August 8, 2013

Chembio Diagnostics Reports Second Quarter 2013 Financial Results

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

NEW YORK, Aug. 8, 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 and six months ended June 30, 2013.

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

- Total revenues of $5.39 million, down 11% compared with $6.08 million
- Product sales of $5.06 million, down 13% compared with $5.81 million
- Operating loss of $(380,000), compared with operating income of $512,000
- Net loss of $(241,000) or $(0.03) per diluted share, compared with net income of $309,000 or $0.04 per diluted share

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

- Total revenues of $12.07 million, down 5% compared with $12.74 million
- Product sales of $11.37 million, down 7% compared with $12.17 million
- Operating income of $107,000, compared with $1.23 million
- Net income of $76,000, or $0.01 per diluted share, compared with $742,000, or $0.09 per diluted share

As previously reported in June, we received the single-largest purchase order in our history of $5.3 million for our HIV 1/2 STAT-PAK product, approximately $869,000 was shipped in the second quarter of 2013

Lawrence Siebert, Chembio's Chief Executive Officer, stated, "The operating loss in the second quarter is primarily due to a combination of increased operating expenses, especially an increase in clinical trial expenses related to our DPP® HIV 1/2 Assay CLIA waiver study, and decreased product sales. We also made the decision to add a significant number of manufacturing personnel in the second quarter in order to meet the larger unit volumes that were anticipated for the balance of this year. Although this level of cost would not have been justified based on second quarter revenues, it was critical in order to meet current demand based on our backlog and anticipated orders.

"The second quarter was marked by a number of other important milestones both for our lateral flow and our patented Dual Path Platform (DPP®) products and technologies. In addition to the $5.3 million order mentioned above, our SURE CHECK® HIV 1/2 product received CE Mark approval from European regulators and is now cleared for commercialization within the European Union (EU). Chembio is currently working with commercialization partners in Europe for this and our other lateral flow and DPP® assays that are pending CE marking.

"On the DPP HIV 1/2 Assay CLIA waiver study, we are now well on our way to completing the study and submitting our CLIA waiver application to the FDA. However enrollment is slower than planned, which will delay our FDA CLIA waiver submission from our previous estimate of July to the fourth quarter. This means that we would not reasonably expect to receive a CLIA waiver decision until early 2014. Although disappointing, we believe this kind of delay is not unusual in these circumstances. We are finalizing our launch plan and establishing our direct sales organization and distribution partners in order to be ready to commercialize this and our other products in the U.S. market beginning in 2014.

"Our DPP® tests and technology have received additional validation from leading clinical, government and commercialization groups around the world," continued Siebert. "During the second quarter, Chembio executed agreements with contractors of the U.S. Centers for Disease Control and another U.S. government agency to work toward the development of multiplex, rapid, point-of-care diagnostic tests for influenza and febrile illnesses. Also, Mexico's Institute of Epidemiological Diagnosis and Reference (InDRE) evaluated the sensitivity and specificity of the Chembio DPP® HIV-Syphilis product. This multiplex test adds the syphilis marker to our recently FDA-approved DPP® HIV 1/2 test, and should greatly strengthen the prevention of mother-to-child transmission (PMTCT) of syphilis. In the InDRE's testing, the Chembio DPP® HIV-Syphilis test performed with 100%

sensitivity and 100% specificity on all samples. We believe this is a powerful validation of the Chembio DPP® HIV-Syphilis product that will positively influence sales worldwide. And lastly, during the second quarter Chembio entered into an international assembly and distribution agreement for the company's DPP® products in Brazil with Labtest Diagnostica SA (Labtest), a leading diagnostics manufacturer and marketing organization. This agreement with Labtest represents a second distribution arm for Chembio's DPP® products in the sizable Brazilian point-of-care diagnostic market. We are pleased to be working with them in commercializing our technology in this important region.

"We look forward to an exciting period ahead for Chembio. As we continue to serve and expand our global customer base, we are moving ever closer to entering the U.S. market with the first FDA-approved, DPP® point-of-care product, helping to save and improve lives."

Second Quarter Results

Total revenues for the second quarter of 2013 of $5.39 million were down 11% compared with total revenues of $6.08 million in the prior-year period. Product sales in the 2013 second quarter of $5.06 million were down 13% compared with product sales of $5.81 in the prior-year period, primarily due to declines in DPP® product sales in Brazil to FIOCRUZ, partially offset by an increase in HIV lateral flow sales. Research and development ("R&D"), milestone, grant and royalty revenues for the three months ended June 30, 2013 increased to $332,000 from $273,000 in the prior-year period.

Gross margin for the 2013 second quarter decreased 11% to $2.28 million compared with $2.57 million for the prior-year period, due primarily to the lower DPP® sales and a product mix resulting in a higher cost of products sold. Product gross margin for the second quarter of 2013 decreased 15% to $1.95 million, from $2.30 million in the prior-year period.

R&D expenses in the second quarter of 2013 were $1.50 million, compared with $.98 million in the prior-year period. The 2013 second quarter included $422,000 of clinical trial expenses related to our DPP® HIV 1/2 Assay CLIA waiver study, compared with $72,000 in the prior-year period.

Selling, general and administrative expenses in the second quarter of 2013 increased to $1.16 million from $1.08 million in the prior-year period, largely due to changes in the allowance for doubtful accounts in 2012.

Operating loss for the second quarter of 2013 was ($380,000), compared with operating income of $512,000 for the prior-year period.

Net loss for the second quarter of 2013 was ($241,000), or $0.03 per diluted share, compared with net income of $309,000, or $0.04 per diluted share, for the prior-year period.

Six-Month Results

Total revenues for the first six months of 2013 of $12.07 million were down 5% compared with total revenues of $12.74 million in the prior-year period. Product sales in the 2013 first six months of $11.37 million were down 7% compared with product sales of $12.17 in the prior-year period, primarily due to declines in DPP® product sales in Brazil to FIOCRUZ and partially offset by stronger sales of lateral flow technology products in South America and the U.S. Research and development ("R&D"), milestone, grant and royalty revenues for the six months ended June 30, 2013 increased to $697,000 from $563,000 in the prior-year period.

Gross margin for the 2013 first six months decreased 16% to $4.98 million compared with $5.90 million for the prior-year period, due primarily to the lower DPP® sales and a product mix resulting in a higher cost of products sold. Product gross margin for the first six months of 2013 decreased 20% to $4.28 million, from $5.34 million in the prior-year period.

R&D expenses in the first six months of 2013 were $2.55 million, compared with $2.36 million in the prior-year period. The 2013 first six months included $520,000 of clinical trial expenses related to our DPP® HIV 1/2 Assay CLIA waiver study, compared with $556,000 in the prior-year period.

Selling, general and administrative expenses in the first six months of 2013 increased slightly to $2.32 million from $2.31 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 six months of 2013 was $107,000, compared with operating income of $1,232,000 for the prior-year period.

Net income for the first six months of 2013 was $76,000 or $0.01 per diluted share, compared with net income of $742,000 or $0.09 per diluted share, for the prior-year period.

Balance Sheet Highlights

The Company had cash and cash equivalents of $8.65 million as of June 30, 2013, compared with $2.95 million as of December 31, 2012. The primary driver for this increase was net cash received from the April 2013 common stock funding of $5.40 million. Additional cash for the six months was provided from decreased accounts receivable of $927,000, and increased accounts payable and other accrued liabilities of $626,000. Partially offsetting these provisions was a use of cash for increased inventories of $1.36 million in preparation to meet third quarter sales. Overall, working capital increased by $5.56 million during the second quarter to $13.19 million. The April 2013 common stock funding of $5.41 million accounted for most of this increase.

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 November 8, 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 #: 418478. The conference call may also be accessed via the Internet at **http://www.investorcalendar.com/IC/CEPage.asp?ID=171395**. An archive of the web cast 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 six months ended	
	June 30, 2013	**June 30, 2012**	**June 30, 2013**	**June 30, 2012**
Net product sales	**$ 5,061,691**	$ 5,811,190	**$ 11,374,881**	$ 12,174,342

R&D, milestone and grant revenue	**331,831**	272,701	**696,794**	562,801
TOTAL REVENUES	**$ 5,393,522**	$ 6,083,891	**$ 12,071,675**	$ 12,737,143
GROSS MARGIN	**$ 2,281,175**	$ 2,570,624	**$ 4,975,065**	$ 5,903,487
Research and development expenses	**$ 1,500,645**	$ 979,044	**$ 2,545,904**	$ 2,358,174
Selling, general and administrative expenses	**$ 1,160,256**	$ 1,079,201	**$ 2,322,336**	$ 2,313,169
INCOME (LOSS) FROM OPERATIONS	**$ (379,726)**	$ 512,379	**$ 106,825**	$ 1,232,144
OTHER INCOME (EXPENSE):	**$ 8,397**	$ (719)	**$ 9,400**	$ (1,641)
Income tax provision (benefit)	**$ (130,340)**	$ 203,130	**$ 40,090**	$ 488,530
NET INCOME (LOSS)	**$ (240,989)**	$ 308,530	**$ 76,135**	$ 741,973
Basic earnings (loss) per share	**$ (0.03)**	$ 0.04	**$ 0.01**	$ 0.09
Diluted earnings (loss) per share	**$ (0.03)**	$ 0.04	**$ 0.01**	$ 0.09
Weighted average number of shares outstanding, basic	**9,259,506**	7,987,105	**8,664,478**	7,960,714
Weighted average number of shares outstanding, diluted	**9,259,506**	8,525,199	**9,230,840**	8,512,770

Chembio Diagnostics, Inc. & Subsidiary

Summary of Condensed Consolidated Balance Sheets

	June 30, 2013	**December 31, 2012**
	(UNAUDITED)	
CURRENT ASSETS:		
Cash and cash equivalents	**$ 8,645,392**	$ 2,951,859
Accounts receivable, net of allowance for doubtful accounts of $24,000 and $58,000 at June 30, 2013 and December 31, 2012, respectively	**3,894,207**	4,821,357
Inventories	**3,848,295**	2,488,071
Prepaid expenses and other current assets	**730,383**	747,463
TOTAL CURRENT ASSETS	**17,118,277**	11,008,750
FIXED ASSETS, net of accumulated depreciation	**1,832,570**	1,427,646
OTHER ASSETS	**4,591,064**	4,898,754
TOTAL ASSETS	**$ 23,541,911**	$ 17,335,150
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**3,929,431**	3,303,923
Current portion of loans payable	**--**	51,236

Customer deposits	--	23,224
TOTAL CURRENT LIABILITIES	**3,929,431**	3,378,383
TOTAL STOCKHOLDERS' EQUITY	**19,612,480**	13,874,520
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 23,541,911**	$ 17,335,150

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

	For the six months ended	
	June 30, 2013	**June 30, 2012**
Net cash provided by operating activities	$ 802,771	$ 1,785,354
Net cash used in investing activities	(415,649)	(447,621)
Net cash provided by financing activities	5,306,411	41,354
INCREASE IN CASH AND CASH EQUIVALENTS	**$ 5,693,533**	**$ 1,379,087**

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Source: Chembio Diagnostics, Inc.