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Zacks Small-Cap Research

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# Chembio Diagnostics Inc. (CEMI- NASDAQ)

***CEMI:*** **Decent Q1. New Product Launches Should Make Near-Term Contribution**

| | |
|---|---|
| **Current Recommendation** | **Buy** |
| Prior Recommendation | N/A |
| Date of Last Change | 06/14/2010 |
| Current Price (05/12/15) | $4.32 |
| **Target Price** | **$7.50** |

## OUTLOOK

CLIA Waiver granted for DPP HIV assay. CEMI signed distribution agreements and also bldg direct sales force to sell direct in the U.S. Int'l lateral flow sales remain variable which negatively impacted 2014 revenue. DPP international sales have been very strong with FIOCRUZ still very active and HIV/Syph launch in Mexico the drivers in 2014. DPP HIV/Syph launching in Brazil could be major catalyst in 2015. Next up could be the U.S. mrkt.

Pipeline progress continues - recent partnerships announced to develop Ebola, Dengue Fever, Febrile illness, TBI, malaria and cancer test on DPP platform. CEMI also focused on complementary revenue opportunities including add'l R&D contracts/grants, expansion of international commercialization footprint, and potentially in-licensing products.
CEMI maintains strong cash position and balance sheet.
We are maintaining our Buy rating.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$5.20** |
| **52-Week Low** | **$3.00** |
| **One-Year Return (%)** | **44.59** |
| **Beta** | **0.11** |
| **Average Daily Volume (sh)** | **13,587** |
| **Shares Outstanding (mil)** | **10** |
| **Market Capitalization ($mil)** | **$42** |
| **Short Interest Ratio (days)** | **1.67** |
| **Institutional Ownership (%)** | **22** |
| **Insider Ownership (%)** | **6** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **19.8** |
| **Earnings Per Share (%)** | **-31.0** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2015 Estimate** | **N/A** |
| **P/E using 2016 Estimate** | **22.3** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Average,** |
| **Type of Stock** | **Small-Blend** |
| **Industry** | **Med Products** |

## ZACKS ESTIMATES

**Revenue**
(millions)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | $5.81 A | $7.42 A | $7.31 A | $7.10 A | $27.65 A |
| 2015 | $6.23 A | $6.95 E | $6.88 E | $7.07 E | $27.13 E |
| 2016 | | | | | $31.43 E |
| 2017 | | | | | $36.53 E |

**Adjusted Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | -$0.04 A | -$0.02 A | -$0.03 A | -$0.07 A | -$0.16 A |
| 2015 | -$0.09 A | -$0.06 E | -$0.04 E | $0.00 E | -$0.18 E |
| 2016 | | | | | $0.04 E |
| 2017 | | | | | $0.22 E |

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

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## WHAT'S NEW

### Q1 2015: *Decent Quarter, Expect Contribution from New Product Launches To Steepen Revenue Curve…*

Chembio turned in a decent, although not terrific Q1 financially with revenue eking out single digit growth compared to a relatively very soft year-earlier comp. The most recent period saw international DPP sales exhibiting their usually volatility, U.S. lateral flow sales falling just over 50% (as we had expected) and international lateral flow sales showing unusual (as of late) relative strength.

U.S. lateral flow sales began to slide with the transition from distribution via Alere to CEMI's own sales force and their distribution partners. And while we don't expect much in the way of growth from these products in the U.S. as the DPP HIV test, which was recently granted CLIA waiver, will almost certainly take share, and the sales force still climbs the productivity curve, we think revenue from lateral flow will remain meaningful for some time. International lateral flow revenue is mostly a function of ordering patterns from international aid agencies – and since there is no obvious pattern to these, revenue from these products will almost certainly remain unpredictable.

And DPP – which currently is mostly from sales in Brazil, has also been somewhat erratic. But DPP-Brazil was a major driver of the top-line in 2014, made a meaningful contribution in Q1 (although well below our number) and, per management's comments on the call, should remain significant throughout the remainder of 2015. We continue to think DPP HIV/Syphilis, which (anecdotally) has been very successful in Mexico since the launch in late-2013 has the potentially to be a big winner in Brazil as well. The test was approved by Brazilian regulators in February of this year.

Product margin, while slightly softer than our estimate, has shown recent strength, benefitting from manufacturing efficiency initiatives implemented in 2H 2014. On the OpEx side, R&D ticked up much higher than we had expected in Q1 – which we think relates to progress with several of the new development programs. But we expect these investments to pay dividends in future periods with new product launches and still model much more leverage in the income statement with a continued firming in product margin and steepening revenue.

And while the Q1 numbers didn't incite rabid giddiness, progress with product development, regulatory approvals and near-term new product launches does warrant excitement in our opinion. Recent and upcoming product launches on the DPP platform, including HIV ½ and HIV/Syphilis and in several territories including Brazil, the U.S. and Europe are where we see near-term catalysts for revenue. And with the pipeline getting deeper and deeper, we think there could be a fairly steady stream of new products reaching the market and providing additional tailwinds to revenue for some time to come.

**Q1 Financials**
Q1 revenue of $6.2 million was up 7% yoy, down 12% sequentially and about 5% lower than our $6.6M estimate. Revenue in the year-earlier period was very soft so the single-digit yoy growth is even less substantial – although we do note that product sales increased by almost 15%. So while not overly impressive in terms of revenue, there were some highpoints. DPP sales increased 111% yoy, although down 37% sequentially. As noted, this has been a volatile line and tough to model accurately. FIOCRUZ, despite meeting most of the minimum purchase requirements to trigger the tech transfer agreement, continues to purchase product from Chembio. And with the impending roll-out of DPP HIV/Syhpilis, we think DPP-FIOCRUZ sales could actually tick up throughout the remainder of 2015. We could also see initial contribution from DPP HIV in the U.S. – although we continue to model this as more measured and likely to make a much more significant contribution next year.

In lateral flow, U.S. sales came down 54% yoy and 23% sequentially to $1.2M in Q1 – which was dead-on with our number. Internationally, lateral flow did much better – up 98% yoy and doubling from Q4 2014. This, as noted, is also difficult to model given the reliance on unpredictable tenders. For 2015 we model contraction of about 26% on U.S. lateral flow as CEMI introduces DPP HIV to the domestic market but international holding up much better.

Q1 gross margin at 43.1% was the beefiest since Q1 2012 and bolstered by a combination of the aforementioned manufacturing cost initiatives as well as a healthy amount of contract revenue in the quarter. We continue to expect to see improvement in both product and gross margin in 2015 as compared to 2014.

**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 ~35.1% is ~90% non-cash until they exhaust (which, based on our current model will occur sometime in 2019) their entire deferred tax asset which stood at $4.3 million at the end of Q1.

Q1 adjusted net income and EPS of approximately ($875)k and ($0.07) compares to our ($404)k and ($0.04) estimates. Most of the difference relates to higher than modeled R&D expense.

**Cash**
Excluding changes in working capital, cash used in operations was $419k in Q1. CEMI exited Q1 with $2.8M in cash and equivalents, compared to $4.6M at the end of 2014.

**Business / Pipeline Update:**

**U.S. Direct Roll-Out Gaining Steam**
Highlights since the close of 2013 include CEMI terminating the domestic distribution agreement with Alere related to their STAT-PAK HIV rapid lateral flow test. The agreement terminated on June 3, 2014. Alere will continue to distribute CEMI's other lateral flow HIV test, branded as Clearview Complete. CEMI has already hired a small sales force including a director of sales, director of marketing and a handful of sales reps to handle direct sales of STAT-PAK as well as the DPP products.

Management has indicated their initial direct sales strategy for STAT-PAK HIV is focused on public health facilities. With CLIA waiver of DPP HIV now granted they expect to incrementally grow their direct sales force which will be complemented with third-party distribution - the company now has at least three distribution agreements in place which includes the major medical device companies, McKesson/PSS, Fisher Healthcare and Henry Schein.

***Ebola, Febrile illness…***
CEMI is collaborating with Gaithersburg, MD-based Integrated Biotherapeutics in development of DPP tests for Ebola and Febrile illness for the POC market. Integrated Bio is providing Ebola antibodies, that CEMI noted have already undergone initial testing, in development of an Ebola assay.

Since the October collaboration announcement, CEMI has made substantive progress which includes successful lab testing of the Ebola assay, signing a research agreement with CDC to develop and validate both an Ebola and Febrile illness test, testing the Ebola assay at CDC's lab, submitting pre-qualification for DPP Ebola to WHO as well as to FDA for Emergency Use Authorization. Next steps include field testing the Ebola assay, which is expected to commence in Q2 and then, hopefully WHO pre-qualification and initial OUS commercialization. We think a DPP Ebola test, depending on continued successful development, could possibly be a fairly near-term contributor.

Relative to febrile illness, CEMI should be able to leverage much of what they have learned from the U.S. government grant that was awarded to the company in May 2013 for development of a POC assay for five infectious diseases associated with febrile illness. CEMI envisions a commercial product under their recent collaboration that would be a multiplex test on the DPP platform that could test for several infectious diseases including Ebola, Febrile illness and potentially Dengue fever.

And specific to Dengue fever, the company entered into another recent collaboration - this time with an unnamed partner, for development of a DPP POC test for Dengue fever. Management noted that they think they can move at least some of these projects (most notably Ebola) along fairly rapidly. Preclinical studies are expected to begin in Q2 2015.

***Malaria…***
In late January 2015 CEMI was awarded a grant from the Bill and Melinda Gates Foundation to evaluate the feasibility of developing a malaria test on the DPP platform. We see this as another high-potential area, given the dearth of rapid and accurate testing options for malaria and the devastation that the disease causes in certain emerging countries. Development progress of this, along with the Ebola assay, is something that we will be following closely.

***Traumatic Brain Injury…***
Another recent addition to the product pipeline was announced in January when CEMI disclosed they are collaborating with the Concussion Science Group (CSG) Division of Perseus Science Group LLC in development of a DPP test for traumatic brain injury. Under the agreement CSG will make milestone payments to CEMI in 2015.

Traumatic brain injuries have received significant mainstream media attention of late due to their association with injuries of NFL players and a potential cause for severe depression and some resultant suicides. Identifying the presence of traumatic brain injuries is currently often not possible until either well into their progression or, in some cases, until an autopsy is done. A reliable POC test that could identify traumatic brain injuries therefore would likely have massive appeal.

***Cancer…***
Recently signed a collaboration agreement with an unnamed (international diagnostics) company for development of a DPP cancer test. The type of cancer was not disclosed

***Influenza…***
CEMI has had an ongoing DPP Influenza development program which most recently included a follow-on grant awarded in November 2014 which is in collaboration with a private company which is working on behalf of the U.S. CDC. The product is a multiplex, seven band flu test which completed in Q1 2015.

**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.

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 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 2012 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, clinical trials could commence in the near future with potential commercialization possibly sometime in 2016.

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**
We think this DPP Syphilis / HIV combo test is a potentially significant needle-mover for CEMI - initial meaningful revenue contribution from which materialized during 2014. In late October 2013 CEMI announced the test launched in Mexico and that they received their first P.O. for the test from their Mexican distributor. That same month they also announced that the test was accepted on the USAID list of products eligible to be used in international procurement programs. This is the only Syphilis / HIV combo test currently on the USAID waiver list. Management noted the test contributed several million $ worth of revenue during the first 12 months following launch in Mexico. The test looks like it could have potentially significant appeal in emerging markets, particularly for prenatal testing where relatively high rates of both HIV and syphilis are commonplace and programs to reduce the incidence of mother-to-child transmission have been implemented.

Relative to the FDA approval pathway, CEMI submitted a guidance request to the FDA to determine the appropriate regulatory pathway. FDA recently responded that PMA pathway would be required - as opposed to the quicker 510(k). Most recently CEMI announced that FDA indicated to the company that performance of the test will need to comply with a new (higher) standard. CEMI has been under discussions with FDA relative to design of a study which would eventually be used to support regulatory filing in the U.S. On the Q1 2015 call management noted that they expect the study design to be finalized and the trial initiated by the end of the current year.

***Could Be A Big Contributor in 2015 With Launch in Brazil…***
The success of the DPP HIV/Syphilis test in Mexico may be duplicated, or even surpassed in Brazil where it was granted approval by regulators in February 2015. We think the test makes a substantial contribution to product revenue - potentially starting during the current year. CEMI has also submitted the test for evaluation by CDC and for pre-qualification by WHO for its global procurement programs.

**DPP HIV Multiplex P24 Antigen / Antibody**

CEMI continues to look to leverage the multiplexing 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 multiplex 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 was initially only sold ex-U.S. In late October 2013 Alere received FDA approval of their test (Determine HIV 1/2 Ag/Ab Combo) and in December the test was granted CLIA waiver, allowing it to be used at the point-of-care. While it's currently difficult to judge the potential demand for a P24 test, in part due to somewhat conflicting performance results in clinical studies (earlier P24 test versions suffered from poor sensitivity, although Alere's published clinical test results for their Determine test indicate relatively very high sensitivity and specificity) the advantages of an accurate rapid test that can detect both acute and chronic HIV infection would likely have broad appeal.

In August 2013 CEM announced that they expected to pursue a similar test using its DPP technology. CEMI most recently noted (on the Q1 2015 call) that development progress continues on this test including completing a prototype and securing a source for antibodies.

**SURE CHECK ½ Self-testing kits launch in Europe**

SURE CHECK ½, the company's later flow test, was launched in Europe in late April of this year. The test is the first to receive CE Mark for self-testing. The test will be sold in the U.K. and France under distribution partners' private label brands.

**Complementary Revenue Opportunities**

CEMI has recently dedicated a greater focus on what we characterize as complementary revenue opportunities - essentially non-core commercialization activities that have the potential to provide incremental revenue with little additional operating expense. The company has had significant success over the years with scoring R&D contracts and grants from private and government entities related to development of various diagnostic tests which have provided a meaningful contribution to both revenue and margins. Management has indicated that they will be very active in pursuing future contracts.

The other complementary revenue opportunities come from expanding their international footprint with their existing suite of products, something that management has clearly put additional effort into recently and is expected to be an ongoing focus going forward. In May 2013 CEMI entered into an assembly and distribution agreement with Labtest Diagnostica of Brazil whereby CEMI will sell Labtest components to certain DPP tests which will be assembled and sold by the Brazilian company. CEMI will receive a royalty on sales.

In February 2014 CEMI penned technology transfer agreement with RVR Diagnostics or Malaysia whereby RVR will manufacture and distribute the DPP HIV 1/2 and DPP HIV/Syphilis tests in parts of Asia (ex-China) and will pay CEMI a royalty on sales as well as consummation and milestone fees. Chembio indicated that they think this RVR opportunity, in particular, could have significant revenue potential.

## OUR OUTLOOK

**Revenue**

We look for 2015 revenue of $27.1 million, implying a decrease of 2% from 2014. We think there may continue to be some lingering near-term softness in domestic lateral flow sales as CEMI completes the transition from distribution via Alere but think this business can stabilize in 2H 2015. International lateral flow sales, as indicated, are particularly difficult to predict given their inherent variability – we had been modeling flat to mid-single digit growth but, given the very strong showing in Q1, this business could be a sizeable contributor to revenue in 2015.

DPP sales were extraordinarily strong in 2014 as FIOCRUZ continued to purchase well beyond their minimum purchase requirements for most of the products under the tech transfer agreement and uptake of DPP HIV/Syphilis in Mexico was tremendous. Given no obvious indication that FIOCRUZ will trigger the transfer and an expectation that DPP HIV/Syphilis comes out strong in Brazil and remains so in Mexico, we think roughly flat to single-digit contraction of the DPP portfolio is a reasonable estimate for 2015.

We think commercialization of the pipeline should begin to make a more substantive contribution towards the back half of 2015 and even more so in 2016.

We currently do not model any of the pipeline products – launch of any of which could provide some upside to our estimates.

**Net Income / EPS**
We look for adjusted net income and EPS of ($1.7)M and ($0.18) in 2015, compared to ($1.1) million and ($0.16) in 2014.

## RECOMMENDATION / VALUATION

We continue to use OSUR as a comp for valuation purposes. OSUR trades at approximately 2.8x 2015 estimated sales and 2.3x EV/2015 sales. P/S comp values CEMI at ~$8/share, EV/S values CEMI at ~$7/share. We use the average, $7.50, as our price target. We are maintaining our Buy recommendation.

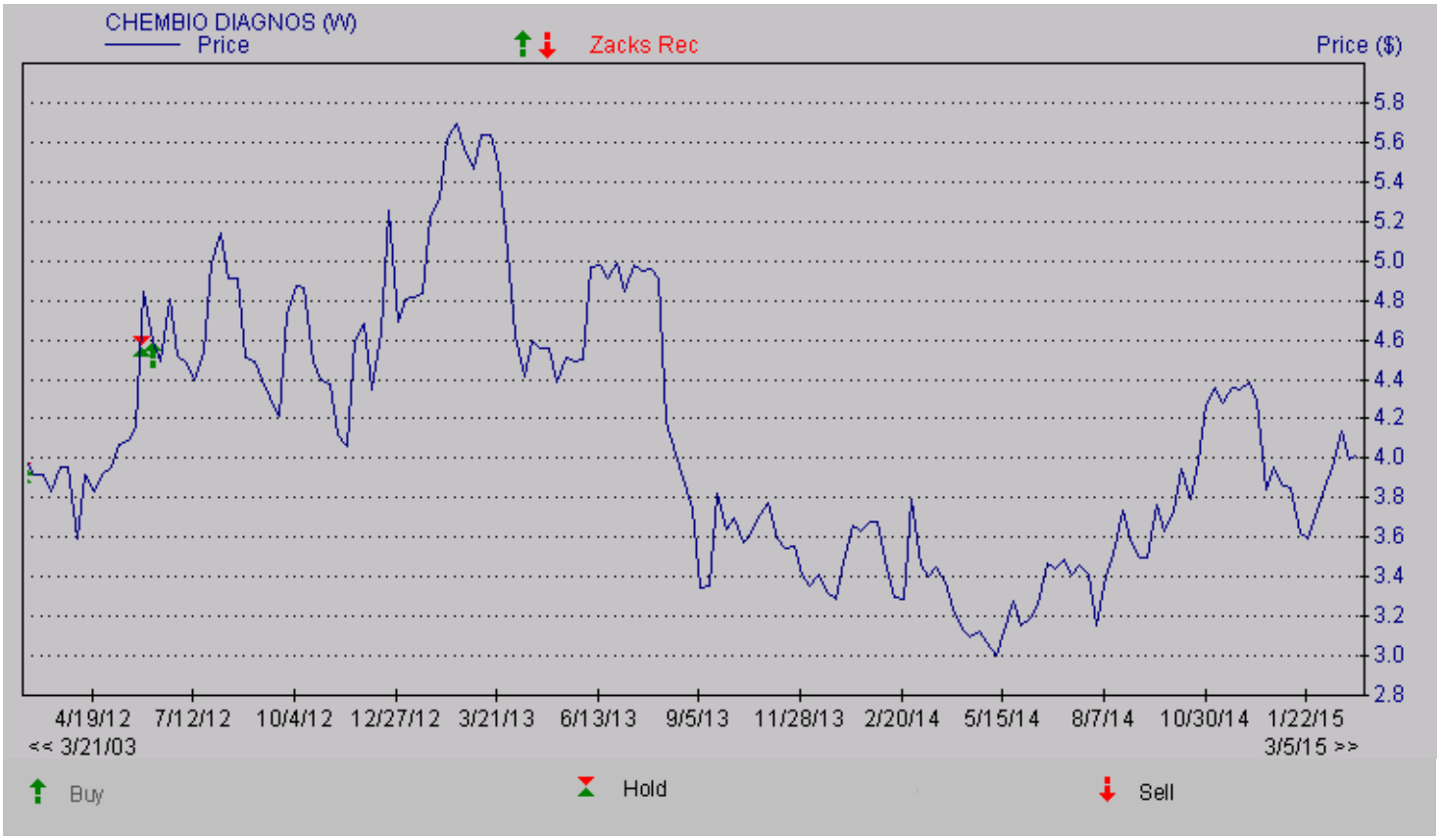
## INCOME STATEMENT

Chembio Diagnostics, Inc.

| | 2014 A | Q1A | Q2E | Q3E | Q4E | 2015 E | 2016 E | 2017 E | 2018 E |
|---|---|---|---|---|---|---|---|---|---|
| **Product sales** | **$25,950** | **$5,615** | **$6,422** | **$6,289** | **$6,316** | **$24,642** | **$29,410** | **$34,270** | **$36,896** |
| *% of total revenue* | *93.9%* | *90.1%* | *92.4%* | *91.4%* | *89.3%* | *90.8%* | *93.6%* | *93.8%* | *93.8%* |
| *YOY Growth* | *-5.7%* | *14.5%* | *-11.4%* | *-13.2%* | *-3.6%* | *-5.0%* | *19.4%* | *16.5%* | *7.7%* |
| **License & royalty income** | **$24** | **$7** | **$90** | **$139** | **$316** | **$552** | **$717** | **$899** | **$1,037** |
| *% of total revenue* | *0.1%* | *0.1%* | *1.3%* | *2.0%* | *4.5%* | *2.0%* | *2.3%* | *2.5%* | *2.6%* |
| **R&D contracts, grants, milestones** | **$1,672** | **$609** | **$441** | **$452** | **$438** | **$1,940** | **$1,300** | **$1,365** | **$1,400** |
| *% of total revenue* | *6.0%* | *9.8%* | *6.3%* | *6.6%* | *6.2%* | *7.2%* | *4.1%* | *3.7%* | *3.6%* |
| Total Revenues | $27,645.3 | $6,231.1 | $6,953.0 | $6,880.0 | $7,070.0 | $27,134.1 | $31,426.6 | $36,533.4 | $39,332.5 |
| *YOY Growth* | *-6.4%* | *7.2%* | *-6.3%* | *-5.9%* | *-0.4%* | *-1.8%* | *15.8%* | *16.2%* | *7.7%* |
| Cost of Revenues | $16,831 | $3,545 | $4,046 | $3,868 | $3,821 | $15,279 | $16,999 | $19,465 | $20,809 |
| Gross Income | $10,814 | $2,687 | $2,907 | $3,012 | $3,249 | $11,855 | $14,428 | $17,068 | $18,523 |
| *Gross Margin* | *39.1%* | *43.1%* | *41.8%* | *43.8%* | *46.0%* | *43.7%* | *45.9%* | *46.7%* | *47.1%* |
| *Product Margin* | *35.1%* | *36.9%* | *37.0%* | *38.5%* | *39.5%* | *40.8%* | *42.2%* | *43.2%* | *43.6%* |
| Research & Development | $4,833 | $1,585 | $1,322 | $1,218 | $1,208 | $5,333 | $5,218 | $4,877 | $4,719 |
| *% R&D* | *17.5%* | *25.4%* | *19.0%* | *17.7%* | *17.1%* | *19.7%* | *16.6%* | *13.3%* | *12.0%* |
| Selling General & Admin | $7,532 | $1,978 | $2,155 | $2,160 | $2,022 | $8,315 | $8,831 | $9,827 | $10,384 |
| *% SG&A* | *27.2%* | *31.7%* | *31.0%* | *31.4%* | *28.6%* | *30.6%* | *28.1%* | *26.9%* | *26.4%* |
| Operating Income | ($1,550) | ($875) | ($570) | ($366) | $19 | ($1,793) | $379 | $2,364 | $3,421 |
| *Operating Margin* | *-5.6%* | *-14.1%* | *-8.2%* | *-5.3%* | *0.3%* | *-6.6%* | *1.2%* | *6.5%* | *8.7%* |
| Other income (expense) | ($6) | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Interest income, net | $6 | $1 | $1 | $1 | $1 | $4 | $18 | $66 | $81 |
| Pre-Tax Income | ($1,550) | ($874) | ($569) | ($365) | $20 | ($1,789) | $397 | $2,430 | $3,502 |
| Taxes | ($413) | ($228) | ($199) | ($128) | $7 | ($548) | $149 | $911 | $1,313 |
| *Tax Rate* | *26.6%* | *26.0%* | *35.0%* | *35.0%* | *35.0%* | *37.5%* | *37.5%* | *37.5%* | *37.5%* |
| Net Income | ($1,137) | ($647) | ($370) | ($237) | $13 | ($1,241) | $248 | $1,519 | $2,188 |
| *YOY Growth* | *-314.1%* | *187.8%* | *153.5%* | *-12.3%* | *-102.6%* | *9.2%* | *-120.0%* | *512.4%* | *44.1%* |
| *Net Margin* | *-4.1%* | *-10.4%* | *-5.3%* | *-3.4%* | *0.2%* | *-4.6%* | *0.8%* | *4.2%* | *5.6%* |
| GAAP EPS | ($0.12) | ($0.07) | ($0.04) | ($0.02) | $0.00 | ($0.13) | $0.02 | $0.14 | $0.20 |
| Adjusted EPS | ($0.16) | ($0.09) | ($0.06) | ($0.04) | $0.00 | ($0.18) | $0.04 | $0.22 | $0.31 |
| *YOY Growth* | *-302.1%* | *136.4%* | *141.3%* | *32.7%* | *-102.9%* | *7.1%* | *-119.5%* | *474.1%* | *41.7%* |
| Weighted Avg. Shares O/S | 9,529 | 9,625 | 9,700 | 9,728 | 9,788 | 9,710 | 9,955 | 10,620 | 10,800 |

*Brian Marckx, CFA*

## HISTORICAL ZACKS RECOMMENDATIONS

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