Zacks Small-Cap Research

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# iCAD Inc (ICAD-NASDAQ)

## ICAD: Q1 Revenue Soft. Look For Turnaround in NMSC, Tomo Launch

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

| | |
|---|---|
| Current Price (05/03/16) | $5.02 |
| **Valuation** | **$7.00** |

## OUTLOOK

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

Detection remains poised to enter what we believe will be a cycle of long-term growth on the heels of the launch of the initial tomosynthesis launch. While 1H 2016 may be somewhat soft, PowerLook upgrades and ICAD's breast density software which continue to perform well will help buoy revenue. iReveal just launched in July 2015 and will provide another impetus for 2016 and beyond. These, the tomo launch, a next-gen tomo product and the overall move towards leveraging growth of 3D imaging space should bode well for sustained strength in Detection revenue growth for many years.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$9.24** |
| **52-Week Low** | **$3.13** |
| **One-Year Return (%)** | **-40.38** |
| **Beta** | **1.99** |
| **Average Daily Volume (sh)** | **36,497** |
| **Shares Outstanding (mil)** | **16** |
| **Market Capitalization ($mil)** | **$84** |
| **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 (%)** | **15.0** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2016 Estimate** | **N/A** |
| **P/E using 2017 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

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

## ZACKS ESTIMATES

**Revenue**
(in '000 of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2015 | 13220 A | 11143 A | 9582 A | 7609 A | 41554 A |
| 2016 | 6038 A | 7041 E | 8033 E | 8668 E | 29780 E |
| 2017 | | | | | 39855 E |
| 2018 | | | | | 50224 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 | -$0.15 E | -$0.10 E | -$0.08 E | -$0.48 E |
| 2017 | | | | | -$0.11 E |
| 2018 | | | | | $0.09 E |

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

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## Q1 2016 Results: Revenue Disappoints. Continue To Look For Tomo Launch, NMSC Reimbursement Improvement…

iCAD announced financial results for the first quarter ending March 31. Results, particularly Therapy revenue, were fairly disappointing and well below ours as well as management's expectations. While we had expected a double digit decline in Detection due in large part to roll-off of the MRI distribution license with Invivo and a much bigger decrease in Therapy revenue due to continued weakness related to the skin reimbursement issue, Q1 actuals were meaningfully lower. The non-melanoma skin cancer reimbursement issue looks to have taken its biggest toll since it first began to impact Therapy revenue back in in Q2 2015. Meanwhile, while Detection service revenue turned in a solid showing of 11% yoy growth, product revenue in this segment plummeted 37% on weaker mammography sales and roll-off of the Invivo MRI license (as well as a timing issue), resulting in an overall 18% yoy decline in total Detection revenue.

Total revenue came in at just better $6M, the lowest level since Q2 2012 and down 21% sequentially and 54% yoy. This compares to management's prior expectation for it to be roughly flat from the $7.6M posted in Q4 and our $7.5M estimate. But despite the sizeable top-line miss, Q1 did have some positives on the financial side. This includes a continued robust gross margin (69.3%) and demonstration of ongoing cost control with operating expenses coming in on the low-end of management's prior guidance.

More importantly, in our opinion, is that fundamentals of a return to top and bottom line growth remain intact – albeit potentially slightly delayed from previous expectations. Operational progress towards this quest were meaningful over the last few months.

On the Therapy side, management believes that there is now enough evidence of positive and sufficient reimbursement for NMSC to entice a large portion of their existing customer base to restart using Axxent for this indication and to onboard new customers. Clearly this will be a focus. But while we think Q1 may have been a bottom in terms of NMSC-related revenue, we are modeling a more incremental returning ramp then we had previously as we think the onboarding process may be more prolonged than what we had been estimating.

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

But while NMSC has struggled as of late, IORT appears to be faring much better – balloon applicator sales increased 10% yoy. International has been the main IORT driver recently, although most of the Q1 balloon applicator sales growth was concentrated in the domestic market. Management expects continued strong growth in international IORT in 2016 in both system placements (just one 'multi-use' system was sold in Q1) and balloon applicator sales with a bigger push in existing territories and initial entry into others. In the U.S., ICAD continues to focus on expanding the clinical evidence database to demonstrate the benefits of IORT over traditional external beam radiation therapy. ICAD expects their 1,000-patient ExBRT (Safety and Efficacy Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft Axxent eBx System at the Time of Breast Conservation Surgery for Early-Stage Breast Cancer) study to complete enrollment in 2016. The study has enrolled at 20+ sites in the U.S. and Canada and will evaluate safety, efficacy, cosmetic outcomes and quality of life of patients for 10 years post-treatment. The company expects to present initial data from the study at ASTRO later this year.

But Detection is where we think the majority of the potential near-term growth lies. As noted, this segment underperformed expectations in Q1 but has the potential to exhibit a significant steepening of the revenue curve, beginning as early as 2H of this year with the roll-out of ICAD's first 3D tomosynthesis product (for GE's SenoiClair tomo instruments). In the European reader study supporting regulatory filing the product demonstrated an ability to reduce average time to read an exam by 24%. The product received CE Mark last month and the first customer order has already been received. Management noted that they received highly positive feedback from radiologists during the introduction of the product at ECR in March noting on the Q4 call that feedback included that radiologists "would not want to read a tomosynthesis exam in the future without it."

The U.S. launch could come shortly afterwards. The U.S. reader study completed and demonstrated 29% reduction in reading time. ICAD subsequently filed the final PMA module in early April. If all goes well ICAD could have FDA clearance and launch in Q3 – inline with management's prior expectations.

We continue to think tomo holds inflection-point and significant long-term growth opportunity. While we don't expect much in the way of contribution until late 2016, GE's current installed base of ~600 units already represents an enormous opportunity for ICAD and one which we think makes its initial significant showing on the revenue line in 2017 – perhaps slightly earlier, depending on timing of the U.S. launch.

This current tomo product is the first of what could be more to come. ICAD already has a follow-on product in late-stage development which is expected to not only reduce reading time but to also improve on accuracy to the point where radiologists will only need to read abnormal exams – this combination could prove of significant value in reducing reading time and, potentially, reduce staffing needs – thereby having a potentially significant benefit in lowering related costs. And while the first (i.e. current) tomo product is compatible with GE's SenoClaire instrument, the next-gen product is being developed for use on all manufacturers' machines. ICAD is currently shooting to have development and testing completed and have the product launched in Europe as soon as late 2016 and in the U.S. in mid-2017. Given the wider breadth of machines that this second-gen product has availability for and the enhanced features, introduction of this could result in another new wave of Detection segment growth.

**Revenue**
Q1 revenue of $6.0M (vs. $7.5M estimate) was down 54% yoy and down 21% sequentially

- **Cancer Detection(Q1):** $3.9M (vs. $4.3M estimate): -18% yoy, -9% sequentially
    - MRI products have been a big driver of Cancer detection over the recent past. However, with Invivo having exercised their right (in return for a $2M payment) to distribute the current version of the respective MRI product, these related revenues dissipated. This has been a major contributor to the 17% and 9% sequential decline in Detection revenue in Q4 2015 and Q1 2016, respectively.

      In July 2015 ICAD announced the launch of iReveal breast density software, the latest addition to the PowerLook line. The timing was good with almost one-half of all states already having enacted some form of legislation supporting breast density screening and more likely to follow. Management indicated that there has already been significant interest in iReveal. If and when mandated and widespread insurance coverage follows, breast density screening would almost certainly be fueled even further.

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

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

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

      Follow-on, next-gen tomo products already in the works. This product is not only expected to reduce reading time but to also improve on accuracy to the point where radiologists will only need to read abnormal exams – this combination could prove of significant value in reducing reading time and, potentially, reduce staffing needs – thereby having a potentially significant benefit in lowering related costs. It will also being developed for use on all manufacturers' machines. ICAD is currently shooting to have development and testing completed and have the product launched in Europe as soon as late 2016 and in the U.S. in mid-2017. Given the wider breadth of machines that this second-gen product has

availability for and the enhanced features, introduction of this could result in another new wave of Detection segment growth.

While we had been looking for Detection to turn in mid-single digit growth in 2016, we have moved this down to a 4% contraction given the much weaker than anticipated results in Q1. We look for Detection revenue growth to turn in ~35% growth in 2017 when we think there will be a full-years' worth of contribution from tomo in both Europe and the U.S.

- **Cancer Therapy (Q1):** $2.1M (vs. $3.2M estimate): -75% yoy, -36% sequentially

The non-melanoma skin cancer reimbursement issue looks to have taken its biggest toll since it first began to impact Therapy revenue back in in Q2 2015. Management believes that there is now enough evidence of positive and sufficient reimbursement for NMSC to entice a large portion of their existing customer base to restart using Axxent for this indication and to onboard new customers. Clearly this will be a focus. But while we think Q1 may have been a bottom in terms of NMSC-related revenue, we are modeling a more incremental returning ramp then we had previously as we think the onboarding process may be more prolonged than what we had been estimating.

Encouraging is that ICAD had previously noted that they believe the rate of reimbursement that have been paid so far this year is at levels that they think will support utilization. In addition, denials have not been an issue.

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

Clinical data continues to show excellent outcomes including superior cosmetic results and patient satisfaction as compared to surgery, which should help support the quest for favorable insurance reimbursement. And in the meantime ICAD will pursue a CPT I code – granting of which would all but eliminate ambiguity or significant differences in reimbursement policy and values. In November 2015 the company initiated a retrospective study of ~500 patients, results of which they hope to use to support an eventual CPT I code application. While the study will follow patients for five years, they will be able to include patients that completed treatment in 2013 and, therefore, believe that they may have sufficient 3-year supporting data by the end of 2016 and potentially be able to file for a CPT I code sometime in 2017.

Meanwhile IORT breast therapy continues to trend positively – particularly overseas where Xoft has experienced greater uptake, increasing procedural volume and geographical/distributor expansion. Balloon applicator sales in the most recent quarter increased 10% yoy. International has been the main IORT driver recently, although most of the Q1 balloon applicator sales growth was concentrated in the domestic market. Management expects continued strong growth in international IORT in 2016 in both system placements (just one 'multi-use' system was sold in Q1) and balloon applicator sales with a bigger push in existing territories and initial entry into others. In the U.S., ICAD continues to focus on expanding the clinical evidence database to demonstrate the benefits of IORT over traditional external beam radiation therapy. ICAD expects their 1,000-patient ExBRT (Safety and Efficacy Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft Axxent eBx System at the Time of Breast Conservation Surgery for Early-Stage Breast Cancer) study to complete enrollment. The study has enrolled at 20+ sites in the U.S. and Canada and will evaluate safety, efficacy, cosmetig outcomes and quality of life of patients for 10 years post-treatment. The company expects the present initial data from the study at ASTRO later this year.

**Model Updates**

We have made some updates to our financial model following Q1 results. As noted, we have adjusted Detection revenue down in 2016 but continue to look for this to significantly steepen in 2017, fueled by tomo in Europe and the U.S. and continued traction of PowerLook and breast density. We have Detection revenue contracting by about 15% in 1H 2016 but then turning in 8% growth (including 23% in Q4) in the second half of the year, fueled by contribution from tomo in Europe. Our Therapy line has also been adjusted lower – which reflects our assumption

that while we think the NMSC indication returns to growth, that the revenue curve may be more extended than what we had been previously modeling. We have Therapy revenue falling by 50% in 2016 (revised from a 40% contraction) as gains in IORT breast are more than offset by continued weakness in NMSC – this could prove conservative, however, which could depend on how the reimbursement scenario plays out and the pace of restarting existing customers and scoring new accounts. Expect to have more clarity in the coming months as the dynamics play out and there's some more history with onboarding of accounts.

We have total revenue of $29.8M in 2016 – implying a decrease of 28% from 2015 – but almost all of the contraction we have modeled in 1H, with the second half showing a contraction of just 3% and Q4 growing 14%. We think this momentum carries into and picks up in 2017.

ICAD was quick to cut costs following revelation of the NMSC reimbursement change. They are guiding for OpEx of ~$14.0M - $14.3M in 1H 2016 – which compares to ~$17.2M in 1H 2015. We have about $7.3M/qtr average in the remaining three quarters of the year. ICAD exited Q1 with $12.9M in cash and is guiding for ending the year with between $10M and $13M, depending on how the NMSC business plays out.

We model 2016 EPS of ($0.48).

## VALUATION

We continue to value iCAD based on competitor price/sales (P/S) and enterprise value /sales (EV/S) multiples. Using analyst's revenue estimates for the years 2016 and 2017, we calculated P/S and EV/S ratios from imaging (HOLX) as well as surgical (VAR, ARAY, ISR, EKTAF) companies. The five companies currently trade at an average P/S-2016 of 3.1x and P/S-2017 of 2.7x and average EV/S-2016 of 2.5x and EV/S-2017 of 2.0x.

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

## FINANCIAL MODEL

iCAD Inc.

| | 2015 A | Q1A | Q2E | Q3E | Q4E | 2016 E | 2017 E | 2018 E | 2019 E |
|---|---|---|---|---|---|---|---|---|---|
| **Cancer Detection** | $19,243.0 | $3,930.0 | $4,376.0 | $4,947.7 | $5,263.4 | $18,517.1 | $25,023.9 | $32,142.4 | $37,082.0 |
| *YOY Growth* | *3.4%* | *-17.9%* | *-11.7%* | *-4.9%* | *22.5%* | *-3.8%* | *35.1%* | *28.4%* | *15.4%* |
| *% of total revenue* | *46.3%* | *65.1%* | *62.2%* | *61.6%* | *60.7%* | *62.2%* | *62.8%* | *64.0%* | *64.7%* |
| **Therapy** | $22,311.0 | $2,108.0 | $2,665.0 | $3,085.0 | $3,405.0 | $11,263.0 | $14,831.0 | $18,082.0 | $20,229.0 |
| *YOY Growth* | *-11.9%* | *-75.0%* | *-56.9%* | *-29.6%* | *2.8%* | *-49.5%* | *31.7%* | *21.9%* | *11.9%* |
| *% of total revenue* | *53.7%* | *34.9%* | *37.8%* | *38.4%* | *39.3%* | *37.8%* | *37.2%* | *36.0%* | *35.3%* |
| Total Revenues | $41,554.0 | $6,038.0 | $7,041.0 | $8,032.7 | $8,668.4 | $29,780.1 | $39,854.9 | $50,224.4 | $57,311.0 |
| *YOY Growth* | *-5.4%* | *-54.3%* | *-36.8%* | *-16.2%* | *13.9%* | *-28.3%* | *33.8%* | *26.0%* | *14.1%* |
| Cost of Revenues | $12,204.0 | $1,852.0 | $2,187.1 | $2,353.2 | $2,456.1 | $8,848.4 | $11,043.1 | $13,610.5 | $15,128.1 |
| Gross Income | $29,350.0 | $4,186.0 | $4,853.9 | $5,679.5 | $6,212.3 | $20,931.7 | $28,811.8 | $36,614.0 | $42,182.9 |
| *Gross Margin* | *70.6%* | *69.3%* | *68.9%* | *70.7%* | *71.7%* | *70.3%* | *72.3%* | *72.9%* | *73.6%* |
| R&D | $9,163.0 | $2,271.0 | $2,401.0 | $2,280.0 | $2,310.0 | $9,262.0 | $9,288.0 | $9,575.0 | $10,101.0 |
| *% R&D* | *22.1%* | *37.6%* | *34.1%* | *28.4%* | *26.6%* | *31.1%* | *23.3%* | *19.1%* | *17.6%* |
| Selling & Mktg | $12,404.0 | $2,496.0 | $2,534.8 | $2,650.8 | $2,687.2 | $10,368.8 | $11,199.2 | $13,610.8 | $15,187.4 |
| *% Sell&Mktg* | *29.9%* | *41.3%* | *36.0%* | *33.0%* | *31.0%* | *28.9%* | *28.1%* | *27.1%* | *26.5%* |
| G&A | $10,519.0 | $1,912.0 | $2,221.0 | $2,265.0 | $2,488.0 | $8,886.0 | $10,210.0 | $12,004.0 | $12,889.0 |
| *% G&A* | *25.3%* | *31.7%* | *31.5%* | *28.2%* | *28.7%* | *29.8%* | *25.6%* | *23.9%* | *22.5%* |
| Operating Income | ($30,179.0) | ($2,493.0) | ($2,302.9) | ($1,516.3) | ($1,272.9) | ($7,585.0) | ($1,885.4) | $1,424.1 | $4,005.5 |
| *Operating Margin* | *-72.6%* | *-41.3%* | *-32.7%* | *-18.9%* | *-14.7%* | *-25.5%* | *-4.7%* | *2.8%* | *7.0%* |
| Other income | ($1,706.0) | $4.0 | $1.0 | $1.0 | $1.0 | $7.0 | $125.0 | $0.0 | $0.0 |
| Interest income, net | ($646.0) | ($22.0) | ($44.0) | ($51.0) | ($88.0) | ($205.0) | ($100.0) | $58.0 | $121.0 |
| Pre-Tax Income | ($32,531.0) | ($2,511.0) | ($2,345.9) | ($1,566.3) | ($1,359.9) | ($7,783.0) | ($1,860.4) | $1,482.1 | $4,126.5 |
| Taxes | $16.0 | $22.0 | ($23.5) | ($15.7) | ($13.6) | ($30.7) | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | *0.0%* | *-0.9%* | *1.0%* | *1.0%* | *1.0%* | *0.1%* | *0.0%* | *0.0%* | *0.0%* |
| Net Income | ($32,547.0) | ($2,533.0) | ($2,322.4) | ($1,550.6) | ($1,346.3) | ($7,752.3) | ($1,860.4) | $1,482.1 | $4,126.5 |
| *YOY Growth* | *-3125.7%* | *-36.4%* | *91.7%* | *-285.7%* | *44.0%* | *76.2%* | *76.0%* | *179.7%* | *-178.4%* |
| *Net Margin* | *-78.3%* | *-42.0%* | *-33.0%* | *-19.3%* | *-15.5%* | *-26.0%* | *-4.7%* | *3.0%* | *7.2%* |
| EPS | ($2.07) | ($0.16) | ($0.15) | ($0.10) | ($0.08) | ($0.48) | ($0.11) | $0.09 | $0.24 |
| *YOY Growth* | *-2850.6%* | *-34.5%* | *91.8%* | *-272.1%* | *46.2%* | *76.8%* | *77.0%* | *177.8%* | *-173.6%* |
| 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) | ($0.15) | ($0.10) | ($0.08) | ($0.48) | ($0.11) | $0.09 | $0.24 |
| Diluted Shares O/S | 15,686 | 15,826 | 16,000 | 16,300 | 16,400 | 16,132 | 16,800 | 17,200 | 17,500 |

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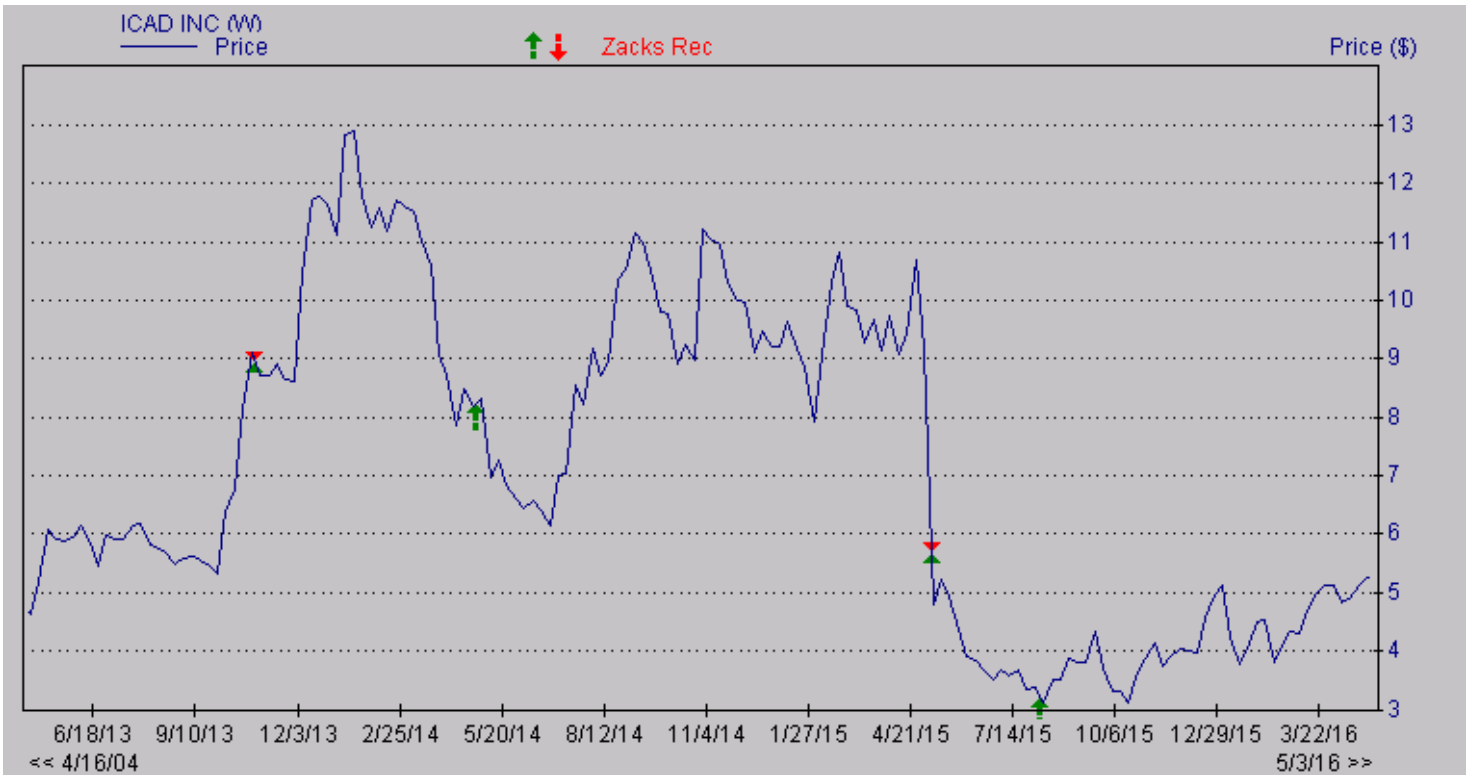
## HISTORICAL ZACKS RECOMMENDATIONS

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