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Zacks Small-Cap Research

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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)

ProFound AI Makes U.S. Debut, Roll-Out Accelerating. More AI Products Could Soon Follow

Based on average EV/S and P/S multiples of five comparable companies, iCAD is valued at approximately $7.50/share.

Current Price (03/22/19)	$4.16
Valuation	**$7.50**

OUTLOOK

ICAD noted that ProFound AI has already been adopted by a significant number of high-profile hospitals and imaging centers in different parts of the country. Soliciting feedback from influential KOL's, establishment of key reference sites and leveraging evidentiary and testimonial experience will be part of the initial adoption-driving strategy and supplement efforts of the direct sales force.

ICAD is putting the proceeds from a new $7M financing (5%, 3yr unsecured convertible (@$4/share) debt) to work, with a portion going to supporting the launch and U.S. roll-out of ProFound AI. As it relates to the sales force, ICAD noted that they recently more doubled their field infrastructure and may incrementally add to the sales team over the coming months as ProFound AI installations accelerate. Initial sales training on the new software has also been completed as has establishment of new marketing and promotional materials. Launch via GE, sales training of which has also been completed, is expected in the near-term. We note that while ICAD's build-out of their S&M infrastructure is directed at supporting the roll-out of ProFound AI, it also appears to be related to ICAD's strategy of eventually moving away from distribution-related reliance on OEM's, most notably, GE.

Our price target has moved up slightly, from $7.00 to $7.50/share.

SUMMARY DATA

52-Week High	**$6.10**
52-Week Low	**$2.42**
One-Year Return (%)	**21.39**
Beta	**1.36**
Average Daily Volume (sh)	**176,451**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$72**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**17**
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**
52-Week High	**$6.05**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**138.7**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Dev-Software**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	6313 A	6162 A	6192 A	6954 A	25621 A
2019	6101 E	6735 E	8191 E	8634 E	29661 E
2020					45328 E
2021					56253 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.20 A	-$0.06 A	-$0.08 A	-$0.20 A	-$0.54 A
2019	-$0.15 E	-$0.09 E	-$0.04 E	-$0.02 E	-$0.31 E
2020					$0.03 E
2021					$0.31 E

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

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Q4 2018 Results: *ProFound AI Makes U.S. Debut, Roll-Out Accelerating. More AI Products Could Soon Follow…*

iCAD reported financial results for their fourth quarter and provided a very comprehensive business update. As it relates to the financials, while revenue was down 12% yoy, it was up the same % on a sequential basis. As durable medical equipment sales are typically seasonally better in Q4, the qoq growth was not unexpected. It was, however, moderately stronger than we had anticipated. Notably, the ~6% (~$400k) beat to our topline number appears to be largely related to relative strength in AI (i.e. ICAD's new artificial intelligence product platform) sales – which management noted increased by $1M sequentially. The ~$600k beat to our Detection product sales estimate was partially offset by one-fewer (~$200k worth) IORT (Therapy) system sales, while Services revenue in both segments was inline with our respective estimates.

While we were in the ballpark on revenue, we missed big on EPS, ($0.08) E vs ($0.20) A. Gross margin was inline (77.4% E vs 77.8% A) but we did not anticipate the big jump in operating expenses, which increased 37%, or $2.2M, from Q3'18 including doubling of G&A. Some of the opex increase likely relates to non-repeating legal and severance expenses while other relates to initial build-out of the sales and marketing infrastructure for supporting the roll-out of ProFound AI for digital tomosynthesis, which secured FDA marketing clearance in December.

We show additional spend related to the same in 1H'19 as management noted that they have since more than doubled the size of their direct sales force and may incrementally add resources over the coming months. But, with the first sales of ProFound AI already on the books, "overwhelmingly positive" initial feedback from customers and what appears to be a well laid out roll-out strategy, Detection product sales are likely to begin to more than cover the incremental spend before current year-end.

Cancer Detection: $4.9M (vs $4.3M E) down 6% yoy, up 26% sequentially

While Detection revenue had missed our respective estimates in each of the first three quarters of 2018, it surprised on the upside in the final period. Almost all of the $600k+ beat in Detection relates to product sales. As noted, ICAD credited AI with $1M of incremental (sequential) revenue in the quarter. Management did not disclose U.S. sales of ProFound AI, although did note that initial installations occurred in Q4.

Notably, ICAD indicated that GE's efforts continue to disappoint (our word), which we think implies that attachment rates of Version 1 via direct sales and/or OUS 2.0 sales picked up. Given that ProFound AI will largely be detailed by in-house efforts (at least initially), indications of continued progress of direct sales wins and in accelerating the adoption curve are obviously promising. To that point, management indicated that they are taking great efforts to ensure that they have substantially capable and effective sales and support teams leading the roll out of their new 3D tomo product.

ICAD has wasted no time in building awareness about ProFound AI, which is the only FDA-approved product for 3D tomosynthesis. In fact, even prior to it receiving FDA clearance, the product and the reader study data that supported U.S. regulatory approval were showcased at the RSNA Annual Meeting in November. That was followed by a presentation at the European Congress of Radiology conference earlier this year (ProFound AI for 2D, which is awaiting CE Mark, was also showcased ECR).

As a reminder, results of the reader study that supported FDA approval 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.

ICAD noted that ProFound AI has already been adopted by a significant number of high-profile hospitals and imaging centers in different parts of the country. Soliciting feedback from influential KOL's, establishment of key reference sites and leveraging evidentiary and testimonial experience will be part of the initial adoption-driving strategy and supplement efforts of the direct sales force.

ICAD is putting the proceeds from a new $7M financing (5%, 3yr unsecured convertible (@$4/share) debt) to work, with a portion going to supporting the launch and U.S. roll-out of ProFound AI. As it relates to the sales force, ICAD noted that they recently more doubled their field infrastructure and may incrementally add to the sales team over the coming months as ProFound AI installations accelerate. Initial sales training on the new software has also been completed as has establishment of new marketing and promotional materials. Launch via GE, sales training of

which has also been completed, is expected in the near-term. We note that while ICAD's build-out of their S&M infrastructure is directed at supporting the roll-out of ProFound AI, it also appears to be related to ICAD's strategy of eventually moving away from distribution-related reliance on OEM's, most notably, GE.

Unlike the initial version, ProFound AI is compatible with all manufacturer's machines – but, unlike ICAD's heavy reliance on GE for selling Version 1, which in hindsight may have been a mistake, the company appears eager to have more control over the sales and marketing strategy and processes with ProFound AI. This will undoubtedly result in higher sales and marketing expense, but should all but eliminate any complacency risk and presumably provide management with much more direct control over the ultimate 'success' of ProFound AI and the ProFound platform as a whole. It also offers significantly greater margin (and profit) opportunity.

ICAD was clear that they expect to leverage the 'platform' utility of ProFound AI and in doing so, further reduce their dependence on the OEMs. They are already working on a next-gen version of ProFound AI, which could launch next year. In addition, add-on capability including ProFound Cloud, which will allow for cloud-based processing, storage and transfer of images and reduce or eliminate the need for costly, bulky and high maintenance peripheral storage and related equipment has been under development for well over a year. Management believes they will have ProFound Could on the market sometime next year.

Meanwhile, a recently penned collaboration with researchers at The Karolinska Institutet in Stockholm, Sweden to develop an AI-based individual breast cancer risk prediction solution could result in another complementary offering to ProFound AI. Using tens of thousands of mammography images and ProFound AI's algorithm, a risk prediction model was built that allows for individual assessment of risk of developing breast cancer. The parties will now work to refine the model for commercial use. If successful in developing an 'accurate' risk-assessment model that can predict an individual's risk of developing breast cancer, we think it could represent a potential paradigm shift in screening methods and recommendations. ICAD hopes to have a first-generation module on the market in 2020 and noted on the Q4 call that they expect to unveil an early version of it at the RSNA conference in November of this year. We will be eager to updates.

Detection model updates…

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.

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.

GE's apparent lack of enthusiasm in promoting the first version was undoubtedly a headwind to adoption. While OEM revenue fell 21% through Q3'18 (as the 10-K has yet to be filed we do not have the full year numbers), Detection revenue through ICAD's direct sales force increased 5% over the same period (including 31% in Q3). And while we do not know what to expect as it relates to GE's efforts with ProFound AI, we are very encouraged to learn that ICAD appears to be hedging that risk by building out their own sales and marketing resources. This will, as ICAD laid out on the Q4 call, result in higher S&M spend but, hopefully pay dividends via a steeper-than-otherwise sales curve (as well as wider margins).

As Q1 is typically seasonally soft, we model rather unexciting Detection revenue with product sales up just 2.5% yoy and down 26% sequentially from Q4'18. We think fruits of the sales infrastructure build-out, establishment of key reference sites, GE's launch and further dissemination of results of the reader study and benefits of ProFound AI on accuracy and reading time begin to make a much more formidable impact beginning in Q3. In addition, given the first-contact to sales-close to installation sales cycle, we should see a greater proportion of the initial launch efforts close in 2H'19. Budget resets could have a significant benefit going into 2020.

Meanwhile, ProFound AI for 2D mammography is awaiting CE Mark. Management noted that of the ~9k systems in Europe, only about 1.5k are 3D and the shift to tomo is relatively slow moving. As such and continued growth in the 2D market, ICAD could find meaningful demand for ProFound AI 2D when launched.

Cancer Therapy: $2.0M (vs. $2.3M estimate): -24% yoy, -11% sequentially

Therapy product sales were $396k, representing two system sales, compared to our $650k, three systems, estimate. Therapy services/supplies was $1.6M, inline with our $1.6M estimate. Total Therapy revenue was down 24% yoy and down 11% from Q3'18.

For the full year, while total Therapy revenue fell 11%, Therapy product sales increased 22%. In addition, management noted that utilization (as measured by applicator sales) grew 7% for the year. So, while divestiture of the subscription business in early 2018 stunted NMSC growth in the year, it appears that the IORT breast cancer segment continues to grow.

And shedding the subscription business has had a significantly positive effect on gross margins and relative profitability. Q4'18 and FY2018 gross margins were 77.8% and 75.8%, compared to 54.9% and 64.7% in the comparable prior year periods. And while one-time expenses and initial build-out of ICAD's sales and marketing resources resulted in elevated operating expenses (as compared to other q's in 2018) in the most recent quarter, Q4'18's operating loss was still relatively mild as compared to the prior year. Operating loss was $2.8M and $8.1M in the three and twelve months ending 12/31/18, compared to $4.2M and $12.0M (excluding charge related to subscription segment) in the year-earlier periods.

While ICAD has not given up on the non-melanoma skin cancer business as a whole, they mentioned that they are seeking a commercial partner to lead the sales and marketing functions of what remains of that business (i.e. capital sales). We think that move is being made so they can dedicate their Therapy-related efforts to IORT breast, gyn and other cancers. We continue to believe that IORT breast has potentially significant upside in both the U.S. and internationally.

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 Nov 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.

As it relates to the international opportunity, 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 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. Xoft received approval from India's Atomic Energy Board in late-August 2018. The first installation

in India, at Omega Hospitals Hyderabad, occurred in Q3'18 while the first installation in China happened later same year.

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 is working on new applicators which has the potential to expand the market into additional applications. In addition to China, India, Spain, Taiwan and Australia, they are also seeing increasing interest from Japan – which could offer another significant growth opportunity.

Therapy model updates…

We think the decision to hand over the sales function for the remaining NMSC business may imply there is even more limited upside to that business than we had recently thought. We have made some slight downward revisions to our modeled Therapy revenue to reflect this assumption and now look for low-single digit growth of the Therapy segment in 2019, revised from mid-to-high single digit growth. Longer term we do continue to like the outlook for IORT given clinical data (and related awareness) catalysts in the U.S. and accelerating adoption and geographic expansion on the international side.

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 3.7x and P/S-2020 of 3.2x and average EV/S-2019 of 3.4x and EV/S-2020 of 3.0x.

Based on the average of the EV/S and P/S multiples iCAD is valued approximately $7.50share (revised up from $7.00).

FINANCIAL MODEL

iCAD Inc.

	2017 A	Q1A	Q2A	Q3A	Q4A	2018 A	Q1E	Q2E	Q3E	Q4E	2019 E	2020 E	2021 E
Cancer Detection	$18,310.0	$4,011.0	$3,990.0	$3,927.0	$4,936.0	$16,864.0	$4,076.8	$4,513.8	$5,789.8	$6,332.2	$20,712.5	$35,956.7	$46,391.0
YOY Growth	6.9%	-10.6%	-5.7%	-9.6%	-5.9%	-7.9%	1.6%	13.1%	47.4%	28.3%	22.8%	73.6%	29.0%
% of total revenue	65.2%	63.5%	64.8%	63.4%	71.0%	65.8%	66.8%	67.0%	70.7%	73.3%	69.8%	79.3%	82.5%
Therapy	$9,792.0	$2,302.0	$2,172.0	$2,265.0	$2,018.0	$8,757.0	$2,024.0	$2,221.0	$2,401.0	$2,302.0	$8,948.0	$9,371.0	$9,862.0
YOY Growth	6.4%	0.0%	-0.3%	-14.7%	-24.1%	-10.6%	-12.1%	2.3%	6.0%	14.1%	2.2%	4.7%	5.2%
% of total revenue	34.8%	36.5%	35.2%	36.6%	29.0%	34.2%	33.2%	33.0%	29.3%	26.7%	30.2%	20.7%	17.5%
Total Revenues	$28,102.0	$6,313.0	$6,162.0	$6,192.0	$6,954.0	$25,621.0	$6,100.8	$6,734.8	$8,190.8	$8,634.2	$29,660.5	$45,327.7	$56,253.0
YOY Growth	6.7%	-7.0%	-3.9%	-11.5%	-12.0%	-8.8%	-3.4%	9.3%	32.3%	24.2%	15.8%	52.8%	24.1%
Cost of Revenues	$9,926.0	$1,815.0	$1,378.0	$1,454.0	$1,544.0	$6,191.0	$1,382.9	$1,435.0	$1,727.0	$1,741.1	$6,286.0	$9,390.1	$10,804.3
Gross Income	$18,176.0	$4,498.0	$4,784.0	$4,738.0	$5,410.0	$19,430.0	$4,717.9	$5,299.7	$6,463.7	$6,893.1	$23,374.4	$35,937.7	$45,448.7
Gross Margin	64.7%	71.2%	77.6%	76.5%	77.8%	75.8%	77.3%	78.7%	78.9%	79.8%	78.8%	79.3%	80.8%
R&D	$9,327.0	$3,339.0	$2,057.0	$2,035.0	$2,014.0	$9,445.0	$2,231.0	$2,019.0	$2,012.0	$2,002.0	$8,264.0	$10,596.0	$11,210.2
% R&D	33.2%	52.9%	33.4%	32.9%	29.0%	36.9%	36.6%	30.0%	24.6%	23.2%	27.9%	23.4%	19.9%
Selling & Mktg	$10,503.0	$2,166.0	$2,006.0	$2,100.0	$2,421.0	$8,693.0	$2,507.4	$2,653.5	$2,793.0	$2,866.5	$10,820.5	$13,145.0	$14,907.1
% Sell&Mktg	37.4%	34.3%	32.6%	33.9%	34.8%	33.9%	41.1%	39.4%	34.1%	33.2%	36.5%	29.0%	26.5%
G&A	$8,329.0	$2,141.0	$1,660.0	$1,852.0	$3,769.0	$9,422.0	$2,216.0	$2,012.4	$2,157.0	$2,274.5	$8,659.9	$10,898.6	$11,874.6
% G&A	29.6%	33.9%	26.9%	29.9%	54.2%	36.8%	36.3%	29.9%	26.3%	26.3%	29.2%	24.0%	21.1%
Operating Income	($16,676.0)	($3,148.0)	($939.0)	($1,249.0)	($2,794.0)	($8,130.0)	($2,236.6)	($1,385.1)	($498.3)	($250.0)	($4,370.0)	$1,298.0	$7,456.9
Operating Margin	-59.3%	-49.9%	-15.2%	-20.2%	-40.2%	-31.7%	-36.7%	-20.6%	-6.1%	-2.9%	-14.7%	2.9%	13.3%
Other income, net	$2,402.0	($120.0)	($84.0)	($90.0)	($551.0)	($845.0)	($227.0)	($208.0)	($189.0)	($170.0)	($794.0)	($683.0)	($607.0)
Pre-Tax Income	($14,274.0)	($3,268.0)	($1,023.0)	($1,339.0)	($3,345.0)	($8,975.0)	($2,463.6)	($1,593.1)	($687.3)	($420.0)	($5,164.0)	$615.0	$6,849.9
Taxes	($18.0)	$13.0	$4.0	$26.0	($1.0)	$42.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$856.2
Tax Rate	0.1%	-0.4%	-0.4%	-1.9%	0.0%	-0.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	12.5%
Net Income	($14,256.0)	($3,281.0)	($1,027.0)	($1,365.0)	($3,344.0)	($9,017.0)	($2,463.6)	($1,593.1)	($687.3)	($420.0)	($5,164.0)	$615.0	$5,993.7
YOY Growth	-41.2%	-617.9%	61.0%	80.3%	21.0%	-36.7%	24.9%	-55.1%	49.6%	87.4%	-42.7%	111.9%	-874.5%
Net Margin	-50.7%	-52.0%	-16.7%	-22.0%	-48.1%	-35.2%	-40.4%	-23.7%	-8.4%	-4.9%	-17.4%	1.4%	10.7%
EPS	($0.87)	($0.20)	($0.06)	($0.08)	($0.20)	($0.54)	($0.15)	($0.09)	($0.04)	($0.02)	($0.31)	$0.03	$0.31
YOY Growth	-38.0%	-598.5%	61.8%	80.6%	22.3%	-38.0%	25.8%	-53.9%	50.5%	87.7%	-43.5%	110.9%	-834.2%
Diluted Shares O/S	16,343	16,583	16,664	16,700	16,774	16,680	16,780	16,795	17,000	17,100	16,919	18,500	19,300

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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.

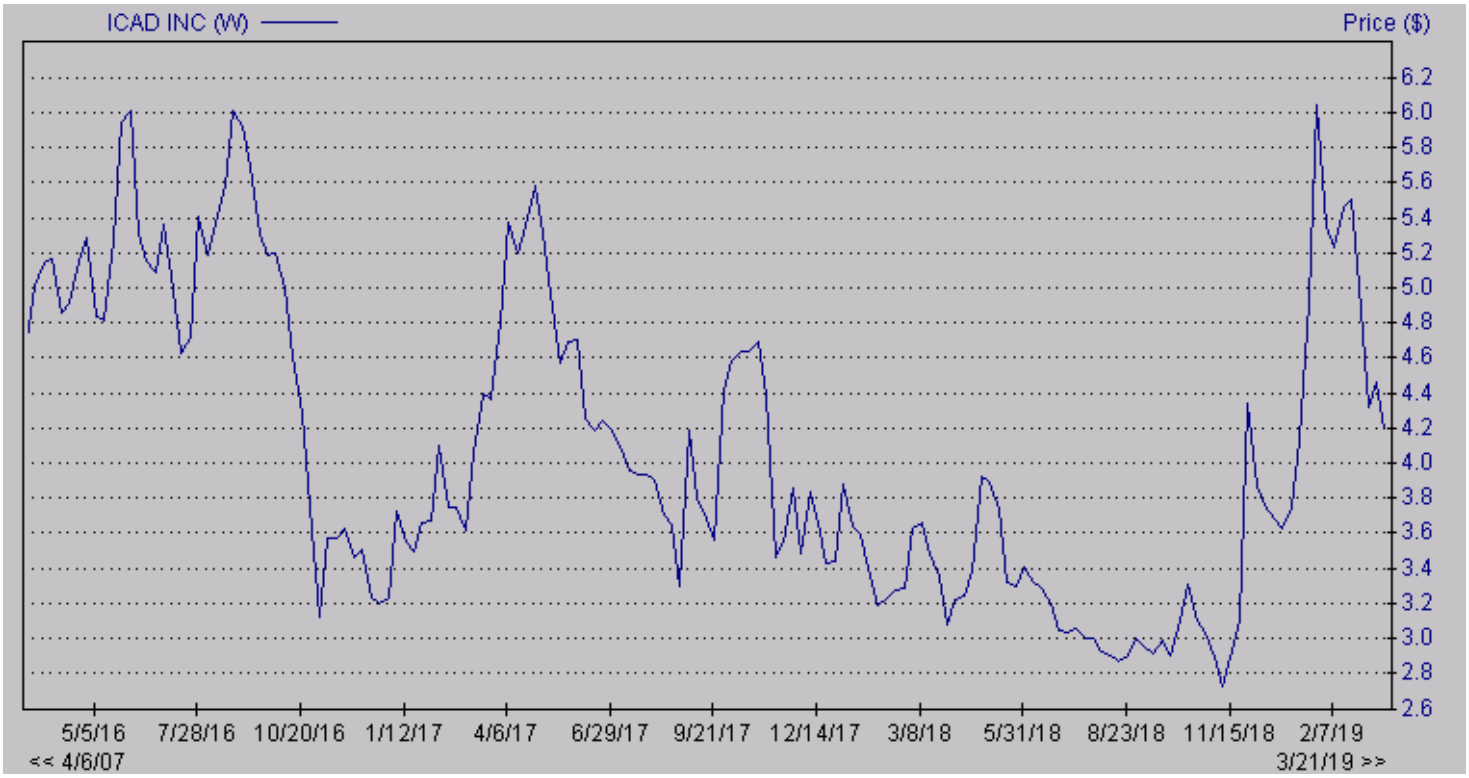
The authors also note that the cost-advantage of IORT is also a benefit to the overall healthcare system. Another advantage of IORT versus EBRT is that the former is performed in one session while the latter requires the patient to return for several radiation treatments – which means less disruptions 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.

HISTORICAL STOCK CHART



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