Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: **DPP Zika Could Generate Significant Revenue in 2H 2016**

We look for 2017 revenue of $28.9M. We use OSUR as a comp for valuation purposes. OSUR trades at approximately 3x 2017 estimated sales which values CEMI at ~$9/share.

Current Price (05/16/16)	$8.68
Valuation	**$9.00**

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 and DPP STD was solid in Brazil in Q1– 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.

SUMMARY DATA

52-Week High	**$8.78**
52-Week Low	**$3.33**
One-Year Return (%)	**90.79**
Beta	**1.03**
Average Daily Volume (sh)	**46,818**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$84**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**16**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**7.4**
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	**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	$6.60 A	$5.04 E	$5.71 E	$6.33 E	$23.68 E
2017					$28.87 E
2018					$34.69 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	-$0.05 A	-$0.12 E	-$0.13 E	-$0.12 E	-$0.42 E
2017					-$0.23 E
2018					$0.06 E

Zacks Projected EPS Growth Rate - Next 5 Years % **25**

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WHAT'S NEW

Q1 2016: *Big Beat on Revenue. DPP STD Remains Strong in Brazil. DPP Zika Could Be Driver in 2H 2016….*

Chembio reported financial results for the first quarter ending March 31st. Product sales, which missed our number in a big way the prior quarter (i.e. Q4 2015), did just the opposite in the most recent period, coming in about 53% better than our estimate ($5.9M A vs. $3.9M E).

While part of the beat is almost certainly related to Alere stocking of SURE CHECK HIV 1/2, the lateral flow assay which CEMI will begin detailing with its own sales force on June 1st, DPP product sales also surprised big on the upside. The DPP revenue beat is noteworthy in our opinion as there has yet to be any contribution from the Fever portfolio or any other recently under-development assays – implying the DPP sexual transmitted disease tests (specifically HIV and HIV-Syphilis combo) continue to see strong demand - particularly in Brazil.

As a reminder, CEMI noted on the Q4 call that DPP HIV sales to FIOCRUZ fell significantly in that period due to a competitor under-pricing a tender for which CEMI decided against under-bidding. Management further noted that that would result in lower related DPP HIV FIOCRUZ sales in 2016. While we continue to view the Fever portfolio (inc. Malaria, Dengue, Chikungunya, Zika, Ebola, etc) as the likely near-term driver of the top-line, if CEMI can maintain significant base-business in international DPP STD revenue it would provide upside to our revenue estimates.

Regarding lateral flow, U.S. sales were $2.3M, up 86% yoy and the highest level since Q1 2014 ($2.7M). Q1 2014 was the period just prior to Alere's marketing rights to STAT-PAK rolling off and, similar to Q1 2016, resulted in a large stocking order. But while Alere will no longer be detailing any of CEMI's products, there is reason to be optimistic that lateral flow revenue can remain meaningful, including that CEMI already has in place a U.S. marketing strategy, sales force and third-party distributors to support sales of their DPP HIV assay (already FDA cleared), DPP HIV-Syphilis (clinical trials commenced Q1 2016) and their lateral flow products.

International lateral flow was the only disappointment in Q1 – falling 55% yoy, down 25% yoy and missing our number by 26% ($741 A vs. $1,008k E). But, as we've discussed in the past, international lateral flow is inherently difficult to model given the reliance on unpredictable aid tenders.

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 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). The first of the fever assays is nearing commercialization. And with a recently penned collaboration with Bio-Manguinhos/FIOCRUZ CEMI could have a Zika test on the Brazilian market very soon. 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. With the summer Olympics being held in Brazil, we think this could be a tremendous early opportunity if regulatory clearance is obtained by that time.

A DPP Zika assay has already completed development and has been filed for regulatory clearance with Brazilian regulators as well as for emergency use in the U.S. CEMI anticipates filing for emergency use with WHO by the end of this month. Management believes their DPP Zika assay will generate significant revenue in 2016.

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

- **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 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 Q2

- 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 19% 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. 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. While we had previously believed (and continue to model) that DPP HIV to FIOCRUZ would significantly contract in 2016, Q1 may suggest the opposite – if DPP STD to FIOCRUZ continues to hold up, it would provide upside to our related revenue estimates. 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 about 9% 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 9-12 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.

Q1 Financials

Q1 revenue of $6.6M was up 6% yoy, up 49% sequentially and about 45% better than our $4.6M estimate. Total HIV lateral flow sales were $3.1M, up 6% from the prior year period and about 32% better than our number – as noted we attribute most of the beat to our estimate to Alere stocking of SURE CHECK HIV 1/2. But we also note that we had often underestimated U.S. lateral flow sales since early 2014 given an expected greater contraction from Alere's STAT-PAK rights rolling off in June 2014 as well as anticipated headwinds from 4th –gen laboratory testing. So while we continue to model a contraction in U.S. lateral flow sales with the impending roll-off of the Alere SURE CHECK agreement, our numbers could end up conservative.

Meanwhile, international lateral flow sales were $741k representing yoy and sequential contraction of 55% and 25%, respectively, and lower than our $1,008k 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 $2.7M, up 8% yoy and more than 2.5x as much as the $1.0M generated in Q4 2015. As explained above, we attribute the beat to much stronger than expected STD sales to FIOCRUZ. This will be something to keep an eye on. If FIOCRUZ continues to order significant DPP STD product, that could push the DPP line up above our numbers in future periods as well.

Gross margin and product margin were 48.0% and 41.9%, compared to 43.1% and 36.9% in the year-earlier comparable period and our 43.3% and 33.2% estimates. The difference compared to our forecast relates to the beat on revenue and favorable product mix, particularly much higher than expected U.S. product sales.

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 $5.6 million at Q1 quarter-end.

Q1 adjusted net income and EPS of approximately ($449)k and ($0.05) compares to our ($1,166)k and ($0.12) estimates – the difference from a combination of the beat on revenue and better GM.

Cash
Cash used in operating activities was $2.7M in Q1. But excluding changes in working capital, which includes a $2.5M increase in A/R, cash used in operating activities was just $120k. CEMI exited the quarter with $2.7M in cash and equivalents. Management noted on the call that they believe the receivables are collectable. We note that CEMI's A/R have fluctuated, sometimes significantly, in the past and collections have not been problematic.

OUR OUTLOOK

Revenue
We look for 2016 revenue of $23.7 million, implying a decrease of 2% from 2015.

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

- **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 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 Q2
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Net Income / EPS
We look for adjusted net income and EPS of ($4.0)M and ($0.42) in 2016, compared to ($3.8) million and ($0.40) in 2015.

VALUATION

We continue to use OSUR as a comp for valuation purposes. OSUR trades at approximately 3x 2017 estimated sales which values CEMI at ~$9/share.

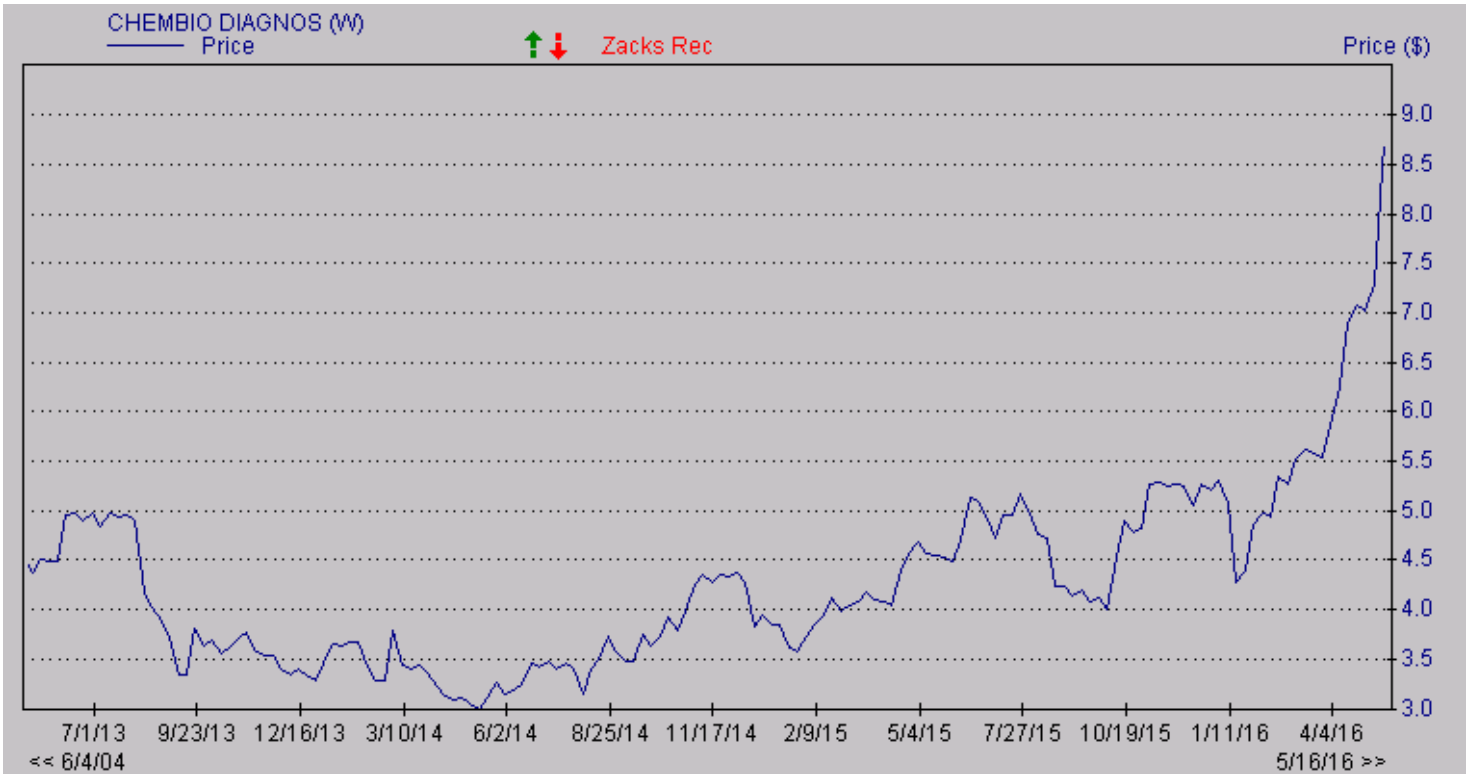
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2015 A	Q1A	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Product sales	**$21,887**	**$5,917**	**$4,225**	**$4,862**	**$5,470**	**$20,474**	**$25,440**	**$31,119**	**$36,856**
% of total revenue	*90.2%*	*89.6%*	*83.9%*	*85.1%*	*86.4%*	*86.5%*	*88.1%*	*89.7%*	*94.1%*
YOY Growth	*-15.7%*	*5.4%*	*-33.2%*	*-21.7%*	*46.2%*	*-6.5%*	*24.3%*	*22.3%*	*18.4%*
License & royalty income	**$53**	**$22**	**$27**	**$22**	**$26**	**$97**	**$432**	**$574**	**$310**
% of total revenue	*0.2%*	*0.3%*	*0.5%*	*0.4%*	*0.4%*	*0.4%*	*1.5%*	*1.7%*	*0.8%*
R&D contracts, grants, milestones	**$2,316**	**$662**	**$783**	**$830**	**$835**	**$3,110**	**$3,000**	**$3,000**	**$2,000**
% of total revenue	*9.5%*	*10.0%*	*15.6%*	*14.5%*	*13.2%*	*13.1%*	*10.4%*	*8.6%*	*5.1%*
Total Revenues	$24,255.5	$6,601.6	$5,035.0	$5,714.0	$6,331.0	$23,681.6	$28,871.6	$34,693.6	$39,165.9
YOY Growth	*-12.3%*	*5.9%*	*-25.0%*	*-17.0%*	*43.2%*	*-2.4%*	*21.9%*	*20.2%*	*12.9%*
Cost of Revenues	$13,769	$3,436	$2,772	$3,136	$3,501	$12,844	$15,823	$18,298	$20,824
Gross Income	$10,486	$3,166	$2,263	$2,578	$2,830	$10,838	$13,048	$16,395	$18,342
Gross Margin	*43.2%*	*48.0%*	*45.0%*	*45.1%*	*44.7%*	*45.8%*	*45.2%*	*47.3%*	*46.8%*
Product Margin	*37.1%*	*41.9%*	*34.4%*	*35.5%*	*36.0%*	*37.3%*	*37.8%*	*41.2%*	*43.5%*
Research & Development	$6,377	$1,634	$1,821	$1,994	$2,038	$7,487	$6,781	$6,315	$6,485
% R&D	*26.3%*	*24.8%*	*36.2%*	*34.9%*	*32.2%*	*31.6%*	*23.5%*	*18.2%*	*16.6%*
Selling General & Admin	$7,663	$1,999	$1,616	$1,840	$2,026	$7,481	$8,806	$9,437	$10,379
% SG&A	*31.6%*	*30.3%*	*32.1%*	*32.2%*	*32.0%*	*31.6%*	*30.5%*	*27.2%*	*26.5%*
Operating Income	($3,554)	($468)	($1,174)	($1,256)	($1,234)	($4,131)	($2,539)	$644	$1,478
Operating Margin	*-14.7%*	*-7.1%*	*-23.3%*	*-22.0%*	*-19.5%*	*-17.4%*	*-8.8%*	*1.9%*	*3.8%*
Other income (expense)	($5)	$0	$0	$0	$0	$0	$0	$0	
Interest income, net	$1	$3	$0	$0	$0	$4	$14	$10	$22
Pre-Tax Income	($3,558)	($465)	($1,173)	($1,255)	($1,233)	($4,127)	($2,525)	$654	$1,500
Taxes	($1,161)	($162)	($305)	($326)	($321)	($1,114)	($947)	$245	$563
Tax Rate	*32.6%*	*34.7%*	*26.0%*	*26.0%*	*26.0%*	*27.0%*	*37.5%*	*37.5%*	*37.5%*
Net Income	($2,397)	($304)	($868)	($929)	($913)	($3,014)	($1,578)	$409	$938
YOY Growth	*110.8%*	*-53.1%*	*30.8%*	*112.5%*	*40.6%*	*25.7%*	*-47.6%*	*-125.9%*	*129.5%*
Net Margin	*-9.9%*	*-4.6%*	*-17.2%*	*-16.3%*	*-14.4%*	*-12.7%*	*-5.5%*	*1.2%*	*2.4%*
GAAP EPS	($0.25)	($0.03)	($0.09)	($0.10)	($0.09)	($0.31)	($0.15)	$0.04	$0.08
Adjusted EPS	($0.40)	($0.05)	($0.12)	($0.13)	($0.12)	($0.42)	($0.23)	$0.06	$0.13
YOY Growth	*108.7%*	*-48.7%*	*30.7%*	*116.4%*	*-21.0%*	*25.7%*	*-52.5%*	*-125.5%*	*121.3%*
Weighted Avg. Shares O/S	9,626	9,632	9,628	9,628	9,628	9,629	10,620	10,800	11,200

Brian Marckx, CFA

HISTORICAL ZACKS RECOMMENDATIONS



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