



May 9, 2013

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 (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 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 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 prior-year 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 www.chembio.com or <http://www.investorcalendar.com/IC/CEPage.asp?ID=170929>. 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.

(Tables to follow)

Summary of Condensed Consolidated Results of Operations

UNAUDITED

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	<u>364,963</u>	<u>290,100</u>
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

Chembio Diagnostics, Inc. & Subsidiary

Summary of Condensed Consolidated Balance Sheets

March 31, 2013 December 31, 2012

(UNAUDITED)

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	<u>754,648</u>	<u>747,463</u>
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
	<u>17,473,345</u>	<u>17,335,150</u>

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

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	<u>17,473,345</u>	<u>17,335,150</u>
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Chembio Diagnostics, Inc. & Subsidiary
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	<u>\$ (353,114)</u>	<u>\$ (56,678)</u>

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