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Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-OTC)

CEMI: Q4 2011: Another Record Quarter. 2012 DPP Guidance Strong.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (03/08/12)	$0.50
Target Price	**$1.20**

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 - although progress to that end has been hampered by ongoing development and clinical trial delays. Revenue in Q4 2011 was an all-time record, besting the previous record set in Q3. DPP FIOCRUZ sales are expected to be at least $9MM in 2012 (and account for 40%+ of total sales) - 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 $1.10 to $1.20.

SUMMARY DATA

52-Week High	**$0.58**
52-Week Low	**$0.21**
One-Year Return (%)	**10.84**
Beta	**0.07**
Average Daily Volume (sh)	**30,444**
Shares Outstanding (mil)	**69**
Market Capitalization ($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 (%)	**22.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**25.0**
P/E using 2012 Estimate	**16.7**
P/E using 2013 Estimate	**8.3**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
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	$5.55 E	$5.34 E	$6.07 E	$6.48 E	$23.44 E
2013					$28.82 E
2014					$35.71 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 E	$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

Q4 2011 Financial Results: *Int'l Lateral Flow Revenue Surprises. DPP FIOCRUZ Revenue Continues to Ramp Nicely and Is Expected to More Than Double in 2012…*

Chembio reported financial results for the fourth quarter ending December 31, 2011 on March 8th. Revenue of $6.22 million set a new record high for Chembio and was well ahead of our $5.45 million estimate as a result of international sales of the lateral flow products holding up better than we anticipated.

Total product sales were $5.91 million, up 14% y-o-y and over $800k better than our $5.08 million estimate. Sales of DPP products sold to FIOCRUZ were $1.65 million (right in-line with our $1.70 million estimate) - while this is roughly flat from Q3, this trend is not expected to continue. Management noted earlier this year and again on the call that DPP FIOCRUZ revenue should be at least $9 million in 2012, more than double the $4.3 million in 2011. As we have noted in the past, the DPP technology is the future for Chembio and the indication that there is substantial pull-through demand from FIOCRUZ and this technology is the major driver of near-term revenue is a clear positive for the company. We currently model DPP sales to account for over 40% of Chembio's total revenue in 2012, up from just 22% in 2011.

Q4 product sales also benefitted from another sequential jump in international HIV lateral flow sales - although this revenue of $2.33 million was down about 12% yoy, it was up ~25% sequentially. International lateral flow sales are somewhat choppy quarter to quarter but fell 17% for the full year in 2011 as a result of weakness in Africa. We model similar softness in 2012 and then for sales to flatten out the following year.

Conversely, U.S. sales of the lateral flow products, marketed through Alere, were very strong in 2011, growing 37% for the year and about 5% in Q4. Management believes growth in this business will continue into 2012 (albeit not expected at the 2011 rate) - we model very modest growth in 2012 and beyond, although this could prove conservative as there continues to be increasing demand for rapid HIV testing in both the acute-care and clinical practice settings.

Q4 net income and EPS, excluding a $5.16 million benefit from the reversal a deferred tax asset valuation, were $547k and $0.01, in-line with our $376k and $0.01 estimates. On a GAAP basis (including the tax asset benefit), net income and EPS were $5.68 million and $0.08. Chembio took the tax asset reversal as they expect to generate positive pre-tax income going forward (which has been and continues to be commensurate with our model).

Cash

Cash from operations was an inflow of $709k in Q4 and $2.27 million for the full year. Chembio exited Q4 with $3.0 million in cash and equivalents, flat from the end of Q3. Total debt was about $187k, all of which represents bank loans. Chembio has significant liquidity and we continue to expect the company will be able to manage to fund all operations (including clinical trials, regulatory filings, SG&A, etc.) through cash on hand and funds from operations.

Business / Pipeline Update...

DPP HIV, U.S.

The first FDA PMA module filing was made in April 2011. Second module was filed in early October. Clinical trials are about 98% done (~90% done at end of Q3). CEMI expects trials to complete "as soon as possible" (which is a delay from the prior expectation that trials would complete during Q4 2011) and dependent on the recruitment of the remaining pediatric enrollees. Despite the ongoing delays, notable is that management continues to believe that both the blood and oral fluid sample data will be robust enough to meet FDA requirements. Management's current timeline is to hopefully have the trials completed in May of this year, make the Module III submission to the FDA in Q2 as well, and hopefully have an answer back from the agency on their PMA before the end of the year. Chembio ballparks about three months after that to get CLIA waiver and if all goes without a hitch, to have the DPP HIV test on the U.S. market by mid-2013. We have adjusted our model accordingly.

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-treoponemal) 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) had been expected to start during Q2 2011. This was delayed and now trials are on hold pending inclusion of a reader for this dual marker test. Chembio is now working on incorporating a reader and, if successful, hopes to have clinical trials completed and make a 510(k) filing in 2012 - they now hope to have this syphilis screen and confirmation test on the U.S. market in the first half of 2013. We have also updated our model to account for this delay.

HIV Lateral Flow Home Use Test
In June Chembio announced that it 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 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 $23.4 million - largely unchanged from prior to Q4 results and implies growth of 21% from 2011. As noted, the most significant driver of revenue in 2012 is expected 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 $2.1 million and EPS of $0.03 in 2012, compared to $1.1 million and $0.02 in 2011 (2011 pro forma for the tax asset reversal).

RECOMMENDATION / VALUATION

Competitors (OSUR and TRIB) trade at an average of 3.5x estimated 2012 sales. We look for CEMI to post 2012 sales of $23.4 million which, based on competitor price/sales ratios, values CEMI at about $1.20/share. We are maintaining our Outperform rating. Our price target has moved from $1.10 to $1.20 per share.

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2011 A	Q1E	Q2E	Q3E	Q4E	2012 E	2013 E	2014 E	2015 E
Product sales	**$17,423**	**$5,094**	**$4,888**	**$5,795**	**$6,235**	**$22,012**	**$26,861**	**$34,234**	**$30,913**
% of total revenue	*89.9%*	*91.8%*	*91.5%*	*95.5%*	*96.2%*	*93.9%*	*93.2%*	*95.9%*	*93.2%*
YOY Growth	*28.9%*	*69.0%*	*64.3%*	*4.9%*	*5.6%*	*26.3%*	*22.0%*	*27.4%*	*-9.7%*
2008 FIOCRUZ Tech Trnsfr		$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$568.0
Bio-Rad Multiplex	$0	$0	$0	$0	$10	$10	$235	$255	$250
2004 Tech Transfer agreements	$140	$12	$11	$10	$10	$43	$20	$50	$0
Other misc	$0	$0	$0	$0	$0	$0	$0	$0	$0
License & royalty income	**$140**	**$12**	**$11**	**$10**	**$20**	**$53**	**$255**	**$305**	**$818**
% of total revenue	*0.7%*	*0.2%*	*0.2%*	*0.2%*	*0.3%*	*0.2%*	*0.9%*	*0.9%*	*2.5%*
R&D contracts, grants, milestones	**$1,826**	**$445**	**$445**	**$260**	**$225**	**$1,375**	**$1,705**	**$1,170**	**$1,425**
% of total revenue	*9.4%*	*8.0%*	*8.3%*	*4.3%*	*3.5%*	*5.9%*	*5.9%*	*3.3%*	*4.3%*
Total Revenues	$19,389.1	$5,551.0	$5,344.0	$6,065.0	$6,480.0	$23,440.0	$28,820.9	$35,709.1	$33,156.3
YOY Growth	*16.1%*	*52.7%*	*47.9%*	*2.4%*	*4.2%*	*20.9%*	*23.0%*	*23.9%*	*-7.1%*
Cost of Revenues	$9,998	$2,904	$2,874	$3,390	$3,492	$12,659	$13,968	$16,604	$14,529
Gross Income	$9,391	$2,647	$2,470	$2,675	$2,988	$10,781	$14,853	$19,106	$18,627
Gross Margin	*48.4%*	*47.7%*	*46.2%*	*44.1%*	*46.1%*	*46.0%*	*51.5%*	*53.5%*	*56.2%*
Product Margin	*42.6%*	*43.0%*	*41.2%*	*41.5%*	*44.0%*	*42.5%*	*48.0%*	*51.5%*	*53.0%*
Research & Development	$4,878	$1,050	$1,125	$1,210	$1,205	$4,590	$4,320	$3,500	$3,120
% R&D	*25.2%*	*18.9%*	*21.1%*	*20.0%*	*18.6%*	*19.6%*	*15.0%*	*9.8%*	*9.4%*
Selling General & Admin	$3,424	$988	$989	$1,019	$1,076	$4,071	$5,707	$8,856	$7,958
% SG&A	*17.7%*	*17.8%*	*18.5%*	*16.8%*	*16.6%*	*20.4%*	*19.8%*	*24.8%*	*24.0%*
Operating Income	$1,088	$609	$356	$446	$708	$2,119	$4,827	$6,750	$7,550
Operating Margin	*5.6%*	*11.0%*	*6.7%*	*7.4%*	*10.9%*	*9.0%*	*16.7%*	*18.9%*	*22.8%*
Other income (expense)	$0	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	($13)	($3)	($3)	($2)	($2)	($10)	$35	$80	$125
Pre-Tax Income	$1,075	$606	$353	$444	$706	$2,109	$4,862	$6,830	$7,675
Taxes	($5,133)	$0	$0	$0	$0	$0	$583	$1,161	$1,535
Tax Rate	*-*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*12.0%*	*17.0%*	*20.0%*
Net Income	$6,208	$606	$353	$444	$706	$2,109	$4,278	$5,669	$6,140
YOY Growth	*147.1%*	*-526.1%*	*81.5%*	*-6.7%*	*-87.6%*	*-66.0%*	*102.8%*	*32.5%*	*8.3%*
Net Margin	*32.0%*	*10.9%*	*6.6%*	*7.3%*	*10.9%*	*9.0%*	*14.8%*	*15.9%*	*18.5%*
EPS	$0.09	$0.01	$0.01	$0.01	$0.01	$0.03	$0.06	$0.08	$0.09
YOY Growth	*NA*					*-66.9%*	*102.7%*	*32.5%*	*8.3%*
Weighted Avg. Shares O/S	67,148	68,825	68,870	69,010	69,100	68,951	69,000	69,000	69,000

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HISTORICAL ZACKS RECOMMENDATIONS



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