March 11, 2013

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Chembio Diagnostics Inc. (CEMI- NASDAQ)

CEMI: Q4 2012: DPP Revenue Up 70%. Lateral Flow Sales Post Gains Both Domestically and Int'ly

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (03/11/13)	$5.45
Target Price	**$10.80**

OUTLOOK

Lateral flow sales should buoy revenue. Alere taking market share in the U.S. and recent recommendations on HIV testing should aid U.S. sales. Int'l lateral flow sales were very strong in Q4 and could continue to post gains as CEMI is focused on growing this business - fruits of which are already being seen. This should help offset an expected decline in FIOCRUZ sales in 2013.

Pipeline progress continues and was highlighted by FDA approval of DPP HIV test in December. U.S. launch could happen late-2013/early-2014 which will be a very meaningful milestone. Syphilis test and HIV/syphilis combo test are also in the pipeline, as is a potentially pursuit of OTC approval of the company's (blood sample) lateral flow test.

Cash position and the balance sheet remain very healthy.

We are maintaining our Outperform rating.

SUMMARY DATA

52-Week High	**$5.71**
52-Week Low	**$3.60**
One-Year Return (%)	**44.13**
Beta	**0.03**
Average Daily Volume (sh)	**44,222**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$45**
Short Interest Ratio (days)	**0.41**
Institutional Ownership (%)	**18**
Insider Ownership (%)	**17**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**22.9**
Earnings Per Share (%)	**11.1**
Dividend (%)	**N/A**
P/E using TTM EPS	**32.1**
P/E using 2013 Estimate	**21.8**
P/E using 2014 Estimate	**12.4**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Blend**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(millions)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	$6.65 A	$6.08 A	$5.01 A	$7.87 A	$25.61 A
2013	$7.47 E	$6.39 E	$5.81 E	$6.93 E	$26.60 E
2014					$32.94 E
2015					$30.63 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	$0.08 A	$0.06 A	-$0.06 A	$0.08 A	$0.17 A
2013	$0.09 E	$0.07 E	$0.03 E	$0.06 E	$0.25 E
2014					$0.44 E
2015					$0.51 E

Zacks Projected EPS Growth Rate - Next 4 Years % **28**

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WHAT'S NEW

Q4 2012: *DPP Revenue Up 70%. Lateral Flow Sales Post Gains Both Domestically and Int'ly and Indications On the Conf Call Is That This Lateral Flow Sales Trend May Continue…*

Chembio capped 2012 with another very strong quarter with Q4 setting a new all-time revenue record which helped push full year revenue up 32%. Q4 was cash flow positive (ex changes in working cap) and CEMI's balance sheet remains solid.

All the major product segments posted yoy sales gains in Q4 as well as for the full fiscal year. DPP sales to FIOCRUZ remained on a tear, up 70% in Q4 and +137% for the year. Perhaps even a bigger highlight (and a bigger % upside surprise to our Q4 modeled revenue) in terms of revenue in Q4 was rebounded strength in lateral flow sales - both domestically and internationally. Management indicated on the call that market share gains by Alere, combined with the potential benefits of recent recommendations by the U.S. Preventative Services Task Force (USPSTF) relative to routine HIV testing bode well for continued revenue growth of the domestic lateral flow products. We had already baked at least some of that into our model, however, more of a wildcard in terms of forecasting out sales of the lateral flow products has been to international markets - sales of which dipped 17% in 2011 and were up just 2% in 2012. Management noted on the call that they've recently focused more efforts on jumpstarting growth in this business, including expanding distribution, which has started dividends - specifically pointing to a recent large order to a U.N. agency related to a national testing program. Expectations are that both domestic and international lateral flow sales will continue to grow.

On the operational side, the major highlight during Q4 was the announcement in December that the FDA approved CEMI's DPP HIV 1/2 test for blood and oral fluid samples. The next step will be to obtain CLIA waiver to allow the test to be sold to the POC market. CEMI expects to have the related trials complete and the CLIA waiver package submitted around the middle of 2013. If all goes to plan the test will roll out in late 2013 or early 2014, supported by a small internal sales force (targeting the public health market) as well as via distributors (targeting hospitals and physician offices).

And as we detail below, CEMI continues to make progress on several of their pipeline products including the high-potential DPP Syphilis Screen and Confirm test as well as the DPP HIV/Syphilis test.

Q4 / Full-Year 2012 Financial Results
2012 revenue of $25.6 million was up 32% and was an all-time record. About 94% of the $6.2 million increase in revenue from 2011 to 2012 came from DPP product sales to FIOCRUZ. As we've noted in the past, as the DPP product portfolio represents a major catalyst to CEMI's potential mid-to-long term growth (in the U.S. and other countries), the recent strong performance of these products is an obvious positive. 2012 GAAP and adjusted EPS were $0.11 and $0.17, compared to $0.74 and $0.13 in 2011.

Q4 revenue of $7.86 million (+27%) beat our $7.25 million number by about 9%, with both domestic and international lateral flow as well as DPP product sales beating our estimates. Meanwhile, non-product revenue (R&D contracts, grants, milestones) of $458k was about dead-on with our number.

Sales of the company's lateral flow products to Alere increased 4% yoy and 59% sequentially to $1.9 million compared to our $1.5 million estimate. As noted, market share gains by Alere have recently helped buoy sales which, along with new HIV testing recommendations should provide a catalyst to further growth. International lateral flow sales were up 12% yoy and +162% sequentially to $2.6 million compared to our $2.5 million estimate. International sales benefitted from a ~$3 million order, about $1.8 million of which was booked during the quarter (the remainder should hit Q1 2013). The order appears to be a direct result of CEMI's renewed efforts on growing this business which includes expanding their distribution base. DPP sales remained very strong in Q4, up 70% yoy, up 11% sequentially and 9% better than our $2.6 million estimate. This level of DPP sales may not repeat in 2013, however.

As a reminder, the majority of DPP sales to-date have been to FIOCRUZ related to a technology transfer agreement for five DPP tests (HIV, HIV confirm, syphilis, leishmaniasis, and leptospirosis) . Per terms of the agreement, FIOCRUZ is obligated to purchase a total of $23MM worth (each test has a minimum purchase amount assigned) before the technology is transferred to FIOCRUZ - at that point FIOCRUZ can take ownership for the Brazil market and CEMI will receive a royalty on sales. FIOCRUZ may purchase significantly more than the $23

million and substantially exceeded the minimums under an earlier tech transfer agreement. Through the end of 2012 we estimate FIOCRUZ had purchased ~$14+ million. As we noted in prior updates, we had expected FIOCRUZ to meet its minimum purchase quota around the end of 2013 - which remains our assumption, but not take ownership of manufacturing until 2015. CEMI notes in their recent 10-K that FIOCRUZ recently notified them that scale-up in Brazil's national HIV and syphilis testing programs is going slower than had been expected. CEMI notes that this will likely result in lower DPP related revenue from FIOCRUZ in 2013 compared to 2012 (2012 FIOCRUZ DPP revenue was ~$10MM). As such we have since trimmed our FIOCRUZ related revenue contribution for 2013.

Q4 Operating expenses were about 6% higher than our numbers but as a percentage of revenue (31% A vs. 32% E) were slightly better than our estimate.

EPS
We use adjusted net income and EPS for consistency purposes. As a reminder, in Q4 2011 CEMI took a non-cash gain of $5.16 million to income from the reversal of deferred tax asset as they expected to generate positive pre-tax income from that point forward. Their GAAP income tax rate of ~39.7% is 90% non-cash until they exhaust (which, based on our current model will occur sometime in 2015) their entire deferred tax asset which stood at $4.2 million at the end of 2012. Q4 adjusted net income and EPS of approximately $697k and $0.08 were just about dead-on with our $682k and $0.08 estimates.

Cash
Excluding changes in working capital (which included a spike in A/R related to the large int'l order and an increase in inventory), cash from operations was an inflow of $929k in Q4 and $2.3 million for the full year 2012. Chembio exited 2012 with $2.95 million in cash and equivalents and relatively immaterial debt.

Business / Pipeline Update

DPP HIV, U.S.
FDA approval for all sample types (oral fluid, whole blood, serum, and plasma) came in December. Studies to support CLIA waiver are expected to start in March and an FDA submission to happen by July. CLIA waiver and launch could happen by late 2013 or early 2014.

In clinical studies the product has shown to have superior performance to OraSure's oral fluid test as well as other rapid HIV tests using blood samples. CEMI's DPP HIV test's FDA approved label includes claims of sensitivity/specificity on oral fluid and whole blood of 98.9%/99.9% and 99.9%/100%, respectively. Oral fluid sensitivity was 100% among patients not on anti-retroviral medication.

Certain advantages of CEMI's DPP HIV product, including superior performance, long shelf-life, broader label including approved for patients 2 years and older (versus 13 yrs and older with competitors'), and earlier detection on serum samples should bode well for it competing against OraSure's oral fluid rapid HIV test. CEMI's plan for selling the test includes detailing to the public health sector with its own (very small) sales force as well as through distributors to target hospitals and physicians' offices. We model the test to launch in early 2014 (which may be slightly more conservative than management's expectations).

DPP HIV®1/2 Assay: FDA-Approved December, 2012

Clinical Trial Performance Data on Finger Stick Whole Blood and Oral Fluid



Diagnostic Accuracy of the POC DPP HIV 1/2 Assay

Country *Specimen Type*	Reference Positive	No. of Positive	Sensitivity, % (95% CI)	Reference Negative	No. of Negative	Specificity, % (95% CI)
Mozambique						
Oral Fluid	516	516	100 (99.3-100.0)	1157	1157	100 (99.7-100)
Nigeria						
Oral Fluid	225	225	100 (98.4-100.0)	420	420	100 (99.1-100.0)
Fingerstick Whole Blood	225	225	100 (98.4-100.0)	418	418	100 (99.1-100.0)
United States						
Oral Fluid	963	953	98.9 (98.1-99.5)	1816	1815	99.9 (99.7-99.9)
Fingerstick Whole Blod	963	962	99.9 (99.4-99.9)	1815	1815	100 (99.8-100.0)

Sensitivity of the POC DPP HIV 1/2 Assay with Oral Fluid Specimens from Persons with a Previous Diagnosis of HIV Infection

	Known HIV-1 infected persons taking antiretroviral medication			Known HIV-1 infected persons NOT taking antiretroviral medications		
Country	n	No. of Positive	Sensitivity, % (95% CI)	n	No. of Positive	Sensitivity, % (95% CI)
Nigeria	129	129	100 (97.2-100.0)	86	86	100 (95.8-100.0)
United States	731	723	98.9 (97.9-99.5)	137	137	100 (97.3-100.0)
Total	860	852	99.1 (98.2-99.6)	223	223	100 (98.4-100.0)

Analytical Data Show Detection of Sero-conversion Samples Earlier than all FDA Approved Lateral Flow HIV Tests

SOURCE: Chembio's Jan 2013 Investor Presentation

DPP Syphilis Screen and Confirm

Syphilis Screen and Confirm (treponemal / non-treponemal) test was CE Marked in Europe in early October 2011. CEMI noted that during Q2 they established distribution for the test in the U.K.

Relative to the road to FDA approval, CEMI now believes the data they have, which includes data from a multi-site study done in China with over 3,000 samples and published late last year online in the journal Clinical Infectious Diseases (link: http://cid.oxfordjournals.org/content/early/2012/10/29/cid.cis928.abstract) provides significant support to reinitiate clinical trials in their quest to gain 510(k) clearance from the FDA. CEMI submitted the additional data to the FDA and the regulator responded in February. CEMI will meet with the agency this month to go over some questions related to the FDA's response. CEMI noted on the call that they have already identified 3 study sites and drafted contracts related to the studies - clearly indicating that they expect the FDA to give the green light to run the studies to support 510(k) clearance. CEMI hopes to commence the studies in April or May, submit the 510(k) application by end of Q3 and have FDA clearance by mid-2014.

We think CEMI's DPP POC syphilis screen and confirm test could have significant appeal given that it would be the first POC treponemal/non-treponemal test on the market with accuracy competitive to lab tests. The test would potentially draw significant demand overseas as well, particularly in developing countries where infectious diseases (including HIV and syphilis) can be overly problematic. Our model assume the test launches in the U.S. in late 2014.

DPP HCV

Chembio is now even more focused on development of a competitive DPP hepatitis C test following the recently released draft recommendation by the CDC that all Americans ages 45 - 65 be tested for the virus as well as independent data published in the Journal of Virology which indicated relatively high accuracy of CEMI's HCV test (see our June 19 Investor Note).

Chembio efforts relative to DPP HCV have most recently focused on improving upon accuracy and competitiveness compared to rapid HCV tests already on the market. Chembio is now looking at including antigen detection on top of antibody detection. All the rapid HCV tests currently on the U.S. market are all antibody tests, which can fail to detect the virus especially in the early stages of the disease when antibody presence is low.

In Q3 CEMI completed an initial feasibility study on proprietary antigens and had been awaiting additional proprietary materials to further improve the performance of their initial DPP HCV test (the initial test was used in the

study cited in The Journal of Virology article) compared to competitive products. CEMI has since received these and is continuing with development of the test.

Assuming development continues with positive results, CEMI believes clinical trials could commence in early 2014.

We note that we had removed a DPP HCV test from our model in early 2011 when it looked like CEMI may abandon the program. While we still do not model the test, we will revisit this depending on how things progress.

DPP Syphilis / HIV Combo

CEMI still looking at opportunities in international markets for the test including donor-funded pre-natal testing programs in emerging markets aimed at mother to child transmission. CEMI has submitted the test to the CDC and the World Health Organization accepted it for prequalification in their global procurement scheme.

Relative to the FDA approval pathway, CEMI hopes to submit a guidance request to the FDA in the near-term. Given that the HIV portion of this test is the same as the one approved by the FDA in December, the expectation is that CEMI can use the data from the syphilis studies (to begin April/May) to support the syphilis part of the test.

OTC HIV

CEMI had been waiting for FDA's decision on OraSure's OTC HIV test before going full-bore on their OTC HIV program. In early July the FDA approved OraSure's OraQuick over-the-counter rapid HIV. The test, which uses an oral swab (saliva) as the sample and is basically identical to the test sold to the clinical market, is the first HIV test to be approved for home use.

FDA's decision essentially green-lighted CEMI's move to proceed with their home-use HIV test. Chembio continues to evaluate the OTC market size and opportunity and will proceed cautiously before committing to expensive clinical trials to gain OTC approval of their Sure Check rapid HIV test, which is already FDA approved for the clinical market. The design, scope, size and cost of CEMI's OTC program are yet to be nailed down but Chembio has almost certainly reviewed the path that OraSure already paved and can use that as (at least) a rough guide for what to expect to gain FDA approval. They will also have the advantage of seeing exactly how well OSUR's test sells and the demand for OTC HIV testing.

Chembio expects to submit an IDE to the FDA in the near-term. Assuming it's granted (which we expect it to be), CEMI can then work towards their clinical trials. It's difficult to gauge the scope of the development program that CEMI will need to follow but for reference, OraSure enrolled ~5,800 people in its final clinical trial. We think it's probably safe to assume that this will be a multi-year and multi-million dollar endeavor. As it is now, we assume FDA approval will not happen prior to the out-year (2015) of our model but our model does now include (best-guess) development/regulatory expenses beginning in 2013 related to the OTC HIV program. CEMI may also look to partner - we will update our assumptions as necessary. If, however, CEMI determines that the market opportunity does not warrant an investment in pursuing OTC approval, we will update our model accordingly.

We think, if and when Chembio gets regulatory approval for and launches their OTC HIV test, it can be very competitive to OraSure's OTC test, particularly on performance. We also note that FDA approved OSUR's OraQuick OTC test, despite seemingly low (~92%) sensitivity when administered by consumers (as opposed to by doctors). This low sensitivity is likely in CEMI's sights and we think that if they can show better performance, that would be a very compelling message when the product rolls out. We do note that OSUR's test uses an oral swab as the sample, whereby CEMI's current Sure Check uses blood. Assuming equal performance, oral swab would be considered an advantage from an ease and comfort of administration basis - but this advantage could be potentially largely negated with superior performance. For obvious reasons, FDA and physicians (and consumers) have serious concerns relative to accuracy of HIV home tests - oral swab versus blood sampling may be a relatively benign convenience gap if CEMI's test shows greater accuracy.

OUR OUTLOOK

Revenue

We now look for 2013 revenue of $26.6 million, which is adjusted down from $29.4 million prior to Q4 results - largely due to trimming our FIOCRUZ related contribution (as detailed above). While we now model DPP sales to contract in 2013, total revenue should still grow given expected continued strength in domestic lateral flow sales and what we think could be a better than previously anticipated showing from international lateral flow sales.

As we have previously, we continue to use the assumption that FIOCRUZ will meet their purchasing quota in 2013, although we have absolutely no insight into when to expect that FIOCRUZ will begin to manufacture the products. We also continue to use beginning of 2015 as a placeholder for this to occur. Our model reflects this and is the reason we have 2015 revenue falling ~7% - we also model some trimming in expenses which somewhat mutes the impact to the bottom line.

Net Income / EPS

We model adjusted net income and EPS of $2.1 million and $0.25 in 2013, compared to $1.4 million and $0.17 in 2012.

RECOMMENDATION / VALUATION

We continue to believe that CEMI trades significantly cheaper than warranted. We value CEMI using 3.5x our estimated 2013 revenue which values the company at approximately $10.80/share. We are maintaining our Outperform rating.

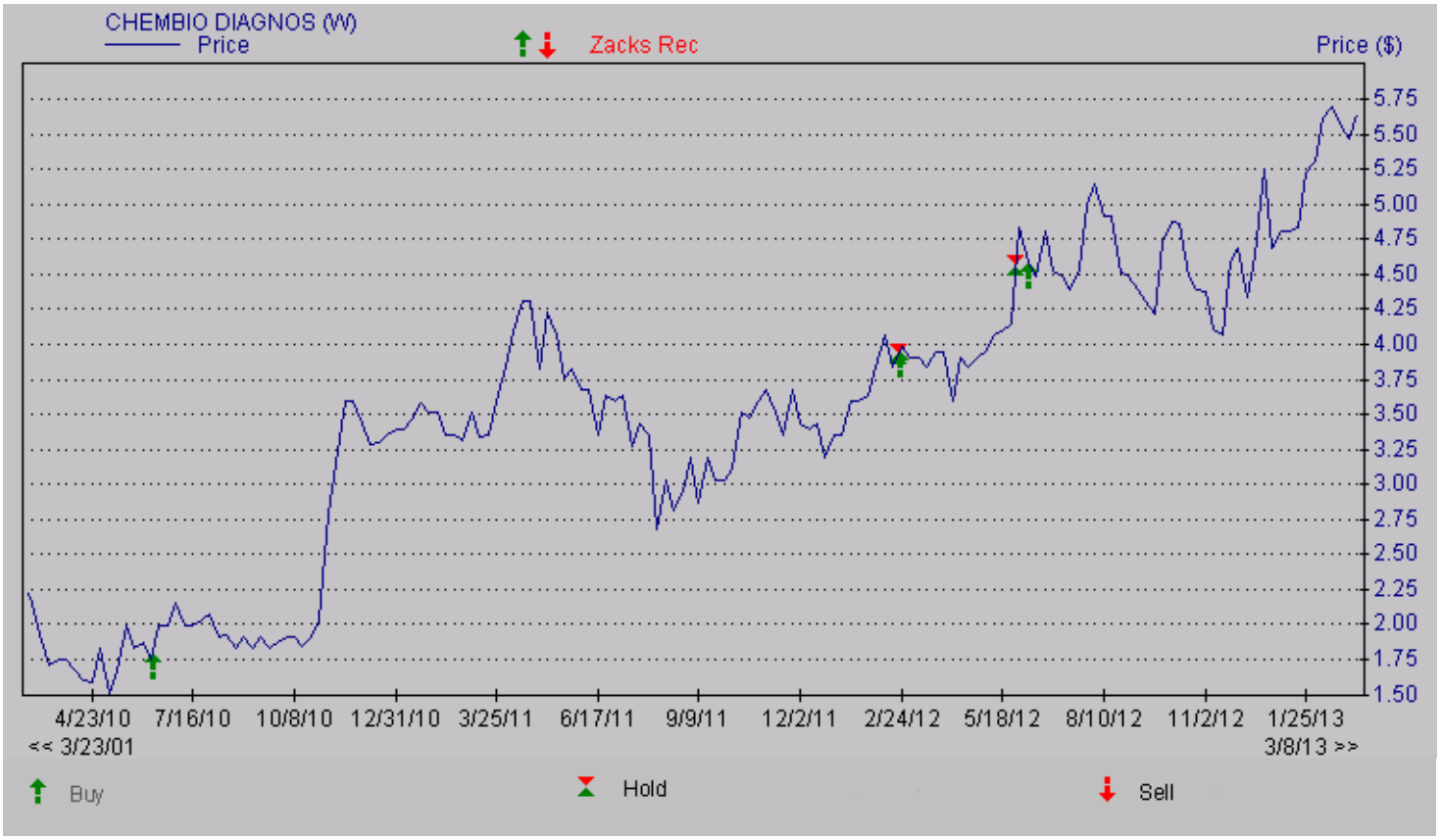
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2012 A	Q1E	Q2E	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
Product sales	**$24,327**	**$7,068**	**$5,978**	**$5,452**	**$6,554**	**$25,052**	**$31,665**	**$28,591**	**$34,560**
% of total revenue	*95.0%*	*94.6%*	*93.6%*	*93.8%*	*94.6%*	*94.2%*	*96.1%*	*93.3%*	*94.8%*
YOY Growth	*39.6%*	*11.1%*	*2.9%*	*14.9%*	*-11.5%*	*3.0%*	*26.4%*	*-9.7%*	*20.9%*
License & royalty income	**$0**	**$0**	**$8**	**$12**	**$16**	**$36**	**$75**	**$613**	**$613**
% of total revenue	*0.0%*	*0.0%*	*0.1%*	*0.2%*	*0.2%*	*0.1%*	*0.2%*	*2.0%*	*1.7%*
R&D contracts, grants, milestones	**$1,283**	**$402**	**$400**	**$350**	**$355**	**$1,507**	**$1,200**	**$1,425**	**$1,300**
% of total revenue	*5.0%*	*5.4%*	*6.3%*	*6.0%*	*5.1%*	*5.7%*	*3.6%*	*4.7%*	*3.6%*
Total Revenues	$25,610.5	$7,470.0	$6,386.0	$5,814.0	$6,925.0	$26,595.0	$32,940.0	$30,628.8	$36,473.1
YOY Growth	*32.1%*	*12.3%*	*5.0%*	*16.1%*	*-12.0%*	*3.8%*	*23.9%*	*-7.0%*	*19.1%*
Cost of Revenues	$14,820	$4,304	$3,515	$3,266	$4,011	$15,096	$17,986	$15,439	$18,317
Gross Income	$10,790	$3,166	$2,871	$2,548	$2,914	$11,499	$14,954	$15,190	$18,156
Gross Margin	*42.1%*	*42.4%*	*45.0%*	*43.8%*	*42.1%*	*43.2%*	*45.4%*	*49.6%*	*49.8%*
Product Margin	*39.1%*	*39.1%*	*41.2%*	*40.1%*	*38.8%*	*39.7%*	*43.2%*	*46.0%*	*47.0%*
Research & Development	$4,487	$1,080	$1,057	$1,185	$1,210	$4,532	$4,721	$4,620	$4,855
% R&D	*17.5%*	*14.5%*	*16.6%*	*20.4%*	*17.5%*	*17.0%*	*14.3%*	*15.1%*	*13.3%*
Selling General & Admin	$4,852	$1,277	$1,207	$1,122	$1,163	$4,770	$6,292	$6,095	$7,076
% SG&A	*18.9%*	*17.1%*	*18.9%*	*19.3%*	*16.8%*	*17.9%*	*19.1%*	*19.9%*	*19.4%*
Operating Income	$1,452	$808	$607	$241	$541	$2,197	$3,942	$4,475	$6,225
Operating Margin	*5.7%*	*10.8%*	*9.5%*	*4.1%*	*7.8%*	*8.3%*	*12.0%*	*14.6%*	*17.1%*
Other income (expense)	$1	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	($2)	$2	$2	$3	$0	$7	$50	$95	$125
Pre-Tax Income	$1,451	$810	$609	$244	$541	$2,204	$3,992	$4,570	$6,350
Taxes	$509	$322	$242	$97	$215	$875	$1,585	$1,814	$2,521
Tax Rate	*35.1%*	*39.7%*	*39.7%*	*39.7%*	*39.7%*	*39.7%*	*39.7%*	*39.7%*	*39.7%*
Net Income	$942	$489	$367	$147	$326	$1,329	$2,407	$2,755	$3,829
YOY Growth	*-84.8%*	*12.6%*	*19.0%*	*-150.4%*	*-33.7%*	*41.1%*	*81.1%*	*14.5%*	*39.0%*
Net Margin	*3.7%*	*6.5%*	*5.8%*	*2.5%*	*4.7%*	*5.0%*	*7.3%*	*9.0%*	*10.5%*
GAAP EPS	$0.11	$0.06	$0.04	$0.02	$0.04	$0.15	$0.28	$0.32	$0.44
Adjusted EPS	$0.17	$0.09	$0.07	$0.03	$0.06	$0.25	$0.44	$0.51	$0.49
YOY Growth	*-84.9%*	*11.1%*	*17.6%*	*-146.6%*	*-25.4%*	*46.2%*	*81.1%*	*14.5%*	*39.0%*
Weighted Avg. Shares O/S	8,419	8,625	8,625	8,625	8,625	8,625	8,625	8,625	8,625

Brian Marckx, CFA

HISTORICAL ZACKS RECOMMENDATIONS



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