Zacks Small-Cap Research

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# Chembio Diagnostics Inc. (CEMI-NASDAQ)

## *CEMI:* Poised For 'Fever'ish Growth With RVR Acquisition, Isla Lab Distribution and Impending Regulatory Approvals

We look for 2017 revenue of $25.5M. We use OSUR as a comp for valuation purposes. Given expected outsized growth in fever we value CEMI at 4.2x P/S, a slight premium to OSUR (4.0x), or ~$9/share.

| | |
|---|---|
| Current Price (11/22/16) | $6.85 |
| **Valuation** | **$9.00** |

## OUTLOOK

We look for 2016 revenue of $18.1 million, implying a decrease of 26% from 2015. We have lateral flow falling 26% and DPP down 45% - although, we think DPP begins to show yoy growth in Q4 with contribution from DPP fever. We think upside to our model could come from more substantial sequential growth in U.S. lateral flow or higher international lateral flow, the latter from aid-agency tenders.

We think fever, with a full year of DPP Zika in some territories and additional fever assays that could come to market on a fairly regular basis, drives most of the top-line in 2017. DPP HIV/Syphilis could also launch in the U.S. and contribute in 2017. We currently model revenue of $25.5M in 2017, implying growth of 41%.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$9.40** |
| **52-Week Low** | **$4.03** |
| **One-Year Return (%)** | **32.38** |
| **Beta** | **0.86** |
| **Average Daily Volume (sh)** | **50,883** |
| **Shares Outstanding (mil)** | **12** |
| **Market Capitalization ($mil)** | **$82** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **17** |
| **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 2016 Estimate** | **N/A** |
| **P/E using 2017 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Above Avg.,** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med Products** |

## ZACKS ESTIMATES

**Revenue**
(millions)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2015 | $6.23 A | $6.72 A | $6.89 A | $4.42 A | $24.26 A |
| 2016 | $6.60 A | $3.27 A | $3.75 A | $4.44 E | $18.06 E |
| 2017 | | | | | $25.54 E |
| 2018 | | | | | $31.57 E |

**Adjusted Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2015 | -$0.07 A | -$0.07 A | -$0.05 A | -$0.07 A | -$0.37 A |
| 2016 | -$0.03 A | -$0.25 A | -$0.19 A | -$0.20 E | -$0.70 E |
| 2017 | | | | | -$0.33 E |
| 2018 | | | | | $0.13 E |

Zacks Projected EPS Growth Rate - Next 5 Years % **10**

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## WHAT'S NEW

**Q3 2016:** *Poised For 'Fever'ish Growth With RVR Acquisition, Isla Lab Distribution and Impending Reg Approvals…*

Chembio reported financial results for the third quarter ending September 30th. Total revenue of $3.8M was about 22% higher than our $3.1M estimate with much of the difference coming from better than expected U.S. lateral flow sales. While there were several financial and operational highlights over the last few months, the sequential rebound in U.S. lateral flow sales (+15% from Q2) and comments on the call that suggest this business is firming up, is one that we did not expect.

And while we still believe there will be a shift from the company's historic heavy reliance on their sexually transmitted disease business to their rapidly growing fever portfolio, we are encouraged by the relative strength in lateral flow as well as continued progress with the quest to bring DPP HIV/Syphilis to the U.S. market. As a reminder the last of Alere's marketing rights rolled off at the end of May, resulting in U.S. lateral flow sales falling from a total of $2.5M in Q2 and Q3 2015 to $1.3M over the same periods in 2016. But, again, the qoq growth from Q2 ($617k) to Q3 ($707k) this year and implications that this business has more room to run may mean that CEMI's transition from supplier to direct sales in the U.S. is gaining traction.

And CEMI still expects their U.S. DPP HIV/Syphilis study to complete in Q1 2017. If all goes well, including timely FDA clearance, we think the test could launch in this country sometime later that same year. Eventual commercialization should not only benefit U.S.-related revenue but gross margins as well. The company recently brought on two experienced sales executives, one of which is tasked with managing the America's (the other with EMEA region) – which we think is another sign that CEMI remains focused on growing their domestic business as well as the international side.

Most of the rest of the revenue beat in Q3 was related to initial income from the BARDA (U.S. HHS) grant that the company scored in August for development and commercialization of DPP Zika and other related tests. This is not only a major financial milestone (the largest in CEMI's history, at least $5.9M and up to $13.2M) but, in our opinion, also symbolic in terms of validation of the DPP technology and Chembio's quality reputation.

***International DPP STD Opportunities…***
While DPP HIV and related product sales via FIOCRUZ remain soft in Brazil (largely related to due to a competitor under-pricing a tender for which CEMI decided against under-bidding), we think there are opportunities for growth of the international STD business. Their DPP HIV/Syphilis test, which has had significant success in Mexico, could be available in Europe and the Caribbean region in the near term – CEMI noted that they are now in the process of submitting the technical dossier required to obtain CE Mark.

While POC testing in general remains relatively nascent in most of Europe which we think may limit its uptake in that part of the world, the Caribbean could hold significant promise. CEMI penned a distribution agreement with Isla Lab Caribbean to distribute their DPP and lateral flow STD products as well as their DPP fever products. Isla Lab, as noted by management on the call, is the leading distributor of diagnostic products in the Caribbean.

Southeast Asia is another territory that CEMI clearly sees opportunity in both STD and fever which prompted their move to acquire the company. In early February CEMI entered a technology transfer and licensing agreement with Malaysia-based RVR, allowing that company to manufacture and sell certain DPP products, including DPP HIV and DPP HIV/Syphilis. CEMI, which expects to close on the acquisition in Q1 2017, noted that being able to manufacture in Malaysia allows for lower cost which, in-turn, makes commercialization into SE Asia feasible from a profitability standpoint. This opens up a relatively large population to CEMI that would not have been as accessible and should also help to streamline the regulatory processes in that part of the world.

- **Lateral flow**:
    - U.S. sales held up well in 2015, generating $5.3M of revenue, representing ~24% of product revenue last year. Alere's distribution rights to SURE-CHECK ended on May 31, 2016. CEMI is now marketing this via their own sales force and third party distributors. The 48% drop in revenue from Q2 and Q3 2015 to the same periods in 2016 is indicative of the greatly reduced distribution reach. CEMI noted that they recently implemented a new pricing program, significantly cutting prices to the U.S. public health segment (included in this is CEMI's lateral flow as well as DPP HIV assays). While the yoy comparisons suggest difficulties, the 15%

sequential growth from Q2 to Q3 of this year, combined with management's comments on the call indicating that this business is showing signs of firming up are certainly encouraging. The company recently brought on two sales executives, one of which is responsible for the Americas markets, which could provide another potential catalyst towards turning U.S. lateral flow sales back to growth.

- International – contributed $4.6M in 2015, or ~24% of product revenue. 2015 was a good, but not exceptional year for international lateral flow – for reference, 2013 did $11.4M. We are modeling a 38% contraction from 2015 to 2016 – this line item has significant potential to beat, or miss as, again it's tough to model. The SURE CHECK HIV 1/2 (lateral flow) self-testing product launched in the U.K. and France in 2015 and contributed ~$1M. That may not repeat in 2016, however, given some stocking in 2015 and the lower prevalence of POC in Europe.

- **DPP**: generated $11.3M in revenue in 2015, down 28% from 2014 ($15.7M) with 65% of the decrease coming in Q4. While CEMI does not break out DPP sales by channel, FIOCRUZ likely still represents a meaningful portion. DPP held up well in Q1 (+8% yoy to $2.7M) but tumbled 79% in Q2 to just $835k and fell 74% to $998k in Q3. While we model contraction of 45% for the full year, we think Q4 could show a return to growth from initial contribution from the DPP fever assays.

  We think 2017 DPP sales benefit from a full year of the initial fever assays. U.S. clinical study for DPP HIV/Syphilis is expected to complete in Q1 2017. If all goes well, this could launch in the U.S. in 2017 – we think this could be a significant product once commercialized and potentially be another catalyst to revenue next year. The other major catalyst should be DPP fever – with additional assays that could come to market on a fairly regular basis.

- **Tech Collaborations**: CEMI has several irons in the fire including developing tests for DPP Cancer, DPP TBI and DPP Bovine. The most recent tech collaboration came in September 2016 when CEMI received a $600k grant from the U.S. Department of Agriculture to develop a DPP test for bovine tuberculosis.
  - **DPP Cancer**: feasibility completed, in product development stage
  - **DPP TBI:** completed IRB agreements with several hospitals, initial studies commenced with prototype DPP TBI assay
  - **DPP Bovine:** 2-year grant for development of DPP BovidTB Assay

**Q3 Financials**

Q3 revenue of $3.8M was down 46% yoy but increased 15% from Q2 of this year. Total HIV lateral flow sales were $1.5M, down 48% yoy but up 26% from Q2 with both international (+39% from Q2) and U.S. (+15% from Q2) markets contributing to the sequential growth. As noted, while the roll-off of the remainder of Alere's domestic marketing rights has taken a toll on domestic lateral flow sales, CEMI's efforts towards reviving this business which has included a renewed sales and marketing strategy and allocation of additional resources, could return it to growth. And while the downsized distribution and headwinds from newer technologies (such as CEMI's DPP as well as 4$^{th}$ –gen testing) likely means domestic lateral flow sales will not return to historic levels, if CEMI can maintain even relatively flat growth of this business going forward, it would provide upside to our current estimates.

DPP sales came in at $998k, down 74% yoy but up 20% sequentially. As noted above, the contraction mostly relates to lower DPP HIV sales to FIOCRUZ as a result of a competitor under-pricing a tender. But, again, we look for initial contribution from the fever portfolio in Q4 and a much more significant contribution in 2017 when we expect additional fever-related regulatory approvals and launches in high fever-risk geographies such as S. America, the Caribbean and S.E Asia. The broad and deep distribution and strategically located manufacturing brought on with the recent addition of Isla Lab and impending acquisition of RVR should provide CEMI the ability to launch quickly upon regulatory green-lighting in these high potential territories.

Q3 gross margin and product margin were 52.1% and 28.3%, compared to 42.3% and 36.0% in the year-earlier comparable period and 48.4% and 17.1% in Q2 of this year.

**EPS**

Q3 net loss and EPS were $2.1M and ($0.19), inline with our $2.1M and ($0.19) estimates.

**Cash**
Cash used in operating activities was $1.8M in Q3. Excluding changes in working capital, cash used in operating activities was also $1.8M. Cash balance, which was recently bolstered by the $13.8M gross ($12.5M net) equity raise, cash balance at Q3 quarter-end was approximately $12.2M.

***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 impending RVR acquisition, CEMI made additional substantive progress towards realizing exploiting the potential of their DPP fever portfolio.

This includes the first regulatory approvals for the DPP Zika test. In July 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). CEMI notes in the Q3 10-Q that they expect initial sales of DPP Zika in these areas in Q4 of this year.

DPP Zika also received approval from Brazil's health regulatory agency (ANVISA). CEMI is now awaiting ANVISA approval of the Micro Reader and as well as INCQS approval of the test and 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. Timely regulatory approval could potentially coincide with the start of summer in Brazil, which is less than two weeks away and when risk of infection of the Zika virus, which is transmitted by the Aedes-species mosquito, is the highest.

The stand-alone DPP Dengue assay, which was developed in collaboration with RVR, has completed validation studies. CEMI expects commercialization to commence in S.E. Asia via RVR in Q4 of this year. CEMI noted that RVR is expected to generate sales of approximately $1.5M in 2016. Given the expectation of additional fever-related launches in 2017 and the large populations of S.E. Asia in Zika-prone geographies, we think the RVR channel could be another significant near-term contributor.

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.

DPP Zika and DPP Zika/Chikungunya/Dengue Combination Assay and the DPP Micro Reader will also be 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.

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 with validation expected to complete in the coming weeks, followed by field testing, which could start early next year.

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 expects to complete 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. CEMI expects verification testing to begin in Q1 2017.

## OUR OUTLOOK
**Revenue**
We look for 2016 revenue of $18.1 million, implying a decrease of 26% from 2015. We have lateral flow falling 26% and DPP down 45% - although, we think DPP begins to show yoy growth in Q4 with contribution from DPP fever. We think upside to our model could come from more substantial sequential growth in U.S. lateral flow or higher international lateral flow, the latter from aid-agency tenders.

We think fever, with a full year of DPP Zika in some territories and additional fever assays that could come to market on a fairly regular basis, drives most of the top-line in 2017. DPP HIV/Syphilis could also launch in the U.S. and contribute in 2017. We currently model revenue of $25.5M in 2017, implying growth of 41%.

**Net Income / EPS**
We look for net income and EPS (excluding tax valuation) of ($7.4)M and ($0.70) in 2016, improving to ($4.3)M and ($0.33) in 2017.

## VALUATION

Given expected outsized growth in Fever, we value CEMI at a slight premium to OSUR. We value CEMI at 4.2x 2017 estimated revenue (vs OSUR @ 4.0), or approximately $9/share.

## INCOME STATEMENT

Chembio Diagnostics, Inc.

| | 2015 A | Q1A | Q2A | Q3A | Q4E | 2016 E | 2017 E | 2018 E | 2019 E |
|---|---|---|---|---|---|---|---|---|---|
| **Product sales** | **$21,887** | **$5,917** | **$2,034** | **$2,502** | **$3,373** | **$13,828** | **$21,433** | **$27,546** | **$34,588** |
| *% of total revenue* | *90.2%* | *89.6%* | *62.3%* | *66.8%* | *75.9%* | *76.6%* | *83.9%* | *87.2%* | *92.5%* |
| *YOY Growth* | *-15.7%* | *5.4%* | *-67.8%* | *-59.7%* | *-9.8%* | *-36.8%* | *55.0%* | *28.5%* | *25.6%* |
| **License & royalty income** | **$53** | **$22** | **$34** | **$78** | **$41** | **$175** | **$411** | **$526** | **$310** |
| *% of total revenue* | *0.2%* | *0.3%* | *1.0%* | *2.1%* | *0.9%* | *1.0%* | *1.6%* | *1.7%* | *0.8%* |
| **R&D contracts, grants, milestones** | **$2,316** | **$662** | **$1,198** | **$1,167** | **$1,030** | **$4,057** | **$3,700** | **$3,500** | **$2,500** |
| *% of total revenue* | *9.5%* | *10.0%* | *36.7%* | *31.1%* | *23.2%* | *22.5%* | *14.5%* | *11.1%* | *6.7%* |
| Total Revenues | $24,255.5 | $6,601.6 | $3,266.4 | $3,746.5 | $4,444.0 | $18,059.4 | $25,544.1 | $31,571.2 | $37,397.2 |
| *YOY Growth* | *-12.3%* | *5.9%* | *-51.4%* | *-45.6%* | *0.5%* | *-25.5%* | *41.4%* | *23.6%* | *18.5%* |
| Cost of Revenues | $13,769 | $3,436 | $1,686 | $1,794 | $2,429 | $9,345 | $13,632 | $16,582 | $20,130 |
| Gross Income | $10,486 | $3,166 | $1,580 | $1,952 | $2,015 | $8,715 | $11,912 | $14,989 | $17,267 |
| *Gross Margin* | *43.2%* | *48.0%* | *48.4%* | *52.1%* | *45.4%* | *48.3%* | *46.6%* | *47.5%* | *46.2%* |
| *Product Margin* | *37.1%* | *41.9%* | *17.1%* | *28.3%* | *28.0%* | *32.4%* | *36.4%* | *39.8%* | *41.8%* |
| Research & Development | $6,377 | $1,634 | $2,367 | $2,264 | $2,339 | $8,604 | $7,341 | $6,815 | $6,684 |
| *% R&D* | *26.3%* | *24.8%* | *72.5%* | *60.4%* | *52.6%* | *47.6%* | *28.7%* | *21.6%* | *17.9%* |
| Selling General & Admin | $7,663 | $1,999 | $1,599 | $1,832 | $2,133 | $7,564 | $8,864 | $9,913 | $11,032 |
| *% SG&A* | *31.6%* | *30.3%* | *48.9%* | *48.9%* | *48.0%* | *41.9%* | *34.7%* | *31.4%* | *29.5%* |
| Operating Income | ($3,554) | ($468) | ($2,386) | ($2,144) | ($2,457) | ($7,453) | ($4,292) | ($1,740) | ($449) |
| *Operating Margin* | *-14.7%* | *-7.1%* | *-73.0%* | *-57.2%* | *-55.3%* | *-41.3%* | *-16.8%* | *-5.5%* | *-1.2%* |
| Other income (expense) | ($5) | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Interest income, net | $1 | $3 | $2 | $6 | $5 | $15 | ($8) | ($20) | ($10) |
| Pre-Tax Income | ($3,558) | ($465) | ($2,384) | ($2,138) | ($2,452) | ($7,438) | ($4,300) | ($1,760) | ($459) |
| Taxes | ($1,161) | ($162) | $5,963 | $0 | $0 | $5,801 | $0 | $0 | $0 |
| *Tax Rate* | *32.6%* | *34.7%* | *-250.1%* | *0.0%* | *0.0%* | *-78.0%* | *0.0%* | *0.0%* | *0.0%* |
| Net Income | ($2,397) | ($304) | ($8,347) | ($2,138) | ($2,452) | ($13,240) | ($4,300) | ($1,760) | ($459) |
| *YOY Growth* | *110.8%* | *-53.1%* | *1156.9%* | *389.1%* | *277.6%* | *452.3%* | *-67.5%* | *-59.1%* | *-73.9%* |
| *Net Margin* | *-9.9%* | *-4.6%* | *-255.5%* | *-57.1%* | *-55.2%* | *-73.3%* | *-16.8%* | *-5.6%* | *-1.2%* |
| EPS | ($0.25) | ($0.03) | ($0.86) | ($0.19) | ($0.20) | ($1.25) | ($0.33) | ($0.13) | ($0.03) |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| Weighted Avg. Shares O/S | 9,626 | 9,632 | 9,668 | 11,142 | 12,000 | 10,610 | 13,000 | 13,800 | 14,000 |

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