August 12, 2019

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iCAD Inc (ICAD-NASDAQ)

Q2 Results: ProFound AI Drives Detection Product Sales to ~8-year High. New Therapy Catalysts

Based on average EV/S and P/S multiples of five comparable companies, iCAD is valued at approximately $8.00/share.

Current Price (08/12/19)	$6.19
Valuation	**$8.00**

OUTLOOK

Revenue remains very strong, up 19% yoy, +8% qoq and the highest since Q3'17. GM was also a highlight. At 78.1%, looks to be the highest since Q4 2010 – this is particularly noteworthy in our opinion given recent incremental cost-of-products expenses related to enhanced server functionality and other growth-oriented investments. Relative weakness in Therapy, which may soon find catalysts in a change in CMS' radiation oncology reimbursement as well as in product-extensions, was more than offset by very strong Detection product sales, which reached a level not seen since Q3 2011. Management indicated that ProFound AI was the major driver of Detection product sales growth and expects this growth rate to steepen. We see several catalysts that support that outlook including adoption of ProFound AI 3D by SimonMed Imaging, continued productivity gains by ICAD's recently beefed-up U.S. sales team, increasing awareness of the compelling and unprecedented clinical performance of the technology, new vendor relationships and, as it relates to international, the recent 2D launch in Europe. Meanwhile CMS's RO Model would incentivize providers for quality instead of quantity of care and would almost certainly increase demand for ICAD's Xoft system and provide a catalyst to Therapy sales. We should know more later this year following ongoing 60-day comment period.

SUMMARY DATA

52-Week High	**$7.45**
52-Week Low	**$2.42**
One-Year Return (%)	**116.55**
Beta	**1.18**
Average Daily Volume (sh)	**158,938**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$117**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-12.8**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Dev-Software**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	6313 A	6162 A	6192 A	6954 A	25621 A
2019	6773 A	7329 A	7426 E	8132 E	29660 E
2020					45692 E
2021					58798 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.20 A	-$0.06 A	-$0.08 A	-$0.20 A	-$0.54 A
2019	-$0.22 A	-$0.20 A	-$0.10 E	-$0.08 E	-$0.58 E
2020					-$0.06 E
2021					$0.26 E

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

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Q2 2019 Results: *ProFound AI Drives Detection Product Sales to ~8-year High. New Therapy Catalysts Emerge…*

iCAD reported financial results for their second quarter and provided a business update. As it relates to the financials, revenue remained relatively very strong, up 19% yoy, +8% on a sequential basis and about 10% ahead of our estimate. The $7.3M of revenue in Q2 was the highest topline number since Q3'17 and this is despite Therapy sales (in Q2) at their second lowest level since Q3'2016. Gross margin was also a highlight which, at 78.1%, looks to be the highest since Q4 2010 – this is particularly noteworthy in our opinion given recent incremental cost-of-products expenses related to enhanced (3D) server functionality and other growth-oriented investments.

The relative weakness in the Therapy segment, which may soon find catalysts in a (favorable) change in CMS' radiation oncology reimbursement policy as well as potential product-extension growth opportunities, was more than offset by very strong Detection product sales, which reached a level not seen since Q3 2011. For context of how technologically distant that was, CAD for film-based analog mammo was a substantial part of ICAD's Detection segment revenue at that time.

Encouragingly, management indicated on the call that ProFound AI was the major driver of Detection product sales growth and, while 3D was the most significant catalyst, that both 3D and 2D attachment rates have been accelerating. Even more encouraging is that ICAD expects this growth rate to steepen further. We see several catalysts that support that outlook including adoption of ProFound AI 3D by SimonMed Imaging ('the largest physician owned imaging provider with 150 locations across the U.S.'), continued productivity gains by ICAD's recently beefed-up U.S. sales team, increasing awareness of the compelling and unprecedented clinical performance of the technology, new vendor relationships (OEMs and PACS) and, as it relates to international, the recent 2D launch in Europe and expanded OUS distribution.

New growth initiatives aimed at steepening the revenue curve will result in a near-term increase in the operating expense base but, if all goes to plan, ICAD expects these investments will pay off for the longer-term. The company will reinvest a portion of the proceeds from their recent $9.5M (net) equity raise towards exploiting opportunities in both Detection and Therapy (the latter which, until now, we had expected to largely tread water over the next few years) and anticipates initial realization of ROI on these investments to materialize in 2H 2020.

Total revenue was $7.3M, compared to our $6.7M estimate, and included $5.2M (+31% yoy, +25% qoq) from Detection and $2.1M (-2% yoy, -19% qoq) from the Therapy segment. Gross margin was 78.1% (vs. 77.6% Q2'18, 78.0% Q1'19 and 77.3% Zacks' E) with services and product margins at 71.2% (75% E) and 85.2% (81.7% E), respectively. Gross margin also averaged almost 78.1% through the first half of 2019, a level that ICAD has not seen for almost nine years.

Much of this margin growth appears to be related to a combination of a greater proportion of revenue coming from the Detection segment, which carries a significantly higher margin than that of the Therapy business, and the prior restructuring of the Therapy segment (i.e. discontinuation of the NMSC subscription business model). While Detection margin fell to 84% in Q2'19 from 86% in the prior year period, this was more than offset by a combination of Detection revenue increasing to 71.1% of total sales (from 64.8% in Q2'18) and Therapy margin widening from 61% (in Q2'18) to 65% in the most recent quarter (note that Q2'19 Therapy GM growth was organic as Q2'18 was the first full quarter benefitting from NMSC restructuring-related margin enhancement).

Aside from the most recent quarter and Q4'18, when Detection accounted for 71.0% of total sales, this segment has not contributed more than 69.0% of total revenue since Q2'12 (when Detection accounted for $4.4M, or 74.7% of total revenue). While incremental expenses from enhancements to support the 3D functionality and other growth-oriented investments may put some pressure on Detection product margins, we think this is offset by continued outsized growth of Detection as a percentage of total revenue. In addition, while ICAD's renewed focus on jumpstarting growth of (the lower-margin) Therapy business has prompted some upward revisions to our related revenue forecasts, we think any margin dilution is easily absorbed by a combination of Detection's more robust growth rate and eventual steeping of (relatively high margin) service/supplies revenue (which will benefit as recently-placed products' initial-year warranties expire).

Operating expenses increased by 26% and 14% from the prior year and quarter, respectively, and were about 9% higher than our estimate. The increases relate to the initial build-out of the sales and marketing infrastructure for supporting the roll-out of ProFound AI. The difference relative to our estimate relates almost entirely to sales and marketing expenses – which we had anticipated would steepen but had underestimated the degree. Management

noted that they anticipate opex will increase further in the back half of the year as additional resources come online and other growth-oriented investments are made.

Some of these expenses relate to new objectives in reigniting growth of the Therapy segment – the initial related strategy of which management outlined on the call. As a result and combined with slightly greater than anticipated spend in building out the ProFound AI S&M infrastructure, we have made substantive upward revisions to estimated operating expenses. We now look for total opex of $28.8M and $37.3M in FY2019 and FY2020, revised from $26.8M and $34.5M previously.

Q2 operating loss was $1.46M, inline with our $1.44M estimate. While we expect these incremental growth-oriented expenses to delay reaching a point of operating profitability (which we had previously anticipated to happen sometime next year but now think this is more likely a 2021 event), management was clear that they expect these investments will pay off in the longer term. And despite what we think will now be a slight delay to profitability, we do continue to model fairly consistent qoq improvement in operating loss (with some exceptions, including Q2 to Q3'19).

Cancer Detection: $5.2M (vs $4.5M E) up 31% yoy, up 25% sequentially

Detection revenue has now surprised on the upside relative to our estimates for the last three consecutive quarters. The beat in each of these periods largely relates to product sales and indications, based on comments on the respective earnings calls, are that the upside was from ICAD's AI products. This includes U.S. sales of ProFound AI, initial installations of which happened in Q4'18 and which management has indicated continue to gain traction (with product mix continuing to shift to ProFound AI). Importantly, management noted on the Q2 call that they expect to "gain meaningful traction with this product in the second half of 2019."

Given that ProFound AI will largely be detailed by in-house efforts (at least initially), indications of continued progress of direct sales wins and in accelerating the adoption curve are obviously promising. To that point, management indicated that they are taking great efforts to ensure that they have substantially capable and effective sales and support teams leading the roll out of their new 3D tomo product.

ICAD has wasted no time in building awareness about ProFound AI, which is the only FDA-approved product for 3D tomosynthesis. In fact, even prior to it receiving FDA clearance, the product and the reader study data that supported U.S. regulatory approval were showcased at the RSNA Annual Meeting in November 2018. That was followed by a presentation at the European Congress of Radiology conference earlier this year (ProFound AI for 2D, which received CE Mark in early July 2019, was also showcased at ECR) and most recently at the 2019 Society of Breast Imaging Symposium in early April.

ICAD's awareness-building efforts, which will continue later this year when the company attends additional upcoming industry events (including ASTRO and RSNA in September and December, respectively), is now being supplemented by articles in leading industry publications. ProFound AI pivotal FDA clinical data (discussed below) was the subject of a recent article by Aunt Minnie (a leading online source for everything radiology related) staff writer Erik Ridley titled "AI Enhances Radiologist Performance for DBT" and by the Radiological Society of North America in a July 31, 2019 article titled "AI Improves Efficiency and Accuracy of Digital Breast Tomosynthesis".

As a reminder, results of the reader study that supported FDA approval were compelling and unprecedented – showing an 8% increase in accurately detecting cancer (i.e. 8.0% increase in sensitivity), 6.9% reduction in the number of false positives (i.e. 6.9% increase in specificity) and 52.7% reduction in reading time (as compared to reading without ProFound AI). The fact that the study showed a simultaneous increase in both sensitivity and specificity, combined with the magnitude of improvement (for context, a 5% increase in detection is considered clinically meaningful) and massive reduction in reading time, is rather extraordinary and should be a very persuasive marketing message as to why radiologists should adopt the tool.

ICAD will be introducing a return-on-investment tool as part of their marketing strategy which shows how much money and time a hospital can save by adopting ProFound AI. As cost and ROI, per a July 23rd article (not specifically related to ICAD's product) in Aunt Minnie, are among the most significant non-performance related criteria that hospitals look at when considering which system to adopt (or to adopt at all), we are encouraged by ICAD's prescience in proactively addressing this.

ICAD noted that ProFound AI has already been adopted by a significant number of high-profile hospitals and imaging centers in different parts of the country, one of which is SimonMed Imaging. SimonMed ('the largest physician owned imaging provider with 150 locations across the U.S.'), per management's comments on the call,

will begin implementing ProFound AI into their practices which will have a positive impact on 2H 2019. Soliciting feedback from influential KOL's, establishment of key reference sites and leveraging evidentiary and testimonial experience will be part of the initial adoption-driving strategy and supplement efforts of the direct sales force. ICAD noted that they expect to leverage this positive feedback and independent results of clinicians' experiences with ProFound AI via abstract presentations as industry conferences. This 'real world' data may prove to be particularly powerful in spreading word-of-mouth awareness and influential in driving adoption of the technology.

As it relates to the sales force, ICAD noted that they recently more than doubled their field infrastructure and have a sales force of 12 now fully trained. In addition, a national accounts manager will be focused on selling to large accounts, such as imaging centers and government facilities. Promotional and marketing materials for ProFound AI have also been completed. ProFound AI is also now fully integrated in GE's price book (with other OEM's expected to do the same in 2H'19) and related sales training is completed. But while the GE channel could supplement that of ICAD's direct sales force, given the somewhat lackluster results of the former with Version 1, we continue to expect the latter to account for the majority of future installations. We also reiterate that while ICAD's build-out of their S&M infrastructure is directed at supporting the roll-out of ProFound AI, it also appears to be related to ICAD's strategy of eventually moving away from distribution-related reliance on OEM's, most notably, GE.

Unlike the initial version, ProFound AI is compatible with all manufacturer's machines – but, unlike ICAD's heavy reliance on GE for selling Version 1, which in hindsight may have been a mistake, the company appears eager to have more control over the sales and marketing strategy and processes with ProFound AI. This has already resulted in higher sales and marketing expense, but should all but eliminate any complacency risk and presumably provide management with much more direct control over the ultimate 'success' of ProFound AI and the ProFound platform as a whole. It also offers significantly greater margin (and profit) opportunity.

Other potential near-term catalysts to drive Detection revenue includes;

- growing adoption of breast density imaging in the U.S. While the majority of state legislature's mandate that health care facilities provide patients with breast density reporting/disclosures, in March 2019 FDA announced a proposed amendment to the MQSA Act of 1992 that would require all mammography facilities to provide information to patients about high breast density and its relation to breast cancer risk. It also provides the agency with additional oversight and enforcement of MQSA facilities that do not comply with regulations. We think this amendment could act as a significant catalyst to further driving adoption of breast density screening and ICAD's PowerLook Density Assessment software. ICAD noted that they are rebranding and relaunching their breast density offering to leverage the growing interest and demand for dense breast imaging and analysis.
- expansion of ICAD's OUS distribution footprint, including other OEMs and PACS vendors.
    - ICAD recently noted that they have established relationships with the majority of PACS vendors and that they "expect that we'll have multiple formal PACS relationships in place before year end" (Q2'19 CC). This, in our opinion, could represent one of the most significant near-term catalysts in helping to drive organic sales of ProFound AI
    - ICAD has also been busy in building out their OUS distribution network – noting that they now have third-party distribution in 16 countries (via 10 distributors) and expect to further build out their OUS distribution footprint
- Europe
    - CE Marking of ProFound AI 2D happened in July and the product is now officially launched in Europe. Management noted on the Q2 call that they have already received several orders of the product. We think this offers another potentially potent contributor to Detection revenue, particularly given that demand for 3D tomography in much of Europe significant lags that of the U.S. While we view the U.S. 3D market as representing the most significant opportunity for ICAD, we think the potential of the European 2D market may not be fully appreciated by investors
    - France: management noted that a recent (direct) sale was made to a 24-center imaging provider in France. This potentially might act as somewhat of a proxy reference site/customer to help build awareness of the technology throughout that country
    - OEM relationships. ICAD is also actively working to build out its OEM relationships in Europe, also noting that multiple large tenders will be bid later this year which could provide additional potential revenue upside

ICAD was clear that they expect to leverage the 'platform' utility of ProFound AI and in doing so, further reduce their dependence on the OEMs. They are already working on a next-gen version of ProFound AI, which could launch next year. In addition, add-on capability including ProFound Cloud, which will allow for cloud-based processing,

storage and transfer of images and reduce or eliminate the need for costly, bulky and high maintenance peripheral storage and related equipment has been under development for well over a year. Management believes they will have ProFound Could on the market sometime next year.

Meanwhile, a recently penned collaboration with researchers at The Karolinska Institutet in Stockholm, Sweden to develop an AI-based individual breast cancer risk prediction solution could result in another complementary offering to ProFound AI. Using tens of thousands of mammography images and ProFound AI's algorithm, a risk prediction model was built that allows for individual assessment of risk of developing breast cancer. The parties will now work to refine the model for commercial use. If successful in developing an 'accurate' risk-assessment model that can predict an individual's risk of developing breast cancer, we think it could represent a potential paradigm shift in screening methods and recommendations. ICAD hopes to have a first-generation module on the market in 2020 and recently indicated that they expect to unveil an early version of it at the RSNA conference in December of this year. We will be eager to hear updates.

Detection model updates…

The U.S. market is where the majority of the opportunity lies. And, we still like the big-picture view. Rates of adoption of new 3D capable machines has been somewhat slow-going – perhaps related to budget resets and/or lack of widespread insurance coverage for tomo (both of which can be an impediments to hospitals committing to the technology). But, with new budgets and building awareness of the benefits of 3D vs. 2D (such as lower recall rates), adoption should increase. Reading 3D images is more time consuming, however, which will drive demand for ICAD's software. Insurers who do not already reimburse for tomo will likely soon have little choice but to do so, which should help alleviate any ROI-related concerns at the provider level. And, finally, providers will leverage tomo as competitive differentiation, prompting other hospitals to follow suit and also adopt the technology. While much of the volume is still for the 2D product (even for new machines that are capable of both 2D and 3D), we expect current headwinds to adoption of 3D tomo to dissipate over time. The fact that the majority of ICAD's Q2'19 installations were 3D suggest that this shift may now be well underway. With approximately two-thirds of the U.S. market still yet to adopt tomosynthesis, significant upside remains.

Given the industry shift from 2D to 3D and wider breadth of machines that this second-gen product has availability for (~75% of tomo systems are non-GE machines) and its enhanced features, U.S. adoption of this should result in an accelerated growth curve of the Detection segment.

GE's apparent lack of enthusiasm in promoting the first version was undoubtedly a headwind to adoption. While OEM revenue fell 20% for the full year 2018 (including 17% in Q4), Detection revenue through ICAD's direct sales force increased 7% (including 14% in Q4). Sales via GE could commence soon as ProFound AI is now quotable in the OEM's price book (and their sales force is now trained). And while we do not know what to expect as it relates to GE's efforts with ProFound AI, we are very encouraged that ICAD is hedging that risk by building out their own sales and marketing resources. This has resulted in higher S&M spend but, hopefully, pay dividends via a steeper-than-otherwise sales curve (as well as wider margins).

We think fruits of the sales infrastructure build-out, establishment of key reference sites, GE's launch and further dissemination of results of the reader study and benefits of ProFound AI on accuracy and reading time begin to make a much more formidable impact in the near term. In addition, given the first-contact to sales-close to installation sales cycle, we should see a greater proportion of the initial launch efforts close in 2H'19. Budget resets could have a significant benefit going into 2020. We also look for a more significant contribution from their breast density offering and will be eager to hear how FDA's enhanced oversight of mammography providers and related reporting may be influencing demand for breast density imaging.

Meanwhile, ProFound AI for 2D mammography is now CE Marked and launched in Europe. Comments from management indicate meaningful initial interest and adoption. With only approximately 15% of the ~8k systems in Europe having adopted any form of CAD, the shift to tomo is slow. But, this also means that ICAD has a potentially enormous opportunity (particularly given the implied current lack of brand relationships of most European machines). As such and continued growth in the 2D market, ICAD could find meaningful demand for ProFound AI 2D in Europe.

Cancer Therapy: $2.1M (vs. $2.2M estimate): -2% yoy, -19% sequentially

The decrease in Therapy revenue (on both a yoy and qoq basis) relates to product sales, which can exhibit somewhat short-term variability and which fell $163k yoy and $487k qoq. Therapy product revenue was $545k,

representing 3 unit placements. This compares to $708k (5 systems) and $1.032M (10 systems) in the prior year and quarter periods, respectively and our $700k estimate.

Through 1H'19, Therapy product sales are up 28%. Management indicated that they are seeing a resurgence in interest, particularly in IORT applications, as well as initial adoption in certain international territories. Of the 11 system placements in 1H, eight were for IORT and three for NMSC. Despite what has been a massive slowdown in NMSC-demand, further geographic expansion, introduction of new applicators (for additional cancers) and evidence-based demand in the U.S. should bode well for continued growth of the Therapy segment.

Additionally, a new potential catalyst has emerged in the form of a change in CMS's radiation oncology reimbursement model. Announced in July, CMS's Radiation Oncology (RO) Model, if finalized (following the ongoing 60-day comment period) would (per CMS.gov) "improve the quality of care for cancer patients receiving radiotherapy treatment, and reduce provider burden by moving toward a simplified and predictable payment system. The aim of this Model, which would involve required participation, is to test whether prospective site neutral, episode-based payments to physician group practices (PGPs), hospital outpatient departments (HOPD), and freestanding radiation therapy centers for radiotherapy (RT) episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries."

The gist is that it is aimed at reducing the cost of radiation but without a compromise to outcomes. This could, in our opinion, be a significant boon to adoption and utilization of breast IORT – which has always been impeded by less than equitable reimbursement as compared to external beam radiation therapy (EBRT). The difference in total reimbursement between IORT and EBRT mostly relates to the latter requiring a significantly greater number of procedures – which is typically in the providers' best financial interest. As CMS's RO Model would incentivize providers for quality instead of quantity of care, it would almost certainly increase demand for ICAD's Xoft system – outcomes of which (clinical studies have shown) are comparable to that of EBRT. As an estimated 70% of all radiation-appropriate breast cancer cases qualify for brachytherapy, this proposal could result in significant shift in procedural volume away from EBRT and to IORT. While the comment period may result in modifications to the initial proposal, we should know the final result by later this year – with implementation (assuming ratification) either in January or April of next year.

Clinical data continues to support the benefits of IORT. With more data supporting the benefits of IORT versus traditional radiation therapy, we continue to think adoption in the U.S. market could soon begin to accelerate. *Intraoperative Radiation Therapy (IORT): A Series of 1000 Tumors*, a study of 984 breast cancer patients which received IORT breast cancer therapy (between June 2010 and August 2017), was published in Annals of Surgical Oncology in July 2018. Results to-date showed local recurrence rates (i.e. primary endpoint) at median follow-up of 36-months which are comparable to that of the landmark prospective TARGIT-A and ELIOT trials.

Results of ICAD's 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 were presented at ASTRO 2018 in San Antonio in late-October. Results through (median follow-up of) two years showed less than 1% of patients had cancer regrowth or developed new cancer in the other breast. Moreover, treatment was well tolerated and mean treatment time was just 10.5 minutes. Results of the study, which enrolled 1,201 patients at 28 U.S. and international sites, are expected to be submitted for publication in the near term.

And, data with a mean follow-up of 55 months further supporting the low recurrence rates of IORT, was published in October 2018 in The American Journal of Surgery (*Application of 21-gene recurrence score results and ASTRO suitability criteria in breast cancer patients treated with intraoperative radiation therapy (IORT)*). Specifically, the study showed recurrence rates at 55 months (i.e. 4.6 years) among patients treated with IORT and (standard of care) adjuvant medical therapy (such as chemotherapy and endocrine therapy) were comparable to referenced recurrence rates in TARGIT-A. The study included 184 breast cancer patients (from Nov 2011 to Jan 2016).

Also adding to the evidence supporting the use of IORT instead of traditional EBRT was a study that was recently published in *Cost Effectiveness and Resource Allocation.* The study (see our Appendix) demonstrated that IORT is associated with a longer quality of life, lower overall cost and higher monetary benefit as compared with external beam radiation therapy among patients with early-stage breast cancer.

As it relates to the international opportunity, given the size of China and India and their ever-increasing prosperity, these countries may represent significant growth opportunities. The relatively enormous population, combined with the convenience of radiation therapy at the time of surgery with eBx (versus traditional radiation which requires multiple trips back following lumpectomy), are reasons why China could represent another significant market for Xoft. ICAD's IORT balloon applicators recently received CFDA approval. This follows prior approval of the console

in that country. Xoft received approval from India's Atomic Energy Board in late-August 2018. The first installation in India, at Omega Hospitals Hyderabad, occurred in Q3'18 while the first installation in China happened later that same year.

Newer applications represent another growth opportunity. ICAD notes that they continue to see growing international demand in several newer applications – including brain, rectal and prostate. This is in addition to breast and gyn, which have already witnessed meaningful demand. ICAD is working on new applicators which has the potential to expand the market into additional applications. In addition to China, India, Spain, Taiwan and Australia, they are also seeing increasing interest from Japan – which could offer another significant growth opportunity.

As it relates to the non-melanoma skin cancer business – ICAD has recently noted that they are seeking a commercial partner to lead the sales and marketing functions of what remains of that business (i.e. capital sales). We think that move is being made so they can dedicate their Therapy-related efforts to IORT breast, gyn, brain, rectal and other cancers. Noteworthy is that the first prostate cancer patient was treated with ICAD's system recently and the company believes prostate cancer represents a near-term growth catalyst (including with robotic surgery). We continue to believe that IORT breast has potentially significant upside in both the U.S. and internationally.

Robotic surgery is another new area that ICAD is exploring on the Therapy side. Specifically, the use of Xoft radiation therapy during robotic surgical prostatectomies. The benefits of which would allow for delivering radiation in a non-shielded room during surgery and doing so in just minutes, as opposed to the traditional method – which is typically done with several sessions over a number of days. Management noted that clinical use trials and product testing are ongoing – including use with "a world-renowned da Vinci robot surgeon, who has done more robotic prostatectomies than anyone in the world." ICAD, which estimates as many as 40% of radical prostatectomy patients could be candidates for IORT robotic surgery, will use a portion of the proceeds of the recent equity raise to fund additional validation of the robotic surgery opportunity.

Therapy model updates…

We think the decision to hand over the sales function for the remaining NMSC business may imply there is even more limited upside to that business than we had recently thought. But, we are encouraged by comments suggesting that there are real growth opportunities in IORT as ICAD expands their OUS footprint, brings new applicators to market, continues to place significant importance on building the evidence databases and plays important roles in spreading awareness about the benefits of IORT.

CMS's updated RO reimbursement model represents the most significant potential near-term catalyst of the Therapy segment in our opinion – we will be eagerly awaiting updates on this. Meanwhile, new applications including in gyn, brain, rectal and other cancers as well as robotic surgery represent potential incremental mid-to-longer term revenue drivers. While the slight miss to Therapy revenue in Q2 moves our FY'19 estimate from $9.35M to $9.22M for that segment, we have upwardly adjusted our out-year Therapy revenue estimates to account for the potential benefits of the CMS action (which is subject to further revision depending on the final outcome). We now look for Therapy revenue of $9.8M (2020) and $10.4M (2021), revised from $9.4M and $9.9M.

Valuation

We model total revenue of;
FY2019: $29.7M, revised from $29.6M
FY2020: $45.7M, revised from $45.4M
FY2021: $58.8M, revised from $56.3M

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 2019 and 2020, we calculated P/S and EV/S ratios from imaging (HOLX) as well as surgical (VAR, ISR, EKTAF, SRTS) companies. We use the average of the two highest metrics in each ratio to account for the anticipated relatively outsized growth rate of ICAD as compared to these industry comparables. This results in an average P/S-2019 of 3.5x and P/S-2020 of 3.3x and average EV/S-2019 of 4.0x and EV/S-2020 of 3.7x.

Based on the average of the EV/S and P/S multiples iCAD is valued approximately $8.00/share (revised from $7.50/share).

FINANCIAL MODEL

iCAD Inc.

	2017 A	Q1A	Q2A	Q3A	Q4A	2018 A	Q1A	Q2E	Q3E	Q4E	2019 E	2020 E	2021 E
Cancer Detection	$18,310.0	$4,011.0	$3,990.0	$3,927.0	$4,936.0	$16,864.0	$4,168.0	$5,209.0	$5,148.0	$5,910.7	$20,435.7	$35,880.2	$48,444.2
YOY Growth	6.9%	-10.6%	-5.7%	-9.6%	-5.9%	-7.9%	3.9%	30.6%	31.1%	19.7%	21.2%	75.6%	35.0%
% of total revenue	65.2%	63.5%	64.8%	63.4%	71.0%	65.8%	61.5%	71.1%	69.3%	72.7%	68.9%	78.5%	82.4%
Therapy	$9,792.0	$2,302.0	$2,172.0	$2,265.0	$2,018.0	$8,757.0	$2,605.0	$2,120.0	$2,278.0	$2,221.0	$9,224.0	$9,812.0	$10,354.0
YOY Growth	6.4%	0.0%	-0.3%	-14.7%	-24.1%	-10.6%	13.2%	-2.4%	0.6%	10.1%	5.3%	6.4%	5.5%
% of total revenue	34.8%	36.5%	35.2%	36.6%	29.0%	34.2%	38.5%	28.9%	30.7%	27.3%	31.1%	21.5%	17.6%
Total Revenues	$28,102.0	$6,313.0	$6,162.0	$6,192.0	$6,954.0	$25,621.0	$6,773.0	$7,329.0	$7,426.0	$8,131.7	$29,659.7	$45,692.2	$58,798.2
YOY Growth	6.7%	-7.0%	-3.9%	-11.5%	-12.0%	-8.8%	7.3%	18.9%	19.9%	16.9%	15.8%	54.1%	28.7%
Cost of Revenues	$9,926.0	$1,815.0	$1,378.0	$1,454.0	$1,544.0	$6,191.0	$1,491.0	$1,603.0	$1,629.0	$1,640.0	$6,362.9	$8,960.6	$11,015.3
Gross Income	$18,176.0	$4,498.0	$4,784.0	$4,738.0	$5,410.0	$19,430.0	$5,282.0	$5,726.0	$5,797.1	$6,491.7	$23,296.8	$36,731.7	$47,782.9
Gross Margin	64.7%	71.2%	77.6%	76.5%	77.8%	75.8%	78.0%	78.1%	78.1%	79.8%	78.5%	80.4%	81.3%
R&D	$9,327.0	$3,339.0	$2,057.0	$2,035.0	$2,014.0	$9,445.0	$2,127.0	$2,139.0	$2,157.0	$2,208.0	$8,631.0	$10,997.2	$11,887.4
% R&D	33.2%	52.9%	33.4%	32.9%	29.0%	36.9%	31.4%	29.2%	29.0%	27.2%	29.1%	24.1%	20.2%
Selling & Mktg	$10,503.0	$2,166.0	$2,006.0	$2,100.0	$2,421.0	$8,693.0	$2,573.0	$3,120.0	$3,282.3	$3,434.0	$12,409.3	$17,162.0	$18,639.0
% Sell&Mktg	37.4%	34.3%	32.6%	33.9%	34.8%	33.9%	38.0%	42.6%	44.2%	42.2%	41.8%	37.6%	31.7%
G&A	$8,329.0	$2,141.0	$1,660.0	$1,852.0	$3,769.0	$9,422.0	$1,616.0	$1,925.0	$2,041.6	$2,167.5	$7,750.1	$9,110.7	$10,504.9
% G&A	29.6%	33.9%	26.9%	29.9%	54.2%	36.8%	23.9%	26.3%	27.5%	26.7%	26.1%	19.9%	17.9%
Operating Income	($16,676.0)	($3,148.0)	($939.0)	($1,249.0)	($2,794.0)	($8,130.0)	($1,034.0)	($1,458.0)	($1,683.8)	($1,317.8)	($5,493.6)	($538.2)	$6,751.5
Operating Margin	-59.3%	-49.9%	-15.2%	-20.2%	-40.2%	-31.7%	-15.3%	-19.9%	-22.7%	-16.2%	-18.5%	-1.2%	11.5%
Other income, net	$2,402.0	($120.0)	($84.0)	($90.0)	($551.0)	($845.0)	($2,675.0)	($2,053.0)	($189.0)	($170.0)	($5,087.0)	($683.0)	($607.0)
Pre-Tax Income	($14,274.0)	($3,268.0)	($1,023.0)	($1,339.0)	($3,345.0)	($8,975.0)	($3,709.0)	($3,511.0)	($1,872.8)	($1,487.8)	($10,580.6)	($1,221.2)	$6,144.5
Taxes	($18.0)	$13.0	$4.0	$26.0	($1.0)	$42.0	$8.0	$19.0	$0.0	$0.0	$27.0	$0.0	$768.1
Tax Rate	0.1%	-0.4%	-0.4%	-1.9%	0.0%	-0.5%	-0.2%	-0.5%	0.0%	0.0%	-0.3%	0.0%	12.5%
Net Income	($14,256.0)	($3,281.0)	($1,027.0)	($1,365.0)	($3,344.0)	($9,017.0)	($3,717.0)	($3,530.0)	($1,872.8)	($1,487.8)	($10,607.6)	($1,221.2)	$5,376.5
YOY Growth	-41.2%	-617.9%	61.0%	80.3%	21.0%	-36.7%	-13.3%	-243.7%	-37.2%	55.5%	17.6%	88.5%	540.3%
Net Margin	-50.7%	-52.0%	-16.7%	-22.0%	-48.1%	-35.2%	-54.9%	-48.2%	-25.2%	-18.3%	-35.8%	-2.7%	9.1%
EPS	($0.87)	($0.20)	($0.06)	($0.08)	($0.20)	($0.54)	($0.22)	($0.20)	($0.10)	($0.08)	($0.58)	($0.06)	$0.26
YOY Growth	-38.0%	-598.5%	61.8%	80.6%	22.3%	-38.0%	-9.2%	-224.7%	-20.6%	60.8%	7.7%	89.1%	514.5%
Diluted Shares O/S	16,343	16,583	16,664	16,700	16,774	16,680	17,200	17,640	19,005	19,020	18,216	19,300	20,500

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APPENDIX

Decision-Tree Analysis of Published Studies Indicates IORT Superior To EBRT in QoL, Cost:
A study which was recently published in *Cost Effectiveness and Resource Allocation* (a peer-reviewed online publication "aimed at health economists, health services researchers, and policy-makers with an interest in enhancing the flow and transfer of knowledge relating to efficiency in the health sector") demonstrated that IORT is associated with a longer quality of life, lower overall cost and higher monetary benefit as compared with external beam radiation therapy among patients with early-stage breast cancer.

The study, *Lifetime cost-effectiveness analysis of intraoperative radiation therapy versus external beam radiation therapy for early stage breast cancer*[1], incorporated data from previously published peer-reviewed studies of IORT and EBRT into a Markov decision tree. Key inputs into the model (for both IORT and EBRT tree branches) included life expectancy, amount of radiation exposure and related complications, probability of acute and long-term complications, probability of recurrent cancer, probability of death due to cancer, probability of death due to other causes, cost of each treatment (including cost of treating potential complications and cancer recurrence) as well as several quality of life measures including those related to complications (associated with each therapy, radiation exposure or other factors) and cancer recurrence.

Results showed that IORT was not only less costly than (up to 6-weeks of) EBRT, but that it was also associated with a greater number of 'quality adjusted life years' or QALYs (i.e. a commonly used measure of both quality and length of life). This also meant that the 'net monetary benefit' favored IORT as compared to EBRT.

In terms of cost, which included cost of not only the individual breast cancer treatments, but also that related potential complications, estimated lifetime cost of IORT was $53,179, while EBRT lifetime cost was $63,828. The higher cost of EBRT largely relates to greater risk of radiation-exposure complications (such as major coronary events and development of other solid cancers) and the related cost to treat these.

In terms of QALY, the analysis showed that IORT was associated with QALY of 17.86, while EBRT was 17.06. Greater risk of radiation-related complications associated with EBRT were, again, the major factors that favored IORT.

Finally, cost and QALY were used to calculate what the authors called '**net monetary benefit**' (NMB), which was used to determine which treatment modality was the most cost effective over a lifetime. NMB is calculated as: (amount a person is willing to pay per QALY x QALYs) – lifetime costs. The authors assumed a person is willing to pay $50k per QALY, which is based on its use in prior clinical studies spanning more than decade. NMB for the two treatment modalities was:

IORT: ($50,000 x 17.86) - $53,179 = $839,821
EBRT: ($50,000 x 17.06) - $63,828 = $789,172

In other words, assuming that a patient with early-stage breast cancer values each QALY at $50k and will choose between either EBRT or IORT, this study indicates that they would benefit (on average) by $50,649 (i.e. $839,921 - $789,172) over their lifetime by choosing IORT.

While previous studies have shown that IORT is more cost-effective than EBRT, **this is the only study that evaluates QALY, cost and net monetary benefit of the two modalities over the lifetime of patients**. Authors of this study note that the difference is important given that the higher radiation doses of EBRT are associated with long-term complications, particularly major cardiac events due to a larger area of the chest being exposed to radiation (and at higher doses versus IORT). As noted, these cardiac-related complications are largely the reason why IORT results in a lifetime NMB which is superior to that of EBRT.

The authors also note that the cost-advantage of IORT is also a benefit to the overall healthcare system. Another advantage of IORT versus EBRT is that the former is performed in one session while the latter requires the patient to return for several radiation treatments – which means less disruptions to patients' lives, lower transportation burdens and, potentially, faster recovery of those patients which choose IORT. In fact, ICAD's management has pointed to these advantages as potentially helping to facilitate uptake in not only the U.S. but certain overseas markets as well. For example, IORT therapy's lower treatment burden could be attractive to patients living in rural

[1] Patel et al. Cost Eff Resour Alloc (2017) 15:22 DOI 10.1186/s12962-017-0084-5

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areas of China (where ICAD's Axxent system and balloon applicators recently received regulatory clearance) which have to travel long distances to access radiation therapy.

HISTORICAL STOCK CHART



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