Zacks Small-Cap Research

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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Chembio Diagnostics Inc. (CEMI-NASDAQ)

CEMI: Q2 Inline. Expect 2H Revenue Acceleration As Catalysts Kick In

We look for 2017 revenue of $21.9M. We value CEMI at 6.5x 2017 estimated revenue (for reference, OSUR currently trades at @ 7.5x consensus 2017 revenue), or approximately $12/share.

Current Price (08/17/17)	$6.05
Valuation	**$12.00**

OUTLOOK

Save for a $1.1M (28%) miss in product sales, financial results were largely inline with our estimates. And the difference in product sales relates almost entirely to a delay in shipping ~$1M worth of product under a recently penned agreement to furnish DPP HIV 1/2 test components and related materials to Brazil's Ministry of Health. With ~$4.9M expected to be recognized from the Brazil order and other potential catalysts, such as accelerating U.S. lateral flow sales, growing traction in HIV self-testing in Europe (and possibly parts of Africa) and additional contribution from international tenders, we think 2H could generate the highest level of product sales in any six-month period since Q2 – Q3 2015. And additional upside to our current estimates could happen if, for example, initial meaningful commercialization of DPP Zika in Brazil commences prior to year-end or particularly large tenders materialize.

On the operating front, a major recent highlight was the receipt of approval for the DPP Micro Reader from ANVISA – the last of the regulatory-related approvals needed before the DPP Zika test can be sold in Brazil – a hotbed for that virus.

SUMMARY DATA

52-Week High	**$7.42**
52-Week Low	**$5.15**
One-Year Return (%)	**13.89**
Beta	**1.19**
Average Daily Volume (sh)	**29,928**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$74**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**31**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-8.7**
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	$4.11 A	$5.64 E	$5.81 E	$21.89 E
2018					$29.07 E
2019					$36.47 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	-$0.18 A	-$0.13 E	-$0.12 E	-$0.55 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

Q2 2017: *Results Inline, Expect Revenue Acceleration in 2H From Brazil Order, Other Catalysts …*

Chembio reported financial results for Q2 2017. Save for a $1.1M (28%) miss in product sales, financial results were largely inline with our estimates. And the difference in product sales relates almost entirely to a delay in shipping ~$1M worth of product under a recently penned agreement to furnish DPP HIV 1/2 test components and related materials to Brazil's Ministry of Health. Approximately $4.9M remains under the contract – which is anticipated to be shipped in Q3 and Q4 of this year. Meanwhile, lateral flow sales came in very close to our expectations, as did revenue related to contracts and grants. And while gross margin was tighter than expected, that was more than offset by lower operating expenses.

On the operating front, a major recent highlight was the receipt of approval for the DPP Micro Reader from ANVISA – the last of the regulatory-related approvals needed before the DPP Zika test can be sold in Brazil. While management was non-committal on a specific commercialization timeline, they did note that they are working with their Brazilian partners on that goal.

Product sales, at $2.9M, were up 42% yoy. However, the prior-year period was particularly very weak and at just $2.0M, was at the lowest level since Q1 2007. On a sequential basis product sales fell 47%. But, it's not nearly as scary as those comps make it sound – as indicated, CEMI had expected to book $1.9M in sales from the aforementioned $5.8M DPP HIV 1/2 Brazilian contract – instead they booked just $900k. Additionally, Q1 2017 benefitted from a $1.4M tender in Malaysia (via RVR).

With almost $2.5M (on average) expected to be recognized in both Q3 and Q4 from the Brazil order and other potential catalysts, such as accelerating U.S. lateral flow sales (as we expect), growing traction in HIV self-testing in Europe (and possibly parts of Africa) and additional contribution from international tenders, we think 2H could generate the highest level of product sales in any six-month period since Q2 – Q3 2015. And additional upside to our current 2H estimates could happen if, for example, initial meaningful commercialization of DPP Zika in Brazil commences prior to year-end or CEMI wins particularly large tenders – such as an outstanding UNICEF RFP (potentially worth up to $10M) related to rapid Zika tests.

DPP sales, at $1.2M were up 42% yoy (from $835k) and down 47% sequentially (from $2.2M) and $1.1M below our estimate due to the delayed Brazil shipment. Brazil should continue to be the majority contributor to DPP sales in 2017 as a result of the aforementioned order from FIOCRUZ. With the Micro Reader now approved by ANVISA, DPP Zika should also eventually be a meaningful contributor in that country.

We could also see additional DPP Dengue sales via RVR (captured in "Other Product Sales" on the income statement) in 2017, although the large $1.4M tender recognized 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 (and registrations in additional countries) 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.

Another likely catalyst (if and when approved) expected to come out of the DPP portfolio is HIV/Syphilis for the U.S. market. While HIV and syphilis testing of pregnant women is already commonplace in the U.S., potential leading accuracy and the convenience of both markers on the same test could provide a significant competitive advantage. While the timeline for U.S. commercialization was recently pushed back, indications are that CEMI continues to make substantive progress in that regard. As a reminder, while the study which was expected to support CEMI's FDA PMA filing completed (the data from which CEMI noted looked good), in March the agency requested that the company conduct additional clinical studies. On the Q2 call management said that they expect to complete the additional studies in Q4 of this year. If all goes well, we think a reasonable guess in terms of U.S. launch is mid-to-late 2018.

Meanwhile, the U.S., DPP HIV/Syphilis test received CE Mark in Q1 – opening it up to Europe and the Caribbean (ex-Puerto Rico). CEMI recently entered an agreement with Isla Lab for distribution of their products in the Caribbean which could be key in exploiting this opportunity and with DPP Zika, which is also CE Marked. As a reminder, DPP HIV/Syphilis generated significant demand almost immediately following launch in Mexico in 2014. Given the concern of mother-to-child transmission of both HIV and syphilis - which can be particularly problematic among certain emerging-status countries, along with WHO guidelines recommending HIV and syphilis testing of all pregnant women, we think this product has significant long-term growth potential OUS.

DPP Syphilis Screen and Confirm, which is the only rapid test that can detect both active and past syphilis infections, is another product that we think could have substantial appeal in developing areas of the world. The test is CE Marked and being used in pilot programs in Africa.

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, eventual commercialization of DPP Zika in the U.S. could also be significant for Chembio.

Relative to lateral flow, Q2 sales of $1.6M were flat sequentially and up 37% (from $1.2M) – but it is worth noting that the prior-year period was an easy comp given weakness created by a large stocking order in Q1 2016 from Alere, CEMI's ex-distribution partner for their U.S. HIV lateral flow products. Nonetheless, $1.6M is a solid number, especially since U.S. sales in Q2, at just $454k, were not particularly strong – that should pick up, however, particularly given that CEMI recently won two sizeable state tenders for their HIV tests.

Meanwhile upside in lateral flow came from relative strength in Europe as well as from Africa. Management noted that HIV self-testing aided European sales – that is not something that we had expected but might be an area of future growth. CEMI also indicated that certain parts of Africa hold promise for the HIV self-testing market given the initiation of significant funding programs.

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 July ANVISA approved the Micro Reader – the final sign-off needed for commercialization. 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 in that it signals 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. UNICEF has an outstanding RFP for POC Zika test that could be worth up to $10M – this presents another potentially meaningful opportunity. 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.

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. 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.

Revenue

We look for 2017 revenue of $21.9 million, implying growth of 23% from 2016. We have product sales growing 28% 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 as well as new opportunities such as HIV self-testing, 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

We value CEMI at 6.5x 2017 estimated revenue (for reference, OSUR currently trades at @ 7.5x consensus 2017 revenue), or approximately $12/share.

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2016 A	Q1A	Q2A	Q3E	Q4E	2017 E	2018 E	2019 E
Product sales	**$13,679**	**$5,427**	**$2,893**	**$4,539**	**$4,663**	**$17,522**	**$25,408**	**$33,413**
% of total revenue	*76.6%*	*85.8%*	*70.3%*	*80.5%*	*80.3%*	*80.1%*	*87.4%*	*91.6%*
YOY Growth	*-37.5%*	*-8.3%*	*42.2%*	*81.4%*	*44.5%*	*28.1%*	*45.0%*	*31.5%*
License & royalty income	**$450**	**$100**	**$228**	**$107**	**$103**	**$538**	**$526**	**$310**
% of total revenue	*2.5%*	*1.6%*	*5.5%*	*1.9%*	*1.8%*	*2.5%*	*1.8%*	*0.8%*
R&D contracts, grants, milestones	**$3,739**	**$798**	**$994**	**$992**	**$1,043**	**$3,827**	**$3,140**	**$2,742**
% of total revenue	*20.9%*	*12.6%*	*24.2%*	*17.6%*	*18.0%*	*17.5%*	*10.8%*	*7.5%*
Total Revenues	$17,868.9	$6,325.2	$4,114.8	$5,638.0	$5,809.0	$21,887.0	$29,073.8	$36,464.8
YOY Growth	*-26.3%*	*-4.2%*	*26.0%*	*50.5%*	*36.5%*	*22.5%*	*32.8%*	*25.4%*
Cost of Revenues	$9,418	$3,219	$2,204	$2,769	$2,891	$11,083	$14,711	$18,878
Gross Income	$8,451	$3,106	$1,911	$2,869	$2,918	$10,804	$14,362	$17,586
Gross Margin	*47.3%*	*49.1%*	*46.4%*	*50.9%*	*50.2%*	*49.4%*	*49.4%*	*48.2%*
Product Margin	*31.2%*	*40.7%*	*23.8%*	*39.0%*	*38.0%*	*36.8%*	*42.1%*	*43.5%*
Research & Development	$8,428	$2,247	$1,982	$1,904	$1,888	$8,021	$7,612	$7,244
% R&D	*47.2%*	*35.5%*	*48.2%*	*33.8%*	*32.5%*	*36.6%*	*26.2%*	*19.9%*
Selling General & Admin	$7,596	$2,488	$2,109	$2,531	$2,585	$9,714	$10,525	$11,742
% SG&A	*42.5%*	*39.3%*	*51.3%*	*44.9%*	*44.5%*	*44.4%*	*36.2%*	*32.2%*
Operating Income	($7,572)	($1,629)	($2,181)	($1,566)	($1,555)	($6,931)	($3,774)	($1,399)
Operating Margin	*-42.4%*	*-25.8%*	*-53.0%*	*-27.8%*	*-26.8%*	*-31.7%*	*-13.0%*	*-3.8%*
Other income (expense)	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	$26	$13	$8	$10	$18	$49	($20)	($10)
Pre-Tax Income	($7,546)	($1,616)	($2,173)	($1,556)	($1,537)	($6,882)	($3,794)	($1,409)
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)	($2,173)	($1,556)	($1,537)	($6,882)	($3,794)	($1,409)
YOY Growth	*456.8%*	*431.3%*	*-74.0%*	*-27.2%*	*-39.9%*	*-48.4%*	*-44.9%*	*-62.9%*
Net Margin	*-74.7%*	*-25.5%*	*-52.8%*	*-27.6%*	*-26.5%*	*-31.4%*	*-13.1%*	*-3.9%*
EPS	($1.26)	($0.13)	($0.18)	($0.13)	($0.12)	($0.55)	($0.27)	($0.10)
YOY Growth	-	-	-	-	-	-	-	-
Weighted Avg. Shares O/S	10,622	12,271	12,299	12,310	12,800	12,420	13,800	14,000

Brian Marckx, CFA

HISTORICAL ZACKS RECOMMENDATIONS



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