



March 7, 2017

ChemBio Diagnostics Reports 2016 Financial Results

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

MEDFORD, N.Y., March 07, 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 year ended December 31, 2016.

John J. Sperzel III, Chief Executive Officer, stated, "During 2016, the Company made significant advances to diversify its product portfolio, build its global sales & marketing infrastructure, and expand its operational capabilities. To diversify its product portfolio, the Company is leveraging its patented DPP[®] technology platform to strengthen its core sexually transmitted disease business, build a highly-differentiated fever and tropical disease business, and establish technology collaborations to enter new POC markets.

"The Company expects to complete the U.S. clinical trial for its DPP[®] HIV-Syphilis Assay on schedule during Q1 2017, and the preliminary results are highly encouraging. We also advanced multiple fever and tropical disease assays, which we expect to make important future revenue contributions, including DPP[®] Malaria Assay, DPP[®] Zika Assay, DPP[®] Dengue Assay, DPP[®] Chikungunya Assay, DPP[®] Zika/Dengue/Chikungunya Assay, and DPP[®] Fever Panel Assay. These efforts were accelerated due to funding and collaboration from the U.S. Government (i.e., HHS/ASPR/BARDA, CDC), the Paul G. Allen Family Foundation, and the Bill & Melinda Gates Foundation.

"To build its first-ever global sales and marketing infrastructure, the Company expanded its sales team during Q4 2016 by appointing experienced senior commercial leaders and recruiting experienced sales executives to focus on key markets, such as the United States, Latin America, Africa and Asia Pacific. Following the termination of our previous U.S. distributor in May 2016, and the expansion of our global sales & marketing infrastructure, we are well-positioned to commercialize our new and existing products, strengthen and expand our global distribution channels, and provide local support to customers and commercial partners around the world. During Q4 2016, the Company won a two-year HIV contract with the state of Florida, which is expected to contribute revenue of approximately \$1.5 million between 2017 and 2018. Subsequent to the end of 2016, the Company won a two-year HIV contract with another state, which is expected to contribute revenue of approximately \$0.5 million between 2017 and 2018.

"To expand our operational capabilities, we contracted to acquire Malaysia-based RVR Diagnostics to increase manufacturing capacity, establish a presence in Southeast Asia, and provide important regulatory access to key markets. Subsequent to the end of 2016, we completed the acquisition of RVR Diagnostics, hired an experienced Vice President of Global Manufacturing Operations, and secured multiple tenders in Southeast Asia which are expected to contribute revenue of approximately \$1.5 million during 2017."

Addressing the Company's financial results, Mr. Sperzel commented, "Despite reporting a decrease in product sales during 2016, we are seeing important quarter-over-quarter sales growth. The 2016 decrease in product sales was primarily due to the previously disclosed loss of DPP[®] HIV and DPP[®] Syphilis product sales as a result of a tender offer in Brazil having been awarded to a competitor at an extremely low price point, as well as the impact of the Company's decision to separate from its previous SURE CHECK[®] HIV 1/2 Assay distributor in the U.S. market. Despite this decline, quarter-over-quarter analysis shows sales growth with total revenues for the fourth quarter of 2016 up 13.3% and product sales for the fourth quarter of 2016 up 29.2%, as compared to the third quarter of 2016. In addition, total revenues for the fourth quarter of 2016 were up 30.0% and product sales for the fourth quarter of 2016 were up 59.1%, as compared to the second quarter of 2016.

"In the U.S., sales of the Company's POC HIV Assays showed positive trends. During 2016, U.S. sales of the HIV 1/2 STAT-PAK[®] Assay increased 34.7% as compared to 2015. We are also seeing very encouraging U.S. sales of the SURE CHECK[®] HIV 1/2 Assay. During the fourth quarter of 2016, U.S. sales of the SURE CHECK[®] HIV 1/2 Assay increased by

approximately \$516,000 or 230.5% as compared to the third quarter of 2016. This growth provides evidence that we are effectively rebuilding the U.S. HIV STAT-PAK[®] and SURE CHECK[®] HIV business, after we re-gained the U.S. distribution rights to these products in June 2014 and June 2016, respectively."

Selected Summary Financial Information comparing the 2016 fourth quarter to the 2015 fourth quarter:

- | Total revenues of \$4.25 million, compared with \$4.42 million.
- | Product sales of \$3.23 million, compared with \$3.74 million.
- | Operating loss of \$2.57 million, compared with operating loss of \$1.20 million.
- | Net loss of \$2.56 million, or \$0.21 per diluted share, compared with net loss of \$.65 million, or \$0.07 per diluted share.

Selected Summary Financial Information comparing the year of 2016 to the year of 2015:

- | Total revenues of \$17.87 million, compared with \$24.26 million.
- | Product sales of \$13.68 million, compared with \$21.89 million.
- | Operating loss of \$7.57 million, compared with operating loss of \$3.55 million.
- | Net loss of \$13.35 million, or \$1.26 per diluted share, compared with net loss of \$2.40 million, or \$0.25 per diluted share. The 2016 Net Loss includes a \$5.80 million non-cash income tax provision as a result of the Company decreasing its deferred tax asset and taking a full valuation allowance against its carry forward loss; and the Net Loss for 2015 period, which resulted in an increase in the Company's deferred tax asset, includes a non-cash income tax benefit of \$1.16 million.

Additional Financial Information

Fourth Quarter:

Total revenues in the 2016 fourth quarter of \$4.25 million decreased 3.8% compared with \$4.42 million in the prior-year period. Product sales in the 2016 fourth quarter of \$3.23 million decreased 13.7% compared with \$3.74 million in the prior-year period. R&D milestone, and grant and royalty revenues in the 2016 fourth quarter of \$1.03 million increased 51.2% compared with \$.68 million in the prior-year period.

Gross margin dollars in the 2016 fourth quarter of \$1.75 million decreased 6.3% compared with \$1.87 million in the prior-year period, due primarily to decreased product revenues. Product gross margin dollars in the 2016 fourth quarter of \$0.73 million decreased 39.1% compared with \$1.19 million in the prior-year period, which also was primarily due to the decreased product revenues.

R&D expenses in the 2016 fourth quarter of \$2.16 million increased 47.5%, compared with \$1.47 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 in the 2016 fourth quarter of \$2.16 million increased 34.8% compared with \$1.61 million in the prior-year period, largely due to increases in wages and related costs, increased commissions, which were due to increased sales in Brazil, as well as increases in professional fees, which were partially offset by a decrease in stock-based compensation.

Operating loss in the 2016 fourth quarter was \$2.57 million, compared with an operating loss of \$1.20 million in the prior-year period.

Net loss in the 2016 fourth quarter was \$2.56 million, or \$0.21 per diluted share, compared with net loss of \$.65 million, or \$0.07 per diluted share, in the prior-year period.

2016 Year:

Total revenues for the year of 2016 of \$17.87 million decreased 26.3% compared with \$24.26 million in the prior-year period. Product sales for the year of 2016 of \$13.68 million decreased 37.5% compared with \$21.89 million in the prior-year period. R&D milestone, and grant and royalty revenues for the year of 2016 of \$4.19 million increased 76.8% compared with \$2.37 million in the prior-year period.

Gross margin dollars for the year of 2016 of \$8.45 million decreased 19.4% compared with \$10.49 million in the prior-year period, due primarily to the decrease in product sales. The amount of product gross margin for the year of 2016 of \$4.26 million decreased 47.5% compared with \$8.12 million in the prior-year period.

R&D expenses for the year of 2016 of \$8.43 million increased 32.1%, compared with \$6.38 million in the prior-year period. This increase is due primarily to increased R&D activities for projects and grants.

Selling, general and administrative expenses for the year of 2016 of \$7.60 million decreased 0.9%, compared with \$7.66 million in the prior-year period, largely due to decreased commissions on sales in Brazil, decreased stock-based compensation, and consulting, which were partially offset by increases in wages and related costs, marketing materials, investor relations expenses and professional fees.

Operating loss for the year of 2016 was \$7.57 million, compared with an operating loss of \$3.55 million in the prior-year period.

Net loss for the year of 2016 was \$13.35 million, or \$1.26 per diluted share, compared with net loss of \$2.40 million, or \$0.25 per diluted share, in the prior-year period. The net loss in the 2016 period includes a non-cash tax provision for the recording of a valuation allowance on the Company's deferred tax asset of \$5.80 million. Net Loss for 2015 period, which resulted in an increase in the Company's deferred tax asset, includes a non-cash income tax benefit of \$1.16 million.

Balance Sheet Highlights:

The Company had cash and cash equivalents of \$10.55 million as of December 31, 2016, compared with \$5.38 million as of December 31, 2015. The increase was primarily due to net cash raised in the sale of common stock, partially offset by cash used in operating activities for the year of 2016. The Company's working capital increased by \$5.23 million from \$9.48 million as of December 31, 2015 to \$14.71 million.

In August 2016, the Company sold 2,300,000 common shares for a total of \$13.8 million, which after expenses resulted in approximately \$12.5 million in net funds to the Company.

Conference Call

To participate on the conference call, please dial (877) 407-0778 from the U.S. or (201) 689-8566 from outside the U.S. To listen live via the Internet, please visit the Investor Relations section of Chembio's website at www.chembio.com.

To listen to a replay of the call, which will be accessible until March 14, 2017 at 11:59 p.m. ET, please dial (877) 481-4010 from the U.S. or (919) 882-2331 from outside the U.S., and enter conference ID #:10255. An archive of the webcast will be available for 90 days on the Company's website at 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 each of its DPP[®] HIV 1/2 Assay, HIV 1/2 STAT-PAK[®] Assay, and SURE CHECK[®] HIV 1/2 Assay, with these Chembio brand names, in the U.S. and internationally both directly and through third-party distributors. The Company's SURE CHECK[®] HIV 1/2 Assay previously has been exclusively sold in the U.S. as Clearview[®] Complete HIV 1/2 Assay.

Chembio has developed a patented point-of-care (POC) test platform technology, the Dual Path Platform (DPP[®]) 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.

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>	
	December 31, 2016	December 31, 2015	December 31, 2016	December 31, 2015
Net product sales	\$ 3,226,919	\$ 3,740,824	\$ 13,680,107	\$ 21,886,688
License and royalty revenue	315,835	18,736	449,685	52,753
R&D, milestone and grant revenue	712,122	661,256	3,739,049	2,316,044
TOTAL REVENUES	\$ 4,254,876	\$ 4,420,816	\$ 17,868,841	\$ 24,255,485
GROSS MARGIN	\$ 1,753,386	\$ 1,870,543	\$ 8,451,336	\$ 10,486,827
Research and development expenses	\$ 2,162,072	\$ 1,466,252	\$ 8,427,554	\$ 6,377,839
Selling, general and administrative expenses	\$ 2,164,890	\$ 1,605,814	\$ 7,595,559	\$ 7,663,035
LOSS FROM OPERATIONS	\$ (2,573,576)	\$ (1,201,523)	\$ (7,571,777)	\$ (3,554,047)
OTHER INCOME (EXPENSE):	\$ 15,819	\$ (4,334)	\$ 25,548	\$ (3,238)
Income tax provision (benefit)	\$ -	\$ (556,873)	\$ 5,800,818	\$ (1,160,243)
NET LOSS	\$ (2,557,757)	\$ (648,984)	\$ (13,347,047)	\$ (2,397,042)
Basic loss per share	\$ (0.21)	\$ (0.07)	\$ (1.26)	\$ (0.25)
Diluted loss per share	\$ (0.21)	\$ (0.07)	\$ (1.26)	\$ (0.25)
Weighted average number of shares outstanding, basic	12,026,847	9,628,248	10,622,331	9,626,028
Weighted average number of shares outstanding, diluted	12,026,847	9,628,248	10,622,331	9,626,028

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

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
CURRENT ASSETS:		
Cash and cash equivalents	\$ 10,554,464	\$ 5,376,931
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at December 31, 2016 and 2015, respectively	3,383,729	2,422,971
Inventories	3,335,188	3,578,025
Prepaid expenses and other current assets	840,145	1,256,879
TOTAL CURRENT ASSETS	18,113,526	12,634,806

FIXED ASSETS, net of accumulated depreciation	1,709,321	2,374,308
OTHER ASSETS:	752,389	5,807,230
TOTAL ASSETS	\$ 20,575,236	\$ 20,816,344
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,013,133	\$ 2,801,432
Deferred revenue	392,517	353,406
TOTAL CURRENT LIABILITIES	3,405,650	3,154,838
TOTAL LIABILITIES	3,405,650	3,154,838
STOCKHOLDERS' EQUITY:		
Common stock - \$.01 par value; 100,000,000 shares authorized, 12,026,847 and 9,611,139 shares issued and outstanding for 2016 and 2015, respectively	120,268	96,282
Additional paid-in capital	60,721,783	47,890,642
Accumulated deficit	(43,672,465)	(30,325,418)
TOTAL STOCKHOLDERS' EQUITY	17,169,586	17,661,506
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 20,575,236	\$ 20,816,344

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

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Net cash provided by (used in) operating activities	\$ (6,704,734)	\$ 1,792,978
Net cash used in investing activities	(668,706)	(1,030,585)
Net cash provided by financing activities	12,550,973	-
INCREASE IN CASH AND CASH EQUIVALENTS	\$ 5,177,533	\$ 762,393

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