Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: **Weakness in STD, Significant Growth in Fever Accelerating Shift**

We look for 2017 revenue of $22.8M. We use OSUR as a comp for valuation purposes. Given expected outsized growth in fever we value CEMI at 3.8x P/S, a slight premium to OSUR (3.3x), or ~$7.5/share.

Current Price (08/15/16)	$5.91
Valuation	**$7.50**

OUTLOOK

We look for 2016 revenue of $16.5 million, implying a decrease of 32% from 2015. We have lateral flow falling 33% and DPP down 49% - although, we think DPP begins to show yoy growth in Q4 with contribution from DPP fever. We think upside to our model could come from stabilization in U.S. lateral flow or higher international lateral flow, the latter from aid-agency tenders.

We think fever, with a full year of DPP Zika in some territories and additional fever assays that could come to market on a fairly regular basis, drives most of the top-line in 2017. DPP HIV/Syphilis could also launch in the U.S. and contribute in 2017.

SUMMARY DATA

52-Week High	**$9.40**
52-Week Low	**$3.33**
One-Year Return (%)	**37.13**
Beta	**0.95**
Average Daily Volume (sh)	**126,770**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$71**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**3.9**
Earnings Per Share (%)	**-55.9**
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	**High,**
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	$6.60 A	$3.27 A	$3.08 E	$3.54 E	$16.49 E
2017					$23.77 E
2018					$29.38 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.07 A	-$0.07 A	-$0.05 A	-$0.07 A	-$0.37 A
2016	-$0.03 A	-$0.25 A	-$0.19 E	-$0.19 E	-$0.67 E
2017					-$0.35 E
2018					$0.15 E

Zacks Projected EPS Growth Rate - Next 5 Years % **10**

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WHAT'S NEW

Q2 2016: *Weakness in STD, Significant Growth Opportunity in Fever Accelerating Shift in Focus…*

While we think CEMI's sexually transmitted disease business will continue to contribute meaningfully, Q2 may mark somewhat of the beginning of an inflection for Chembio - moving further away from heavy reliance on their STD business to fever (i.e Zika, Malaria, Dengue, Chikingunya, Ebola, etc), which has quickly developed into a significant opportunity. Recent accelerated development of the fever portfolio, facilitated by grants from the Paul G. Allen and Gates foundations, resulting in CE Mark of their first fever assay (DPP Zika IgG/IgM) and late-stage development of others, coupled with the recent change in domestic lateral flow HIV distribution and significant contraction in DPP HIV FIOCRUZ sales all point to a major shift from STD to fever. And the unmet demand for accurate POC fever diagnostics and overall growing competitive landscape in POC HIV testing has provided timely conditions for this shift.

In late July Chembio preannounced expected Q2 revenue of $3.2M - $3.3M. Lower U.S. lateral flow sales and DPP sales to FIOCRUZ were cited as the reasons for the implied ~50% contraction from both the prior year period as well as from Q1 of this was year. Following the preannouncement we downwardly revised our $5.0M estimate to $3.3M, including $2.6M in product sales (from $4.2M) and $677k from license, R&D contracts and grants income (from $810k).

Last week Chembio reported financial results for the second quarter ending June 30th. While grant income was well ahead of our number ($1.2M A vs. $677k E) due to greater and earlier than anticipated recognition of a bulk of the Paul G. Allen fever panel grant, product sales came in about 21% shy ($2.0M A vs. $2.6m E) of our revised estimate. The difference in actual and our revised product sales number is mostly concentrated in lower international lateral flow - which is not a particular concern given the great historical variability in this line item and the relationship to (hard to predict) international aid tenders.

However, we do expect U.S. lateral flow sales, which contributed $5.3M in 2015 (accounting for 24% of product sales) but just $617k in Q2 (30% of product sales) to continue to remain relatively weak at least over the near term. As a reminder the last of Alere's marketing rights rolled off at the end of May. While we had anticipated this would have a negative effect to sales, the 40% yoy drop in Q2 likely indicates that we underestimated the impact and believe our current estimates are more indicative of reasonable expectations. Total lateral flow sales fell 48% yoy and accounted for 25% of the contraction in product sales.

However, as we have noted in our ongoing coverage of CEMI, while lateral flow and the sexual transmitted disease business has been an important contributor to revenue over the years, DPP and the growing fever portfolio continues to represent most of the opportunity for growth.

DPP HIV sales to FIOCRUZ were similarly relatively weak and the major contributor to the 79% yoy and 69% sequential contraction in DPP sales in Q2. As a reminder CEMI noted on the Q4 call that they expected DPP HIV sales to FIOCRUZ to contract in 2016 due to a competitor under-pricing a tender for which CEMI decided against under-bidding. Total DPP sales fell 79% yoy in Q2 and accounted 73% of the contraction in product sales.

We continue to view the majority of near-term opportunity for growth coming from the fever segment, although we think there are spots within infectious disease that could be significant incremental contributors. In particular, DPP HIV/Syphilis for the U.S. market, could have significant appeal - a U.S.-based study commenced in Q1 of this year and is expected to complete in Q1 2017. A similar (U.S. test utilizes a different algorithm) test could be available in Europe in the near-term as well (although POC testing in general remains relatively nascent in most of Europe). CEMI also continues to work on a multiplex (7 band) DPP flu immunostatus assay, recently applying for additional U.S. government funding - this is another example of potential future catalysts in infectious disease. And if CEMI can regain a significant base in international DPP STD revenue it would provide upside to our infectious disease-related revenue estimates.

Fever Portfolio Continues to Grow, Nearing Commercialization…
CEMI has done an impressive job in a short period of time in building its fever portfolio. Clearly their capabilities and technology have not gone unnoticed as well, scoring several grants from leading donors in the fight against pandemic diseases such as the Bill and Melinda Gates Foundation and the Paul G. Allen Family Foundation.

These grants have helped to speed development of the fever portfolio, which is shaping up to take the reins from STD as the catalyst to revenue growth. In total there are nine DPP fever-related assays under development. This includes three Zika-related assays; 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). In July CEMI announced their DPP Zika (IgM/IgM) assay received CE Mark, making it the first POC Zika test to receive E.U.'s marketing stamp of approval. The test, along with the proprietary DPP Micro Reader, is expected to launch in Europe and parts of the Caribbean and begin contributing to revenue in 2H 2016. The test could see meaningful demand, particularly in parts of the Caribbean that have been hard hit by Zika. Relative to the fever panel, CEMI is shooting to have development completed by current year-end.

CEMI also recently submitted applications for approval of DPP Zika (IgM/IgM) with; FDA for Emergency Use Authorization (EUA), Brazil's regulatory agency (ANVISA), WHO under EUA and Mexico's regulatory agency. As there is no FDA approved POC antibody-based test for Zika approved by FDA, the market remains wide open.

CEMI also recently expanded their collaboration with FIOCRUZ. Initially this only included development of the DPP Zika IgM/IgG test for the Brazilian market but was since expanded to also include DPP Dengue IgM/IgG, DPP Chikungunya IgM/IgG, DPP Zika/Chikungunya/Dengue IgM/IgG combo and the DPP Micro Reader. Given the prevalence of Zika in Brazil and CEMI's long-standing relationship with FIOCRUZ, we think this partnership could present a meaningful near-term opportunity.

DPP Dengue, DPP Ebola and DPP Malaria-Ebola also could come to market. CEMI expects DPP Dengue to begin commercialization in 2H 2016. Meanwhile, 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 expects to complete 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. CEMI expects results of the feasibility study in Q1 2017.

- **Lateral flow**:
    - U.S. sales held up well in 2015, generating $5.3M of revenue, representing ~24% of product revenue last year. Alere's distribution rights to SURE-CHECK ended on May 31, 2016. CEMI is now marketing this via their own sales force and third party distributors. The 40% drop in revenue in Q2 is indicative of the greatly reduced distribution reach. CEMI noted that they recently implemented a new pricing program, significantly cutting prices to the U.S. public health segment (included in this is CEMI's lateral flow as well as DPP HIV assays). This has potential to reduce attrition, although this may also eat into margins.
    - international – contributed $4.6M in 2015, or ~24% of product revenue. 2015 was a good, but not exceptional year for international lateral flow – for reference, 2013 did $11.4M. We are modeling a 40% 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 1/2 (lateral flow) self-testing product launched in the U.K. and France in 2015 and contributed ~$1M. That may not repeat in 2016, however, given some stocking in 2015 and the lower prevalence of POC in Europe.

- **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 likely still represents the bulk. DPP held up well in Q1 (+8% yoy to $2.7M) but tumbled 79% in Q2 to just $835k. While we model contraction of 49% for the full year, we think Q4 could show a return to growth from initial contribution from the DPP fever assays. And if DPP STD to FIOCRUZ holds up better than expected, it would provide upside to our related revenue estimates.

- We think 2017 DPP sales benefit from a full year of the initial fever assays. U.S. clinical study for DPP HIV/Syphilis has commenced and expected to complete in Q1 2017. 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 another 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 regular progress updates. One or more of these could represent future growth drivers for the company.

Q2 Financials
Q2 revenue of $6.6M was down 51% on both a yoy and sequential basis. Total HIV lateral flow sales were $1.7M, down 48% yoy and 62% from Q1 of this year. As noted, we attribute large part of the contraction to roll-off of the remainder of Alere's domestic marketing rights, in addition to headwinds from 4th –gen testing.

DPP sales came in at $835k, down 79% yoy and 69% sequentially. As noted above, the contraction mostly relates to lower DPP HIV sales to FIOCRUZ as a result of a competitor under-pricing a tender.

Gross margin and product margin were 48.4% and 17.1%, compared to 45.0% and 41.5% in the year-earlier comparable period and our 42.4% and 27.2% estimates. The difference compared to our forecast mostly relates to a "vendor quality issue" that shaved off $119k of gross profit.

EPS
We had been using adjusted net income and EPS to reflect a (Q4 2011) non-cash gain of $5.16 million to income from the reversal of deferred tax asset as CEMI had been expecting to generate positive pre-tax income from that point forward. But in Q2 CEMI recorded a valuation allowance on the deferred tax asset due to their belief that it is more likely than not that it will not be realized (i.e. do not expect taxable income in the foreseeable future).

Excluding the (non-cash) valuation allowance, Q2 net income and EPS were approximately ($2.4)M and ($0.25), compared to ($898)k and ($0.09) in Q2 2015.

Cash
Cash used in operating activities was $1.2M in Q2. Excluding changes in working capital, cash used in operating activities was $2.0M. Pro forma for the $13.8M gross ($12.5M net) equity raise in August, cash balance at Q2 quarter-end was approximately $13.9M.

OUR OUTLOOK

Revenue
We look for 2016 revenue of $16.5 million, implying a decrease of 32% from 2015. We have lateral flow falling 33% and DPP down 49% - although, we think DPP begins to show yoy growth in Q4 with contribution from DPP fever. We think upside to our model could come from stabilization in U.S. lateral flow or higher international lateral flow, the latter from aid-agency tenders.

We think fever, with a full year of DPP Zika in some territories and additional fever assays that could come to market on a fairly regular basis, drives most of the top-line in 2017. DPP HIV/Syphilis could also launch in the U.S. and contribute in 2017.

Net Income / EPS
We look for net income and EPS (excluding tax valuation) of ($7.2)M and ($0.67) in 2016, improving to ($4.5)M and ($0.35) in 2017.

VALUATION

Given expected outsized growth in Fever, we value CEMI at a slight premium to OSUR. We value CEMI at 3.8x 2017 estimated revenue (vs OSUR @ 3.3x), or approximately $7.50/share.

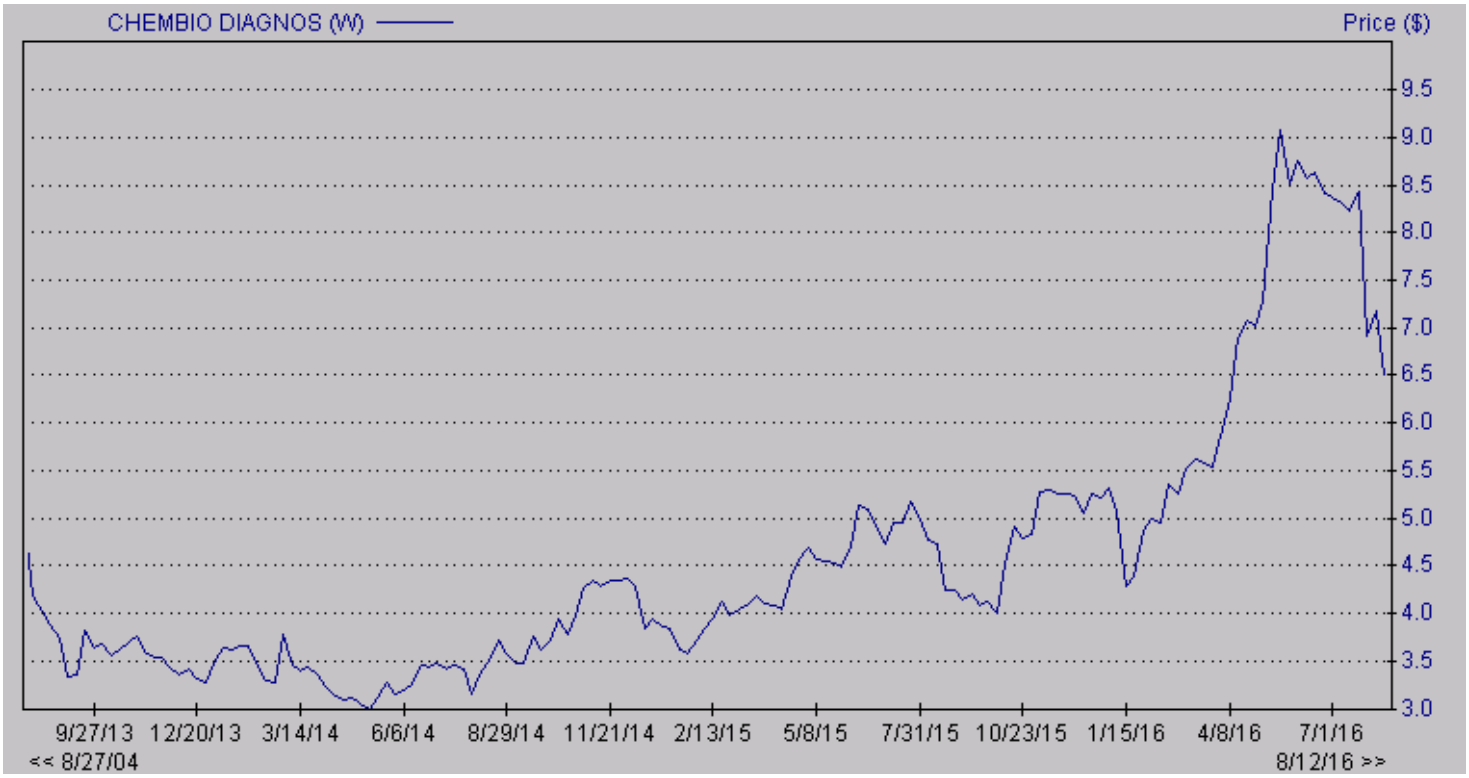
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2015 A	Q1A	Q2A	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Product sales	**$21,887**	**$5,917**	**$2,034**	**$2,230**	**$2,808**	**$12,990**	**$19,913**	**$25,655**	**$32,510**
% of total revenue	*90.2%*	*89.6%*	*62.3%*	*72.4%*	*79.3%*	*78.8%*	*83.8%*	*87.3%*	*92.0%*
YOY Growth	*-15.7%*	*5.4%*	*-67.8%*	*-64.1%*	*-24.9%*	*-40.6%*	*53.3%*	*28.8%*	*26.7%*
License & royalty income	**$53**	**$22**	**$34**	**$22**	**$26**	**$104**	**$411**	**$526**	**$310**
% of total revenue	*0.2%*	*0.3%*	*1.0%*	*0.7%*	*0.7%*	*0.6%*	*1.7%*	*1.8%*	*0.9%*
R&D contracts, grants, milestones	**$2,316**	**$662**	**$1,198**	**$829**	**$709**	**$3,398**	**$3,450**	**$3,200**	**$2,500**
% of total revenue	*9.5%*	*10.0%*	*36.7%*	*26.9%*	*20.0%*	*20.6%*	*14.5%*	*10.9%*	*7.1%*
Total Revenues	$24,255.5	$6,601.6	$3,266.4	$3,081.0	$3,543.0	$16,492.9	$23,774.1	$29,380.9	$35,319.1
YOY Growth	*-12.3%*	*5.9%*	*-51.4%*	*-55.3%*	*-19.9%*	*-32.0%*	*44.1%*	*23.6%*	*20.2%*
Cost of Revenues	$13,769	$3,436	$1,686	$1,673	$2,078	$8,872	$12,665	$15,445	$18,921
Gross Income	$10,486	$3,166	$1,580	$1,409	$1,465	$7,621	$11,109	$13,936	$16,399
Gross Margin	*43.2%*	*48.0%*	*48.4%*	*45.7%*	*41.4%*	*46.2%*	*46.7%*	*47.4%*	*46.4%*
Product Margin	*37.1%*	*41.9%*	*17.1%*	*25.0%*	*26.0%*	*31.7%*	*36.4%*	*39.8%*	*41.8%*
Research & Development	$6,377	$1,634	$2,367	$1,994	$2,038	$8,034	$7,341	$6,815	$6,684
% R&D	*26.3%*	*24.8%*	*72.5%*	*64.7%*	*57.5%*	*48.7%*	*30.9%*	*23.2%*	*18.9%*
Selling General & Admin	$7,663	$1,999	$1,599	$1,510	$1,665	$6,773	$8,250	$9,226	$10,419
% SG&A	*31.6%*	*30.3%*	*48.9%*	*49.0%*	*47.0%*	*41.1%*	*34.7%*	*31.4%*	*29.5%*
Operating Income	($3,554)	($468)	($2,386)	($2,095)	($2,238)	($7,186)	($4,481)	($2,104)	($705)
Operating Margin	*-14.7%*	*-7.1%*	*-73.0%*	*-68.0%*	*-63.2%*	*-43.6%*	*-18.9%*	*-7.2%*	*-2.0%*
Other income (expense)	($5)	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	$1	$3	$2	$5	$4	$13	($8)	($20)	($10)
Pre-Tax Income	($3,558)	($465)	($2,384)	($2,090)	($2,234)	($7,173)	($4,489)	($2,124)	($715)
Taxes	($1,161)	($162)	$5,963	$0	$0	$5,801	$0	$0	$0
Tax Rate	*32.6%*	*34.7%*	*-250.1%*	*0.0%*	*0.0%*	*-80.9%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($2,397)	($304)	($8,347)	($2,090)	($2,234)	($12,974)	($4,489)	($2,124)	($715)
YOY Growth	*110.8%*	*-53.1%*	*1156.9%*	*378.2%*	*244.1%*	*441.3%*	*-65.4%*	*-52.7%*	*-66.4%*
Net Margin	*-9.9%*	*-4.6%*	*-255.5%*	*-67.8%*	*-63.1%*	*-78.7%*	*-18.9%*	*-7.2%*	*-2.0%*
EPS	($0.25)	($0.03)	($0.86)	($0.19)	($0.19)	($1.22)	($0.35)	($0.15)	($0.05)
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Avg. Shares O/S	9,626	9,632	9,668	11,240	12,000	10,635	13,000	13,800	14,000

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