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

Zacks Small-Cap Research

scr.zacks.com

10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

Chembio Diagnostics Inc. (CEMI- NASDAQ)

CEMI: **Fever Portfolio Charging Out of the Gate. Could Be the Next Wave of Growth**

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (11/13/15)	$5.34
Target Price	**$7.00**

OUTLOOK

CLIA Waiver granted for DPP HIV assay. CEMI signed distribution agreements and also bldg direct sales force to sell direct in the U.S. Int'l lateral flow sales remain variable which negatively impacted 2014 revenue but could turn back positive with recent launch for self-testing in Europe. DPP international sales have been very strong with FIOCRUZ still very active and HIV/Syph launch in Mexico the drivers in 2014. DPP HIV/Syph in Brazil could be major catalyst. Next up could be the U.S. mrkt. – clinical trials for which slated to commence H1 2016. Meanwhile, new fever portfolio looks like it could be a needle-mover – off to a strong start but still too early to make any concrete predictions.

CEMI also focused on complementary revenue opportunities including add'l R&D contracts/grants, expansion of international commercialization footprint, and potentially in-licensing products.

We are maintaining our Buy rating.

SUMMARY DATA

52-Week High	**$5.34**
52-Week Low	**$3.33**
One-Year Return (%)	**21.64**
Beta	**0.73**
Average Daily Volume (sh)	**29,082**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$51**
Short Interest Ratio (days)	**0.86**
Institutional Ownership (%)	**18**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**14.8**
Earnings Per Share (%)	**-40.6**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(millions)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	$5.81 A	$7.42 A	$7.31 A	$7.10 A	$27.65 A
2015	$6.23 A	$6.72 A	$6.89 A	$6.87 E	$26.71 E
2016					$29.47 E
2017					$35.78 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.04 A	-$0.02 A	-$0.03 A	-$0.07 A	-$0.16 A
2015	-$0.09 A	-$0.09 A	-$0.06 A	-$0.07 E	-$0.31 E
2016					-$0.11 E
2017					$0.16 E

Zacks Projected EPS Growth Rate - Next 4 Years % **NA**

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WHAT'S NEW

Q3 2015: *New Products, Including Fever Portfolio, Off to Strong Start. Is This the New Wave of Growth? ….*

Chembio reported financial results for the third quarter ending September 30th. It was a solid quarter on both the tops and bottom lines. Product sales hit our number just about right on the nose (in fact lateral flow hit our estimate exactly) – and although there were some differences in the details (i.e. U.S. vs int'l), the fundamentals behind the revenue numbers look to be solid. Particularly encouraging, and in-fact more surprisingly than we had expected, is that the company's relatively new disease segment – that being fever – appears to be charging out of the gate.

The fever segment – which right now includes DPP assays for Malaria/Ebola and Ebola (as well as Dengue and other Malaria assays under development) contributed over $150k to revenue in Q3 and will add another $900k in Q4. And the bigger kicker is that these initial sales are just for CDC testing in W. Africa – validation is expected to be fairly swift-moving with commercialization potentially happening sometime in 1H 2016. The pace of development, initial outside validation and related front-end sales has been impressive – as management noted on the call, the fever segment was borne at Chembio only about one-year ago and today they're already booking revenue at a $2M+ annual run-rate. And again, these sales relate to field testing – a commercialized product (via international aid tenders) could be a real needle-mover for CEMI.

In addition, these initial assays may be just the first of several to come. The company has seen impressive accuracy of other of its DPP Malaria pipeline portfolio and with additional development could have several more tests on the market in the coming quarters. Malaria is a sizeable market – over 300M tests are sold each year and Chembio could be sitting in the cat-bird's seat. Not only are their tests demonstrating potentially market-leading accuracy, they have the experience, background and infrastructure to enable them to rapidly bring products to market to exploit the opportunity.

Their early success with their fever assays is almost certainly largely attributable to their experience with infectious diseases - while HIV has been the bread-and-butter for years, they have had their hands in several other areas for some time, development of which has been funded mostly via grants. That includes infectious diseases associated with febrile illness. That also likely explains the rapid turnaround from initial development to being now already on the brink of launch into international tender programs. And while it is still too early to confidently predict that their fever segment will be a big winner for the company, it is undoubtedly off to a good start and is where we think the majority of the potential to surprise on the upside now lies.

CEMI's capabilities and DPP technology received another vote of confidence when in early October they were awarded a $2.1M, 12-month grant from the Paul G. Allen Ebola Program to develop a multiplex test on the DPP platform for detection of multiple febrile illnesses including Malaria, Dengue, Ebola, Lassa, Marburg and Chikungunya. The program is managed by Allen's company, Vulcan Inc. The grant to Chembio is part of $11M in new grants that Vulcan announced today (10/5) which (per Vulcan's PR) "are intended to disrupt the cycle of epidemics and shorten the time in which the world responds to health crises" and "are part of Mr. Allen's efforts to help ensure that tools are in place to prevent future outbreaks from escalating into epidemics."

As we noted following announcement of the award, we view this as a significant vote of confident in the DPP technology given that the Paul G. Allen Ebola Program is on the forefront of infectious research with Mr. Allen pledging $100M to address the Ebola outbreak in West Africa.

But fever was not the only highlight in Q3. CEMI, through its third-party distributors, launched their SURE CHECK HIV ½ (lateral flow) self-testing product in the U.K. and France in Q2 of this year and this is also off to a very strong start. It booked $400k+ revenue (over 6% of total product sales) in Q3 and, per management, will do ~$1M for the full year – which we estimate will equal ~8% of total product sales for 2H 2015.

Q3 Financials

Q3 revenue of $6.9M was down 6% yoy, up 3% sequentially and about 2% better than our $6.7M estimate. Total HIV lateral flow sales were $2.3M, up 37% from the prior year period and dead-on with our number. DPP was $3.8M, down 30% yoy, down 5% sequentially and in-line with our $3.8M estimate.

In the lateral flow number is $1.5M in U.S. sales – this was up 30% from Q3 2014 and up 46% from Q2 of this year. This strength in US sales was a surprise – we were looking for only $1.1M, implying roughly flat growth from both comparable periods – this is because 4th –gen laboratory testing has become a recent headwind. So we don't know

what to make of the strong Q3 result in US lateral flow – we suspect that it may mostly relate to Alere's sales of SURE CHECK HIV ½ given the overall product margin was relatively narrow. Alere's marketing rights run through May 31, 2016 at which time CEMI will be detailing all of the U.S. lateral flow portfolio in-house. CEMI currently has a small sales force currently selling STAT-PAK HIV and the more recently launched DPP HIV ½ – mostly focused on public health facilities. They expect to incrementally grow their direct sales force which will be complemented with third-party distribution - the company now has at least three distribution agreements in place which includes the major medical device companies, McKesson/PSS, Fisher Healthcare and Henry Schein. We continue to model contraction in the lateral flow portfolio as we think DPP will take share and the loss of Alere has potential to be impactful (which was the case when Alere's STAT-PAK rights rolled off in June 2014).

Meanwhile, international lateral flow sales were $789k, representing yoy growth of 54% and a contraction of 34% from Q2 of this year. As we have noted in the past, international sales can vary widely from q-to-q as these have largely relied on tenders from international aid organizations. However, Q3 was somewhat different – that's because SURE CHECK HIV 1/2 self-testing kits, which launched in Q2 in the U.K. and France and which is being sold via third-party distribution, contributed more than 50% of total international lateral flow sales in the quarter – that level of sales was an upside surprise to us.

This also suggests that any emerging market tenders were relatively very little in the quarter – which further implies that subsequent periods could see much healthier international sales – particularly because management noted that full-year 2015 SURE CHECK HIV self-testing revenue should be ~$1M (or $500k+ in Q4). This, along with the DPP fever portfolio, has potential to surprise on the upside over the near-term – both of which we will be very interested in hearing more about on future calls. Prior to Q3 we had been modeling a regular contraction in international lateral flow sales beginning in 2016 – and while we continue to carry this assumption forward, it has the potential to be updated which may largely depend on if this recent strength in European sales can hold.

DPP sales came in at $3.8M – right where we had them modeled. $150k of this is sales of DPP Ebola to CDC for field testing in W. Africa. The majority of the remainder relates to sales to FIOCRUZ (Brazil) and Mexico. Management noted on the call that, based on forecasts by FIOCRUZ, that they expect DPP sales to Brazil to remain strong in 2016.

Gross margin and product margin were 42.3% and 36.0%, which is better than the 39.1% and 35.1% respective averages for the full-year 2014, although lower than the first half of the current year which averaged about 44% and 39%. For the full-year 2015 we continue to model improvement in both gross and product margins as compared to 2014.

EPS

We use adjusted net income and EPS for consistency purposes. As a reminder, in Q4 2011 CEMI took a non-cash gain of $5.16 million to income from the reversal of deferred tax asset as they expected to generate positive pre-tax income from that point forward. Their GAAP income tax rate of ~35.1% is ~90% non-cash until they exhaust (which, based on our current model will occur sometime in 2019 or 2020) their entire deferred tax asset which stood at $4.6 million at the end of Q3.

Q3 adjusted net income and EPS of approximately ($565)k and ($0.06) compares to our ($935)k and ($0.10) estimates. Most of the difference relates to a ~$400k (11%) lower than modeled operating expenses.

Cash

Excluding changes in working capital, cash used in operating activities was $191k. CEMI exited Q3 with $1.1M in cash and equivalents, compared to $1.6M at the end of Q2. Subsequent to quarter-end the company collected $6.8M in A/R which will provide a significant supplement to the cash position.

OUR OUTLOOK

Revenue

We look for 2015 revenue of $26.7 million, implying a decrease of 3% from 2014.

U.S. lateral flow sales have contracted which we think is a result of the transition from Alere to the in-house sales force. Some shifting of HIV testing from POC to the new-gen lab tests could bring in the overall market. These two factors could further hamper domestic lateral flow sales going forward, particularly following the May 2016 expiration of the Alere agreement covering SURE CHECK HIV ½.

International lateral flow sales, as indicated, are particularly difficult to predict given their inherent variability – we model about 76% growth in 2015, which is more of a function of 2014 being a relatively weak year. This line, we think, is one that has some of the most potential to beat our number on the upside in the near, as well as the medium terms – some of which relates to the strong initial sales of SURE CHECK HIV ½ self-testing in Europe.

DPP sales were extraordinarily strong in 2014 as FIOCRUZ continued to purchase well beyond their minimum purchase requirements for most of the products under the tech transfer agreement and uptake of DPP HIV/Syphilis in Mexico was tremendous. DPP has contracted by double-digit percentages the last two quarters as a result of lower purchasing from Brazil, and most recently, from Mexico. But we are optimistic that DPP can return to growth in 2016 given the DPP fever catalysts just now coming online and which have significant potential to expand, the recently launch of DPP HIV in the U.S. and the indication from FIOCRUZ that sales to Brazil may remain meaningful goring forward – DPP HIV/Syphilis, in particular, could make a meaningful impact in Brazil in the coming year. And that product, which has been a great success in Mexico and is expected to enter U.S. trials in early 2016, could prove to be another catalyst to drive the DPP revenue line higher over the mid-term.

And CEMI continues to investigate the possibility of full development of a multiplex P24 antigen/antibody test. This product, if and when developed and launched, could be spur additional growth of the DPP franchise.

Net Income / EPS

We look for adjusted net income and EPS of ($2.9)M and ($0.31) in 2015, compared to ($1.1) million and ($0.16) in 2014.

RECOMMENDATION / VALUATION

We continue to use OSUR as a comp for valuation purposes. OSUR trades at approximately 2.7x 2015 estimated sales and 2.1x EV/2015 sales. P/S comp values CEMI at ~$7.50/share, EV/S values CEMI at ~$6/share. We use the approximate average, $7/share, as our price target. We are maintaining our Buy recommendation.

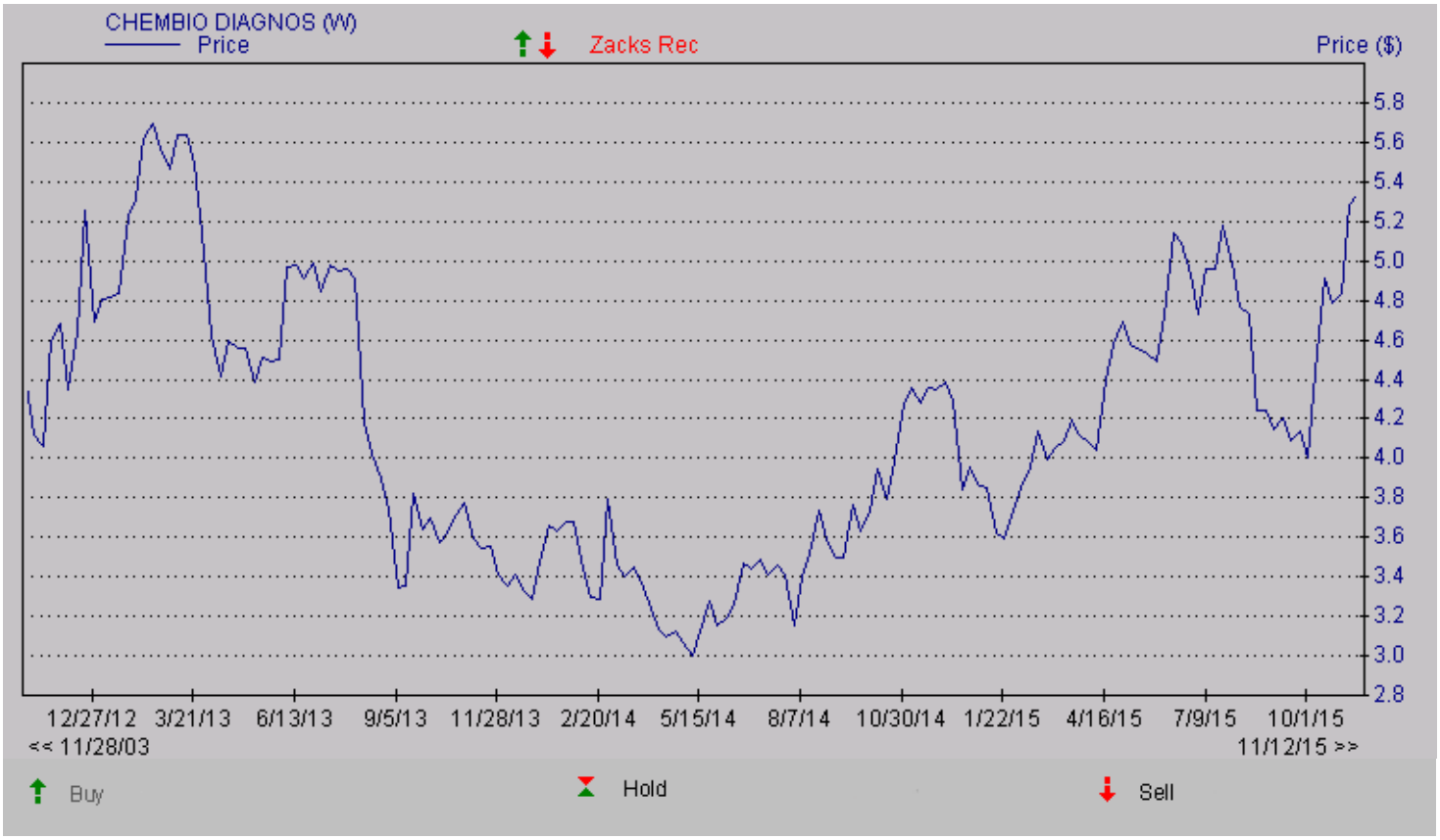
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2014 A	Q1A	Q2A	Q3A	Q4E	2015 E	2016 E	2017 E	2018 E
Product sales	**$25,950**	**$5,615**	**$6,322**	**$6,210**	**$6,188**	**$24,334**	**$27,450**	**$33,468**	**$36,181**
% of total revenue	*93.9%*	*90.1%*	*94.1%*	*90.2%*	*90.0%*	*91.1%*	*91.1%*	*93.7%*	*93.7%*
YOY Growth	*-5.7%*	*14.5%*	*-12.8%*	*-14.3%*	*-5.5%*	*-6.2%*	*12.8%*	*21.9%*	*8.1%*
License & royalty income	**$24**	**$7**	**$8**	**$19**	**$35**	**$69**	**$697**	**$899**	**$1,037**
% of total revenue	*0.1%*	*0.1%*	*0.1%*	*0.3%*	*0.5%*	*0.3%*	*2.3%*	*2.5%*	*2.7%*
R&D contracts, grants, milestones	**$1,672**	**$609**	**$387**	**$659**	**$650**	**$2,305**	**$1,975**	**$1,365**	**$1,400**
% of total revenue	*6.0%*	*9.8%*	*5.8%*	*9.6%*	*9.5%*	*8.6%*	*6.6%*	*3.8%*	*3.6%*
Total Revenues	$27,645.3	$6,231.1	$6,716.2	$6,887.4	$6,873.0	$26,708.0	$30,121.4	$35,731.8	$38,617.5
YOY Growth	*-6.4%*	*7.2%*	*-9.5%*	*-5.8%*	*-3.1%*	*-3.4%*	*12.8%*	*18.6%*	*8.1%*
Cost of Revenues	$16,831	$3,545	$3,697	$3,977	$3,806	$15,024	$16,195	$19,412	$20,840
Gross Income	$10,814	$2,687	$3,019	$2,911	$3,067	$11,684	$13,926	$16,320	$17,777
Gross Margin	*39.1%*	*43.1%*	*45.0%*	*42.3%*	*44.6%*	*43.7%*	*46.2%*	*45.7%*	*46.0%*
Product Margin	*35.1%*	*36.9%*	*41.5%*	*36.0%*	*38.5%*	*38.3%*	*41.0%*	*42.0%*	*42.4%*
Research & Development	$4,833	$1,585	$1,757	$1,570	$1,788	$6,700	$6,818	$5,744	$4,844
% R&D	*17.5%*	*25.4%*	*26.2%*	*22.8%*	*26.0%*	*25.1%*	*22.6%*	*16.1%*	*12.5%*
Selling General & Admin	$7,532	$1,978	$2,160	$1,920	$1,966	$8,023	$8,283	$8,861	$9,809
% SG&A	*27.2%*	*31.7%*	*32.2%*	*27.9%*	*28.6%*	*30.0%*	*27.5%*	*24.8%*	*25.4%*
Operating Income	($1,550)	($875)	($898)	($579)	($686)	($3,038)	($1,175)	$1,715	$3,125
Operating Margin	*-5.6%*	*-14.1%*	*-13.4%*	*-8.4%*	*-10.0%*	*-11.4%*	*-3.9%*	*4.8%*	*8.1%*
Other income (expense)	($6)	$0	$0	$0	$0	$0	$0	$0	$0
Interest income, net	$6	$1	$0	($0)	$1	$2	$18	$66	$81
Pre-Tax Income	($1,550)	($874)	($898)	($579)	($685)	($3,036)	($1,157)	$1,781	$3,206
Taxes	($413)	($228)	($234)	($142)	($240)	($843)	($434)	$668	$1,202
Tax Rate	*26.6%*	*26.0%*	*26.0%*	*35.0%*	*35.0%*	*37.5%*	*37.5%*	*37.5%*	*37.5%*
Net Income	($1,137)	($647)	($664)	($437)	($445)	($2,193)	($723)	$1,113	$2,003
YOY Growth	*-314.1%*	*187.8%*	*354.9%*	*61.5%*	*-10.2%*	*92.9%*	*-67.0%*	*-253.9%*	*80.0%*
Net Margin	*-4.1%*	*-10.4%*	*-9.9%*	*-6.3%*	*-6.5%*	*-8.2%*	*-2.4%*	*3.1%*	*5.2%*
GAAP EPS	($0.12)	($0.07)	($0.07)	($0.05)	($0.05)	($0.23)	($0.07)	$0.10	$0.19
Adjusted EPS	($0.16)	($0.09)	($0.09)	($0.06)	($0.07)	($0.31)	($0.11)	$0.16	$0.29
YOY Growth	*-302.1%*	*136.4%*	*286.9%*	*115.1%*	*1.0%*	*90.9%*	*-68.1%*	*-244.2%*	*77.0%*
Weighted Avg. Shares O/S	9,529	9,625	9,628	9,628	9,628	9,627	9,955	10,620	10,800

Brian Marckx, CFA

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