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iCAD Inc

(ICAD-NASDAQ)

ICAD: Therapy Drops On Reimbursement Issue. Detection Takes The Reins Going Into 2016

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	08/05/2015
Current Price (08/05/15)	$3.31
Target Price	**$8.50**

OUTLOOK

Therapy, which had been the major catalyst driving revenue, is now contracting with disappointing reimbursement policy change. This could turn back around with new dedicated non-melanoma skin cancer code effective Jan 1, 2016. But reimbursement uncertainty will stifle Therapy biz for at least the next 6 months - possibly indefinitely. In the meantime ICAD cut costs to stem the bleeding.

Breast IORT could reappear as a bright area. In Detection, continue to look for flat to low-single growth in 2H 2015. 2016 could see significant steepening in Detection revenue with tomo launch in Europe (late 2015?) and U.S. (mid-2016?).

SUMMARY DATA

52-Week High	**$11.63**
52-Week Low	**$2.95**
One-Year Return (%)	**-63.22**
Beta	**1.88**
Average Daily Volume (sh)	**247,049**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$52**
Short Interest Ratio (days)	**0.52**
Institutional Ownership (%)	**45**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**11.8**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	8,520 A	9,667 A	12,572 A	13,165 A	43,924 A
2015	13220 A	11143 A	8102 E	8027 E	40,492 E
2016					37,412 E
2017					47,297 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.02 A	-$0.07 A	$0.02 A	-$0.01 A	-$0.07 A
2015	-$0.12 A	-$1.78 A	-$0.07 E	-$0.07 E	-$2.03 E
2016					-$0.12 E
2017					$0.07 E

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

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Q2 2015 Results: Therapy Drops on Reimbursement Issue, Detection Holding Firm - Should Accelerate in 2016

iCAD (ICAD) announced financial results for the second quarter ending June 30th. Detection continues to hold up well turning in positive growth on both a yoy and sequential basis. Detection has been consistently turning in close to $5M per quarter since Q2 2014 with MRI products, breast density and regular upgrades to PowerLook contributing the bulk of revenue. Detection should continue to chug along at right about these same levels through the end of the current year. But 2016, as we have noted in past, could see a big upward inflection in Detection as the initial tomosynthesis products roll out in Europe (early 2016) and the U.S. (possibly mid-2016).

Meanwhile Therapy slid by almost 27% from Q2 (although posted 28% yoy growth) as a result of the adverse decision by Noridian Healthcare, the west coast Medicare contractor, relative to reimbursement for use of eBx in non-melanoma skin cancer. The Therapy business will continue to be negatively impacted through at least the end of the current year. A dedicated non-melanoma skin cancer code goes into affect Jan 1, 2016 which could improve the reimbursement picture. However, there remains significant uncertainty surrounding at where the rate levels will be established and the relative incentive to providers to use eBx for that indication. iCAD almost immediately implemented a cost-cutting initiative to help stem the hit to the bottom line which included significant headcount reduction in sales and marketing.

There does appear to be some more light on the horizon in breast IORT, however, as management noted on the call procedural volume has picked up considerably overseas. And additional regulatory approvals in countries such as Russia, India and China could create additional demand. And a cervical cancer applicator was just launched which provides another revenue opportunity for the Therapy business.

Relative to the non-melanoma skin cancer reimbursement issue - as a reminder a memo issued by Noridian Healthcare Solutions, the Medicare contractor covering 13 states on the west coast, instructed physicians that CPT Code 0182T ("High dose rate electronic brachytherapy, per fraction") should not be used to bill for brachytherapy for non-melanoma skin cancer. Code 0182T was set up to be used to treat breast cancer. For non-melanoma skin cancer, effective June 8, 2015, Noridian says Code 17999 ("Unlisted procedure, skin, mucous membrane and subcutaneous tissue") should be used along with a code designating the location and size of the lesion. No reimbursement rate for 17999 has yet to be published

It has been industry standard to use 0182T (established by the AMA) to bill for non-melanoma skin cancer and an outstanding opinion by The American Society for Radiation Oncology (ASTRO) was that 0182T "is the appropriate code for outpatient services provided for electronic brachytherapy. It has mostly been used and reimbursed for breast cancer but is also being applied to gynecologic and other sites."

iCAD's guidance, prior to this issue, was for 2015 revenue of $55M - $59M, or growth of 25% - 34%. On May 27th the company announced that they were withdrawing that guidance due to this reimbursement issue.

Management noted on the Q2 call that despite this reimbursement issue - which has clearly had a significant effect on system and consumable sales - that clinicians remain interested in the system but many of have postponed purchases. And while Noridian's change in policy affects much of ICAD's Therapy business, certain customers have been successful in billing under 17999 and others, outside of the Noridian footprint, may be in a more favorable reimbursement position. Management indicated that there continues to be substantial ambiguity in terms of current and future reimbursement rates but is working with others in the industry, including Medicare contractors, to hopefully get more clarity on the subject and to advocate for rates sufficient to cover the cost of providing the treatment. At the very least, the new dedicated code should reduce much of the uncertainty relative to reimbursement rates.

Revenue
Q2 revenue of $11.1M was up 15% yoy but down 16% sequentially

- **Cancer Detection(Q2):** $5.0M: +3% yoy, +4% sequentially
    - Cancer detection continues to be driven mostly by MRI products, breast density and regular upgrades to PowerLook. In July ICAD announced the launch of iReveal breast density software, the latest addition to the PowerLook line. 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. We continue to model barely better than flat growth for the full year 2015, although we think PowerLook AMP and MRI licensing will continue to be significant contributors. However with the launch of the initial 3D breast tomosynthesis products, expected in Q4 2014 in Europe, we think Detection will see a significant acceleration, particularly once the products are in both the U.S. and Europe.

We continue to expect the Detection segment to remain on track for sustained growth over the long term. This being fueled by the recent and expected new product launches (PowerLook AMP, CAD for tomosynthesis, the recent M-Vu breast density product, etc.), more annual licensing agreements, increased service contracts (to iCAD's 4k+ installed base as well as OEM partners'), partnership deals with OEM's with new products, development projects and service contracts, and the MRI software development deal with Invivo.

And as we've noted in the past, while CT colon CAD revenue has yet to gain much traction in the U.S. as a result of a dearth of reimbursement, management recently indicated they are seeing some growth internationally and this remains a viable domestic growth opportunity with sufficient reimbursement. As improvement in the reimbursement picture could improve in the near-term, we see this as one area that could surprise on the upside over the near-term. The additional data from the ACRIN study that were recently published could be a catalyst to eventually gaining Medicare reimbursement for CT colon CAD. iCAD has been active in attending and presenting at industry conferences, which have included featuring their VeraLook CTC product.

However, the Detection pipeline product that likely holds the most promise is the company's CAD platform for 3D breast tomosynthesis. The reader study to support European approval has been completed and launch on GE's SenoClair tomosynthesis instruments is expected in late 2015. SenoClaire received CE Mark in July 2013 and FDA clearance in August 2014. The U.S. reader study is slated to begin this quarter - if all goes well an FDA filing would happen in early 2016 and launch might be somewhere around mid-next year. We think this 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. GE's instrument is billed as producing lower x-ray dose (i.e. - safer) than Hologic's Selenia Dimensions machine (FDA cleared in 2011), currently the only other 3D breast tomosynthesis instrument sold in the U.S., providing a real opportunity for GE's machine.

Our modeled significant step-up in Detection revenue beginning in 2016 represents meaningful contribution from ICAD's 3D breast tomosynthesis platform.

- **Cancer Therapy (Q2):** $6.2M: +28% yoy, -27% sequentially

Cancer therapy revenue had been on a tear, growing 57% in 2014 and 94% in Q1 of this year - which was facilitated in part by the DermEbx acquisition (Q1 2014). The new leasing option (in lieu of outright purchase of the console) had been warmly received and also appears to have been a meaningful driver of uptake of the system. Non-melanoma skin cancer was where almost all of the growth in utilization was coming from - management noted on the Q1 2015 call that procedure volume (at locations using Radion Hub that launched prior to 2014) increased by 20% sequentially and 31% yoy.

Non-melanoma skin cancer was a tremendous opportunity for ICAD with expansion of the Therapy user base and increase in utilization coming from several fronts, including more favorable reimbursement, positive clinical outcomes data and greater awareness of the benefits the therapy. And with skin cancer treatment requiring more than one visit, this indication has been a boon to ICAD's revenue. With the DermEbx acquisition providing significant bolt-on revenue, increasing adoption for skin cancer, ramping utilization, increased awareness and a regular flow of positive outcomes data we had expected the Therapy business could ride a non-melanoma skin cancer wave of growth for some time.

This has hit, at the very least, a major speed bump with the Noridian change in policy. As indicated it's possible that the reimbursement improves - and potentially significantly so - but based on management's comments on the call, we expect Therapy revenue to continue to be negatively impacted through at least the remainder of 2015. Hopefully the new dedicated non-melanoma skin cancer CPT code provides, at minimum, greater clarity relative to providers' expectations on reimbursement levels. Even better would be uniform reimbursement at levels that encourage utilization. But, until there's greater clarity providers will be sitting on the sideline and we don't expect much in the way of new subscriptions or console sales. Existing

subscriptions and consumable contracts as well as providers that continue to have success in billing at "acceptable" rates should still provide meaningful Therapy revenue.

And IORT breast may be gaining some more traction. Management noted on the call that they are seeing a pick up in activity for this indication with applicator sales up 38% (yoy) in the first half of 2015. Much of this growth is coming from OUS - pointing to Portugal and Taiwan specifically as recent catalysts. And with new or near-term regulatory approvals in Russia, India and China, breast IORT could see another wave of growth. And a new indication is just coming online - that being gynecological cancers with the recent introduction of a cervical applicator.

So while the non-melanoma skin cancer reimbursement issue has stalled growth in that indication, not all is lost in the Therapy business - and, again, with the potential for an improved reimbursement environment, skin cancer could return to growth. For now, management is guiding Therapy service/supplies revenue at about $3M/quarter for the rest of 2015 - this compares to about $7.4M in Q1 and $6.1M in Q2. We now model total Therapy revenue of $20.9M for the full year, down from $37.8M prior to the Noridian announcement.

Model Updates

We have made significant updates to our financial model - most of which relates to the Noridian issue. As noted, we have trimmed Therapy revenue in 2015 by 45%. Our out-years have also moved down considerably - which are subject to change based on the reimbursement picture - which has the potential to be pretty dynamic over the next ~6 months. We now have 2016 Therapy at $13.5M, which implies a quarterly run-rate of about $3.8M - slightly better than the ~$3M expected in Q3 and Q4 of this year - our estimated growth is coming exclusively from IORT breast as well as some contribution from cervical. So this conservatively assumes little to no improvement in skin reimbursement - we will update this if and when there is more clarity on the subject.

Relative to Detection - again, this is where we now see the most opportunity for growth going into 2016 and being driven by tomo and breast density. We have moved our numbers down a notch as the tomo launch in Europe has been pushed back slightly from earlier expectations and we think the U.S. launch may come closer to Q3/Q4 instead of mid-2016. But we still think Detection can do 20%+ growth in 2016 and significantly better in 2017 with a full-year of U.S. tomo contribution.

ICAD was quick to cut costs and is guiding for OpEx of about $7M/quarter through the rest of 2015 - this is down from $8.6M/quarter in the first half of the year. Management has in the past demonstrated willingness and great ability to slash costs in time of need, benefitting cash burn and the income statement. So, we would expect in the event the reimbursement issue lingers that the cost base will continue to be right-sized to fit revenue.

We now model 2015 EPS (excluding Q2 impairment charge) of ($0.28), down from $0.00.

Cash

Excluding changes in working capital, cash used in operating activities was $1.4M in Q2. ICAD exited the quarter with $18.2M. They expect to use between $1M and $3M in 2H 2015, with about 50% of that going toward inventory building.

VALUATION / RECOMMENDATION

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 2015 and 2016, we calculated P/S and EV/S ratios from imaging (HOLX, MRGE) as well as surgical (VAR, ARAY, ISR, EKTAF) companies. The six companies currently trade at an average P/S-2015 of 4.4x and P/S-2016 of 2.5x and average EV/S-2015 of 3.9x and EV/S-2016 of 2.4x.

Based on the average of the 2015 and 2016 EV/S multiples iCAD is valued at $8.20/share. Based on the average of the 2015 and 2016 P/S multiples iCAD is valued at $8.5/share. We use the approximate average of the two which values iCAD at approximately $8.50/share. We are maintaining our moving our rec from Hold to Buy based on valuation.

FINANCIAL MODEL

iCAD Inc.

	2014 A	Q1A	Q2A	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
Cancer Detection	$18,604.0	$4,788.0	$4,955.0	$4,970.2	$4,858.9	$19,572.1	$23,884.1	$30,501.4	$36,553.4
YOY Growth	*10.1%*	*14.7%*	*2.5%*	*0.7%*	*4.2%*	*5.2%*	*22.0%*	*27.7%*	*19.8%*
% of total revenue	*42.4%*	*36.2%*	*44.5%*	*61.3%*	*60.5%*	*48.3%*	*63.8%*	*64.5%*	*62.6%*
Therapy	$25,320.0	$8,432.0	$6,188.0	$3,132.0	$3,168.0	$20,920.0	$13,528.0	$16,796.0	$21,836.0
YOY Growth	*56.7%*	*94.1%*	*28.0%*	*-59.0%*	*-62.7%*	*-17.4%*	*-35.3%*	*24.2%*	*30.0%*
% of total revenue	*57.6%*	*63.8%*	*55.5%*	*38.7%*	*39.5%*	*51.7%*	*36.2%*	*35.5%*	*37.4%*
Total Revenues	$43,924.0	$13,220.0	$11,143.0	$8,102.2	$8,026.9	$40,492.1	$37,412.1	$47,297.4	$58,389.4
YOY Growth	*31.0%*	*55.2%*	*15.3%*	*-35.6%*	*-39.0%*	*-7.8%*	*-7.6%*	*26.4%*	*23.5%*
Cost of Revenues	$12,697.0	$3,858.0	$3,265.0	$2,115.0	$2,102.7	$11,340.7	$9,672.1	$11,914.0	$14,310.3
Gross Income	$31,227.0	$9,362.0	$7,878.0	$5,987.2	$5,924.2	$29,151.4	$27,740.0	$35,383.5	$44,079.1
Gross Margin	*71.1%*	*70.8%*	*70.7%*	*73.9%*	*73.8%*	*72.0%*	*74.1%*	*74.8%*	*75.5%*
R&D	$8,490.0	$2,256.0	$2,272.0	$2,551.0	$2,526.0	$9,605.0	$9,771.0	$10,222.0	$10,517.0
% R&D	*19.3%*	*17.1%*	*20.4%*	*31.5%*	*31.5%*	*23.7%*	*26.1%*	*21.6%*	*18.0%*
Selling & Mktg	$12,526.0	$3,830.0	$3,165.0	$2,268.6	$2,247.5	$11,511.1	$10,550.2	$12,864.9	$15,648.4
% Sell&Mktg	*28.5%*	*29.0%*	*28.4%*	*28.0%*	*28.0%*	*28.4%*	*28.2%*	*27.2%*	*26.8%*
G&A	$9,396.0	$2,833.0	$2,926.0	$2,286.0	$2,294.0	$10,339.0	$9,661.0	$10,855.0	$13,141.0
% G&A	*21.4%*	*21.4%*	*26.3%*	*28.2%*	*28.6%*	*25.5%*	*25.8%*	*23.0%*	*22.5%*
Operating Income	$815.0	$443.0	($27,928.0)	($1,118.4)	($1,143.3)	($29,746.7)	($2,242.2)	$1,441.6	$4,772.7
Operating Margin	*1.9%*	*3.4%*	*-250.6%*	*-13.8%*	*-14.2%*	*-73.5%*	*-6.0%*	*3.0%*	*8.2%*
Other income	$969.0	($1,714.0)	$5.0	$0.0	$0.0	($1,709.0)	$150.0	$125.0	$0.0
Interest income, net	($2,640.0)	($507.0)	($70.0)	($75.0)	($75.0)	($727.0)	($374.0)	$25.0	$104.0
Pre-Tax Income	($856.0)	($1,778.0)	($27,993.0)	($1,193.4)	($1,218.3)	($32,182.7)	($2,466.2)	$1,591.6	$4,876.7
Taxes	$153.0	$79.0	($107.0)	($167.1)	($170.6)	($365.6)	($542.6)	$413.8	$1,463.0
Tax Rate	*-17.9%*	*-4.4%*	*0.4%*	*14.0%*	*14.0%*	*13.5%*	*22.0%*	*26.0%*	*30.0%*
Net Income	($1,009.0)	($1,857.0)	($27,886.0)	($1,026.3)	($1,047.8)	($31,817.1)	($1,923.7)	$1,177.8	$3,413.7
YOY Growth	*85.9%*	*-877.4%*	*-2697.0%*	*474.6%*	*-991.4%*	*-3053.3%*	*94.0%*	*161.2%*	*-189.8%*
Net Margin	*-2.3%*	*-14.0%*	*-250.3%*	*-12.7%*	*-13.1%*	*-78.6%*	*-5.1%*	*2.5%*	*5.8%*
EPS	($0.07)	($0.12)	($1.78)	($0.07)	($0.07)	($2.03)	($0.12)	$0.07	$0.20
YOY Growth	*89.3%*	*-615.8%*	*-2410.7%*	*490.0%*	*-973.5%*	*-2782.5%*	*94.3%*	*160.9%*	*-183.1%*
Pro-forma adjustments	$0.0	$0.0	$27,443.0	$0.0	$0.0	$27,443.0	$0.0	$0.0	$0.0
Pro-forma EPS	($0.07)	($0.12)	($0.03)	($0.07)	($0.07)	($0.28)	($0.12)	$0.07	$0.20
Diluted Shares O/S	14,348	15,605	15,679	15,700	15,800	15,696	16,700	16,800	17,200

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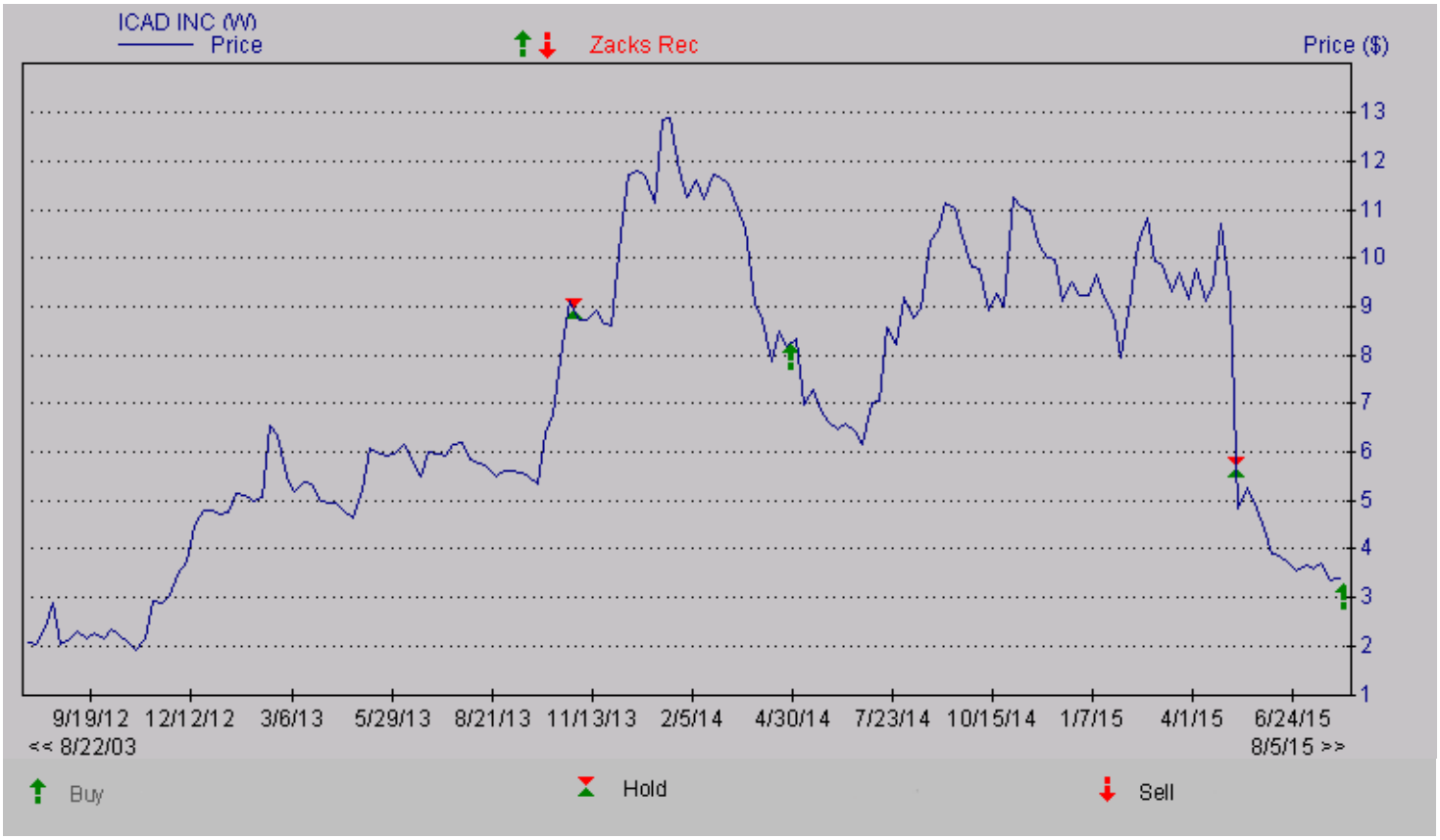

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