



May 9, 2017

## **ChemBio Diagnostics Reports First Quarter 2017 Financial Results**

### **Conference Call and Webcast Today at 4:30 p.m. Eastern Time**

MEDFORD, N.Y., May 09, 2017 (GLOBE NEWSWIRE) -- ChemBio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care ("POC") diagnostic tests for infectious diseases, today reported financial results for the quarter ended March 31, 2017.

John J. Sperzel III, Chief Executive Officer, stated, "We are pleased with the early results of the strategy to expand our commercial channels, focusing on the United States (U.S.), Latin America, Asia Pacific, Europe, and Africa. During the fourth quarter of 2016, we made key appointments to strengthen our commercial leadership team, and during the first quarter of 2017 we added experienced diagnostic sales executives in Latin America, Africa and Asia Pacific. With this enhanced organization, we achieved a geographic mix of product sales for the first quarter of 2017, consisting of 39% of sales in Latin America, 26% in Asia Pacific, 20% in the U.S., 8% in Europe, and 7% in Africa.

"During the quarter, the Company continued to expand its product portfolio by leveraging our patented DPP<sup>®</sup> technology platform, which we believe will result in near-term and long-term growth opportunities. The Company's product development strategy includes two primary objectives: 1) to strengthen our core business in the sexually transmitted disease market, and 2) to build a strong position in the fever and tropical disease market.

"To strengthen our core business in the sexually transmitted disease market, the Company continues to focus on our DPP<sup>®</sup> HIV-Syphilis Assay in response to the global concerns related to co-infection and mother-to-child transmission of both HIV and Syphilis. During the first quarter of 2017, we received a CE mark for our DPP<sup>®</sup> HIV-Syphilis Assay, which allows us to market and sell the product within the member states of the European Union and in the Caribbean, except for Puerto Rico. The U.S. clinical trial to support our FDA application for the DPP<sup>®</sup> HIV-Syphilis Assay, which was initiated during the first quarter of 2016, has been completed. In March 2017, the FDA requested further clinical studies in addition to those recently completed. As a result, ChemBio is in discussion with the FDA regarding the timing of filing the Premarket Approval Application. Another important development subsequent to the end of the first quarter of 2017 is that ChemBio received a \$5.8 million order from Bio-Manguinhos/Fiocruz to supply test components and intermediate product for the production of DPP<sup>®</sup> HIV 1/2 Assays in Brazil and subsequent supply to Brazil's Ministry of Health. We believe that substantially all of this order will be shipped prior to year-end 2017.

To build a strong position in the fever and tropical disease market, we continue to make significant progress toward the goal of commercializing multiple products during 2017. During the first quarter of 2017, we initiated sales of our DPP<sup>®</sup> Zika Assay and our DPP<sup>®</sup> Zika/Dengue/Chikungunya Assay to the Centers for Disease Control and Prevention for use in a pilot surveillance program in Peru, India, Guatemala and Haiti. Also during the 2017 first quarter, we initiated sales of our DPP<sup>®</sup> Dengue Assay in Asia Pacific, and we continue to pursue important regulatory approvals for our DPP<sup>®</sup> Zika System with the U.S. FDA Emergency Use Authorization (EUA), World Health Organization Emergency Use Assessment And Listing (EUAL), and Brazil Agência Nacional de Vigilância Sanitária (ANVISA)."

Addressing the Company's financial results, Mr. Sperzel commented, "During the first quarter of 2017, we achieved total revenue of \$6.3 million which included product revenue of \$5.4 million. While total revenue represented a 4.2% decrease from the first quarter of 2016, it is important to note that the first quarter of 2016 included approximately \$1.8 million in product purchases by our previous U.S. distributor, while the first quarter of 2017, included approximately \$1.4 million in sales from our recently acquired Malaysia subsidiary. During the first quarter of 2017, we continue to see important quarter-on-quarter sales growth.

"Within a number of geographic regions, we had several notable sales successes during the first quarter of 2017. In Asia Pacific, we achieved \$1.4 million in product sales, driven by key tender wins in Malaysia, representing the first time the Company has achieved meaningful sales in Asia. In the U.S., we achieved \$1.1 million in product sales, driven by a number of HIV tenders, which were won during the last two quarters, and much of which we expect to realize over the next 18

months. In Latin America, we achieved product sales of \$2.1 million driven by sales to Brazil and, as mentioned above, we received a \$5.8 million order from Bio-Manguinhos/Fiocruz and we believe that substantially all of this order will be shipped prior to year-end 2017. In Europe and Africa, we achieved \$0.8 million in combined product sales, largely driven by HIV sales in the HIV self-testing and professional HIV testing business.

"In closing, we believe the advances made during the first quarter of 2017 demonstrate our commitment to continue building global commercial channels, thereby strengthening our core business in the sexually transmitted disease market, and building a strong position in the high-growth fever and tropical disease market."

#### **Selected Summary Financial Information comparing the 2017 first quarter with the 2016 first quarter:**

- | Total revenues of \$6.3 million, compared with \$6.6 million.
- | Product sales of \$5.4 million, compared with \$5.9 million.
- | Operating loss of \$1.6 million, compared with operating loss of \$0.47 million.
- | Net loss of \$1.6 million, or \$0.13 per diluted share, compared with net loss of \$0.30 million, or \$0.03 per diluted share.

#### **Additional Financial Information**

##### First Quarter:

Total revenues for the first quarter of 2017 of \$6.3 million decreased 4.2% compared with \$6.6 million in the prior-year period. Product sales for the first quarter of 2017 of \$5.4 million decreased 8.3% compared with \$5.9 million in the prior-year period, again largely due to the \$1.8 million of product purchases in the 2016 period by our former U.S. SURE CHECK<sup>®</sup> distributor, which did not make any material purchases after March 31, 2016. R&D milestone, and grant and royalty revenues for the first quarter of 2017 of \$0.9 million increased 31.2% compared with \$0.7 million in the prior-year period.

Gross margin dollars for the first quarter of 2017 of \$3.1 million decreased 1.9% compared with \$3.2 million in the prior-year period, due primarily to the decrease in product sales. The amount of product gross margin for the first quarter of 2017 of \$2.2 million decreased 11.0% compared with \$2.5 million in the prior-year period.

R&D expenses for the first quarter of 2017 of \$2.2 million increased 37.5%, compared with \$1.6 million in the prior-year period. This increase is due primarily to increased clinical trial expenses as well as R&D activities for projects and grants.

Selling, general and administrative expenses for the first quarter of 2017 of \$2.5 million increased 24.5%, compared with \$2.0 million in the prior-year period, largely due to increased wages and related costs, marketing materials, stock-based compensation, and travel, entertainment and trade shows, which were partially offset by decreased commissions on sales, decreased consulting, and decreases in investor relations expenses and professional fees.

Operating loss for the first quarter of 2017 was \$1.6 million, compared with an operating loss of \$0.47 million in the prior-year period.

Net loss for the first quarter of 2017 was \$1.6 million, or \$0.13 per diluted share, compared with net loss of \$0.3 million, or \$0.03 per diluted share, in the prior-year period.

##### Balance Sheet Highlights:

The Company had cash and cash equivalents of \$5.6 million as of March 31, 2017, compared with \$10.6 million as of December 31, 2016. The decrease was primarily due to cash used in operating activities for the first quarter of 2017, as well as cash used in investing activities. The Company's working capital decreased by \$2.3 million from \$14.7 million as of December 31, 2016 to \$12.4 million as of March 31, 2017.

The Company had Accounts Receivable net of allowance for doubtful accounts of \$5.7 million as of March 31, 2017, compared with \$3.4 million as of December 31, 2016. Cash and Accounts Receivable combined as of March 31, 2017 was \$11.3 million as compared to \$13.9 million at December 31, 2016. During the months of April and May 2017 we collected \$2.8 million of the March 31, 2017 accounts receivable balance.

#### **About Chembio Diagnostics**

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing \$8.0 billion point-of-care testing market. Chembio markets each of its DPP<sup>®</sup> HIV 1/2 Assay, HIV 1/2 STAT-PAK<sup>®</sup> Assay, and

SURE CHECK<sup>®</sup> HIV 1/2 Assay, with these Chembio brand names, in the U.S. and internationally, both directly and through third-party distributors.

Chembio has developed a patented point-of-care test platform technology, the Dual Path Platform (DPP<sup>®</sup>) technology, which has significant advantages over lateral-flow technologies. This technology is providing Chembio with a significant pipeline of business opportunities for the development and manufacture of new products.

Headquartered in Medford, NY, Chembio is licensed by the U.S. Food and Drug Administration (FDA) as well as the U.S. Department of Agriculture (USDA), and is certified for the global market under the International Standards Organization (ISO) directive 13485. Each of Chembio Diagnostic Systems, Inc. and RVR Diagnostics Sdn Bhd is a wholly-owned subsidiary of Chembio Diagnostics, Inc. For more information, please visit: [www.chembio.com](http://www.chembio.com).

## Forward-Looking Statements

*Statements contained herein that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933, as amended. Forward-looking statements include statements regarding the intent, belief or current expectations of the Company and its management. Such statements, which are estimates only, reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events, or performance may differ materially from the above forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to Chembio's ability to obtain additional financing and to obtain regulatory approvals in a timely manner, as well as the demand for Chembio's products. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.*

(TABLES TO FOLLOW)

**Chembio Diagnostics, Inc. & Subsidiaries**  
**Summary of Consolidated Results of Operations**  
**(UNAUDITED)**

	<b><u>For the three months ended</u></b>	
	<b><u>March 31, 2017</u></b>	<b><u>March 31, 2016</u></b>
<b>Net product sales</b>	<b>\$ 5,427,427</b>	<b>\$ 5,917,019</b>
<b>License and royalty revenue</b>	<b>100,000</b>	<b>22,201</b>
<b>R&amp;D, milestone and grant revenue</b>	<b>797,740</b>	<b>661,879</b>
<b>TOTAL REVENUES</b>	<b>\$ 6,325,167</b>	<b>\$ 6,601,099</b>
<b>GROSS MARGIN</b>	<b>\$ 3,105,952</b>	<b>\$ 3,165,548</b>
<b>Research and development expenses</b>	<b>\$ 2,246,572</b>	<b>\$ 1,634,298</b>
<b>Selling, general and administrative expenses</b>	<b>\$ 2,488,337</b>	<b>\$ 1,999,404</b>
<b>LOSS FROM OPERATIONS</b>	<b>\$ (1,628,957)</b>	<b>\$ (468,154)</b>
<b>OTHER INCOME:</b>	<b>\$ 13,382</b>	<b>\$ 2,564</b>
<b>Income tax provision (benefit)</b>	<b>\$ -</b>	<b>\$ (162,000)</b>
<b>NET LOSS</b>	<b>\$ (1,615,575)</b>	<b>\$ (303,590)</b>
<b>Basic loss per share</b>	<b>\$ (0.13)</b>	<b>\$ (0.03)</b>
<b>Diluted loss per share</b>	<b>\$ (0.13)</b>	<b>\$ (0.03)</b>

Weighted average number of shares outstanding, basic	12,270,679	9,631,686
Weighted average number of shares outstanding, diluted	12,270,679	9,631,686

**Chembio Diagnostics, Inc. & Subsidiaries**  
**Summary of Consolidated Balance Sheets**  
**(UNAUDITED)**

	<u>March 31,</u> <u>2017</u>	<u>December 31, 2016</u>
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 5,582,482	\$ 10,554,464
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at March 31, 2017 and December 31, 2016, respectively	5,681,524	3,383,729
Inventories	3,754,481	3,335,188
Prepaid expenses and other current assets	910,413	840,145
<b>TOTAL CURRENT ASSETS</b>	<b>15,928,900</b>	18,113,526
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>1,901,557</b>	1,709,321
<b>OTHER ASSETS</b>	<b>3,057,049</b>	752,389
<b>TOTAL ASSETS</b>	<b>\$ 20,887,506</b>	<b>\$ 20,575,236</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>TOTAL CURRENT LIABILITIES</b>	<b>\$ 3,514,825.00</b>	\$ 3,405,650.00
<b>TOTAL LIABILITIES</b>	<b>3,514,825</b>	3,405,650
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock - \$.01 par value; 100,000,000 shares authorized; 12,229,122 and 12,026,847 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	122,991	120,268
Additional paid-in capital	62,537,730	60,721,783
Accumulated deficit	(45,288,040)	(43,672,465)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>17,372,681</b>	17,169,586
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 20,887,506</b>	<b>\$ 20,575,236</b>

**Chembio Diagnostics, Inc. & Subsidiaries**  
**Summary of Consolidated Cash Flows**  
**For the three Months ended**  
**(UNAUDITED)**

	<u>March 31, 2017</u>	<u>March 31, 2016</u>
Net cash used in operating activities	\$ (3,871,811)	\$ (2,690,610)
Net cash used in investing activities	(1,100,171)	(28,407)
Net cash provided by financing activities	-	-
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>\$ (4,971,982)</b>	<b>\$ (2,719,017)</b>

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