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Chembio Diagnostics Inc. (CEMI-OTC)

CEMI: Q1 2011 Results

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (05/05/11)	$0.52
Target Price	**$1.00**

OUTLOOK

Chembio continues to hit major milestones in development of its DPP tests. Sales should begin to ramp in Brazil during 2011 under multi-year contracts worth at least $23MM. The DPP tests could launch in the U.S. in 2013. While we have trimmed our outlook for 2011, we still expect it to be another record year for revenue. Lateral flow sales remained very strong in Q1 and are expected to continue to be so throughout the year. Cash position and the balance sheet remain very healthy.

We are maintaining our Outperform rating on Chembio. Our price target is $1.00.

SUMMARY DATA

52-Week High	**$0.58**
52-Week Low	**$0.16**
One-Year Return (%)	**67.70**
Beta	**-0.16**
Average Daily Volume (sh)	**116,566**
Shares Outstanding (mil)	**71**
Market Capitalization ($mil)	**$32**
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 (%)	**30.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**13.0**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**26.0**
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	$3.78 E	$5.06 E	$5.42 E	$17.83 E
2012					$24.62 E
2013					$34.96 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 E	$0.00 E	$0.00 E	$0.00 E
2012					$0.02 E
2013					$0.06 E

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

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WHAT'S NEW

Q1 2011 Financial Results...

Chembio reported financial results for the first quarter ending March 31, 2011 on May 5, 2011. Revenue of $3.64 million was about 8% below our $3.94 million estimate. The difference due to lower than modeled product sales ($3.02MM versus $3.72MM estimate), partially offset by higher R&D contracts and milestone revenue ($592MM versus $225MM estimate). The miss in product sales relative to our estimate was mostly a result of significantly lower than modeled sales of DPP tests to FIOCRUZ. However, domestic sales of the lateral flow tests to Allere remained very strong in the quarter. Coming in at $2.1MM, U.S. lateral flow sales grew 77% y-o-y and 18% sequentially.

EPS was $0.00, in-line with our estimate. Despite the lower than modeled revenue figure, net loss came in at $142k, slightly better than our $254k figure as a result of significant improvement in gross margin. Gross margin of 53% was driven by an impressive 43% product margin (product margin has historically run in the 35% - 38% range). Margins benefitted from a greater percentage of sales coming the U.S. market. Operating expenses were largely in-line with our estimates.

Cash...

Cash flow from operations was $1.6 million in the quarter, which included $2.23 million from collections of accounts receivable, mostly reflecting large shipments made during December 2010. Chembio exited the quarter with $2.8 million in cash and equivalents, up from $2.1 million at the end of 2010. In January 2011 the final $875k due Bio-Rad under the HIV-2 licensing agreement was made. Chembio also noted that just over $200k was raised through the exercise of stock options (@ $0.40 strike) in April. We continue to expect Chembio to 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 Update...

- **DPP Leishmania Approval -** In April 2011 Chembio announced FIOCRUZ had received regulatory approval for its DPP rapid test for canine leishmania in Brazil. Per the technology transfer agreement, the approval triggered a $305k milestone payment to Chembio (recognized in Q1). FIOCRUZ is also obligated to make minimum purchases of $2.4 million of this test. Sales of this test should commence in 2011.

- **U.S. DPP HIV Regulatory Filing -** In March 2011 Chembio submitted a request to the FDA seeking approval to file for PMA regulatory approval through three separate modules. In an April 19, 2011 press release, Chembio announced the FDA approved its modular filing request and also that the company submitted the first of three modules. The module filing process allows regulators to look over each filing when submitted, therefore potentially significantly reducing the time it takes to gain FDA approval. Chembio hopes to have the second and third modules filed in the third and fourth quarters of 2011.

- **Final Bio-Rad Payment -** Chembio made the final payment ($875k) to Bio-Rad in January 2011 relative to their HIV-2 licensing agreement

- **DPP Syphilis Approval -** 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 triggers a $100k milestone payment to Chembio which will be 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 is currently gearing up for the initiation of U.S. clinical trials in support of a 510(k) regulatory filing. Chembio expects clinical trials to begin in June of this year.

Pipeline Update...

DPP HIV, U.S.
Clinical trials about 2/3 way done (were about 1/2 way through at early March). CEMI shooting for completion in summer 2011. CEMI received FDA approval to submit modular PMA regulatory filing. First of three modules was filed in April 2011. Expectations for the second and third filings to be made during Q3 and Q4 2011.
Impact to our model: None - timeline relatively in-line with our prior expectations. We still look for launch in Q4 2012.

DPP Syphilis (U.S.)
Clinical trials in support of 510(k) expected to start during Q2 2011. Chembio, along with a partner, is evaluating this product in a multi-site program in China.
Impact to our model: None - timeline relatively in-line with our prior expectations. We still look for launch in Q2 2012.

DPP Flu A/B
CEMI expects to complete validation by end of Q2 2011. Hope to submit pre-IDE to 510(k) in July 2011 and start clinical trials in Q4 2011.
Impact to our model: None - timeline relatively in-line with our prior expectations. We still look for launch in Q4 2012.

DPP HCV Antibody
Prototypes being developed and validated which includes a study organized by the National Center for Hiv/AIDS, Viral Hepatitis, STD and TB Prevention at the CDC. CEMI received results and submitted them for publication.
Impact to our model: None - in-line with our prior expectations. We still model launch in Q1 2013.

DPP Leptospirosis (FIOCRUZ)
Expect regulatory approval soon.
Impact to our model: None - timeline relatively in-line with our prior expectations. We look for the test to launch in 2011.

DPP Syphilis (FIOCRUZ)
Treponemal - approved. Multiplex Syphilis - Chembio and FIOCRUZ expect to submit for approval in Brazil later this year.
Impact to our model: None - timeline relatively in-line with our prior expectations.

OUR 2011 OUTLOOK

Revenue
We now look for 2011 revenue of $17.8 million, implying growth of 7% from 2010. This is revised down from $20.7 million prior to Q1 2011 results due to DPP sales to FIOCRUZ ramping slower than we had earlier anticipated. Management noted on the Q1 call that they expect to provide an update on shipments to FIOCRUZ for the four approved DPP tests during the course of the current year - at which time we will update our model, if appropriate. Sales of the high margin U.S. lateral flow products are expected to remain robust throughout 2011 which should help soften the impact to the bottom line if DPP FIOCRUZ sales due lag our earlier expectations.

Net Income / EPS
We model Chembio to post net income of $286k and EPS of $0.00 in 2011, both revised slightly lower from prior to Q1 ($1,310k and EPS of $0.02) in 2011. Our estimates for operating expenses remain largely unchanged. However, our gross margin, which we had previously modeled to come in around 45%, looks like it may be low. We now look for gross margin of 47%. The change, a result of expectations that domestic sales will account for an even greater portion of total revenue.

RECOMMENDATION / VALUATION

Valuation

We are maintaining our Outperform rating of Chembio Diagnostics with an Outperform rating. Based on the potential for the DPP product portfolio to significantly ramp long-term revenue, cash flow and earnings we continue to feel the company is grossly undervalued.

We value Chembio based on comparable price/sales ratio of 3.7x 2011 sales. We look for Chembio to post sales of $17.8MM in 2011 which values the company at approximately $1.00 per share.

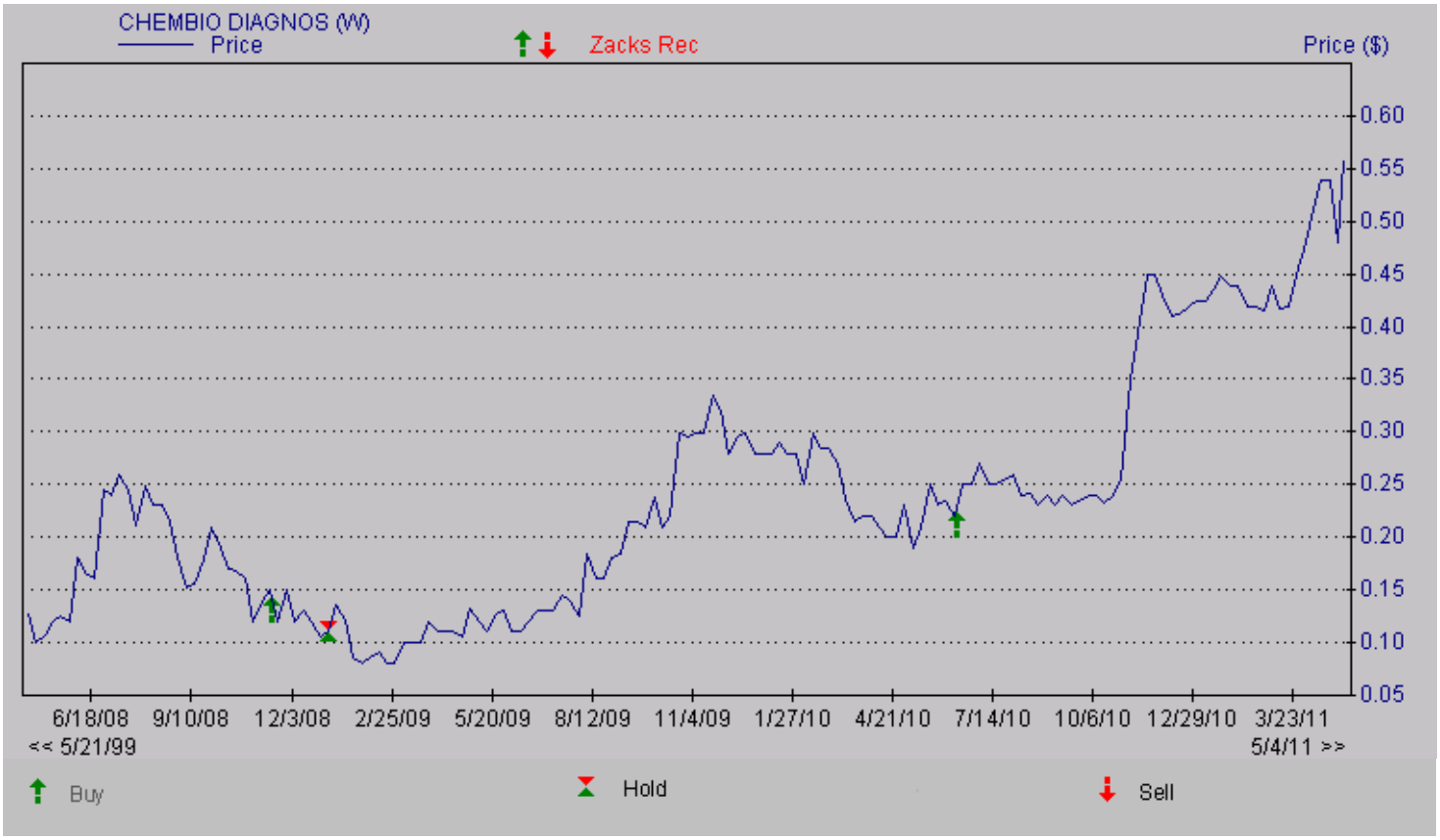
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2010 A	Q1A	Q2E	Q3E	Q4E	2011 E	2012 E	2013 E	2014 E
Product sales	**$13,516**	**$3,015**	**$3,325**	**$4,628**	**$4,990**	**$15,958**	**$23,050**	**$33,139**	**$43,010**
% of total revenue	*80.9%*	*82.9%*	*88.0%*	*91.4%*	*92.2%*	*89.5%*	*93.6%*	*94.8%*	*96.8%*
YOY Growth	*9.2%*	*36.1%*	*42.4%*	*22.2%*	*-3.6%*	*18.1%*	*44.4%*	*43.8%*	*29.8%*
License & royalty income	**$433**	**$29**	**$30**	**$30**	**$35**	**$124**	**$132**	**$205**	**$275**
% of total revenue	*2.6%*	*0.8%*	*0.8%*	*0.6%*	*0.6%*	*0.7%*	*0.5%*	*0.6%*	*0.6%*
R&D contracts, grants, milestones	**$2,756**	**$592**	**$425**	**$404**	**$390**	**$1,747**	**$1,441**	**$1,616**	**$1,154**
% of total revenue	*16.5%*	*16.3%*	*11.2%*	*8.0%*	*7.2%*	*9.8%*	*5.9%*	*4.6%*	*2.6%*
Total Revenues	$16,705.4	$3,635.7	$3,780.0	$5,062.0	$5,415.0	$17,829.0	$24,623.0	$34,960.0	$44,439.0
YOY Growth	*20.8%*	*30.6%*	*0.8%*	*12.4%*	*-4.4%*	*6.7%*	*38.1%*	*42.0%*	*27.1%*
Cost of Revenues	$8,604	$1,709	$1,879	$2,777	$3,044	$9,409	$12,447	$16,072	$20,000
Gross Income	$8,101	$1,926	$1,901	$2,285	$2,371	$8,420	$12,176	$18,888	$24,439
Gross Margin	*48.5%*	*53.0%*	*50.3%*	*45.1%*	*43.8%*	*47.2%*	*49.4%*	*54.0%*	*55.0%*
Product Margin	*36.3%*	*43.3%*	*43.5%*	*40.0%*	*39.0%*	*41.0%*	*46.0%*	*51.5%*	*53.5%*
Research & Development	$2,586	$1,290	$1,325	$1,307	$1,280	$5,202	$5,050	$4,050	$3,700
% R&D	*15.5%*	*35.5%*	*35.1%*	*25.8%*	*23.6%*	*29.2%*	*20.5%*	*11.6%*	*8.3%*
Selling General & Admin	$2,941	$775	$711	$734	$731	$2,951	$5,220	$9,439	$12,443
% SG&A	*17.6%*	*21.3%*	*18.8%*	*14.5%*	*13.5%*	*16.6%*	*21.2%*	*27.0%*	*28.0%*
Operating Income	$2,573	($139)	($135)	$244	$360	$331	$1,906	$5,398	$8,296
Operating Margin	*15.4%*	*-3.8%*	*-3.6%*	*4.8%*	*6.7%*	*1.9%*	*7.7%*	*15.4%*	*18.7%*
Other income (expense)	($4)	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	($11)	($3)	($5)	($6)	($6)	($20)	$4	$35	$80
Pre-Tax Income	$2,559	($142)	($140)	$238	$354	$310	$1,910	$5,433	$8,376
Taxes	$46	$0	$0	$12	$12	$24	$229	$924	$2,094
Tax Rate	*1.8%*	*0.0%*	*0.0%*	*5.2%*	*3.4%*	*7.9%*	*12.0%*	*17.0%*	*25.0%*
Net Income	$2,513	($142)	($140)	$226	$342	$286	$1,681	$4,510	$6,282
YOY Growth	*NA*	*-9.6%*	*-122.5%*	*34.8%*	*-81.8%*	*-88.6%*	*487.8%*	*168.3%*	*39.3%*
Net Margin	*15.0%*	*-3.9%*	*-3.7%*	*4.5%*	*6.3%*	*1.6%*	*6.8%*	*12.9%*	*14.1%*
EPS	$0.04	($0.00)	($0.00)	$0.00	$0.00	$0.00	$0.02	$0.06	$0.09
YOY Growth	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*451.7%*	*168.3%*	*39.3%*
Weighted Avg. Shares O/S	70,921	62,285	62,800	70,700	70,771	66,639	71,000	71,000	71,000

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HISTORICAL ZACKS RECOMMENDATIONS



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