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iCAD Inc (ICAD-NASDAQ)

Therapy Buoys Q1 Sales, Benefits Operating Loss. Detection Acceleration Still Expected in 2H

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

Current Price (05/14/19)	$5.85
Valuation	**$7.50**

OUTLOOK

Q1 revenue was relatively very strong, particularly as compared to our estimates, up 7% yoy and down just 3% on a sequential basis. The low single-digit qoq contraction is notably encouraging given that Q4 is typically a seasonal best. Much of the strength in Q1 revenue relates to Therapy product sales, which at just over $1.0M were at the highest level in the last 3.5 years and accounted for 27% of the topline – up from historical mid-to-high teen %s.

However, indications continue to be that ProFound AI, which launched in December, will soon begin to make a much more substantial contribution and become the most significant driver of revenue. This, along with other Detection-related catalysts including what we expect to be burgeoning interest in ICAD's breast density offering, should push that segment to double-digit yoy growth before current year-end.

Q1'19 operating loss was just $1.0M, less than one-half our $2.2M estimate, with the difference coming from a $660k topline beat, inline gross margins and ~$640 lower-than-expected opex. This operating loss is also significantly lower than all but one quarter in 2018 and the second lowest since Q3'15. And while we think operating loss may tick up in Q2 with added infrastructure-related expenses, we also think profitability begins to improve in 2H as Detection revenue begins to steepen.

SUMMARY DATA

52-Week High	**$6.10**
52-Week Low	**$2.42**
One-Year Return (%)	**44.13**
Beta	**1.34**
Average Daily Volume (sh)	**116,660**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$98**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**23**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-12.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**117.0**
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	6773 A	6686 E	7611 E	8563 E	29632 E
2020					45378 E
2021					56319 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	-$0.22 A	-$0.10 E	-$0.06 E	-$0.03 E	-$0.40 E
2020					$0.05 E
2021					$0.31 E

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

Q1 2019 Results: *Therapy Buoys Q1 Sales, Benefits Operating Loss. Detection Acceleration Still Expected in 2H…*

iCAD reported financial results for their first quarter and provided a business update. As it relates to the financials, revenue was relatively very strong, particularly as compared to our estimates, up 7% yoy and down just 3% on a sequential basis. The low single-digit qoq contraction is notably encouraging given that Q4 is typically a seasonal best. Much of the strength in Q1 revenue relates to Therapy product sales, which at just over $1.0M were at the highest level in the last 3.5 years and accounted for 27% of the topline – up from historical mid-to-high teen %s.

However, indications continue to be that ProFound AI, which launched in December, will soon begin to make a much more substantial contribution and become the most significant driver of revenue. This, along with other Detection-related catalysts including what we expect to be burgeoning interest in ICAD's breast density offering, should push that segment to double-digit yoy growth before current year-end.

Management made a point to stress that much of their focus for the first quarter was on setting the stage for accelerated growth. Including in that was investing in their sales and marketing infrastructure, forging new vendor relationships and extending their OUS reach and capabilities. Indications are that the fruits of these initiatives (initiatives which will continue to build) will begin to be realized in short order.

Total revenue was $6.8M, compared to our $6.1M estimate, and included $4.2M (+3.9% yoy, -15.6% qoq) from Detection and $2.6M (+13.2% yoy, +29.1% qoq) from the Therapy segment. Gross margin was 78.0% (vs 77.3% E) with services and product margins at 75.7% and 82.2%, respectively. Product and total gross margin held up very well despite relatively low ASP on at least some of the Therapy system sales/placements which was largely attributed to geographic- and distributor-mix.

Operating expenses fell by 17% and 23% from the prior year and quarter, respectively. This is despite previously-announced initial build-out of the sales and marketing infrastructure for supporting the roll-out of ProFound AI. While we show additional spend related to S&M and personnel additions (management noted on the Q1 call that they are fully staffed with a direct sales force of 11, which is more than twice that from the close of 2018) and think opex, particularly SG&A, increases throughout the remainder of the year, we have since made some slight downward adjustments to expenses given our 10% overestimate as it relates to the same in Q1. But, as we noted following ICAD's reporting of Q4'18 results in March, 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.

Q1'19 operating loss was just $1.0M, less than one-half our $2.2M estimate, with the difference coming from a $660k topline beat, inline gross margins and ~$640 lower-than-expected opex. This operating loss is also significantly lower than all but one quarter in 2018 and the second lowest since Q3'15. And while we think operating loss may tick up in Q2 with added infrastructure-related expenses, we also think profitability begins to improve in 2H as Detection revenue begins to steepen.

Cancer Detection: $4.2M (vs $4.1M E) up 4% yoy, down 16% sequentially

Detection revenue has now surprised on the upside relative to our estimates for the last two consecutive quarters. The beat in both Q4'18 and Q1'19 largely relates to product sales and indications, based on comments on the respective earnings calls, are that the upside was from ICAD's AI products. This presumably includes U.S. sales of ProFound AI, initial installations of which happened in Q4'18 and which management indicated continue to gain traction.

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 2018. 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 at ECR) and most recently at the 2019 Society of Breast Imaging Symposium in early April. Their awareness-building efforts will continue as ICAD expects to attend additional upcoming industry events.

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 ProFound AI). 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 will be introducing a return-on-investment tool as part of their marketing strategy which shows how much money and time a hospital can save by adopting ProFound AI.

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.

As it relates to the sales force, ICAD noted that they recently more doubled their field infrastructure and have a sales force of 11 now fully trained. In addition, a national accounts manager will be focused on selling to large accounts, such as imaging centers and government facilities. Promotional and marketing materials for ProFound AI have also been completed. Launch via GE, sales training of which has also been recently 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.

Other potential near-term catalysts to drive Detection revenue includes;

- growing adoption of breast density imaging in the U.S. While the majority of state legislature's mandate that health care facilities provide patients with breast density reporting/disclosures, in March 2019 FDA announced a proposed amendment to the MQSA Act of 1992 that would require all mammography facilities to provide information to patients about high breast density and its relation to breast cancer risk. It also provides the agency with additional oversight and enforcement of MQSA facilities that do not comply with regulations. We think this amendment could act as a significant catalyst to further driving adoption of breast density screening and ICAD's PowerLook Density Assessment software. ICAD noted that they are rebranding and relaunching their breast density offering to leverage the growing interest and demand for dense breast imaging and analysis.
- expansion of ICAD's OUS distribution footprint, including other OEMs and PACS vendors.
    - ICAD noted on the Q1'19 call that they have already established relationships with the majority of PACS vendors and that they are "close to establishing formal relationships with a significant number of partners in the months ahead." This, in our opinion, could represent one of the most significant near-term catalysts in helping to drive organic sales of ProFound AI
    - ICAD has also been busy in building out their OUS distribution network – noting that they now have third-party distribution in 10 countries, have received their first ProFound AI order from this network and expect to further build out their OUS distribution footprint in the remainder of 2019
- European launch of ProFound AI for 2D, CE Marking of which could happen any day now. We think this offers another potentially potent contributor to Detection revenue, particularly given that demand for 3D tomography in much of Europe significant lags that of the U.S.

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 recently indicated 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. adoption 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 20% for the full year 2018 (including 17% in Q4), Detection revenue through ICAD's direct sales force increased 7% (including 14% in Q4). Sales via GE could commence soon as, per ICAD's comments on the Q1'19 call, ProFound AI is now quotable in GE's price book (and their sales force is now trained). 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).

We model single-digit Detection revenue growth from Q1 to Q2 and continue to look for the growth curve to steepen in the back half of this year. 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. We also look for a more significant contribution from their breast density offering and will be eager to hear how FDA's enhanced oversight of mammography providers and related reporting may be influencing demand for breast density imaging.

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 – which ICAD anticipates happening in the coming months.

Cancer Therapy: $2.6M (vs. $2.0M estimate): +13% yoy, +29% sequentially

Therapy product sales were $1.03M, the highest since Q3'15, and represented 10 system placements (6 for IORT, 4 for skin) – which consisted of eight sales and two leases. This was nearly double our $550k estimate. Management indicated that they are seeing a resurgence in interest, particularly in IORT applications, as well as initial adoption in certain international territories. Despite what has been a massive slowdown in NMSC-demand, further geographic expansion, introduction of new applicators (for additional cancers) and evidence-based demand in the U.S. should bode well for continued growth of the Therapy segment.

And shedding the subscription business has had a significantly positive effect on gross margins and relative profitability. ICAD disclosed segment-specific margins on the Q1 call (which we think may be a first). Therapy

gross margins were 70% in Q1'19, compared to 42% in the year-earlier period. As a reminder, the NMSC business, which ICAD exited in late-February 2018 (i.e. ~2/3 through Q1'18) carried relatively low margins.

Total gross margins were 78% in Q1'18, compared to 71% and 78% in the year- and quarter-earlier periods, respectively. The qoq flattening of total GM appears related to some contraction in Detection gross margins as a result of recent service and support investments that were made in that segment. But, as noted, as those investments were made with growth initiatives in mind, we think Detection margins will eventually begin to widen from what is already a very healthy level (for context Detection margins were 83% in Q1'19).

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, brain, rectal and other cancers. Noteworthy is that the first prostate cancer patient was treated with ICAD's system recently and the company believes prostate cancer represents a near-term growth catalyst. 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 that 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. But, we are encouraged by comments suggesting that there are real growth opportunities in IORT as ICAD expands their OUS footprint, brings new

applicators to market, continues to place significant importance on building the evidence databases and plays important roles in spreading awareness about the benefits of IORT. While the beat to our Therapy revenue in Q1'19 has moved our estimated FY2019 segment-specific number from $9.0M (i.e. 2% growth) to $9.4M (i.e. 7% growth), our Therapy out-year estimates remain unchanged.

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 3.6x 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 (unchanged from prior update).

FINANCIAL MODEL

iCAD Inc.

	2017 A	Q1A	Q2A	Q3A	Q4A	2018 A	Q1A	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	$4,168.0	$4,462.5	$5,309.6	$6,342.2	$20,282.4	$36,007.2	$46,456.5
YOY Growth	6.9%	-10.6%	-5.7%	-9.6%	-5.9%	-7.9%	3.9%	11.8%	35.2%	28.5%	20.3%	77.5%	29.0%
% of total revenue	65.2%	63.5%	64.8%	63.4%	71.0%	65.8%	61.5%	66.7%	69.8%	74.1%	68.4%	79.3%	82.5%
Therapy	$9,792.0	$2,302.0	$2,172.0	$2,265.0	$2,018.0	$8,757.0	$2,605.0	$2,223.0	$2,301.0	$2,221.0	$9,350.0	$9,371.0	$9,862.0
YOY Growth	6.4%	0.0%	-0.3%	-14.7%	-24.1%	-10.6%	13.2%	2.3%	1.6%	10.1%	6.8%	0.2%	5.2%
% of total revenue	34.8%	36.5%	35.2%	36.6%	29.0%	34.2%	38.5%	33.3%	30.2%	25.9%	31.6%	20.7%	17.5%
Total Revenues	$28,102.0	$6,313.0	$6,162.0	$6,192.0	$6,954.0	$25,621.0	$6,773.0	$6,685.5	$7,610.6	$8,563.2	$29,632.4	$45,378.2	$56,318.5
YOY Growth	6.7%	-7.0%	-3.9%	-11.5%	-12.0%	-8.8%	7.3%	8.5%	22.9%	23.1%	15.7%	53.1%	24.1%
Cost of Revenues	$9,926.0	$1,815.0	$1,378.0	$1,454.0	$1,544.0	$6,191.0	$1,491.0	$1,517.2	$1,685.5	$1,906.5	$6,600.1	$9,280.7	$10,967.2
Gross Income	$18,176.0	$4,498.0	$4,784.0	$4,738.0	$5,410.0	$19,430.0	$5,282.0	$5,168.4	$5,925.1	$6,656.8	$23,032.3	$36,097.6	$45,351.3
Gross Margin	64.7%	71.2%	77.6%	76.5%	77.8%	75.8%	78.0%	77.3%	77.9%	77.7%	77.7%	79.5%	80.5%
R&D	$9,327.0	$3,339.0	$2,057.0	$2,035.0	$2,014.0	$9,445.0	$2,127.0	$2,019.0	$2,012.0	$2,002.0	$8,160.0	$10,596.0	$11,210.2
% R&D	33.2%	52.9%	33.4%	32.9%	29.0%	36.9%	31.4%	30.2%	26.4%	23.4%	27.5%	23.4%	19.9%
Selling & Mktg	$10,503.0	$2,166.0	$2,006.0	$2,100.0	$2,421.0	$8,693.0	$2,573.0	$2,640.8	$2,732.2	$2,843.0	$10,789.0	$13,114.3	$14,924.4
% Sell&Mktg	37.4%	34.3%	32.6%	33.9%	34.8%	33.9%	38.0%	39.5%	35.9%	33.2%	36.4%	28.9%	26.5%
G&A	$8,329.0	$2,141.0	$1,660.0	$1,852.0	$3,769.0	$9,422.0	$1,616.0	$1,944.6	$2,075.8	$2,182.4	$7,818.8	$10,764.7	$11,612.9
% G&A	29.6%	33.9%	26.9%	29.9%	54.2%	36.8%	23.9%	29.1%	27.3%	25.5%	26.4%	23.7%	20.6%
Operating Income	($16,676.0)	($3,148.0)	($939.0)	($1,249.0)	($2,794.0)	($8,130.0)	($1,034.0)	($1,436.0)	($894.9)	($370.6)	($3,735.5)	$1,622.6	$7,603.8
Operating Margin	-59.3%	-49.9%	-15.2%	-20.2%	-40.2%	-31.7%	-15.3%	-21.5%	-11.8%	-4.3%	-12.6%	3.6%	13.5%
Other income, net	$2,402.0	($120.0)	($84.0)	($90.0)	($551.0)	($845.0)	($2,675.0)	($208.0)	($189.0)	($170.0)	($3,242.0)	($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)	($3,709.0)	($1,644.0)	($1,083.9)	($540.6)	($6,977.5)	$939.6	$6,996.8
Taxes	($18.0)	$13.0	$4.0	$26.0	($1.0)	$42.0	$8.0	$0.0	$0.0	$0.0	$8.0	$0.0	$874.6
Tax Rate	0.1%	-0.4%	-0.4%	-1.9%	0.0%	-0.5%	-0.2%	0.0%	0.0%	0.0%	-0.1%	0.0%	12.5%
Net Income	($14,256.0)	($3,281.0)	($1,027.0)	($1,365.0)	($3,344.0)	($9,017.0)	($3,717.0)	($1,644.0)	($1,083.9)	($540.6)	($6,985.5)	$939.6	$6,122.2
YOY Growth	-41.2%	-617.9%	61.0%	80.3%	21.0%	-36.7%	-13.3%	-60.1%	20.6%	83.8%	-22.5%	113.5%	-551.6%
Net Margin	-50.7%	-52.0%	-16.7%	-22.0%	-48.1%	-35.2%	-54.9%	-24.6%	-14.2%	-6.3%	-23.6%	2.1%	10.9%
EPS	($0.87)	($0.20)	($0.06)	($0.08)	($0.20)	($0.54)	($0.22)	($0.10)	($0.06)	($0.03)	($0.40)	$0.05	$0.31
YOY Growth	-38.0%	-598.5%	61.8%	80.6%	22.3%	-38.0%	-9.2%	-54.7%	24.2%	84.6%	-25.7%	112.3%	-519.0%
Diluted Shares O/S	16,343	16,583	16,664	16,700	16,774	16,680	17,200	17,240	17,500	17,600	17,385	19,000	20,000

Brian Marckx, CFA

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.

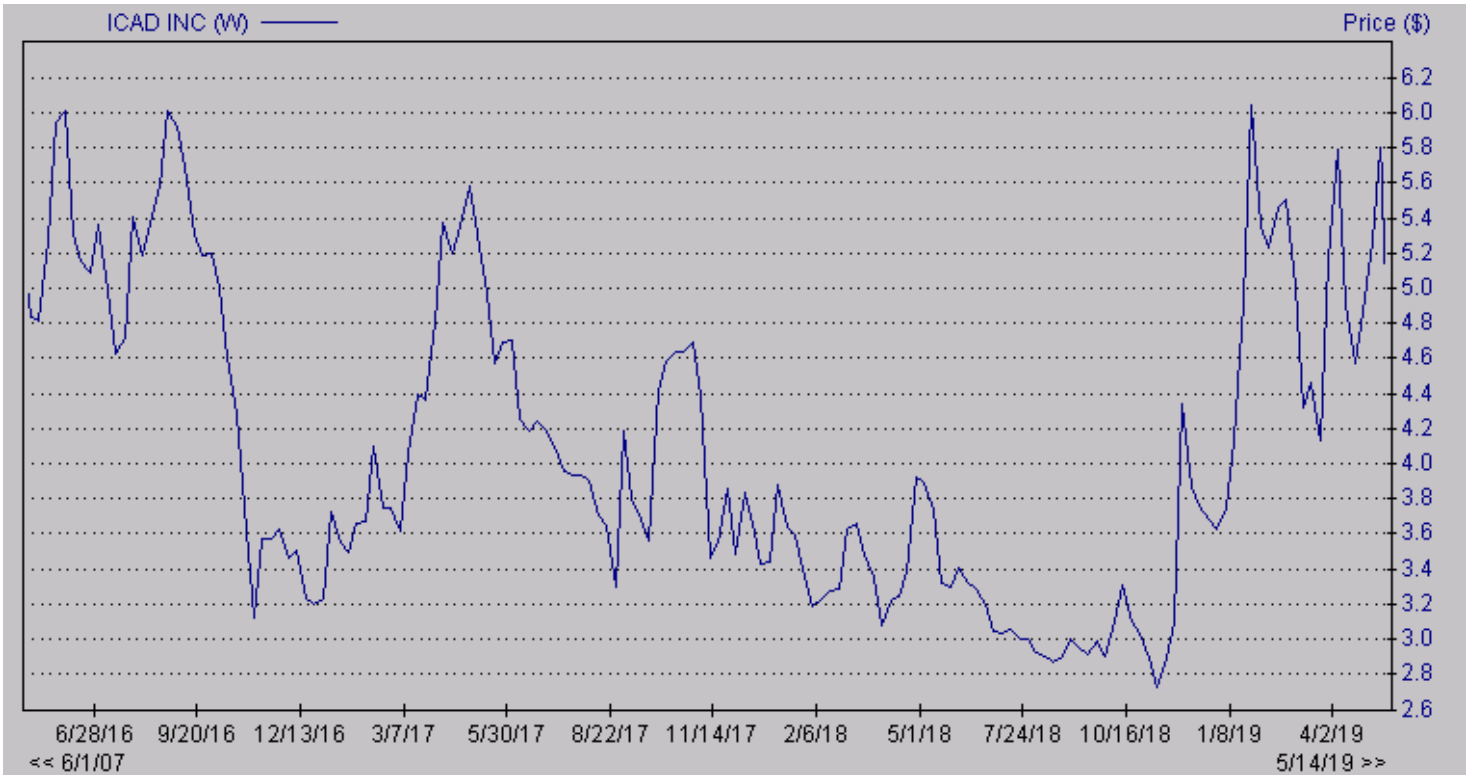
While previous studies have shown that IORT is more cost-effective than EBRT, **this is the only study that evaluates QALY, cost and net monetary benefit of the two modalities over the lifetime of patients**. Authors of this study note that the difference is important given that the higher radiation 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

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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