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iCAD Inc (ICAD-NASDAQ)

ICAD: Detection Disappointing But Still Looking For 2.0-Related Inflection in 2H

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

Current Price (05/21/18)	$3.32
Valuation	**$6.75**

OUTLOOK

While Q1 Therapy revenue was just about dead-on with what we had been expecting, Detection revenue was quite disappointing. While management provided some color on the Q1 call, it is not completely clear why Detection performed so relatively poorly. On the brighter side, indications are that Q2 may have started off at a much stronger pace and that interest remains high. Importantly, ICAD is still guiding for Version 2.0 shipments to begin in Europe in the very near term and result in meaningful revenue contribution starting in Q3. Other potential catalysts to Detection include the ongoing shift from 2D to 3D, awareness from ECR and attendance at upcoming events, (the impending) U.S. launch of ICAD's 3D breast density software and eventual U.S. launch of tomo Version 2.0 – PMA filing for which is expected any day. Meanwhile, shuttering of Therapy skin subscription business has already resulted in significant improvement in margins and profitability of that segment - and those benefits should further improve going into Q2. Given expectations of meaningful Detection revenue growth and further gross margin expansion in Therapy (on flattish modeled sequential revenue), we think operating loss should improve throughout the remainder of 2018. Management is guiding for reaching cash flow break-even (on a quarterly basis) later this year.

SUMMARY DATA

52-Week High	**$4.89**
52-Week Low	**$2.93**
One-Year Return (%)	**-27.35**
Beta	**1.41**
Average Daily Volume (sh)	**31,556**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$55**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**19**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-7.1**
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	6839 E	7323 E	8121 E	28560 E
2019					38327 E
2020					48459 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	-$0.13 E	-$0.10 E	-$0.07 E	-$0.51 E
2019					-$0.23 E
2020					$0.01 E

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

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Q1 2018 Results: Detection Disappointing But Still Looking For 2.0-Related Inflection in 2H …

iCAD reported financial results for their first quarter ending March 31st. While Therapy revenue was just about dead-on with what we had been expecting, Detection revenue was quite disappointing. Detection revenue was 15% lower than where we thought it would come in, with almost all of the miss related to product sales. While we had anticipated Detection revenue would contract sequentially given some lumpiness in Q4 '17, we did think tomo-related momentum would result in solid double-digit yoy growth in product sales in that segment. Instead, total Detection revenue fell (ex-MRI) approximately 4% yoy with Detection product revenue contracting by about 3%. While management provided some color on the Q1 call, it is not completely clear why Detection performed so relatively poorly.

On the brighter side, indications are that Q2 may have started off at a much stronger pace and that interest remains high. Importantly, ICAD is still guiding for Version 2.0 shipments to begin in Europe in the very near term and result in meaningful revenue contribution starting in Q3. Other potential catalysts to Detection include the ongoing shift from 2D to 3D, awareness from ECR and attendance at upcoming events, (the impending) U.S. launch of ICAD's 3D breast density software and eventual U.S. launch of tomo Version 2.0 – PMA filing for which is expected any day.

The release and potential publishing of the U.S. reader study (which will support the 2.0 PMA filing) could also help facilitate adoption. In fact, management indicated that performance in the reader study was compelling – including a significant increase in sensitivity, specificity and meaningful reduction in reading time – and potentially strong enough to support a superiority (vs. reading w/o tool) claim. That could further significantly enhance the marketing message.

Total Therapy revenue was flat yoy, Both product sales and service/supplies revenue were inline with our estimates. As a reminder, in January ICAD decided to pull the plug on the Xoft subscription business. Noting that growth in the number of active sites lost steam after peaking in Q3 '17 and lack of sufficient treatment volumes (necessary to cover costs, much less to generate profit), the decision was made to shutter the business. But, the Xoft capital-customer segment not only remains intact, (per comments on the Q4 call) it was responsible for ~80% of treatment volume in 2017.

As a whole, the Therapy segment was a loser. Mostly related to adverse change in NMSC-treatment reimbursement policy and rates, since the end of 2014 ICAD wrote down more than $34M in Xoft-related goodwill and intangible assets. Over the same period, the Therapy segment generated $41M in revenue and incurred aggregate operating losses (excluding the impairment charges) of $17M.

The good news is that elimination of the NMSC-subscription business has already begun to improve Therapy margins and related cash burn – and those benefits should further improve going into Q2. As we noted in our Q4 '17 update following news of shuttering of the subscription skin business, the potential opportunities in the (relatively much higher volume) NMSC-capital segment as well as in IORT breast and gyn, means that the value of the Therapy business might be the greatest that it has been in years.

Total Revenue: $6.3M (vs. $7.0M estimate) down 7% yoy(ex-MRI), down 20% sequentially

ICAD generated ~$300k in MRI revenue in Q1 '17. Those assets were sold that same quarter. Detection (ex-MRI) was down 4% yoy and, despite shedding of the skin subscription business (February), Therapy managed to maintain flat growth.

In terms of segment-related profitability, pulling the plug on subscription skin business looks to already be making a major difference. Q1 '18 gross margin was 71.2% - improved from 69% in Q1 '17 and 54.9% in Q4 '17. In fact, gross margin has not been at this level since Q2 '16. Therapy operating loss improved from $2.4 in Q1 '17 to $1.1M in the most recent quarter. Unfortunately, Detection profitability went the other way – from $1.5M in operating income in Q1 '17 to $13k operating loss in Q1 '18.

Given expectations of meaningful Detection revenue growth and further gross margin expansion in Therapy (on flattish modeled sequential revenue), we think operating loss should improve throughout the remainder of 2018. Management is guiding for reaching cash flow break-even (on a quarterly basis) later this year.

Cancer Detection (Q1): $4.0M (vs. $4.7M estimate): -11% -4% organic) yoy, -24% sequentially

Benefitting from strong demand for both 2D and 3D tomo software, Detection revenue was extraordinarily robust in Q4 '17, up 40% yoy and +21% sequentially. But, with Q4 typically seasonally stronger, we had expected Detection revenue to fall sequentially into Q1 '18. Clearly, we underestimated the relative softness. But, apparently, so did management – noting on the call that results were weaker than they expected.

Some of that weakness may be a result of GE's efforts – which were pointed to as somewhat wanting. Whether that has bled into Q2 is unclear, although based on comments surrounding what sounds like a relatively strong start to April, we are hopeful that any slack on GE's side has been more than taken up with ICAD's direct efforts. But, given the disappointing start to the year, we think our prior implied q-to-q scaling to Detection in our model may have been too optimistic. We have since moderated our forecast – although do still think Detection product sales show a new(er) inflection point beginning in Q3.

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 will be used to support the 2.0 PMA filing) could also help facilitate adoption. In fact, management indicated that performance in the reader study was compelling – including a significant increase in sensitivity, specificity and meaningful reduction in reading time – and potentially strong enough to support a superiority (vs. reading w/o tool) claim. That could further significantly enhance the marketing message.

Feedback of 2.0 has already been encouraging – which includes that garnered from ICAD's attendance at ECR in late-Feb / early-March. Version 2.0 received CE Mark in February and was showcased not only by ICAD but also in GE's and Siemens' booths. Feedback, including that of some KOL's, was "incredibly positive". Management continues to guide for meaningful sales of 2.0 to begin in Q3 '18 – as system manufacturers (i.e. GE, Siemens, Hologic, etc) finalize interface work. Meanwhile, with the U.S. reader study completed, ICAD's FDA PMA filing for 2.0 could be imminent. If all goes perfectly, U.S launch might happen in late-2018 (although we think U.S. launch is much more likely a 2019 event).

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

Cancer Therapy (Q1): $2.3M (vs. $2.3M estimate): 0% yoy, -13% sequentially

Therapy product sales were $525k, inline with our $550k estimate. Therapy services/supplies revenue was $1.8M, inline with our $1.7M estimate. OUS IORT-related growth remains robust. Procedure growth OUS pushed IORT applicator sales up 31% yoy to a new record high. 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.

Given the size of the country and ever-increasing prosperity, China may represent a significant growth opportunity. 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. We look forward to hearing updates on China.

Meanwhile breast IORT in the U.S. may be experiencing incrementally greater uptake which could accelerate with the release and publication of more clinical data. ICAD's ExBRT (Safety and Efficacy Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft Axxent eBx System at the Time of Breast Conservation Surgery for Early-Stage Breast Cancer) study recently completed enrollment. So far 1,200 patients have been treated with a median follow-up of just over 19 months. Following analysis, ICAD will look to have the data published (possibly later in 2018). The study is being conducted at 20+ sites in the U.S. and Canada and is evaluating safety, efficacy, cosmetic outcomes and quality of life of patients for 10 years post-treatment.

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

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.

Model / Valuation

Model Updates

With shuttering of the subscription business, on the Therapy side we have revenue falling 8% 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 growing 9% (ex-MRI) in 2018, with a steeper inflection in Q3 as 2.0 is introduced in Europe. We show another upward inflection in Q4, with assumed 2.0 momentum in Europe as well as benefits from seasonal higher tides. We have 2.0 U.S. launch occurring in 2019, which represents much of the catalyst to our ~45% Detection revenue growth. 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 3.8x and P/S-2019 of 3.2x and average EV/S-2018 of 3.6x and EV/S-2019 of 3.0x.

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	Q2E	Q3E	Q4E	2018 E	2019 E	2020 E
Cancer Detection	$18,310.0	$4,011.0	$4,538.7	$5,175.6	$5,880.2	$19,605.5	$28,322.9	$37,096.5
YOY Growth	6.9%	-10.6%	7.3%	19.1%	12.1%	7.1%	44.5%	31.0%
% of total revenue	65.2%	63.5%	66.4%	70.7%	72.4%	68.6%	73.9%	76.6%
Therapy	$9,792.0	$2,302.0	$2,300.0	$2,147.0	$2,241.0	$8,990.0	$10,004.0	$11,362.0
YOY Growth	6.4%	0.0%	5.6%	-19.1%	-15.7%	-8.2%	11.3%	13.6%
% of total revenue	34.8%	36.5%	33.6%	29.3%	27.6%	31.4%	26.1%	23.4%
Total Revenues	$28,102.0	$6,313.0	$6,838.7	$7,322.6	$8,121.2	$28,595.5	$38,326.9	$48,458.5
YOY Growth	6.7%	-7.0%	6.7%	4.6%	2.8%	1.8%	34.0%	26.4%
Cost of Revenues	$9,926.0	$1,815.0	$1,876.1	$1,930.4	$2,060.2	$7,681.8	$9,679.4	$11,620.0
Gross Income	$18,176.0	$4,498.0	$4,962.6	$5,392.1	$6,061.0	$20,913.7	$28,647.6	$36,838.5
Gross Margin	64.7%	71.2%	72.6%	73.6%	74.6%	73.1%	74.7%	76.0%
R&D	$9,327.0	$3,339.0	$2,668.0	$2,584.2	$2,401.0	$10,992.2	$10,668.0	$10,874.0
% R&D	33.2%	52.9%	39.0%	35.3%	29.6%	38.4%	27.8%	22.4%
Selling & Mktg	$10,503.0	$2,166.0	$2,188.4	$2,211.4	$2,720.6	$9,286.4	$11,536.4	$13,568.4
% Sell&Mktg	37.4%	34.3%	32.0%	30.2%	33.5%	32.5%	30.1%	28.0%
G&A	$8,329.0	$2,141.0	$2,215.0	$2,178.0	$2,068.0	$8,602.0	$10,158.0	$11,845.0
% G&A	29.6%	33.9%	32.4%	29.7%	25.5%	30.1%	26.5%	24.4%
Operating Income	($16,676.0)	($3,148.0)	($2,108.8)	($1,581.5)	($1,128.6)	($7,966.9)	($3,714.8)	$551.2
Operating Margin	-59.3%	-49.9%	-30.8%	-21.6%	-13.9%	-27.9%	-9.7%	1.1%
Other income	$2,526.0	$22.0	$0.0	$0.0	$0.0	$22.0	$0.0	$0.0
Other income, net	$2,402.0	($120.0)	($113.0)	($113.0)	($113.0)	($459.0)	($466.0)	($370.0)
Pre-Tax Income	($14,274.0)	($3,268.0)	($2,221.8)	($1,694.5)	($1,241.6)	($8,425.9)	($4,180.8)	$181.2
Taxes	($18.0)	$13.0	$0.0	$0.0	$0.0	$13.0	$0.0	$0.0
Tax Rate	0.1%	-0.4%	0.0%	0.0%	0.0%	-0.2%	0.0%	0.0%
Net Income	($14,256.0)	($3,281.0)	($2,221.8)	($1,694.5)	($1,241.6)	($8,438.9)	($4,180.8)	$181.2
YOY Growth	-41.2%	-617.9%	15.6%	75.6%	70.7%	-40.8%	50.5%	104.3%
Net Margin	-50.7%	-52.0%	-32.5%	-23.1%	-15.3%	-29.5%	-10.9%	0.4%
EPS	($0.87)	($0.20)	($0.13)	($0.10)	($0.07)	($0.51)	($0.23)	$0.01
YOY Growth	-38.0%	-598.5%	17.0%	75.9%	71.1%	-41.9%	53.7%	104.2%
Pro-forma adjustments	$6,693.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pro-forma EPS	($0.62)	($0.20)	($0.13)	($0.10)	($0.07)	($0.51)	($0.23)	$0.01
Diluted Shares O/S	16,343	16,583	16,600	16,650	16,725	16,640	17,800	18,250

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APPENDIX

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

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

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

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

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

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

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

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

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

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

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

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

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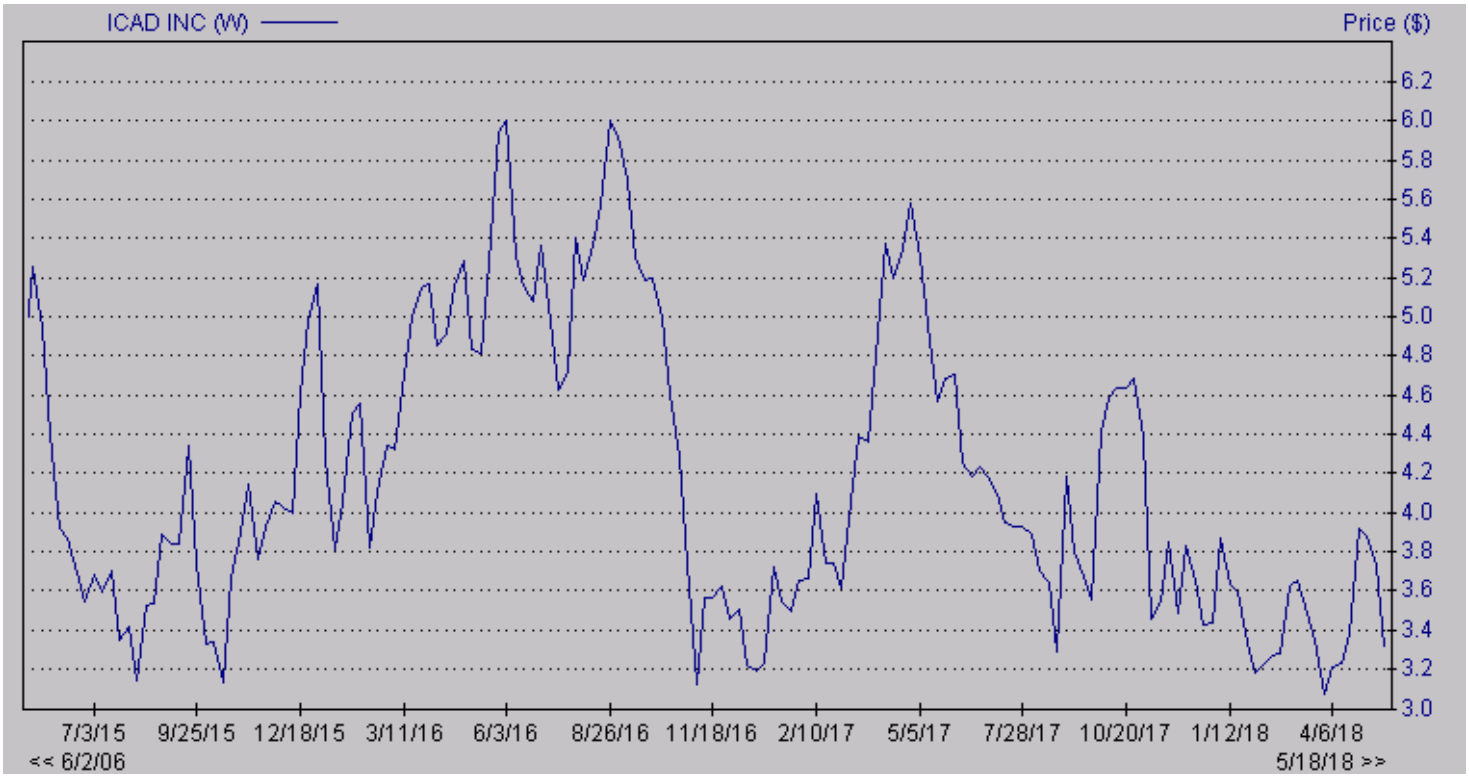
areas of China (where ICAD's Axxent system and balloon applicators recently received regulatory clearance) which have to travel long distances to access radiation therapy.

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

HISTORICAL STOCK CHART



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