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Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI- NASDAQ)

CEMI: New Opportunities Could Offset Anticipated Slowdown From FIOCRUZ

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (05/10/13)	$4.40
Target Price	**$8.50**

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 have been very strong but can be variable q-to-q. CEMI is focused on growing this business - fruits of which are already being seen - with more expected as "new opportunities" appear to be on the horizon. DPP sales ex-Brazil could also accelerate. These should help offset a bigger and earlier than anticipated 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 in 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 and were further beefed up by $6MM stock sale.

We are maintaining our Outperform rating.

SUMMARY DATA

52-Week High	**$5.80**
52-Week Low	**$3.61**
One-Year Return (%)	**4.57**
Beta	**0.18**
Average Daily Volume (sh)	**43,017**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$35**
Short Interest Ratio (days)	**0.22**
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	**25.9**
P/E using 2013 Estimate	**29.3**
P/E using 2014 Estimate	**14.7**
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	$6.68 A	$6.41 E	$6.35 E	$7.07 E	$26.52 E
2014					$32.96 E
2015					$30.52 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	$0.05 E	$0.03 E	$0.02 E	$0.05 E	$0.15 E
2014					$0.30 E
2015					$0.34 E

Zacks Projected EPS Growth Rate - Next 4 Years % **22**

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Q1 2013: *Revenue Flat As DPP-FIOCRUZ Sales Fall But Very Strong Showing From Lateral Flow. New Opportunities Could Offset Anticipated Slowdown From FIOCRUZ…*

Q1 2013 revenue was just barely better (+0.4%) than flat from Q1 2012. DPP sales to FIOCRUZ dropped by more than 50% from the year-earlier period which was offset by very strong (+34%) sales of the lateral flow products, particularly overseas (+100%) with the U.S. also posting growth (+3%). While DPP-FIOCRUZ sales have begun to slowdown faster and earlier than we had anticipated, management noted on the call that other new international opportunities, which may relate to both the lateral flow and DPP products, could offset the recent decline in DPP-FIOCRUZ sales. On the domestic front, the recent final recommendation by the USPSTF in favor of HIV screening for all individuals (regardless of risk profile) ages 15 to 65, is a clear positive for continued growth of CEMI's current lateral flow products as well as the expected near-term introduction of the DPP HIV test in the U.S.

Slowdown in the DPP-FIOCRUZ sales was anticipated to eventually happen although we had expected at least one more ~$10 million year (similar to 2012). As a reminder, per terms of the technology transfer 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 Q1 FIOCRUZ had purchased ~$14+ million. Management noted on the call that their most recent forecasts from FIOCRUZ indicate 2013 related sales are expected to be about $6 million and CEMI also noted 2014 related sales could be as much as $9 million (based on the minimum purchase agreements - which may suggest the aforementioned $6MM anticipated orders may relate to purchases of tests that have already met the minimum purchase requirements).

We have made some updates to our revenue forecasts following Q1 results, although the net effect ended up being neutral as our downward revisions to our DPP-FIOCRUZ sales were offset by upward revisions to international lateral flow sales (and to a lesser extent, ex-Brazil DPP sales and U.S. lateral flow sales).

On the operational side, almost all CEMI's development projects are tracking earlier expectations with no major surprises. CLIA waiver studies for the DPP HIV 1/2 test, which received FDA approval in Q4, are still expected to complete and an FDA submission happen by July. CEMI is still hoping to have CLIA waiver in Q4 and launch the test in early 2014. If all goes to plan the test will roll out in early 2014, supported by a small internal sales force (targeting the public health market) as well as via distributors (targeting hospitals and physician offices).

The one addition to the product pipeline is a potential multiplex HIV test for the detection of P24 antigen as well as HIV antibodies. The test would be developed to be capable of detecting both chronic and acute infection and would compete with other P24 antigen tests including those from Alere which are currently sold only ex-U.S. CEMI's test development is still in the early stage.

Q1 2013 Financial Results

Q1 revenue of $6.7 million was roughly flat yoy and was well below our $7.5 million forecast. DPP sales fell 55% to $1.1 million (vs. $2.6 million estimate) while lateral flow sales increased 34% to $4.9 million (vs. $4.3 million forecast). Meanwhile, non-product revenue of $365k was in-line with our $402k number.

Market share gains by Alere appear to continue to benefit U.S. lateral flow sales (+3%, $2.6MM A vs. $2.3MM E). The new HIV testing recommendations should provide a catalyst to further growth of both lateral flow and U.S. DPP sales. International lateral flow sales doubled from Q1 2012 to $2.3 million and were better than our $2.1 million estimate. International sales have always been somewhat (and sometimes, highly) variable q-to-q so while the recent performance is not necessarily indicative of an expected trend, management did note on the call that they are working on new opportunities (namely donor funder programs) that could potentially lead to significant near-term orders. As such, we have beefed up our related forecast for the remainder of the current year (particularly for the second half).

Q1 operating expenses were $2.2 million, slightly below (on an absolute basis) our $2.4 million estimate but slightly above (33% vs. 32%) on a percentage of sales basis.

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 $4.1 million at the end of Q1. Q1 adjusted net income and EPS of approximately $471k and $0.05 compared to our $778k and $0.09 estimates.

Cash
Excluding changes in working capital, cash from operations was an inflow of $716k. CEMI exited Q1 with $2.6 million in cash and equivalents and no debt. Subsequent to quarter-end they raised $6 million (~$5.5 million, net) through the sale of 1.2 million common shares @ $5.00/share. CEMI also has a $2.0 million credit line (untapped at Q1 quarter-end).

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 started in April and an FDA submission to happen by July. CLIA waiver and launch could happen by 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.

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 Q4 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 just submitted a guidance request to the FDA to determine the appropriate regulatory pathway. 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 upon feedback from FDA) 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. This would initially involve phase II observed clinical studies (potentially during 2013) followed by a pivotal trial (potentially in 2014).

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 pivotal 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.

DPP HIV Multiplex P24 Antigen / Antibody

CEMI continues to look to leverage the mutliplexing capability of the DPP technology and is now in the early development stages of a DPP HIV P24 Antigen / Antibody test. The potential advantage over their other HIV tests is this mutliplex test would be capable of identifying acute (P24 antigen) as well as chronic (antibody) HIV infection, potentially allowing for diagnosis at an earlier state of infection. Alere has a P24 antigen test which is sold ex-U.S., although performance of the test has been questionable, namely observations of poor sensitivity (64% in one small study, for example). As such, P24 antigen testing in the U.S. is mostly relegated to clinical lab assays. A better performing rapid P24 antigen / antibody multiplex test would likely draw significant demand in the U.S. and elsewhere - which potentially offers CEMI an attractive opportunity with their DPP technology. Progress of development will be something to keep our eye on.

OUR OUTLOOK

Revenue

We now look for 2013 revenue of $26.5 million, which is substantially unchanged from our pre-Q1 estimate. While we have trimmed our DPP-FIOCRUZ forecast, this has been mostly offset by an increase to our estimated international lateral flow (and to a lesser extent, ex-Brazil DPP sales and U.S. lateral flow sales), which reflects the "new opportunities" that management alluded to on the call.

As we have previously, we continue to use the assumption that FIOCRUZ will meet their purchasing quota in 2013 (or possibly 2014), 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 now model adjusted net income and EPS of $1.6 million and $0.15 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 $8.50/share. We are maintaining our Outperform rating.

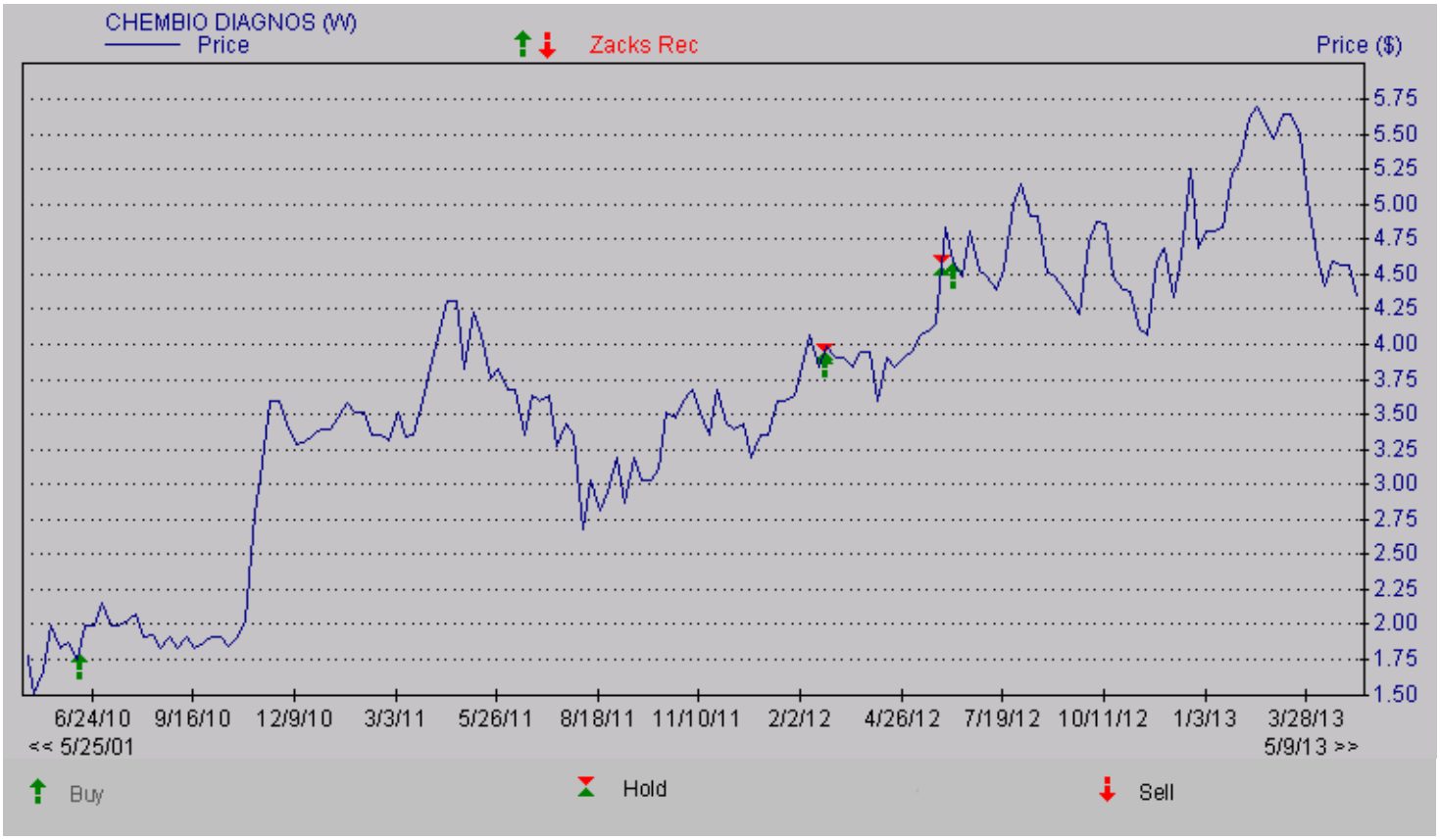
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2012 A	Q1A	Q2E	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
Product sales	**$24,327**	**$6,313**	**$6,017**	**$5,992**	**$6,682**	**$25,004**	**$31,681**	**$28,672**	**$34,694**
% of total revenue	*95.0%*	*94.5%*	*93.9%*	*94.3%*	*94.5%*	*94.3%*	*96.1%*	*93.9%*	*95.3%*
YOY Growth	*39.6%*	*-0.8%*	*3.5%*	*26.3%*	*-9.8%*	*2.8%*	*26.7%*	*-9.5%*	*21.0%*
License & royalty income	**$0**	**$0**	**$8**	**$12**	**$16**	**$36**	**$75**	**$425**	**$425**
% of total revenue	*0.0%*	*0.0%*	*0.1%*	*0.2%*	*0.2%*	*0.1%*	*0.2%*	*1.4%*	*1.2%*
R&D contracts, grants, milestones	**$1,283**	**$365**	**$386**	**$350**	**$375**	**$1,476**	**$1,200**	**$1,425**	**$1,300**
% of total revenue	*5.0%*	*5.5%*	*6.0%*	*5.5%*	*5.3%*	*5.6%*	*3.6%*	*4.7%*	*3.6%*
Total Revenues	$25,610.5	$6,678.2	$6,411.0	$6,354.0	$7,073.0	$26,516.0	$32,955.9	$30,522.0	$36,419.0
YOY Growth	*32.1%*	*0.4%*	*5.4%*	*26.9%*	*-10.1%*	*3.5%*	*24.3%*	*-7.4%*	*19.3%*
Cost of Revenues	$14,820	$3,984	$3,761	$3,745	$4,176	$15,666	$18,375	$15,770	$18,735
Gross Income	$10,790	$2,694	$2,650	$2,609	$2,897	$10,850	$14,581	$14,752	$17,684
Gross Margin	*42.1%*	*40.3%*	*41.3%*	*41.1%*	*41.0%*	*40.9%*	*44.2%*	*48.3%*	*48.6%*
Product Margin	*39.1%*	*36.9%*	*37.5%*	*37.5%*	*37.5%*	*37.3%*	*42.0%*	*45.0%*	*46.0%*
Research & Development	$4,487	$1,045	$1,135	$1,095	$1,102	$4,377	$4,721	$4,620	$4,855
% R&D	*17.5%*	*15.7%*	*17.7%*	*17.2%*	*15.6%*	*16.5%*	*14.3%*	*15.1%*	*13.3%*
Selling General & Admin	$4,852	$1,162	$1,212	$1,226	$1,188	$4,788	$6,295	$6,074	$7,065
% SG&A	*18.9%*	*17.4%*	*18.9%*	*19.3%*	*16.8%*	*18.1%*	*19.1%*	*19.9%*	*19.4%*
Operating Income	$1,452	$487	$304	$288	$606	$1,684	$3,565	$4,059	$5,764
Operating Margin	*5.7%*	*7.3%*	*4.7%*	*4.5%*	*8.6%*	*6.4%*	*10.8%*	*13.3%*	*15.8%*
Other income (expense)	$1	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	($2)	$1	$2	$3	$0	$6	$50	$95	$125
Pre-Tax Income	$1,451	$488	$306	$291	$606	$1,690	$3,615	$4,154	$5,889
Taxes	$509	$170	$121	$115	$241	$648	$1,435	$1,649	$2,338
Tax Rate	*35.1%*	*35.0%*	*39.7%*	*39.7%*	*39.7%*	*38.3%*	*39.7%*	*39.7%*	*39.7%*
Net Income	$942	$317	$184	$175	$366	$1,042	$2,180	$2,505	$3,551
YOY Growth	*-84.8%*	*-26.9%*	*-40.3%*	*-160.0%*	*-25.6%*	*10.7%*	*109.1%*	*14.9%*	*41.8%*
Net Margin	*3.7%*	*4.7%*	*2.9%*	*2.8%*	*5.2%*	*3.9%*	*6.6%*	*8.2%*	*9.8%*
GAAP EPS	$0.11	$0.04	$0.02	$0.02	$0.03	$0.10	$0.19	$0.22	$0.31
Adjusted EPS	$0.17	$0.05	$0.03	$0.02	$0.05	$0.15	$0.30	$0.34	$0.38
YOY Growth	*-84.9%*	*-33.4%*	*-56.2%*	*-141.2%*	*-37.9%*	*-11.1%*	*96.0%*	*14.9%*	*41.8%*
Weighted Avg. Shares O/S	8,419	8,699	11,625	11,625	11,625	10,894	11,625	11,625	11,625

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HISTORICAL ZACKS RECOMMENDATIONS



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