Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: Product Sales Off To Strong Start, And Should Steepen From Here

OSUR trades at 5.3x consensus 2018 sales and 4.8x consensus 2019 sales. Based on our estimated CEMI 2018 revenue of $33.0M and 2019 revenue of $43.5M, CEMI is valued at approximately $13.5/share.

Current Price (05/11/18) $8.60
Valuation $13.50

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 |

OUTLOOK

As we indicated in our Q4 ‘17 update (March 13, 2018: Recent Wins Mean 2018 Could Set Product Sales Record), given significant progress in development of the product pipeline (including U.S. DPP HIV/Syphilis and several fever-related assays), proven success of the recently expanded (and clearly, very capable) sales team, new large contract wins (i.e. $15.8M Ethiopian tender and $8.5M Bio-Manguinhos order) and recently penned collaboration with AstraZeneca (for development of a biomarker assay) that 2018 was primed to be another strong year for CEMI. We, however, did not expect 2018 to start out nearly as strong as Q1 results show that it has. And as we have also indicated recently, we expect revenue to continue to climb into 2019 on the back of several catalysts in addition to recognition of more of the Ethiopian order, 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 (UNICEF Zika alone could be worth up to $4.9M) increasing demand for HIV self-testing and potential meaningful contribution from collaboration agreements (such as with AZN and LumiraDX) could all be significant revenue drivers.

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Zacks Projected EPS Growth Rate - Next 5 Years % NA
WHAT'S NEW

Q1 2018: Product Sales Off To Strong Start, And Should Steepen From Here...

As we indicated in our Q4 ’17 update (March 13, 2018: Recent Wins Mean 2018 Could Set Product Sales Record), given significant progress in development of the product pipeline (including U.S. DPP HIV/Syphilis and several fever-related assays), proven success of the recently expanded (and clearly, very capable) sales team, new large contract wins (i.e. $15.8M Ethiopian tender and $8.5M Bio-Manguinhos order) and recently penned collaboration with AstraZeneca (for development of a biomarker assay) that 2018 was primed to be another strong year for CEMI. We, however, did not expect 2018 to start out nearly as strong as Q1 results show that it has.

And while product sales were the highest since Q4 ‘14’, they did not benefit from any of the $15.8M Ethiopian tender (~$4M of which is expected to be recognized throughout the remainder of 2018). In addition to ~$6M of the Bio-Manguinhos order that remains outstanding (and which is also expected to be booked during 2018) just these two new contracts represent approximately $800k (on average) of incremental (vs. Q1 ‘18) product revenue in the remaining three quarters of 2018.

And as we have also indicated recently, we expect revenue to continue to climb into 2019 on the back of several catalysts – in addition to recognition of more of the Ethiopian order, 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 (UNICEF Zika alone could be worth up to $4.9M) increasing demand for HIV self-testing and potential meaningful contribution from collaboration agreements (such as with AZN and LumiraDX) could all be significant revenue drivers.

Product Sales Up 18% yoy, 31% qoq

Q1 product sales were $6.4M, up 18%, up 31% sequentially and 24% higher than our $5.2M estimate. As CEMI no longer itemizes revenue in their filings by product technology, it is a little but more difficult to parse pieces and compare to our estimates. However, it is clear that both Africa and Asia were relatively very strong and the major catalysts to product sales growth.

Africa product sales were $1.6M in Q1, up 344% yoy (vs $369k) and down 6% (vs $1.7M) from Q4 ‘17. Asia product sales were $968k, while down 32% (vs $1.4M), this is up more than 4,000% (vs $23k) from Q4 ‘17. Africa sales, we think, continue to benefit from growing demand for HIV self-testing (and CEMI’s lateral flow products).

Meanwhile, CEMI’s Asia-related product sales may being seeing additional ordering of DPP Dengue – which was responsible for just about the entire $1.4M of product revenue booked from Asia in Q1 ’17. With fever assay product registrations, including Dengue, 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).

Total Sales Up 22% yoy, up 29% sequentially

Total sales, which includes license and grant revenue, were $7.7M up 22% yoy and 29% sequentially. Approximately $2.8M 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 that they have completed the phase 1 milestone and that they are on track to complete assay development and file for 510(k) clearance and CE Mark in 1H 2019.

As a reminder, the deal with AZN 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. As we have noted in the recent past, just their successes with their fever portfolio is a testament to their abilities. LumiraDx, a privately-held UK
organization with a focus on diagnostics – and founded by executives from major diagnostics companies (including Alere) – was the latest to come knocking on CEMI’s door. 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 both the AZN and LumiraDx 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 margin was 35.6% in Q1. Gross margin was 46.6%. For context, product and gross margins over the three prior years were 37.1%/43.2% (2015), 31.2%/47.3% (2016) and 33.1%/46.2%. 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.

**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 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
- LumiraDx collaboration for development, commercial support of POC infectious disease assays
- $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 Zika demand from State Health Depts (CA, TX so far, more could come)
- 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 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.

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 cannibalizes 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 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 – the Ethiopian contract may be the first of more large tender wins to come. $2.5M of this was recognized in Q1 '18, the remainder is expected to be booked in Q2 through Q4 '18.

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.

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.

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. The evaluation will take place via an independent lab.

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. On the Q1 ’18 call management noted that the state health departments of California and Texas have already begun purchasing of their DPP Zika assay. Expect that more could come online soon. 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 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. 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 $33.0M, implying growth of 38% from 2017. We have product sales growing 45% 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 both the AZN and LumiraDx 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.

**VALUATION**
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## Chembio Diagnostics, Inc.

### INCOME STATEMENT

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