Zacks Small-Cap Research

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iCAD Inc (ICAD-NASDAQ)

ICAD: U.S. 3D Tomo Launched, Should Be 2017 Revenue Catalyst

Based on the average of the EV/S multiples iCAD is valued at $7.40/share. Based on the average of the P/S multiples iCAD is valued at ~$7.50/share. We use the approximate average of the two which values iCAD at about $7.50/share.

Current Price (05/10/17)	$4.91
Valuation	**$7.50**

OUTLOOK

From a revenue standpoint, particularly as it relates to the Detection business, Q1 was a fairly solid quarter – and somewhat even more encouraging to that point is that 3D tomo just recently received FDA clearance and has yet to make a significant contribution. But, on the less than exciting side was that the Therapy business continues to struggle to gain any meaningful revenue traction despite procedural volumes continuing to rapidly grow. Both of these topics – that is, U.S. roll-out of 3D tomo as well as NMSC procedural volumes translating into growing Therapy revenue – remain potential significant 2H catalysts. We have made updates to our financial model following Q1 results. On the Therapy side, we have again made some small downward adjustments to our assumed near-term utilization-related revenue growth rate in NMSC. On the Detection side, our changes are slightly net-positive in terms of 2017 forecasted revenue. Specifically, while our Q2 number came in by about 5% - the difference is more than offset by the beat in Q1. And with 3D tomo launching in the U.S. several weeks ahead of our prior forecast, coupled with what sounds like potentially steepening sales in Europe for the product, we have upwardly adjusted our Q3 and Q4 Detection revenue estimates by an average of approximately 5%.

SUMMARY DATA

52-Week High	**$6.49**
52-Week Low	**$2.82**
One-Year Return (%)	**-5.47**
Beta	**1.13**
Average Daily Volume (sh)	**45,685**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$79**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**25**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**5.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Blend**
Industry	**Comp-Software**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	6038 A	7369 A	6003 A	6928 A	26338 A
2017	6791 A	6025 E	6992 E	7996 E	27804 E
2018					39381 E
2019					49705 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.16 A	-$0.10 A	-$0.17 A	-$0.20 A	-$0.63 A
2017	-$0.18 A	-$0.20 E	-$0.15 E	-$0.13 E	-$0.67 E
2018					-$0.28 E
2019					$0.05 E

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

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Q1 2017 Results: Strong Showing in Detection Offsets Ongoing Weakness in NMSC Revenue…

iCAD reported results for their first quarter ending March 31st. From a revenue standpoint, particularly as it relates to the Detection business, it was a fairly solid quarter – and somewhat even more encouraging to that point is that 3D tomo just recently received FDA clearance and has yet to make a significant contribution. But, on the less than exciting side was that the Therapy business continues to struggle to gain any meaningful revenue traction despite procedural volumes continuing to rapidly grow. Both of these topics – that is, U.S. roll-out of 3D tomo as well as NMSC procedural volumes translating into growing Therapy revenue – remain potential significant 2H catalysts.

Total Revenue: $6.8M (vs. $6.2M estimate) was up 13% yoy, down 2% sequentially

Relative to our estimates, Q1 Detection revenue was about 20% better which more than offset a 7% miss to our Therapy number – the net result was a 9% beat to our total revenue estimate. Detection was the clear highlight with revenue up 14% yoy – but excluding MRI revenues (i.e. related to sold assets) Detection revenue was up by an even more impressive 25%. Again, Detection has yet to fully benefit from 3D tomo in the U.S. – which we continue to think represents the next major growth catalyst for the company.

Cancer Detection (Q1): $4.5M (vs. $3.7M estimate): +14% (+25% organic) yoy, +8% sequentially

Strength in Detection was attributed to 3D tomo sales in Europe – management noted 7 or 8 systems were sold in Q1 – as well as from "several very large (2D) tenders." Management mentioned that Q1 set a new record in terms of international CAD orders. We note that since ordering patterns can be somewhat lumpy, we have not carried that level of revenue through to our Q2 number – but we also note that management indicated interest in 3D tomo in Europe continues to solidify and, as such, we think it is reasonable to expect that product will to continue to gain traction.

Relative to the U.S., indications were that PowerLook sales continue to remain robust. And while we had not expected 3D tomo launch to commence until Q2, ICAD noted that they booked initial domestic sales of the product in Q1 – just days after it received PMA approval in late March. ICAD indicated that they will be making an active marketing push behind 3D tomo and will be detailing to GE's installed base. Meanwhile GE's sales team will be marketing to new customers following the recent FDA approval of Pristina, their next-gen mammography platform.

So while Detection was relatively strong in Q1 and backed by reasonably decent fundamentals – namely what appears to be growing interest in and demand for 3D tomo in Europe – as well as initial contribution from the product in the U.S., we still do not model sequential revenue growth in this business until late this year. Our reasoning remains that we think it may take another few months for U.S. launch activities to accelerate. In addition, as noted, we think international legacy product sales may not necessarily remain consistent from Q1 levels.

Nonetheless, we continue to expect significant steepening of Detection product sales in 2H 2017 (ex-MRI CAD) on accelerating adoption of the 3D tomo product in the U.S. Breast density and tomosynthesis are the major growth areas in mammography and ICAD has been positioning their Detection product line to ride this burgeoning wave. The European and U.S. 3D tomo reader studies demonstrated a reduction in reader times of 24% and 29%, respectively. Additional analysis demonstrated savings in reader time of closer to 30%. Feedback from radiologists, including that they would not want to read another exam without ICAD's tomo product, has been encouraging.

Initial sale in Europe of the 3D breast tomosynthesis product came in Q2 2016 and it appears sales are accelerating with management noting on the Q1 call that 7 or 8 orders were booked in the quarter and they expect at least this many in Q2. We model additional traction in European tomo sales throughout 2017 and think Detection will see a significant acceleration once the products are in both the U.S. and Europe.

Another potential near-term catalyst in Detection is iReveal 3D. While ICAD had noted previously that they filed a 510(k) application for the product in November 2016, more recently management mentioned that additional development work needed to be completed in order to improve upon accuracy. The current timeline (per the Q1 call in May) is to have a 510(k) submitted by Q3 of this year – assuming that happens, we think the product could be contributing by early 2018. Given the success of iReveal 2D coupled with the ongoing industry shift towards 3D, we think this next-gen product could be a meaningful addition.

GE's Pristina should provide another opportunity for ICAD's Detection segment. As should ICAD s follow-on, next-gen tomo product which is already in the works. 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 is also being developed for use on all manufacturers machines which would massively increase the (low-hanging fruit) upgrade opportunity (ICAD s worldwide mammography installed base is ~5k units).

ICAD noted that their preliminary testing has shown much higher performance then they had anticipated. Competitive performance could be key relative to maximizing market share among the various manufacturers' installed bases – particularly given that Hologic (HOLX), a major player in the mammography and digital breast tomosynthesis space, will likely be competing in the 3D tomo CAD market as well.

ICAD mentioned on the Q1 call that they are still shooting to have development and testing completed and have their next-gen product launched in Europe by late 2017 and introduce it to the U.S. market by mid-2018. U.S. clearance, similar to the initial tomo product, will follow a PMA pathway and must be supported by a reader study. Given the swift industry shift from 2D to 3D and wider breadth of machines that this second-gen product has availability for and its enhanced features, introduction of this could result in another, and potentially much steeper, new wave of Detection segment growth. We model initial revenue contribution from this product in 1H 2018.

And while we had not been modeling much in the way of incremental contribution from VeraLook (CTC), we did see this product as having potential meaningful upside – which was largely dependent on the availability of Medicare reimbursement (the lack of which has been an impediment to uptake). The USPSTF's recommendation in June 2016 for CTC as an acceptable option for colorectal cancer screening had us hopeful that CMS would respond by updating their policy and begin reimbursing for the procedure. But, in a surprise move (Medicare typically follows USPSTF recommendations), in December 2016 CMS announced that they would not re-examine their non-coverage of CTC (which they base on inadequate evidence that CTC is appropriate for colorectal cancer screening). So while 33 states and the District of Columbia mandate that private insurers cover CTC, many (perhaps, most) people in the age group (50 – 75 years) most likely to benefit from the procedure rely on Medicare and therefore will not be covered (at least as of now). However, we expect there will be continued pressure from industry advocates of CTC, including the American College of Radiology, USPSTF, FDA and other organizations including private insurers, for CMS to again revisit their policy. As such, Medicare reimbursement may still materialize in the future.

Cancer Therapy (Q1): $2.3M (vs. $2.5M estimate): +9% yoy, -16% sequentially

While Therapy revenue was up 9% yoy and only 7% below our estimate in Q1, it continues to trend very flattish and remains disappointing, particularly given expectations that revenue from the NMSC business would have returned to growth. Clearly the optimism that the reimbursement issue hangover would dissipate and NMSC revenue would quickly rebound was wrong. Despite NMSC procedural volume, per management on the Q1 call, increasing by about 100% from Q3 2016 (~5k treatments) to Q1 2017 (~10k treatments), Therapy services and supplies revenue remained almost exactly flat over the same period ($1.85M Q3 '16 vs. $1.84M Q1 '17).

The disconnect between volume growth and lack of commensurate effect on revenue appears to be at least partially (perhaps mostly or even completely) related to the mix of treatments performed by capital purchase sites (i.e. those that own the system) versus subscription customers – the latter which are more profitable to ICAD but which remain a much smaller portion of total procedural volume.

Management indicated that while there has been a trend in capital customers not renewing source contracts, that at least some of this has been offset by some positive traction on the subscription side. In fact, they also noted that subscription-related procedural volume doubled from Q4 '16 to Q1 '17. While the capital-customer attrition continues to raise the question regarding a "sufficient" level of reimbursement - particularly given that these are customers that would have significant capital at risk – it's clearly a positive sign that procedural volume and the subscription business appears to be firming up. ICAD indicated that more existing subscription customers are coming back online and that their recently implemented sales efforts towards that end have been bearing fruit. In addition, the company has dedicated resources towards helping their customers bring in NMSC patients. So, assuming procedural volume and the subscription base continue to grow, we would expect to see a more obvious relationship between total procedural volume growth and related revenue within the next couple of quarters.

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. And in the meantime ICAD will pursue a CPT I code granting of which would all but eliminate ambiguity or significant differences in reimbursement policy and values. In November 2015 the company initiated a retrospective study of ~500 patients, results of which they hope to use to support an eventual CPT I code application. While the study will follow patients for five years, they will be able to include patients that completed treatment in 2013. Additional study data could be published in the near-term. The scope and breadth of the clinical portfolio will likely dictate timing of an eventual submission to CMS of a CPT I application.

But while NMSC related revenue has not been a highlight as of late, indications are that the IORT breast business has been at least stable. All of the $464k in capital system sales in Q1 related to IORT. ICAD noted that they added customers in both the U.S. and internationally during the quarter and also saw increases in procedural volume.

ICAD's success in building their IORT business has been to drive sales in the U.S. on the back of positive clinical data and to continue to expand internationally. They will continue that strategy, with data from ongoing studies expected to be available in the near term. ICAD s 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 recently completed enrollment. Following analysis, ICAD will look to have the data published. 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.

Other IORT-related growth initiatives include to continue to expand internationally by gaining regulatory approvals and establishing distribution in more countries throughout the globe. ICAD will also look to expand their applicator menu to be able to treat additional types of cancer.

Model Updates

We have made updates to our financial model following Q1 results. On the Therapy side, we have again made some small downward adjustments to our assumed near-term utilization-related revenue growth rate in NMSC.

On the Detection side, our changes are slightly net-positive in terms of 2017 forecasted revenue. Specifically, while our Q2 number came in by about 5% - the difference is more than offset by the beat in Q1. And with 3D tomo launching in the U.S. several weeks ahead of our prior forecast, coupled with what sounds like potentially steepening sales in Europe for the product, we have upwardly adjusted our Q3 and Q4 Detection revenue estimates by an average of approximately 5%.

We have Therapy revenue essentially flat from Q1 to Q2 but growing 11% for the full year in 2017, catalyzed by gains in both the number of active subscription sites and aggregate utilization in NMSC in the second half of the year as well as more moderate growth in IORT on both the product and services/supply side. Meanwhile, we have Detection revenue growing 3% (updated from our prior assumed 3% contraction) - as noted this is not adjusted for the MRI CAD revenue that will not repeat in 2017. And importantly, we show Detection exhibiting relatively very strong growth on both a yoy and sequential basis starting in Q4 ’17 – which, again, is largely attributable to expected substantive revenue from tomo in the U.S. and additional gains overseas.

ICAD was quick to cut costs following revelation of the NMSC reimbursement change. While they have recently added some sales personnel to help facilitate uptake and utilization in NMSC, we expect the company will be diligent on cost control.

Pro forma for the $2.5M gain on sale of MRI assets (in Q1), we model 2017 EPS of ($0.67).

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 2017 and 2018, we calculated P/S and EV/S ratios from imaging (HOLX) as well as surgical (VAR, ISR, EKTAF) companies. These companies currently trade at an average P/S-2017 of 3.6x and P/S-2018 of 3.3x and average EV/S-2017 of 3.6x and EV/S-2018 of 3.2x.

Based on the average of the EV/S multiples iCAD is valued at $7.40/share. Based on the average of the P/S multiples iCAD is valued at ~$7.50/share. We use the approximate average of the two which values iCAD at about $7.50/share.

FINANCIAL MODEL

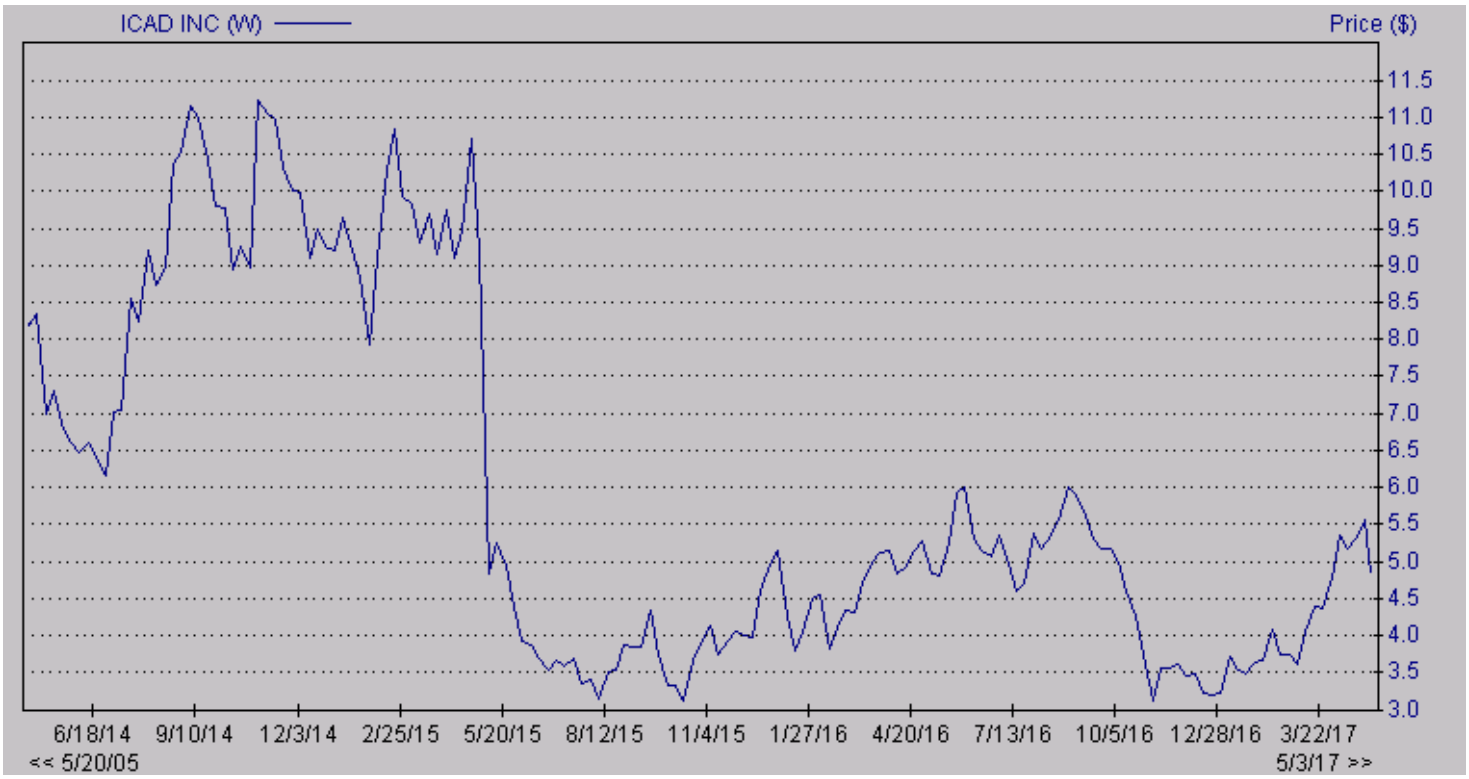
iCAD Inc.

	2016 A	Q1A	Q2E	Q3E	Q4E	2017 E	2018 E	2019 E
Cancer Detection	$17,133.0	$4,489.0	$3,666.6	$4,227.1	$5,245.8	$17,628.5	$26,890.9	$34,680.0
YOY Growth	*-11.0%*	*14.2%*	*-25.1%*	*2.3%*	*25.7%*	*2.9%*	*52.5%*	*29.0%*
% of total revenue	*65.1%*	*66.1%*	*60.9%*	*60.5%*	*65.6%*	*63.4%*	*68.3%*	*69.8%*
Therapy	$9,205.0	$2,302.0	$2,358.0	$2,765.0	$2,750.0	$10,175.0	$12,490.0	$15,025.0
YOY Growth	*-58.7%*	*9.2%*	*-4.6%*	*47.9%*	*-0.2%*	*10.5%*	*22.8%*	*20.3%*
% of total revenue	*34.9%*	*33.9%*	*39.1%*	*39.5%*	*34.4%*	*36.6%*	*31.7%*	*30.2%*
Total Revenues	$26,338.0	$6,791.0	$6,024.6	$6,992.1	$7,995.8	$27,803.5	$39,380.9	$49,705.0
YOY Growth	*-36.6%*	*12.5%*	*-18.2%*	*16.5%*	*15.4%*	*5.6%*	*41.6%*	*26.2%*
Cost of Revenues	$7,820.0	$2,102.0	$1,945.6	$2,143.6	$2,391.4	$8,582.6	$10,897.6	$13,457.2
Gross Income	$18,518.0	$4,689.0	$4,079.0	$4,848.6	$5,604.4	$19,220.9	$28,483.3	$36,247.8
Gross Margin	*70.3%*	*69.0%*	*67.7%*	*69.3%*	*70.1%*	*69.1%*	*72.3%*	*72.9%*
R&D	$9,518.0	$2,574.0	$2,411.0	$2,284.0	$2,414.0	$9,683.0	$9,575.0	$10,101.0
%R&D	*36.1%*	*37.9%*	*40.0%*	*32.7%*	*30.2%*	*34.8%*	*24.3%*	*20.3%*
Selling & Mktg	$10,179.0	$2,902.0	$2,717.1	$2,733.9	$3,070.4	$11,423.4	$12,916.9	$13,619.2
%Sell&Mktg	*38.6%*	*42.7%*	*45.1%*	*39.1%*	*38.4%*	*41.1%*	*32.8%*	*27.4%*
G&A	$8,791.0	$2,156.0	$2,265.0	$2,260.0	$2,351.0	$9,032.0	$10,864.0	$11,744.0
% G&A	*33.4%*	*31.7%*	*37.6%*	*32.3%*	*29.4%*	*32.5%*	*27.6%*	*23.6%*
Operating Income	($9,970.0)	($2,943.0)	($3,314.1)	($2,429.4)	($2,231.0)	($10,917.5)	($4,872.6)	$783.6
Operating Margin	*-37.9%*	*-43.3%*	*-55.0%*	*-34.7%*	*-27.9%*	*-39.3%*	*-12.4%*	*1.6%*
Other income	$9.0	$2,508.0	$0.0	$0.0	$0.0	$2,508.0	$0.0	$0.0
Interest income, net	($62.0)	($5.0)	($2.0)	($2.0)	($8.0)	($17.0)	$16.2	$44.0
Pre-Tax Income	($10,023.0)	($440.0)	($3,316.1)	($2,431.4)	($2,239.0)	($8,426.5)	($4,856.4)	$827.6
Taxes	$76.0	$17.0	$26.5	$19.5	$17.9	$80.9	$0.0	$0.0
Tax Rate	*-0.8%*	*-3.9%*	*-0.8%*	*-0.8%*	*-0.8%*	*-1.0%*	*0.0%*	*0.0%*
Net Income	($10,099.0)	($457.0)	($3,342.6)	($2,450.8)	($2,256.9)	($8,507.4)	($4,856.4)	$827.6
YOY Growth	*69.0%*	*82.0%*	*-112.2%*	*8.4%*	*31.9%*	*15.8%*	*42.9%*	*117.0%*
Net Margin	*-38.3%*	*-6.7%*	*-55.5%*	*-35.1%*	*-28.2%*	*-30.6%*	*-12.3%*	*1.7%*
EPS	($0.63)	($0.03)	($0.20)	($0.15)	($0.13)	($0.52)	($0.28)	$0.05
YOY Growth	*69.5%*	*82.3%*	*-105.8%*	*11.9%*	*34.3%*	*18.4%*	*46.2%*	*116.8%*
Pro-forma adjustments	$0.0	($2,508.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pro-forma EPS	($0.63)	($0.18)	($0.20)	($0.15)	($0.13)	($0.67)	($0.28)	$0.05
Diluted Shares O/S	15,975	16,135	16,400	16,600	16,800	16,484	17,500	17,800

Brian Marckx, CFA

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