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

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

iCAD Inc (ICAD-NASDAQ)

ICAD: U.S. Tomo 2.0, Organic Therapy Growth and Leaner Ops Mean Profitability is Realistic

Based on average EV/S and P/S multiples of five comparable companies, iCAD is valued at approximately $6.75/share.

Current Price (08/30/18)	$3.03
Valuation	**$6.75**

OUTLOOK

iCAD reported financial results for their second quarter ending June 30th. Total revenue missed our number pretty handily, Detection revenue was well-below what we were looking for and tomo adoption does not appear to be as robust as hoped – and despite all that, Q2 2018 was one ICAD's best quarters in a long time.

Apples-to-apples total revenue was up 8% yoy, gross margins widened 730 bps and operating loss improved by $1.7M to just $939k – the lowest (i.e. best) since Q3 '15. While much of the improvement in operating loss relates to lower stock comp in the current year period, expenses have already been shed, cash burn is falling and both are expected to continue to improve. As we hoped, shedding of the cash and resource-intensive therapy subscription business has resulted in a rapid improvement in margins and profitability. It is becoming increasingly clear that ICAD's only misstep in dumping that business was that they didn't do so sooner (but, of course, hindsight is always 20/20).

So, with that big fat anchor now cut loose, we think near-term operating profitability and positive cash flow generation is foreseeably realistic within the next 18 months (based on our model), and possibly sooner - with timing likely hinging on rate of U.S. adoption of tomo 2.0

SUMMARY DATA

52-Week High	**$4.89**
52-Week Low	**$2.80**
One-Year Return (%)	**-18.06**
Beta	**1.40**
Average Daily Volume (sh)	**39,377**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$51**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**17**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-8.6**
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	6356 E	7017 E	25848 E
2019					34420 E
2020					45830 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 E	-$0.07 E	-$0.41 E
2019					-$0.17 E
2020					$0.05 E

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

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Q2 2018 Results: U.S. Tomo 2.0, Organic Therapy Growth and Leaner Ops Mean Profitability is Realistic …

iCAD reported financial results for their second quarter ending June 30th. Total revenue missed our number pretty handily, Detection revenue was well-below what we were looking for and tomo adoption does not appear to be as robust as hoped – and despite all that, Q2 2018 was one ICAD's best quarters in a long time.

Apples-to-apples total revenue was up 8% yoy, gross margins widened 730 bps and operating loss improved by $1.7M to just $939k – the lowest (i.e. best) since Q3 '15. While much of the improvement in operating loss relates to lower stock comp in the current year period, expenses have already been shed, cash burn is falling and both are expected to continue to improve. As we hoped, shedding of the cash and resource-intensive therapy subscription business has resulted in a rapid improvement in margins and profitability. It is becoming increasingly clear that ICAD's only misstep in dumping that business was that they didn't do so sooner (but, of course, hindsight is always 20/20).

So, with that big fat anchor now cut loose, we think near-term operating profitability and positive cash flow generation is foreseeably realistic within the next 18 months (based on our model), and possibly sooner - with timing likely hinging on rate of U.S. adoption of tomo 2.0 and the related revenue curve. That, in turn, hinges on timing of FDA clearance – ICAD filed the PMA 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 do 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. While we think management's timelines are realistic, we continue to (more conservatively) model U.S. launch in early 2019.

Total Revenue: $6.2M (vs. $6.8M estimate) down 4% yoy, down 2% sequentially

While yoy total revenue fell 4% in Q2 and fell 5% in 1H'18, excluding contribution from MRI and subscription-Therapy from the prior year period, total revenue (on a current-operations basis) actually **increased 8% for the quarter and was up 3% through the first six months of 2018.**

As a reminder, the MRI assets were sold in January '17 and contributed ~$0.3M in Q1'17 and (for some reason still generated revenue of) ~$0.1M in Q2 '17. Per the Q1 and Q2 '18 10-Qs, Therapy revenue from subscription NMSC contributed ~$0.3M and $40k in Q1 and Q2 of this year, compared to ~$0.4M and $0.6M in the prior year periods.

Cancer Detection: $4.0M (vs $4.5M E) down 6% yoy, down 1% sequentially

As Q2 '17 included ~$100k of MRI-related revenue, cancer Detection performed slightly better on an adjusted (current ops) basis, falling 5% yoy. Through the first six months, Detection revenue fell 8% as-reported and 4% as-adjusted.

Given that we had expected to see more obvious accelerating adoption of tomo by now, Detection has been fairly disappointing so far in 2018. Q2 Detection revenue was nearly identical to that of Q1 of this year - with product revenue of $2.5M and service/supplies revenue of $1.5M in both periods. And, it appears the similarities between the first and second quarter don't end there, as GE's lack of sufficient sales effort was cited as a major reason for the lackluster Detection performance in both periods.

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) account for ~50% of total Detection revenue. OEM revenue fell 18% yoy to $1.7M in Q2 and fell 10% yoy (which included a 3% decline in Q1'18) to $3.9M through 1H'18. Meanwhile, Detection revenue from ICAD's direct sales force, which also accounts for ~50% of total Detection revenue, increased 7% yoy to $2.1M in Q2 and fell 7% yoy (which included a 19% decline in Q1'18) to $3.8M through 1H'18. So, while it's clear that most of the weakness through the first six months of 2018 does indeed point to the OEM channel, direct sales were also quite weak in Q1 before turning back to meaningful growth in the most recent quarter.

Given the rather lackluster Detection numbers through the first half of 2018, we have again lowered our growth estimates. We had previously modeled a much steeper ramp going into Q3 with the expectation that the European tomo 2.0 roll-out would begin to accelerate, although have since tempered that optimism. But while the initial roll-out in Europe may be somewhat flatter than what we had envisioned, we do expect it to gain momentum through the end of this year and continue to like the long-term adoption and growth fundamentals. We are also encouraging 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.

But, 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.

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 – showing an 8% increase in accurately detecting cancer (ie 8% increase in sensitivity), 7% reduction in the number of false positives (ie 7% increase in specificity) and 53% 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 will be presented at the RSNA Annual Meeting in November.

ICAD filed their 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 do 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. While we think management's timelines are realistic, we continue to model U.S. launch in early 2019. ICAD noted that they expect to add to their direct sales force to support the U.S. launch of tomo 2.0.

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: $2.2M (vs. $2.3M estimate): 0% yoy, -6% sequentially

Therapy product sales were $708k, slightly ahead of our $650k estimate. Therapy services/supplies was $1.5M, about 11% shy of our $1.7M number. Total Therapy revenue was flat through 1H'18 ($4.5M). While slightly below our estimate, Therapy revenue actually held up very well. Q2 numbers further highlight how much of a drag the skin subscription business was on the segment and ICAD as a whole.

Subscription NMSC contributed ~$0.3M and $40k in Q1 and Q2 of this year, compared to ~$0.4M and $0.6M in the prior year periods. So, excluding skin-subscription, Therapy revenue grew 46% yoy in Q2 and 24% through 1H'18. 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 1H'18 balloon volumes are up 22% worldwide – that includes 20% growth in the U.S. (and 25% OUS).

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 Q2 call that they will be installing the first two systems in China later this year. Meanwhile, Xoft received approval from India's Atomic Energy Board in late-August of this year and the first Xoft system was placed in that country at Omega Hospitals Hyderabad.

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.

Publication 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 could happen later this year and further spur adoption. Enrollment (n=1,200) recently completed with median follow-up of just under two years. The study is being conducted at 20+ sites in the U.S. and Canada and is evaluating safety, efficacy, cosmetic outcomes and quality of life of patients for 10 years post-treatment.

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

Relative to NMSC, ICAD noted that they are now 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. 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

Gross margin was 77.6% in Q2 and 74.4% in 1H '18 which compares to 69.0% and 69.6% in the prior year periods. Operating loss was $939k and $4.1M in Q2 and 1H'18, compared to $2.6M and $5.6M in the prior year periods. So, while (as-reported) revenue fell 4% and 5% yoy in Q2 and 1H'18, COGS and OpEx fell significantly more. COGS fell 28% and 20% over those same periods while OpEx fell 20% and 9%.

Cash used in operating activities was $822k and $1.5M ($422k and $3.0M, ex-changes in working capital) in the three and six months ending 6/30/18, compared to $1.6M and $3.3M ($572k and $1.7M, ex-changes in working capital) in the prior year periods.

Model / Valuation

Model Updates
With shuttering of the subscription business, on the Therapy side we have revenue falling 9% 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 throughout 2018.

With a slower than expected start, we now have Detection falling 8% (ex-MRI) in 2018 but continue to expect growth to steepen late in the year (with greater contribution of 2.0 in Europe) and going into 2019 (as 2.0 enters the U.S. We have 2.0 U.S. launch occurring in 2019, which represents much of the catalyst to our ~46% 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 2018 and 2019, we calculated P/S and EV/S ratios from imaging (HOLX) as well as surgical (VAR, ISR, EKTAF, SRTS) companies. These companies currently trade at an average P/S-2018 of 4.6x and P/S-2019 of 3.4x and average EV/S-2018 of 3.8x and EV/S-2019 of 3.3x.

Based on the average of the EV/S and P/S multiples iCAD is valued approximately $6.75/share.

FINANCIAL MODEL

iCAD Inc.

	2017 A	Q1A	Q2A	Q3E	Q4E	2018 E	2019 E	2020 E
Cancer Detection	$18,310.0	$4,011.0	$3,990.0	$4,188.8	$4,745.4	$16,935.2	$24,720.2	$34,869.0
YOY Growth	*6.9%*	*-10.6%*	*-5.7%*	*-3.6%*	*-9.5%*	*-7.5%*	*46.0%*	*41.1%*
% of total revenue	*65.2%*	*63.5%*	*64.8%*	*65.9%*	*67.6%*	*65.5%*	*71.8%*	*76.1%*
Therapy	$9,792.0	$2,302.0	$2,172.0	$2,167.0	$2,272.0	$8,913.0	$9,700.0	$10,961.0
YOY Growth	*6.4%*	*0.0%*	*-0.3%*	*-18.3%*	*-14.5%*	*-9.0%*	*8.8%*	*13.0%*
% of total revenue	*34.8%*	*36.5%*	*35.2%*	*34.1%*	*32.4%*	*34.5%*	*28.2%*	*23.9%*
Total Revenues	$28,102.0	$6,313.0	$6,162.0	$6,355.8	$7,017.4	$25,848.2	$34,420.2	$45,830.0
YOY Growth	*6.7%*	*-7.0%*	*-3.9%*	*-9.2%*	*-11.2%*	*-8.0%*	*33.2%*	*33.1%*
Cost of Revenues	$9,926.0	$1,815.0	$1,378.0	$1,460.4	$1,535.7	$6,189.1	$7,386.4	$9,411.9
Gross Income	$18,176.0	$4,498.0	$4,784.0	$4,895.4	$5,481.7	$19,659.1	$27,033.8	$36,418.2
Gross Margin	*64.7%*	*71.2%*	*77.6%*	*77.0%*	*78.1%*	*76.1%*	*78.5%*	*79.5%*
R&D	$9,327.0	$3,339.0	$2,057.0	$2,147.2	$2,110.0	$9,653.2	$9,551.0	$10,596.0
% R&D	*33.2%*	*52.9%*	*33.4%*	*33.8%*	*30.1%*	*37.3%*	*27.7%*	*23.1%*
Selling & Mktg	$10,503.0	$2,166.0	$2,006.0	$2,161.0	$2,350.8	$8,683.8	$10,670.3	$13,290.7
% Sell&Mktg	*37.4%*	*34.3%*	*32.6%*	*34.0%*	*33.5%*	*33.6%*	*31.0%*	*29.0%*
G&A	$8,329.0	$2,141.0	$1,660.0	$1,886.2	$2,068.0	$7,755.2	$9,419.0	$11,221.0
% G&A	*29.6%*	*33.9%*	*26.9%*	*29.7%*	*29.5%*	*30.0%*	*27.4%*	*24.5%*
Operating Income	($16,676.0)	($3,148.0)	($939.0)	($1,299.0)	($1,047.1)	($6,433.1)	($2,606.5)	$1,310.4
Operating Margin	*-59.3%*	*-49.9%*	*-15.2%*	*-20.4%*	*-14.9%*	*-24.9%*	*-7.6%*	*2.9%*
Other income	$2,526.0	$22.0	$29.0	$0.0	$0.0	$51.0	$0.0	$0.0
Other income, net	$2,402.0	($120.0)	($84.0)	($113.0)	($113.0)	($430.0)	($466.0)	($370.0)
Pre-Tax Income	($14,274.0)	($3,268.0)	($1,023.0)	($1,412.0)	($1,160.1)	($6,863.1)	($3,072.5)	$940.4
Taxes	($18.0)	$13.0	$4.0	$0.0	$0.0	$17.0	$0.0	$0.0
Tax Rate	*0.1%*	*-0.4%*	*-0.4%*	*0.0%*	*0.0%*	*-0.2%*	*0.0%*	*0.0%*
Net Income	($14,256.0)	($3,281.0)	($1,027.0)	($1,412.0)	($1,160.1)	($6,880.1)	($3,072.5)	$940.4
YOY Growth	*-41.2%*	*-617.9%*	*61.0%*	*79.6%*	*72.6%*	*-51.7%*	*55.3%*	*130.6%*
Net Margin	*-50.7%*	*-52.0%*	*-16.7%*	*-22.2%*	*-16.5%*	*-26.6%*	*-8.9%*	*2.1%*
EPS	($0.87)	($0.20)	($0.06)	($0.08)	($0.07)	($0.41)	($0.17)	$0.05
YOY Growth	*-38.0%*	*-598.5%*	*61.8%*	*80.2%*	*73.3%*	*-52.9%*	*58.3%*	*129.9%*
Pro-forma adjustments	$6,693.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pro-forma EPS	($0.62)	($0.20)	($0.06)	($0.08)	($0.07)	($0.41)	($0.17)	$0.05
Diluted Shares O/S	16,343	16,583	16,664	16,865	16,900	16,753	17,950	18,400

Brian Marckx, CFA

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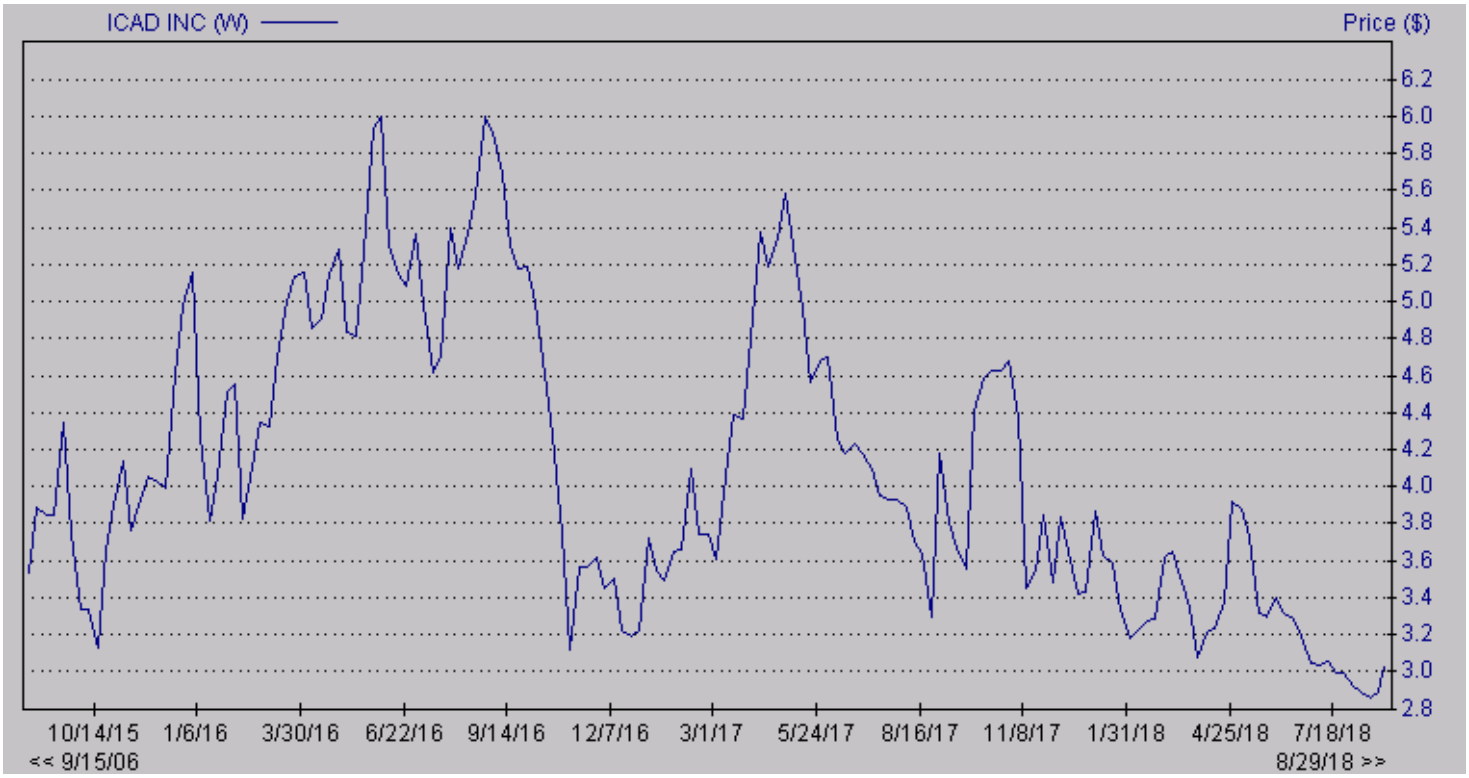
areas of China (where ICAD's Axxent system and balloon applicators recently received regulatory clearance) which have to travel long distances to access radiation therapy.

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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