



August 9, 2012

ChemBio Diagnostics Reports Second Quarter 2012 Financial Results

Product Sales Increase 95%, Operating Income Increases 160%

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

MEDFORD, N.Y., Aug. 9, 2012 (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 six months ended June 30, 2012.

Financial highlights for the second quarter of 2012 include the following (all comparisons are with the second quarter of 2011):

- Total revenues of \$6.08 million, up 68% compared with \$3.61 million
- Product sales of \$5.81 million, up 95% compared with \$2.97 million
- Operating income of \$512,000, compared with \$197,000
- Net income of \$309,000 or \$0.04 per diluted share, compared with \$195,000 or \$0.02 per diluted share

Financial highlights for the first six months of 2012 include the following (all comparisons are with the first six months of 2011):

- Total revenues of \$12.74 million, up 76% compared with \$7.25 million
- Product sales of \$12.17 million, up 103% compared with \$5.99 million
- Operating income of \$1.23 million, compared with \$58,000
- Net income of \$742,000, or \$0.09 per diluted share, compared with \$53,000, or \$0.01 per diluted share

Commenting on the Company's strong financial performance, Lawrence Siebert, ChemBio's Chief Executive Officer, said, "Our second quarter results continued the strong momentum begun earlier in the year, with product sales that nearly doubled compared with the second quarter of last year. These gains were led by 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. We look forward to continued growth of our Dual Path Platform (DPP®) product line in Brazil by FIOCRUZ and expect this collaboration to drive revenue growth throughout 2012 and 2013.

"During the quarter, we made considerable progress strengthening our rapid HIV test franchise. We completed a 3,000-patient clinical trial in support of U.S. Food and Drug Administration (FDA) approval of our DPP® HIV 1/2 Assay, a rapid, point-of-care test designed for use with oral fluid or blood samples. Our FDA submission has been made and is pending approval, which we expect to receive by the end of the year. Also, we are uniquely positioned to participate in the HIV self-test or over-the-counter opportunity with our unitized Sure Check® HIV 1/2 finger-stick whole blood test. This test is FDA-approved for the professional market, is well established in the U.S. by our marketing partner, Alere, as Clearview® Complete HIV 1/2, and is more sensitive than the existing competitive oral fluid test."

Mr. Siebert explained that in order to begin the regulatory process for an over-the-counter consumer self-test, a company must first have a product that is FDA-approved for the professional market, making ChemBio the only current practical alternative to another company's recently approved oral fluid self-test. "As such, we are accelerating our development plans to bring our rapid, in-home HIV test to market. We are working toward filing an Investigation New Device application with the FDA by year-end and look forward to reporting on our progress with this program," he said.

"We were especially pleased to announce our listing on the NASDAQ Capital Markets® which we believe offers ChemBio a significantly expanded trading platform for its securities and provides increased investor interest in what we consider to be a very compelling growth story. We look forward to building on the strong momentum from the first half of 2012 and believe that we will finish the year with record revenues and operating income," concluded Mr. Siebert.

Second Quarter Results

Total revenues for the second quarter of 2012 were \$6.08 million, an increase of 68% compared with total revenues of \$3.61 million for the second quarter of 2011. Product sales increased 95% to \$5.81 million from \$2.97 million in the prior-year period.

Research and development (R&D), milestone, grant and royalty revenues for the second quarter of 2012 decreased to \$273,000 from \$640,000 in the same period of 2011.

Gross margin for the second quarter of 2012 of \$2.57 million increased 25% compared with \$2.01 million for the 2011 second quarter, due to higher product revenue partially offset by lower R&D, licensing and royalty revenues. Product gross margin for the second quarter of 2012, which excludes R&D, milestone, grant, and royalty revenues, increased 63% to \$2.30 million, compared with \$1.41 million for the comparable period in 2011, while product gross margin percentage declined due to higher scrap and product mix.

R&D expenses were \$0.98 million in the second quarter of 2012 and \$1.16 million in the prior year. The 2012 second quarter included \$72,000 of clinical trial expenses compared with \$282,000 in the 2011 period, reflecting completion of the Company's pivotal clinical trial of DPP[®] HIV 1/2 Assay, which completed patient enrollment and follow-up early in the second quarter of 2012.

For the three months ended June 30, 2012, selling, general and administrative expenses increased to \$1.08 million from \$688,000 in the prior year, largely due to higher commissions on DPP product sales to Brazil, the initiation fee paid to become listed on NASDAQ, and higher wages and stock-based compensation.

Operating income for the second quarter of 2012 was \$512,000, compared with \$197,000 for the second quarter of 2011.

Net income for the second quarter of 2012 was \$309,000, or \$0.04 per diluted share, compared with \$195,000, or \$0.02 per diluted share, for the comparable period in 2011. The 2012 second quarter net income included a charge of \$203,000 in income tax provision, which approximates the amount of income taxes that would be attributable to Chembio if the Company did not have an operating loss carryforward to offset income taxes payable.

Six Month Results

Total revenues for the first six months of 2012 were \$12.74 million, an increase of 76%, compared with total revenues of \$7.25 million for the first six months of 2011. Product sales increased 103% to \$12.17 million from \$5.99 million in the prior-year period. R&D, milestone, grant and royalty revenues for the first half of 2012 decreased to \$563,000 from \$1.26 million in the same period of 2011.

Gross margin increased 48% to \$5.90 million in the 2012 six months compared with \$3.98 million in the 2011 period due to higher product revenue partially offset by lower R&D, licensing and royalty revenues. Product gross margin for the six months of 2012 increased 97% to \$5.34 million, compared with \$2.72 million for the comparable period in 2011, while product gross margin percentage declined due to higher scrap and product mix.

R&D expenses were \$2.36 million in the first six months of 2012 and \$2.46 million in the prior year.

For the six months ended June 30, 2012, selling, general and administrative expenses increased to \$2.31 million from \$1.46 million in the prior year, largely due to higher commissions on DPP product sales to Brazil, the initiation fee paid to become listed on NASDAQ, and higher wages and stock-based compensation.

Operating income for the first six months of 2012 was \$1.23 million, compared with \$58,000 for the first six months of 2011.

Net income for the first half of 2012 was \$742,000, or \$0.09 per diluted share, compared with \$53,000, or \$0.01 per diluted share, for the comparable period in 2011. Net income for the 2012 period included a charge of \$489,000 in income tax provision, which approximates the amount of income taxes that would be attributable to Chembio if the Company did not have an operating loss carryforward to offset income taxes payable.

Balance Sheet Highlights

The Company had cash and cash equivalents of \$4.39 million as of June 30, 2012, compared with \$3.01 million as of December 31, 2011.

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 August 16, 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 #: 398076. The conference call may also be accessed via the internet at <http://www.investorcalendar.com/IC/CEPage.asp?ID=169238>. 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 \$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.

Chembio Diagnostics, Inc. & Subsidiary
Summary of Condensed Consolidated Results of Operations
UNAUDITED

	For the three months ended		For the six months ended	
	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
Net product sales	\$ 5,811,190	\$ 2,974,379	\$ 12,174,342	\$ 5,989,442
License and royalty revenue	--	71,468	--	100,322
R&D, milestone and grant revenue	<u>272,701</u>	<u>568,304</u>	<u>562,801</u>	<u>1,160,068</u>
TOTAL REVENUES	\$ 6,083,891	\$ 3,614,151	\$ 12,737,143	\$ 7,249,832
GROSS MARGIN	\$ 2,570,624	\$ 2,050,278	\$ 5,903,487	\$ 3,976,620
Research and development expenses	\$ 979,044	\$ 1,164,872	\$ 2,358,174	\$ 2,455,014
Selling, general and administrative expenses	\$ 1,079,201	\$ 688,259	\$ 2,313,169	\$ 1,463,630
INCOME FROM OPERATIONS	\$ 512,379	\$ 197,147	\$ 1,232,144	\$ 57,976
Income tax provision	\$ 203,130	\$ --	\$ 488,530	\$ --
NET INCOME	\$ 308,530	\$ 194,839	\$ 741,973	\$ 52,542
Basic net income per share	\$ 0.04	\$ 0.02	\$ 0.09	\$ 0.01

Diluted net income per share	\$ 0.04	\$ 0.02	\$ 0.09	\$ 0.01
Weighted average number of shares outstanding, basic	7,987,105	7,882,573	7,960,714	7,834,384
Weighted average number of shares outstanding, diluted	8,525,199	8,716,228	8,512,770	8,647,045

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

	<u>June 30, 2012</u>	<u>December 31, 2011</u>
	Unaudited	
CURRENT ASSETS:		
Cash and cash equivalents	\$ 4,390,041	\$ 3,010,954
Accounts receivable, net of allowance for doubtful accounts of \$30,000 for 2012 and 2011	2,215,477	2,998,449
Inventories	3,141,322	2,300,286
Prepaid expenses and other current assets	736,458	681,893
TOTAL CURRENT ASSETS	10,483,298	8,991,582
FIXED ASSETS, net of accumulated depreciation	1,144,296	1,062,276
OTHER ASSETS		
Deferred tax asset, net of valuation allowance	4,309,945	4,749,622
License agreements and other assets	777,471	682,264
	<u>\$ 16,715,010</u>	<u>\$ 15,485,744</u>
TOTAL CURRENT LIABILITIES	\$ 3,106,036	\$ 2,857,626
TOTAL OTHER LIABILITIES	<u>108,217</u>	<u>133,484</u>
TOTAL LIABILITIES	3,214,253	2,991,110
TOTAL STOCKHOLDERS' EQUITY	<u>13,500,757</u>	<u>12,494,634</u>
	<u>\$ 16,715,010</u>	<u>\$ 15,485,744</u>

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

	<u>For the six months ended</u>	
	<u>June 30, 2012</u>	<u>June 30, 2011</u>
Net cash provided by operating activities	\$ 1,785,354	\$ 926,164
Net cash used in investing activities	(447,621)	(288,402)

Net cash provided by (used in) financing activities	<u>41,354</u>	<u>(634,784)</u>
INCREASE IN CASH AND CASH EQUIVALENTS	<u>\$ 1,379,087</u>	<u>\$ 2,978</u>

CONTACT: Chembio Diagnostics

Susan Norcott

(631) 924-1135, ext. 125

snorcott@chembio.com

LHA

Anne Marie Fields

(212) 838-3777

AFields@lhai.com

@LHA_IR_PR

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