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Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: **Ethiopian Tender, Bio-Manguinhos Order Propel Q2 Product Sales. More Revenue Catalysts Emerge…**

OSUR trades at 5.4x consensus 2018 sales and 5.0x consensus 2019 sales. Based on our estimated CEMI 2018 revenue of $33.5M and 2019 revenue of $42.4M, CEMI is valued at approximately $13.75/share.

Current Price (08/20/18)	$11.15
Valuation	**$13.75**

OUTLOOK

Product sales remain very strong, up 137% yoy and +7% from Q1 and bolstered by the recent Ethiopian tender and Bio-Manguinhos order. Approximately $2.9M remains under the Bio-Manguinhos order, all of which is expected to be booked as revenue in 2H '18. Meanwhile, another $2.8M of the Ethiopian tender should be recognized through the end of the current year and the remaining $11.5M in 2019 and 2020. In addition to the opportunities in Asia and recognition of the remainder of the Ethiopian tender and Bio-Manguinhos order, there are other catalysts that could further benefit near-term revenue growth including initial sales through the newly penned commercialization agreement with Bio-Manguinhos (for Zika, Dengue and Chikungunya), FDA approval of DPP HIV/Syphilis, ramping U.S. infectious disease sales efforts (including bringing on MTMC to detail to U.S. private segment), launch/roll-out of fever assays (potentially including Dengue and Malaria), additional tenders (initial UNICEF Zika could be worth up to $4.9M), 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). And while maybe not a near-term catalyst, a program that could potentially hold tremendous upside value is CEMI's cancer diagnostic.

SUMMARY DATA

52-Week High	**$9.20**
52-Week Low	**$5.70**
One-Year Return (%)	**19.85**
Beta	**1.21**
Average Daily Volume (sh)	**28,896**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$122**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**32**
Insider Ownership (%)	**5**
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	**Below Avg.,**
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	$7.72 A	$8.72 A	$7.70 E	$8.39 E	$32.53 E
2019					$42.35 E
2020					$49.95 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	-$0.15 E	-$0.12 E	-$0.44 E
2019					-$0.12 E
2020					$0.09 E

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

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Q2 2018: *Ethiopian Tender, Bio-Manguinhos Order Propel Product Sales. More Revenue Catalysts Emerge…*

For the second consecutive quarter we significantly underestimated product sales growth, missing Q1 and Q2 by an average of more than 18%. Most of our $1.2M miss in Q2 was related to recognition of a greater than anticipated amount from the Bio-Manguinhos order ($3.2M A vs $2.5M E) and Ethiopian tender ($1.5M A vs. $1.1M E), coupled with stronger sales in Europe ($636k A vs $400k E) and partially offset by slightly lower than estimated U.S. sales.

Product sales remain very strong, up 137% yoy and +7% from Q1 and bolstered by both of these recent contract wins (i.e. $15.8M Ethiopian tender and $8.5M Bio-Manguinhos order). Approximately $2.9M remains under the Bio-Manguinhos order, all of which is expected to be booked as revenue in 2H '18. And with a new long-term agreement with Bio-Manguinhos signed in May for the commercialization (in Brazil) of the company's DPP Dengue, Zika and Chikungunya tests, revenue via their long-established partner should continue for the foreseeable future. Both the DPP Zika and Chikungunya tests have received ANVISA approval. Meanwhile, another $2.8M of the Ethiopian tender should be recognized through the end of the current year and the remaining $11.5M in 2019/2020.

And while product sales by technology (i.e. DPP vs lateral flow) were not disclosed, based on the geographical break-out, it looks like lateral flow HIV self-testing likely remains a material contributor – which we suspect was the reason for European sales coming in relatively strong (and may have also contributed to the strength in Africa). As a reminder, HIV self-testing related sales have only recently been a material growth catalyst for CEMI – and likely also contributed to the relatively strong Africa revenue in Q1.

Chembio clearly views HIV self-testing as holding additional growth potential and has made additional preparations to leverage the opportunity. Recently expanded manufacturing significantly increases capacity and also has the benefit of bringing down unit costs – potentially key for cost-competitive emerging market tenders. 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).

Product Sales Up 137% yoy, 7% qoq

Q2 product sales were $6.9M, up 137% yoy, up 7% sequentially and 21% higher (~$1.2M) than our $5.7M estimate. Sales in both Latin America ($3.3M +216% yoy, +21% qoq) and Africa ($2.2M, +351% yoy, +36% qoq) were extraordinarily strong and benefitted from the Bio-Manguinhos and Ethiopian tenders, respectively.

And while Asia revenue was immaterial ($22k) in Q2, we think this territory may soon return to being a significant contributor to revenue. As a reminder, CEMI booked $1.4M of product sales in Asia in Q1 '17 – all of which was related to DPP Dengue. With fever assay product registrations, including Dengue (which just received regulatory approval in Brazil), expected to happen on a regular basis and the impending opening of CEMI's Malaysian manufacturing operation, Asia looks to be a near and long-term growth catalyst. Manufacturing from their Malaysian operation is important in not only adding capacity and having production closer to end-markets, but also in getting manufacturing costs down – beneficial not only for margins but also potentially key to win large tenders (e.g. WHO cites lower costs as important in driving HIV self-testing adoption).

In addition to the opportunities in Asia and recognition of the remainder of the Ethiopian tender and Bio-Manguinhos order, there are other catalysts that could further benefit near-term revenue growth. These includes initial sales through the newly penned commercialization agreement with Bio-Manguinhos (for Zika, Dengue and Chikungunya), FDA approval of DPP HIV/Syphilis, ramping U.S. infectious disease sales efforts (including bringing on MTMC to detail to U.S. private segment), launch/roll-out of fever assays (potentially including Dengue and Malaria), 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).

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 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.

Total Sales Up +112% yoy, +13% qoq
Total sales, which includes license and grant revenue, were $8.7M. up 112% yoy and 13% sequentially. Approximately $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, CEMI is making progress on their $2.9M (total) product development agreement with AstraZeneca, noting on the Q2 call that that they have completed assay development, are now conducting validation and verification activities and, if all goes to plan anticipate being ready to file for 510(k) clearance and CE Mark by the end of Q2 2019.

As a reminder, the deal with AZN (announced Dec 2017) 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 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.

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 the front-end nature of these collaborations, it is currently 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.

Margin
Product and gross margin were 14% and 32% in Q2, compared to 24% and 46% in the prior-year period. Through the first half of the year, product and gross margin were 25% and 39%, compared to 32% and 48% 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 pressured PM in Q2. For context, product and gross margins over the three prior years were 37%/43% (2015), 31%/47% (2016) and 33%/46%.

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 recognition of the remainder of the Ethiopian HIV STAT-PAK tender (i.e. big, relatively low-margin) and expanded manufacturing capacity (including in NY and Malaysia-based manufacturing). Approximately $2.8M of the former is expected to be recognized in 2H '18 (and the remaining $11.5M in 2019/2020) while ribbon-cutting on the latter may happen later this year through early next (commencement of Malaysian manufacturing will first require WHO pre-qualification, an application for which has been submitted). We also think increasing U.S. sales should benefit margin – and believe DPP HIV/Syphilis, PMA application for which was filed in Q1 2018, could prove to be one of the company's most successful products.

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 significant contributions through the rest of 2018 (and, in the case of the Ethiopian tender, into 2019 and 2020). 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. 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 (and 2nd RFP)
- AstraZeneca collaboration for development, regulatory submission of quantitative assay
- LumiraDx collaboration for development, commercial support of POC infectious disease assays
- FIND HCV feasibility program (decision if DPP HCV is chosen by December 2018)
- MOU (May 2018) with Mass. General for joint development of POC fever test
- $8.5M commitment from Bio-Manguinhos to purchase DPP HIV and DPP Leishmania intermediate product and test components during 2018
- New (May 2018) long-term agreement with Bio-Manguinhos for commercialization (in Brazil) of DPP Dengue, Zika and Chikungunya tests
- 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 Zika demand from State Health Depts
- 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
- Contracting with MTMC to sell infectious disease assays to private health segment
- 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 (ANVISA) received in Brazil
- DPP Chikungunya ANVISA approval
- DPP Fever panels development progress on both
- DPP Cancer development completed with "excellent analytical performance". Now in validation
- Progress on DPP Bovine TB. 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.

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 on the Q1 call (May 2018) that they just 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.

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. That was then followed in May 2018 by a long-term agreement with Bio-Manguinhos for commercialization (in Brazil) of DPP Dengue, Zika and Chikungunya tests.

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 $4.3M (ind $1.5M recognized in Q2) revenue of the $15.8M Ethiopian contract 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.

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 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. The evaluation will take place via an independent lab. CEMI also responded to a 2nd UNICEF RFP.

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. Expect roll-out to broaden. 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.

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 and more. 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 $33.5M, implying growth of 35% from 2017. We have product sales growing 39% 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. Africa and Asia have begun to make much significant contributions – which we think continue to grow.

Given the front-end nature of the AZN and LumiraDx collaborations and 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. 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.

VALUATION

OSUR trades at 5.4x consensus 2018 sales and 5.0x consensus 2019 sales. Based on our estimated CEMI 2018 revenue of $33.5M and 2019 revenue of $42.4M, **CEMI is valued at approximately $13.75/share.**

FINANCIAL STATEMENTS

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2016 A	Q1A	Q2A	Q3A	Q4A	2017 A	Q1A	Q2A	Q3E	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**	**$6,580**	**$6,958**	**$26,794**	**$39,158**	**$46,732**
% of total revenue	*76.6%*	*85.8%*	*70.3%*	*80.8%*	*81.3%*	*80.5%*	*82.9%*	*78.6%*	*85.5%*	*82.9%*	*82.4%*	*92.5%*	*93.6%*
YOY Growth	*-37.5%*	*-8.3%*	*42.2%*	*145.1%*	*50.9%*	*41.3%*	*17.9%*	*137.1%*	*7.3%*	*42.9%*	*38.7%*	*46.1%*	*19.3%*
License & royalty income	**$450**	**$100**	**$228**	**$150**	**$264**	**$742**	**$202**	**$277**	**$241**	**$290**	**$1,009**	**$968**	**$1,097**
% of product sales	*3.3%*	*1.8%*	*7.9%*	*2.4%*	*5.4%*	*3.8%*	*3.2%*	*4.0%*	*3.1%*	*3.5%*	*3.1%*	*2.3%*	*2.2%*
R&D contracts, grants, milestones	**$3,739**	**$798**	**$994**	**$1,305**	**$855**	**$3,952**	**$1,117**	**$1,586**	**$878**	**$1,144**	**$4,725**	**$2,225**	**$2,125**
% of total revenue	*20.9%*	*12.6%*	*24.2%*	*17.2%*	*14.3%*	*16.5%*	*14.5%*	*18.2%*	*11.4%*	*13.6%*	*14.5%*	*5.3%*	*4.3%*
Total Revenues	$17,869	$6,325	$4,115	$7,587	$5,988	$24,015	$7,717	$8,720	$7,699	$8,392	$32,528	$42,351	$49,954
YOY Growth	*-26.3%*	*-4.2%*	*26.0%*	*102.5%*	*40.7%*	*34.4%*	*22.0%*	*111.9%*	*1.5%*	*40.1%*	*35.4%*	*30.2%*	*18.0%*
Cost of Revenues	$9,418	$3,219	$2,204	$4,065	$3,433	$12,921	$4,118	$5,935	$5,100	$5,281	$20,434	$24,513	$27,245
Gross Income	$8,451	$3,106	$1,911	$3,523	$2,555	$11,094	$3,599	$2,785	$2,600	$3,111	$12,095	$17,838	$22,709
Gross Margin	*47.3%*	*49.1%*	*46.4%*	*46.4%*	*42.7%*	*46.2%*	*46.6%*	*31.9%*	*33.8%*	*37.1%*	*37.2%*	*42.1%*	*45.5%*
Product Margin	*31.2%*	*40.7%*	*23.8%*	*33.7%*	*29.5%*	*33.1%*	*35.6%*	*13.5%*	*22.5%*	*24.1%*	*23.7%*	*37.4%*	*41.7%*
Research & Development	$8,428	$2,247	$1,982	$1,806	$2,521	$8,555	$1,847	$1,991	$1,942	$2,104	$7,885	$8,341	$8,789
% R&D	*47.2%*	*35.5%*	*48.2%*	*23.8%*	*42.1%*	*35.6%*	*23.9%*	*22.8%*	*25.2%*	*25.1%*	*24.2%*	*19.7%*	*17.6%*
Selling General & Admin	$7,596	$2,488	$2,109	$2,305	$2,118	$9,021	$2,407	$2,547	$2,725	$2,660	$10,339	$11,223	$12,488
% SG&A	*42.5%*	*39.3%*	*51.3%*	*30.4%*	*35.4%*	*37.6%*	*31.2%*	*29.2%*	*35.4%*	*31.7%*	*31.8%*	*26.5%*	*25.0%*
Operating Income	($7,572)	($1,629)	($2,181)	($589)	($2,084)	($6,483)	($654)	($1,754)	($2,068)	($1,653)	($6,129)	($1,726)	$1,431
Operating Margin	*-42.4%*	*-25.8%*	*-53.0%*	*-7.8%*	*-34.8%*	*-27.0%*	*-8.5%*	*-20.1%*	*-26.9%*	*-19.7%*	*-18.8%*	*-4.1%*	*2.9%*
Other income (expense)	$0	$0	$0	$0	$0	$0					$0	$0	
Interest income, net	$26	$13	$8	$4	($2)	$22	$2	$25	$9	$8	$43	($14)	($20)
Pre-Tax Income	($7,546)	($1,616)	($2,173)	($585)	($2,087)	($6,460)	($652)	($1,728)	($2,059)	($1,646)	($6,086)	($1,740)	$1,411
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)	($2,059)	($1,646)	($6,086)	($1,740)	$1,411
YOY Growth	*456.8%*	*431.3%*	*-74.0%*	*-72.7%*	*-21.9%*	*-52.3%*	*-59.6%*	*-20.5%*	*252.2%*	*-17.6%*	*-4.5%*	*-71.4%*	*-181.1%*
Net Margin	*-74.7%*	*-25.5%*	*-52.8%*	*-7.7%*	*-33.4%*	*-26.5%*	*-8.5%*	*-19.8%*	*-26.7%*	*-19.6%*	*-18.7%*	*-4.1%*	*2.8%*
EPS	($1.26)	($0.13)	($0.18)	($0.05)	($0.16)	($0.52)	($0.05)	($0.12)	($0.15)	($0.12)	($0.44)	($0.12)	$0.09
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted Avg. Shares O/S	10,622	12,271	12,299	12,311	12,506	12,347	13,267	14,165	14,170	14,170	13,943	14,400	15,000

Brian Marckx, CFA

HISTORICAL STOCK PRICE



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