Zacks Small-Cap Research

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iCAD Inc (ICAD-NASDAQ)

ICAD: Disappointing Q3 But Fundamentals For Growth Remain Intact

Based on the average of the EV/S multiples iCAD is valued at $6/share. Based on the average of the P/S multiples iCAD is valued at ~$6.5/share. We use the approximate average of the two which values iCAD at about $6.25/share.

Current Price (11/03/16)	$3.30
Valuation	**$6.25**

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. Mgmt guiding for rapid re-onboarding of skin customers through YE2016 Meanwhile breast IORT remains a bright spot.

Detection remains poised to enter what we believe will be a cycle of long-term growth on the initial tomosynthesis launch. PowerLook upgrades and ICAD's breast density software which continue to perform well should remain solid contributors. 3D iReveal could launch soon and will provide another impetus to growth. 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	**$6.49**
52-Week Low	**$3.00**
One-Year Return (%)	**-16.46**
Beta	**1.14**
Average Daily Volume (sh)	**54,126**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$54**
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 (%)	**10.7**
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	7369 A	6003 A	6600 E	26010 E
2017					32934 E
2018					42336 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	-$0.10 A	-$0.17 A	-$0.17 E	-$0.60 E
2017					-$0.33 E
2018					$0.07 E

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

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Q3 2016 Results: Disappointing Financials But Fundamentals For Growth Remain Intact...

iCAD announced financial results for the third quarter ending September 30. Results were mostly disappointing with Therapy revenue turning in its worst quarter in over four years and hampered by continued lackluster NMSC procedural volumes, moderate sequential contraction in IORT consumables sales and zero Xoft system placements. The Detection business fared better from a revenue standpoint but additional delay to FDA clearance of the 3D tomosynthesis software was somewhat of spirit dampener.

But despite total revenue at the lowest level since Q2 2012 and gross margin the weakest since Q2 2013, lack of meaningful rebound in the skin business and what seems like perennial delays to U.S. regulatory clearance of what could eventually be one ICAD's biggest products to date, we believe that fundamentals for a steepening revenue curve and path towards profitability remain intact – but we expect the pace will be slightly slower than previously anticipated.

Based on management's comments on the call, the skin reimbursement environment remains encouraging and continues to facilitate the onboarding of additional dermatology practices – while that progress was less than evident in the Q3 numbers, ICAD indicates that new sites typically need ~60 – 90 days to get up to speed before they see much in the way of patient flow. As a reminder, ICAD added 17 new sites between Q1 and the end of Q2 (for a total of 35 at that time) and brought on roughly 15 more since then (for a total of ~50 today). And with each site forecast to generate ~$100k in annualized recurring revenue, we would expect to see meaningful incremental revenue in Q4 from (at least) the new sites onboarded during the first half of 2016.

Management now believes they could have ~70 sites (revised lower from 100 as of the Q2 call) under agreement (either capital purchase or solutions customers) by the end of this year. Again, the growth in the skin customer base is attributed to practitioners' increased comfort level with the reimbursement picture - which presumably includes several months of evidence of payers reimbursing under the CPT III code and at levels that are economically viable. If re-onboarding along with some new customer wins can indeed build the client base to as many as 70 sites by year-end, the annual run-rate in the first half of 2017 would be ~$7M. Assuming continued growth in the total number of sites under agreement and adding in system sales and growth in IORT, and the Therapy business could be back to being a very meaningful revenue driver. Clearly management believes there is an opportunity to quickly rebuild their customer base and noted that they have recently dedicated more sales and marketing resources towards that endeavor.

As we noted in our prior update, while we continue to think Therapy begins to make a more significant contribution, we are hesitant to jump back in with both feet given the potential for ongoing lack of clarity on the robustness of eBx skin reimbursement. We would view growth in the new skin customer base (as opposed to just legacy customers coming back online) - whether it be solutions or capital purchase customers - as a particularly favorable trend given the presumed due diligence relative to reimbursement that new customers would perform prior to entering the market. Certainly growth in Axxent system sales (i.e. customer putting significant capital at risk) related to skin would be a particularly positive sign and one which we think could likely be interpreted as providers being confident that the reliability and level of reimbursement is acceptable. However, for at least the near-term, we expect most new customer wins will likely come as solutions customers.

IORT has been, at least as of late, much more stable than that of skin. While IORT balloon sales in Q3 were flat compared to Q3 2015 and down by about 15% sequentially, through the first nine months of 2016 they grew 21% compared to the same period in 2015. International sales continue to be the main impetus to IORT consumables growth although the U.S. remains the most significant market in terms of total sales. Internationally, balloon volumes grew 21% and 33% yoy in the three and nine months ending September 30, 2016 and accounted for 44% of total unit IORT balloon unit sales in Q3. Meanwhile, U.S. balloon volumes contracted 13% and grew 15% over the same periods and accounted for 56% of total balloon unit sales in Q3. And while U.S. balloon volumes in Q3 (202 units) were also down from the 283 in Q1 and 425 in Q2 of this year, we continue to believe that clinical evidence supporting the use of the procedure should help to buoy the opportunity for domestic market growth. Meanwhile, we also expect international growth to continue – which should be further catalyzed by ICAD's impending entry into new overseas territories including China, Saudi Arabia, India and Egypt.

Relative to the Detection business, Q3 product revenue surprised on the low-side – coming in well below our number ($2.5M E vs. $2.0M A). But, to be fair, we attribute most of the 'miss' to a modeling error on our part. We reiterate that while mammography, including PowerLook upgrades and iReveal, has performed very well as of late

and Q2 included the first sale of the breast tomo product in Europe, we are modeling roughly flat sequential growth of Detection until the 3D tomosynthesis software gains FDA clearance and launches in the U.S. This could prove conservative, particularly if the pace of the ongoing roll-out of 3D tomo in Europe exceeds our expectations. Nonetheless, we continue to expect significant steepening of Detection product sales in 2017 on the back of the initial 3D tomo product in the U.S.and expected initial contribution from the next-gen tomo product.

Other near-term catalysts in Detection include iReveal 3D (510k filed in early November), expected to launch in the coming months, and potentially VeraLook (CTC) which could see increasing demand as a result of inclusion of virtual colonoscopy on USPSTF's recent recommendations for colon cancer screening. This should immediately and significantly improve availability of reimbursement for CTC, the prior widespread lack of (CTC reimbursement had previously been mandated in only 22 states) which was an impediment to uptake of the procedure.

Revenue
Q3 revenue of $6.0M (vs. $7.6M estimate) was down 37% yoy and down 19% sequentially

- **Cancer Detection(Q3):** $4.1M (vs. $4.9M estimate): -21% yoy, -16% 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 yoy decline in Detection revenue since Q3 2015.

    In July 2015 ICAD announced the launch of iReveal breast density software, the latest addition to the PowerLook line. The timing was good as at the time almost one-half of all states already enacted some form of legislation supporting breast density screening. Today that number is 28 states and more are 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. ICAD is also developing iReveal 3D - expected to be available later this year or early next and able to integrate with the 3D tomo products, it provides another growth opportunity.

    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. Initial sale in Europe of the 3D breast tomosynthesis product came in Q2. 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 could happen by early 2017.

    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 and noted on the Q3 call that FDA responded in October with additional questions. Management noted that the questions do not relate to performance demonstrated in the reader study but instead a specific portion of the study protocol. ICAD provided a detailed description of the "issue" on the Q3 call we feel comfortable that this is not a performance issue or even necessarily a violation of trial design or protocol. ICAD and FDA have a meeting set for ~mid-November to further discuss this, and in which the company will provide a response to the agency's questions. While we no insight into the length of delay that this may cause, we now model an assumed launch in the U.S. of the 3D tomo software in Q2 2017 – a slight delay from our prior assumption of Q1 of next year.

    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 around mid-2017, 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 is 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 or early 2017 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 look for Detection to turn in roughly flat growth in Q4 and decline about 10% for the full year 2016 but for this to steepen to ~24% growth in 2017 when we think there will be initial contribution from tomo in the U.S. Upside to our estimates could come from a more rapid roll-out of tomo in Europe, early introduction than what we expect in the U.S. and/or meaningful uptick in demand for VeraLook as a result of the favorable USPSTF recommendation.

- **Cancer Therapy (Q3):** $1.9M (vs. $2.6M estimate): -57% yoy, -24% sequentially

The non-melanoma skin cancer reimbursement issue looked to have taken its biggest toll in Q1 of this year since it first began to impact Therapy revenue back in Q2 2015. Management noted on the Q1 call that they believed that there was 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.

While there was little evidence of financial progress related to skin in the Q2 and Q3 numbers, management has indicated that the groundwork has already started including making progress in restarting skin sites and attracting new customers. And with a typical 2 - 3 month lag between when a site goes live and when it shows up in ICAD's revenue, expectations are that the recent growth in the customer base should show up in the income statement later this year. Clearly the fact that they have almost tripled the number of skin sites that have come back onboard between Q1 and the end of Q3 (from 17 to ~50) is an encouraging sign that skin's worst days may be in the rearview mirror.

ICAD thinks the onboarding pace will accelerate and believes that they will have up to 70 sites under agreement by year-end. Management attributes the recent and expected continued acceleration in bringing skin sites back onboard to practitioners' increased comfort level with the reimbursement picture - which presumably includes several months of evidence of payers reimbursing under the CPT III code and at levels that are economically viable.

Management estimates each skin site, on average, should generate $100k in annual recurring revenue. If re-onboarding along with some new customer wins can indeed build the client base to as many as 70 sites by year-end, the annual run-rate in the first half of 2017 would be ~$7M. Assuming continued growth in the total number of sites under agreement and adding in system sales and growth in IORT, and the Therapy business could be back to being a very meaningful revenue driver.

As we noted in our prior update, while we continue to think Therapy begins to make a more significant contribution, we are hesitant to jump back in with both feet given the potential for ongoing lack of clarity on the robustness of eBx skin reimbursement. We would view growth in the new skin customer base (as opposed to just legacy customers coming back online) - whether it be solutions or capital purchase customers - as a particularly favorable trend given the presumed due diligence relative to reimbursement that new customers would perform prior to entering the market. Certainly growth in Axxent system sales (i.e. customer putting significant capital at risk) related to skin would be a particularly positive sign and one which we think could likely be interpreted as providers being confident that the reliability and level of reimbursement is acceptable. However, for at least the near-term, we expect most new customer wins will likely come as solutions customers.

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. ICAD noted on the Q2 call that the SMART solution is indeed providing efficiencies and margin growth.

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. If all goes well, ICAD believes they could have the data published next year and submitted to CMS in June 2017 in support of a CPT I application.

Part of our expected rebound in Therapy relates to growth in the skin business. The other catalyst in Therapy is IORT. IORT has been, at least as of late, much more stable than that of skin. International sales continue to be the main impetus to IORT consumables growth although the U.S. remains the most significant market in terms of total sales. And while U.S. balloon volumes in Q3 (202 units) were also down from the 283 in Q1 and 425 in Q2 of this year, we continue to believe that clinical evidence supporting the use of the procedure should help to buoy the opportunity for domestic market growth. Meanwhile, we also expect international growth to continue – which should be further catalyzed by ICAD's impending entry into new overseas territories including China, Saudi Arabia, India and Egypt.

In addition, three of the four Axxent system sales in Q2 were for IORT. ICAD's success in building their IORT business has been to drive sales in the U.S. on the back of positive clinical data and to continue to expand internationally. They will continue that strategy, with data from ongoing studies expected to be available in the near term. 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 shortly. 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

Model Updates

We have made updates to our financial model following Q3 results – most of which relates to incorporating a slight 'delay' to both the assumed rebound in Therapy (mostly related to the ramp in new skin sites) as well as initial introduction of 3D tomo in the U.S. (as a result of delay to assumed FDA clearance).

We have Therapy revenue falling by 61% in 2016 (revised from a 52% contraction) as gains in IORT breast are more than offset by weakness (albeit dissipating weakness) in NMSC. Expect to have more clarity on the reimbursement picture as well as onboarding and restarting new customer sites in the coming months as the dynamics play out.

We have total revenue of $26M in 2016 – implying a decrease of 37% from 2015 – but the majority of the contraction relates to the first nine months with Q4 showing a relatively smaller contraction of 13%. We think the turnaround in both Therapy and Detection is much more robust in 2017.

ICAD was quick to cut costs following revelation of the NMSC reimbursement change. We have OpEX at about $7.3M in Q4. ICAD used ~$900k in cash for operations in Q3 and exited the quarter with $10.5M in cash. Management noted on the Q3 call that they continue to make progress with a potential sale of their MRI business and believe they will have a deal consummated later this year or early next. If that happens, it would further strengthen the balance sheet.

We model 2016 EPS of ($0.60).

VALUATION

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 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 3.4x and P/S-2017 of 3.1x and average EV/S-2016 of 3.2x and EV/S-2017 of 3.0x.

Based on the average of the EV/S multiples iCAD is valued at $6/share. Based on the average of the P/S multiples iCAD is valued at ~$6.5/share. We use the approximate average of the two which values iCAD at about $6.25/share.

FINANCIAL MODEL

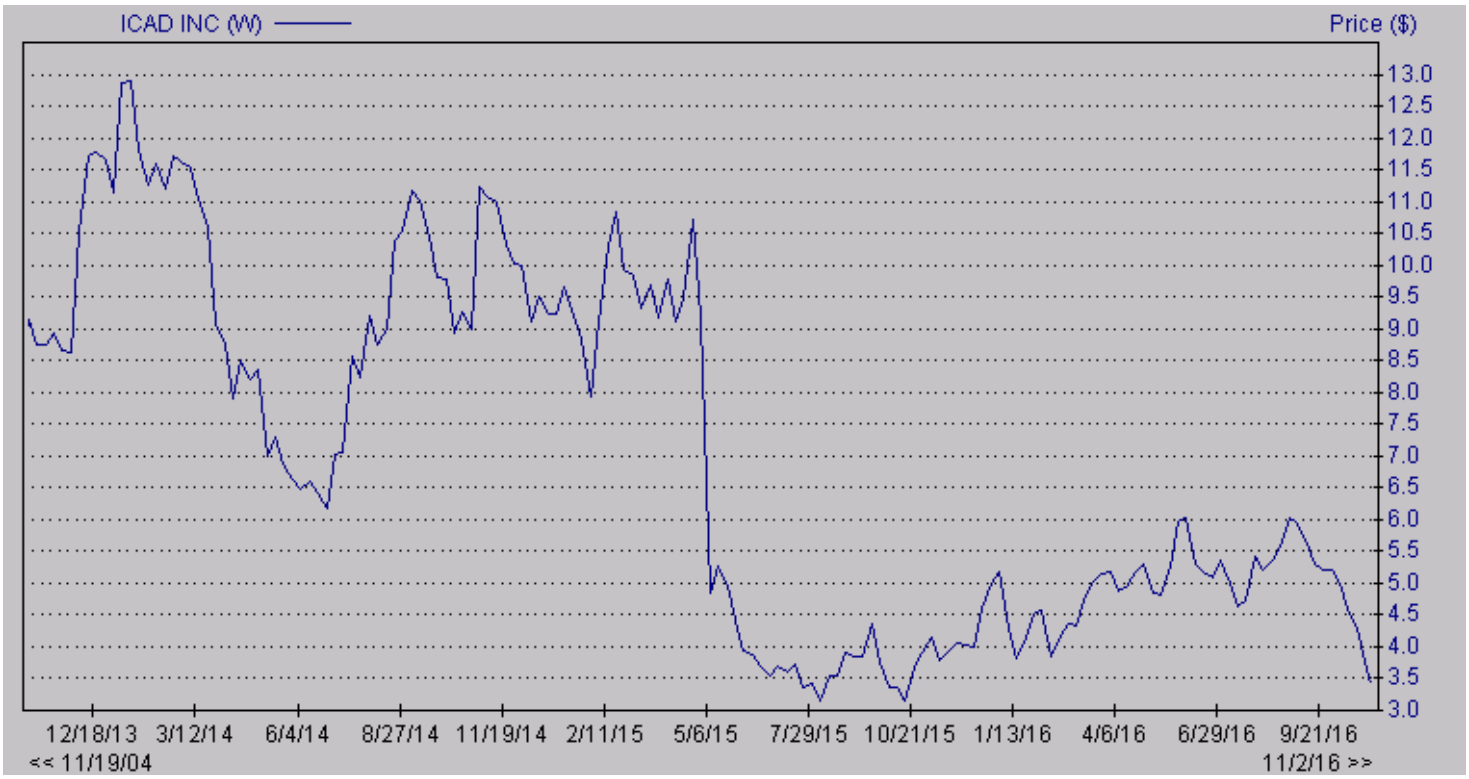
iCAD Inc.

	2015 A	Q1A	Q2A	Q3A	Q4E	2016 E	2017 E	2018 E	2019 E
Cancer Detection	$19,243.0	$3,930.0	$4,897.0	$4,134.0	$4,250.0	$17,211.0	$21,306.7	$28,163.3	$32,164.7
YOY Growth	*3.4%*	*-17.9%*	*-1.2%*	*-20.5%*	*-1.1%*	*-10.6%*	*23.8%*	*32.2%*	*14.2%*
% of total revenue	*46.3%*	*65.1%*	*66.5%*	*68.9%*	*64.4%*	*66.2%*	*64.7%*	*66.5%*	*63.2%*
Therapy	$22,311.0	$2,108.0	$2,472.0	$1,869.0	$2,350.0	$8,799.0	$11,627.0	$14,173.0	$18,715.0
YOY Growth	*-11.9%*	*-75.0%*	*-60.1%*	*-57.3%*	*-29.0%*	*-60.6%*	*32.1%*	*21.9%*	*32.0%*
% of total revenue	*53.7%*	*34.9%*	*33.5%*	*31.1%*	*35.6%*	*33.8%*	*35.3%*	*33.5%*	*36.8%*
Total Revenues	$41,554.0	$6,038.0	$7,369.0	$6,003.0	$6,600.0	$26,010.0	$32,933.7	$42,336.3	$50,879.7
YOY Growth	*-5.4%*	*-54.3%*	*-33.9%*	*-37.4%*	*-13.3%*	*-37.4%*	*26.6%*	*28.6%*	*20.2%*
Cost of Revenues	$12,204.0	$1,852.0	$1,667.0	$1,902.0	$2,064.8	$7,485.8	$8,980.4	$11,017.6	$13,026.2
Gross Income	$29,350.0	$4,186.0	$5,702.0	$4,101.0	$4,535.3	$18,524.3	$23,953.3	$31,318.7	$37,853.5
Gross Margin	*70.6%*	*69.3%*	*77.4%*	*68.3%*	*68.7%*	*71.2%*	*72.7%*	*74.0%*	*74.4%*
R&D	$9,163.0	$2,271.0	$2,204.0	$2,360.0	$2,420.0	$9,255.0	$9,288.0	$9,575.0	$10,101.0
% R&D	*22.1%*	*37.6%*	*29.9%*	*39.3%*	*36.7%*	*35.6%*	*28.2%*	*22.6%*	*19.9%*
Selling & Mktg	$12,404.0	$2,496.0	$2,561.0	$2,322.0	$2,475.0	$9,854.0	$10,571.7	$12,065.8	$13,635.8
% Sell&Mktg	*29.9%*	*41.3%*	*34.8%*	*38.7%*	*37.5%*	*37.9%*	*32.1%*	*28.5%*	*26.8%*
G&A	$10,519.0	$1,912.0	$2,470.0	$2,071.0	$2,388.0	$8,841.0	$9,655.0	$10,864.0	$11,744.0
% G&A	*25.3%*	*31.7%*	*33.5%*	*34.5%*	*36.2%*	*34.0%*	*29.3%*	*25.7%*	*23.1%*
Operating Income	($30,179.0)	($2,493.0)	($1,533.0)	($2,652.0)	($2,747.8)	($9,425.8)	($5,561.4)	($1,186.1)	$2,372.7
Operating Margin	*-72.6%*	*-41.3%*	*-20.8%*	*-44.2%*	*-41.6%*	*-36.2%*	*-16.9%*	*-2.8%*	*4.7%*
Other income	($1,706.0)	$4.0	$2.0	$2.0	$2.0	$10.0	$125.0	$0.0	$0.0
Interest income, net	($646.0)	($22.0)	($21.0)	($15.0)	($18.0)	($76.0)	($100.0)	$58.0	$121.0
Pre-Tax Income	($32,531.0)	($2,511.0)	($1,552.0)	($2,665.0)	($2,763.8)	($9,491.8)	($5,536.4)	($1,128.1)	$2,493.7
Taxes	$16.0	$22.0	$23.0	$10.0	$27.6	$82.6	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*-0.9%*	*-1.5%*	*-0.4%*	*-1.0%*	*0.1%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($32,547.0)	($2,533.0)	($1,575.0)	($2,675.0)	($2,791.4)	($9,574.4)	($5,536.4)	($1,128.1)	$2,493.7
YOY Growth	*-3125.7%*	*-36.4%*	*94.4%*	*-565.4%*	*-16.2%*	*70.6%*	*42.2%*	*79.6%*	*321.1%*
Net Margin	*-78.3%*	*-42.0%*	*-21.4%*	*-44.6%*	*-42.3%*	*-36.8%*	*-16.8%*	*-2.7%*	*4.9%*
EPS	($2.07)	($0.16)	($0.10)	($0.17)	($0.17)	($0.60)	($0.33)	($0.07)	$0.14
YOY Growth	*-2850.6%*	*-34.5%*	*94.4%*	*-555.7%*	*-14.6%*	*71.0%*	*45.2%*	*80.1%*	*317.3%*
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)	($0.10)	($0.17)	($0.17)	($0.60)	($0.33)	($0.07)	$0.14
Diluted Shares O/S	15,686	15,826	15,904	15,957	15,960	15,912	16,800	17,200	17,500

Brian Marckx, CFA

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