Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: New Strategy Paying Dividends As Product Sales Bounce Back

We look for 2017 revenue of $22.4M. We use OSUR as a comp for valuation purposes. Given expected outsized growth in fever we value CEMI at 6.5x P/S, a slight premium to OSUR (6.0x), or ~$12/share.

Current Price (05/17/17)	$6.50
Valuation	**$12.00**

OUTLOOK

Recent "wins" relative to regaining control of their destiny include the resurgence of U.S. lateral flow sales, meaningful European sales, the recent $5.8M FIOCRUZ order, quickly closing on the RVR acquisition and generating $1.4M in DPP Dengue sales - this is a product was approved and launched in relatively short order and could end up being tremendously successful.
The recent Isla Lab distribution partnership is also with this 'control-your-own-destiny' strategy as is layering in more high potential products for sale in high potential territories. The FIND-related fever panel which could be a perfect fit for RVR is a good example of this. So, now with U.S. lateral flow business back in CEMI's court and the assemblage of international sales and manufacturing infrastructure the pieces seem to be falling in place. Q1 was the first real evidence that management's strategy does appear to have legs. This, coupled with the very rapid growth of their fever portfolio presents potentially significantly greater opportunity than what had been the case less than two years ago.

SUMMARY DATA

52-Week High	**$9.40**
52-Week Low	**$5.05**
One-Year Return (%)	**0.53**
Beta	**0.76**
Average Daily Volume (sh)	**25,385**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$80**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**33**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**0.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Average,**
Type of Stock	**Small-Growth**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(millions)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	$6.60 A	$3.27 A	$3.75 A	$4.25 A	$17.87 A
2017	$6.33 A	$5.02 E	$5.49 E	$5.58 E	$22.41 E
2018					$29.82 E
2019					$36.95 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.03 A	-$0.25 A	-$0.19 A	-$0.21 A	-$0.71 A
2017	-$0.13 A	-$0.15 E	-$0.11 E	-$0.10 E	-$0.49 E
2018					$0.27 E
2019					$0.10 E

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

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WHAT'S NEW

Q1 2017: *Control-Your-Own-Destiny Strategy Paying Dividends As Product Sales Bounce Back…*

Chembio reported financial results for Q1 2017. There were several noteworthy items in both the financial results and in the operating update – almost all of which we would categorize as positive. Relative to the financials, this includes relatively strong product sales and product margin. Relative to the operating update, this includes a host of "wins" as it relates to the company's recently implemented strategy to gain more control over their destiny including indications that they are off to a strong start in that regard. Q1 is also the first period where CEMI disclosed itemized sales by region and by underlying technology (i.e. lateral flow vs. DPP) which should provide analysts and investors with a better picture of the relationship between strategic decision-making and product sales.

Product sales increased 68% sequentially to $5.4M – while that was down 8% yoy, the comparable prior-year period included a large (~$1.8M) stocking order from Alere, CEMI's prior exclusive U.S. distribution partner for their lateral flow products. That relationship ended in-full on May 31, 2016, since which Chembio has sold their U.S. products via a combination of a small direct sales force and hand-picked distributors (such as McKesson and Fisher).

Product sales have now increased for the last three consecutive quarters with Q1 clearly the beneficiary of management's deliberate efforts to both diversify their product menu and to gain substantially more control over sales/marketing/distribution. An obvious example is the $1.4M (~25% of total product sales) in DPP Dengue sales to Malaysia in Q1 via RVR which came in relatively short order considering development of this test began in late 2014 and CEMI closed on the RVR acquisition in January of this year. Other examples in Q1 are meaningful lateral flow sales in both the U.S. ($861k) and in Europe ($439k) – in fact, the level of sales in Europe was well ahead of what we had anticipated given the typically less robust demand for POC testing in that part of the world.

And product sales in future periods will also benefit from a large DPP order from FIOCRUZ and HIV-related tenders in the U.S. A $5.8M order to supply FIOCRUZ with test components to produce the DPP HIV assay for sale to Brazil's national health system was announced in early May. This is also telling of management's efforts as well as the quality of the DPP technology, particularly as CEMI had only recently lost out on a large tender (in 2016) to Brazil due to a competitor under-pricing. The order is expected to be fully realized throughout the remainder of 2017. As it relates to the U.S., there was a real question about what the post-Alere impact would be to domestic sales – the fact that U.S. sales in Q1 were more than respectable and CEMI recently won U.S. HIV tenders, which they noted should be realized over the next ~18 months, is highly encouraging.

DPP sales, at $2.2M were up 144% sequentially (from $910k), down 17% yoy (from $2.7M) and well ahead of our $1.5M estimate due to stronger than anticipated sales in Brazil. Brazil should continue to be the majority contributor to DPP sales in 2017 as a result of the aforementioned order from FIOCRUZ. And while DPP Zika has yet to launch in that country as approval for the Micro Reader from ANVISA still remains outstanding, eventual commercialization of that product in Brazil could be another meaningful contributor.

We could also see additional DPP Dengue sales via RVR (captured in "Other Product Sales" on the income statement) in 2017, although the large tender in Q1 is not expected to be indicative of a regular pattern. Nonetheless, 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. Clearly CEMI has already successfully leveraged RVR's manufacturing and distribution advantages in that part of the world and may soon be able to layer on additional products through that channel. In April they penned a collaboration agreement with FIND to develop (over the next 12 months) a DPP fever panel to simultaneously detect multiple diseases common to in the Asia Pacific region – the panel will include malaria, dengue, Zika, chikungunya, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi.

But while we were hoping DPP HIV/Syphilis, which has been a particularly successful product for CEMI, would soon enter the U.S. market, the timeline for potential approval likely has slipped. This was one of the few meaningful disappointments announced with Q1 results. While the study which was expected to support CEMI's FDA PMA filing completed, in March the agency requested that the company conduct additional clinical studies. Management indicated on the call that the data looks good and that they hope to have additional information regarding next steps and timing of an eventual regulatory filing in the near future. We had previously modeled launch of the test in the U.S. later this year but have since delayed that until 2018.

While likely delayed in the U.S., DPP HIV/Syphilis received CE Mark in Q1 – opening it up to Europe and the Caribbean (ex-Puerto Rico). DPP Zika is also CE Marked. CEMI recently entered an agreement with Isla Lab for distribution of their products in the Caribbean which could be key in exploiting this opportunity.

CEMI also recently submitted applications for approval of DPP Zika with; FDA for Emergency Use Authorization (EUA), WHO under EUA and Mexico's regulatory agency. Another factor that could work in CEMI's favor is that their DPP Zika test is the only rapid Zika test submitted to FDA under EUA and one of two submitted to WHO under EUA – and that pathway is now no longer available to enter. As such, upon approval, CEMI's DPP Zika test should have a fairly captive market. And Zika remains a major problem in the U.S. and is actually getting worse despite not getting nearly the headlines that it did last year. In fact a CDC report published earlier in 2017 found that there were more than 1,600 cases of Zika in the U.S. last year in pregnant women and the cases are not slowing down. As such, eventually commercialization of DPP Zika in the U.S. could be significant for Chembio.

Relative to lateral flow, Q1 sales of $1.6M were down 27% sequentially (from $2.3M) and down 47% yoy (from $3.1M. But that is not indicative of the fundamentals. As mentioned earlier, the prior year comparable period included a large stocking order from Alere. U.S. lateral flow sales started to again regain momentum in late 2016 – which we think is likely reflective of some of the sequential decrease as is relative softness in international lateral flow sales in the most recent quarter – international lateral flow has historical been volatile.

As indicated, we think U.S. lateral flow sales should remain significant through at least the remainder of 2017, particularly given the recent HIV tenders that CEMI won. As a reminder, CEMI noted on the Q4 call that they won two state contracts, which are expected to generate ~$2M of revenue through 2018.

Q1 gross margin and product margin were 49.1% and 40.7%, compared to 48.0% and 41.9% in the year-earlier comparable period and 41.2% and 22.5% in Q4 '16.

EPS
Q1 net loss and EPS were $1.6M and ($0.13), significantly better than our $2.3M and ($0.19) estimates. The upside to our numbers reflects sizeable beats on both gross margin and total revenue.

Cash
Cash used in operating activities was $3.9M in Q1 but excluding changes in working capital (including $2.3M increase in A/R), cash used in operating activities was $1.0M. Cash balance at quarter end was $5.6M. Management noted on the call that subsequent to Q1 quarter-end, they collected $2.8M in A/R.

Fever Portfolio Should Move Revenue Needle…
CEMI's pace in building its fever portfolio and related manufacturing and distribution capabilities is showing no signs of slowing. In addition to the BARDA grant, Isla Lab distribution agreement and RVR acquisition, CEMI made additional substantive progress towards exploiting the potential of their DPP fever portfolio.

This includes the first regulatory approvals for the DPP Zika test. In July 2016 DPP Zika and the DPP Micro Reader received CE Mark – opening it up to Europe and most Caribbean nations (excluding Puerto Rico and U.S. Virgin Islands). This test, along with DPP HIV/Syphilis, which was CE Marked in Q1 2017, could be meaningful contributors this year.

DPP Zika also received approval from Brazil's health regulatory agency (ANVISA) and in Q1 '17 CEMI received notice that the test and Micro Reader successfully passed evaluation by INCQS. Now they just need ANVISA approval of the Micro Reader. We expect that eventual commercialization in Brazil could be a significant revenue catalyst given not only the almost epidemic-like Zika outbreak in that country (~1.5M people infected) but also the proven commercialization capabilities of FIOCRUZ. The more recent $5.8M order from FIOCRUZ for DPP HIV test components is encouraging that not only is this relationship alive and well, but that it could be a harbinger for further large orders for other of CEMI's products in the future.

The stand-alone DPP Dengue assay, which was developed in collaboration with RVR, has already made a major splash with $1.4M in related revenue booked in Q1 2017. Given the outsized potential market for POC Dengue testing and CEMI's efforts to gain approval of their product in other Asia Pacific countries, we think this test could eventually be a tremendously successful product for the company. 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 the

RVR channel. 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.

CEMI also recently submitted applications for approval of DPP Zika with; FDA for Emergency Use Authorization (EUA), WHO under EUA and Mexico's regulatory agency. Another factor that could work in CEMI's favor is that their DPP Zika test is the only rapid Zika test submitted to FDA under EUA and one of two submitted to WHO under EUA – and that pathway is now no longer available to enter. As such, upon approval, CEMI's DPP Zika test should have a fairly captive market. And Zika remains a major problem in the U.S. and is actually getting worse despite not getting nearly the headlines that it did last year. In fact a CDC report published earlier in 2017 found that there were more than 1,600 cases of Zika in the U.S. last year in pregnant women and the cases are not slowing down. As such, eventually commercialization of DPP Zika in the U.S. could be significant for Chembio.

DPP Zika and DPP Zika/Chikungunya/Dengue Combination Assay and the DPP Micro Reader are also now being used in a POC surveillance pilot program in India, Peru, Guatemala and Haiti under a $330k CDC grant that Chembio was awarded in late September 2016. CEMI began selling the test under this program during Q1 '17.

Development of the DPP Fever panel (multiplex for Malaria, Dengue, Chikungunya, Zika, Ebola, Lassa and Marburg), funded by a grant from the Paul G. Allen Foundation, is also progressing. Validation has been completed and in Q1 '17 field testing commenced.

DPP Ebola and DPP Malaria-Ebola also could come to market. DPP Ebola has been submitted to FDA and WHO for EUA and both DPP Ebola and DPP Malaria-Ebola continue to undergo field testing (via CDC) in West Africa.

DPP Malaria also holds meaningful near-term promise. With additional funding from the Gates foundation, CEMI recently completed feasibility testing of a DPP oral fluid malaria test - 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. Laboratory verification testing is expected to begin imminently. Given the relatively massive size of the malaria testing market, if eventually commercialized, we think this DPP Malaria saliva/blood could potentially be a tremendous success.

OUR OUTLOOK

The company has been deliberate in finding ways to grow all of their product lines and this has shown early success. This included hiring two experienced sales executives during 2016 to manage the America's and EMEA region. Then in January 2017 they brought on three international sales directors tasked with increasing sales of the company's products in each of their respective regions (Latin America, Africa and Asia/Pacific). This is a deliberate move to lessen (or potentially eliminate) the company's historic reliance on a small handful of third-party companies and governmental organizations in regulatory affairs, marketing and distribution.

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

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Revenue

We look for 2017 revenue of $22.4 million, implying growth of 25% from 2016. We have product sales growing almost 31% given our expectation of a rebound in DPP from initial meaningful sales from the fever portfolio, the $5.8M FIOCRUZ order (DPP HIV test components) and stabilization of lateral flow as CEMI fully regroups this business under its own umbrella. We think upside to our model could come from more substantial sequential

growth in U.S. lateral flow or higher international lateral flow – with the recent additions of regional sales directors who are tasked with growing (and initiating) sales in their respective regions, we think the lateral flow business (as well as other currently CE Marked products) in particular could potentially have meaningful upside in the near-term. Additional potential upside could come from DPP Fever in Europe or the Caribbean. In addition, further DPP fever-related regulatory approvals in Asia Pacific could also offer upside.

VALUATION

Given expected outsized growth in Fever, we value CEMI at a slight premium to OSUR. We value CEMI at 6.5x 2017 estimated revenue (vs OSUR @ 6.0), or approximately $12/share.

FINANCIAL STATEMENTS

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2016 A	Q1A	Q2E	Q3E	Q4E	2017 E	2018 E	2019 E
Product sales	**$13,678**	**$5,427**	**$4,033**	**$4,181**	**$4,259**	**$17,900**	**$26,112**	**$34,031**
% of total revenue	*76.5%*	*85.8%*	*80.4%*	*76.2%*	*76.3%*	*79.9%*	*87.6%*	*92.1%*
YOY Growth	*-37.5%*	*-8.3%*	*98.3%*	*67.1%*	*32.0%*	*30.9%*	*45.9%*	*30.3%*
License & royalty income	**$450**	**$100**	**$117**	**$107**	**$103**	**$427**	**$526**	**$310**
% of total revenue	*2.5%*	*1.6%*	*2.3%*	*2.0%*	*1.8%*	*1.9%*	*1.8%*	*0.8%*
R&D contracts, grants, milestones	**$3,739**	**$798**	**$867**	**$1,198**	**$1,218**	**$4,081**	**$3,180**	**$2,610**
% of total revenue	*20.9%*	*12.6%*	*17.3%*	*21.8%*	*21.8%*	*18.2%*	*10.7%*	*7.1%*
Total Revenues	$17,868.9	$6,325.2	$5,017.0	$5,486.0	$5,580.0	$22,408.2	$29,817.8	$36,951.0
YOY Growth	*-26.3%*	*-4.2%*	*53.6%*	*46.4%*	*31.1%*	*25.4%*	*33.1%*	*23.9%*
Cost of Revenues	$9,418	$3,219	$2,561	$2,509	$2,577	$10,865	$15,119	$19,228
Gross Income	$8,451	$3,106	$2,456	$2,977	$3,003	$11,543	$14,699	$17,723
Gross Margin	*47.3%*	*49.1%*	*49.0%*	*54.3%*	*53.8%*	*51.5%*	*49.3%*	*48.0%*
Product Margin	*31.2%*	*40.7%*	*36.5%*	*40.0%*	*39.5%*	*39.3%*	*42.1%*	*43.5%*
Research & Development	$8,428	$2,247	$1,955	$1,904	$1,888	$7,994	$7,612	$7,244
% R&D	*47.2%*	*35.5%*	*39.0%*	*34.7%*	*33.8%*	*35.7%*	*25.5%*	*19.6%*
Selling General & Admin	$7,596	$2,488	$2,398	$2,463	$2,483	$9,833	$10,794	$11,898
% SG&A	*42.5%*	*39.3%*	*47.8%*	*44.9%*	*44.5%*	*43.9%*	*36.2%*	*32.2%*
Operating Income	($7,572)	($1,629)	($1,897)	($1,390)	($1,368)	($6,284)	($3,707)	($1,419)
Operating Margin	*-42.4%*	*-25.8%*	*-37.8%*	*-25.3%*	*-24.5%*	*-28.0%*	*-12.4%*	*-3.8%*
Other income (expense)	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	$26	$13	$13	$10	$18	$54	($20)	($10)
Pre-Tax Income	($7,546)	($1,616)	($1,885)	($1,380)	($1,350)	($6,230)	($3,727)	($1,429)
Taxes	$5,801	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*-76.9%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($13,347)	($1,616)	($1,885)	($1,380)	($1,350)	($6,230)	($3,727)	($1,429)
YOY Growth	*456.8%*	*431.3%*	*-77.4%*	*-35.5%*	*-47.2%*	*-53.3%*	*-40.2%*	*-61.7%*
Net Margin	*-74.7%*	*-25.5%*	*-37.6%*	*-25.2%*	*-24.2%*	*-27.8%*	*-12.5%*	*-3.9%*
EPS	($1.26)	($0.13)	($0.15)	($0.11)	($0.10)	($0.49)	($0.27)	($0.10)
YOY Growth	-	-	-	-	-	-	-	-
Weighted Avg. Shares O/ S	10,622	12,271	12,299	13,000	13,500	12,767	13,800	14,000

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HISTORICAL ZACKS RECOMMENDATIONS



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