August 4, 2011

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Chembio Diagnostics Inc. (CEMI-OTC)

CEMI: Q2 2011 Results Solid

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (08/04/11)	$0.38
Target Price	**$1.10**

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. While there may be a setback with the oral fluid claim with the DPP HIV test, even in a worse-case scenario, this will not be a crushing blow for Chembio. Cash position and the balance sheet remain very healthy.

We are maintaining our Outperform rating on Chembio. Our price target is $1.10.

SUMMARY DATA

52-Week High	**$0.58**
52-Week Low	**$0.21**
One-Year Return (%)	**72.00**
Beta	**-0.20**
Average Daily Volume (sh)	**54,225**
Shares Outstanding (mil)	**69**
Market Capitalization ($mil)	**$26**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**14**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**26.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**9.5**
P/E using 2011 Estimate	**38.0**
P/E using 2012 Estimate	**12.7**
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)
2010	$2.78 A	$3.75 A	$4.51 A	$5.67 A	$16.71 A
2011	$3.64 A	$3.61 A	$4.61 E	$5.15 E	$16.89 E
2012					$22.66 E
2013					$29.35 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	$0.00 A	$0.01 A	$0.00 A	$0.03 A	$0.04 A
2011	$0.00 A	$0.00 A	$0.00 E	$0.00 E	$0.01 E
2012					$0.03 E
2013					$0.06 E

Zacks Projected EPS Growth Rate - Next 5 Years % **20**

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WHAT'S NEW

Q2 2011 Financial Results...

Chembio reported financial results for the second quarter ending June 30, 2011 on August 4th. Revenue of $3.61 million was about 4% below our $3.78 million estimate. The difference almost entirely attributable to lower than modeled product sales ($3.33 MM E vs. $2.97MM A). While DPP sales to FIOCRUZ handily beat our estimate ($275k E vs. $848k A), this was more than offset by softer than expected revenue from lateral flow HIV tests. The likely culprit was a backlog of inventory that management mentioned in the earnings release and again on the call. The backlog is expected to be worked through during the second half of the year, which is also typically stronger from a product sales standpoint than is the first two quarters. DPP sales to FIOCRUZ should also show a greater ramp going into Q3 (and beyond). The combination of all three factors should help push product sales up in 2H significantly higher than the $6.0MM in the first two quarters of 2011.

EPS was $0.00 on net income of $197k, which, despite the lower than modeled revenue number, was slightly ahead of our ($0.00) and ($140k) estimates due mostly to product margin continuing to widen faster and further than anticipated. Shift in product mix towards higher margin U.S. lateral flow tests as well as DPP sales to FIOCRUZ, coupled with manufacturing efficiencies continues to benefit margins. We have again adjusted our product margins up in our model, although only slightly - which could prove conservative.

Cash...

Cash from operations was an outflow of $634k in Q2 which largely reflects the inventory build that should ship during the second half of the year. Barring the increase in inventories, cash from (inflow) operations would have been approximately $691k. Chembio exited the quarter with $2.14 million in cash and equivalents. We continue to expect Chembio 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. Chembio expects to file second module in the very near-term. Clinical trials are about 3/4 done (were about 2/3 way through at end of Q1). CEMI had been shooting for completion in summer 2011 but this is now pushed back to this fall. Chembio also noted that while the data from blood samples looks like it will exceed requirements for FDA approval that oral fluid samples may not. Management expects to have the full data by October and at that point make a determination whether to file for approval of both blood and oral fluid sampling or blood alone. Depending on the strength of the oral fluid data, additional clinical testing might be required. While this news is a disappointment, it's far from a crushing blow. A worse-case scenario, where the claim for oral fluid fails to get through FDA, would have no impact on projected revenue in 2011, a very slight effect in 2012, and may represent only a 15% - 20% haircut (from where we were modeling revenue) to total revenue in 2013 and 2014. We have made changes to our model and risk-adjusted our estimate for U.S. DPP HIV sales, reflecting a greater risk that the test is approved for blood only or approval for oral fluid is significantly delayed.

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 later this year. 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.

Per the technology transfer agreement signed between Chembio and FIOCRUZ in November 2010, the approval of the Treponemal test triggered a $100k milestone payment to Chembio which was recorded in Q2. The agreement also calls for minimum purchases of $5.7 million of these two tests over three years.
Chembio began evaluating this multiplex Syphilis product in China with a collaboration partner during Q1 2011 and noted on the Q2 call that results have looked encouraging.

DPP Syphilis (U.S. / Europe)
Clinical trials in support of 510(k) had been expected to start during Q2 2011. This has been slightly delayed. Chembio now expects to have trials completed in early 2012 and gain 510(k) clearance shortly afterwards. This screen and confirmation (Treponemal / Non-treoponemal) test will be the first of its kind when approved. We expect the test to be a big driver of Chembio's revenue over the next several years.
Chembio has already submitted for CE Mark to allow sale of the test in Europe, which is expected to be granted by the end of 2011.

HIV Lateral Flow Tests CE Mark
Study data to support CE Mark of Chembio's HIV 1/2 Stat Pak and Sure Check HIV 1/2 lateral flow tests will be filed later this month.

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). Chembio is in the process of submitting for an Investigational Device Exemption (IDE) - which could happen later this year. If the FDA grants an IDE, Chembio would then need to conduct clinical trials. Eventual approval is highly uncertain at this point and not a near-term event. As such we do not yet model a contribution from an OTC HIV test.

DPP Flu A/B Antigen
Chembio is completing validation of this test, however, noted that due to recent FDA updates to gaining clearance for this type of test, that the company is evaluating whether to continue to pursue development. This is a very minor setback as we had only modeled a small contribution from this test beginning in 2012.

DPP HCV Antibody
Chembio's Q2 10-Q notes that they are putting development of this on hold. As management had previously indicated that demand for such a test may not justify further development, the recent news is not overly surprising. We had been modeling a relatively insignificant revenue contribution from this product.

DPP Leptospirosis (FIOCRUZ)
Approved in July 2011. Triggers a $100k milestone which will be recognized in Q3.

OUR 2011 OUTLOOK

Revenue
We now look for 2011 revenue of $16.9 million. While this implies growth of only 1% from 2010, it's important to note that we model product sales (i.e. - Chembio's fundamental business) to grow 10% in 2011. Meanwhile we model revenue from licenses, grants and milestones (an ancillary part of the company's operations) to fall 36%. The expected drop in revenue from these ancillary sources is relatively meaningless from a longer-term perspective, however, as product sales will be the ongoing driver of Chembio's revenue.

DPP sales to FIOCRUZ have ramped right out of the gate and are expected to be at least $3 million in 2011. Revenue from lateral flow tests is also expected to pick up in the second half of the year.

Net Income / EPS
We model Chembio to post net income of $727k and EPS of $0.01 in 2011. This is up slightly from the $286k and $0.00 that we modeled prior to Q2 results, reflecting better than expected continued improvement gross margin and slightly lower operating expenses.

RECOMMENDATION / VALUATION

Valuation
We are maintaining our Outperform rating of Chembio and have adjusted our price target slightly upwards (from $1.00 to $1.10 per share).

Comparable valuations have moved significantly higher since our last report on Chembio. We value Chembio based on comparable price/2011 sales ratio which currently stands at 4.6x. We look for Chembio to post sales of $16.9MM in 2011 which values the company at approximately $1.10 per share.

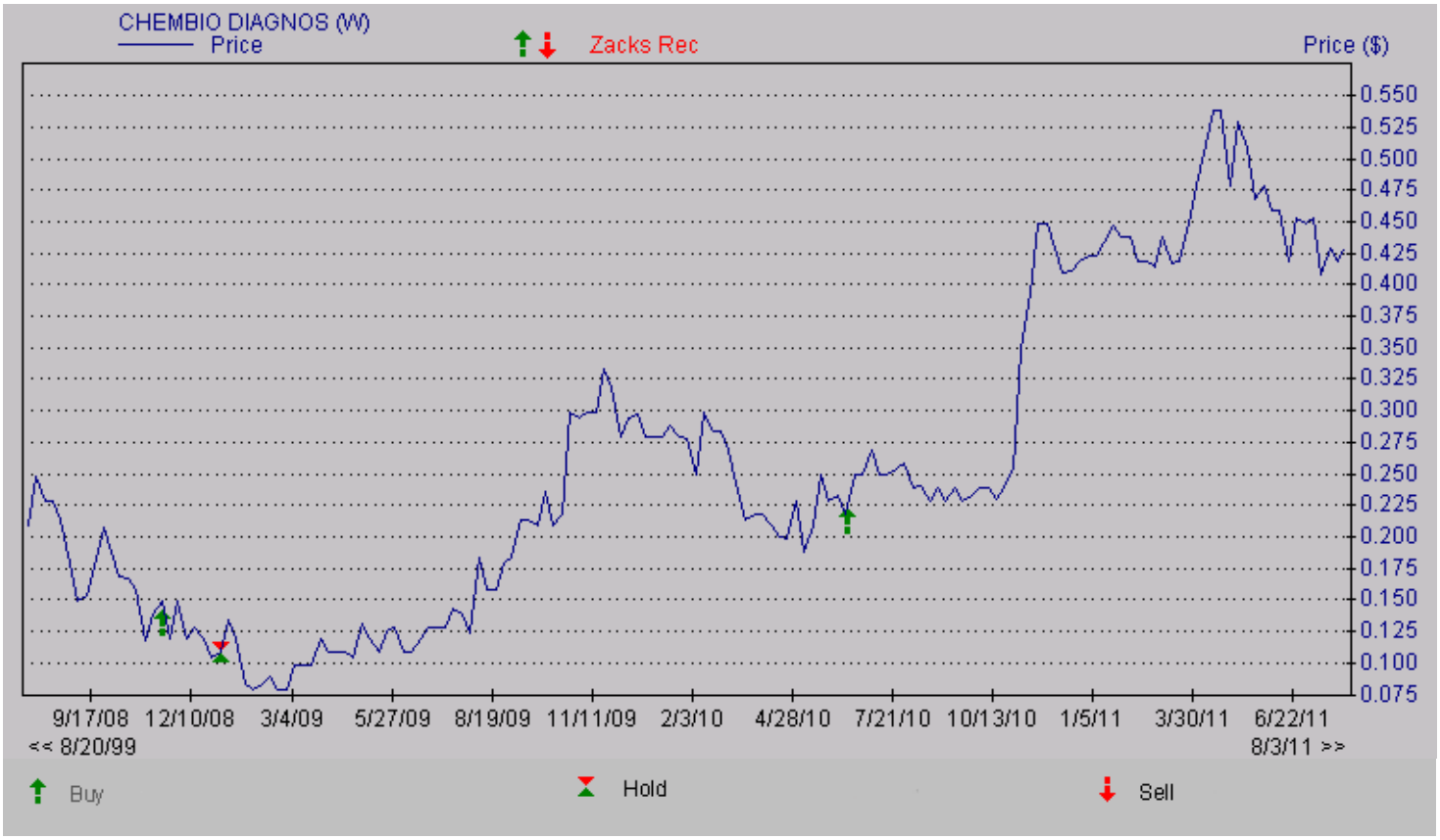
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2010 A	Q1A	Q2A	Q3E	Q4E	2011 E	2012 E	2013 E	2014 E
Product sales	**$13,516**	**$3,015**	**$2,974**	**$4,144**	**$4,767**	**$14,900**	**$20,525**	**$27,200**	**$34,800**
% of total revenue	*80.9%*	*82.9%*	*82.3%*	*89.9%*	*92.6%*	*88.2%*	*90.6%*	*92.7%*	*96.0%*
YOY Growth	*9.2%*	*36.1%*	*27.3%*	*9.4%*	*-8.0%*	*10.2%*	*37.8%*	*32.5%*	*27.9%*
License & royalty income	**$433**	**$29**	**$71**	**$50**	**$65**	**$165**	**$175**	**$255**	**$305**
% of total revenue	*2.6%*	*0.8%*	*2.0%*	*1.1%*	*1.3%*	*1.0%*	*0.8%*	*0.9%*	*0.8%*
R&D contracts, grants, milestones	**$2,756**	**$592**	**$568**	**$414**	**$315**	**$1,825**	**$1,966**	**$1,891**	**$1,154**
% of total revenue	*16.5%*	*16.3%*	*15.7%*	*9.0%*	*6.1%*	*10.8%*	*8.7%*	*6.4%*	*3.2%*
Total Revenues	$16,705.4	$3,635.7	$3,613.9	$4,608.0	$5,147.0	$16,890.6	$22,666.0	$29,346.0	$36,259.0
YOY Growth	*20.8%*	*30.6%*	*-3.6%*	*2.3%*	*-9.2%*	*1.1%*	*34.2%*	*29.5%*	*23.6%*
Cost of Revenues	$8,604	$1,709	$1,564	$2,321	$2,765	$8,359	$11,084	$13,192	$16,182
Gross Income	$8,101	$1,926	$2,050	$2,287	$2,382	$8,532	$11,583	$16,154	$20,077
Gross Margin	*48.5%*	*53.0%*	*56.7%*	*49.6%*	*46.3%*	*50.5%*	*51.1%*	*55.0%*	*55.4%*
Product Margin	*36.3%*	*43.3%*	*47.4%*	*44.0%*	*42.0%*	*43.9%*	*46.0%*	*51.5%*	*53.5%*
Research & Development	$2,586	$1,290	$1,165	$1,292	$1,270	$5,017	$4,550	$4,050	$3,500
% R&D	*15.5%*	*35.5%*	*32.2%*	*28.0%*	*24.7%*	*29.7%*	*20.1%*	*13.8%*	*9.7%*
Selling General & Admin	$2,941	$775	$688	$714	$711	$2,889	$4,624	$7,337	$9,609
% SG&A	*17.6%*	*21.3%*	*19.0%*	*15.5%*	*13.8%*	*17.1%*	*20.4%*	*25.0%*	*26.5%*
Operating Income	$2,573	($139)	$197	$281	$401	$740	$2,409	$4,768	$6,968
Operating Margin	*15.4%*	*-3.8%*	*5.4%*	*6.1%*	*7.8%*	*4.4%*	*10.6%*	*16.2%*	*19.2%*
Other income (expense)	($4)	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	($11)	($3)	($2)	($4)	($4)	($13)	$4	$35	$80
Pre-Tax Income	$2,559	($142)	$195	$277	$397	$727	$2,413	$4,803	$7,048
Taxes	$46	$0	$0	$0	$0	$0	$0	$576	$1,198
Tax Rate	*1.8%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*12.0%*	*17.0%*
Net Income	$2,513	($142)	$195	$277	$397	$727	$2,413	$4,226	$5,850
YOY Growth	*NA*	*-9.6%*	*-68.7%*	*65.6%*	*-78.9%*	*-71.1%*	*231.9%*	*75.2%*	*38.4%*
Net Margin	*15.0%*	*-3.9%*	*5.4%*	*6.0%*	*7.7%*	*4.3%*	*10.6%*	*14.4%*	*16.1%*
EPS	$0.04	($0.00)	$0.00	$0.00	$0.01	$0.01	$0.03	$0.06	$0.08
YOY Growth	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*219.3%*	*75.2%*	*38.4%*
Weighted Avg. Shares O/S	70,921	62,285	69,390	70,700	70,771	68,286	71,000	71,000	71,000

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HISTORICAL ZACKS RECOMMENDATIONS



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