



March 7, 2013

ChemBio Diagnostics Reports Fourth Quarter and Full-Year 2012 Financial Results

Fourth Quarter Product Sales Up 25%, Full-Year Product Sales Up 40%
Conference Call Begins at 5:00 p.m. Eastern Time Today

MEDFORD, N.Y., March 7, 2013 (GLOBE NEWSWIRE) -- **ChemBio Diagnostics, Inc.** (Nasdaq:CEMI), a leader in point-of-care diagnostic tests for infectious diseases, today reported financial results for the fourth quarter and year ended December 31, 2012.

Financial highlights for the 2012 fourth quarter include the following (all comparisons are with the 2011 fourth quarter):

- Total revenues of \$7.87 million, up 27% compared with \$6.22 million
- Product sales of \$7.41 million, up 25% compared with \$5.91 million
- Operating income of \$705,000, compared with operating income of \$551,000
- Net income of \$492,000 or \$0.06 per diluted share, compared with net income of \$5.68 million or \$0.66 per diluted share, which included a tax benefit of \$5.13 million or \$0.60 per diluted share

Financial highlights for 2012 full year include the following (all comparisons are with the 2011 full year):

- Total revenues of \$25.61 million, up 32% compared with \$19.39 million
- Product sales of \$24.33 million, up 40% compared with \$17.42 million
- Operating income of \$1.45 million, compared with operating income of \$1.09 million
- Net income of \$941,000 or \$0.11 per diluted share, compared with net income of \$6.21 million or \$0.73 per diluted share, which included a tax benefit of \$5.13 million or \$0.60 per diluted share

Commenting on the Company's financial performance, Lawrence Siebert, ChemBio's Chief Executive Officer, said, "During 2012 ChemBio achieved strong growth and profitability and made considerable progress in our strategic plan. ChemBio's US products are well positioned, growing both in sales and market share. We reached milestones on key product development programs and listed our common shares on the NASDAQ capital markets. We start the year with a backlog of orders and a strong outlook for 2013.

"Late in the fourth quarter we received U.S. Food and Drug Administration (FDA) approval for our DPP[®] HIV 1/2 Assay, a rapid point-of-care test for the detection of antibodies to HIV 1 and 2 in oral fluid, finger-stick whole blood, venous whole blood, serum or plasma. We believe our DPP[®] HIV 1/2 Assay has superior performance compared with the only other oral fluid HIV rapid test on the market. The market for these tests is expected to grow significantly with the recent recommendations by the U.S. Preventive Services Task Force to mandate insurance reimbursement for routine HIV testing.

"We are in the process of preparing a request for a Clinical Laboratory Improvement Amendment (CLIA) waiver and we plan to make this submission during the first half of 2013. In the meantime, we continue to develop our go-to-market strategy for DPP[®] HIV 1/2 and expect a commercial launch in the second half of the year," concluded Mr. Siebert.

Fourth Quarter Results

Total revenues for the fourth quarter of 2012 were \$7.87 million, an increase of 27% compared with total revenues of \$6.22 million in the prior-year period. Product sales increased 25% to \$7.41 million from \$5.91 million in the prior-year period. Research and development (R&D), milestone, grant and royalty revenues increased to \$458,000 from \$295,000 in the prior-year period.

Gross margin for the 2012 fourth quarter increased 15% to \$3.16 million compared with \$2.74 million for the prior-year period, due primarily to higher product sales, and R&D, licensing and royalty revenues. Product gross profit for the fourth quarter of 2012 increased 11% to \$2.70 million, from \$2.43 million in the prior-year period, and product gross margin declined primarily due to scrap and product mix.

R&D expenses in the fourth quarter of 2012 were \$1.12 million compared with \$1.18 million in the prior-year period. The 2012 fourth quarter included \$157,000 of clinical trial expenses compared with \$190,000 in the prior-year period.

Selling, general and administrative expenses in the fourth quarter of 2012 increased to \$1.33 million compared with \$1.01 million in the prior-year period, largely due to higher commissions on DPP[®] product sales to Brazil, and higher wages and other expenses.

Operating income for the fourth quarter of 2012 was \$705,000, compared with operating income of \$551,000 for the prior-year period.

Net income for the fourth quarter of 2012 was \$492,000 or \$0.06 per diluted share, compared with net income of \$5.68 million or \$0.66 per diluted share for the prior-year period. The 2012 fourth quarter includes a charge for income tax provision of \$214,000 or \$0.02 per diluted share, which approximates the amount of income taxes that would be attributable to the Company if it did not have a net operating loss carryforward to offset income taxes payable. The 2011 fourth quarter net income included an income tax benefit of \$5.13 million in income tax provision or \$0.60 per diluted share, as the Company recognized a deferred tax asset relevant to its net operating loss carryforwards.

2012 Full-Year Results

Total revenues for 2012 were \$25.61 million, an increase of 32% compared with total revenues of \$19.39 million for 2011. 2012 product sales increased 40% to \$24.33 million compared with \$17.42 million in 2011. R&D, milestone, grant and royalty revenues for 2012 decreased to \$1.28 million from \$1.83 million in 2011.

Gross margin for 2012 increased 15% to \$10.79 million compared with \$9.39 million for 2011, due to higher product sales partially offset by lower R&D, licensing and royalty revenues. Product gross margin for 2012 increased 28% to \$9.51 million, compared with \$7.42 million for 2011, while product gross margin declined due to higher scrap and product mix.

R&D expenses in 2012 were \$4.49 million compared with \$4.88 million in 2011.

Selling, general and administrative expenses increased to \$4.85 million in 2012 from \$3.42 million in 2011, largely due to higher commissions on DPP[®] product sales to Brazil, the initial listing fee paid to list on NASDAQ, and higher wages, professional fees and stock-based compensation.

Operating income for 2012 was \$1.45 million, compared with operating income of \$1.09 million for 2011.

Net income for 2012 was \$941,000 or \$0.11 per diluted share, compared with net income of \$6.21 million or \$0.73 per diluted share for 2011. Net income for 2012 included a charge for income tax provision of \$509,000 or \$0.06 per diluted share, which approximates the amount of income taxes that would be attributable to the Company if it did not have a net operating loss carryforward to offset the recorded amount of income taxes otherwise payable. Net income for 2011 included a benefit of \$5.13 million in income tax provision or \$0.60 per diluted share, as the Company booked a deferred tax asset for its net operating loss carryforwards.

Balance Sheet Highlights

The Company had cash and cash equivalents of \$2.95 million as of December 31, 2012, compared with \$3.01 million as of December 31, 2011. Accounts receivable increased by \$1.82 million to \$4.82 million which was primarily responsible for an increase in current assets of \$2.02 million. Accounts payable and accrued liabilities increased by \$514,000. Overall, our working capital increased by \$1.50 million to \$7.63 million.

Conference Call

Chembio has scheduled a conference call and webcast for 5:00 p.m. Eastern time today. To participate in the call, 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 May 6, 2013 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 #409687. The conference call may also be accessed via the internet at www.chembio.com or <http://www.investorcalendar.com/IC/CEPage.asp?ID=170616>. An archive of the webcast will be available for 90 days at www.chembio.com.

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing \$10 billion point-of-care testing market. Chembio's two FDA PMA-approved, CLIA-waived, rapid HIV tests are marketed in the U.S.

by Alere, Inc. (formerly, Inverness Medical Innovations, Inc.). Chembio markets its HIV STAT-PAK® line of rapid HIV tests internationally to government and donor-funded programs directly and through distributors. Chembio has developed a patented point-of-care 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 based on DPP®. Headquartered in Medford, NY, with approximately 170 employees, 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 13.485. 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 are estimates only, reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual revenues and other 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, to obtain regulatory approvals in a timely manner and 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 Condensed Consolidated Results of Operations

	<u>UNAUDITED</u>			
	<u>For the three months ended</u>		<u>For the years ended</u>	
	<u>December 31, 2012</u>	<u>December 31, 2011</u>	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Net product sales	\$ 7,407,919	\$ 5,905,986	\$ 24,327,355	\$ 17,422,311
License and royalty revenue	-	15,000	-	140,322
R&D, milestone and grant revenue	<u>458,147</u>	<u>295,431</u>	<u>1,283,240</u>	<u>1,825,403</u>
TOTAL REVENUES	\$ 7,866,066	\$ 6,216,417	\$ 25,610,595	\$ 19,388,036
GROSS MARGIN	\$ 3,157,589	\$ 2,742,950	\$ 10,789,991	\$ 9,390,303
Research and development expenses	\$ 1,122,483	\$ 1,180,810	\$ 4,486,302	\$ 4,878,119
Selling, general and administrative expenses	\$ 1,330,035	\$ 1,011,430	\$ 4,851,587	\$ 3,424,297
INCOME FROM OPERATIONS	\$ 705,071	\$ 550,710	\$ 1,452,102	\$ 1,087,887
OTHER INCOME (EXPENSE):	\$ 603	\$ (3,295)	\$ (1,584)	\$ (12,325)
Income tax provision (benefit)	\$ 214,017	\$ (5,133,229)	\$ 509,237	\$ (5,133,229)
NET INCOME	\$ 491,657	\$ 5,680,646	\$ 941,281	\$ 6,208,791
Basic earnings per share	\$ 0.06	\$ 0.72	\$ 0.12	\$ 0.79
Diluted earnings per share	\$ 0.06	\$ 0.66	\$ 0.11	\$ 0.73

Weighted average number of shares outstanding, basic	8,020,525	7,916,053	7,986,030	7,874,807
Weighted average number of shares outstanding, diluted	8,638,205	8,597,530	8,614,944	8,556,284

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

	<u>December 31, 2012</u>	<u>December 31, 2011</u>
CURRENT ASSETS:		
Cash and cash equivalents	\$ 2,951,859	\$ 3,010,954
Accounts receivable, net of allowance for doubtful accounts of \$58,000 and \$30,000 at December 31, 2012 and 2011, respectively	4,821,357	2,998,449
Inventories	2,488,071	2,300,286
Prepaid expenses and other current assets	747,463	681,893
TOTAL CURRENT ASSETS	11,008,750	8,991,582
FIXED ASSETS, net of accumulated depreciation	1,427,646	1,062,276
OTHER ASSETS		
Deferred tax asset, net of valuation allowance	4,233,194	4,749,622
License agreements and other assets	665,560	682,264
	<u>\$ 17,335,150</u>	<u>\$ 15,485,744</u>
TOTAL CURRENT LIABILITIES	\$ 3,378,383	\$ 2,857,626
TOTAL OTHER LIABILITIES	<u>82,247</u>	<u>133,484</u>
TOTAL LIABILITIES	3,460,630	2,991,110
TOTAL STOCKHOLDERS' EQUITY	<u>13,874,520</u>	<u>12,494,634</u>
	<u>\$ 17,335,150</u>	<u>\$ 15,485,744</u>

Chembio Diagnostics, Inc. & Subsidiary
Summary of Condensed Consolidated Cash Flow

	<u>For the years ended</u>	
	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Net cash provided by operating activities	\$ 761,084	\$ 2,268,408
Net cash used in investing activities	(872,442)	(726,680)
Net cash provided by (used in) financing activities	52,263	(667,125)
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	<u>\$ (59,095)</u>	<u>\$ 874,603</u>

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