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Chembio Diagnostics Inc. (CEMI-OTC)

CEMI: Revenue +68%, Beats Our Number Again. OTC Program Moving Forward

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (08/10/12)	$5.00
Target Price	**$10.40**

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.

For the fourth consecutive quarter, revenue was ahead of our estimate. DPP FIOCRUZ sales have ramped quickly and the lateral flow products remain very strong. 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. CEMI could remain cash flow and net income positive from here on out.
We are maintaining our Outperform rating as well as our $10.40 price target.

SUMMARY DATA

52-Week High	**$5.18**
52-Week Low	**$2.80**
One-Year Return (%)	**63.82**
Beta	**0.03**
Average Daily Volume (sh)	**44,111**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$40**
Short Interest Ratio (days)	**1.58**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**17**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**21.0**
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	$6.22 E	$6.70 E	$25.72 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	$0.07 E	$0.11 E	$0.32 E
2013					$0.51 E
2014					$0.70 E

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

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WHAT'S NEW

Q2 2012: *Continued Strong Revenue Growth. OTC Program Moving Forward…*

Chembio reported financial results for the second quarter ending 6/30/2012 on August 9th. Revenue again beat our estimate, marking the fourth straight quarter that happened. Lateral flow product sales continue to be on a tear, posting y-o-y gains of 51% domestically and 63% internationally. DPP sales were also strong at $2.2MM, up 163% y-o-y although slightly below our estimate.

On the operational side, Chembio continues to make progress on several pipeline products and, following the news in July that FDA approved OraSure's OTC HIV test, Chembio affirmed that they will proceed full speed ahead with their OTC HIV program. As noted in our prior updates, we had yet to incorporate the OTC program (or eventual related revenue from the test) into our model due to uncertainty on which way Chembio would go - with the decision to move forward now in place, we've now included related financial assumptions into our model.

Q2 Financial Results

Revenue of $6.08 million (+68%) beat our $5.76 million number by about 6%, mostly due to stronger than modeled lateral flow sales.

Total product sales were $5.8 million, up 95% and about 10% better than our $5.3 million estimate. Sales of the company's lateral flow products have not flattened like we anticipated would happen beginning in early 2012. By contrast sales have increased 39% (34% domestically and 50% overseas) through the first half of 2012. Sales of DPP products to FIOCRUZ were $2.2 million, up 163% y-o-y but slightly below our more optimistic $2.8 million estimate. We model $9.6 million in DPP sales for the full year.

Operating expenses came down significantly sequentially, dropping from $2.6 million in Q1 2012 to $2.1 million in Q2. Reduction of $400k in R&D expense is reflective of the wrapping up of clinical trials for the DPP HIV test for the U.S. market.

Adjusted for the non-cash portion of income taxes from the use of operating loss carryforwards, Q2 adjusted net income and EPS of $491k and $0.06 were slightly better than our $394k and $0.05 estimates. 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 $4.3 million at the end of Q2.

Cash

Cash from operations was an inflow of $1.6 million in Q2. Chembio exited the quarter with $4.4 million in cash and equivalents, up $1.4 million from the $3.0 million balance at the end of Q1. Debt remains relatively immaterial. As noted, we have now 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…

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. 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 Q2 they made progress in starting clinical trials to support a 510(k), which they think could be 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…http://scr.zacks.com/News/Press-Releases/Press-Release-Details/2012/CEMI-Study-May-Offer-Support-for-DPP-HCV-Test/default.aspx).

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.

CEMI noted that they recently received proprietary antigens and will use them to run a feasibility study to determine if they can improve on 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.

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 test (see our July 5 Investor Note…http://scr.zacks.com/News/Press-Releases/Press-Release-Details/2012/CEMI---OraSures-Rapid-HIV-FDA-Approved-For-OTC-Market/default.aspx). 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 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.

Chembio expects to submit an IDE to the FDA and have it granted by year-end 2012. 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've only made very small tweaks for 2012. We now look for 2012 revenue of $25.7 million, up from $25.2 million prior to Q2 results, which mostly reflects the beat in Q2 as well as contribution from the recently announced $480k contract extension related to the development of a multiplex flu test. $25.7 million implies growth of almost 33% from 2011. We continue to expect the main catalyst to come from ramping sales of DPP products to FIOCRUZ. We also note that we model lateral flow products sales to contract about 14% in 2H 2012 compared to the same period in 2011, despite the ~39% growth of these products in 1H 2012 - we have no particular insight that sales will indeed fall in 2H 2012 and have clearly modeled this conservatively in the recent past but given the historical variability in these sales, we feel it's prudent to err on the side of conservative. This could result in CEMI beating our revenue numbers again - for Q3 and potentially Q4.

And as we noted in our last update, 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 $2.7 million and $0.32 in 2012.

RECOMMENDATION / VALUATION

We continue to believe that CEMI trades significantly cheaper than warranted. We also think it bears repeating that our revenue estimates have proven conservative over the last four quarters and may continue to be so. We value CEMI using 3.5x our estimated 2012 revenue which values the company at approximately $10.40/share. We are maintaining our Outperform rating.

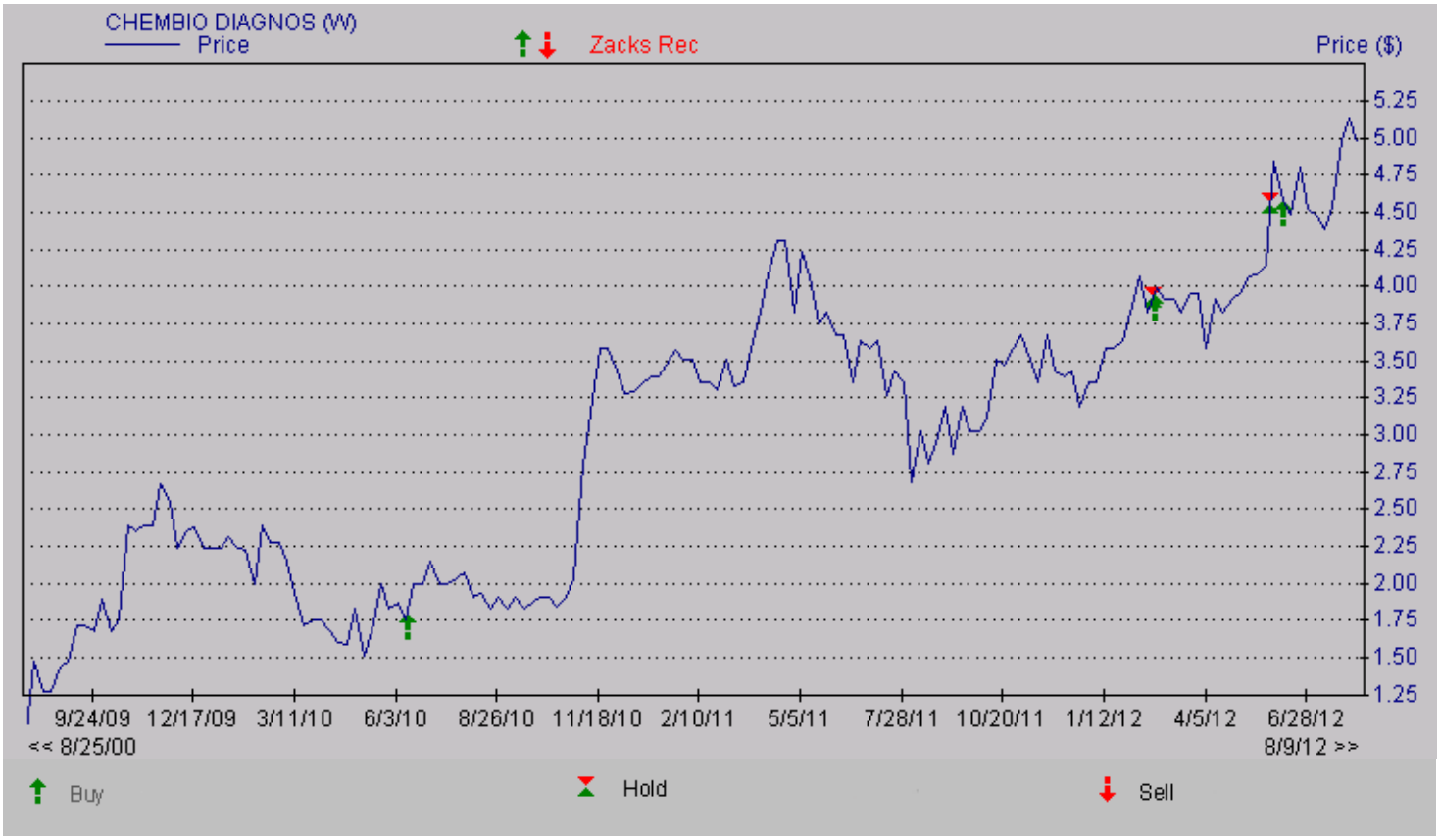
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2011 A	Q1A	Q2A	Q3E	Q4E	2012 E	2013 E	2014 E	2015 E
Product sales	**$17,423**	**$6,363**	**$5,811**	**$5,820**	**$6,310**	**$24,304**	**$27,922**	**$35,275**	**$32,519**
% of total revenue	*89.9%*	*95.6%*	*95.5%*	*93.6%*	*94.0%*	*94.5%*	*93.5%*	*96.1%*	*93.9%*
YOY Growth	*28.9%*	*111.0%*	*95.4%*	*5.3%*	*6.8%*	*39.5%*	*14.9%*	*26.3%*	*-7.8%*
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%*	*1.9%*
R&D contracts, grants, milestones	**$1,826**	**$290**	**$273**	**$400**	**$390**	**$1,405**	**$1,705**	**$1,170**	**$1,425**
% of total revenue	*9.4%*	*4.4%*	*4.5%*	*6.4%*	*5.8%*	*5.5%*	*5.7%*	*3.2%*	*4.1%*
Total Revenues	$19,389.1	$6,653.0	$6,083.9	$6,220.0	$6,710.0	$25,719.3	$29,862.4	$36,700.4	$34,617.7
YOY Growth	*16.1%*	*83.0%*	*68.3%*	*5.0%*	*7.9%*	*32.6%*	*16.1%*	*22.9%*	*-5.7%*
Cost of Revenues	$9,998	$3,320	$3,513	$3,405	$3,534	$13,772	$14,520	$17,109	$15,284
Gross Income	$9,391	$3,333	$2,571	$2,815	$3,176	$11,948	$15,343	$19,592	$19,334
Gross Margin	*48.4%*	*50.1%*	*42.3%*	*45.3%*	*47.3%*	*46.5%*	*51.4%*	*53.4%*	*55.8%*
Product Margin	*42.6%*	*47.8%*	*39.5%*	*41.5%*	*44.0%*	*43.3%*	*48.0%*	*51.5%*	*53.0%*
Research & Development	$4,878	$1,379	$979	$1,020	$980	$4,358	$4,740	$4,621	$4,520
% R&D	*25.2%*	*20.7%*	*16.1%*	*16.4%*	*14.6%*	*16.9%*	*15.9%*	*12.6%*	*13.1%*
Selling General & Admin	$3,424	$1,234	$1,079	$1,120	$1,174	$4,607	$5,763	$8,368	$7,962
% SG&A	*17.7%*	*18.5%*	*17.7%*	*18.0%*	*17.5%*	*17.9%*	*19.3%*	*22.8%*	*23.0%*
Operating Income	$1,088	$720	$512	$676	$1,022	$2,930	$4,839	$6,603	$6,852
Operating Margin	*5.6%*	*10.8%*	*8.4%*	*10.9%*	*15.2%*	*11.4%*	*16.2%*	*18.0%*	*19.8%*
Other income (expense)	$0	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	($13)	($1)	($1)	($2)	($2)	($6)	$35	$80	$125
Pre-Tax Income	$1,075	$719	$512	$674	$1,020	$2,925	$4,874	$6,683	$6,977
Taxes	($5,133)	$285	$203	$267	$405	$1,161	$1,935	$2,653	$2,770
Tax Rate	*-*	*39.6%*	*39.7%*	*39.7%*	*39.7%*	*39.7%*	*39.7%*	*39.7%*	*39.7%*
Net Income	$6,208	$434	$309	$406	$615	$1,764	$2,939	$4,030	$4,207
YOY Growth	*147.1%*	*-405.1%*	*58.5%*	*-14.6%*	*-89.2%*	*-71.6%*	*66.6%*	*37.1%*	*4.4%*
Net Margin	*32.0%*	*6.5%*	*5.1%*	*6.5%*	*9.2%*	*6.9%*	*9.8%*	*11.0%*	*12.2%*
GAAP EPS	$0.74	$0.05	$0.04	$0.05	$0.07	$0.21	$0.34	$0.47	$0.49
Adjusted EPS	$0.13	$0.08	$0.06	$0.07	$0.11	$0.32	$0.51	$0.70	$0.58
YOY Growth	*NA*	*-379.0%*	*61.3%*	*-15.7%*	*-89.2%*	*-72.2%*	*65.7%*	*37.1%*	*4.4%*
Weighted Avg. Shares O/S	8,394	8,512	8,525	8,626	8,638	8,575	8,625	8,625	8,625

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HISTORICAL ZACKS RECOMMENDATIONS



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