Zacks Small-Cap Research

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iCAD Inc (ICAD-NASDAQ)

ICAD: Solid Revenue Rebound, Skin Biz Showing Signs of Life

Based on the average of comp EV/S multiples iCAD is valued at $7.25/share. Based on the average of the P/S multiples iCAD is valued at ~$6.80/share. We use the approximate average of the two which values iCAD at about $7/share.

Current Price (07/28/16)	$5.50
Valuation	**$7.00**

OUTLOOK

Therapy, which had been the major catalyst driving revenue, has contracted with disappointing reimbursement policy change. More recently ICAD noted that they believe that there is now enough evidence of positive and sufficient reimbursement for NMSC to entice a large portion of their existing customer base to restart using Axxent for this indication and to onboard new customers. Mgmt guiding for rapid re-onboarding of skin customers through YE2016 Meanwhile breast IORT remains a bright spot.

Detection remains poised to enter what we believe will be a cycle of long-term growth on the initial tomosynthesis launch. PowerLook upgrades and ICAD's breast density software which continue to perform well should remain solid contributors. 3D iReveal could launch soon and will provide another impetus to growth. These, the tomo launch, a next-gen tomo product and the overall move towards leveraging growth of 3D imaging space should bode well for sustained strength in Detection revenue growth for many years.

SUMMARY DATA

52-Week High	**$6.23**
52-Week Low	**$2.95**
One-Year Return (%)	**38.94**
Beta	**1.99**
Average Daily Volume (sh)	**37,657**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$75**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**26**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**13.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Average,**
Type of Stock	**Small-Blend**
Industry	**Comp-Software**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	13220 A	11143 A	9582 A	7609 A	41554 A
2016	6038 A	7369 A	7573 E	8668 E	29648 E
2017					38967 E
2018					48779 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.12 A	-$1.78 A	-$0.03 A	-$0.15 A	-$2.07 A
2016	-$0.16 A	-$0.10 A	-$0.14 E	-$0.09 E	-$0.49 E
2017					-$0.12 E
2018					$0.07 E

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

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Q2 2016 Results: Solid Rebound in Revenue From Strength in Detection Products, Skin Therapy Showing Signs of Life…

iCAD announced financial results for the second quarter ending June 30. Results were decent and highlighted by revenue coming in well ahead of the relative disaster in Q1, big gross margin and reasonable cost containment. Revenue was up 22% from Q1 and ahead of our number by almost 5% - while obviously good news, the mix (Therapy vs. Detection) differed fairly significantly from what we were expecting and, with Therapy service and supplies revenue essentially flat, suggested little revenue traction in the skin business.

But, based on management's comments on the call, including that they have doubled the number of skin sites that have come back onboard between Q1 and the end of Q2 (from 17 to 35) and that they believe they will have up to 100 sites under agreement by year-end, we expect traction in this business to begin to show a more consistent ramp (there's a typical 2 - 3 month lag for a site to be fully operational). Management attributes the recent and expected continued acceleration in bringing skin sites back onboard to practitioners' increased comfort level with the reimbursement picture - which presumably includes a few months of evidence of payers reimbursing under the CPT III code and at levels that are economically viable.

Management estimates each skin site, on average, should generate $100k in annual recurring revenue. If re-onboarding along with some new customer wins can indeed build the client base to as many as 100 sites by year-end, the annual run-rate at the beginning of 2017 would be ~$10M. Assuming continued growth in the total number of sites under agreement and adding in system sales and expected continued strong growth in IORT, and the Therapy business could be back to being a very meaningful revenue driver.

But while we continue to think Therapy begins to make a more significant contribution in Q4 of this year, we are hesitant to jump back in with both feet given the potential for ongoing lack of clarity on the robustness of eBx skin reimbursement. We would view growth in the new skin customer base (as opposed to just legacy customers coming back online) - whether it be solutions or capital purchase customers - as a particularly favorable trend given the presumed due diligence relative to reimbursement that new customers would perform prior to entering the market. Certainly growth in Axxent system sales (i.e. customer putting significant capital at risk) related to skin would be a particularly positive sign and one which we think could likely be interpreted as providers being confident that the reliability and level of reimbursement is acceptable.

Part of our expected rebound in Therapy relates to growth in the skin business. The other catalyst in Therapy is IORT - which, unlike skin, has recently surprised us on the upside, particularly in the U.S. While international IORT has shown solid growth in both system sales and utilization, the U.S. until recently was somewhat of a laggard. That may have turned the corner, however, as ICAD has recently experienced strong double-digit balloon applicator sales in both the U.S. and internationally. In addition, three of the four Axxent system sales in Q2 were for IORT. 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 and their impending entry into new overseas territories including China, Saudi Arabia, India and Egypt.

Relative to the Detection business, Q2 product revenue surprised on the upside - beating our number by about $900k ($2.5M E vs. $3.4M A). Approximately $250k of this relates to more Axxent (IORT) system sales then we had expected in the quarter. The other ~$650k relates the mammography business - the beat could be either favorable timing or just fundamentally greater demand then we had anticipated. While we note that mammography, including PowerLook upgrades and iReveal, has performed very well as of late and Q2 included the first sale of the breast tomo product in Europe, we are modeling roughly flat sequential growth of Detection product sales throughout the remainder of the year. This could prove conservative, particularly if the pace of the ongoing roll-out of 3D tomo in Europe exceeds our expectations or if tomo makes an initial contribution in the U.S. this year (as management expects). Nonetheless, we continue to expect significant steepening of Detection product sales in 2017 on the back of the initial 3D tomo product in the U.S. (we are more conservatively modeling initial U.S. sales in early 2017) and expected initial contribution from the next-gen tomo product. Other near-term catalysts in Detection include iReveal 3D, expected to launch later this year, and potentially VeraLook (CTC) which could see increasing demand as a result of inclusion of virtual colonoscopy on USPSTF's recent recommendations for colon cancer screening. This should immediately and significantly improve availability of reimbursement for CTC, the prior widespread lack of (CTC reimbursement had previously been mandated in only 22 states) which was an impediment to uptake of the procedure.

Revenue
Q2 revenue of $7.4M (vs. $7.0M estimate) was down 34% yoy and up 22% sequentially

- **Cancer Detection(Q2):** $4.9M (vs. $4.4M estimate): -1% yoy, +24% sequentially
  - MRI products have been a big driver of Cancer detection over the recent past. However, with Invivo having exercised their right (in return for a $2M payment) to distribute the current version of the respective MRI product, these related revenues dissipated. This has been a major contributor to the 17% and 9% sequential decline in Detection revenue in Q4 2015 and Q1 2016, respectively.

    In July 2015 ICAD announced the launch of iReveal breast density software, the latest addition to the PowerLook line. The timing was good as at the time almost one-half of all states already enacted some form of legislation supporting breast density screening. Today that number is 28 states and more are likely to follow. Management indicated that there has already been significant interest in iReveal. If and when mandated and widespread insurance coverage follows, breast density screening would almost certainly be fueled even further. ICAD is also developing iReveal 3D - expected to be available later this year and able to integrate with the 3D tomo products, it provides another growth opportunity.

    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. Initial sale in Europe of the 3D breast tomosynthesis product came in Q2. We look for the second half of the year for this to be more meaningful. We think Detection will see a significant acceleration, particularly once the products are in both the U.S. and Europe – which should happen by early 2017 – perhaps slightly earlier, depending on timing of the U.S. launch.

    The European and U.S. reader studies demonstrated a reduction in reader times of 24% and 29%, respectively. Feedback from radiologists, including that they would not want to read another exam with ICAD's tomo product, has been encouraging. ICAD filed the final PMA module for U.S. clearance in early April. If all goes well ICAD could have FDA clearance and launch in Q3 – inline with management's prior expectations. We continue to take a more conservative timeline for the U.S. market, incorporating initial contribution happening in early 2017.

    We think tomo could be a big winner for ICAD given the criticism and debate over the utility of stand-alone mammography and increased demand for more accurate detection of breast cancer. Upgrades from 2D to 3D, the new breast density software and the roll-out of tomo in Europe and the U.S. have the potential to provide inflection in the Detection segment. While we don't expect much in the way of contribution until late 2016, GE's current installed base of ~600 units already represents an enormous opportunity for ICAD.

    Follow-on, next-gen tomo products already in the works. This product is not only expected to reduce reading time but to also 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 having a potentially significant benefit in lowering related costs. It will also being developed for use on all manufacturers' machines. ICAD is currently shooting to have development and testing completed and have the product launched in Europe as soon as late 2016 and in the U.S. in mid-2017. Given the wider breadth of machines that this second-gen product has availability for and the enhanced features, introduction of this could result in another new wave of Detection segment growth.

    While look for Detection to turn in roughly flat growth in 2016 but for this to steepen to ~32% growth in 2017 when we think there will be a full-years' worth of contribution from tomo in both Europe and the U.S. Upside to our estimates could come from a more rapid roll-out of tomo in Europe, early introduction than what we expect in the U.S. and/or meaningful uptick in demand for VeraLook as a result of the favorable USPSTF recommendation.

- **Cancer Therapy (Q2):** $2.5M (vs. $2.7M estimate): -60% yoy, +17% sequentially

  The non-melanoma skin cancer reimbursement issue looked to have taken its biggest toll in Q1 of this year since it first began to impact Therapy revenue back in Q2 2015. Management noted on the Q1 call that

they believed that there was enough evidence of positive and sufficient reimbursement for NMSC to entice a large portion of their existing customer base to restart using Axxent for this indication and to onboard new customers.

While there was little evidence of financial progress related to skin in the Q2 numbers, management indicated on the call that the groundwork has already started including making progress in restarting skin sites and attracting new customers. And with a typical 2 - 3 month lag between when a site goes live and when it shows up in ICAD's revenue, expectations are that the recent growth in the customer base should show up in the income statement later this year. Clearly the fact that they have doubled the number of skin sites that have come back onboard between Q1 and the end of Q2 (from 17 to 35) is an encouraging sign that skin's worst days may be in the rearview mirror.

ICAD thinks the onboarding pace will accelerate and believes that they will have up to 100 sites under agreement by year-end. Management attributes the recent and expected continued acceleration in bringing skin sites back onboard to practitioners' increased comfort level with the reimbursement picture - which presumably includes a few months of evidence of payers reimbursing under the CPT III code and at levels that are economically viable.

Management estimates each skin site, on average, should generate $100k in annual recurring revenue. If re-onboarding along with some new customer wins can indeed build the client base to as many as 100 sites by year-end annual run-rate at the beginning of 2017 would be ~$10M. Assuming continued growth in the total number of sites under agreement and adding in system sales and expected continued strong growth in IORT, and the Therapy business could be back to being a very meaningful revenue driver.

But while we continue to think Therapy begins to make a more significant contribution in Q4 of this year, we are hesitant to jump back in with both feet given the potential for ongoing lack of clarity on the robustness of eBx skin reimbursement. We would view growth in the new skin customer base (as opposed to just legacy customers coming back online) - whether it be solutions or capital purchase customers - as a particularly favorable trend given the presumed due diligence relative to reimbursement that new customers would perform prior to entering the market. Certainly growth in Axxent system sales (i.e. customer putting significant capital at risk) related to skin would be a particularly positive sign and one which we think could likely be interpreted as providers being confident that the reliability and level of reimbursement is acceptable.

And another potential catalyst which could help restart activity at existing sites and to score new accounts is ICAD’s new SMART (Streamlined Module for Advanced Radiation Therapy) solution and extended x-ray source – both of which are aimed at increasing efficiency and reducing cost of using the Axxent system. ICAD believes this could improve efficiency (i.e. reduce cost) by as much as 40% - which we think could be enticement given the recent downward pressure on margins from the NMSC reimbursement problem. ICAD noted on the Q2 call that the SMART solution is indeed providing efficiencies and margin growth.

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 and, therefore, believe that they may have sufficient 3-year supporting data by the end of 2016 and potentially be able to file for a CPT I code sometime in 2017.

Part of our expected rebound in Therapy relates to growth in the skin business. The other catalyst in Therapy is IORT - which, unlike skin, has recently surprised us on the upside, particularly in the U.S. While international IORT has shown solid growth in both system sales and utilization, the U.S. until recently was somewhat of a laggard. That may have turned the corner, however, as ICAD has recently experienced strong double-digit balloon applicator sales in both the U.S. and internationally. Balloon applicator sales were up 34% in 1H 2016 which included 30% growth in the U.S. and 42% internationally.

In addition, three of the four Axxent system sales in Q2 were for IORT. 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 expects their 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 to complete enrollment shortly. The study has enrolled at 20+ sites in the U.S. and Canada and will evaluate safety, efficacy, cosmetic outcomes and quality of life of patients for 10 years post-treatment. The company expects the present initial data from the study at ASTRO later this year. Meanwhile, international IORT growth will come from increasing utilization at existing sites as well as impending entry into new overseas territories including China, Saudi Arabia, India and Egypt.

Model Updates

We have made only minor updates to our financial model following Q2 results. We have Therapy revenue falling by 52% in 2016 (revised from a 50% contraction) as gains in IORT breast are more than offset by weakness (albeit dissipating weakness) in NMSC – this could prove conservative, however, and will depend on the pace of re-onboarding legacy customers and scoring new ones. This, in turn, will likely hinge on the robustness of the reimbursement picture. Expect to have more clarity in the coming months as the dynamics play out and there's some more history with onboarding of accounts.

We have total revenue of $29.7M in 2016 – implying a decrease of 29% from 2015 – but the majority of the contraction we have modeled in 1H, with the second half showing a contraction of just 6% and Q4 growing 14%. We think this momentum carries into and picks up in 2017.

ICAD was quick to cut costs following revelation of the NMSC reimbursement change. We have about $7.6M/qtr average in the remaining two quarters of the year. ICAD used $1M in cash for operations in Q2 and exited the quarter with $11.5M in cash. The are guiding for ending the year with between $11M and $13M (revised from $10M to $13M), depending on how the NMSC business plays out.

We model 2016 EPS of ($0.48).

VALUATION

We continue to value iCAD based on competitor price/sales (P/S) and enterprise value /sales (EV/S) multiples. Using analyst's revenue estimates for the years 2016 and 2017, we calculated P/S and EV/S ratios from imaging (HOLX) as well as surgical (VAR, ARAY, ISR, EKTAF) companies. The five companies currently trade at an average P/S-2016 of 3.2x and P/S-2017 of 3.1x and average EV/S-2016 of 3.1x and EV/S-2017 of 3.0x.

Based on the average of the EV/S multiples iCAD is valued at $7.25/share. Based on the average of the P/S multiples iCAD is valued at ~$6.80/share. We use the approximate average of the two which values iCAD at about $7/share.

FINANCIAL MODEL

iCAD Inc.

	2015 A	Q1A	Q2A	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Cancer Detection	$19,243.0	$3,930.0	$4,897.0	$4,947.7	$5,263.4	$19,038.1	$25,049.3	$32,175.4	$37,120.4
YOY Growth	*3.4%*	*-17.9%*	*-1.2%*	*-4.9%*	*22.5%*	*-1.1%*	*31.6%*	*28.4%*	*15.4%*
% of total revenue	*46.3%*	*65.1%*	*66.5%*	*65.3%*	*60.7%*	*64.2%*	*64.3%*	*66.0%*	*65.8%*
Therapy	$22,311.0	$2,108.0	$2,472.0	$2,625.0	$3,405.0	$10,610.0	$13,918.0	$16,604.0	$19,256.0
YOY Growth	*-11.9%*	*-75.0%*	*-60.1%*	*-40.1%*	*2.8%*	*-52.4%*	*31.2%*	*19.3%*	*16.0%*
% of total revenue	*53.7%*	*34.9%*	*33.5%*	*34.7%*	*39.3%*	*35.8%*	*35.7%*	*34.0%*	*34.2%*
Total Revenues	$41,554.0	$6,038.0	$7,369.0	$7,572.7	$8,668.4	$29,648.1	$38,967.3	$48,779.4	$56,376.4
YOY Growth	*-5.4%*	*-54.3%*	*-33.9%*	*-21.0%*	*13.9%*	*-28.7%*	*31.4%*	*25.2%*	*15.6%*
Cost of Revenues	$12,204.0	$1,852.0	$1,667.0	$2,125.2	$2,473.3	$8,117.4	$10,547.4	$12,831.0	$14,587.9
Gross Income	$29,350.0	$4,186.0	$5,702.0	$5,447.5	$6,195.1	$21,530.7	$28,419.9	$35,948.4	$41,788.5
Gross Margin	*70.6%*	*69.3%*	*77.4%*	*71.9%*	*71.5%*	*72.6%*	*72.9%*	*73.7%*	*74.1%*
R&D	$9,163.0	$2,271.0	$2,204.0	$2,415.0	$2,360.0	$9,250.0	$9,288.0	$9,575.0	$10,101.0
% R&D	*22.1%*	*37.6%*	*29.9%*	*31.9%*	*27.2%*	*31.2%*	*23.8%*	*19.6%*	*17.9%*
Selling & Mktg	$12,404.0	$2,496.0	$2,561.0	$2,688.3	$2,730.5	$10,475.9	$10,949.8	$13,219.2	$14,939.7
% Sell&Mktg	*29.9%*	*41.3%*	*34.8%*	*35.5%*	*31.5%*	*28.9%*	*28.1%*	*27.1%*	*26.5%*
G&A	$10,519.0	$1,912.0	$2,470.0	$2,555.0	$2,488.0	$9,425.0	$10,210.0	$12,004.0	$12,889.0
% G&A	*25.3%*	*31.7%*	*33.5%*	*33.7%*	*28.7%*	*31.8%*	*26.2%*	*24.6%*	*22.9%*
Operating Income	($30,179.0)	($2,493.0)	($1,533.0)	($2,210.8)	($1,383.4)	($7,620.2)	($2,027.9)	$1,150.2	$3,858.7
Operating Margin	*-72.6%*	*-41.3%*	*-20.8%*	*-29.2%*	*-16.0%*	*-25.7%*	*-5.2%*	*2.4%*	*6.8%*
Other income	($1,706.0)	$4.0	$2.0	$1.0	$1.0	$8.0	$125.0	$0.0	$0.0
Interest income, net	($646.0)	($22.0)	($21.0)	($30.0)	($50.0)	($123.0)	($100.0)	$58.0	$121.0
Pre-Tax Income	($32,531.0)	($2,511.0)	($1,552.0)	($2,239.8)	($1,432.4)	($7,735.2)	($2,002.9)	$1,208.2	$3,979.7
Taxes	$16.0	$22.0	$23.0	$22.4	$14.3	$81.7	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*-0.9%*	*-1.5%*	*-1.0%*	*-1.0%*	*0.1%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($32,547.0)	($2,533.0)	($1,575.0)	($2,262.2)	($1,446.7)	($7,816.9)	($2,002.9)	$1,208.2	$3,979.7
YOY Growth	*-3125.7%*	*-36.4%*	*94.4%*	*-462.7%*	*39.8%*	*76.0%*	*74.4%*	*160.3%*	*-229.4%*
Net Margin	*-78.3%*	*-42.0%*	*-21.4%*	*-29.9%*	*-16.7%*	*-26.4%*	*-5.1%*	*2.5%*	*7.1%*
EPS	($2.07)	($0.16)	($0.10)	($0.14)	($0.09)	($0.49)	($0.12)	$0.07	$0.23
YOY Growth	*-2850.6%*	*-34.5%*	*94.4%*	*-449.6%*	*41.7%*	*76.5%*	*75.6%*	*158.9%*	*-223.7%*
Pro-forma adjustments	$27,443.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pro-forma EPS	($0.33)	($0.16)	($0.10)	($0.14)	($0.09)	($0.49)	($0.12)	$0.07	$0.23
Diluted Shares O/S	15,686	15,826	15,904	16,100	16,250	16,020	16,800	17,200	17,500

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