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Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-OTC)

CEMI: Déjà vu: Another Record Quarter, Another Top-line Beat

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (05/09/12)	$0.51
Target Price	**$1.30**

OUTLOOK

DPP sales have already begun to ramp in Brazil under multi-year contracts worth at least $23MM. The DPP tests could launch in the U.S. in 2013. Final FDA module filing for DPP HIV test expected in June.

For the third consecutive quarter revenue in Q1 2012 set an all-time record and was well ahead of our estimates. 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 on Chembio. Our price target has moved from $1.20 to $1.30.

SUMMARY DATA

52-Week High	**$0.55**
52-Week Low	**$0.21**
One-Year Return (%)	**10.84**
Beta	**0.07**
Average Daily Volume (sh)	**30,644**
Shares Outstanding (mil)	**69**
Market Capitalization ($mil)	**$35**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**21.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**24.5**
P/E using 2012 Estimate	**17.0**
P/E using 2013 Estimate	**8.5**
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	$5.76 E	$6.07 E	$6.53 E	$25.16 E
2013					$29.77 E
2014					$36.70 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.00 A	$0.00 A	$0.01 A	$0.08 A	$0.09 A
2012	$0.01 A	$0.01 E	$0.01 E	$0.01 E	$0.03 E
2013					$0.06 E
2014					$0.08 E

Zacks Projected EPS Growth Rate - Next 5 Years % **18**

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WHAT'S NEW

Q1 2012: *Record Revenue Beats Big on Strong Sales of Both DPP and Lateral Flow. U.S. DPP HIV Submission On-Track…*

Chembio reported financial results for the first quarter ending 3/31/2012 on May 8th. This marks the third consecutive quarter with record revenue that came in well ahead of our estimates. This time strong sales of both the DPP and lateral flow products contributed to the beat on the top-line and resulted in the new record for quarterly revenues. We've made some small upward revisions to revenue but, given the strength in all the product lines, our numbers could still prove conservative.

On the business side, Chembio continues to get closer to filing the third module for the DPP HIV test for the U.S. market (still anticipated in Q2) and is making meaningful progress on several pipeline products and new product development. Of particular note is that the company is now looking to potentially develop a DPP syphilis/HIV combination test for the international market. Management also noted that discussions with potential partners including diagnostic and pharma companies for a DPP hepatitis C test are ongoing (albeit still preliminary). Feasibility of an OTC HIV test should become more clear over the next few months.

Our model currently does not include any contribution from any of these proposed pipeline products which are still mostly in the planning stage - a such, eventual commercialization of one or more of these and/or a meaningful collaboration agreement could provide material upside to our estimates.

Q1 Financial Results

Revenue of $6.65 million (+83%) set a new quarterly record and handily beat our $5.55 million estimate as a result of better than modeled revenue from both the lateral flow and DPP products.

Total product sales were $6.36 million, up 96% and almost $1.3 million better than our estimate. Sales of DPP products sold to FIOCRUZ are ramping very rapidly, coming in at $2.5 million in Q1 versus our $2.2 million estimate. As reminder, DPP product sales commenced in late 2010 and were $4.3 million in all of 2011, including $3.4 million during the second half of the year. The current $2.5 million quarterly run-rate implies management's previous guidance of at least $9 million in DPP sales in 2012 might be modest. We currently model approximately $10.5 million in DPP revenue for the full-year 2012, implying only very modest average sequential growth from Q1 - which also could end up conservative. Meanwhile, sales of the lateral flow products to Alere remained very strong in Q1, up 22% and continuing to benefit from demand for rapid HIV testing. International lateral flow sales were also very strong, up 40%. Important to note is that lateral flow revenue can jump around quarter to quarter.

Q1 net income and EPS of $434k and $0.01 were inline with our $606k and $0.01 estimates. The slight difference in net income a result of the better revenue number which was offset by higher R&D ($191k of which was related to 2011) and income tax expense.

Cash

Cash from operations was an inflow of $149k in Q1. Chembio exited the quarter with $3.0 million in cash and equivalents, flat from the end of Q4. Debt remains relatively immaterial. We continue to forecast that the company will be able to manage 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. The third and final module is expected to be filed with the FDA in June. Management continues to expect that both the blood and oral fluid sample data will be robust enough to meet FDA requirements. Chembio expects 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 Q1 2013.

DPP Syphilis (FIOCRUZ)
On May 3, 2011 Chembio announced that FIOCRUZ had received approval of its DPP Syphilis Treponemal test from Brazilian regulatory authorities. The Treponemal test is a single-parameter test for the detection of antibodies specific to Syphilis. Chembio and FIOCRUZ expect to submit a second Syphilis test for approval in Brazil in the future (the prior expectation was that this would happen either in late 2011 or early 2012). This second test is a multiplex screen and confirm assay that incorporates the Treponemal as well as non-Treponemal parameters. Launch of the multiplex test, which enables the detection and differentiation of past versus active infections, will likely significantly broaden the market for the DPP Syhpilis tests.

The agreement calls for minimum purchases of $5.7 million of these two tests over three years.

DPP Syphilis Screen and Confirmation (U.S. / Europe)
The screen and confirmation (treponemal / non-treponemal) test received CE Marking in early October and Chembio is currently working to finalize distribution of the test in Europe.

Clinical trials in support of 510(k) for the treponemal / non-treoponemal test had been expected to start during Q2 2011. This has been delayed due in order to best determine how to meet the FDA requirements of showing substantially 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 has since 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. Chembio hopes to have the studies completed and submit a 510(k) during 1H 2013. 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 Diagnostic
Chembio had previously noted that they were in discussions with potential partners for commercialization of a DPP hepatitis C test. Chembio had already done significant work on an HCV test so, depending on the circumstances, we think further development could potentially move along quickly. Management noted that discussions with potential collaborators for an HCV diagnostic, including diagnostic and pharma companies remain in the early stages but are ongoing.

DPP Syphilis / HIV Combo
Management noted on the call that they have developed a prototype DPP syphilis/HIV combo test that they will look to further develop for the international market.

HIV Lateral Flow Home Use Test
Last year Chembio announced that they may pursue FDA approval of its Sure Check HIV 1/2 test for home use (i.e. - OTC). In September the FDA provided guidance that Chembio will need to perform additional studies in order to submit for an Investigational Device Exemption (IDE). FDA clarified the regulatory pathway and Chembio has since completed the instructional manual for home-use testing - the initial validation of the manual has been initiated. Chembio will now wait to see the FDA's recommendation (in the coming weeks) on OraSure's application for approval of its oral fluid HIV test for OTC use which will likely provide very valuable insight into the approvability of such a product.

As eventual approval is highly uncertain at this point and not a near-term event we do not yet model a contribution from an OTC HIV test.

OUR OUTLOOK

Revenue
We now look for 2012 revenue of $25.2 million, up from $23.4 million prior to Q1 results, which mostly reflects the beat in Q1. $25.2 million implies growth of almost 30% from 2011. We continue to expect the main catalyst to come from ramping sales of DPP products to FIOCRUZ.

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 ~7% - we also model some trimming in expenses which somewhat mutes the impact to the bottom line.

Net Income / EPS

We model net income of $2.3 million and EPS of $0.03 in 2012, compared to $2.1 million $0.03 prior to Q1 results.

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 three quarters and may continue to be so. We value CEMI using 3.5x our estimated 2012 revenue which values the company at approximately $1.30/share. We are maintaining our Outperform rating.

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2011 A	Q1A	Q2E	Q3E	Q4E	2012 E	2013 E	2014 E	2015 E
Product sales	**$17,423**	**$6,363**	**$5,302**	**$5,795**	**$6,285**	**$23,745**	**$27,807**	**$35,226**	**$31,932**
% of total revenue	*89.9%*	*95.6%*	*92.1%*	*95.5%*	*96.2%*	*94.4%*	*93.4%*	*96.0%*	*93.4%*
YOY Growth	*28.9%*	*111.0%*	*78.3%*	*4.9%*	*6.4%*	*36.3%*	*17.1%*	*26.7%*	*-9.4%*
License & royalty income	**$140**	**$0**	**$11**	**$10**	**$20**	**$41**	**$255**	**$305**	**$818**
% of total revenue	*0.7%*	*0.0%*	*0.2%*	*0.2%*	*0.3%*	*0.2%*	*0.9%*	*0.8%*	*2.4%*
R&D contracts, grants, milestones	**$1,826**	**$290**	**$445**	**$260**	**$225**	**$1,375**	**$1,705**	**$1,170**	**$1,425**
% of total revenue	*9.4%*	*4.4%*	*7.7%*	*4.3%*	*3.4%*	*5.5%*	*5.7%*	*3.2%*	*4.2%*
Total Revenues	$19,389.1	$6,653.0	$5,758.0	$6,065.0	$6,530.0	$25,161.0	$29,767.4	$36,700.7	$34,174.7
YOY Growth	*16.1%*	*83.0%*	*59.3%*	*2.4%*	*5.0%*	*29.8%*	*18.3%*	*23.3%*	*-6.9%*
Cost of Revenues	$9,998	$3,320	$3,118	$3,390	$3,520	$13,347	$14,460	$17,084	$15,008
Gross Income	$9,391	$3,333	$2,640	$2,675	$3,010	$11,814	$15,308	$19,616	$19,167
Gross Margin	*48.4%*	*50.1%*	*45.9%*	*44.1%*	*46.1%*	*47.0%*	*51.4%*	*53.4%*	*56.1%*
Product Margin	*42.6%*	*47.8%*	*41.2%*	*41.5%*	*44.0%*	*43.8%*	*48.0%*	*51.5%*	*53.0%*
Research & Development	$4,878	$1,379	$1,125	$1,210	$1,205	$4,919	$4,320	$3,500	$3,120
% R&D	*25.2%*	*20.7%*	*19.5%*	*20.0%*	*18.5%*	*19.6%*	*14.5%*	*9.5%*	*9.1%*
Selling General & Admin	$3,424	$1,234	$1,065	$1,019	$1,084	$4,402	$5,894	$9,102	$8,202
% SG&A	*17.7%*	*18.5%*	*18.5%*	*16.8%*	*16.6%*	*20.4%*	*19.8%*	*24.8%*	*24.0%*
Operating Income	$1,088	$720	$450	$446	$721	$2,338	$5,094	$7,014	$7,845
Operating Margin	*5.6%*	*10.8%*	*7.8%*	*7.4%*	*11.0%*	*9.3%*	*17.1%*	*19.1%*	*23.0%*
Other income (expense)	$0	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	($13)	($1)	($3)	($2)	($2)	($8)	$35	$80	$125
Pre-Tax Income	$1,075	$719	$447	$444	$719	$2,330	$5,129	$7,094	$7,970
Taxes	($5,133)	$285	$54	$53	$86	$479	$1,026	$1,419	$1,594
Tax Rate	*-*	*39.7%*	*12.0%*	*12.0%*	*12.0%*	*20.5%*	*20.0%*	*20.0%*	*20.0%*
Net Income	$6,208	$434	$394	$391	$633	$1,851	$4,103	$5,676	$6,376
YOY Growth	*147.1%*	*-404.8%*	*102.2%*	*-17.9%*	*-88.9%*	*-70.2%*	*121.7%*	*38.3%*	*12.3%*
Net Margin	*32.0%*	*6.5%*	*6.8%*	*6.4%*	*9.7%*	*7.4%*	*13.8%*	*15.5%*	*18.7%*
EPS	$0.09	$0.01	$0.01	$0.01	$0.01	$0.03	$0.06	$0.08	$0.09
YOY Growth	*NA*	*-378.7%*	*103.7%*	*-18.9%*	*-88.9%*	*-70.9%*	*120.9%*	*38.3%*	*12.3%*
Weighted Avg. Shares O/S	67,148	68,099	68,870	69,010	69,100	68,770	69,000	69,000	69,000

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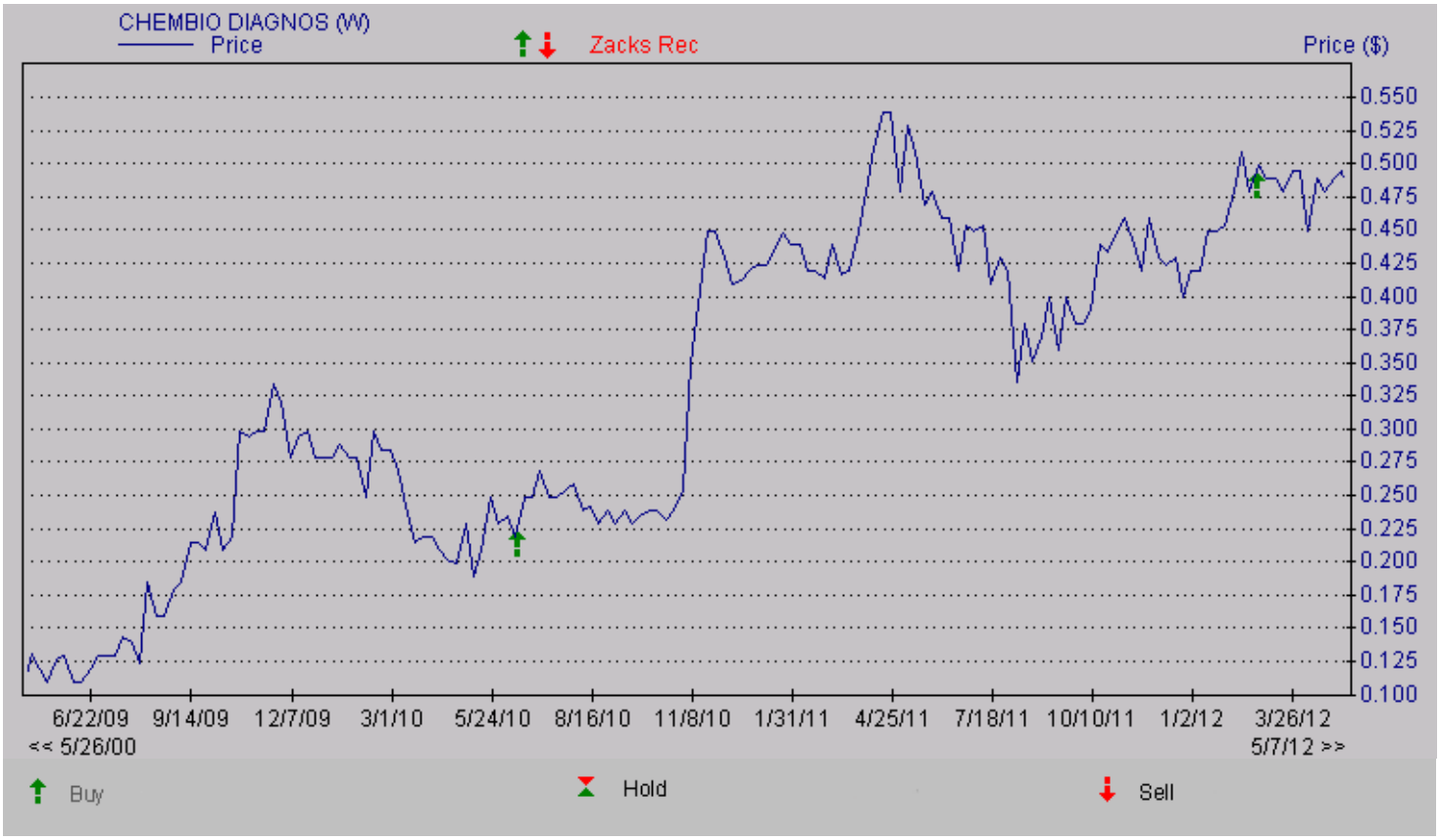
HISTORICAL ZACKS RECOMMENDATIONS



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