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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

Zacks Small-Cap Research

scr.zacks.com

10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

iCAD Inc

(ICAD-NASDAQ)

ICAD: Q4 Mostly Inline. 1H 2016 May Be Soft, Look for Pick Up in 2H on Tomo Contribution

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	08/05/2015
Current Price (03/02/16)	$4.33
Target Price	**$7.25**

OUTLOOK

Therapy, which had been the major catalyst driving revenue, is now contracting with disappointing reimbursement policy change. Expect more clarity on NMSC reimbursement in the coming weeks which, if positive, could turn this indication around. 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 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	**$10.86**
52-Week Low	**$2.95**
One-Year Return (%)	**-56.80**
Beta	**1.93**
Average Daily Volume (sh)	**48,631**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$68**
Short Interest Ratio (days)	**1.13**
Institutional Ownership (%)	**25**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**15.5**
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	**Above Avg.,**
Type of Stock	**Small-Blend**
Industry	**Comp-Software**

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	41,554 A
2016	7447 E	8045 E	8633 E	9033 E	33,158 E
2017					42,303 E
2018					51,717 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	-$0.13 E	-$0.09 E	-$0.07 E	-$0.05 E	-$0.34 E
2017					$0.04 E
2018					$0.12 E

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

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Q4 2015 Results: Mostly Inline. 1H 2016 May Be Soft, Look for Pick Up in 2H on Tomo Contribution

iCAD (ICAD) announced financial results for the fourth quarter ending December 31. Results were mostly inline with our estimates with EPS coming in dead-on but a slight miss on the top-line related to the Detection segment. Therapy revenue came in right on our estimate and continues to struggle as a result of lack of clarity over non-melanoma skin cancer reimbursement.

Detection revenue fell on a yoy basis for the first time since Q1 2014. This relates to the roll-off of the MRI distribution license with Invivo - and while management had guided on the Q3 call that MRI sales were likely to slip in Q4, we had underestimated the impact. This shaved about $800k from the top-line compared to Q3 – or ~$200k more than the $600k haircut that we were ballparking. However, we do not view the contraction (8% yoy, 17% sequential) in Q4 as particularly reflective of the fundamentals of this segment, which 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 product. We have moved our forecasted Detection numbers down slightly as it looks as if MRI-Invivo was contributing somewhat more than we had estimated. This is subject to change, however as ICAD noted that they remain in "strategic" discussions with Invivo which includes a potential sale of the MRI business.

Timeline for the European tomo launch appears to be tracking management's most recent expectations. ICAD continues to guide for the European launch to happen this quarter – specifically a kick-off is at the European Congress of Radiology this week. CE Mark is expected to come this month as well. Relative to the U.S., the U.S. reader study has completed and is now awaiting final analysis. Per management, "preliminary results are encouraging". As of the Q3 earnings call management was hoping to have the PMA final module filed with FDA in January. While that didn't happen, assuming final analysis is also positive, management believes the final module will be submitted this month and U.S. launch could happen this summer. We continue to take a more conservative timeline for the U.S. market, incorporating initial contribution happening in early 2017.

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.

And Detection has other tailwinds – including PowerLook upgrades (15% unit placement growth in 2015) and ICAD's breast density software (113 licenses in 2015, up from 40 in 2014) which continue to perform well. iReveal just launched in July and will provide another impetus for 2016 and beyond. These, along with the overall move towards leveraging growth of 3D imaging space should bode well for sustained strength in Detection revenue growth for many years.

Meanwhile, while ICAD did place one Xoft system in Q4 for non-melanoma skin cancer, the Therapy segment remains hampered by the ambiguity surrounding reimbursement for this indication. While there have been some updates to CMS coding which took effect Jan 1, 2016, it unfortunately seems to have done little to clear up the reimbursement picture. As a reminder, in May 2015 Noridian Healthcare, the west coast Medicare contractor, said to no longer bill skin procedures under CPT Code 0182T (High dose rate electronic brachytherapy, per fraction). Instead providers were to begin using Code 17999 (Unlisted procedure, skin, mucous membrane and subcutaneous tissue) along with a code designating the location and size of the lesion.

Then, as expected, a dedicated non-melanoma skin cancer code (CPT III code 0394T) went into effect on Jan 1, 2016. While the hope was that this would clear up at least some ambiguity relative to what providers could expect in terms of payment, given that the code is "carrier priced" (i.e. determined by the Medicare contractor) and that average pricing has not been made public, the payment picture remains cloudy.

However, management noted on the Q4 call that they hope to have some more data points to anchor off of in the near future as more payments are processed. While ~1,500 procedures have been done since the beginning of the year, there is only about 20 – 30 payments so far to use as gauge. ICAD said, relative to the rates that they've seen so far, that it is "solid" and indicated that they think it, assuming the average remains at these levels, is sufficient enough to encourage use of Xoft for this indication. Management expects that enough payments will be processed within the next few months in order to make a more informed opinion relative to expectations of reimbursement rates. Importantly, ICAD noted that denials have not been an issue.

Clinical data continues to show excellent outcomes including superior cosmetic results and patient satisfaction as compared to surgery, which should help support the long-term quest for favorable insurance reimbursement. ICAD will continue their efforts in pursuit of 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 supporting data to file for a CPT I code sometime in 1H 2017.

Meanwhile IORT breast therapy continues to trend positively – particularly overseas where Xoft has experienced greater uptake, increasing procedural volume and geographical/distributor expansion. Additional clinical data, including recently presented data which continues to confirm low recurrence rates of IORT, could also help fuel traction in the U.S. as well as internationally. And ICAD continues to look to expand applications for Xoft in other cancers including prostate – a feasibility study for which is being planned for this year.

Revenue
Q4 revenue of $7.6M (vs. $7.8M estimate) was down 42% yoy and down 21% sequentially

- **Cancer Detection(Q4):** $4.3M (vs. $4.6M estimate): -8% yoy, -17% 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. While we had expected this to reduce Detection revenue by about $600k in Q4 as compared to Q3, the actual reduction was ~$800k – which accounts for the bulk of the miss to our estimate. But the expected near and long-term drivers of Detection is still expected to be from breast density and 3D tomo products.

      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 1H, 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.

      Both the European and U.S. reader studies are now completed. Results have been “encouraging”. CE Marking is expected this month. The U.S. reader study is awaiting final analysis. Assuming final analysis is also positive, management believes the final module will be filed this month and U.S. launch could happen this summer. 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.

      While we had been looking for Detection to turn in ~10% growth in 2016, we have moved this down to the low single digits given that we had underestimated contribution via Invivo and have pushed our tomo launches out by about another 3 months. But as we have noted before, slipping a quarter or two from management’s timelines is relatively immaterial, particularly given the significant potential of the products. We look for Detection revenue growth to step up to ~35% 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 (Q4):** $3.3M (vs. $3.2M estimate): -61% yoy, -24% 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.

  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.

  But this 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 we expect Therapy revenue to continue to be negatively impacted through at least the first half of 2016.

  ICAD expects to have more payment data by ~mid-year to form a better informed opinion on what providers can expect in the way of reimbursement rates. Encouraging is that ICAD believes 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. But, until there's greater clarity we think providers will be sitting on the sideline and we don't expect much in the way of new subscriptions or console sales related to NMSC until that time. 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, however.

  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 supporting data to file for a CPT I code sometime in 1H 2017.

  Meanwhile IORT breast therapy continues to trend positively – particularly overseas where Xoft has experienced greater uptake, increasing procedural volume and geographical/distributor expansion. Additional clinical data, including recently presented data which continues to confirm low recurrence rates of IORT, could also help fuel traction in the U.S. as well as internationally. And ICAD continues to look to expand applications for Xoft in other cancers including prostate – a feasibility study for which is being planned for this year.

Model Updates

We have made some updates to our financial model following Q4 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 8% in 1H 2016 but then turning in 15% in the second half of the year, fueled by contribution from tomo in Europe. Our Therapy line remains largely intact with what we had previously forecasted. We have Therapy revenue falling by 40% in 2016 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. Expect to have more clarity in the coming months as more payment data becomes available.

We have total revenue of $33.2M in 2016 – implying a decrease of 20% from 2015 – but all of the contraction we have modeled in 1H, with the second half showing 3% growth. 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 to move to ~$6.8M - $7.2M per quarter in 1H 2016 – which compares to ~$8.6M/quarter in the first half of 2014. We have about $7.1M/qtr average in 1H, stepping up to $7.3M in 2H. Management is guiding for reaching cash flow positive in 2H – which is slightly more aggressive than our estimates, although we do show marked improvement in both profitability and cash flow status as the year progresses.

We model 2016 EPS of ($0.34).

Cash
ICAD used $1.9M of cash for operating activities in both Q4 and the full year 2015. Cash balance at year-end stood at $15.2M

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 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 3.2x and P/S-2017 of 2.7x and average EV/S-2016 of 2.6x and EV/S-2017 of 2.0x.

Based on the average of the EV/S multiples iCAD is valued at $7.5/share. Based on the average of the P/S multiples iCAD is valued at ~$7/share. We use the approximate average of the two which values iCAD at about $7.25/share. We are maintaining our Buy rec based on valuation.

FINANCIAL MODEL

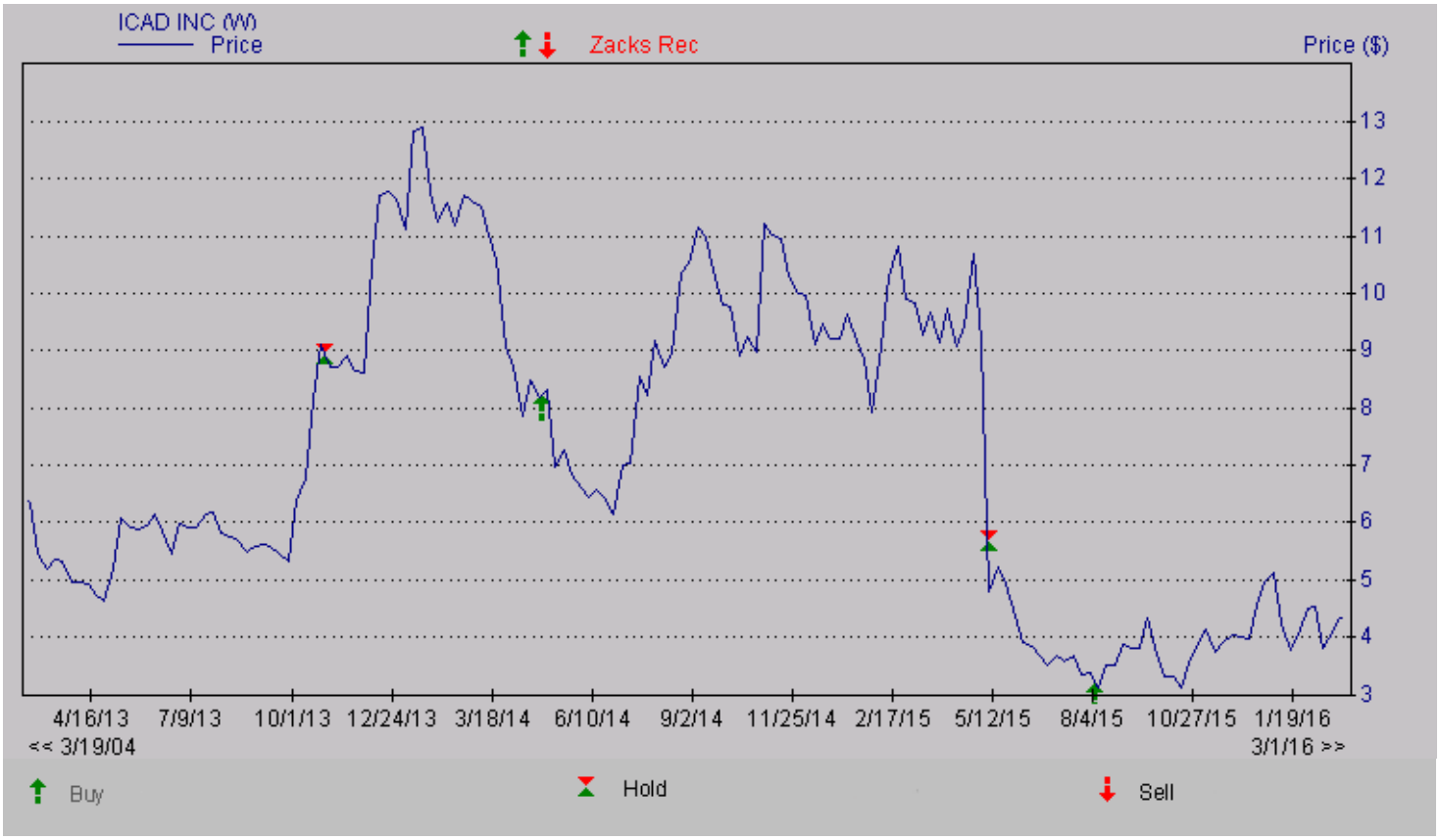
iCAD Inc.

	2015 A	Q1E	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Cancer Detection	$19,243.0	$4,252.0	$4,730.4	$5,298.3	$5,577.7	$19,858.4	$26,790.9	$33,006.5	$34,839.5
YOY Growth	*3.4%*	*-11.2%*	*-4.5%*	*1.9%*	*29.8%*	*3.2%*	*34.9%*	*23.2%*	*5.6%*
% of total revenue	*46.3%*	*57.1%*	*58.8%*	*61.4%*	*61.8%*	*59.9%*	*63.3%*	*63.8%*	*62.5%*
Therapy	$22,311.0	$3,195.0	$3,315.0	$3,335.0	$3,455.0	$13,300.0	$15,512.0	$18,710.0	$20,936.0
YOY Growth	*-11.9%*	*-62.1%*	*-46.4%*	*-23.9%*	*4.3%*	*-40.4%*	*16.6%*	*20.6%*	*11.9%*
% of total revenue	*53.7%*	*42.9%*	*41.2%*	*38.6%*	*38.2%*	*40.1%*	*36.7%*	*36.2%*	*37.5%*
Total Revenues	$41,554.0	$7,447.0	$8,045.4	$8,633.3	$9,032.7	$33,158.4	$42,302.9	$51,716.5	$55,775.5
YOY Growth	*-5.4%*	*-43.7%*	*-27.8%*	*-9.9%*	*18.7%*	*-20.2%*	*27.6%*	*22.3%*	*7.8%*
Cost of Revenues	$12,204.0	$2,314.2	$2,438.9	$2,482.0	$2,518.6	$9,753.8	$11,571.0	$13,906.4	$14,692.6
Gross Income	$29,350.0	$5,132.8	$5,606.4	$6,151.2	$6,514.2	$23,404.6	$30,731.8	$37,810.2	$41,082.9
Gross Margin	*70.6%*	*68.9%*	*69.7%*	*71.3%*	*72.1%*	*70.6%*	*72.6%*	*73.1%*	*73.7%*
R&D	$9,163.0	$2,434.0	$2,108.0	$2,081.0	$2,021.0	$8,644.0	$9,176.0	$9,575.0	$10,101.0
% R&D	*22.1%*	*32.7%*	*26.2%*	*24.1%*	*22.4%*	*26.1%*	*21.7%*	*18.5%*	*18.1%*
Selling & Mktg	$12,404.0	$2,368.2	$2,453.8	$2,590.0	$2,691.8	$10,103.7	$11,717.9	$14,015.2	$14,780.5
% Sell&Mktg	*29.9%*	*31.8%*	*30.5%*	*30.0%*	*29.8%*	*28.9%*	*27.7%*	*27.1%*	*26.5%*
G&A	$10,519.0	$2,375.0	$2,421.0	$2,501.0	$2,615.0	$9,912.0	$10,480.0	$12,191.0	$13,107.0
% G&A	*25.3%*	*31.9%*	*30.1%*	*29.0%*	*29.0%*	*29.9%*	*24.8%*	*23.6%*	*23.5%*
Operating Income	($30,179.0)	($2,044.4)	($1,376.4)	($1,020.8)	($813.6)	($5,255.1)	($642.0)	$2,029.0	$3,094.4
Operating Margin	*-72.6%*	*-27.5%*	*-17.1%*	*-11.8%*	*-9.0%*	*-15.8%*	*-1.5%*	*3.9%*	*5.5%*
Other income	($1,706.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$125.0	$0.0	$0.0
Interest income, net	($646.0)	($85.0)	($89.0)	($94.0)	($101.0)	($369.0)	($100.0)	$58.0	$121.0
Pre-Tax Income	($32,531.0)	($2,129.4)	($1,465.4)	($1,114.8)	($914.6)	($5,624.1)	($617.0)	$2,087.0	$3,215.4
Taxes	$16.0	($21.3)	($14.7)	($11.1)	($9.1)	($56.2)	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*0.1%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($32,547.0)	($2,108.1)	($1,450.8)	($1,103.6)	($905.4)	($5,567.9)	($617.0)	$2,087.0	$3,215.4
YOY Growth	*-3125.7%*	*-13.5%*	*94.8%*	*-174.5%*	*62.3%*	*82.9%*	*88.9%*	*438.2%*	*-54.1%*
Net Margin	*-78.3%*	*-28.3%*	*-18.0%*	*-12.8%*	*-10.0%*	*-16.8%*	*-1.5%*	*4.0%*	*5.8%*
EPS	($2.07)	($0.13)	($0.09)	($0.07)	($0.05)	($0.34)	($0.04)	$0.12	$0.18
YOY Growth	*-2850.6%*	*-11.1%*	*95.0%*	*-161.6%*	*64.3%*	*83.6%*	*89.2%*	*430.4%*	*-51.4%*
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)	($0.13)	($0.09)	($0.07)	($0.05)	($0.34)	($0.04)	$0.12	$0.18
Diluted Shares O/S	15,686	15,950	16,200	16,500	16,600	16,313	16,800	17,200	17,500

Brian Marckx, CFA

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HISTORICAL ZACKS RECOMMENDATIONS



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The current distribution is as follows: Buy/Outperform- 24.2%, Hold/Neutral- 52.1%, Sell/Underperform – 17.6%. Data is as of midnight on the business day immediately prior to this publication.