March 13, 2018

Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: **Recent Wins Mean 2018 Could Set Product Sales Record**

OSUR trades at 5.4x consensus 2018 sales. We model CEMI 2018 revenue of $32.3M, which at a 5.4x multiple, values the company approximately $12.50/share.

Current Price (03/13/18)	$7.75
Valuation	**$12.50**

OUTLOOK

Bringing sales functions in-house which included hiring experienced sales executives to manage the America's and EMEA regions and recruiting international sales directors tasked with increasing sales of the company's products in each of their respective regions (Latin America, Africa and Asia/Pacific) has paid major dividends. This 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 has already been transformational.

Recent "wins" relative to regaining control of their destiny include the resurgence of U.S. lateral flow sales, OTC HIV segment growth, Bio-Manguinhos contracts worth more than $14M over two years, acquiring RVR (providing direct commercial and manufacturing access to large SE Asia markets), $15.8M Ethiopian tender, AstraZeneca development collaboration and more. With increased manufacturing capacity coming online in NY and followed by additional capacity and low-cost manufacturing in Malaysia, CEMI is preparing for what we expect to be the next wave of growth, catalyzed by new product launches in both the STD and Fever portfolios and leveraging opportunities with legacy products – in both the U.S. and internationally.

SUMMARY DATA

52-Week High	**$9.20**
52-Week Low	**$5.05**
One-Year Return (%)	**49.53**
Beta	**1.18**
Average Daily Volume (sh)	**31,566**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$110**
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 (%)	**-9.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 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)
2017	$6.33 A	$4.11 A	$7.59 A	$5.99 A	$24.02 A
2018	$6.10 E	$7.23 E	$8.43 E	$10.54 E	$32.31 E
2019					$40.95 E
2020					$48.91 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.13 A	-$0.18 A	-$0.05 A	-$0.17 A	-$0.52 A
2018	-$0.10 E	-$0.08 E	-$0.08 E	-$0.04 E	-$0.30 E
2019					-$0.02 E
2020					$0.11 E

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

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WHAT'S NEW

Q4 2017: *Strategic Successes and Recent Wins Sets Up 2018 To Be Another Strong Year…*

Chembio reported Q4 2017 financial results and provided a business update. Despite declining on a sequential basis, both product sales and total revenue remained fundamentally very strong. The ~$1.2M qoq dip in product sales relates entirely (and more) to the timing in recognition of the May 2017 $5.8M DPP HIV 1/2 Brazilian contract. Product sales were about 10% and total revenue about 7% better than our respective estimates. More importantly, recent contract wins and near-term new product launches mean product sales growth in 2018 could actually eclipse the 41% posted in 2017. We are now modeling 2018 product sales of $27.9M, which would be an all-time record for CEMI.

Product Sales Up 51% in Q4, 41% FY 2017
Q4 and full-year 2017 product sales were $4.9M and $19.3M, up 51% and 41%, respectively. While revenue per product technology (i.e. DPP vs lateral flow) was not disclosed, CEMI did note that the remaining $1.4M of the $5.8M (all of which was recognized during 2017) Bio-Manguinhos contract shipped in Q4 (compared to ~$3.2M in Q3 2017).

While we had modeled that final payment, the beat to our number on product sales appears to be related to Africa – revenue from which was $1.8M in Q4 (37% of total product sales vs. $678k or 21% in Q4 2016) – or almost exactly the same $ amount that that territory contributed over the entire first nine months of 2017. Africa, has been a strong territory for CEMI as of late and, as we noted in our Q3 2017 update, was also the source of the beat to our product sales estimate in that quarter. A significant portion of that strength appears to be coming from OTC HIV products – a segment that showed initial success in Europe but which looks to have also gained traction in parts of Africa and could represent significant growth potential in other territories. CEMI's OTC HIV revenue grew 91% in 2017.

Africa was responsible for $3.6M (18%) of product sales in all of 2017, including $2.7M (25%) in 1H, and accounted for 21% of the years' total product sales growth. Africa's contribution will increase, however, as CEMI expects to book more than $4M in 2018 (commencing in Q2) from a new 3-year $15.8M Ethiopian government tender. The remainder will be recognized during 2019 and 2020.

That contract (from the Ethiopian Pharmaceuticals Fund and Supply Agency) is just the latest addition to a long and growing list of (publicly disclosed) contract wins over the last several quarters that represent at least $35M worth of revenue recognizable over just four years. These wins (detailed below) are testament to success of the company's recently implemented strategy aimed at gaining more control over their destiny.

Total Sales Up 41% in Q4, 34% FY 2017
Total sales, which includes license and grant revenue, were $6.0M and $24.0M in Q4 and 2017, up 41% and 34% yoy. Approximately $3.2M remains under the BARDA Zika grant. With EUA authorization completed, CEMI is turning their attention to CLIA waiver and 510(k) clearance. Farther down the road is a possible $7.3M follow-on funding from BARDA for a DPP Zika/Chikun/Dengue combination assay. In the meantime and in addition to the remainder of the current BARDA contract, initial revenue will be booked from a new $2.9M product development agreement with AstraZeneca.

That deal, announced in December, relates to the development of a quantitative DPP assay for the detection of a (not disclosed) biomarker. The funding is expected over a term of 18 months. CEMI noted on the Q4 call (which we missed due to a timing conflict) that the timeline includes an expected mid-2019 510(k) clearance filing. CEMI might also play a role in commercialization, if and when launched. While neither the assay or target application were disclosed, given a mutual relationship with Genisphere's technology, we think it may relate to oncological companion diagnostics. We should learn some more details with future company updates.

Product, Gross Margin
Product margin was 29.5% and 33.1% in Q4 and the full-year. Gross margin was 42.7% and 46.2% over the same periods. For context, product and gross margins over the three prior years were 35.1%/39.1% (2014), 37.1%/43.2% (2015) and 31.2%/47.3% (2016). While we expect revenue mix (including product vs grant revenue and international, particularly EM tenders, vs U.S. sales) will continue to move margin around, two of the more significant influences may be the $15.8M Ethiopian HIV STAT-PAK tender (i.e. big, relatively low-margin) and Malaysia-based manufacturing (i.e. significant and relatively low-cost throughput). The former is expected to commence in Q2 and run through 2020 while ribbon-cutting on the latter will likely be a 2019 event (possibly early 2019, depending on timing of WHO certification). We also think increasing U.S. sales should benefit margin – and

believe DPP HIV/Syphilis, PMA application for which was filed in Q1, could prove to be one of the company's most successful products.

Cash
Bolstered by $3.7M collection of A/R, CEMI had a $2.1M inflow and $5.0M outflow of cash from operations in the three and twelve months ending December 31, 2017, respectively. Excluding changes in working capital, cash used in operations was $1.8M and $4.9M over the same periods, compared to $2.2M and $6.1M used in the comparable prior year periods. CEMI exited 2017 with $1.9M in cash and equivalents and subsequent to year-end, raised ~$11.0M, net, ($12.0M gross) via the public sale of 1.784M common shares @ $6.75/share.

Operational update:
The $8.5M Bio-Manguinhos order for DPP HIV and Leishmania product and $15.8M Ethiopian STAT-PAK contract were two of several recent highlights on the operational front that will make either an initial contribution or larger contribution to revenue in 2018 and beyond. In terms of regulatory-related activities, FDA decision on the DPP HIV/Syphilis PMA filing is one of the most anticipated, as is OUS approval of the DPP Malaria and Dengue assays. And as it relates to business development and other related activities focused on further diversifying the revenue base and increasing shots on goal, the recent deal with AstraZeneca may represent the first of future similar development/commercialization collaborations. Among the recent highlights are;

- $15.8M Ethiopian tender for HIV STAT-PAK over 2018 – 2020
- UNICEF conditional award for DPP Zika worth $1.5M - $4.9M over 2018 – 2020
- AstraZeneca collaboration for development, regulatory submission of quantitative assay
- $8.5M commitment from Bio-Manguinhos to purchase DPP HIV and DPP Leishmania intermediate product and test components during 2018
- DPP Zika granted Emergency Use Authorization (EUA) by FDA in Sept 2017 – 1st and only rapid test to receive EUA. Launched in U.S. and Caribbean via public health channels
- DPP Syph/HIV U.S. clinical trial completed. FDA PMA filing made in Q1 2018. Expected to be 1st rapid HIV/Syph test on market
- DPP Syph/HIV OUS: already had significant success in Mexico. Initiated clinical study in 10 countries via WHO
- DPP Syph Screen/Confirm: CE Marked. Completed pilot studies in Africa – sales initiated
- DPP Malaria, DPP Dengue – development progress on both including Malaysia approval of DPP Dengue. Add'l approvals expected and commercialization in initial markets in 2018. These represent huge markets
- 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
- Progress on DPP Cancer and Bovine TB, completion of both expected in 2018. DPP Concussion could follow

STD Portfolio:

DPP HIV/Syph: Could launch in the U.S by current year-end. 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. 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.

Outside the U.S. the product had previously had significant commercial success in Mexico. Additional OUS regulatory approvals for DPP HIV/Syph and their other HIV products could come on a regular basis as CEMI implements an aggressive regulatory strategy. With ~2M pregnancies worldwide affected by mother-to-child HIV or Syphilis transmission, global demand could be substantial.

Bio-Manguinhos/FIOCRUZ has been an important partner for CEMI and one that we think will continue be a significant customer for the foreseeable future (for not only CEMI's sexually transmitted disease assays, but also for its burgeoning DPP fever portfolio). The $5.8M contract in May 2017 related to DPP HIV test components was filled and paid in less than seven months. That was followed in December by an $8.5M commitment for the purchase of $8.5M worth of DPP HIV and DPP Leishmania intermediate product and test components with the related sales to occur in 2018.

Lateral flow: we expect 2018 to be an extraordinarily strong year for the lateral flow business as a result of certain recent catalysts. This includes $4M+ revenue of the $15.8M Ethiopian contract is expected to be recognized during the year. In addition, final expiration of stocked U.S. products' expiration dates occurred in February 2018 – as a

reminder, just prior to roll-off of Alere's marketing rights they made large stocking purchases – that related inventory has now been fully burned. Growth in the HIV self-testing segment is also expected to continue and benefit OUS lateral flow sales. CEMI's increased manufacturing capacity (initially in NY and, later, also in Malaysia) provides ability to satisfy larger tenders – the Ethiopian contract may be the first of more large tender wins to come.

Fever Portfolio:

DPP Malaria / Dengue: 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.

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 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 may be 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.

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. Analysis of the data and final report is expected in the near-term. A second fever panel – this one for the Asian market, is also under development in collaboration with FIND.

DPP Zika: DPP Zika and the micro reader are approved in Brazil. While it is too early to predict order flow, the prior 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. 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.

Under the UNICEF award CEMI has a firm commitment for sales of $1.5M with a potential of up to $4.9M. Sales are conditioned upon CEMI first receiving WHO Emergency Use Assessment, clinical and analytical evaluation and quality management system inspection.

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 noted that initial detailing focused on state and local health departments - also noting that early feedback was 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 next step, which CEMI expects to take at least all of 2018 to complete, is to secure CLIA-waiver and 510(k) clearance – if successful those could significantly broaden access and demand for the test in the U.S.

OUR OUTLOOK

The company has been deliberate in finding ways to grow all of their product lines, diversify their revenue base and increase shots on goal. They have shown an ability to deliver on this strategy. Bringing sales functions in-house which included hiring experienced sales executives to manage the America's and EMEA regions and recruiting international sales directors tasked with increasing sales of the company's products in each of their respective regions (Latin America, Africa and Asia/Pacific) has paid major dividends. This 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 has already been transformational.

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Revenue

We now look for 2018 revenue of $32.3M, implying growth of 44% from 2017. We have product sales growing 44% as certain of the DPP fever assays make initial contribution, $8.5M from Bio-Manguinhos, more than $4M from the Ethiopia tender, anticipated moderate growth of U.S. lateral flow products and leveraging opportunities in OTC HIV overseas. DPP HIV/Syphilis, assuming FDA approval, could also make a meaningful mark in 2018, although we more conservatively model initial U.S. contribution next year. And given the potential significant opportunity that this product also has OUS, ramp in initial adoption of the product could provide upside to our numbers.

VALUATION

OSUR trades at 5.4x consensus 2018 sales. We model CEMI 2018 revenue of $32.3M, which at a 5.4x multiple, values the company approximately $12.50/share.

FINANCIAL STATEMENTS

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2016 A	Q1A	Q2A	Q3A	Q4A	2017 A	Q1E	Q2E	Q3E	Q4E	2018 E	2019 E	2020 E
Product sales	**$13,679**	**$5,427**	**$2,893**	**$6,133**	**$4,869**	**$19,322**	**$5,151**	**$5,985**	**$7,351**	**$9,377**	**$27,864**	**$37,487**	**$45,686**
%of total revenue	*76.6%*	*85.8%*	*70.3%*	*80.8%*	*81.3%*	*80.5%*	*84.4%*	*82.7%*	*87.2%*	*88.9%*	*86.2%*	*91.5%*	*93.4%*
YOY Growth	*-37.5%*	*-8.3%*	*42.2%*	*145.1%*	*50.9%*	*41.3%*	*-5.1%*	*106.9%*	*19.9%*	*92.6%*	*44.2%*	*34.5%*	*21.9%*
License & royalty income	**$450**	**$100**	**$228**	**$150**	**$264**	**$742**	**$178**	**$225**	**$205**	**$247**	**$855**	**$968**	**$1,097**
%of total revenue	*2.5%*	*1.6%*	*5.5%*	*2.0%*	*4.4%*	*3.1%*	*2.9%*	*3.1%*	*2.4%*	*2.3%*	*2.6%*	*2.4%*	*2.2%*
R&D contracts, grants,	**$3,739**	**$798**	**$994**	**$1,305**	**$855**	**$3,952**	**$775**	**$1,023**	**$878**	**$920**	**$3,596**	**$2,495**	**$2,125**
%of total revenue	*20.9%*	*12.6%*	*24.2%*	*17.2%*	*14.3%*	*16.5%*	*12.7%*	*14.1%*	*10.4%*	*8.7%*	*11.1%*	*6.1%*	*4.3%*
Total Revenues	$17,869	$6,325	$4,115	$7,587	$5,988	$24,015	$6,104	$7,233	$8,434	$10,544	$32,315	$40,949	$48,908
YOY Growth	*-26.3%*	*-4.2%*	*26.0%*	*102.5%*	*40.7%*	*34.4%*	*-3.5%*	*75.8%*	*11.2%*	*76.1%*	*34.6%*	*26.7%*	*19.4%*
Cost of Revenues	$9,418	$3,219	$2,204	$4,065	$3,433	$12,921	$3,220	$3,884	$4,852	$6,329	$18,285	$21,292	$25,082
Gross Income	$8,451	$3,106	$1,911	$3,523	$2,555	$11,094	$2,885	$3,349	$3,582	$4,214	$14,030	$19,657	$23,826
Gross Margin	*47.3%*	*49.1%*	*46.4%*	*46.4%*	*42.7%*	*46.2%*	*47.3%*	*46.3%*	*42.5%*	*40.0%*	*43.4%*	*48.0%*	*48.7%*
Product Margin	*31.2%*	*40.7%*	*23.8%*	*33.7%*	*29.5%*	*33.1%*	*37.5%*	*35.1%*	*34.0%*	*32.5%*	*34.4%*	*43.2%*	*45.1%*
Research & Development	$8,428	$2,247	$1,982	$1,806	$2,521	$8,555	$2,012	$2,159	$2,177	$2,212	$8,560	$8,415	$8,789
%R&D	*47.2%*	*35.5%*	*48.2%*	*23.8%*	*42.1%*	*35.6%*	*33.0%*	*29.8%*	*25.8%*	*21.0%*	*26.5%*	*20.5%*	*18.0%*
Selling General & Admin	$7,596	$2,488	$2,109	$2,305	$2,118	$9,021	$2,198	$2,322	$2,530	$2,615	$9,664	$11,548	$13,401
%SG&A	*42.5%*	*39.3%*	*51.3%*	*30.4%*	*35.4%*	*37.6%*	*36.0%*	*32.1%*	*30.0%*	*24.8%*	*35.1%*	*28.2%*	*27.4%*
Operating Income	($7,572)	($1,629)	($2,181)	($589)	($2,084)	($6,483)	($1,325)	($1,132)	($1,125)	($612)	($4,194)	($306)	$1,636
Operating Margin	*-42.4%*	*-25.8%*	*-53.0%*	*-7.8%*	*-34.8%*	*-27.0%*	*-21.7%*	*-15.7%*	*-13.3%*	*-5.8%*	*-13.0%*	*-0.7%*	*3.3%*
Other income (expense)	$0	$0	$0	$0	$0	$0					$0	$0	
Interest income, net	$26	$13	$8	$4	($2)	$22	$2	$2	$0	($1)	$3	($14)	($20)
Pre-Tax Income	($7,546)	($1,616)	($2,173)	($585)	($2,087)	($6,460)	($1,323)	($1,130)	($1,125)	($613)	($4,191)	($320)	$1,616
Taxes	$5,801	$0	$0	$0	($88)	($88)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*-76.9%*	*0.0%*	*0.0%*	*0.0%*	*4.2%*	*1.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($13,347)	($1,616)	($2,173)	($585)	($1,998)	($6,372)	($1,323)	($1,130)	($1,125)	($613)	($4,191)	($320)	$1,616
YOY Growth	*456.8%*	*431.3%*	*-74.0%*	*-72.7%*	*-21.9%*	*-52.3%*	*-18.1%*	*-48.0%*	*92.4%*	*-69.3%*	*-34.2%*	*-92.4%*	*-605.3%*
Net Margin	*-74.7%*	*-25.5%*	*-52.8%*	*-7.7%*	*-33.4%*	*-26.5%*	*-21.7%*	*-15.6%*	*-13.3%*	*-5.8%*	*-13.0%*	*-0.8%*	*3.3%*
EPS	($1.26)	($0.13)	($0.18)	($0.05)	($0.16)	($0.52)	($0.10)	($0.08)	($0.08)	($0.04)	($0.30)	($0.02)	$0.11
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted Avg. Shares O/S	10,622	12,271	12,299	12,311	12,506	12,347	13,241	14,165	14,170	14,170	13,937	14,400	15,000

Brian Marckx, CFA

HISTORICAL STOCK PRICE



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