Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: **Surprise Rebound in Lateral Flow, DPP Disappoints But Still Expect DPP Fever Strong Showing in 2017**

We look for 2017 revenue of $23.8M. We use OSUR as a comp for valuation purposes. Given expected outsized growth in fever we value CEMI at 5.0x P/S, a slight premium to OSUR (4.8x), or ~$9.50/share.

Current Price (03/09/17)	$5.70
Valuation	**$9.50**

OUTLOOK

We look for 2017 revenue of $23.8 million, implying growth of 33% from 2016. We have product sales growing over 80% given our expectation of a rebound in DPP from initial meaningful sales from the fever portfolio and stabilization of lateral flow as CEMI fully regroups this business under its own umbrella. We think upside to our model could come from more substantial sequential growth in U.S. lateral flow or higher international lateral flow – with the recent additions of regional sales directors who are tasked with growing (and initiating) sales in their respective regions, we think the lateral flow business (as well as other currently CE Marked products) in particular could potentially have meaningful upside in the near-term.

We think fever, with a full year of DPP Zika in some territories is a meaningful contributor to 2017 revenue, particularly in 2H. DPP HIV/Syphilis could also launch in the U.S., although we do not model any meaningful contribution until 2H 2018.

SUMMARY DATA

52-Week High	**$9.12**
52-Week Low	**$5.15**
One-Year Return (%)	**0.53**
Beta	**0.76**
Average Daily Volume (sh)	**25,385**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$70**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**33**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**0.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(millions)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	$6.60 A	$3.27 A	$3.75 A	$4.25 A	$17.87 A
2017	$5.14 E	$5.66 E	$6.09 E	$6.87 E	$23.76 E
2018					$30.47 E
2019					$37.59 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.03 A	-$0.25 A	-$0.19 A	-$0.21 A	-$0.71 A
2017	-$0.19 E	-$0.13 E	-$0.08 E	-$0.05 E	-$0.45 E
2018					$0.21 E
2019					$0.06 E

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

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WHAT'S NEW

Q4 2016: *Surprise Rebound in Lateral Flow, DPP Disappoints But Still Expect DPP Fever Strong Showing in 2017…*

Chembio reported financial results for the fourth quarter ending December 31st. Both revenue and EPS came in very much inline with our estimates, although within the itemized revenue there were some differences – most notably lateral flow coming in much stronger than we had anticipated but which was offset by weaker than expected DPP sales.

DPP sales, at just $910k, were at the second lowest level since Q2 2013 (Q2 '16 were slightly lower at $835k) and well below our modeled $1.7M – much of the difference which we think may relate to a more muted (than we anticipated) revenue contribution from DPP Zika's initial introduction in certain parts of the Caribbean. We hope to see Zika gain momentum in the Caribbean region throughout the current year and will be eager to hear updates on future calls. In addition, DPP Zika launch in Brazil should be a needle-mover – CEMI recently received INCQS sign-off of the Micro Reader and now just needs approval of the reader from ANVISA – which we think could come at anytime. And finally, as it relates to DPP Zika – EUA applications are outstanding, approval of which are additional shots on goal for the test.

And while DPP has been relatively soft as of late, there are several assays (in addition to Zika) in late-stage development that could come to market over the near term. Among them is DPP HIV/Syphilis in the U.S. – data from the clinical trial, which is still slated to complete later this month, is (per management) "highly encouraging". This assay, which if eventually FDA-cleared, would be the only rapid POC HIV/Syphilis assay in the U.S. and, in our opinion, could generate massive interest given the particularly high HIV/Syph co-infection rates among men that have sex with men. We will also closely follow developments of the DPP fever portfolio, including malaria and the fever panel – both of which could hold 'game-changer' status given that DPP Malaria could be the first and only rapid POC test for both blood and saliva for that huge market and DPP Fever Panel would also have no direct competition.

Relative to lateral flow, Q4 sales of $2.25M were relatively very strong and about 36% better than we were expecting. And perhaps even more encouraging is that U.S. sales of SURE CHECK HIV 1/2 assay jumped $516k (231%) sequentially (i.e. from Q3 '16) in Q4 and U.S. sales of STAT-PAK HIV increased almost 35% for the full year 2016.

As a reminder, CEMI regained marketing rights to SURE CHECK from Alere effective June 1, 2016 and for STAT-PAK HIV in June 2014. While U.S. sales of the tests have been negatively impacted, management has been quick to implement a strategy aimed at reigniting growth of the products. It appears they are off to a strong start as evidenced not only by the recent sales levels but also with the win of two state contracts, which are expected to generate ~$2M of revenue through 2018. Lateral flow sales will be another thing to watch in 2017 – if the company can indeed return the U.S. business back to positive growth, that in our opinion, could be a significant value driver.

The move to regain distribution rights to the lateral flow products may have been just one of many aimed at CEMI having more control over their destiny. In 2016 the company hired two experienced sales executives to manage the America's and EMEA region. Then in January 2017 CEMI brought on three international sales directors who will be tasked with increasing sales of the company's products in each of their respective regions (Latin America, Africa and Asia/Pacific). This is a deliberate move to lessen (or potentially eliminate) the company's historic reliance on a small handful of third-party companies and governmental organizations in regulatory affairs, marketing and distribution. An example is Brazil's FIOCRUZ which has been a tremendously important partner of CEMI's for well over a decade and likely contributed tens of millions of revenue to the company via sales of their products in Brazil. But, with the roll-off of the technology transfer agreements, FIOCRUZ-related revenue has been much less significant over the last ~18 months. This played significantly into CEMI's product sales falling 16% in 2015 and another 38% in 2016.

In addition to the five recent hires, the RVR acquisition which closed in January and recent Isla Lab distribution partnership, seem to be aligned with this 'control-your-own-destiny' strategy. So, now with U.S. lateral flow business back in CEMI's court and the company beginning to assemble international sales and manufacturing infrastructure we think the company could be transforming into a more independent organization. This, coupled with the very rapid growth of their fever portfolio presents potentially significantly greater opportunity than what had been the case less than two years ago.

Q4 Financials
Q4 revenue of $4.3M was down 4% yoy but increased 14% from Q3 of this year. Total HIV lateral flow sales were $2.2M, down 12% yoy but up 53% from Q3. As indicated, while the roll-off of the remainder of Alere's domestic marketing rights has taken a toll on domestic lateral flow sales, CEMI's efforts towards reviving this business which has included a renewed sales and marketing strategy and allocation of additional resources, could return it to growth. And while we think the downsized distribution and headwinds from newer technologies (such as CEMI's DPP as well as 4th –gen testing) likely means domestic lateral flow sales will not return to historic levels, if CEMI can maintain even single digit percentage growth of this business over the long-term it would provide upside to our current estimates.

DPP sales came in at $910k, down 12% yoy and 9% sequentially. For the full year 2016, DPP sales were $5.4M, a decrease of 52% from 2015 - the contraction mostly relates to lower DPP HIV sales to FIOCRUZ as a result of a competitor under-pricing a tender. But, we think DPP returns to positive growth in 2017 with contribution from the fever portfolio in high fever-risk geographies such as S. America, the Caribbean and S.E Asia. The broad and deep distribution and strategically located manufacturing brought on with the recent addition of Isla Lab and acquisition of RVR should provide CEMI the ability to launch quickly upon regulatory green-lighting in these high potential territories.

Q4 gross margin and product margin were 41.2% and 22.5%, compared to 42.3% and 31.8% in the year-earlier comparable period and 52.1% and 28.3% in Q3 '16.

EPS
Q4 net loss and EPS were $2.6M and ($0.21), inline with our $2.5M and ($0.20) estimates.

Cash
Cash used in operating activities was $1.0M in Q4 and $6.7M in 2016. Excluding changes in working capital, cash used in operating activities was $2.2M and $6.1M over the same periods. Cash balance 2016 year-end was $10.6M.

Fever Portfolio Should Move Revenue Needle…
CEMI's pace in building its fever portfolio and related manufacturing and distribution capabilities is showing no signs of slowing. In addition to the BARDA grant, Isla Lab distribution agreement and RVR acquisition, CEMI made additional substantive progress towards realizing exploiting the potential of their DPP fever portfolio.

This includes the first regulatory approvals for the DPP Zika test. In July 2016 DPP Zika and the DPP Micro Reader received CE Mark – opening it up to Europe and most Caribbean nations (excluding Puerto Rico and U.S. Virgin Islands). While Q4 2016 DPP Zika sales were clearly not a highlight, we continue to believe the test will be a meaningful contributor going forward – a country-by-country roll-out is now in process in the Caribbean.

DPP Zika also received approval from Brazil's health regulatory agency (ANVISA) and in Q1 '17 CEMI received notice that the test and Micro Reader successfully passed evaluation by INCQS. Now they just need ANVISA approval of the Micro Reader. We expect that eventual commercialization in Brazil could be a significant revenue catalyst given not only the almost epidemic-like Zika outbreak in that country (~1.5M people infected) but also the proven commercialization capabilities of FIOCRUZ.

The stand-alone DPP Dengue assay, which was developed in collaboration with RVR, has completed validation studies. CEMI noted on the Q4 call (March 7th) that RVR has begun selling DPP Dengue in SE Asia and that they expect to have more than $1M in related sales in Q1. Given the expectation of additional fever-related launches in the near-term and the large populations of S.E. Asia in Zika-prone geographies, we think the RVR channel could be another significant near-term contributor.

CEMI also recently submitted applications for approval of DPP Zika with; FDA for Emergency Use Authorization (EUA), WHO under EUA and Mexico's regulatory agency. Another factor that could work in CEMI's favor is that their DPP Zika test is the only rapid Zika test submitted to FDA under EUA and one of two submitted to WHO under EUA – and that pathway is now no longer available to enter. As such, upon approval, CEMI's DPP Zika test should have a fairly captive market.

DPP Zika and DPP Zika/Chikungunya/Dengue Combination Assay and the DPP Micro Reader will also be used in a POC surveillance pilot program in India, Peru, Guatemala and Haiti under a $330k CDC grant that Chembio was awarded in late September 2016. CEMI began selling the test under this program during Q1 '17.

Development of the DPP Fever panel (multiplex for Malaria, Dengue, Chikungunya, Zika, Ebola, Lassa and Marburg), funded by a grant from the Paul G. Allen Foundation, is also progressing. Validation has been completed and in Q1 '17 field testing commenced.

DPP Ebola and DPP Malaria-Ebola also could come to market. DPP Ebola has been submitted to FDA and WHO for EUA and both DPP Ebola and DPP Malaria-Ebola continue to undergo field testing (via CDC) in West Africa.

DPP Malaria also holds meaningful near-term promise. With additional funding from the Gates foundation, CEMI recently completed feasibility testing of a DPP oral fluid malaria test - development of which would make it the first POC oral fluid malaria diagnostic. An oral fluid version could generate tremendous interest, particularly in remote areas and among asymptomatic individuals given the user-friendliness and greater ease of providing saliva as opposed to blood samples. Saliva testing offers the potential to significantly increase malaria testing in pandemic areas of the world and, as such, the value-add could command pricing premium to the current blood-based POC tests currently on the market. Laboratory verification testing is expected to begin imminently. Given the relatively massive size of the malaria testing market, if eventually commercialized, we think this DPP Malaria saliva/blood could potentially be a tremendous success.

OUR OUTLOOK

Revenue

We look for 2017 revenue of $23.8 million, implying growth of 33% from 2016. We have product sales growing over 80% given our expectation of a rebound in DPP from initial meaningful sales from the fever portfolio and stabilization of lateral flow as CEMI fully regroups this business under its own umbrella. We think upside to our model could come from more substantial sequential growth in U.S. lateral flow or higher international lateral flow – with the recent additions of regional sales directors who are tasked with growing (and initiating) sales in their respective regions, we think the lateral flow business (as well as other currently CE Marked products) in particular could potentially have meaningful upside in the near-term.

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Net Income / EPS

We look for net income and EPS of ($5.7)M and ($0.45) in 2017, compared to ($7.5)M and ($0.71) (ex-tax asset revaluation).

VALUATION

Given expected outsized growth in Fever, we value CEMI at a slight premium to OSUR. We value CEMI at 5.0x 2017 estimated revenue (vs OSUR @ 4.8), or approximately $9.5/share.

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2016 A	Q1E	Q2E	Q3E	Q4E	2017 E	2018 E	2019 E
Product sales	**$13,679**	**$4,468**	**$4,776**	**$5,011**	**$5,646**	**$19,901**	**$27,114**	**$34,547**
% of total revenue	*76.5%*	*87.0%*	*84.4%*	*82.3%*	*82.2%*	*83.8%*	*89.0%*	*91.9%*
YOY Growth	*-37.5%*	*-24.5%*	*134.8%*	*100.3%*	*75.0%*	*45.5%*	*36.2%*	*27.4%*
License & royalty income	**$450**	**$96**	**$117**	**$107**	**$103**	**$423**	**$526**	**$310**
% of total revenue	*2.5%*	*1.9%*	*2.1%*	*1.8%*	*1.5%*	*1.8%*	*1.7%*	*0.8%*
R&D contracts, grants, milestones	**$3,739**	**$571**	**$767**	**$973**	**$1,123**	**$3,434**	**$2,830**	**$2,730**
% of total revenue	*20.9%*	*11.1%*	*13.6%*	*16.0%*	*16.3%*	*14.5%*	*9.3%*	*7.3%*
Total Revenues	$17,869.4	$5,135.0	$5,660.0	$6,091.0	$6,872.0	$23,758.0	$30,470.0	$37,586.8
YOY Growth	*-26.3%*	*-22.2%*	*73.3%*	*62.6%*	*61.5%*	*33.0%*	*28.3%*	*23.4%*
Cost of Revenues	$9,418	$3,195	$3,224	$3,207	$3,642	$13,267	$16,513	$20,245
Gross Income	$8,452	$1,940	$2,436	$2,884	$3,230	$10,491	$13,957	$17,342
Gross Margin	*47.3%*	*37.8%*	*43.0%*	*47.3%*	*47.0%*	*44.2%*	*45.8%*	*46.1%*
Product Margin	*31.2%*	*28.5%*	*32.5%*	*36.0%*	*35.5%*	*33.3%*	*39.1%*	*41.4%*
Research & Development	$8,428	$2,104	$1,860	$1,744	$1,610	$7,318	$6,815	$6,684
% R&D	*47.2%*	*41.0%*	*32.9%*	*28.6%*	*23.4%*	*30.8%*	*22.4%*	*17.8%*
Selling General & Admin	$7,596	$2,136	$2,219	$2,217	$2,371	$8,943	$9,994	$11,539
% SG&A	*42.5%*	*41.6%*	*39.2%*	*36.4%*	*34.5%*	*34.7%*	*32.8%*	*30.7%*
Operating Income	($7,571)	($2,300)	($1,643)	($1,077)	($751)	($5,770)	($2,852)	($881)
Operating Margin	*-42.4%*	*-44.8%*	*-29.0%*	*-17.7%*	*-10.9%*	*-24.3%*	*-9.4%*	*-2.3%*
Other income (expense)	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	$26	$14	$13	$10	$18	$55	($20)	($10)
Pre-Tax Income	($7,545)	($2,286)	($1,630)	($1,067)	($733)	($5,715)	($2,872)	($891)
Taxes	$5,801	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*-76.9%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($13,347)	($2,286)	($1,630)	($1,067)	($733)	($5,715)	($2,872)	($891)
YOY Growth	*456.8%*	*652.8%*	*-80.5%*	*-50.1%*	*-71.4%*	*-57.2%*	*-49.8%*	*-69.0%*
Net Margin	*-74.7%*	*-44.5%*	*-28.8%*	*-17.5%*	*-10.7%*	*-24.1%*	*-9.4%*	*-2.4%*
EPS	($1.26)	($0.19)	($0.13)	($0.08)	($0.05)	($0.45)	($0.21)	($0.06)
YOY Growth	-	-	-	-	-	-	-	-
Weighted Avg. Shares O/S	10,622	12,290	12,300	13,000	13,500	12,773	13,800	14,000

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