,868.9)	$478.1
YOY Growth	-41.2%	-617.9%	61.0%	80.3%	67.5%	-50.6%	45.1%	112.4%
Net Margin	-50.7%	-52.0%	-16.7%	-22.0%	-21.0%	-28.0%	-11.7%	1.1%
EPS	($0.87)	($0.20)	($0.06)	($0.08)	($0.08)	($0.42)	($0.22)	$0.03
YOY Growth	-38.0%	-598.5%	61.8%	80.6%	68.1%	-51.6%	49.0%	112.1%
Diluted Shares O/S	16,343	16,583	16,664	16,700	16,780	16,682	17,950	18,400

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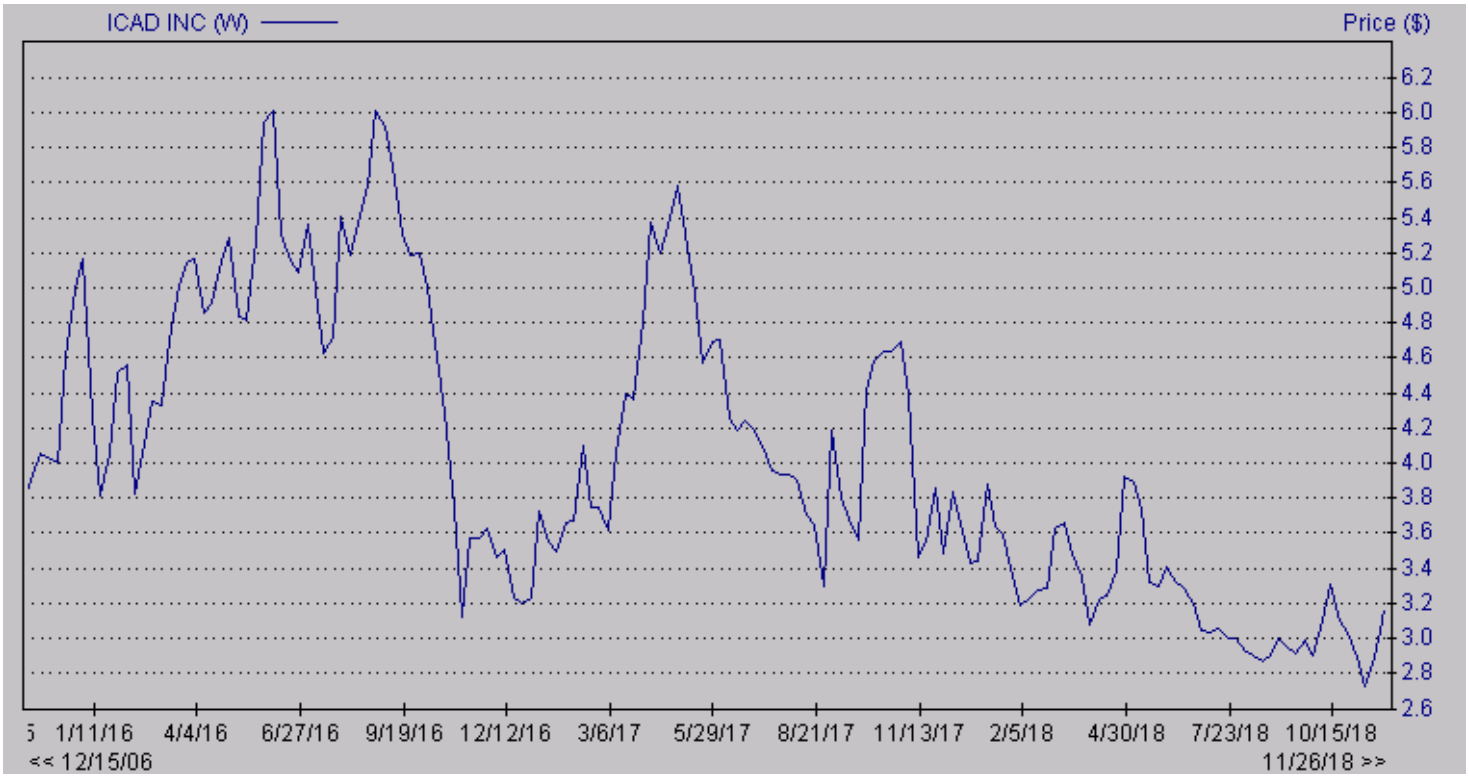
areas of China (where ICAD's Axxent system and balloon applicators recently received regulatory clearance) which have to travel long distances to access radiation therapy.

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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