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Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: ***Q3: Record YTD Revenue, Margin Improvement Should Soon Follow…***

OSUR trades at 4.6x consensus 2018 sales and 4.2x consensus 2019 sales. Based on our estimated CEMI 2018 revenue of $32.5M and 2019 revenue of $40.0M, CEMI is valued at approximately $9.50/share.

Current Price (11/29/18)	$6.45
Valuation	**$9.50**

OUTLOOK

Product and total sales increased yoy 28% and 24% in Q3 and by 46% and 43% YTD. While it is unclear exactly what is catalyzing product revenue, recently secured contracts (such as that with Bio-Manghinos) and international tenders (including the $15.8M tender from Ethiopia) are undoubtedly significant contributors to the record YTD revenue. For context of how relatively strong 2018 has been, revenue through the first nine months is greater than only three of the last the last 12 full fiscal years and is 19% higher than the prior best through Q3. However, with a greater percentage of product sales originating from OUS, including from (typically low-margin) aid tenders, a lower proportion of revenue is flowing through to gross income. Product revenue from North America, which includes direct sales via CEMI's sales force (and distribution partners) and which we estimate carry healthier margins (at least, in general), accounted for just 10% of the YTD total. This is down from 20% in the same period in 2017 and from 37% and 30% in fiscal 2017 and 2016, respectively. The good news is that there are several anticipated near-term margin-related catalysts including imminent commencement of CEMI's new automated manufacturing line, initial production in Malaysia, lower reader production costs and launch of DPP HIV-Syphilis in the U.S.

SUMMARY DATA

52-Week High	**$11.55**
52-Week Low	**$5.72**
One-Year Return (%)	**-12.62**
Beta	**1.46**
Average Daily Volume (sh)	**88,838**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$111**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**40**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-4.9**
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	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Diagnostics**

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	$7.72 A	$8.72 A	$9.38 A	$6.74 E	$32.55 E
2019					$40.03 E
2020					$48.38 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	-$0.05 A	-$0.12 A	-$0.16 A	-$0.18 E	-$0.53 E
2019					-$0.34 E
2020					$0.02 E

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

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Q3 2018: *Record YTD revenue, margins take a hit but should begin to rebound…*

Q3 made it three-for-three with us substantially underestimating product and total revenue every quarter so far in 2018. Product and total sales increased 28% yoy and 24% in Q3 and by 46% and 43% YTD. While it is unclear exactly what is catalyzing product revenue or where we're missing, recently secured contracts (such as that with Bio-Manghinos) and international tenders (including the $15.8M tender from Ethiopia) are undoubtedly significant contributors to the record YTD revenue. For context of how relatively strong 2018 has been, revenue through the first nine months is greater than only three of the last the last 12 full fiscal years and is 19% higher than the prior best through Q3.

However, with a greater percentage of product sales originating from OUS, including from (typically low-margin) aid tenders, a lower proportion of revenue is flowing through to gross income. Product revenue from North America, which includes direct sales via CEMI's sales force (and distribution partners) and which we estimate carry healthier margins (at least, in general), accounted for just 10% of the YTD total. This is down from 20% in the same period in 2017 and from 37% and 30% in fiscal 2017 and 2016, respectively.

The good news is that there are several anticipated near-term margin-related catalysts including imminent commencement of CEMI's new automated manufacturing line, initial production in Malaysia, lower reader production costs and launch of DPP HIV-Syphilis in the U.S.

Production of the DPP tests is expected to begin on CEMI's new automated line (in New York) in Q4'18. Meanwhile, CEMI anticipates site inspection of their Malaysian production facility in December. If all goes well, manufacturing will begin there next year and bring down production and shipping costs of certain tests sold overseas. And with the recent acquisition of OpTricon, cost of CEMI's quantitative readers will also come down. And finally, DPP HIV-Syphilis, which we continue to believe could eventually prove to be one CEMI's most successful products, could receive FDA approval and launch in the coming months (or even weeks). As a reminder, the PMA package seeking FDA approval was filed in in Q1'18.

CEMI's/OpTronics' Quant Readers



DPP® Micro Reader



opTrilyzer® Analyzer

Source: Chembio Nov presentation

Product Sales Up 28% yoy, 15% qoq

Q3 product sales were $7.9M, up 28% yoy, up 15% sequentially and 19% higher (~$1.3M) than our $6.6M estimate. Similar to the first two quarters of the year, the majority of revenue related to sales in Africa and Latin America, which accounted for 39% and 40% of product revenue, respectively.

Through the first nine months, total product revenue increased 46%, or $6.7M, while revenue from Africa and Latin America increased 279% ($5.1) and 35% ($2.4), respectively. While specific sources of product revenue were not disclosed, much of the growth in Africa is coming from the $15.8M Ethiopian tender and growth in Latin America from the recent $8.5M Bio-Manghinos (for Brazil's Ministry of Health) order. We think this highlights what is behind product margins falling to just 14% in Q3 and to an average of 21% YTD. For comparison, product margins were 34% and 33% in the comparable prior-year periods and averaged low-to-mid 30% over the last four fiscal years. The good news, as noted, is that margins should improve.

And, with a newly-won contract from Bio-Manghinos for $10.5M (for the production of DPP® HIV and DPP® Leishmania assays), we think revenue should remain relatively elevated. In addition, ~$11.5M of the Ethiopian tender is expected to be recognized during 2019 and 2020. Other potential revenue catalysts going into 2019, in addition to U.S. DPP HIV-Syphilis, include DPP Ebola (which was recently granted U.S. Emergency Use), DPP Zika (in several areas of the world), one or more DPP Dengue assay launches (including stand-alone Dengue, Dengue/Zika/Chikungunya Authorization), a DPP fever panel and revenue via opTricon.

Additional tenders (initial UNICEF Zika could be worth up to $4.9M and CEMI recently applied for a second UNICEF RFP), increasing demand for HIV self-testing and potential meaningful contribution from collaboration agreements (such as with AZN, LumiraDx and, most recently, FIND for HCV rapid test development) could also contribute. As it relates specifically to the collaboration with AstraZenecas, a CE Mark application was filed for a (yet-to-be

disclosed) POC DPP test to detect a certain biomarker (we may know more details in the coming weeks/months with CE Marking).

And while maybe not a near-term catalyst, a program that could potentially hold tremendous upside value is CEMI's cancer diagnostic. While this has been somewhat of an 'under-the-radar' program (our wording and characterization) with only scant details disclosed publicly, indications are that this is progressing and with promising results. In fact, management noted on the Q2 call in August that their cancer test has completed development "with excellent analytical performance" – the test is now in the validation phase. So far, we know that it is built on the DPP platform and is a multiplex test for cancer which uses just a finger-prick worth of blood and can deliver results in 15 minutes. While we do not have nearly enough information about the test and initial results to include it in our model, given that early, accurate and non-invasive cancer diagnosis could have multi billion-dollar potential, this will be a program that we will be eager to know more about.

Recent and potential near-term regulatory approvals

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification &Validation	Phase IV Clinical/ Regulatory	Phase V Commercial Launch
DPP HIV-Syphilis (US)	Self-funded	✓	✓	✓	Submitted FDA Q1 2018	
DPP Dengue (International)	Fiocruz	✓	✓	✓	Submitted ANVISA[1] Q3 2018	
DPP Dengue NS1 (International)	Fiocruz	✓	✓	Ongoing		
DPP Zika (US/International)	Fiocruz	✓	✓	✓	✓	Received FDA EUA[2], ANVISA, CE mark
DPP Chikungunya (International)	Fiocruz	✓	✓	✓	✓	Received ANVISA, Malaysia
DPP Dengue-Zika-Chik (International)	Fiocruz	✓	✓	✓	Submitted ANVISA Q3 2018	Received Malaysia
DPP Malaria (International)	Bill & Melinda Gates Foundation	✓	✓	Ongoing		
DPP Ebola (US, International)	Centers for Disease Control	✓	✓	✓	Submitted FDA EUA Q1 2018	
DPP Fever Panel (Africa)	The Paul G. Allen Family Foundation	✓	✓	✓	Field Testing: Africa, South America	
DPP Fever Panel (Asia)	FIND	✓	Ongoing			

1 Agência Nacional de Vigilância Sanitária (Brazil)
2 Emergency Use Authorization

Source: Chembio 8-k 10.22.2018

Total Sales Up 24%, +8% qoq

Total sales, which includes license and grant revenue, were $9.4M, up 24% yoy and 8% sequentially. Approximately $300k of the $1.3M in R&D, milestone and grant revenue in Q3 relates to the initial $5.9M BARDA Zika grant. We estimate that ~$1.7M remains under the grant, which was awarded in August 2016. As a reminder, the grant relates to the development of a DPP Zika assay and subsequent EUA, 510(k) FDA clearance and eventual CLIA waiver. To-date, the assay has received FDA EUA (as of 9/27/17), in addition to CE Mark and approval from Brazilian regulators (ANVISA). Upon successful completion of the DPP Zika grant, CEMI may be eligible to receive a follow-on $7.3M grant related to the development Zika/Dengue/Chikungunya Combination Assay (a similar assay was submitted for ANVISA approval in Q3'18).

CEMI has made very rapid progress on their $2.9M (total) product development agreement with AstraZeneca. On the Q2 call in August, management noted that assay development had completed and validation and verification was ongoing. Just three months later, the initial regulatory approval application had been made. On the Q3 call in November CEMI disclosed that an application for CE Mark had been filed and that they now have their eyes set on FDA 510(k) clearance. As CE Marking is typically a relatively expedited process, it is possible this test could be cleared for sale in Europe (and other parts of the world that accept CE Mark) by current year-end or shortly afterwards. At that point, we'll know exactly what the biomarker is that the assay tests for – and a better idea of the potential market opportunity for the product. As we hypothesized in prior updates, 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.

Collaborations

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification & Validation	Phase IV Clinical/ Regulatory	Phase V Commercial Launch
DPP Undisclosed Biomarker	AstraZeneca	✓	✓	Ongoing		
DPP Cancer	Undisclosed	✓	✓	Ongoing		
Infectious Disease Portfolio	lumiraDx	Initiated Q3 2018				
DPP Concussion	Perseus Science	✓	Ongoing			
DPP Bovine Tuberculosis	USDA	✓	Ongoing			
DPP Hepatitis C Ab	FIND	✓	Ongoing			
DPP Hepatitis C Ag	FIND	Initiated Q3 2018				

Source: Chembio 8-k 10.22.2018

CEMI continues to draw outside interest for their expertise, technology and proven success in bringing high-potential diagnostics through the regulatory process(es) and to commercialization. The most recent collaboration came in July 2018 when CEMI announced an agreement with FIND for the potential development of a rapid HCV test (CEMI and FIND already have an ongoing collaboration for a DPP fever panel). CEMI is one of three companies that FIND chose to participate in their HCV RFP – the test selected for development will be announced in December. This could be a win for CEMI – and represent incremental revenue that otherwise may have never materialized. That's because CEMI has had a DPP HCV program in the past – but that was essentially mothballed way back in 2011 (based on our notes, the program was halted based on questions of economic feasibility of rapid HCV testing). So, if CEMI's DPP HCV test is chosen to move forward with FIND, it could eventually result in a new source of revenue (that may not have happened otherwise). Also, if successful, we think it might also potentially lead to development of a combination HCV test, such as HIV/HCV.

CEMI also recently penned a collaboration agreement with LumiraDx, a privately-held UK organization with a focus on diagnostics – and founded by executives from major diagnostics companies (including Alere). LumiraDx chose CEMI to help them develop POC infectious disease assays. CEMI will receive milestone-based funding and upon commercialization, will sell reagents to LumiraDx as well as receive a royalty on sales.

Given limited disclosures as to specifics of the tests under development related to these collaborations, it is difficult to handicap the probability of 'success' (in terms of both product development and commercialization) or potential contribution to CEMI. But, our model will be updated accordingly as CEMI provides future updates. Until then, we think investors should view these as representing option-like value – with potential upside (potentially significantly so, although tough to estimate right now) and effectively no downside. We should know fairly soon about the AZN test.

Margin

Product and gross margin were 14% and 28% in Q3, compared to 34% and 46% in the prior-year period. Through the first nine months of the year, product and gross margin were 20% and 35%, compared to 34% and 47% in the prior year. YTD product and gross margins were negatively impacted by a greater mix of sales to markets with lower selling prices - which, generally, refers to international tenders – and more specifically, likely means the Ethiopian tender was a significant contributor to depressed for the last two consecutive quarters. For context, product and gross margins over the three prior years were 37%/43% (2015), 31%/47% (2016) and 33%/46% (2017).

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, some of the more significant influences may be recognition of the remainder of the Ethiopian HIV STAT-PAK tender (i.e. big, relatively low-margin) and automated and expanded manufacturing (including in NY and Malaysia-based manufacturing). We also expect the opTricon acquisition – which means CEMI now owns the proprietary quant reader – will benefit gross margins as they no longer pay mark-up on the devices. Interestingly, these readers may also generate revenue for CEMI as disclosures suggest there is an active market (beyond CEMI themselves) for these products.

As it relates automating the New York-based manufacturing, CEMI took delivery of their initial automated production line in the summer and, as of the Q3 call, expects to go live with that line before current year-end. This equipment, which will provide for the first (of an expected more to come) tranche of moving from manual to automated production, will be used for the DPP assays manufacture. Indications are that CEMI will continue to bring more of its manufacturing under automated processes – which should further reduce COGS, benefit margins and expand overall manufacturing capacity. Next-up, per comments on the call, is to automate the lateral flow products – including SureCheck, which is sold in the U.S. and Europe (the latter for self-testing) and STAT-PAK, which is sold in Africa. Management anticipates that the related equipment will be delivered in 1H'19 and, following validation, the automated lines will be up and running later that same year.

Meanwhile, CEMI anticipates site inspection of their Malaysian production facility in December. If all goes well, manufacturing will begin there next year and bring down production and shipping costs of certain tests sold overseas.

CEMI's fully-automated DPP manufacturing line



Source: Chembio Nov 2018 investor presentation

Operational update:
CEMI continues to secure high-revenue product orders and international tenders. Over just the last 18 months Bio-Manguinhos, alone, has committed to purchasing nearly $25M worth of product (for DPP HIV and DPP Leishmania). The latest came in October 2018 – a $10.5M commitment from Bio-Manguinhos for DPP HIV and DPP Leishmania test components and related product. All of this is expected to be recognized as revenue in 2019.

These Bio-Manguinhos purchase commitments and $15.8M Ethiopian STAT-PAK contract were two of several recent highlights on the operational front that will make significant contributions through the rest of 2018 (and, in the case of the Ethiopian tender, into 2019 and 2020). And, given Bio-Manguinos' long history as a customer of CEMIs and their recent purchase volume, we think it is not unlikely that they may continue purchase beyond the current agreements.

In terms of regulatory-related activities, FDA decision on the DPP HIV/Syphilis PMA filing is one of the most anticipated, as is OUS (country-by-country) 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 (well-aimed and placed) shots on goal, the recent deal with AstraZeneca may represent the first of future similar development/commercialization collaborations.

STD Portfolio:

DPP HIV/Syph: Could launch in the U.S by 1H'19. 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.

For some context and back-of-the-envelope math on the U.S. DPP HIV/Syph opportunity….. while CEMI has never disclosed revenue per product per country, they did mention in 2015 that sales of DPP HIV/Syph in Mexico fell by $3.5M. U.S. has about 3x the number of annual HIV infections (and is about 2.5x the total population) as Mexico. So, if we assume (perhaps conservatively) that peak annual sales of DPP HIV/Syph in Mexico were $3.5M, then (proportionally) the U.S. could represent a $10M per year market for the product. CEMI's U.S. sales in 2016 were about $4M, most of which we think relates to their lateral flow HIV products. But, if we assume that DPP HIV/Syph cannabilizes 100% of CEMI's U.S. demand (which we think is unreasonably conservative), this product represents incremental revenue (of a minimum) of $6M per year. In addition, given that DPP HIV/Syph would be first HIV/Syph rapid test on the market, we think it is also highly conservative to assume (as this back-of-the-envelope calculation does) that DPP HIV/Syph does not take additional competitors' share of the HIV rapid testing market.

CEMI appears to already be preparing for launch, noting earlier in 2018 that they contracted with MTMC to facilitate U.S. commercialization of their infectious disease portfolio. CEMI's direct sales team will continue to focus on the public market while MTMC will detail to the private segment – such as physician offices, hospitals and private clinics. MTMC has direct experience in selling HIV diagnostics to this segment and, per CEMI, has strong relationships with Chembio distributors.

Hepatitis C could be another opportunity now with the FIND collaboration (July 2018). The goal is for the development of a rapid HCV test (CEMI and FIND already have an ongoing collaboration for a DPP fever panel). This could be a win for CEMI – and represent incremental revenue that otherwise may have never materialized. Also, if successful, we think it might also potentially lead to development of a combination HCV test, such as HIV/HCV.

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). Over just the past 18 months Bio-Manguinhos signed purchase commitments worth almost $25M. This includes a $5.8M contract in May 2017 related to DPP HIV test components (filled in 2017), $8.5M commitment singed in December 2017 for the purchase of $8.5M worth of DPP HIV and DPP Leishmania intermediate product and test components (for 2018) and $10.5 commitment for the purchase of DPP HIV and DPP Leishmania intermediate product and test components during 2019. This is in addition to an long-term agreement signed in May 2018 for commercialization (in Brazil) of DPP Dengue, Zika and Chikungunya tests.

Lateral flow: $4.3M of revenue of the $15.8M Ethiopian contract is expected to be recognized during 2018. 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.

Africa could represent a growth opportunity as well. Africa, which has historically been a meaningful contributor to CEMI's product sales (accounting for ~17% in both 2015 and 2016 and 36% in 2017), could represent an even greater opportunity going forward given WHO's initiatives focused on ending HIV/AIDS through increasing availability of HIV testing. With a stated goal of diagnosing 90% (an estimated 30% of people with AIDS do not know they have it) of people living with AIDS by the year 2020, WHO's is pushing HIV self-testing to make that happen. WHO's initiatives, per some estimates, could more than triple current demand for HIV self-testing from the nine 'high burden countries in Africa (i.e. those that represent ~50% of people with HIV). Lower-cost manufacturing, via CEMI's Malaysian facility, could be key to driving this opportunity. Also telling of CEMI's focus on winning more HIV self-testing (and international tenders as a whole) business is the recent hire of a new VP of corporate development – Dr. Christine Rousseau has extensive prior experience at the Bill & Melinda Gates Foundation and will be focused on the company's infectious disease initiatives (including HIV self-testing).

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 (which received ANVISA approval in August 2018) 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 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 ongoing. 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. The evaluation will take place via an independent lab. CEMI also responded to a 2nd UNICEF RFP.

DPP Zika also 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. Expect roll-out to broaden. The next step 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.

DPP Ebola: while not much of a market for the test as of today, with recent FDA EUA, it could draw demand in case of future domestic Ebola scares.

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.

CEMI has indicated that they will continue with what has worked – including additional layering of their US sales capabilities. MTMC could generate needle-moving contribution, particularly once DPP HIV/Syph launches. Other recent “wins” relative to regaining control of their destiny include the addition of Dr. Christine Rousseau, resurgence of U.S. lateral flow sales, OTC HIV segment growth, new Bio-Manguinhos contracts and commercialization

agreements, acquiring RVR (providing direct commercial and manufacturing access to large SE Asia markets), the large Ethiopian tender, AstraZeneca development collaboration, acquiring OpTricon and more.

As it relates specifically to opTricon, the acquisition not only offers margin enhancement on the readers, but also provides a tangible European base of operations (the facility will act as CEMI's European HQ) and offers more flexibility in product development and potentially as well in partnering and collaboration arrangements.

The outside collaborations are just the latest iteration of CEMI building their business from the inside, out. AZN was the first of what could be many deals to follow. LumiraDx came to CEMI not just for their technology but also their expertise and success in developing high-potential products and bringing them through regulatory (FDA as well as a host of other countries) and to commercialization. Expect this could be a resume builder and attract additional attention.

Revenue
We now look for 2018 revenue of $32.5M, implying growth of 36% from 2017. We have product sales growing 38%. Going into 2019, DPP HIV/Syphilis could make an initial contribution (assuming FDA approval). Africa and Asia have begun to make much significant contributions – which we think continue to grow.

Given the limited disclosures relative to AZN and LumiraDx collaborations and front-end nature of the HCV FIND agreement, it is currently difficult to handicap the probability of 'success' (in terms of both product development and commercialization) or potential contribution to CEMI. DPP Cancer could also hold tremendous potential but is not at a point where we think it can be reasonably modeled. We also do not yet model any assumed future outside collaborations or acquisitions. Our model will be updated accordingly as CEMI provides future updates. Until then, we think investors should view these as representing option-like value – with potential upside (potentially significantly so, although tough to estimate right now) and effectively no downside.

VALUATION
OSUR trades at 4.6x consensus 2018 sales and 4.2x consensus 2019 sales. Based on our estimated CEMI 2018 revenue of $32.5M and 2019 revenue of $40.0M, **CEMI is valued at approximately $9.50/share.** This is adjusted downward from $13.75 – the change is a combination of contracting sales multiples, some slight downward adjustments and higher share count.

FINANCIAL STATEMENTS

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2016 A	Q1A	Q2A	Q3A	Q4A	2017 A	Q1A	Q2A	Q3A	Q4E	2018 E	2019 E	2020 E
Product sales	$13,679	$5,427	$2,893	$6,133	$4,869	$19,322	$6,398	$6,858	$7,856	$5,542	$26,654	$37,019	$45,158
% of total revenue	76.6%	85.8%	70.3%	80.8%	81.3%	80.5%	82.9%	78.6%	83.8%	82.3%	81.9%	92.5%	93.3%
YOY Growth	-37.5%	-8.3%	42.2%	145.1%	50.9%	41.3%	17.9%	137.1%	28.1%	13.8%	37.9%	38.9%	22.0%
License & royalty income	$450	$100	$228	$150	$264	$742	$202	$277	$229	$261	$968	$984	$1,097
% of product sales	3.3%	1.8%	7.9%	2.4%	5.4%	3.8%	3.2%	4.0%	2.4%	3.9%	3.0%	2.5%	2.3%
R&D contracts, grants, milestones	$3,739	$798	$994	$1,305	$855	$3,952	$1,117	$1,586	$1,292	$932	$4,927	$2,023	$2,125
% of total revenue	20.9%	12.6%	24.2%	17.2%	14.3%	16.5%	14.5%	18.2%	13.8%	13.8%	15.1%	5.1%	4.4%
Total Revenues	$17,869	$6,325	$4,115	$7,587	$5,988	$24,015	$7,717	$8,720	$9,377	$6,735	$32,549	$40,026	$48,379
YOY Growth	-26.3%	-4.2%	26.0%	102.5%	40.7%	34.4%	22.0%	111.9%	23.6%	12.5%	35.5%	23.0%	20.9%
Cost of Revenues	$9,418	$3,219	$2,204	$4,065	$3,433	$12,921	$4,118	$5,935	$6,775	$4,766	$21,594	$26,728	$27,230
Gross Income	$8,451	$3,106	$1,911	$3,523	$2,555	$11,094	$3,599	$2,785	$2,602	$1,969	$10,955	$13,298	$21,149
Gross Margin	47.3%	49.1%	46.4%	46.4%	42.7%	46.2%	46.6%	31.9%	27.7%	29.2%	33.7%	33.2%	43.7%
Product Margin	31.2%	40.7%	23.8%	33.7%	29.5%	33.1%	35.6%	13.5%	13.8%	14.0%	19.0%	27.8%	39.7%
Research & Development	$8,428	$2,247	$1,982	$1,806	$2,521	$8,555	$1,847	$1,991	$1,898	$1,948	$7,684	$7,877	$8,655
% R&D	47.2%	35.5%	48.2%	23.8%	42.1%	35.6%	23.9%	22.8%	20.2%	28.9%	23.6%	19.7%	17.9%
Selling General & Admin	$7,596	$2,488	$2,109	$2,305	$2,118	$9,021	$2,407	$2,547	$3,034	$3,011	$10,998	$11,367	$12,937
% SG&A	42.5%	39.3%	51.3%	30.4%	35.4%	37.6%	31.2%	29.2%	32.4%	44.7%	33.8%	28.4%	26.7%
Operating Income	($7,572)	($1,629)	($2,181)	($589)	($2,084)	($6,483)	($654)	($1,754)	($2,330)	($2,990)	($7,728)	($5,946)	($442)
Operating Margin	-42.4%	-25.8%	-53.0%	-7.8%	-34.8%	-27.0%	-8.5%	-20.1%	-24.8%	-44.4%	-23.7%	-14.9%	-0.9%
Other income (expense)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	
Interest income, net	$26	$13	$8	$4	($2)	$22	$2	$25	$16	$26	$69	$35	$11
Pre-Tax Income	($7,546)	($1,616)	($2,173)	($585)	($2,087)	($6,460)	($652)	($1,728)	($2,314)	($2,963)	($7,658)	($5,911)	($432)
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)	($652)	($1,728)	($2,314)	($2,963)	($7,658)	($5,911)	($432)
YOY Growth	456.8%	431.3%	-74.0%	-72.7%	-21.9%	-52.3%	-59.6%	-20.5%	295.8%	48.3%	20.2%	-22.8%	-92.7%
Net Margin	-74.7%	-25.5%	-52.8%	-7.7%	-33.4%	-26.5%	-8.5%	-19.8%	-24.7%	-44.0%	-23.5%	-14.8%	-0.9%
EPS	($1.26)	($0.13)	($0.18)	($0.05)	($0.16)	($0.52)	($0.05)	($0.12)	($0.16)	($0.18)	($0.53)	($0.34)	($0.02)
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-

Weighted Avg. Shares O/S	10,622	12,271	12,299	12,311	12,506	12,347	13,267	14,165	14,174	16,174	14,445	17,380	18,000

Brian Marckx, CFA

HISTORICAL STOCK PRICE



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