Zacks Small-Cap Research

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iCAD Inc (ICAD-NASDAQ)

ICAD: Tomo FDA Approval. Reiterating $7.50/share Price Target

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 (04/11/17)	$5.45
Valuation	**$7.50**

OUTLOOK

On March 27th iCAD announced that PowerLook Tomo Detection, their 3D tomosynthesis software, received FDA clearance. While long-awaited and hampered by several delays, the U.S. regulatory approval is a major milestone for the company in our opinion given that it represents what we believe to be the beginning of the next major growth catalyst for the company.

As we noted in our March 14th update, we were modeling FDA clearance of the product in Q2 '17 but for meaningful related sales not to materialize until Q3 of this year. While ICAD managed to beat our estimated FDA approval timeline by a few days, we continue to think sales may be immaterial in the current quarter as the company finalizes launch activities. That said, 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. ICAD's follow-on, next-gen tomo product, which is already in the works and compatible across manufacturers, offers long-term opportunity for success of ICAD's tomo product line.

SUMMARY DATA

52-Week High	**$6.49**
52-Week Low	**$2.82**
One-Year Return (%)	**8.20**
Beta	**1.15**
Average Daily Volume (sh)	**40,065**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$86**
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	6224 E	6881 E	7332 E	7829 E	28256 E
2018					40563 E
2019					51783 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	-$0.19 E	-$0.15 E	-$0.14 E	-$0.13 E	-$0.61 E
2018					-$0.23 E
2019					$0.14 E

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

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3D Tomo Receives FDA Approval: Inline with our prior assumptions, continue to model contribution in Q3 …

On March 27th iCAD announced that PowerLook Tomo Detection, their 3D tomosynthesis software, received FDA clearance. While long-awaited and hampered by several delays, the U.S. regulatory approval is a major milestone for the company in our opinion given that it represents what we believe to be the beginning of the next major growth catalyst for the company.

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 European and U.S. 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 the use of ICAD's tomo product, has been encouraging. This has set the stage for a market that we think will be highly receptive to ICAD's product and, based on initial sales in Europe, early indications are positive. Initial sale of the product in Europe came in Q2 2016 and it appears sales are accelerating with management noting on the Q4 2016 call (March 8, 2017) that 6 or 7 orders had already been placed in Q1 '17.

Tomo product line should steepen Detection revenue curve…
As we noted in our March 14th update, we were modeling FDA clearance of the product in Q2 '17 but for meaningful related sales not to materialize until Q3 of this year. While ICAD managed to beat our estimated FDA approval timeline by a few days, we continue to think sales may be immaterial in the current quarter as the company finalizes launch activities. That said, 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.

While ICAD's mammography business, including PowerLook upgrades and iReveal, has performed very well as of late and Q2 '16 included the first sale of the breast tomo product in Europe, we are modeling roughly flat sequential growth (ex-MRI CAD) of Detection until the 3D tomosynthesis software launches in the U.S. But this could prove conservative, particularly if the pace of the ongoing roll-out of 3D tomo in Europe exceeds our expectations. Nonetheless, we continue to expect significant steepening of Detection product sales in 2H 2017 (ex-MRI CAD) on the back of the initial 3D tomo product in the U.S. In addition initial contribution from the next-gen tomo product could happen in 2017, although we think it is more likely a 2018 event.

Follow-on tomo products offer long-term opportunity…
As a reminder, 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). 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 in early March 2017 received 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 had been shooting to have development and testing completed and have their next-gen product launched in Europe as soon as early/mid 2017 – that timeline recently moved to late-2017. U.S. launch had been ballparked for possibly late-2017, but management noted on the Q4 call that they are now shooting for 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.

FINANCIAL MODEL

iCAD Inc.

	2016 A	Q1E	Q2E	Q3E	Q4E	2017 E	2018 E	2019 E
Cancer Detection	$17,133.0	$3,742.0	$3,846.0	$4,232.0	$4,804.0	$16,624.0	$27,186.7	$35,068.1
YOY Growth	*-11.0%*	*-4.8%*	*-21.5%*	*2.4%*	*15.1%*	*-3.0%*	*63.5%*	*29.0%*
% of total revenue	*65.1%*	*60.1%*	*55.9%*	*57.8%*	*61.4%*	*58.8%*	*67.0%*	*67.7%*
Therapy	$9,205.0	$2,482.0	$3,035.0	$3,090.0	$3,025.0	$11,632.0	$13,377.0	$16,715.0
YOY Growth	*-58.7%*	*17.7%*	*22.8%*	*65.3%*	*9.8%*	*26.4%*	*15.0%*	*25.0%*
% of total revenue	*34.9%*	*39.9%*	*44.1%*	*42.2%*	*38.6%*	*41.2%*	*33.0%*	*32.3%*
Total Revenues	$26,338.0	$6,224.0	$6,881.0	$7,322.0	$7,829.0	$28,256.0	$40,563.7	$51,783.1
YOY Growth	*-36.6%*	*3.1%*	*-6.6%*	*22.0%*	*13.0%*	*7.3%*	*43.6%*	*27.7%*
Cost of Revenues	$7,820.0	$1,970.6	$2,067.7	$2,164.9	$2,219.4	$8,422.6	$10,910.5	$13,359.1
Gross Income	$18,518.0	$4,253.4	$4,813.3	$5,157.1	$5,609.6	$19,833.4	$29,653.2	$38,424.0
Gross Margin	*70.3%*	*68.3%*	*70.0%*	*70.4%*	*71.7%*	*70.2%*	*73.1%*	*74.2%*
R&D	$9,518.0	$2,441.0	$2,362.0	$2,284.0	$2,414.0	$9,501.0	$9,575.0	$10,101.0
% R&D	*36.1%*	*39.2%*	*34.3%*	*31.2%*	*30.8%*	*33.6%*	*23.6%*	*19.5%*
Selling & Mktg	$10,179.0	$2,614.1	$2,683.6	$2,862.9	$3,006.3	$11,166.9	$13,304.9	$14,188.6
% Sell&Mktg	*38.6%*	*42.0%*	*39.0%*	*39.1%*	*38.4%*	*39.5%*	*32.8%*	*27.4%*
G&A	$8,791.0	$2,191.0	$2,265.0	$2,260.0	$2,351.0	$9,067.0	$10,864.0	$11,744.0
% G&A	*33.4%*	*35.2%*	*32.9%*	*30.9%*	*30.0%*	*32.1%*	*26.8%*	*22.7%*
Operating Income	($9,970.0)	($2,992.7)	($2,497.3)	($2,249.8)	($2,161.7)	($9,901.5)	($4,090.7)	$2,390.4
Operating Margin	*-37.9%*	*-48.1%*	*-36.3%*	*-30.7%*	*-27.6%*	*-35.0%*	*-10.1%*	*4.6%*
Other income	$9.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest income, net	($62.0)	($4.0)	($2.0)	($2.0)	($8.0)	($16.0)	$16.2	$44.0
Pre-Tax Income	($10,023.0)	($2,996.7)	($2,499.3)	($2,251.8)	($2,169.7)	($9,917.5)	($4,074.5)	$2,434.4
Taxes	$76.0	$24.0	$20.0	$18.0	$17.4	$79.3	$0.0	$0.0
Tax Rate	*-0.8%*	*-0.8%*	*-0.8%*	*-0.8%*	*-0.8%*	*-0.8%*	*0.0%*	*0.0%*
Net Income	($10,099.0)	($3,020.7)	($2,519.3)	($2,269.8)	($2,187.1)	($9,996.8)	($4,074.5)	$2,434.4
YOY Growth	*69.0%*	*-19.3%*	*-60.0%*	*15.1%*	*34.0%*	*1.0%*	*59.2%*	*159.7%*
Net Margin	*-38.3%*	*-48.5%*	*-36.6%*	*-31.0%*	*-27.9%*	*-35.4%*	*-10.0%*	*4.7%*
EPS	($0.63)	($0.19)	($0.15)	($0.14)	($0.13)	($0.61)	($0.23)	$0.14
YOY Growth	*69.5%*	*-16.8%*	*-55.1%*	*18.4%*	*36.3%*	*4.1%*	*61.6%*	*158.7%*
Pro-forma adjustments	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pro-forma EPS	($0.63)	($0.19)	($0.15)	($0.14)	($0.13)	($0.61)	($0.23)	$0.14
Diluted Shares O/S	15,975	16,160	16,400	16,600	16,800	16,490	17,500	17,800

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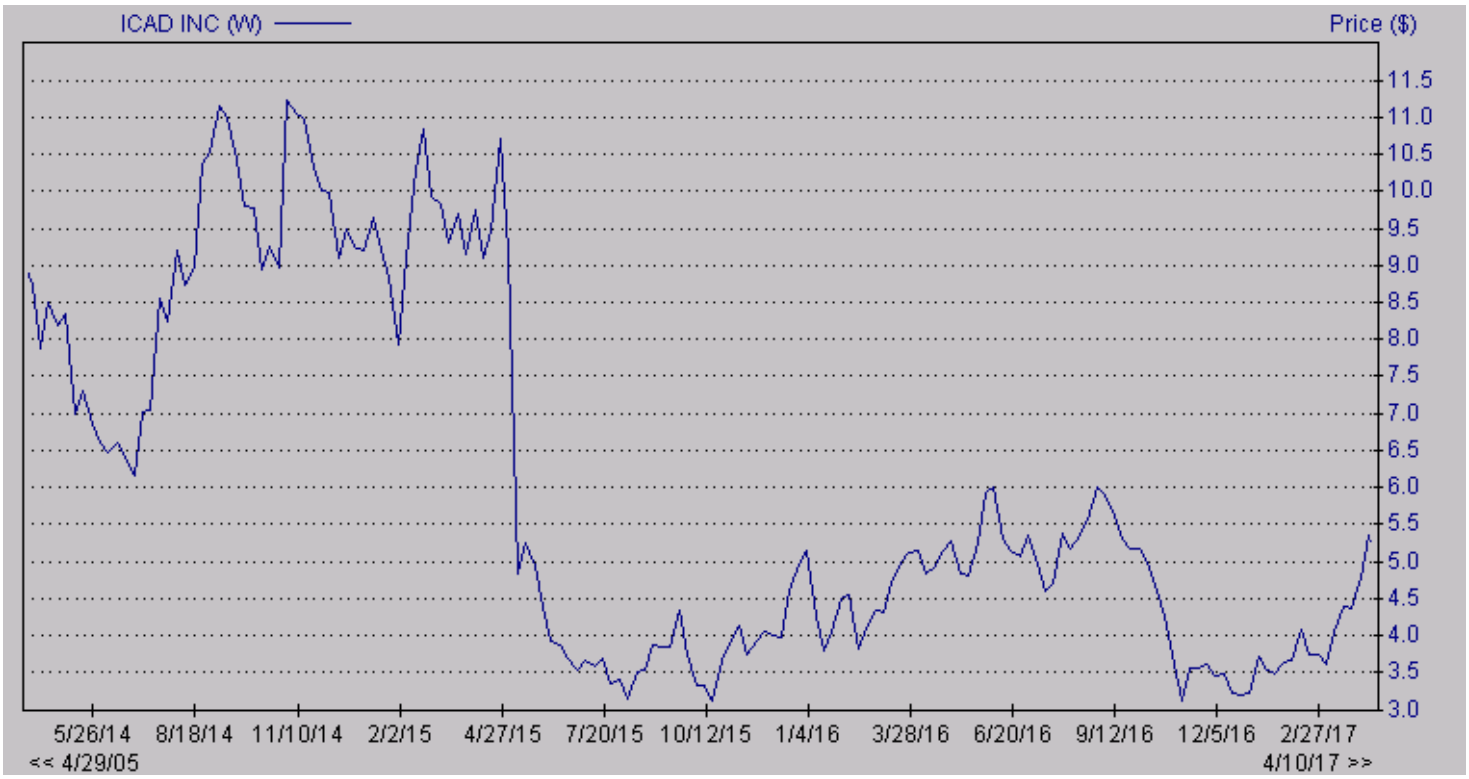

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