November 3, 2011

Chembio Reports 3rd Quarter 2011 Results

Conference Call Scheduled for Thursday, November 3, 2011, at 10:00 a.m. Eastern Time

MEDFORD, N.Y., Nov. 3, 2011 /PRNewswire via COMTEX/ --

Chembio Diagnostics, Inc. (OTC.PK: CEMI and OTC.QB: CEMI),which develops, manufactures, markets and licenses point-of-care diagnostic tests, reported revenues and earnings for the quarter ended September 30, 2011. Total revenues were $5.92million for the quarter ended September 30, 2011, a quarterly record for the Company, which compares to total revenues of $4.51 million for the quarter ended September 30, 2010, a 31.5% increase. The Company recorded net income of approximately $.48 million for the quarter ended September 30, 2011, compared to net income of approximately $.17 million for the quarter ended September 30, 2010, an increase of 183%. Basic earnings per share, after rounding, were approximately $.01 per share for the quarter ended September 30, 2011, as compared with less than $0.01 per share for the year earlier period.

For the nine months ended September 30, 2011, total revenues were $13.17 million which compares to total revenues of $11.04 million for the nine months ended September 30, 2010, a 19% increase. The Company recorded net income of approximately $.53 million for the nine months ended September 30, 2011, compared to net income of approximately $.63 million for the nine months ended September 30, 2010, a decrease of 16.5%. Basic earnings per share, after rounding, were approximately $.01 per share for each of the nine-month periods.

The Company had a 46% increase in Net Product Sales during the third quarter as compared with the comparable period in 2010. This resulted from a $.82 million or 75% increase in sales to Alere, Inc. of our FDA-approved rapid HIV tests for marketing in the U.S. to $1.91 million and a $1.70 million increase in sales of our DPP® products, all to the Oswaldo Cruz Foundation ("FIOCRUZ") in Brazil, to $1.705 million. The approximate $1.74 million increase in Net Product Sales for the third quarter was partially offset by a decrease of $287,000 in R&D, milestone and grant revenue and a decrease of $37,000 in license and royalty revenue. The increased sales to Alere and Brazil together with increased sales to Mexico and Asia, substantially outpaced a decrease in sales to Africa and combined to produce a 52.7% increase in product gross margin dollars as compared to the third quarter of 2010. The product gross margin increased by almost two percentage points, from 39.4% in the third quarter of 2010 to 41.2% in the third quarter of 2011. Overall gross margin was 45% for the three months ended September 30, 2011.

The Company had a record gross margin for the quarter ended September 30, 2011 of $2.67 million as compared to $2.20 million in the quarter ended September 30, 2010. Gross margin for the nine months ended September 30, 2011 was $6.65 million as compared to $5.61 million in the nine months ended September 30, 2010. These product sales, together with increased gross margins have enabled the Company to increase funding of research, development, clinical and regulatory programs by approximately $.88 million in 2011 while still maintaining a net income.

For the nine months ended September 30, 2011, the Company had a 38% increase in Net Product Sales consisting of a 52% increase in sales to Alere, Inc. of our FDA-approved rapid HIV tests for marketing in the U.S. and a $2.60 million increase in sales of our DPP® products to Brazil. The 2010 DPP® net product sales were only $6,500. These increases, together with overall sales increases and changes in product mix, combined to produce a 71.6% increase in product gross margin dollars as compared to the first nine months of 2010. The product gross margin increased by 8.5 percentage points, from 34.9% in the first nine months of 2010 to 43.4% in the first nine months of 2011. Overall gross margin was 50.5% for the nine months ended September 30, 2011.

The Company's cash increased for the nine months ended September 30, 2011 by $909,000, to $3.05 million, as compared to an increase in cash for the same period in 2010 of $268,000. The increases during the 2011 and 2010 periods are primarily attributable to cash provided by operations. The increase in the 2011 period also includes cash received from the change in receivables of $1.29 million, an increase in deferred revenue of $426,000, an increase of $286,000 in loans from HSBC on the revolver for equipment purchases and a $290,000 increase in accounts payable and accrued liabilities. These cash increases for the nine-month period were partially offset by an increase in inventories of $1.24 million. In addition the Company received $205,000 from the exercise of warrants. The increased cash from operations in 2011 was also attributable to non-cash expenses aggregating $458,000, primarily from depreciation and amortization expense.

Lawrence Siebert, Chembio's Chief Executive Officer, commented, "Chembio had a very strong quarter as we manufactured a record volume of products, improved product gross margins, maintained our commitment to investing in our product pipeline, and generated strong bottom line results and cash flow."

Financial Highlights for the Quarter ended September 30, 2011

- Product sales for the quarter ended September 30, 2011 (third quarter) increased 46% to $5.53 million from $3.79 million in the same period of 2010.
- R&D, milestone and grant revenues for the third quarter decreased to $.37 million from $.66 million in the same period of 2010, and license and royalty revenue decreased to $.03 million from $.06 million.
- The increased product revenue, together with changes in product mix, partially offset by decreased R&D and licensing and royalty revenues, combined to produce gross margin dollars that were $.46 million, or 21%, higher ($2.67 million vs. $2.21 million) than the gross margin dollars in the comparable period in 2010. Product gross margin increased by $.79 million, or 52.7% ($2.28 million vs. $1.49 million), over the comparable period in 2010.
- Research and development expenses remained nearly constant compared to the 2010 period. The mix of items did change, for instance an increase in clinical trials of $61,000 was partially offset by a decrease in materials of $58,000.
- Selling General & Administrative Expenses increased in the third quarter of 2011 by $147,000 over the comparable third quarter of 2010. An increase in commissions, due to the higher DPP product sales to Brazil, as well as increases in wages, share-based compensation and other expenses, partially offset by decreased professional fees was responsible for the increase.
- Operating income was approximately $.48 million in the third quarter of 2011 as compared to operating income in the third quarter of 2010 of approximately $.18 million. In addition, net income was approximately $.48 million in the third quarter of 2011 as compared to a net income in the third quarter of 2010 of approximately $.17 million.

Financial Highlights for the nine months ended September 30, 2011

- Product sales for the nine months ended September 30, 2011 increased 38% to $11.52 million from $8.34 million in the same period of 2010.
- R&D, milestone and grant revenues for the nine months decreased to $1.53 million from $2.30 million in the same period of 2010, and license and royalty revenue decreased to $.13 million from $.40 million.
- The increased product revenue, together with changes in product mix, partially offset by decreased R&D and licensing and royalty revenues, combined to produce gross margin dollars that were $1.04 million, or 18.5%, greater ($6.65 million vs. $5.61 million) than the gross margin dollars in the comparable period in 2010. Product gross margin increased by $2.08 million, or 71.6% ($4.99 million vs. $2.91 million), as compared with the comparable period in 2010.
- Research and development expenses increased by $.87 million, or 31%, to $3.70 million compared to $2.82 million in the 2010 period. The increase is primarily due to an increase of $.66 million in clinical trial expenses.
- Selling General & Administrative Expenses increased by $.27 million or 12.6% in the first nine months of 2011 as compared to the first nine months of 2010. This was primarily due to an increase in commissions for the shipment of our DPP® products to Brazil.
- Operating income was approximately $.54 million in the first nine months of 2011 as compared to operating income in the first nine months of 2010 of $.64 million. In addition, net income was approximately $.53 million in the first nine months of 2011 as compared to net income in the first nine months of 2010 of $.63 million.
- The September 30, 2011 cash balance was $3.05 million as compared with $2.14 million at December 31, 2010. The increase in the 2011 period includes cash received from the change in receivables of $1.29 million, an increase in deferred revenue of $426,000, an increase of $289,000 in loans from HSBC on the revolver for equipment purchases and a $290,000 increase in accounts payable partially offset by an increase in inventories of $1.24 million. In addition the Company received $205,000 from the exercise of warrants. The increased cash from operations in 2011 was also attributable to non-cash expenses aggregating $458,000, primarily from depreciation and amortization expense.

Summary of Clinical, Development and Regulatory Activities

CLINICAL & REGULATORY

CE Mark for FDA approved HIV tests -- The final studies for the CE Marking requirements are complete and we submitted this data during October 2011.

Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) -- During 2010 we received notification from FIOCRUZ that our DPP® HIV 1/2 screening test and our DPP® HIV confirmatory test were each approved by Brazil's National Health Surveillance Agency (ANVISA). During 2011 our DPP® visceral canine leishmania ("VL") rapid test was approved by Brazil's Ministry of Agriculture, Livestock and Food Supply ("MAPA"). This is the first diagnostic product that FIOCRUZ has successfully submitted for approval to MAPA. In addition, FIOCRUZ received the required approval from ANVISA for the DPP® Syphilis-Treponemal test and the DPP®-Leptospirosis test. The submission for the DPP® multiplex Syphilis Treponemal-Non-Treponemal has not yet occurred.

FDA Approval for DPP® HIV 1/2 Screening Assay -- We began submitting the PMA (Pre-Marketing Approval) application using the Modular PMA option, and we have thus far submitted Module I containing manufacturing information and Module II containing non-clinical data, which was submitted in the beginning of October 2011. We have experienced some delays in completing the clinical trials, which are the main component for the final Module III. We now expect to finish the clinical trials during the fourth quarter of 2011. As of October 31, 2011 we have completed approximately 90% of the 3,000-patient clinical trials. We believe that the results of the clinical trials thus far indicate that the sensitivity and specificity of this product on all matrices meets or exceeds the performance requirements for FDA approval. However the trials are not complete and there can be no assurance that the FDA will agree with our assessment.

DPP® Syphilis Screen & Confirm -- We are engaged in a number of activities oriented to commercializing this product. We have commenced testing at the first of three sites in support of our planned 510(K) clearance of this product. During October 2011 we received CE Marking for this product and this is allowing us to start commercializing it outside the United States.

Sure Check HIV for Consumer Self-Testing -- In September 2011, the Company received clarification from the Food and Drug Administration for the regulatory requirements for the Sure Check® HIV 1/2 rapid test for sale over-the-counter (OTC). Additional studies are required for submission of an Investigational Device Exemption (IDE) as the first step toward product approval. We believe these studies can be completed by the end of the first quarter of 2012 at which time we would submit our IDE to the FDA.

RESEARCH & DEVELOPMENT

DPP® Leptospirosis -- We have approximately nine months left of the three-year $3 million Small Business Innovative Research (SBIR) Phase II grant we were awarded in 2009 by the United States National Institutes of Health (NIH) to fully develop, validate, and commercialize a rapid diagnostic test for Leptospirosis for general use worldwide. Our work pursuant to this grant is progressing on schedule. The test will be developed with our DPP® technology and will utilize proprietary reagents developed by Yale University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test will be in collaboration with the Division of Infectious Diseases, Yale University in New Haven, CT and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America.

DPP® Tuberculosis -- As reported in February 2011, we were awarded a three-year $2.9 million, subsequently reduced to $2.4 million, Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to continue development of a simple, rapid, accurate, and cost-effective serological test for active tuberculosis that can be utilized in resource-limited settings.

Battelle/CDC DPP® Influenza Immunity Test -- Our prototypes were evaluated by Battelle/CDC and this resulted in a request for additional development work during the summer. Subsequently, in October 2011, we recently entered into an amendment of this contract, beginning November 1, 2011, to continue additional development work for this product in the fourth quarter of 2011 and the first quarter of 2012. This development work will be funded by approximately $250,000 in periodic milestone payments to be received by the Company during this period upon attainment of such milestones.

Other Research & Development Activities -- We are considering certain new DPP® product opportunities, either as OEM development projects and/or as Chembio-branded products. These products are being identified based upon our assessment of unique opportunities in the market and how they can be uniquely addressed by our proprietary technology, as well as by our development and manufacturing experience. We are also identifying and assessing additional technologies that we believe could provide us with additional products, and capabilities, and thereby provide additional revenue streams. Chembio continues to work with commercial, governmental and private organizations in order to obtain R&D contracts and grant funding for development projects. These programs have subsidized the Company's development expenses while expanding the applications for and know-how related to DPP®, and have also served in creating important collaborative relationships.

Conference Call

Chembio has scheduled a conference call and webcast for 10:00 a.m. Eastern time on Thursday, November 3, 2011. To participate on the conference 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 10, 2011 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 #: 381588. The conference call may also be accessed via the internet at http://www.investorcalendar.com/IC/CEPage.asp?ID=166292. 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 $7 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 North America, 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 130 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. They 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.

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(Tables to follow)

Chembio Diagnostics, Inc.
Summary of Results of Operations
(Unaudited)

	For the three months ended		For the nine months ended	
	September 30, 2011	**September 30, 2010**	**September 30, 2011**	**September 30, 2010**
Net product sales	**$ 5,526,883**	$ 3,786,572	**$ 11,516,325**	$ 8,337,133
License and royalty revenue	**25,000**	61,789	**125,322**	400,758
R&D, milestone and grant revenue	**369,904**	656,642	**1,529,972**	2,299,970
TOTAL REVENUES	**$ 5,921,787**	$ 4,505,003	**$ 13,171,619**	$ 11,037,861
GROSS MARGIN	**$ 2,670,733**	$ 2,208,501	**$ 6,647,353**	$ 5,609,841
Research and development expenses	**$ 1,242,295**	$ 1,230,100	**$ 3,697,309**	$ 2,822,455
Selling, general and administrative expenses	**$ 949,237**	$ 801,854	**$ 2,412,867**	$ 2,143,715
NET INCOME FROM OPERATIONS	**$ 479,201**	$ 176,547	**$ 537,177**	$ 643,671
NET INCOME	**$ 475,605**	$ 167,976	**$ 528,147**	$ 632,568
Basic net income per share	**$ 0.01**	$ 0.00	**$ 0.01**	$ 0.01
Weighted average number of shares outstanding, basic	**63,304,584**	62,146,847	**62,887,212**	62,068,204

Chembio Diagnostics, Inc.
Summary of Balance Sheets

	September 30, 2011 **(Unaudited)**	Dec 31, 2010
CURRENT ASSETS:		
Cash and cash equivalents	**$ 3,045,348**	$ 2,136,351
Accounts receivable, net of allowance for doubtful accounts of $20,000 and $35,000 for 2011 and 2010, respectively	**2,657,781**	3,946,398

Inventories	**2,588,225**	1,349,161
Prepaid expenses and other current assets	**188,841**	204,824
TOTAL CURRENT ASSETS	**8,480,195**	7,636,734
FIXED ASSETS, net of accumulated depreciation	**848,799**	813,214
OTHER ASSETS		
Deposits on equipment	**208,460**	-
License agreements and other assets	**561,226**	636,226
	$ 10,098,680	$ 9,086,174
TOTAL CURRENT LIABILITIES	**$ 3,199,016**	$ 3,076,457
TOTAL OTHER LIABILITIES	**145,859**	200,773
TOTAL LIABILITIES	**3,344,875**	3,277,230
TOTAL STOCKHOLDERS' EQUITY	**6,753,805**	5,808,944
	$ 10,098,680	$ 9,086,174

Chembio Diagnostics, Inc.
Summary of Cash Flow

	For the nine months ended (Unaudited)	
	September 30, 2011	**September 30, 2010**
Net cash provided by operating activities	$ 1,559,123	$ 213,731
Net cash used in investing activities	(282,175)	(188,193)
Net cash (used in) provided by financing activities	(367,951)	242,210
INCREASE IN CASH AND CASH EQUIVALENTS	**$ 908,997**	**$ 267,748**

SOURCE Chembio Diagnostics, Inc.