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Chembio Diagnostics Inc. (CEMI- NASDAQ)

CEMI: Updating Model for CLIA Waiver Delay

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (02/10/14)	$3.30
Target Price	**$9.75**

OUTLOOK

Lateral flow sales helping buoy revenue. Alere taking market share in the U.S. and recent recommendations on HIV testing should aid U.S. sales. Alere launching competing product, however, the potential effects of which we will be watching. Int'l lateral flow sales have been very strong but can be variable q-to-q. CEMI is focused on growing this business - fruits of which are already being seen - with more expected as "new opportunities" appear to be on the horizon. DPP sales ex-Brazil could also accelerate. These should help offset a bigger and earlier than anticipated decline in FIOCRUZ sales.

Pipeline progress continues and was highlighted by FDA approval of DPP HIV test in December 2012. U.S. launch of DPP HIV test, while delayed from previous expectations, could still be a near-term event. Syphilis test and HIV/syphilis combo test are also in the pipeline, as is a potentially pursuit of OTC approval of the company's (blood sample) lateral flow test.

Cash position and the balance sheet remain very healthy.

We are maintaining our Outperform rating.

SUMMARY DATA

52-Week High	**$5.75**
52-Week Low	**$3.00**
One-Year Return (%)	**-12.62**
Beta	**0.28**
Average Daily Volume (sh)	**42,187**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$30**
Short Interest Ratio (days)	**2.38**
Institutional Ownership (%)	**19**
Insider Ownership (%)	**15**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**22.6**
Earnings Per Share (%)	**-28.2**
Dividend (%)	**N/A**
P/E using TTM EPS	**19.4**
P/E using 2013 Estimate	**18.3**
P/E using 2014 Estimate	**16.5**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Value**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(millions)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	$6.65 A	$6.08 A	$5.01 A	$7.87 A	$25.61 A
2013	$6.68 A	$5.39 A	$9.62 A	$6.69 E	$28.38 E
2014					$30.29 E
2015					$29.44 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	$0.08 A	$0.06 A	-$0.06 A	$0.08 A	$0.17 A
2013	$0.05 A	-$0.04 A	$0.11 A	$0.05 E	$0.18 E
2014					$0.20 E
2015					$0.30 E

Zacks Projected EPS Growth Rate - Next 4 Years % **25**

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WHAT'S NEW

Updating Model for DPP HIV 1/2 CLIA Waiver Delay

This morning's (2/10/2014) news that CLIA waiver for the DPP HIV 1/2 test will be delayed due to FDA's request of additional positive (i.e. -new infections) test results was unexpected. CEMI filed for CLIA waiver in early December and had previously expected the waiver to be granted in Q1 of this year, with launch of the test anticipated to happen shortly afterwards. As our model had mirrored these timelines, we are now updating our revenue and earnings estimates to reflect a delay in launch and also additional R&D expense to fund the additional sample collection and analysis.

As conversations with FDA are still ongoing, CEMI did not offer expectations relative to how many new infections the agency may request or how long the additional/supplemental study may take. There is also no prior history or comparator to use as guidance as FDA's requirements have changed (i.e. - increased) since OSUR's oral fluid HIV rapid test was granted CLIA waiver (June 2004).

We expect CLIA waiver of the DPP HIV 1/2 test will happen. So while we categorize this as setback as it relates to our near-term financial forecast, we do not view this as significant to our general, overall outlook for CEMI. We have now pushed back our modeled revenue related to sales of the test in the U.S. from commencing in 1H 2014 (previously) to Q1 2015 (currently). We will update expected timing of launch of the test if appropriate when more information relative to timelines and requirements (scope/size) of the additional sample base becomes available.

We now look for revenue and adjusted EPS of $30.3M / $0.20 and $29.4M / $0.30 in 2014 and 2015, respectively, changed from $31.9M / $0.25 and $31.0M / $0.33 prior to the CLIA waiver delay announcement.

Valuation

We use a comp valuation of 3.3x estimated 2014 revenue which values CEMI at approximately $9.75/share. We are moving our per share price target from $10 to $9.75. Maintaining Outperform rating.

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2012 A	Q1A	Q2A	Q3A	Q4E	2013 E	2014 E	2015 E	2016 E
Product sales	**$24,327**	**$6,313**	**$5,062**	**$9,045**	**$6,062**	**$26,482**	**$29,254**	**$27,614**	**$33,186**
% of total revenue	*95.0%*	*94.5%*	*93.9%*	*94.0%*	*90.7%*	*93.3%*	*96.6%*	*93.8%*	*95.1%*
YOY Growth	*39.6%*	*-0.8%*	*-12.9%*	*90.6%*	*-18.2%*	*8.9%*	*10.5%*	*-5.6%*	*20.2%*
License & royalty income	**$0**	**$0**	**$0**	**$1**	**$5**	**$6**	**$75**	**$402**	**$403**
% of total revenue	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.1%*	*0.0%*	*0.2%*	*1.4%*	*1.2%*
R&D contracts, grants, milestones	**$1,283**	**$365**	**$332**	**$572**	**$619**	**$1,888**	**$962**	**$1,425**	**$1,300**
% of total revenue	*5.0%*	*5.5%*	*6.2%*	*5.9%*	*9.3%*	*6.7%*	*3.2%*	*4.8%*	*3.7%*
Total Revenues	$25,610.5	$6,678.2	$5,393.5	$9,617.6	$6,686.0	$28,375.5	$30,291.2	$29,440.4	$34,889.2
YOY Growth	*32.1%*	*0.4%*	*-11.3%*	*92.1%*	*-15.0%*	*10.8%*	*6.8%*	*-2.8%*	*18.5%*
Cost of Revenues	$14,820	$3,984	$3,112	$5,561	$3,758	$16,417	$17,552	$15,740	$18,750
Gross Income	$10,790	$2,694	$2,281	$4,056	$2,928	$11,959	$12,739	$13,701	$16,139
Gross Margin	*42.1%*	*40.3%*	*42.3%*	*42.2%*	*43.8%*	*42.1%*	*42.1%*	*46.5%*	*46.3%*
Product Margin	*39.1%*	*36.9%*	*38.5%*	*38.5%*	*38.0%*	*38.0%*	*40.0%*	*43.0%*	*43.5%*
Research & Development	$4,487	$1,045	$1,501	$1,602	$1,280	$5,428	$5,250	$4,800	$4,925
% R&D	*17.5%*	*15.7%*	*27.8%*	*16.7%*	*19.1%*	*19.1%*	*17.3%*	*16.3%*	*14.1%*
Selling General & Admin	$4,852	$1,162	$1,160	$1,380	$1,123	$4,825	$5,362	$5,800	$6,838
% SG&A	*18.9%*	*17.4%*	*21.5%*	*14.3%*	*16.8%*	*17.0%*	*17.7%*	*19.7%*	*19.6%*
Operating Income	$1,452	$487	($380)	$1,074	$524	$1,705	$2,127	$3,101	$4,376
Operating Margin	*5.7%*	*7.3%*	*-7.0%*	*11.2%*	*7.8%*	*6.0%*	*7.0%*	*10.5%*	*12.5%*
Other income (expense)	$1	$0	$8	$0	$0	$8	$0	$0	$0
Interest income, net	($2)	$1	$1	$1	$0	$3	$50	$95	$125
Pre-Tax Income	$1,451	$488	($371)	$1,076	$524	$1,716	$2,177	$3,196	$4,501
Taxes	$509	$170	($130)	$359	$184	$582	$864	$1,269	$1,787
Tax Rate	*35.1%*	*35.0%*	*35.1%*	*33.4%*	*35.0%*	*33.9%*	*39.7%*	*39.7%*	*39.7%*
Net Income	$942	$317	($241)	$717	$341	$1,134	$1,313	$1,927	$2,714
YOY Growth	*-84.8%*	*-26.9%*	*-178.1%*	*-345.1%*	*-30.7%*	*20.4%*	*15.8%*	*46.8%*	*40.8%*
Net Margin	*3.7%*	*4.7%*	*-4.5%*	*7.5%*	*5.1%*	*4.0%*	*4.3%*	*6.5%*	*7.8%*
GAAP EPS	$0.11	$0.04	($0.03)	$0.07	$0.03	$0.12	$0.13	$0.19	$0.25
Adjusted EPS	$0.17	$0.05	($0.04)	$0.11	$0.05	$0.18	$0.20	$0.30	$0.42
YOY Growth	*-84.9%*	*-33.4%*	*-167.1%*	*-281.6%*	*-36.3%*	*5.0%*	*6.3%*	*45.4%*	*35.6%*
Weighted Avg. Shares O/S	8,419	8,699	9,260	9,824	9,850	9,408	10,250	10,350	10,750

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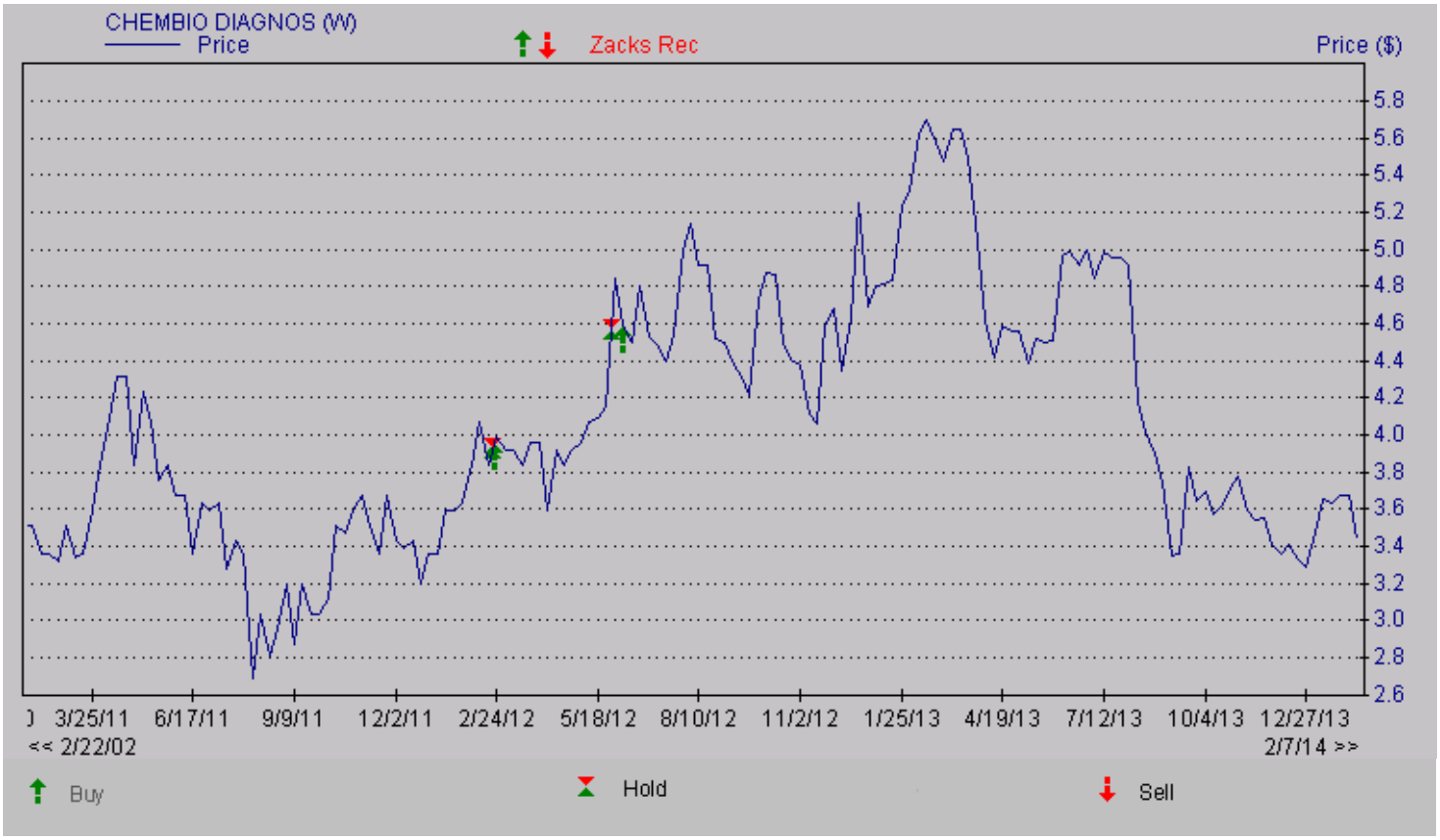

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