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Chembio Diagnostics Inc. (CEMI-OTC)

CEMI: Q3: DPP Sales Up 49% Despite Revenue Miss

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (11/13/12)	$4.12
Target Price	**$10.30**

OUTLOOK

DPP sales have already begun to ramp in Brazil under multi-year contracts worth at least $23MM. Final FDA module filing for DPP HIV test filed, test could launch in the U.S. in 2013. OTC HIV test, development of which is in early stages, could contribute to long-term revenue growth.

DPP FIOCRUZ sales have ramped quickly and the lateral flow products should continue to eke out single-digit growth. As DPP is the future of Chembio, accelerating sales and demand for these products is very encouraging. Key will be to get the DPP tests approved in the U.S. Cash position and the balance sheet remain very healthy.

We are maintaining our Outperform rating.

SUMMARY DATA

52-Week High	**$5.18**
52-Week Low	**$3.12**
One-Year Return (%)	**14.17**
Beta	**0.08**
Average Daily Volume (sh)	**43,046**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$33**
Short Interest Ratio (days)	**0.22**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**17**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**21.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**38.5**
P/E using 2012 Estimate	**15.6**
P/E using 2013 Estimate	**9.8**
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)
2011	$3.64 A	$3.61 A	$5.92 A	$6.22 A	$19.39 A
2012	$6.65 A	$6.08 A	$5.01 A	$7.25 E	$24.99 E
2013					$29.86 E
2014					$36.70 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.02 A	$0.02 A	$0.06 A	$0.06 A	$0.13 A
2012	$0.08 A	$0.06 A	-$0.06 A	$0.08 E	$0.17 E
2013					$0.45 E
2014					$0.61 E

Zacks Projected EPS Growth Rate - Next 4 Years % **45**

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WHAT'S NEW

Q3 2012: *DPP Revenue Up 49%. Lateral Flow Sales Slip Both Domestically and Int'ly But Q4 Should Be Another Record Quarter…*

Chembio reported financial results for the third quarter ending 9/30/2012 on November 13th. While DPP sales to FIOCRUZ were up 49% and about 10% ahead of our forecast, lateral flow sales were significantly softer than anticipated. The net result was revenue falling 15% yoy and coming in about 20% below our number. Domestic sales to Alere came in about 37% lower than our estimate while international lateral flow sales missed our number by 31%. While reduced CDC funding of rapid HIV testing, which CEMI along with OSUR and TRIB have pointed to as to blame for reduced demand for their respective rapid HIV tests, may crimp growth domestically for at least the very near-term, the relative weakness in CEMI's total revenue is not expected to be repeated in Q4 as management noted a large order backlog which accumulated towards the tail end of Q3 should ship before year-end and help push Q4 revenue to an all-time record (i.e. - besting the $6.7MM record set in Q1 of this year).

And while we have materially trimmed our domestic revenue estimate for Q4, we continue to model lateral flow sales to Alere to eke out low-single digit growth (unchanged from expectations prior to Q3 results) in 2013 and beyond for a few reasons. CEMI noted that they continue to take market share from competitors despite the recent drop in revenue from these products. In addition (as we noted in our 8/21/2012 Investor Note) the USPSTF could recommend in the near future that all adolescents and adults be screened for HIV which would significantly expand reimbursable patient population as well as increase awareness of the importance of HIV screening. Obamacare is also geared towards reigning in healthcare costs with a focus on preventative care and early diagnostics - rapid HIV testing seems to be a clear fit with that strategy and as a result could potentially result in greater support and reimbursement for these products and programs over the longer-term.

On the operational side there were no surprises in Q3 as there were no material changes to expected development or commercialization timelines of CEMI's various R&D projects and pipeline candidates.

We have made only minor changes to our financial model following Q3 results. We are maintaining our Outperform.

Q3 Financial Results

Revenue of $5.01 million (-15%) missed our $6.22 million number by about 20% mostly as a result of lower than modeled lateral flow sales both domestically (to Alere) as well as internationally, partially offset by a beat on DPP sales (to FIOCRUZ).

Total product sales were $4.8 million, down 14% and about 19% lower than our $5.8 million estimate. Sales of the company's lateral flow products to Alere fell 38% yoy and 45% sequentially to $1.2 million compared to our $1.9 million estimate. International lateral flow sales fell 47% yoy and 2% sequentially to $992k compared to our $1.4 million estimate. As indicated earlier, we expect to see a major reversal in international lateral flow sales in Q4 while domestic sales may continue to show some weakness at least for the very near-term. Importantly (given that DPP is the long-term catalyst for CEMI), DPP sales were very strong in the quarter, up 49% yoy, up 14% sequentially and 10% better than our $2.3 million estimate. We model $9.9 million in DPP revenue for the full year which calculates to almost 40% of our estimated $25.0 million total revenue for CEMI in 2012.

Operating expenses of $2.2 million were largely in-line with our $2.1 million estimate.

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 $4.5 million at the end of Q3. Q3 adjusted net income and EPS of approximately ($466k) and ($0.06) were well below our $606k and $0.07 estimates. The difference coming from the miss on revenue and lower than modeled (34.5% A vs. 45.3% E) gross margin.

Cash

Cash used in operations was $833k in Q3. Chembio exited the quarter with $3.3 million in cash and equivalents, down from $4.4 million at the end of Q2. Debt remains relatively immaterial. As noted in our previous updates, we

have incorporated assumed/estimated/best-guesses of expenses related to the HIV OTC program into our model - and even with these expenses included, we think CEMI can continue to fund all operations (including clinical trials, product development, regulatory filings, SG&A, etc.) through cash on hand and funds from operations.

Business / Pipeline Update (largely unchanged since our last update)…

DPP HIV, U.S.

In mid-April Chembio announced enrollment of their pivotal 3,000-patient U.S. clinical trial for the DPP HIV 1/2 test had completed. In early June Chembio filed the third and final module with the FDA. As management noted in the recent past, they expect that both the blood and oral fluid sample data will be robust enough to meet FDA requirements. A pre-approval inspection was completed in October - which CEMI believes was satisfactory. Chembio continues to expect an FDA decision by the current year-end. Assuming a positive decision, Chembio will then apply for a CLIA waiver, which could potentially be granted by mid-2013.

We continue to model a U.S. launch sometime in mid-to-late 2013 and a modest amount of revenue during that year.

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. and have since received some small orders to date from Europe.

While the road to the U.S. market has been drawn out longer than anticipated, CEMI continues to make progress towards that end. The delay, as noted in our previous updates, has to do with determining how to meet the FDA requirements of showing substantial equivalence on the non-treponemal marker (which differentiates between past and active infections) compared to the predicate device currently on the market. Chembio had been investigating including a reader for the test but had determined that that will not suffice and is instead now looking to conduct a study to show that their screen and confirm test can detect primary infections equivalent to that of the predicate test. CEMI notes that during Q3 they made further progress in starting clinical trials to support a 510(k). CEMI expects to soon request a meeting with FDA to discuss data that they recently received related to reinitiating clinical trials to support a 510(k) submittal. CEMI is still shooting for a 510(k) application submitted by mid-2013 (unchanged from recent expectations).

In the absence of demonstrating substantial equivalence for a treponemal / non-treoponemal test, the company may look to just bring the single-marker treponemal test to the U.S. market (which is already sold to FIOCRUZ) - although appeal would likely be significantly less than a dual-marker test.

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 is now 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).

Assuming the results of this study are positive (CEMI may know within the next 6 months or so), CEMI expects to go full-speed with development and thinks clinical trials could commence before 2013 year end.

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 over the next 6 - 12 months.

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.

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. OSUR recorded $3.6 million in deferred revenue in Q3 related to shipments of their OTC HIV test - revenue will be recorded as OSUR receives consummation of a sale to the end customer. Assuming the majority of this is eventually recorded as revenue, the implied ~$10 million - $12 million (assumes significant front-end stocking orders) annual revenue run-rate means CEMI's OTC HIV test (which could more competitive than OSUR's) could be a big winner for Chembio.

FDA's decision essentially green-lighted CEMI's move to proceed with their home-use HIV test. Chembio will now pursue OTC approval of its 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 and have it granted by December 2013 or January. Assuming it's granted (which we expect it to be), CEMI will 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.

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 2012 revenue of $25.0 million, down from $25.7 million prior to Q2 results, which mostly reflects the miss in Q3, partially offset by the aforementioned backlog of international lateral flow orders which will be recognized in Q4. $25.0 million implies growth of 29% from 2011. We continue to expect the main catalyst to come from ramping sales of DPP products to FIOCRUZ. Meanwhile we model lateral flow products sales to contract about 22% in 2H 2012 compared to the same period in 2011.

And as we noted in our recent previous updates, our model assumes that FIOCRUZ meets their purchasing quota under the 2008 Technology Transfer agreement sometime during 2013 but does not take ownership of manufacturing until early 2015. As a reminder, FIOCRUZ is obligated to purchase at least ~$23 million in DPP products from Chembio before the technology is transferred and FIOCRUZ has the rights to manufacture themselves. FIOCRUZ may purchase more than the $23 million and vastly exceeded their required quota under a similar 2004 Technology Transfer agreement. When the transfer is complete and FIOCRUZ manufactures the products, Chembio will receive royalties of 4% on sales of the DPP products by FIOCRUZ in Brazil (this agreement only applies to Brazil). Although we feel comfortable with our estimate that FIOCRUZ will meet their purchasing quota in 2013, we have absolutely no insight into when to expect that FIOCRUZ will begin to manufacture the products. As it is now, we use the beginning of 2015 as a placeholder for this to occur. Our model reflects this and

is the reason we have 2015 revenue falling ~6% - 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 $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 2012 revenue which values the company at approximately $10.30/share. We are maintaining our Outperform rating.

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2011 A	Q1A	Q2A	Q3A	Q4E	2012 E	2013 E	2014 E	2015 E
Product sales	**$17,423**	**$6,363**	**$5,811**	**$4,745**	**$6,796**	**$23,715**	**$27,216**	**$34,482**	**$31,670**
% of total revenue	*89.9%*	*95.6%*	*95.5%*	*94.8%*	*93.8%*	*94.9%*	*92.6%*	*96.4%*	*93.8%*
YOY Growth	*28.9%*	*111.0%*	*95.4%*	*-14.1%*	*15.1%*	*36.1%*	*14.8%*	*26.7%*	*-8.2%*
License & royalty income	**$140**	**$0**	**$0**	**$0**	**$10**	**$10**	**$235**	**$255**	**$674**
% of total revenue	*0.7%*	*0.0%*	*0.0%*	*0.0%*	*0.1%*	*0.0%*	*0.8%*	*0.7%*	*2.0%*
R&D contracts, grants, milestones	**$1,826**	**$290**	**$273**	**$262**	**$440**	**$1,265**	**$1,927**	**$1,050**	**$1,425**
% of total revenue	*9.4%*	*4.4%*	*4.5%*	*5.2%*	*6.1%*	*5.1%*	*6.6%*	*2.9%*	*4.2%*
Total Revenues	$19,389.1	$6,653.0	$6,083.9	$5,007.4	$7,246.0	$24,990.5	$29,378.4	$35,786.7	$33,769.2
YOY Growth	*16.1%*	*83.0%*	*68.3%*	*-15.4%*	*16.6%*	*28.9%*	*17.6%*	*21.8%*	*-5.6%*
Cost of Revenues	$9,998	$3,320	$3,513	$3,278	$4,214	$14,325	$14,969	$17,586	$15,518
Gross Income	$9,391	$3,333	$2,571	$1,729	$3,032	$10,665	$14,409	$18,201	$18,251
Gross Margin	*48.4%*	*50.1%*	*42.3%*	*34.5%*	*41.9%*	*42.7%*	*49.0%*	*50.9%*	*54.0%*
Product Margin	*42.6%*	*47.8%*	*39.5%*	*30.9%*	*38.0%*	*39.6%*	*45.0%*	*49.0%*	*51.0%*
Research & Development	$4,878	$1,379	$979	$1,006	$980	$4,344	$4,740	$4,621	$4,520
% R&D	*25.2%*	*20.7%*	*16.1%*	*20.1%*	*13.5%*	*17.4%*	*16.1%*	*12.9%*	*13.4%*
Selling General & Admin	$3,424	$1,234	$1,079	$1,208	$1,341	$4,862	$5,670	$8,159	$7,767
% SG&A	*17.7%*	*18.5%*	*17.7%*	*24.1%*	*18.5%*	*19.5%*	*19.3%*	*22.8%*	*23.0%*
Operating Income	$1,088	$720	$512	($485)	$712	$1,459	$3,999	$5,421	$5,964
Operating Margin	*5.6%*	*10.8%*	*8.4%*	*-9.7%*	*9.8%*	*5.8%*	*13.6%*	*15.1%*	*17.7%*
Other income (expense)	$0	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	($13)	($1)	($1)	($1)	($2)	($4)	$35	$80	$125
Pre-Tax Income	$1,075	$719	$512	($486)	$710	$1,455	$4,034	$5,501	$6,089
Taxes	($5,133)	$285	$203	($193)	$282	$577	$1,602	$2,184	$2,417
Tax Rate	*-*	*39.6%*	*39.7%*	*39.8%*	*39.7%*	*39.6%*	*39.7%*	*39.7%*	*39.7%*
Net Income	$6,208	$434	$309	($292)	$428	$878	$2,433	$3,317	$3,672
YOY Growth	*147.1%*	*-405.1%*	*58.5%*	*-161.4%*	*-92.5%*	*-85.9%*	*177.0%*	*36.3%*	*10.7%*
Net Margin	*32.0%*	*6.5%*	*5.1%*	*-5.8%*	*5.9%*	*3.5%*	*8.3%*	*9.3%*	*10.9%*
GAAP EPS	$0.74	$0.05	$0.04	($0.04)	$0.05	$0.10	$0.28	$0.38	$0.43
Adjusted EPS	$0.13	$0.08	$0.06	($0.06)	$0.08	$0.17	$0.45	$0.61	$0.57
YOY Growth	*NA*	*-379.0%*	*61.3%*	*-165.4%*	*-92.5%*	*-85.9%*	*170.3%*	*36.3%*	*10.7%*
Weighted Avg. Shares O/S	8,394	8,512	8,525	8,001	8,638	8,419	8,625	8,625	8,625

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HISTORICAL ZACKS RECOMMENDATIONS



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