



March 5, 2015

Chembio Diagnostics Reports 2014 Financial Results

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

MEDFORD, N.Y., March 5, 2015 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care diagnostic tests for infectious diseases, today reported financial results for the year ended December 31, 2014.

John J. Sperzel III, Chembio's Chief Executive Officer, stated, "We are pleased to report Q4 revenues of \$7.10 million and year-end revenues of \$27.65 million. This marks the third consecutive quarter in which we have had revenues above the \$7.0 million mark and we are thrilled that our DPP[®] sales for the year increased by 137% as compared to 2013. While total revenues for 2014 represent a slight decrease as compared to 2013, this is due primarily to Chembio's fulfillment of a single \$5.3 million international STAT-PAK[®] order in 2013, which did not recur in 2014, as well as a decrease in U.S. sales revenue of \$2.3 million due to our termination of the STAT-PAK[®] distribution agreement with Alere. Despite the approximately \$7.6 million attributable to these two factors, Chembio was able to report only a \$1.9 million decline in revenue for the year. This was made possible by the dramatic growth we are seeing in DPP[®] product sales, which accounted for 60% of 2014 sales compared to 24% of sales in the prior year."

Mr. Sperzel continued, "It is Chembio's goal to combine our expertise in HIV diagnostics with our innovative DPP[®] technology to create a global diagnostic business that extends well beyond HIV and infectious disease. To this end, the strategy that we implemented in 2014 has already begun to pay dividends. Last year we established and expanded our U.S. sales and marketing team, met multiple regulatory milestones including the CLIA-waiver for our DPP[®] HIV 1/2 Assay for use with oral fluid and blood, generated significant sales growth in Latin America, advanced our partnership in Malaysia, and established new high-potential partnerships to develop new and innovative diagnostics for Dengue fever, Ebola and febrile illness, flu immunostatus and a specific form of cancer."

"Our partnering momentum has continued into 2015 as we've recently entered into an agreement to develop a point-of-care (POC) test for traumatic brain injury (including sports related concussion) and we have partnered with the Bill & Melinda Gates Foundation toward the development of a next-generation POC Malaria assay. With these achievements behind us, we are optimistic that the strategy we implemented in 2014 will strengthen our base business in POC infectious disease testing, create new opportunities to leverage our patented DPP[®] technology, advance our key development programs and commercial partnerships, and establish the foundation for success in 2015 and beyond."

Financial information comparing Q4 and the full-year 2014 are to the 2013 periods (Note: 2013 included the shipment of a single \$5.3 million international STAT-PAK[®] order, which did not recur in 2014 as well as a \$2.3 million decline in sales to Alere following termination of our STAT-PAK[®] distribution agreement).

Financial information comparing the full year 2014 to the full year 2013:

- Total revenues of \$27.65 million compared with \$29.55 million (a decrease of 6.4%);
- DPP[®] revenues of \$15.66 million compared with \$6.59 million (an increase of 137%);
- Operating loss of \$1,550,000, compared with operating income of \$1,005,000;
- Net loss of \$1,137,000, or \$0.12 per diluted share, compared with net income of \$531,000, or \$0.06 per diluted share.

Financial information comparing the 2014 fourth quarter to the 2013 fourth quarter:

- Total revenues of \$7.10 million, compared with \$7.86 million (a decrease of 9.7%).
- Product sales of \$6.55 million, compared with \$7.10 million (a decrease of 7.7%).
- Operating loss of \$672,000, compared with operating loss of \$176,000
- Net loss of \$496,000, or \$0.05 per diluted share, compared with net loss of \$262,000, or \$0.03 per diluted share

Additional 2014 Information

The total revenues for the year 2014 consisted of product sales of \$25.95 million compared with \$27.52 million for the prior-year. R&D, milestone, and grant and royalty revenues for 2014 were \$1,696,000 compared with \$2,034,000 for the prior-year. The decrease in product sales is due primarily to the shipment in 2013 of \$5.30 million from a single non-recurred STAT-PAK[®] order, as well as the decline in sales in Africa and to Alere in 2014, the latter as a result of the termination of our STAT-PAK[®] distribution agreement, partially offset by increased DPP[®] sales. However, during 2014, total aggregate end-user sales of our STAT-PAK[®] and SURE CHECK[®] lateral flow products in the U.S. increased over 2013.

Gross margin for the year 2014 was \$10.81 million compared with \$12.30 million for the prior-year, due primarily to the non-recurrence of the STAT-PAK[®] order described above and also to product mix. Product gross margin for the year 2014 was \$9.12 million compared with \$10.27 million for the prior-year, also due primarily to the non-recurrence of the STAT-PAK[®] order, product mix, and the decline in STAT-PAK[®] sales to Alere.

R&D expenses for the year 2014 were \$4.83 million compared with \$5.83 million for the prior-year. This decrease is due primarily to a reduction in clinical trial expense related to our DPP[®] HIV 1/2 Assay CLIA waiver study.

Selling, general and administrative expenses for the year 2014 were \$7.53 million compared with \$5.46 million for the prior-year, largely due to higher investment in sales and marketing personnel, increased commissions, and related costs.

Operating loss for the year 2014 was \$1,550,000 compared with operating income of \$1,005,000 for the prior-year.

Net loss for the year 2014 was \$1,137,000, or \$0.12 per diluted share, compared with net income of \$531,000, or \$0.06 per diluted share, for the prior-year.

Fourth Quarter Information

Total revenues for the fourth quarter of 2014 of \$7.10 million were down 9.7% compared with total revenues of \$7.86 million in the prior-year period. Product sales in the 2014 fourth quarter of \$6.55 million were down 7.7% compared with product sales of \$7.10 million in the prior-year period. R&D milestone, and grant and royalty revenues for the three months ended December 31, 2014 decreased to \$546,000 from \$764,000 in the prior-year period.

Gross margin for the 2014 fourth quarter decreased 11% to \$2.91 million compared with \$3.27 million for the prior-year period, due primarily to the lower amount of R&D, milestone, and grant and royalty revenues. The amount of product gross margin for the fourth quarter of 2014 decreased 5.7% to \$2.36 million, from \$2.50 million in the prior-year period.

R&D expenses in the fourth quarter of 2014 were \$1.39 million, compared with \$1.69 million in the prior-year period. This decrease is due primarily to a reduction in clinical trial expense related to our DPP[®] HIV 1/2 Assay CLIA waiver study.

Selling, general and administrative expenses in the fourth quarter of 2014 increased to \$2.19 million from \$1.76 million in the prior-year period, largely due to increased wages and related costs and increased marketing materials.

Operating loss for the fourth quarter of 2014 was \$672,000, compared with an operating loss of \$176,000 for the prior-year period.

Net loss for the fourth quarter of 2014 was \$496,000, or \$0.05 per diluted share, compared with net loss of \$262,000, or \$0.03 per diluted share, for the prior-year period.

Balance Sheet Highlights

The Company had cash and cash equivalents of \$4.61 million as of December 31, 2014, compared with \$9.65 million as of December 31, 2013. The decrease was primarily due to net cash used in investing activities to fund deposits on and purchase of fixed assets of \$1.45 million as well as net cash used in operating activities of \$3.82 million, which included an increase in accounts receivable of \$3.77 million, an increase in inventory of \$.45 million and an increase in accounts payable of \$.64 million. Our working capital decreased by \$1.85 million during the year from \$14.22 million to \$12.37 million.

Conference Call

To participate on the conference call, please dial (877) 407-0778 from the U.S. or (201) 689-8565 from outside the U.S. Following the completion of the call, a telephone replay will be accessible until March 12, 2015 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 #:13602180. 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. The conference call may also be accessed via the internet at <http://www.investorcalendar.com/IC/CEPage.asp?ID=173680>. 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 its DPP[®] HIV 1/2 Assay and HIV 1/2 STAT-PAK[®] Assay in the U.S. and internationally. The Company's SURE CHECK[®] HIV 1/2 Assay is marketed exclusively in the U.S. as Clearview[®] Complete by a single entity. Outside the U.S., Chembio markets its SURE CHECK[®] HIV 1/2 Assay primarily through distributors.

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.

Chembio Diagnostics, Inc. & Subsidiary Summary of Consolidated Results of Operations

	<u>For the three months ended</u>		<u>For the years ended</u>	
	<u>(UNAUDITED)</u>			
	<u>December 31, 2014</u>	<u>December 31, 2013</u>	<u>December 31, 2014</u>	<u>December 31, 2013</u>
Net product sales	\$ 6,549,254	\$ 7,096,191	\$ 25,949,769	\$ 27,515,786
License and royalty revenue	7,644	4,008	23,257	4,906
R&D, milestone and grant revenue	538,408	760,096	1,672,258	2,028,917
TOTAL REVENUES	\$ 7,095,306	\$ 7,860,295	\$ 27,645,284	\$ 29,549,609
GROSS MARGIN	\$ 2,908,472	\$ 3,268,908	\$ 10,814,023	\$ 12,300,159
Research and development expenses	\$ 1,393,823	\$ 1,686,048	\$ 4,832,537	\$ 5,834,249
Selling, general and administrative expenses	\$ 2,186,825	\$ 1,758,902	\$ 7,531,739	\$ 5,461,083
(LOSS) INCOME FROM OPERATIONS	\$ (672,176)	\$ (176,042)	\$ (1,550,253)	\$ 1,004,827
OTHER INCOME	\$ 1,312	\$ 2,066	\$ 132	\$ 12,943
Income tax (benefit) provision	\$ (175,002)	\$ 88,011	\$ (412,918)	\$ 486,952
NET (LOSS) INCOME	\$ (495,862)	\$ (261,987)	\$ (1,137,203)	\$ 530,818
Basic (loss) earnings per share	\$ (0.05)	\$ (0.03)	\$ (0.12)	\$ 0.06
Diluted (loss) earnings per share	\$ (0.05)	\$ (0.03)	\$ (0.12)	\$ 0.06
Weighted average number of shares outstanding, basic	9,611,139	9,324,783	9,530,320	8,994,080

Weighted average number of shares outstanding,
diluted

9,611,139

9,324,783

9,530,320

9,519,968

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

	<u>December 31,</u> <u>2014</u>	<u>December 31,</u> <u>2013</u>
CURRENT ASSETS:		
Cash and cash equivalents	\$ 4,614,538	\$ 9,650,275
Accounts receivable, net of allowance for doubtful accounts of \$52,000 and \$24,000 at December 31, 2014 and 2013, respectively	8,338,889	4,592,121
Inventories	3,638,299	3,188,726
Prepaid expenses and other current assets	1,066,473	1,099,379
TOTAL CURRENT ASSETS	17,658,199	18,530,501
FIXED ASSETS, net of accumulated depreciation	2,797,929	1,978,232
OTHER ASSETS:	4,554,064	3,977,859
TOTAL ASSETS	\$ 25,010,192	\$ 24,486,592
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 4,946,030	\$ 4,309,490
Deferred R&D revenue	340,000	--
TOTAL CURRENT LIABILITIES	5,286,030	4,309,490
TOTAL LIABILITIES	5,286,030	4,309,490
STOCKHOLDERS' EQUITY:		
Common stock -- \$.01 par value; 100,000,000 shares authorized, 9,611,139 and 9,324,783 shares issued and outstanding for 2014 and 2013, respectively	96,112	93,248
Additional paid-in capital	47,556,426	46,875,027
Accumulated deficit	(27,928,376)	(26,791,173)
TOTAL STOCKHOLDERS' EQUITY	19,724,162	20,177,102
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 25,010,192	\$ 24,486,592

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

	<u>December 31, 2014</u>	<u>December 31, 2013</u>
Net cash (used in) provided by operating activities	\$ (3,820,299)	\$ 2,277,614
Net cash used in investing activities	(1,452,601)	(885,609)
Net cash provided by financing activities	237,163	5,306,411
(DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	\$ (5,035,737)	\$ 6,698,416

CONTACT: 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