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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

Zacks Small-Cap Research

scr.zacks.com

10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

Chembio Diagnostics Inc. (CEMI- NASDAQ)

CEMI: DPP Fever Set to Take Reins As Growth Driver

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (03/09/16)	$5.56
Target Price	**$6.50**

OUTLOOK

CLIA Waiver granted for DPP HIV assay. CEMI signed distribution agreements and also direct sales force to sell direct in the U.S. Int'l lateral flow sales helped buoy 2015 revenue. HIV self-testing kit launched in Europe with early successes. DPP international sales had been growth driver for last few years but waned in 2015 with slump to FIOCRUZ. We think FIOCRUZ STD sales could continue to decline. Mexico also down in 2015 but could return to growth in 2016.
DPP HIV in U.S. could also pick up in 2016. DPP HIV/Syph in U.S. trials - could launch and contribute in 2017. Meanwhile, new fever portfolio looks like it could be a needle-mover – off to a strong start and most recently added Zika. Zika could make strong showing in 2016.
While we continue to think fever represents the next wave of growth, declining DPP sales to FIOCRUZ could result in total revenue contraction in 2016. Our model could prove conservative, however as DPP Fever could come out much stronger than what we model – stay tuned!
CEMI also focused on complementary revenue opportunities including add'l R&D contracts/grants, expansion of international commercialization footprint, and potentially in-licensing products.

We are maintaining our Buy rating.

SUMMARY DATA

52-Week High	**$5.69**
52-Week Low	**$3.66**
One-Year Return (%)	**41.69**
Beta	**0.97**
Average Daily Volume (sh)	**36,954**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$53**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**17**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**12.3**
Earnings Per Share (%)	**-51.9**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Average,**
Type of Stock	**Small-Blend**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(millions)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	$6.23 A	$6.72 A	$6.89 A	$4.42 A	$24.26 A
2016	$4.55 E	$4.94 E	$5.58 E	$5.52 E	$20.60 E
2017					$35.78 E
2018					$35.78 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.09 A	-$0.09 A	-$0.06 A	-$0.16 A	-$0.40 A
2016	-$0.12 E	-$0.12 E	-$0.13 E	-$0.17 E	-$0.54 E
2017					-$0.29 E
2018					-$0.03 E

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

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WHAT'S NEW

Q4 2015: *DPP FIOCRUZ Sales Contract, CEMI at Pivot Point With DPP Fever Expected to Drive Growth….*

Chembio reported financial results for the fourth quarter ending December 31st. Product sales missed our number in a big way ($3.7M A vs $6.2M E) – the reason looks to be a sizeable drop in FIOCRUZ-related DPP HIV sales. FIOCRUZ (i.e. sales to Brazil) DPP HIV sales fell $2.1 in 2015 - while management did not break out how much relates to Q4, our back-of-the-envelope suggests this was the main culprit to aggregate DPP sales falling 73% sequentially from Q3 ($3.8M to $1.0M) and down 69% from the average ($3.4M) of the first three quarters of 2015. DPP HIV/Syphilis sales fell $3.5M in Mexico from 2014 to 2015 which may also have impacted Q4.

The Q4 drop in DPP HIV sales to FIOCRUZ relates to a competitor under-pricing a tender for which CEMI decided against under-bidding. We note that international POC HIV assay tenders can be bid at extremely tight margins which looks to be the case here. Management noted on the call that this will result in lower related DPP HIV FIOCRUZ sales in 2016. How much and for how long FIOCRUZ would continue to purchase above the technology transfer minimum purchase requirements was an ongoing question that we had – anecdotally, including general comments from management on prior earnings calls which had at least some (probably very general) guidance from FIOCRUZ, it seemed like this might carry at least through 2016. But while FIOCRUZ may continue to purchase other DPP assays, the expected drop in DPP HIV sales to Brazil is a new revelation and has resulted in significant downward revisions to our modelled total revenue for 2016. To be clear, these international tenders are highly uncertain as was any kind of commitment from FIOCRUZ to purchase beyond the already met minimum purchase limits.

Relative to DPP HIV/Syphilis in Mexico – the test had been a catalyst to the 138% DPP sales growth in 2014 - the sales contraction in 2015 relates to inventory that was purchased during 2014 and was still being burned through 2015. CEMI indicated that the inventory issue should not be as meaningful in 2016 and that they are currently competing for several tenders in that country.

That sums up the not-so-good news in Q4. The good news was that lateral flow continues to hold up very well. This is despite the roll-off of Alere's U.S. distribution rights to STAT-PAK in June 2014. In fact U.S. lateral flow sales increased sequentially from Q2 to Q3 and again into Q4 of 2015. International lateral flow sales were a significant contributor to revenue in both Q4 and the full year 2015. International demand is difficult to model however, given the reliance on tenders. International also benefitted to the tune of about $1M in 2015 from the f SURE CHECK HIV ½ (lateral flow) self-testing product which launched in the U.K. and France in during the year.

But, more importantly the fever portfolio, which is shaping up to take the reins from STD as the catalyst to revenue growth, is nearing commercialization. As we had anticipated (per our Feb 2nd Investor Note) following the recent Zika outbreak and WHO declaring it an international public emergency (Feb 1st), CEMI is aggressively pursuing this opportunity and with initial funding from the Paul Allen Foundation, expects to have one or more Zika assays commercialized this year. In development are three Zika-related assays which includes a stand-alone Zika assay, a multiplex for Zika, Dengue and Chikungunya assay, and Zika included on the full fever panel (Malaria, Dengue, Chikingunya, Zika, Ebola, Lassa, and Marburg). CEMI recently teamed up with FIOCRUZ (which we had also anticipated might happen) for development of the tests. As Brazil sits in the eye of the Zika storm and the duo have a long-standing relationship, this could be a significant opportunity for CEMI.

Management noted on the Q4 call that have developed prototypes of the DPP Zika and DPP Zika/Dengue/Chikingunya assays and initiated testing of clinical specimens from several effected countries – further noting that "the data is highly encouraging". With the summer Olympics being held in Brazil, we think this could be a tremendous early opportunity if development and regulatory clearance is obtained by that time. And CEMI expects to not only market in Brazil, but in other areas of the world where Zika and the other diseases are endemic. Management noted on the Q4 call that they expect DPP fever sales to be "significant" in 2016.

For 2016 – there's several moving pieces that could be in play.

- **Lateral flow**:
  - as noted, U.S. sales have held up well and contributed ~$1.6M in Q4 and $5.3M in 2015, or ~42% and ~24% of product revenue in those periods, respectively. Alere's distribution rights to SURE-CHECK end on May 31, 2016 at which time CEMI will also be marketing this via their own sales force and third party distributors. While it is unclear whether this will be a positive or

negative event, we are modeling some sequential contraction to total U.S. lateral flow sales beginning in Q3

  - o international – contributed $990k and $4.6M in 2015, or ~24% and ~21% of product revenue in those periods, respectively. 2015 was a good, but not exceptional year for international lateral flow – for reference, 2013 did $11.4M. We are modeling a single digit contraction from 2015 to 2016 – this line item has significant potential to beat, or miss as, again it's tough to model. The SURE CHECK HIV ½ (lateral flow) self-testing product launched in the U.K. and France in 2015 and contributed ~$1M. While we could see additional contribution in 2016, that may be predicated on burning any remaining inventory stocking.

- **DPP**: generated $11.3M in revenue in 2015, down 28% from 2014 ($15.7M) with 65% of the decrease coming in Q4. While CEMI does not break out DPP sales by channel, FIOCRUZ still represents the bulk. DPP HIV to FIOCRUZ is expected to significantly contract in 2016. DPP HIV/Syph to Mexico could return to growth in 2016 where CEMI is competing for several tenders – while they noted that they are "optimistic", this is currently an unknown. We think DPP HIV U.S. represents an opportunity for growth in 2016. CEMI is developing a micro reader for use with its DPP tests – both in the U.S. and abroad – which could further facilitate uptake. But the most significant DPP-related opportunity in 2016 is with the fever portfolio. Zika is expected to make a significant contribution – we're modeling mostly beginning in 2H, and CEMI has other diseases in testing as well including Ebola and Ebola/Malaria. The big question is, how significant will "significant" be as it relates to DPP fever (Zika) revenue? We are modeling a contraction of total DPP sales of just over 22% in 2016 – which reflects the assumption fever comes on in 2H and helps offset some of the decline in FIOCRUZ STD and U.S. HIV shows moderate growth.

  We think 2017 DPP sales benefit from a full year of the initial fever assays. U.S. clinical study for DPP HIV/Syphilis is now commencing and expected to complete in 6-9 months. If all goes well, this could launch in the U.S. in 2017 – we think this could be a significant product once commercialized and potentially be a catalyst to revenue next year. The other major catalyst should be DPP fever – with additional assays that could come to market on a fairly regular basis.

- **Tech Collaborations**: CEMI has several irons in the fire including developing tests for DPP Cancer, DPP flu and DPP TBI. While none of these are likely to reach the commercial market in 2016, we expect to hear progress updates throughout the year – one or more of these could represent future growth drivers for the company. The RVR (Malaysia) collaboration could see additional contribution during 2016, however.

Q4 Financials

Q4 revenue of $4.4M was down 12% yoy, down 36% sequentially and about 36% below our $6.9M estimate. Total HIV lateral flow sales were $2.6M, up 5% from the prior year period and about 27% better than our number – the beat to our estimate is due to U.S. sales continuing to hold up better than we had anticipated. Not only had we expected more contraction from Alere's STAT-PAK rights rolling off in June 2014 but had anticipated headwinds from 4th –gen laboratory testing. We have since made some upward revisions to our U.S. lateral flow sales estimates for 2016 but still model a contraction – more significantly so beginning in Q3.

Meanwhile, international lateral flow sales were $990k representing yoy and sequential growth of 22% and 25%, respectively, and largely inline with our $902k estimate. As we have noted in the past, international sales can vary widely from q-to-q as these have largely relied on tenders from international aid organizations. SURE CHECK HIV 1/2 self-testing kits are also making a contribution to the international number. This launched in Q2 2015 in the U.K. and France and is being sold via third-party distribution.

DPP sales came in at $1.0M, down 73% on both a yoy and sequential basis and well below our 4.1M estimate. As explained above, the contraction and miss to our number relates to significantly lower sales to Mexico and FIOCRUZ.

Gross margin and product margin were 42.3% and 31.8%, compared to 41% and 36.1% in the year-earlier comparable period and our 44.6% and 38.5% estimates. The difference compared to our forecast relates to the miss on revenue and less coverage of fixed costs.

EPS

We use adjusted net income and EPS for consistency purposes. As a reminder, in Q4 2011 CEMI took a non-cash gain of $5.16 million to income from the reversal of deferred tax asset as they expected to generate positive pre-tax income from that point forward. Their GAAP income tax rate of ~35.1% is ~90% non-cash until they exhaust (which, based on our current model will occur sometime in 2020 or 2021) their entire deferred tax asset which stood at $5.5 million at the end of 2015.

Q4 adjusted net income and EPS of approximately ($1.5)M and ($0.16) compares to our ($661)k and ($0.07) estimates. .

Cash
Excluding changes in working capital, cash used in operating activities in Q4 was $759k. CEMI exited 2015 with $5.4M in cash and equivalents, compared to $1.1M at the end of Q3 – the increase relates mostly to the collection of A/R.

OUR OUTLOOK

Revenue
We look for 2016 revenue of $20.6 million, implying a decrease of 15% from 2015.

For 2016 – there's several moving pieces that could be in play.

- **Lateral flow**:
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growth drivers for the company. The RVR (Malaysia) collaboration could see additional contribution during 2016, however.

Net Income / EPS

We look for adjusted net income and EPS of ($5.2)M and ($0.54) in 2016, compared to ($3.8) million and ($0.40) in 2015.

RECOMMENDATION / VALUATION

We continue to use OSUR as a comp for valuation purposes. OSUR trades at approximately 2.8x 2017 estimated sales and 2.0x EV/2017 sales. P/S comp values CEMI at ~$7.00/share, EV/S values CEMI at ~$6/share. We use the approximate average, $6.5/share, as our price target. We are maintaining our Buy recommendation.

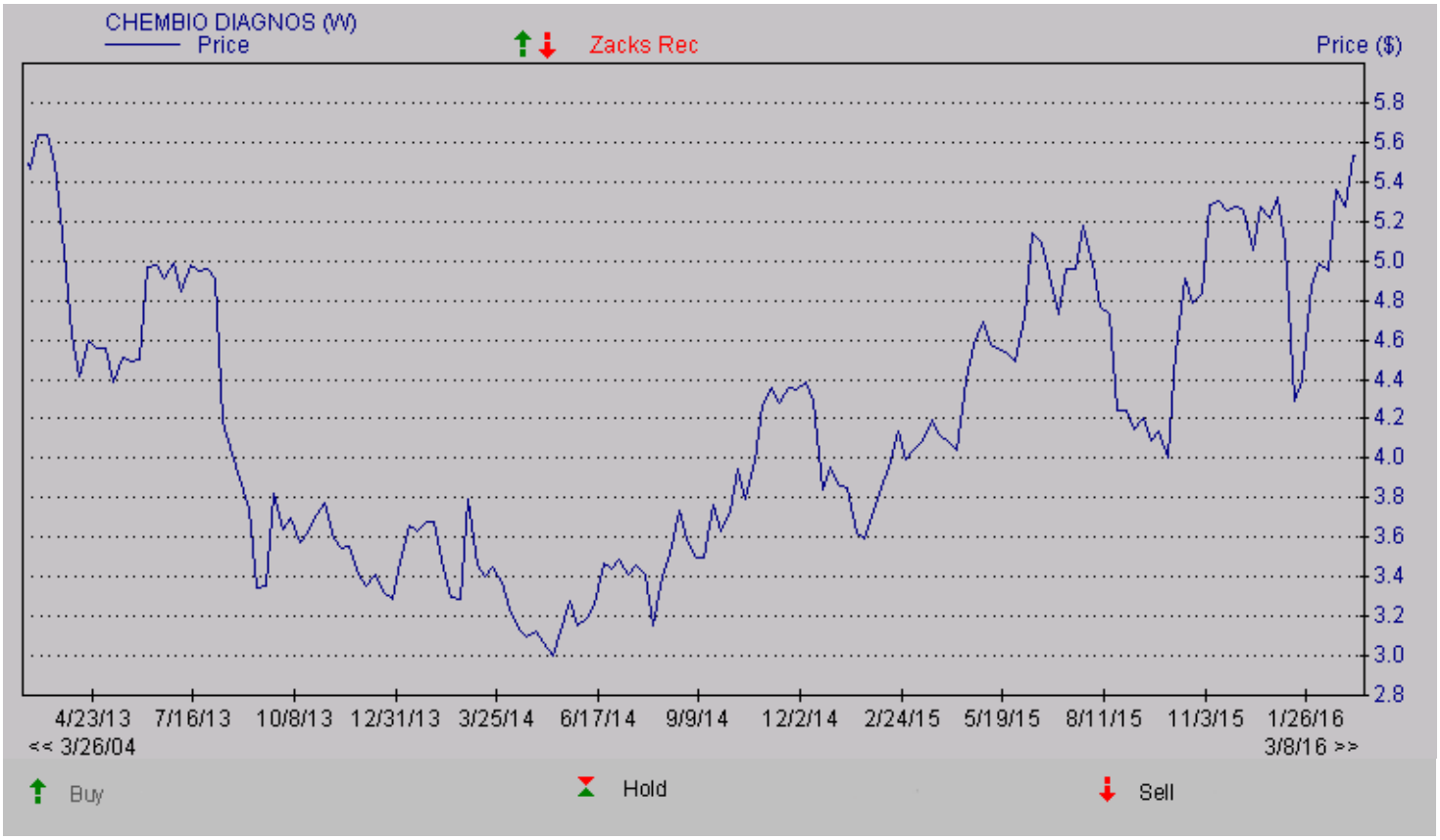
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2015 A	Q1E	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Product sales	**$21,887**	**$3,857**	**$4,225**	**$4,862**	**$5,316**	**$18,260**	**$23,216**	**$29,900**	**$35,807**
% of total revenue	*90.2%*	*84.8%*	*85.5%*	*87.1%*	*96.3%*	*88.7%*	*92.8%*	*93.8%*	*95.4%*
YOY Growth	*-15.7%*	*-31.3%*	*-33.2%*	*-21.7%*	*42.1%*	*-16.6%*	*27.1%*	*28.8%*	*19.8%*
License & royalty income	**$53**	**$32**	**$27**	**$22**	**$26**	**$107**	**$432**	**$574**	**$310**
% of total revenue	*0.2%*	*0.7%*	*0.5%*	*0.4%*	*0.5%*	*0.5%*	*1.7%*	*1.8%*	*0.8%*
R&D contracts, grants, milestones	**$2,316**	**$657**	**$692**	**$700**	**$180**	**$2,229**	**$1,365**	**$1,400**	**$1,421**
% of total revenue	*9.5%*	*14.5%*	*14.0%*	*12.5%*	*3.3%*	*10.8%*	*5.5%*	*4.4%*	*3.8%*
Total Revenues	$24,255.5	$4,546.0	$4,944.0	$5,584.0	$5,522.0	$20,596.0	$25,012.7	$31,874.1	$37,537.4
YOY Growth	*-12.3%*	*-27.0%*	*-26.4%*	*-18.9%*	*24.9%*	*-15.1%*	*21.4%*	*27.4%*	*17.8%*
Cost of Revenues	$13,769	$2,576	$2,772	$3,136	$3,402	$11,886	$14,440	$17,581	$20,231
Gross Income	$10,486	$1,970	$2,172	$2,448	$2,120	$8,710	$10,573	$14,293	$17,307
Gross Margin	*43.2%*	*43.3%*	*43.9%*	*43.8%*	*38.4%*	*42.3%*	*42.3%*	*44.8%*	*46.1%*
Product Margin	*37.1%*	*33.2%*	*34.4%*	*35.5%*	*36.0%*	*34.9%*	*37.8%*	*41.2%*	*43.5%*
Research & Development	$6,377	$1,612	$1,821	$1,994	$2,038	$7,465	$6,266	$6,187	$6,485
% R&D	*26.3%*	*35.5%*	*36.8%*	*35.7%*	*36.9%*	*36.2%*	*25.1%*	*19.4%*	*17.3%*
Selling General & Admin	$7,663	$1,555	$1,577	$1,753	$1,734	$6,619	$7,504	$8,447	$9,459
% SG&A	*31.6%*	*34.2%*	*31.9%*	*31.4%*	*31.4%*	*32.1%*	*30.0%*	*26.5%*	*25.2%*
Operating Income	($3,554)	($1,197)	($1,226)	($1,299)	($1,652)	($5,374)	($3,197)	($341)	$1,362
Operating Margin	*-14.7%*	*-26.3%*	*-24.8%*	*-23.3%*	*-29.9%*	*-26.1%*	*-12.8%*	*-1.1%*	*3.6%*
Other income (expense)	($5)	$0	$0	$0	$0	$0	$0	$0	
Interest income, net	$1	$0	$0	$0	$0	$2	$14	$10	$22
Pre-Tax Income	($3,558)	($1,197)	($1,225)	($1,299)	($1,652)	($5,373)	($3,183)	($331)	$1,384
Taxes	($1,161)	($311)	($319)	($338)	($429)	($1,397)	($1,194)	($124)	$519
Tax Rate	*32.6%*	*26.0%*	*26.0%*	*26.0%*	*26.0%*	*26.0%*	*37.5%*	*37.5%*	*37.5%*
Net Income	($2,397)	($886)	($907)	($961)	($1,222)	($3,976)	($1,990)	($207)	$865
YOY Growth	*110.8%*	*36.9%*	*36.5%*	*119.9%*	*88.2%*	*65.9%*	*-50.0%*	*-89.6%*	*-518.6%*
Net Margin	*-9.9%*	*-19.5%*	*-18.3%*	*-17.2%*	*-22.1%*	*-19.3%*	*-8.0%*	*-0.6%*	*2.3%*
GAAP EPS	($0.25)	($0.09)	($0.09)	($0.10)	($0.13)	($0.41)	($0.19)	($0.02)	$0.08
Adjusted EPS	($0.40)	($0.12)	($0.12)	($0.13)	($0.17)	($0.54)	($0.29)	($0.03)	$0.12
YOY Growth	*108.7%*	*33.2%*	*36.5%*	*123.8%*	*5.8%*	*65.8%*	*-54.6%*	*-89.8%*	*-503.7%*
Weighted Avg. Shares O/S	9,626	9,628	9,628	9,628	9,628	9,628	10,620	10,800	11,200

Brian Marckx, CFA

HISTORICAL ZACKS RECOMMENDATIONS



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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 23.8%, Hold/Neutral- 52.3%, Sell/Underperform – 17.9%. Data is as of midnight on the business day immediately prior to this publication.