March 8, 2012

Chembio Diagnostics Reports Fourth Quarter and 2011 Financial Results

Conference Call Begins at 10:00 a.m. Eastern Time Today

MEDFORD, NY, Mar 08, 2012 (MARKETWIRE via COMTEX) --Chembio Diagnostics, Inc. (PINKSHEETS: CEMI) (OTCQB: CEMI), a leader in point-of-care diagnostic tests for infectious diseases, today reported financial results for the three and 12 months ended December 31, 2011, including record revenues and earnings for the year. The 2011 results reflect the reversal of $5.16 million in deferred tax asset valuation allowance previously recorded against its deferred tax assets, which resulted in a tax benefit increase to net income of that amount. The 2010 results include $1.47 million in Qualified Therapeutic Discovery Project grants ("QTDP") under Section 48D of the Internal Revenue Code, as enacted under the Patient Protection and Affordable Care Act of 2010. This amount was reflected as a reduction of R&D expenses.

Financial highlights for the fourth quarter of 2011 include the following (all comparisons are with the fourth quarter of 2010):

- Total revenues of $6.22 million, up 9.7% compared with $5.67 million
- Product sales of $5.91 million, up 14.1% compared with $5.18 million
- Operating Income of $551,000, down from $1.93 million. Operating income for 2010 includes the effect of QTDP grants of $1.47 million.
- Net income of $5.68 million or $0.09 per diluted share, up from net income of $1.88 million or $0.03 per diluted share. Net income includes the reversal of $5.16 million in deferred tax asset valuation allowance in 2011 and the effect of QTDP grants in 2010

Financial highlights for 2011 include the following (all comparisons are with 2010):

- Total revenues of $19.39 million, up 16.6% compared with $16.70 million
- Product sales of $17.42 million, up 28.9% compared with $13.52 million
- Operating Income of $1.09 million, down from $2.57 million. Operating income for 2010 includes the effect of QTDP grants of $1.47 million
- Net income of $6.21 million or $0.10 per diluted share, up from net income of $2.51 million or $0.04 per diluted share. Net income includes the reversal of $5.16 million in deferred tax asset valuation allowance in 2011 and the effect of QTDP grants in 2010

Commenting on the Company's performance, Lawrence Siebert, Chief Executive Officer, said, "Chembio had a great year in 2011, with a particularly strong second half based on substantially increased purchase orders from the Oswaldo Cruz Foundation ('FIOCRUZ'), our license and technology transfer partner in Brazil, and from continued strong demand for our rapid HIV tests in the U.S. Growing product sales together with higher gross margins have enabled us to increase investment in research, development, clinical and regulatory programs in 2011. We are confident we will post substantially higher revenues for the first half of 2012 compared with the prior year, and are optimistic about the financial outlook for all of 2012, which we believe will include solid gains in revenue and operating income. Our decision to record the value of our net operating loss carry forward as a deferred asset is a reflection of that optimism.

"Throughout 2011 we also made important advances in product development. We have enrolled 98% of subjects in our 3,000-patient clinical trial for U.S. Food and Drug Administration ('FDA') approval of our DPP® HIV 1/2 Screening Assay and expect to complete enrollment as soon as possible. We began submitting the Premarket Approval ('PMA') application to the FDA using the Modular PMA option, and submitted Module I containing manufacturing information and Module II containing non-clinical data in October 2011. We remain satisfied with the results to date and believe they will support product performance that meets or exceeds requirements for PMA approval on oral fluid, finger-stick whole blood, venous whole blood, serum and plasma

samples. Moving forward, our plan is to submit Module III to the FDA by the end of the second quarter of 2012 and we expect a PMA decision by year end. With a positive decision, immediately thereafter we will apply for CLIA waiver, which is expected to take approximately three months to be granted.

"During 2011 we made significant progress with our collaboration with FIOCRUZ. Notably, we received notification from FIOCRUZ that our DPP® Syphilis Treponemal screening test and our DPP® Leptospirosis test each was approved by Brazil's National Health Surveillance Agency. In addition, our DPP® visceral canine leishmania rapid test was approved by Brazil's Ministry of Agriculture, Livestock and Food Supply ('MAPA'). This is the first diagnostic product that FIOCRUZ has successfully submitted for approval to MAPA in Brazil. We look forward to successful launches by FIOCRUZ of these products and expect this collaboration to continue to drive revenue growth throughout 2012," added Mr. Siebert.

Fourth Quarter Results

Total revenues for the fourth quarter of 2011 increased 9.7% to $6.22 million, compared with $5.67 million for the fourth quarter of 2010. Product sales for the quarter increased 14.1% to $5.91 million from $5.18 million in the prior year.

Research and development ("R&D"), milestone and grant revenues for the fourth quarter of 2011 decreased to $295,000 from $456,000 in the same period of 2010, and license and royalty revenue decreased to $15,000 from $31,000 in the prior year.

Higher product revenue, together with changes in product mix, partially offset by lower R&D and licensing and royalty revenues, combined to increase gross profit by 10.0% to $2.74 million, compared with $2.49 million in the fourth quarter of 2010. Product gross profit for the fourth quarter of 2011 increased 21.4% to $2.43 million, compared with $2.00 million for the comparable period in 2010.

R&D expenses increased to $1.18 million in the fourth quarter of 2011 from a credit balance of $236,000 in the prior year. The 2010 number includes a reduction or credit of $1.47 million, for the QTDP grants.

Selling, general and administrative expenses increased in the fourth quarter of 2011 to $1.01 million from $797,000 in the prior year, largely due to higher commissions on DPP product sales to Brazil, as well as to increases in wages and stock-based compensation, partially offset by decreases in other expenses.

Operating income for the fourth quarter of 2011 was $551,000, compared with $1.93 million for the fourth quarter of 2010. Operating income for the fourth quarter of 2010 included the effect of the QTDP grants. Net income for the fourth quarter of 2011 was $5.68 million or $0.08 per diluted share, compared with net income of $1.88 million or $0.03 per diluted share for the comparable period in 2010. Net income included the reversal of $5.16 million in deferred tax asset valuation allowance in 2011 and the effect of the QTDP grants in 2010.

Full Year Results

Total revenues for 2011 increased 16.1% to $19.39 million, compared with $16.70 million for 2010. Product sales for 2011 increased 28.9% to $17.42 million from $13.52 million in 2010. Higher product sales resulted from a 36.5% increase in sales to Alere, Inc., the Company's U.S. marketing partner for its FDA-approved rapid HIV tests, to $7.2 million, and a $3.6 million increase in sales of DPP® products to FIOCRUZ in Brazil, to $4.3 million. The increase in product sales was partially offset by a decrease of $931,000 in R&D, milestone and grant revenue and a decrease of $292,000 in license and royalty revenue. The increased sales to Alere and Brazil, together with increased sales to Mexico and Asia, substantially outpaced a decrease in sales to Africa and combined to produce a 51.1% increase in product gross profit in 2011. Product gross margin increased by more than six percentage points, from 36.3% in 2010 to 42.6% in 2011. Overall gross margin was 48.4% for 2011, compared with 48.5% in 2010.

R&D, milestone and grant revenues for 2011 decreased to $1.83 million from $2.76 million in 2010, and license and royalty revenue decreased to $140,000 from $432,000.

Higher product revenue, together with changes in product mix, partially offset by lower R&D and licensing and royalty revenues, combined to increase gross profit by 15.9% to $9.39 million in 2011, compared with $8.10 million in 2010.

Research and development expenses increased to $4.88 million from $2.6 million in the 2010 period. The increase includes an increase of $590,000 in clinical trial expenses. The 2010 number includes a reduction or credit, for the $1.47 million, for the QTDP grants.

Selling, general and administrative expenses increased in 2011 to $3.42 million from $2.94 million in 2010, primarily due to an increase in commissions for the shipment of DPP® products to Brazil.

Operating income was approximately $1.09 million in 2011, compared with $2.57 million in 2010. Included in the 2010 results is $1.47 million of QTDP grants that were recorded as a reduction of R&D expense. The Company recorded net income of $6.21 million or $0.09 per diluted share for 2011, compared with net income of $2.51 million or $0.04 per diluted share for 2010. Net income included the reversal of $5.16 million in deferred tax asset valuation allowance in 2011 and the effect of the QTDP grants in 2010.

Balance Sheet Highlights

The Company had cash and cash equivalents of $3.01 million as of December 31, 2011, compared with $2.14 million as of December 31, 2010. The increase includes cash received from the change in receivables of $953,000 and a $734,000 increase in accounts payable and accrued liabilities, partially offset by an increase in inventories of $951,000 and the payment to Bio-Rad of $875,000 for a license fee. In addition the Company received $288,000 from the exercise of options and warrants. The increased cash from operations in 2011 was also attributable to non-cash expenses totaling $622,000, primarily from depreciation and amortization expense.

Conference Call

Chembio has scheduled a conference call and webcast for 10:00 a.m. Eastern time today. To participate on 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 March 15, 2012 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 reservation account number 286 and conference ID #: 389813. The conference call may also be accessed via the internet at http://www.investorcalendar.com/IC/CEPage.asp?ID=167559. 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 $7 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 North America, 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 160 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, as the Company has not completed the preparation of its financial statements for those periods, nor has its auditor completed a review or audit of those results. Actual revenue may differ materially from those anticipated in this press release. Such statements 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, 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.

(Tables to follow)

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

For the three months ended (unaudited)		For the years ended	
December 31, 2011	December 31, 2010	December 31, 2011	December 31, 2010

Net product sales	$ 5,905,986	$ 5,179,226	$ 17,422,311	$ 13,516,359
License and royalty revenue	15,000	31,480	140,322	432,238
R&D, milestone and grant revenue	295,431	456,136	1,825,403	2,756,106
TOTAL REVENUES	$ 6,216,417	$ 5,666,842	$ 19,388,036	$ 16,704,703
GROSS MARGIN	$ 2,742,950	$ 2,490,858	$ 9,390,303	$ 8,100,699
Research and development expenses	$ 1,180,810	$ (236,147)	$ 4,878,119	$ 2,586,308
Selling, general and administrative expenses	$ 1,011,430	$ 797,006	$ 3,424,297	$ 2,940,721
INCOME FROM OPERATIONS	$ 550,710	$ 1,929,999	$ 1,087,887	$ 2,573,670
Income tax (benefit) provision	$ (5,133,229)	$ 45,823	$ (5,133,229)	$ 45,823
NET INCOME	$ 5,680,645	$ 1,880,776	$ 6,208,791	$ 2,513,344
Basic net income per share	$ 0.09	$ 0.03	$ 0.10	$ 0.04
Diluted net income per share	$ 0.08	$ 0.03	$ 0.09	$ 0.04
Weighted average number of shares outstanding, basic	63,328,492	62,204,742	62,998,402	62,102,861
Weighted average number of shares outstanding, diluted	68,780,310	70,513,280	68,450,220	70,920,915

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

	December 31, 2011	December 31, 2010
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,010,954	$ 2,136,351
Accounts receivable, net of allowance for		

doubtful accounts of $30,000 and $35,000 for 2011 and 2010, respectively	2,998,449	3,946,398
Inventories	2,300,286	1,349,161
Prepaid expenses and other current assets	681,893	204,824
TOTAL CURRENT ASSETS	8,991,582	7,636,734
FIXED ASSETS, net of accumulated depreciation	1,062,276	813,214
OTHER ASSETS		
Deferred tax asset, net of valuation allowance	4,749,622	-
License agreements and other assets	682,264	636,226
	$ 15,485,744	$ 9,086,174
TOTAL CURRENT LIABILITIES	$ 2,857,626	$ 3,076,457
TOTAL OTHER LIABILITIES	133,484	200,773
TOTAL LIABILITIES	2,991,110	3,277,230
TOTAL STOCKHOLDERS' EQUITY	12,494,634	5,808,944
	$ 15,485,744	$ 9,086,174

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

	For the years ended	
	December 31, 2011	December 31, 2010
Net cash provided by operating activities	$ 2,268,408	$ 1,016,850
Net cash used in investing activities	(726,680)	(182,292)
Net cash (used in) provided by financing activities	(667,125)	233,558
INCREASE IN CASH AND CASH EQUIVALENTS	$ 874,603	$ 1,068,116

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