Zacks Small-Cap Research

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iCAD Inc (ICAD-NASDAQ)

ICAD: Certain Catalysts To Return ICAD To Positive Growth in 2017

Based on the average of the EV/S multiples iCAD is valued at $7.70/share. Based on the average of the P/S multiples iCAD is valued at ~$6.5/share. We use the approximate average of the two which values iCAD at about $7.00/share.

Current Price (02/07/17)	$3.66
Valuation	**$7.00**

OUTLOOK

2016 has been a disappointing year in terms of revenue. Therapy revenue through the first nine months of the year is down 66%, largely as a result of the unfavorable change to reimbursement of non-melanoma skin cancer. Detection revenue has fared much better, but is still down over 13% over the same period and has been hampered by the loss of ICAD's MRI distribution agreement (as of August 2015). And delays to FDA clearance and U.S. launch of the 3D tomosynthesis product have also trimmed Detection revenue expectations for 2016.

While we model full-year 2016 revenue to show a 37% decline from the previous year, reflecting 11% and 61% contractions in Detection and Therapy revenue, respectively, we think both segments return to double-digit positive sales growth in 2017.

SUMMARY DATA

52-Week High	**$6.49**
52-Week Low	**$2.82**
One-Year Return (%)	**-15.12**
Beta	**1.13**
Average Daily Volume (sh)	**35,816**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$59**
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 (%)	**7.9**
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	**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	6003 A	6600 E	26010 E
2017					32934 E
2018					42336 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	-$0.17 A	-$0.17 E	-$0.60 E
2017					-$0.33 E
2018					$0.07 E

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

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Certain Catalysts Expected to Return ICAD to Positive Revenue Growth in 2017

2016 has been a disappointing year in terms of revenue. Therapy revenue through the first nine months of the year is down 66%, largely as a result of the unfavorable change to reimbursement of non-melanoma skin cancer. Detection revenue has fared much better, but is still down over 13% over the same period and has been hampered by the loss of ICAD's MRI distribution agreement (as of August 2015). And delays to FDA clearance and U.S. launch of the 3D tomosynthesis product have also trimmed Detection revenue expectations for 2016.

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Detection:

- **3D Tomosynthesis;** 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. Radiologists are regularly demanding system upgrades from 2D to 3D due to the latter's proven ability to improve cancer detection rates, reduce recall rates, shorten reading time and lessen reading fatigue. This has resulted in a swift transition to 3D tomosynthesis. Armed with clinical studies demonstrating the benefits of 3D tomo, ICAD is looking to capitalize on this industry shift.

  ICAD's 3D tomo product launched in Europe in 1H 2016. In April ICAD filed the final PMA module. FDA clearance has dragged out longer than management had initially anticipated. On the Q3 call (early November) ICAD noted that FDA responded to their application with additional questions. Management noted that the questions do not relate to performance demonstrated in the reader study but instead a specific portion of the study protocol. ICAD provided a detailed description of the "issue" on the Q3 call and we feel comfortable that this is not a performance issue or even necessarily a violation of trial design or protocol. ICAD and FDA were to meet in ~mid-November to further discuss this, and in which the company expected to provide a response to the agency's questions. While ICAD has not provided a detailed update since the Q3 call, they did mention in an early-December presentation that they were still hoping to have FDA clearance in Q1 2017. We have previously, and continue to, model a (more conservative timeline) launch in Q2.

  ICAD's initial 3D tomo product was designed specifically for GE's 3D breast tomosynthesis machines, which has a current installed base of approximately 600 units (300 U.S., 300 OUS). ICAD has received several orders in Europe and GE's machines likely represent ICAD's initial (2017) U.S. target market. Just how substantive U.S.-related revenue of 3D tomo will be in 2017 is largely dependent on ultimate timing of (if and) when ICAD receives FDA clearance.

  GE's stand-alone 3D imager, SenoClair, received FDA clearance in August 2014 but as they look to capitalize on the demand for 3D tomosynthesis, GE is already on the cusp of rolling out a next-gen mammography platform, called Senographe Pristina. Pristina, which performs both 2D and 3D mammography, received FDA clearance in November 2016 and is awaiting FDA clearance for digital breast tomosynthesis.

  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 to 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 having a potentially significant benefit in lowering 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 has been shooting to have development and testing completed and have the product launched in Europe as soon as early/mid 2017. U.S. launch could possibly happen by late-2017 (expect to hear an update on the Q4 call). 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 heading into 2018.

- **iReveal Breast Density:** Along with 3D tomosynthesis, ICAD's iReveal breast density software represents the major growth drivers of the company's PowerLook line. Meaningful adoption and demand for iReveal, which launched in July 2015, has helped stem even greater revenue attrition of the Detection segment. The benefits of improved detection of dense breast tissue has become more widely accepted and today 28 states have enacted some form of legislation supporting breast density screening. More states are expected to follow.

For 2017 we think iReveal-related revenue will benefit from growth in industry demand for breast density screening. ICAD is also developing iReveal 3D which allows for seamless integration with their 3D tomo software – this expected to be available in the near-term and should provide an attractive package offering. Legislation and coverage policies aimed at increasing availability and access to breast density screening could also have a positive impact, particularly over the longer-term.

- **2D Upgrades:** for those installations which choose to not immediately move to 3D imaging, ICAD will be able to offer a new 2D upgrade. While we expect 3D tomo (and to a lesser extent, iReveal) to be the main driver of the PowerLook product line, ICAD's ability to maintain 2D customers with upgraded features and functionality should offer some opportunity for incremental revenue.

- **CT Colonography:** while we had not modeled much in the way of incremental contribution from VeraLook, ICAD's CT colonography software, we did see this product as having some 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 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.

- **MRI assets sale:** per an 8-K filed 12/22/16 ICAD agreed to sell their VersaVue Software and DynaCAD product to Invivo for $3.2M (includes $350k hold-back). The deal closed on 1/31/17. Invivo was ICAD's distribution partner for these MRI products until they exercised their right to a fully paid-up license in August 2015. Since then, the only revenue that ICAD has been recognizing related to these products is amortization of the $2M paid-up license fee (which ends July 2017). The sale further bolsters the company's cash position (Q3 cash balance was $10.5M) and should have no meaningful adverse impact on cash revenue.

Therapy:

- **NMSC:** since it first began to impact Therapy revenue back in Q2 2015, the non-melanoma skin cancer reimbursement issue looked to have taken its biggest toll in Q1 2016. 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 and Q3 2016 numbers, management indicated that the groundwork 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 soon begin to be more obvious in the income statement. Clearly the fact that they almost tripled the number of skin sites that came back onboard between Q1 and the end of Q3 (from 17 to ~50) is an encouraging sign that skin's worst days may be in the rearview mirror.

  ICAD noted that they believe the onboarding pace will accelerate and that they were shooting for having up to 70 sites under agreement by year-end – hopefully we will hear an update on the Q4 call. Management attributed the recent and expected continued acceleration in bringing skin sites back onboard to practitioners' increased comfort level with the reimbursement picture - which presumably includes several 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 70 sites by year-end, the annual run-rate in the first half of 2017 would be ~$7M. Assuming continued growth in the total number of sites under agreement and adding in system sales and growth in IORT, and the Therapy business could be back to being a very meaningful revenue driver.

  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 has noted that they believe 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 2016 call that the SMART solution was 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 in the near-term. If all goes well, the data might be published this year and a submission to CMS for support of a CPT I code may be possible before year-end. And while eventual granting of a CPT I code would not be a near-term event, a successful submission could provide additional confidence to clinicians of eventual dedicated reimbursement.

- **IORT:** The other catalyst in Therapy is IORT. IORT has been, at least as of late, much more stable than that of skin. International sales continue to be the main impetus to IORT consumables growth although the U.S. remains the most significant market in terms of total sales. And while U.S. balloon volumes in Q3 2016 (202 units) were also down from the 283 in Q1 and 425 in Q2, we continue to believe that clinical evidence supporting the use of the procedure should help to buoy the opportunity for domestic market growth. Meanwhile, we also expect international growth to continue – which should be further catalyzed by ICAD's impending entry into new overseas territories including China, Saudi Arabia, India and Egypt.

  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 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.

  ICAD will also look to drive uptake of Axxent for IORT as a boost to whole breast radiation (WBRT) – which is a relatively new application for the technology and which would considerably expand its target market (we estimate by as much as 60%). Results to-date (two years of a ten year study) of a clinical study showed that in a subset of breast cancer patients (n=44) undergoing lumpectomy which received IORT as a boost prior to WBRT had low morbidity, excellent-to-good cosmetic results and mostly low-grade adverse events. In addition the treatment was safe. The results were presented at the San Antonio Breast Cancer Symposium in December.

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 3.0x and P/S-2018 of 2.7x and average EV/S-2017 of 3.0x and EV/S-2018 of 2.8x.

Based on the average of the EV/S multiples iCAD is valued at $7.70/share. Based on the average of the P/S multiples iCAD is valued at ~$6.5/share. We use the approximate average of the two which values iCAD at about $7.00/share.

FINANCIAL MODEL

iCAD Inc.

	2015 A	Q1A	Q2A	Q3A	Q4E	2016 E	2017 E	2018 E	2019 E
Cancer Detection	$19,243.0	$3,930.0	$4,897.0	$4,134.0	$4,250.0	$17,211.0	$21,306.7	$28,163.3	$32,164.7
YOY Growth	*3.4%*	*-17.9%*	*-1.2%*	*-20.5%*	*-1.1%*	*-10.6%*	*23.8%*	*32.2%*	*14.2%*
% of total revenue	*46.3%*	*65.1%*	*66.5%*	*68.9%*	*64.4%*	*66.2%*	*64.7%*	*66.5%*	*63.2%*
Therapy	$22,311.0	$2,108.0	$2,472.0	$1,869.0	$2,350.0	$8,799.0	$11,627.0	$14,173.0	$18,715.0
YOY Growth	*-11.9%*	*-75.0%*	*-60.1%*	*-57.3%*	*-29.0%*	*-60.6%*	*32.1%*	*21.9%*	*32.0%*
% of total revenue	*53.7%*	*34.9%*	*33.5%*	*31.1%*	*35.6%*	*33.8%*	*35.3%*	*33.5%*	*36.8%*
Total Revenues	$41,554.0	$6,038.0	$7,369.0	$6,003.0	$6,600.0	$26,010.0	$32,933.7	$42,336.3	$50,879.7
YOY Growth	*-5.4%*	*-54.3%*	*-33.9%*	*-37.4%*	*-13.3%*	*-37.4%*	*26.6%*	*28.6%*	*20.2%*
Cost of Revenues	$12,204.0	$1,852.0	$1,667.0	$1,902.0	$2,064.8	$7,485.8	$8,980.4	$11,017.6	$13,026.2
Gross Income	$29,350.0	$4,186.0	$5,702.0	$4,101.0	$4,535.3	$18,524.3	$23,953.3	$31,318.7	$37,853.5
Gross Margin	*70.6%*	*69.3%*	*77.4%*	*68.3%*	*68.7%*	*71.2%*	*72.7%*	*74.0%*	*74.4%*
R&D	$9,163.0	$2,271.0	$2,204.0	$2,360.0	$2,420.0	$9,255.0	$9,288.0	$9,575.0	$10,101.0
% R&D	*22.1%*	*37.6%*	*29.9%*	*39.3%*	*36.7%*	*35.6%*	*28.2%*	*22.6%*	*19.9%*
Selling & Mktg	$12,404.0	$2,496.0	$2,561.0	$2,322.0	$2,475.0	$9,854.0	$10,571.7	$12,065.8	$13,635.8
% Sell&Mktg	*29.9%*	*41.3%*	*34.8%*	*38.7%*	*37.5%*	*37.9%*	*32.1%*	*28.5%*	*26.8%*
G&A	$10,519.0	$1,912.0	$2,470.0	$2,071.0	$2,388.0	$8,841.0	$9,655.0	$10,864.0	$11,744.0
% G&A	*25.3%*	*31.7%*	*33.5%*	*34.5%*	*36.2%*	*34.0%*	*29.3%*	*25.7%*	*23.1%*
Operating Income	($30,179.0)	($2,493.0)	($1,533.0)	($2,652.0)	($2,747.8)	($9,425.8)	($5,561.4)	($1,186.1)	$2,372.7
Operating Margin	*-72.6%*	*-41.3%*	*-20.8%*	*-44.2%*	*-41.6%*	*-36.2%*	*-16.9%*	*-2.8%*	*4.7%*
Other income	($1,706.0)	$4.0	$2.0	$2.0	$2.0	$10.0	$125.0	$0.0	$0.0
Interest income, net	($646.0)	($22.0)	($21.0)	($15.0)	($18.0)	($76.0)	($100.0)	$58.0	$121.0
Pre-Tax Income	($32,531.0)	($2,511.0)	($1,552.0)	($2,665.0)	($2,763.8)	($9,491.8)	($5,536.4)	($1,128.1)	$2,493.7
Taxes	$16.0	$22.0	$23.0	$10.0	$27.6	$82.6	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*-0.9%*	*-1.5%*	*-0.4%*	*-1.0%*	*0.1%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($32,547.0)	($2,533.0)	($1,575.0)	($2,675.0)	($2,791.4)	($9,574.4)	($5,536.4)	($1,128.1)	$2,493.7
YOY Growth	*-3125.7%*	*-36.4%*	*94.4%*	*-565.4%*	*-16.2%*	*70.6%*	*42.2%*	*79.6%*	*321.1%*
Net Margin	*-78.3%*	*-42.0%*	*-21.4%*	*-44.6%*	*-42.3%*	*-36.8%*	*-16.8%*	*-2.7%*	*4.9%*
EPS	($2.07)	($0.16)	($0.10)	($0.17)	($0.17)	($0.60)	($0.33)	($0.07)	$0.14
YOY Growth	*-2850.6%*	*-34.5%*	*94.4%*	*-555.7%*	*-14.6%*	*71.0%*	*45.2%*	*80.1%*	*317.3%*
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)	($0.17)	($0.17)	($0.60)	($0.33)	($0.07)	$0.14
Diluted Shares O/S	15,686	15,826	15,904	15,957	15,960	15,912	16,800	17,200	17,500

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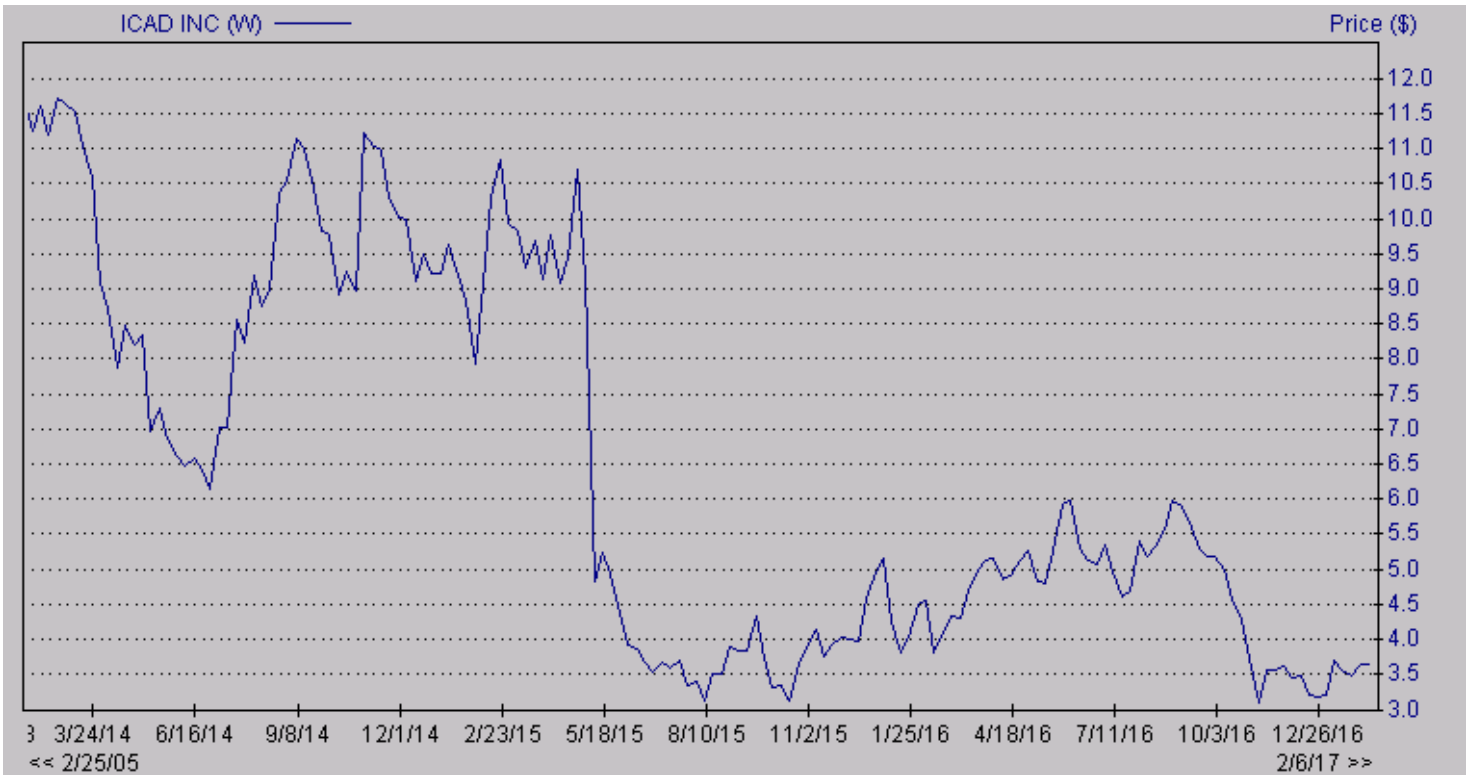

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