Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: **Upside from Lateral Flow OTC. DPP HIV/Syph, Several DPP Fever Products to Drive 2018 Growth**

OSUR trades at 5x consensus 2018 sales. We model CEMI 2018 revenue of $30.2M, which at a 5x multiple, values the company approximately $12.50/share.

Current Price (08/17/17)	$6.67
Valuation	**$12.50**

OUTLOOK

Q3 total revenue was 35% ahead of our number and jumped more 100% yoy and 84% from Q2. As management mentioned on the call, total revenue was also the fourth highest in company history. And while a substantial portion of the beat to our estimate relates to earlier (than anticipated) recognition of a greater percentage of the BARDA Zika grant and DPP HIV 1/2 bulk order ($5.8M total) from FIOCRUZ, relative outperformance of the lateral flow business was also a significant contributor and represented incremental and fundamental upside. We are excited by lateral flow results given that we had not anticipated this segment to rebound as strongly as it has – which appears to largely relate to brisk uptake of the OTC HIV products in overseas markets.

Highlights on the operational front include progress in development of several programs, many of which could hold inflection-point potential including the DPP Syphilis/HIV assay for the U.S. market and DPP Malaria, DPP Dengue and DPP Fever assays (among others) which will mostly target international markets. Our price target has moved from $12.0 to $12.5/share on upward revisions to forecasted revenue.

SUMMARY DATA

52-Week High	**$7.05**
52-Week Low	**$5.05**
One-Year Return (%)	**-2.17**
Beta	**1.17**
Average Daily Volume (sh)	**10,101**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$82**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**31**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-9.8**
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	$6.33 A	$4.11 A	$7.59 A	$5.61 E	$23.64 E
2018					$30.23 E
2019					$37.14 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	-$0.13 A	-$0.18 A	-$0.05 A	-$0.12 E	-$0.48 E
2018					$0.27 E
2019					$0.12 E

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

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WHAT'S NEW

Q3 2017: *Upside from Lateral Flow OTC. DPP HIV/Syph, Several DPP Fever Products to Drive 2018 Growth …*

Chembio reported Q3 2017 financial results and provided a business update. Relative to our estimates as well as to the quarter and year-earlier comparable periods, financial results were extraordinarily strong. In fact, revenue of every major line item was well-ahead of our respective forecasts and, similarly, well-ahead of the prior-period comparisons.

Total revenue was 35% ahead of our number and jumped more 100% yoy and 84% from Q2. As management mentioned on the call (which we missed due to a timing conflict), total revenue was also the fourth highest in company history. And while a substantial portion of the beat to our estimate relates to earlier (than anticipated) recognition of a greater percentage of the BARDA Zika grant and DPP HIV 1/2 components bulk order ($5.8M total) from FIOCRUZ, relative outperformance of the lateral flow business was also a significant contributor and represented incremental and fundamental upside. In fact, while DPP sales which accounted for 58% of total product revenue, were the highest since Q3 2015 (and up 259% yoy and 203% qoq), we think the lateral flow revenue number may be even more exciting given that we had not anticipated this segment to rebound as strongly as it has – which appears to largely relate to brisk uptake of the OTC HIV products in overseas markets.

And revenue wasn't the only financial highlight in Q3. Product margin was the second highest in the last five quarters, operating expenses were flattish qoq (on 84% revenue growth) and net loss was the lowest since Q1 2016 (which was also somewhat of an anomaly given that period benefitted from a large lateral flow stocking order related to the roll-off of Alere's distribution rights to SURE CHECK). Cash usage (or relative lack of) was also a highlight. Excluding changes in working capital (i.e. ~EBITDA), cash used in operating activities was $260k in Q3, which compares to $1.8M in both Q2 of this year and Q3 2016.

Highlights on the operational front include progress in development of several programs, many of which could hold inflection-point potential including the DPP Syphilis/HIV assay for the U.S. market and DPP Malaria, DPP Dengue and DPP Fever assays (among others) which will mostly target international markets. Among the recent highlights are;

- DPP Zika granted Emergency Use Authorization (EUA) by FDA – 1st and only rapid test to receive EUA. Launched in U.S. via public health channels
- DPP Syph/HIV U.S. clinical trial made progress. Expected to complete by year-end. Could be 1st to market
- DPP Malaria, DPP Dengue – development progress on both. These represent huge markets
- DPP Dengue commercialization initiated in SE Asia
- DPP Dengue/Zika/Chikungunya pilot program w/ CDC initiated in India, Peru, Haiti, Guatemala
- DPP Zika final approvals received in Brazil
- DPP Fever panels development progress on both.

Product sales, at $6.1M, were up 145% yoy (from $2.5M) and 112% sequentially (from $2.9M). Approximately 52%, or $3.2M, of product sales relates to a portion of the $5.8M DPP HIV 1/2 Brazilian contract. That contract contributed ~$900k in Q2. So, even excluding contribution from this contract, product sales were still up 45% sequentially. Most of the remainder of the qoq increase relates to lateral flow sales – which posted very strong double-digit growth (on both a yoy and sequential basis).

While we have upped our forecasted lateral flow sales, given that only $1.6M (i.e.~50% of what was recognized in Q3) remains under the Brazil contract (which CEMI expects to recognize in Q4) and we do not anticipate any meaningful new product launches before the end of 2017, product sales will likely fall from Q3 to Q4. That certainly should not be construed as fundamental weakness, however, as 2018 should benefit from several catalysts, which could include high-potential product launches (such as U.S. DPP HIV/Syph and ex-U.S. DPP Malaria and other fever assays).

DPP sales, at $3.6M were up 259% yoy (from $1.0M) and up 203% sequentially (from $1.2M) and $835k better than our $2.8M estimate. As noted, the beat to our estimate relates almost entirely to earlier than modeled recognition of a greater portion of the Brazil order. But, excluding that order, DPP sales were still up about $100k from Q2 – which relates to additional sales in Latin America – which could be initial sales of the DPP Zika test in the Caribbean region (via Isla Lab).

In addition, other product sales increased about $150k from Q2 and by about $1.7M through the first nine months of the year. This might relate to additional sales of CEMI's DPP Dengue assay which commenced commercialization (via Chembio Diagnostics Malaysia, fka RVR). Given the outsized potential market for POC Dengue testing and CEMI's efforts to gain approval of their product in other Asia Pacific countries, this test could eventually be a tremendously successful product for the company. CEMI is also looking to leverage their Malaysian operation for sales of their lateral flow products and in Q3 established a STAT-PAK manufacturing line there.

We think the DPP pipeline holds tremendous potential, particularly as it related to the DPP HIV/Syphilis combo test for the U.S. market and certain DPP fever assays in (mostly) emerging markets. FDA filing for DPP HIV/Syphilis could happen within the next few months and potentially launch in the U.S. sometime next year. We think the U.S. market could be highly receptive to the test given the high rates of HIV/Syphilis co-infection and the fact that CEMI's would likely be the first combination assay to market (assuming no significant delays to approval). And while it might cannibalize some sales of its other HIV products, that should be offset by significantly greater share gains against competing stand-alone rapid HIV tests.

Dengue and malaria annual infections are estimated at approximately 400M and 200M, respectively, and combined, are responsible for almost 450k deaths worldwide. CEMI's DPP Malaria assay (development of which was funded by the Gates Foundation) completed feasibility testing and in Q3, successfully completed a lab evaluation. Management has noted that their malaria test has shown sensitivity levels "between 10 times and 30 times greater than the market-leading rapid malaria test". Meanwhile, commercialization of the DPP Dengue assay could soon be expanded beyond the initial-launch territories in SE Asia. These relatively humongous infected populations are attractive, although pricing of competing rapid tests has pushed so low that economic feasibility is currently a question. CEMI believes they can significantly reduce manufacturing costs through their Malaysian operation – that, coupled with much higher sensitivity of their assays may mean that these epidemic-like fever diseases are not only viable targets for the company, but also potential steep inflection-point catalysts.

Relative to lateral flow, Q3 sales of $2.3M were up 43% sequentially (from $1.6M), up 56% yoy (from $1.5M) and about 35% better than our $1.7M estimate. U.S. sales were relatively strong as compared to both the quarter and year-earlier periods, although at $931k, largely inline with our estimate ($912k). Almost all of the beat to our number and where we think incremental growth can come is in Africa. Africa related lateral flow sales were $958k – which is up from an average of $370k in the first two quarters of 2017 and almost double the $483k generated in Q3 2016.

Based on management's comments, it appears that the HIV OTC products which have been successful in Europe, may have received a similarly warm reception in Africa. In fact, CEMI mentioned that they think the international OTC markets represent significant potential for growth. While we had not anticipated significant demand for OTC HIV products overseas, given the obvious early interest, we have since made upward revisions to our estimates for these products in Europe and Africa. Management also noted that one of their key goals is to further broaden their lateral flow OTC footprint.

Fever Portfolio, DPP HIV/Syphilis 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 exploiting the potential of their DPP fever portfolio.

FIOCRUZ has been an important partner of Chembio's for many years and while related sales tailed off to an extent in 2016, that changed with the $5.8M bulk order for DPP HIV test components. The earlier slump related to a competitor under-pricing where it was not economically feasible for CEMI to compete. Interestingly, they came back around - likely for the quality and accuracy associated with DPP. While there is no guarantee FIOCRUZ will purchase beyond the current order, we are modeling incremental revenue as we think the long and mutually beneficial relationship, coupled with the competitive benefits of DPP, means that future incremental business will materialize from Brazil for DPP HIV.

DPP Zika and the micro reader are now both approved by Brazilian regulators. While it is too early to predict order flow, the almost epidemic-like Zika outbreak in Brazil (~1.5M people infected) and proven commercialization capabilities of FIOCRUZ means commercialization in that country could be a meaningful revenue catalyst. The test is also CE Marked and has generated initial revenue in CEMI's Caribbean territories – further expansion in that area offers upside. Additionally, UNICEF has an outstanding RFP for POC Zika test (for Africa) that could be worth up to $10M – this presents another potentially meaningful opportunity. CEMI is also seeking EUA status from WHO.

DPP Zika also just recently received FDA EUA. It is the first and only rapid Zika test to receive that designation. Initial roll-out has already commenced through the company's direct sales organization. CEMI is now detailing to state and local health departments and noted that early feedback has been very positive. But, given that current Zika testing protocol in the U.S. uses molecular and ELISA testing (i.e. not rapid), along with the fact that Zika is not currently considered an emergency or outbreak in U.S., we are not modeling significant contribution from this product. The second phase of the BARDA grant, if received, would fund 510(k) and CLIA-waiver FDA pathways – which could significantly broaden access and demand for the test in the U.S.

The stand-alone DPP Dengue assay has already made a major splash with $1.4M in related revenue booked in Q1 2017. Given the outsized potential market for POC Dengue testing and CEMI's efforts to gain approval of their product in other Asia Pacific countries, we think this test could eventually be a tremendously successful product for Chembio. Additional fever-related launches in the near-term and the large populations of S.E. Asia in Zika-prone geographies present further opportunity to leverage CEMI's Malaysian operations.

DPP Malaria also holds meaningful near-term promise. Feasibility testing of a DPP oral fluid malaria test was recently completed - 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. Given the relatively massive size of the malaria testing market, if eventually commercialized (and manufactured at a feasible cost), we think this DPP Malaria saliva/blood could potentially be a tremendous success.

The FIND collaboration (April 2017) to develop (over the next 12 months) a DPP fever panel to simultaneously detect multiple diseases common to in the Asia Pacific region fits the mold of layering in other high potential products in high potential territories with proven manufacturing and distribution resources. Field evaluation of the assay was completed in Peru and Nigeria and FIND is now in-process of analyzing the data – with final report expected in Q1 2018. A second fever panel – this one for the Asian market, is also under development in collaboration with FIND.

Other fever-related products that could come make a contribution in the near-term include;
- DPP Zika/Dengue/Chikungunya: began selling to CDC in pilot program in Q1 2017
- DPP Chikungunya: initiated registration in SE Asia
- DPP Ebola and DPP Malaria-Ebola: field studies still ongoing in W. Africa

And on the STD side, in addition to the DPP HIV/Syphilis assay, DPP Syphilis Screen and Confirm is another product that we think could have substantial appeal - particularly in developing areas of the world. CEMI's test, which is CE Marked and been used in pilot programs in Africa (via CDC), is the only rapid test that can detect both active and past syphilis infections.

OUR OUTLOOK

The company has been deliberate in finding ways to grow all of their product lines and this has shown early success. This included hiring experienced sales executives in 2016 to manage the America's and EMEA regions. Then in January 2017 they brought on three international sales directors 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.

Recent "wins" relative to regaining control of their destiny include the resurgence of U.S. lateral flow sales, meaningful European sales, the recent $5.8M FIOCRUZ order, quickly closing on the RVR acquisition and generating $1.4M in DPP Dengue sales - this is a product was approved and launched in relatively short order and could end up being tremendously successful.

The recent Isla Lab distribution partnership is also with this 'control-your-own-destiny' strategy as is layering in more high-potential products for sale in high-potential territories. The FIND-related fever panels which could be a perfect fit for CEMI Malaysia is a good example of this. So, now with U.S. lateral flow business back in CEMI's court and the assemblage of international sales and manufacturing infrastructure the pieces seem to be falling in place. 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.

Revenue

We now look for 2017 revenue of $23.6M (revised from $21.9 million), implying growth of 32% from 2016. We have product sales growing 38% given our expectation of a rebound in DPP from initial meaningful sales from the fever portfolio, the $5.8M FIOCRUZ order (DPP HIV test components) and stabilization of lateral flow as CEMI fully regroups this business under its own umbrella. The surprise in demand from international OTC has been quite encouraging as it relates to the lateral flow portfolio. 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 as well as new opportunities such as HIV self-testing, 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. Additional potential upside could come from DPP Fever in Europe or the Caribbean. In addition, further DPP fever-related regulatory approvals in Asia Pacific could also offer upside. DPP HIV/Syphilis, assuming FDA approval is not delayed, could be a significant contributor as early as 2018.

VALUATION

OSUR trades at 5x consensus 2018 sales. We model CEMI 2018 revenue of $30.2M, which at a 5x multiple, values the company approximately $12.50/share.

FINANCIAL STATEMENTS

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2016 A	Q1A	Q2A	Q3A	Q4E	2017 E	2018 E	2019 E
Product sales	$13,679	$5,427	$2,893	$6,133	$4,438	$18,889	$26,470	$34,636
% of total revenue	76.6%	85.8%	70.3%	80.8%	79.1%	79.9%	87.6%	93.3%
YOY Growth	-37.5%	-8.3%	42.2%	145.1%	37.5%	38.1%	40.1%	30.9%
License & royalty income	$450	$100	$228	$150	$132	$610	$526	$310
% of total revenue	2.5%	1.6%	5.5%	2.0%	2.4%	2.6%	1.7%	0.8%
R&D contracts, grants, milestones	$3,739	$798	$994	$1,305	$1,043	$4,140	$3,230	$2,193
% of total revenue	20.9%	12.6%	24.2%	17.2%	18.6%	17.5%	10.7%	5.9%
Total Revenues	**$17,868.8**	**$6,325.2**	**$4,114.8**	**$7,587.4**	**$5,613.0**	**$23,640.4**	**$30,225.1**	**$37,138.4**
YOY Growth	-26.3%	-4.2%	26.0%	102.5%	31.9%	32.3%	27.9%	22.9%
Cost of Revenues	$9,418	$3,219	$2,204	$4,065	$2,752	$12,239	$15,326	$19,569
Gross Income	**$8,451**	**$3,106**	**$1,911**	**$3,523**	**$2,861**	**$11,401**	**$14,899**	**$17,569**
Gross Margin	47.3%	49.1%	46.4%	46.4%	51.0%	48.2%	49.3%	47.3%
Product Margin	31.2%	40.7%	23.8%	33.7%	38.0%	35.2%	42.1%	43.5%
Research & Development	$8,428	$2,247	$1,982	$1,806	$1,888	$7,923	$7,612	$7,244
% R&D	47.2%	35.5%	48.2%	23.8%	33.6%	33.5%	25.2%	19.5%
Selling General & Admin	$7,596	$2,488	$2,109	$2,305	$2,498	$9,401	$10,941	$11,959
% SG&A	42.5%	39.3%	51.3%	30.4%	44.5%	39.8%	36.2%	32.2%
Operating Income	**($7,572)**	**($1,629)**	**($2,181)**	**($589)**	**($1,524)**	**($5,923)**	**($3,654)**	**($1,633)**
Operating Margin	-42.4%	-25.8%	-53.0%	-7.8%	-27.2%	-25.1%	-12.1%	-4.4%
Other income (expense)	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	$26	$13	$8	$4	$1	$26	($24)	($14)
Pre-Tax Income	**($7,546)**	**($1,616)**	**($2,173)**	**($585)**	**($1,523)**	**($5,897)**	**($3,678)**	**($1,647)**
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)**	**($1,616)**	**($2,173)**	**($585)**	**($1,523)**	**($5,897)**	**($3,678)**	**($1,647)**
YOY Growth	456.8%	431.3%	-74.0%	-72.7%	-40.4%	-55.8%	-37.6%	-55.2%
Net Margin	-74.7%	-25.5%	-52.8%	-7.7%	-27.1%	-24.9%	-12.2%	-4.4%
EPS	**($1.26)**	**($0.13)**	**($0.18)**	**($0.05)**	**($0.12)**	**($0.48)**	**($0.27)**	**($0.12)**
YOY Growth	-	-	-	-	-	-	-	-
Adjustments	$5,817	$0	$0	$0	$0	$0	$0	$0

Adjusted Net Income	($7,530)	($1,616)	($2,173)	($585)	($1,523)	($5,897)	($3,678)	($1,647)
Adjusted EPS	($0.71)	($0.13)	($0.18)	($0.05)	($0.12)	($0.48)	($0.27)	($0.12)
YOY Growth	404.6%	182.2%	-28.4%	-75.3%	-41.7%	-61.8%	-44.4%	-55.9%
Weighted Avg. Shares O/S	10,622	12,271	12,299	12,311	12,315	12,299	13,800	14,000

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