



November 13, 2012

## **ChemBio Diagnostics Reports Third Quarter 2012 Financial Results**

*Expects Record Revenue and Continued Profitability for the Fourth Quarter and Full Year*

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

MEDFORD, N.Y., Nov. 13, 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 nine months ended September 30, 2012.

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

- Total revenues of \$5.01 million, down 15% compared with \$5.92 million
- Product sales of \$4.75 million, down 14% compared with \$5.53 million
- Operating loss of \$485,000, compared with operating income of \$479,000
- Net loss of \$292,000 or \$0.04 per share, compared with net income of \$476,000 or \$0.06 per diluted share

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

- Total revenues of \$17.74 million, up 35% compared with \$13.17 million
- Product sales of \$16.92 million, up 47% compared with \$11.52 million
- Operating income of \$747,000, compared with \$537,000
- Net income of \$450,000 or \$0.05 per diluted share, compared with net income of \$528,000 or \$0.06 per diluted share

Commenting on the Company's financial performance, Lawrence Siebert, ChemBio's Chief Executive Officer, said, "Our third quarter product revenues were lower than each of the first two quarters of 2012, primarily because the manufacture of some large international orders we received in the third quarter could not be completed until the fourth quarter, thereby pushing the revenues into the current fourth quarter. Also, reduced sales to Alere in the third quarter were the result of reductions in U.S. rapid HIV test public health funding, although we are optimistic on the long-term outlook for growth as funding moves from CDC grants to an insurance model under the Affordable Care Act. In the meantime we believe our products are very well positioned in the U.S, relative to our competitors, as our products are being increasingly adopted resulting in increased market share and a solid increase in 2012. Moreover I am pleased to report that we have a record amount of orders on hand that will both enable us to finish the year and fourth quarter again with record revenues, and to also begin 2013 with a strong outlook.

"During the third quarter we made significant progress on all of our key development programs, including our DPP<sup>®</sup> HIV, DPP<sup>®</sup> Syphilis, DPP<sup>®</sup> HIV-Syphilis, DPP<sup>®</sup> Hepatitis-C and our SURE CHECK<sup>®</sup> HIV test for home use," added Mr. Siebert. "In the near term we look forward to hearing from the U.S. Food and Drug Administration (FDA) regarding our Pre-Market Approval (PMA) submission for our DPP<sup>®</sup> HIV 1/2 Assay, a rapid point-of-care test for the detection of antibodies to HIV 1 and 2 in oral fluid, finger-stick whole blood, venous whole blood, serum or plasma. The FDA recently performed a pre-approval inspection (PAI) of our facilities and we look forward to a favorable outcome on our PMA application. With approval we will then seek to obtain a Clinical Laboratory Improvement Amendment (CLIA) waiver while developing our go-to-market strategy.

"Also, we expanded our management team with the addition of Sharon Klugewicz as Vice President of Quality Assurance/Quality Control and Technical Operations, and Michael Steele as Vice President, Sales, Marketing and Business Development. These newly created positions are key to achieving our growth strategy, and both executives already are meaningfully contributing to ChemBio," concluded Mr. Siebert.

### **Third Quarter Results**

Total revenues for the third quarter of 2012 were \$5.01 million, a decrease of 15% compared with total revenues of \$5.92 million for the third quarter of 2011. Product sales decreased 14% to \$4.75 million from \$5.53 million in the prior-year period. Research and development (R&D), milestone, grant and royalty revenues for the third quarter of 2012 decreased to \$262,000 from

\$395,000 in the same period of 2011.

Third quarter 2012 gross profit of \$1.73 million decreased 35% compared with \$2.67 million for the 2011 third quarter, due to lower product sales and lower R&D, licensing and royalty revenues. Product gross profit for the third quarter of 2012 decreased 36% to \$1.47 million, compared with \$2.28 million for the comparable period in 2011, and product gross margin declined primarily due to product mix.

R&D expenses were \$1.01 million in the third quarter of 2012 and \$1.24 million in the prior year. The 2012 third quarter included \$108,000 of clinical trial expenses compared with \$320,000 in the 2011 period, reflecting the completion of the Company's pivotal clinical trial of DPP<sup>®</sup> HIV 1/2 Assay early in the third quarter of 2012.

For the three months ended September 30, 2012, selling, general and administrative expenses increased to \$1.21 million from \$949,000 in the prior year, largely due to higher commissions on DPP product sales to Brazil, and higher wages and stock-based compensation.

Operating loss for the third quarter of 2012 was \$485,000, compared with operating income of \$479,000 for the third quarter of 2011.

Net loss for the third quarter of 2012 was \$292,000 or \$0.04 per share, compared with net income of \$476,000 or \$0.06 per diluted share for the comparable period in 2011. The 2012 third quarter net loss included a benefit of \$193,000 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.

### **Nine Month Results**

Total revenues for the first nine months of 2012 were \$17.74 million, an increase of 35%, compared with total revenues of \$13.17 million for the first nine months of 2011. Product sales increased 47% to \$16.92 million from \$11.52 million in the prior-year period. R&D, milestone, grant and royalty revenues for the first nine months of 2012 decreased to \$825,000 from \$1.66 million in the same period of 2011.

Gross profit increased 15% to \$7.63 million in the first nine months of 2012 compared with \$6.65 million in the comparable 2011 period, due to higher product revenue partially offset by lower R&D, licensing and royalty revenues. Product gross profit for the nine months of 2012 increased 36% to \$6.81 million, compared with \$4.99 million for the comparable period in 2011, while product gross margin declined due to higher scrap and product mix.

R&D expenses were \$3.36 million in the first nine months of 2012 and \$3.70 million in the prior year.

For the nine months ended September 30, 2012, selling, general and administrative expenses increased to \$3.52 million from \$2.41 million in the prior year, largely due to higher commissions on DPP product sales to Brazil, the initial listing fee paid to list on NASDAQ, and higher wages and stock-based compensation.

Operating income for the first nine months of 2012 was \$747,000, compared with \$537,000 for the first nine months of 2011.

Net income for the first nine months of 2012 was \$450,000, or \$0.05 per diluted share, compared with \$528,000, or \$0.06 per diluted share, for the comparable period in 2011. Net income for the 2012 period included a charge for income tax provision of \$295,000, 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 \$3.29 million as of September 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 November 20, 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 conference ID #: 401415. The conference call may also be accessed via the internet at <http://www.investorcalendar.com/IC/CEPage.asp?ID=169868>. An archive of the webcast will be available for 90 days on the Company's website at [www.chembio.com](http://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](http://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)

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

#### **UNAUDITED**

	<u>For the three months ended</u>		<u>For the nine months ended</u>	
	<u>September 30, 2012</u>	<u>September 30, 2011</u>	<u>September 30, 2012</u>	<u>September 30, 2011</u>
Net product sales	\$ 4,745,094	\$ 5,526,883	\$ 16,919,436	\$ 11,516,325
License and royalty revenue	--	25,000	--	125,322
R&D, milestone and grant revenue	<u>262,292</u>	<u>369,904</u>	<u>825,093</u>	<u>1,529,972</u>
<b>TOTAL REVENUES</b>	<b>\$ 5,007,386</b>	<b>\$ 5,921,787</b>	<b>\$ 17,744,529</b>	<b>\$ 13,171,619</b>
<b>GROSS MARGIN</b>	<b>\$ 1,728,915</b>	<b>\$ 2,670,733</b>	<b>\$ 7,632,402</b>	<b>\$ 6,647,353</b>
Research and development expenses	\$ 1,005,645	\$ 1,242,295	\$ 3,363,819	\$ 3,697,309
Selling, general and administrative expenses	\$ 1,208,383	\$ 949,237	\$ 3,521,552	\$ 2,412,867
<b>INCOME (LOSS) FROM OPERATIONS</b>	<b>\$ (485,113)</b>	<b>\$ 479,201</b>	<b>\$ 747,031</b>	<b>\$ 537,177</b>
OTHER INCOME (EXPENSE):	\$ (546)	\$ (3,596)	\$ (2,187)	\$ (9,030)
Income tax provision (benefit)	\$ (193,310)	\$ --	\$ 295,220	\$ --
<b>NET INCOME (LOSS)</b>	<b>\$ (292,349)</b>	<b>\$ 475,605</b>	<b>\$ 449,624</b>	<b>\$ 528,147</b>

Basic earnings (loss) per share	\$ (0.04)	\$ 0.06	\$ 0.06	\$ 0.07
Diluted earnings (loss) per share	\$ (0.04)	\$ 0.06	\$ 0.05	\$ 0.06
Weighted average number of shares outstanding, basic	8,001,472	7,913,081	7,974,447	7,860,904
Weighted average number of shares outstanding, diluted	8,001,472	8,508,740	8,616,917	8,644,940

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

	<u>September 30, 2012</u>	<u>December 31, 2011</u>
	<u>Unaudited</u>	
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 3,290,565	\$ 3,010,954
Accounts receivable, net of allowance for doubtful accounts of \$30,000 at September 30, 2012 and December 31, 2011	2,567,172	2,998,449
Inventories	3,037,880	2,300,286
Prepaid expenses and other current assets	<u>705,850</u>	<u>681,893</u>
<b>TOTAL CURRENT ASSETS</b>	<b>9,601,467</b>	<b>8,991,582</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>1,334,751</b>	<b>1,062,276</b>
<b>OTHER ASSETS</b>		
Deferred tax asset, net of valuation allowance	4,483,924	4,749,622
License agreements and other assets	<u>719,917</u>	<u>682,264</u>
	<u><b>\$ 16,140,059</b></u>	<u><b>\$ 15,485,744</b></u>
<b>TOTAL CURRENT LIABILITIES</b>	<b>\$ 2,760,598</b>	<b>\$ 2,857,626</b>
<b>TOTAL OTHER LIABILITIES</b>	<u><b>95,321</b></u>	<u><b>133,484</b></u>
<b>TOTAL LIABILITIES</b>	<b>2,855,919</b>	<b>2,991,110</b>
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<u><b>13,284,140</b></u>	<u><b>12,494,634</b></u>
	<u><u><b>\$ 16,140,059</b></u></u>	<u><u><b>\$ 15,485,744</b></u></u>

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

For the nine months ended  
September 30, 2012   September 30, 2011

<b>Net cash provided by operating activities</b>	\$ 951,742	\$ 1,559,123
<b>Net cash used in investing activities</b>	(715,195)	(282,175)
<b>Net cash provided by (used in) financing activities</b>	43,064	(367,951)
<b>INCREASE IN CASH AND CASH EQUIVALENTS</b>	<u><u>\$ 279,611</u></u>	<u><u>\$ 908,997</u></u>

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