November 7, 2013

Chembio Diagnostics Reports Third Quarter 2013 Financial Results

Conference Call and Webcast Today at 4:30 pm Eastern

MEDFORD, N.Y., Nov. 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 three and nine months ended September 30, 2013.

Financial highlights for the 2013 third quarter include the following (all comparisons are with the 2012 third quarter):

- Total revenues of $9.62 million, up 92% compared with $5.01 million
- Product sales of $9.04 million, up 91% compared with $4.75 million
- Operating income of $1.07 million, compared with operating loss of $485,000
- Net income of $717,000 or $0.07 per diluted share, compared with net loss of $292,000 or $0.04 per diluted share

Financial highlights for the first nine months of 2013 include the following (all comparisons are with the first nine months of 2012):

- Total revenues of $21.69 million, up 22% compared with $17.74 million
- Product sales of $20.42 million, up 21% compared with $16.92 million
- Operating income of $1.18 million, compared with $747,000
- Net income of $793,000, or $0.08 per diluted share, compared with $450,000, or $0.05 per diluted share

Lawrence Siebert, Chembio's Chief Executive Officer, stated, "We are very pleased with these outstanding quarterly results, which reflect the $5.3 million order we received during the second quarter, continued strong sales to Alere, and despite the overall increases in revenues and income, a significant decrease in our sales to Brazil as compared with the 2012 comparable periods. For the nine-month period ended September 30, 2013, we have increased our year-to-date revenues by 22%, our net income by over 75%, and our earnings per diluted share by 60%, all as compared with the nine month period in 2012.

"In addition to delivering record revenues, during the third quarter Chembio's development, regulatory and clinical programs made important advances. We expect to submit a CLIA Waiver application to the U.S. Food and Drug Administration (FDA) for our DPP® HIV 1/2 Assay soon, and we have made good progress in establishing our commercial organization and product launch plan for this product. This product launch is planned for the beginning of the second quarter of 2014.

"We also expect to submit our Premarket Approval Application (PMA) to the FDA for our DPP® HIV-Syphilis test by the end of this year. We believe there are very significant opportunities for this product in the United States and globally. Just last week we received our first purchase order for this assay from our distributor in Mexico. This innovative product is the first-ever multiplex HIV-Syphilis point-of-care test to be approved by the United States Agency for International Development (USAID), and we believe it will also be the first such product to be submitted for FDA approval.

"Our U.S. sales to Alere of our two FDA-approved lateral flow HIV tests have continued to grow, with significant increases of 22% in the year-to-date period and 82% in the comparable period last year. We are in dialog with Alere concerning a potentially mutually acceptable modification and/or extension of our current agreements. Such modification results from Alere's introduction of a product that will compete with Chembio's lateral flow HIV tests in the U.S. market. If a mutually agreeable modification is not completed, then we will pursue other strategies.

Third Quarter Results

Total revenues for the third quarter of 2013 of $9.62 million were up 92% compared with total revenues of $5.01 million in the prior-year period. Product sales in the 2013 third quarter of $9.04 million were up 91% compared with product sales of $4.75 million in the prior-year period, primarily as a result of shipping a majority of the previously-reported $5.3 million order. Partially offsetting that increase was a decline in DPP® product sales in Brazil. Research and development ("R&D"), milestone, and grant and royalty revenues for the three months ended September 30, 2013 increased to $573,000 from $262,000 in the prior-

year period.

Gross margin for the 2013 third quarter increased 135% to $4.06 million compared with $1.73 million for the prior-year period, due primarily to the higher amount of products sold. The amount of product gross margin for the third quarter of 2013 increased 137% to $3.48 million, from $1.47 million in the prior-year period.

R&D expenses in the third quarter of 2013 were $1.60 million, compared with $1.01 million in the prior-year period. The 2013 third quarter included $505,000 of clinical trial expenses related to our DPP® HIV 1/2 Assay CLIA waiver study, compared with $108,000 in the prior-year period.

Selling, general and administrative expenses in the third quarter of 2013 increased to $1.38 million from $1.21 million in the prior-year period, largely due to increased wages and related costs.

Operating income for the third quarter of 2013 was $1.07 million, compared with an operating loss of ($485,000) for the prior-year period.

Net income for the third quarter of 2013 was $717,000, or $0.07 per diluted share, compared with a net loss of ($292,000), or $0.04 per diluted share, for the prior-year period.

Nine-Month Results

Total revenues for the first nine months of 2013 of $21.69 million were up 22% compared with total revenues of $17.74 million in the prior-year period. Product sales in the 2013 first nine months of $20.42 million were up 21% compared with product sales of $16.92 in the prior-year period, primarily due to stronger sales of lateral flow technology products, particularly, in South America (excluding Brazil) and partially offset by declines in DPP® product sales in Brazil to FIOCRUZ. The research and development ("R&D"), milestone, grant and royalty revenues for the nine months ended September 30, 2013 increased to $1.27 million from $825,000 in the prior-year period.

Gross margin for the 2013 first nine months increased 18% to $9.03 million compared with $7.63 million for the prior-year period, due primarily to the increase of products sold. Product gross margin for the first nine months of 2013 increased 14%, to $7.76 million, from $6.81 million in the prior-year period.

R&D expenses in the first nine months of 2013 were $4.15 million, compared with $3.36 million in the prior-year period. The 2013 first nine months included $1.02 million of clinical trial expenses related to our DPP® HIV 1/2 Assay CLIA waiver study, compared with $663,000 in the prior-year period.

Selling, general and administrative expenses in the first nine months of 2013 increased 5% to $3.70 million from $3.52 million in the prior-year period, largely due to wages and related expenses, and other expenses partially offset by lower commissions paid on DPP® product sales to Brazil, and lower consulting fees.

Operating income for the first nine months of 2013 was $1.18 million, compared with operating income of $747,000 for the prior-year period.

Net income for the first nine months of 2013 was $793,000 or $0.08 per diluted share, compared with net income of $450,000 or $0.05 per diluted share, for the prior-year period.

Balance Sheet Highlights

The Company had cash and cash equivalents of $8.05 million as of September 30, 2013, compared with $2.95 million as of December 31, 2012. The primary reason for this increase was net cash received from the April 2013 common stock funding of $5.40 million. Additional cash for the nine months was provided from net income net of non-cash expenses of $1.85 million and increased accounts payable and other accrued liabilities of $631,000. Partially offsetting these provisions was a use of cash for increased accounts receivable of $650,000 and increased inventories of $1.26 million. Overall, working capital increased by $6.44 million during the nine months to $14.07 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. In addition, following the completion of the call, a telephone replay will be accessible until November 14, 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 #:13572542. The conference call may also be accessed via the internet at http://www.investorcalendar.com/IC/CEPage.asp?ID=171835. An archive of the webcast will be available for 90 days on the Company's website at www.chembio.com.

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. To listen to the live call, please go to the website 15 minutes prior to its start to register, download, and install the necessary audio software. A replay will be available on the website for a limited time.

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 200 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, 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 Condensed Consolidated Results of Operations

UNAUDITED

	For the three months ended		For the nine months ended	
	September 30, 2013	**September 30, 2012**	**September 30, 2013**	**September 30, 2012**
Net product sales	**$ 9,044,714**	$ 4,745,094	**$ 20,419,595**	$ 16,919,436
License and royalty revenue	**898**	--	**898**	--
R&D, milestone and grant revenue	**572,027**	262,292	**1,268,821**	825,093
TOTAL REVENUES	**$ 9,617,639**	$ 5,007,386	**$ 21,689,314**	$ 17,744,529
GROSS MARGIN	**$ 4,056,186**	$ 1,728,915	**$ 9,031,251**	$ 7,632,402
Research and development expenses	**$ 1,602,297**	$ 1,005,645	**$ 4,148,201**	$ 3,363,819
Selling, general and administrative expenses	**$ 1,379,845**	$ 1,208,383	**$ 3,702,181**	$ 3,521,552
INCOME (LOSS) FROM OPERATIONS	**$ 1,074,044**	$ (485,113)	**$ 1,180,869**	$ 747,031
OTHER INCOME (EXPENSE):	**$ 1,477**	$ (546)	**$ 10,877**	$ (2,187)

Income tax provision (benefit)	**$ 358,850**	$ (193,310)	**$ 398,940**	$ 295,220
NET INCOME (LOSS)	**$ 716,671**	$ (292,349)	**$ 792,806**	$ 449,624
Basic earnings (loss) per share	**$ 0.08**	$ (0.04)	**$ 0.09**	$ 0.06
Diluted earnings (loss) per share	**$ 0.07**	$ (0.04)	**$ 0.08**	$ 0.05
Weighted average number of shares outstanding, basic	**9,324,783**	8,001,472	**8,886,998**	7,974,447
Weighted average number of shares outstanding, diluted	**9,824,019**	8,001,472	**9,433,152**	8,616,917

Chembio Diagnostics, Inc. & Subsidiary

Summary of Condensed Consolidated Balance Sheets

	September 30, 2013	**December 31, 2012**
	(UNAUDITED)	
CURRENT ASSETS:		
Cash and cash equivalents	**$ 8,045,805**	$ 2,951,859
Accounts receivable, net of allowance for doubtful accounts of $24,000 and $58,000 at September 30, 2013 and December 31, 2012, respectively	**5,505,215**	4,821,357
Inventories	**3,747,181**	2,488,071
Prepaid expenses and other current assets	**708,615**	747,463
TOTAL CURRENT ASSETS	**18,006,816**	11,008,750
FIXED ASSETS, net of accumulated depreciation	**1,822,746**	1,427,646
OTHER ASSETS	**4,496,847**	4,898,754
TOTAL ASSETS	**$ 24,326,409**	$ 17,335,150
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**3,935,036**	3,303,923
Current portion of loans payable	**--**	51,236
Customer deposits	**--**	23,224
TOTAL CURRENT LIABILITIES	**3,935,036**	3,378,383
Loans payable - net of current portion	**--**	82,247
TOTAL LIABILITIES	**3,935,036**	3,460,630
STOCKHOLDERS' EQUITY:		
Common stock - $.01 par value; 100,000,000 shares authorized, 9,324,783 and 8,036,232 shares issued and outstanding for September 30, 2013 and December 31, 2012, respectively	**93,248**	80,362
Additional paid-in capital	**46,827,310**	41,116,149

Accumulated deficit	**(26,529,185)**	(27,321,991)
TOTAL STOCKHOLDERS' EQUITY	**20,391,373**	13,874,520
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 24,326,409**	$ 17,335,150

Chembio Diagnostics, Inc. & Subsidiary

Summary of Condensed Consolidated Cash Flow

(UNAUDITED)

	For the nine months ended	
	September 30, 2013	**September 30, 2012**
Net cash provided by operating activities	$ 583,808	$ 951,742
Net cash used in investing activities	(796,274)	(715,195)
Net cash provided by financing activities	5,306,412	43,064
INCREASE IN CASH AND CASH EQUIVALENTS	**$ 5,093,946**	**$ 279,611**

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