

Chembio Diagnostics Reports First Quarter 2013 Financial Results

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

MEDFORD, N.Y. (May 9, 2013) – Chembio Diagnostics, Inc. (NASDAQ: CEMI), a leader in pointof-care diagnostic tests for infectious diseases, today reported financial results for the three months ended March 31, 2013.

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

- Total revenues of \$6.68 million, up 0.4% compared with \$6.65 million
- Product sales of \$6.31 million, down 0.8% compared with \$6.36 million
- Operating income of \$487,000, compared with operating income of \$720,000
- Net income of \$317,000 or \$0.04 per diluted share, compared with net income of \$433,000 or \$0.05 per diluted share

Commenting on the Company's financial performance, Lawrence Siebert, Chembio's Chief Executive Officer, said, "Strong growth in sales of lateral flow HIV tests to South America outside Brazil and to our U.S. marketing partner Alere were offset by declines in sales of Dual Path Platform[®] ("DPP") products to FIOCRUZ in Brazil. Moving forward we will continue efforts to realize additional sales to replace reduced revenue from FIOCRUZ that we currently anticipate.

"We are optimistic for continued growth of our lateral flow HIV tests in 2013 by Alere, as the U.S. Preventive Services Task Force reported its final recommendations on April 30, 2013 calling for the routine HIV testing of all people between the ages of 15 and 65. These guidelines fully embrace the routine testing that HIV the Centers for Disease Control and Prevention has been recommending since 2006. The new recommendations should catalyze demand for HIV testing, especially as the Affordable Care Act is implemented and there will be no co-pay required for this preventive service, given the 'A' rating that has been indicated.

"Our DPP[®] HIV 1/2 Assay ("DPP[®] HIV"), for use with oral fluid or blood samples, received U.S. Food and Drug Administration ("FDA") approval in December 2012. We are now focused on completing the requirements for a Clinical Laboratory Improvement Act ("CLIA") waiver for this product in order to enable sales to the point-of-care market segments where these tests are primarily used. We expect to submit the CLIA waiver application to the FDA this July. Our commercial strategy to address the public health market for DPP[®] HIV will feature a small direct sales organization, complemented by distributors to reach the hospital and physician office market. We are increasingly optimistic that, in the future, this sales organization will be able to market our DPP[®] Syphilis Screen & Confirm and DPP[®] HIV-Syphilis multiplex tests by mid-2014, and our Hepatitis-C test in 2015, based upon positive regulatory determinations.

"We are actively developing new revenue opportunities in a number of international markets, including, but not limited to Brazil, with current and new international distribution partners for our DPP[®] HIV-Syphilis test, as well as for our FDA approved lateral flow HIV tests. We are optimistic that these new revenue opportunities will offset lower sales to FIOCRUZ in 2013 and look forward to reporting on these initiatives as they develop," concluded Mr. Siebert.

First Quarter Results

Total revenues for the first quarter of 2013 of \$6.68 million were up less than 1% compared with total revenues of \$6.65 million in the prior-year period. Product sales in the 2013 first quarter of \$6.31 million were down less than 1% compared with product sales of \$6.63 in the prior-year period, primarily due to strong sales of lateral flow technology products in South America and the U.S., offset by declines in DPP[®] product sales in Brazil to FIOCRUZ. Research and development ("R&D"), milestone, grant and royalty revenues for the three months ended March 31, 2013 increased to \$365,000 from \$290,000 in the prior-year period.

Gross profit for the 2013 first quarter decreased 19% to \$2.69 million compared with \$3.33 million for the prior-year period, due primarily to a product mix resulting in a higher cost of products sold. Product gross profit for the first quarter of 2013 decreased 23% to \$2.33 million, from \$3.04 million in the prior-year period, and product gross margin also declined primarily due to product mix.

R&D expenses in the first quarter of 2013 were \$1.05 million, compared with \$1.38 million in the prioryear period. The 2013 first quarter included \$98,000 of clinical trial expenses, compared with \$484,000 in the prior-year period.

Selling, general and administrative expenses in the first quarter of 2013 decreased to \$1.16 million from \$1.23 million in the prior-year period, largely due to lower commissions paid on DPP[®] product sales to Brazil, and to changes in the allowance for doubtful accounts.

Operating income for the first quarter of 2013 was \$487,000, compared with operating income of \$720,000 for the prior-year period.

Net income for the first quarter of 2013 was \$317,000 or \$0.04 per diluted share, compared with net income of \$433,000 or \$0.05 per diluted share, for the prior-year period.

Balance Sheet Highlights

The Company had cash and cash equivalents of \$2.60 million as of March 31, 2013, compared with \$2.95 million as of December 31, 2012. Accounts receivable increased by \$423,000, not including the change in the allowance for doubtful accounts, during the quarter to \$5.28 million, and accounts payable and accrued liabilities decreased by \$114,000. Overall, working capital increased by \$390,000 during the first quarter to \$8.02 million.

In April 2013 the Company completed an underwritten public offering of 1.2 million shares of its common stock at \$5 per share, realizing net proceeds of approximately \$5.5 million.

Conference Call

Chembio has scheduled a conference call and webcast for 10:00 a.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 August 9, 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 #413457. The conference call may also be accessed via the internet at <u>www.chembio.com</u> or <u>http://www.investorcalendar.com/IC/CEPage.asp?ID=170929</u>. An archive of the webcast will be available for 90 days at <u>www.chembio.com</u>.

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 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.

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(Tables to follow)

<u>Chembio Diagnostics, Inc. & Subsidiary</u> <u>Summary of Condensed Consoldidated Results of Operations</u>

	<u>UNAUDITED</u> For the three months ended			
	March 31, 2013		March 31, 2012	
Net product sales	\$	6,313,190	\$	6,363,152
R&D, milestone and grant revenue		364,963		290,100
TOTAL REVENUES	\$	6,678,153	\$	6,653,252
GROSS MARGIN	\$	2,693,890	\$	3,332,864
Research and development expenses	\$	1,045,259	\$	1,379,131
Selling, general and administrative expenses	\$	1,162,080	\$	1,233,968
INCOME FROM OPERATIONS	\$	486,551	\$	719,765
OTHER INCOME (EXPENSE):	\$	1,002	\$	(922)
Income tax provision	\$	170,430	\$	285,400
NET INCOME	\$	317,123	\$	433,443
Basic earnings per share	\$	0.04	\$	0.05
Diluted earnings per share	\$	0.04	\$	0.05
Weighted average number of shares outstanding, basic		8,062,984		7,934,331
Weighted average number of shares outstanding, diluted		8,699,209		8,512,374

	March 31, 2013		December 31, 2012	
	(UI	NAUDITED)		
CURRENT ASSETS:				
Cash and cash equivalents	\$	2,598,745	\$	2,951,859
Accounts receivable, net		5,278,702		4,821,357
Inventories		2,601,489		2,488,071
Prepaid expenses and other current assets		754,648		747,463
TOTAL CURRENT ASSETS		11,233,584		11,008,750
FIXED ASSETS, net of accumulated				
depreciation		1,656,299		1,427,646
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OTHER ASSETS:				
Deferred tax asset, net of valuation allowance		4,079,807		4,233,194
License agreements, net of current portion		375,000		400,000
Deposits on manufacturing equipment		86,679		223,584
Deposits and other assets		41,976		41,976
	\$	17,473,345	\$	17,335,150
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities		3,189,661		3,303,923
Current portion of loans payable				51,236
Customer deposits		23,224		23,224
TOTAL CURRENT LIABILITIES		3,212,885		3,378,383
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OTHER LIABILITIES:				
Loans payable - net of current portion		-		82,247
TOTAL LIABILITIES		3,212,885		3,460,630
COMMITMENTS AND CONTINGENCIES				
STOCKHOLDERS' EQUITY:				
Preferred stock		-		-
Common stock - \$.01 par value		80,861		80,362
Additional paid-in capital		41,184,467		41,116,149
Accumulated deficit		(27,004,868)		(27,321,991)
TOTAL STOCKHOLDERS' EQUITY		14,260,460		13,874,520
TOTAL LIABILITIES AND				
STOCKHOLDERS' EQUITY		17,473,345		17,335,150
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<u>Chembio Diagnostics, Inc. & Subsidiary</u> <u>Summary of Condensed Consolidated Balance Sheets</u>

Summary of Condensed Consolidated Cash Flow								
(UNAUDITED)								
		For the three months ended						
		March 31, 2013		March 31, 2012				
Net cash provided by operating activities	\$	57,438	\$	149,226				
Net cash used in investing activities		(207,507)		(223,716)				
Net cash provided by (used in) financing activities		(203,045)		17,812				
(DECREASE) IN CASH AND CASH EQUIVALENTS	\$	(353,114)	\$	(56,678)				

Chembio Diagnostics, Inc. & Subsidiary

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