



March 8, 2016

## **Chembio Diagnostics Reports 2015 Financial Results**

### **Conference Call and Webcast Today at 10:00 a.m. Eastern Time**

MEDFORD, N.Y., March 08, 2016 (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 year ended December 31, 2015.

John J. Sperzel III, Chief Executive Officer, stated, "During 2015, Chembio took important strategic steps to expand our patented DPP® technology to new markets. While the company continues to strengthen its sexually transmitted disease business, we are also building robust product pipelines in two new areas: fever disease and technology collaborations, and we have been very successful executing our strategy to obtain grant-based or partner-based funding for these projects. In the last year, our fever disease product portfolio has grown to include the following highly differentiated products:

- 1 The DPP® Fever Panel Assay, which is funded by the Paul G. Allen Ebola Program, is a point-of-care (POC) test for the simultaneous detection of Malaria, Dengue Fever, Chikungunya, Zika, Ebola, Lassa and Marburg;
- 1 The DPP® Malaria-Ebola and DPP® Ebola Assays, which were developed through a research collaboration agreement with the Centers for Disease Control and Prevention (CDC), are currently being field tested in West Africa;
- 1 The DPP® Dengue Fever Assays, which have been funded by an undisclosed entity, are currently being field tested in Asia;
- 1 The DPP® Malaria Assay, which has been funded by The Bill and Melinda Gates Foundation, is 10-times more sensitive than the current world-leading POC malaria test; and,
- 1 The recently-announced DPP® Zika Assay, which has received initial funding from the Paul G. Allen Family Foundation.

While sexually transmitted disease products will continue to make important contributions to our business, we believe our new fever disease portfolio and technology collaborations will pave the way for future growth."

Mr. Sperzel continued, "Our new DPP® Zika Assay development showcases the exceptional versatility and broad applicability of our DPP® technology. In February, the World Health Organization (WHO) declared the Zika virus a 'public health emergency of international concern,' and today the virus has spread to more than twenty countries. In response to the outbreak, we began exploring the feasibility of a POC DPP® Zika Assay. We are fortunate that the Paul G. Allen Family Foundation, recognizing the urgency of the matter, moved swiftly to provide Chembio with a grant to support the initiation of the project. We are pleased to report that in a few short weeks, we have developed a prototype assay and are in discussions with a number of agencies, all of which are interested in supporting the rapid development of this critical product. While this program is in the early stages, we hope that success with the DPP® Zika Assay, like our DPP® Ebola Assay, will further demonstrate Chembio's ability to rapidly and effectively deploy our DPP® technology to address the world's most serious health threats."

Addressing the company's financial results, Mr. Sperzel commented, "In the U.S. during 2015, Chembio recorded an increase in lateral flow HIV sales of approximately \$440,000 and an increase of DPP® sales of more than \$1.0 million (primarily as a result of sales to the CDC for DPP® Malaria-Ebola and DPP® Ebola Assays) as compared to the respective U.S. sales in 2014. We are optimistic about the increasing demand for our products in the U.S. We will also have full control of SURE CHECK® HIV Assay, effective June 1, 2016, to add to our U.S. commercial efforts. In Latin America, we experienced a decline in sales in 2015 due primarily to a \$3.5 million decrease in sales of DPP® HIV-Syphilis Assay in Mexico, related to excess inventory from 2014, and a \$2.1 million decrease in sales of DPP® HIV Assay in Brazil. We expect that our recently announced DPP® Zika Assay program will expand our sales in this region, and given our initial indications for 2016, we believe Latin America will continue to be a strong market for Chembio."

Mr. Sperzel concluded, "Lastly, I'd like to comment on Chembio's filings this morning. In addition to our 10-K, we made filings to renew our shareholder rights agreement as well as our shelf registration. Our shareholder rights agreement expired at the end of November 2015 and our shelf registration expired in January 2016. As a standard corporate policy, Chembio management takes steps to keep all such agreements and tools current, and our filings today should not be interpreted to signify anything other than prudent business practice."

#### **Financial information comparing the full year of 2015 to the full year of 2014:**

- | Total revenues of \$24.26 million, compared with \$27.65 million (a decrease of 12.3%).
- | Product sales of \$21.89 million, compared with \$25.95 million (a decrease of 15.7%).
- | Operating loss of \$3.55 million, compared with operating loss of \$1.55 million.
- | Net loss of \$2.40 million, or \$0.25 per diluted share, compared with net loss of \$1.14 million, or \$0.12 per diluted share.

#### **Financial information comparing the 2015 fourth quarter to the 2014 fourth quarter:**

- | Total revenues of \$4.42 million, compared with \$7.10 million (a decrease of 37.7%).
- | Product sales of \$3.74 million, compared with \$6.55 million (a decrease of 42.9%).
- | Operating loss of \$1.20 million, compared with operating loss of \$0.67 million.
- | Net loss of \$.65 million, or \$0.07 per diluted share, compared with net loss of \$.50 million, or \$0.05 per diluted share.

#### **Additional Financial Information**

##### For the Full Year:

Total revenues for the full year of 2015 of \$24.26 million were down 12.3% compared with total revenues of \$27.65 million in the prior-year period. Product sales in the 2015 full year of \$21.89 million were down 15.7% compared with product sales of \$25.95 million for 2014. R&D milestone, and grant and royalty revenues for the full year 2015 increased to \$2.37 million from \$1.70 million in 2014.

Gross margin dollars for the full year 2015 decreased 3.0% to \$10.49 million compared with \$10.81 million for 2014, due primarily to the decrease in product revenues. The amount of product gross margin for the full year of 2015 decreased 11.0% to \$8.12 million, from \$9.12 million in 2014.

R&D expenses for the full year of 2015 were \$6.38 million, compared with \$4.83 million in 2014. This increase is due primarily to increased R&D activities for projects and grants. Some projects are on a milestone basis for which revenue cannot be recognized until the milestone is achieved, while expenses to reach that milestone are expensed in the period incurred.

Selling, general and administrative expenses for the full year of 2015 increased to \$7.66 million from \$7.53 million in 2014, largely due to increased staffing, wages and related costs, increased travel expenses (related to our commercialization efforts), and professional fees.

Operating loss for the full year of 2015 was \$3.55 million, compared with an operating loss of \$1.55 million for 2014.

Net loss for the full year of 2015 was \$2.40 million, or \$0.25 per diluted share, compared with net loss of \$1.14 million, or \$0.12 per diluted share, for 2014.

##### Fourth Quarter:

Total revenues for the fourth quarter of 2015 of \$4.42 million were down 37.7% compared with total revenues of \$7.10 million in the prior-year period. Product sales in the 2015 fourth quarter of \$3.74 million were down 42.9% compared with product sales of \$6.55 million in the prior-year period. R&D milestone, and grant and royalty revenues for the three months ended December 31, 2015 increased to \$680,000 from \$546,000 in the prior-year period.

Gross margin dollars for the 2015 fourth quarter decreased 35.7% to \$1.87 million compared with \$2.91 million for the prior-year period, due primarily to the decrease in product revenues. The amount of product gross margin dollars for the fourth quarter of 2015 decreased 49.6% to \$1.19 million, from \$2.36 million in the prior-year period.

R&D expenses in the fourth quarter of 2015 were \$1.47 million, compared with \$1.39 million in the prior-year period. This increase is due primarily to increased R&D activities for projects and grants. Some projects are on a milestone basis for

which revenue cannot be recognized until the milestone is achieved, while expenses to reach that milestone are expensed in the period incurred.

Selling, general and administrative expenses in the fourth quarter of 2015 decreased to \$1.61 million from \$2.19 million in the prior-year period, largely due to decreased commissions, stock-based compensation and marketing material expenses, partially offset by increases in consulting and professional fees.

Operating loss for the fourth quarter of 2015 was \$1.20 million, compared with an operating loss of \$0.67 million for the prior-year period.

Net loss for the fourth quarter of 2015 was \$.65 million, or \$0.07 per diluted share, compared with net loss of \$0.50 million, or \$0.05 per diluted share, for the prior-year period.

#### Balance Sheet Highlights:

The Company had cash and cash equivalents of \$5.38 million as of December 31, 2015, compared with \$4.61 million as of December 31, 2014. The increase was primarily due to net cash provided by operating activities of \$1.79 million, partially offset by investing activities to fund the purchase of a license and deposits on and purchase of fixed assets of \$1.03 million. Our working capital decreased by \$3.22 million during the year from \$12.37 million to \$9.15 million.

#### **Conference Call**

To participate on the conference call on March 8, 2016 at 10:00 a.m. Eastern Time, please dial (877) 407-0778 from the U.S. or (201) 689-8565 from outside the U.S. In addition, following the completion of the call, a telephone replay will be accessible until March 15, 2016 at 11:59 p.m. Eastern Time by dialing (877) 660-6853 from the U.S. or (201) 612-7415 from outside the U.S. and entering conference ID #: 13631215. Those interested in listening to the conference call live via the internet may do so by visiting the Investor Relations section of Chembio's website at [www.chembio.com](http://www.chembio.com). The conference call may also be accessed via the internet at <http://www.investorcalendar.com/IC/CEPage.asp?ID=174739>. An archive of the webcast will be available for 90 days on the Company's website at [www.chembio.com](http://www.chembio.com).

#### **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 its DPP<sup>®</sup> HIV 1/2 Assay and HIV 1/2 STAT-PAK<sup>®</sup> Assay in the U.S. and internationally. The Company's SURE CHECK<sup>®</sup> HIV 1/2 Assay is marketed exclusively in the U.S. as Clearview<sup>®</sup> Complete by a single entity. Outside the U.S., Chembio markets its SURE CHECK<sup>®</sup> HIV 1/2 Assay primarily through distributors.

Chembio has developed a patented point-of-care (POC) 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. Chembio Diagnostic Systems, Inc. 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. & Subsidiary**  
**Summary of Consolidated Results of Operations**  
**(UNAUDITED)**

	<u>For the three months ended</u>		<u>For the years ended</u>	
	<u>December 31,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>	<u>December 31,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
Net product sales	\$ 3,740,824	\$ 6,549,254	\$ 21,886,688	\$ 25,949,769
License and royalty revenue	18,736	7,644	52,753	23,257
R&D, milestone and grant revenue	661,256	538,408	2,316,044	1,672,258
<b>TOTAL REVENUES</b>	<b>\$ 4,420,816</b>	<b>\$ 7,095,306</b>	<b>\$ 24,255,485</b>	<b>\$ 27,645,284</b>
<b>GROSS MARGIN</b>	<b>\$ 1,870,543</b>	<b>\$ 2,908,472</b>	<b>\$ 10,486,827</b>	<b>\$ 10,814,023</b>
Research and development expenses	\$ 1,466,252	\$ 1,393,823	\$ 6,377,839	\$ 4,832,537
Selling, general and administrative expenses	\$ 1,605,814	\$ 2,186,825	\$ 7,663,035	\$ 7,531,739
<b>LOSS FROM OPERATIONS</b>	<b>\$ (1,201,523)</b>	<b>\$ (672,176)</b>	<b>\$ (3,554,047)</b>	<b>\$ (1,550,253)</b>
<b>OTHER INCOME (LOSS)</b>	<b>\$ (4,334)</b>	<b>\$ 1,312</b>	<b>\$ (3,238)</b>	<b>\$ 132</b>
Income tax provision (benefit)	\$ (556,873)	\$ (175,002)	\$ (1,160,243)	\$ (412,918)
<b>NET LOSS</b>	<b>\$ (648,984)</b>	<b>\$ (495,862)</b>	<b>\$ (2,397,042)</b>	<b>\$ (1,137,203)</b>
Basic loss per share	\$ (0.07)	\$ (0.05)	\$ (0.25)	\$ (0.12)
Diluted loss per share	\$ (0.07)	\$ (0.05)	\$ (0.25)	\$ (0.12)
Weighted average number of shares outstanding, basic	9,628,248	9,611,139	9,626,028	9,530,320
Weighted average number of shares outstanding, diluted	9,628,248	9,611,139	9,626,028	9,530,320

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

	<u>December 31,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 5,376,931	\$ 4,614,538
Accounts receivable, net of allowance for doubtful accounts of \$52,000 and \$52,000 at December 31, 2015 and 2014, respectively	2,422,971	8,338,889

Inventories	3,578,025	3,638,299
Prepaid expenses and other current assets	1,256,879	1,066,473
<b>TOTAL CURRENT ASSETS</b>	<b>12,634,806</b>	<b>17,658,199</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>2,374,308</b>	<b>2,797,929</b>
<b>OTHER ASSETS:</b>	<b>5,807,230</b>	<b>4,554,064</b>
<b>TOTAL ASSETS</b>	<b>\$ 20,816,344</b>	<b>\$ 25,010,192</b>
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 2,801,432	\$ 4,946,030
Deferred revenue	353,406	340,000
<b>TOTAL CURRENT LIABILITIES</b>	<b>3,154,838</b>	<b>5,286,030</b>
<b>TOTAL LIABILITIES</b>	<b>3,154,838</b>	<b>5,286,030</b>
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock - \$.01 par value; 100,000,000 shares authorized, 9,628,248 and 9,611,139 shares issued and outstanding for 2015 and 2014, respectively	96,282	96,112
Additional paid-in capital	47,890,642	47,556,426
Accumulated deficit	(30,325,418)	(27,928,376)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>17,661,506</b>	<b>19,724,162</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 20,816,344</b>	<b>\$ 25,010,192</b>

**Chembio Diagnostics, Inc. & Subsidiary**  
**Summary of Consolidated Cash Flow**  
**For the years ended**  
**(UNAUDITED)**

	<u>December 31, 2015</u>	<u>December 31, 2014</u>
<b>Net cash provided by (used in) operating activities</b>	\$ 1,792,978	\$ (3,820,299)
<b>Net cash used in investing activities</b>	(1,030,585)	(1,452,601)
<b>Net cash provided by financing activities</b>	-	237,163
<b>(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>\$ 762,393</b>	<b>\$ (5,035,737)</b>

Contacts:

Chembio Diagnostics  
Susan Norcott  
(631) 924-1135, ext. 125  
snorcott@chembio.com

Vida Strategic Partners (investor relations)  
Stephanie C. Diaz  
(415) 675-7401  
sdiaz@vidasp.com