August 4, 2011

Chembio Reports 2nd Quarter 2011 Results

Conference Call Scheduled for Thursday, August 4, 2011, at 10:00 a.m. Eastern Time

MEDFORD, NY, Aug 04, 2011 (MARKETWIRE via COMTEX) --

Chembio Diagnostics, Inc. (OTCQB: CEMI) (OTCBB: CEMI), which develops, manufactures, markets and licenses point-of-care diagnostic tests, reported revenues and earnings for the quarter ended June 30, 2011. Total revenues were $3.61 million for the quarter ended June 30, 2011, which compares to total revenues of $3.75 million for the quarter ended June 30, 2010, a 3.6% decrease.

The Company recorded a net income of approximately $.19 million, or less than $0.01 per share, for the quarter ended June 30, 2011, compared to a net income of approximately $.62 million, or $0.01 per share, for the quarter ended June 30, 2010. For the six months ended June 30, 2011, total revenues were $7.25 million which compares to total revenues of $6.53 million for the six months ended June 30, 2010, an 11% increase. The Company recorded a net income of approximately $.05 million, or less than $0.01 per share, for the six months ended June 30, 2011, compared to a net income of approximately $.46 million, or $0.01 per share, for the six months ended June 30, 2010.

The Company had a 27% increase in Net Product Sales during the second quarter which resulted from a 10% increase in sales to Alere, Inc. of our FDA-approved rapid HIV tests for marketing in the U.S. and sales of our DPP products to Brazil. This increase combined to produce a 107% increase in product gross margin dollars as compared to the second quarter of 2010. The product gross margin increased by 18 percentage points, from 29% in the second quarter of 2010 to 47% in the second quarter of 2011; overall gross margin was 56.7% for the three months ended June 30, 2011, a record for the Company. The approximate $639,000 increase in Net Product Sales for the second quarter was offset by a decrease of $528,000 in R&D, milestone and grant revenue and a decrease of $246,000 in license and royalty revenue.

For the six months ended June 30, 2011, the Company has a 31.6% increase in Net Product Sales during the six months as a result of a 42% increase in sales to Alere, Inc. of our FDA-approved rapid HIV tests for marketing in the U.S. and sales of our DPP products to Brazil. This increase combined to produce a 91.4% increase in product gross margin dollars as compared to the first six months of 2010. The product gross margin increased by 14 percentage points, from 31% in the first six months of 2010 to 45% in the first six months of 2011. Overall gross margin was 55% for the three months ended June 30, 2011.

During the six months ended June 30, 2011, the Company's cash balance remained reasonably consistent at approximately $2.13 million. The decrease was primarily as a result of increased inventories and $.88 million paid for the balance due on its HIV-2 license from Bio-Rad Laboratories, Inc. These decreases were partially offset by the collection of large account receivable balances as of December 31, 2010 from shipments made in December 2010, collection of the $.85 million balance due from the previously-reported QTDP grant awards, and also as a result of approximately $.26 million of net non-cash expenses in the period, primarily depreciation and amortization.

Lawrence Siebert, Chembio's Chief Executive Officer, commented, "While we are pleased with the 27% increase in net Product Sales, we were disappointed that we were unable to complete manufacturing and shipment of certain orders during Q2 that significantly limited our financial results. As a result, our order backlog at the end of the second quarter was extraordinarily high. On the other hand, this should enable us to deliver strong growth in our product sales and overall results during the balance of 2011. We continue to move forward in developing our branded and OEM business strategy, with the clinical programs for our Chembio-branded public health products and new OEM opportunities utilizing our DPP® technology both progressing well."

Financial Highlights for the Quarter ended June 30, 2011

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--  Product sales for the quarter ended June 30, 2011 (second quarter)
    increased 27% to $2.97 million from $2.34 million in the same period
    of 2010.
--  R&D, milestone and grant revenues for the second quarter decreased
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to $.57 million from $1.10 million in the same period of 2010, and license and royalty revenue decreased to $.07 million from $.32 million.

-- The increased product revenue, offset by decreased R&D and licensing and royalty revenues, combined to produce gross margin dollars that were $.04 million, or 2%, lower ($2.05 million vs. $2.09 million) than the gross margin dollars in the comparable period in 2010. Product gross margin increased by $.73 million, or 107% ($1.41 million vs. $.68 million), over the comparable period in 2010.
-- Research and development expenses increased by $.37 million, or 47%, to $1.16 million compared to $.79 million in the 2010 period. The increase is primarily due to an increase of $.21 million in clinical trial expenses.
-- Selling General & Administrative Expenses increased marginally in the second quarter of 2011 as compared to the second quarter of 2010.
-- Operating income was approximately $.20 million in the second quarter of 2011 as compared to operating income in the second quarter of 2010 of $.62 million. In addition, net income was approximately $.19 million in the second quarter of 2011 as compared to a net income in the second quarter of 2010 of $.62 million.

Financial Highlights for the six months ended June 30, 2011

-- Product sales for the six months ended June 30, 2011 (six months of 2011) increased 31.6% to $5.99 million from $4.55 million in the same period of 2010.
-- R&D, milestone and grant revenues for the six months decreased to $1.16 million from $1.64 million in the same period of 2010, and license and royalty revenue decreased to $.10 million from $.34 million.
-- The increased product revenue, offset by decreased R&D and licensing and royalty revenues, combined to produce gross margin dollars that were $.58 million, or 17%, greater ($3.98 million vs. $3.40 million) than the gross margin dollars in the comparable period in 2010. Product gross margin increased by $1.30 million, or 91% ($2.72 million vs. $1.42 million), over the comparable period in 2010.
-- Research and development expenses increased by $.86 million, or 54%, to $2.46 million compared to $1.59 million in the 2010 period. The increase is primarily due to an increase of $.60 million in clinical trial expenses.
-- Selling General & Administrative Expenses increased by $.12 million or 9% in the first six months of 2011 as compared to the first six months of 2010. This was primarily due to an increase in commissions for the shipment of our DPP(R) products to Brazil.
-- Operating income was approximately $.05 million in the first six months of 2011 as compared to operating income in the first six months of 2010 of $.46 million. In addition, net income was approximately $.05 million in the first six months of 2011 as compared to a net income in the first six months of 2010 of $.46 million.
-- The June 30, 2011 cash balance was $2.13 million, and remained reasonably consistent to the balance at December 31, 2010. This was primarily due to an increase in inventories and $.88 million paid for the balance due on its HIV-2 license from Bio-Rad Laboratories, Inc. While each of these items decreased cash, they were almost entirely offset by $2.32 million in cash provided from collections of accounts receivable.

Summary of Clinical, Development and Regulatory Activities

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. We have now completed all of the non-clinical data required for submitting Module II, and we anticipate filing this module very soon. We experienced some delays in completing the clinical trials, so that we now will not finish the clinical trials until the fall. We have completed approximately 75% of the 3,000-patient clinical trial, and this must be 100% completed in order to submit the final Module III. We believe that the results of the clinical trial thus far indicate that the sensitivity and specificity of this product on all blood matrices will exceed the performance requirements for FDA approval. However, we believe that the performance of this product on oral fluid samples may or may not meet FDA approval requirements. Alternatively, additional studies may need to be performed in order to achieve the oral fluid claim. FDA approval of an oral fluid claim from the current or additional clinical trials will ultimately depend on several factors, including but not limited to the product performance in the remainder of the clinical trial, the assessment by FDA of such clinical trial data, and the product performance and procedural claims that the Company is seeking versus those that the FDA determines in its sole discretion are supported by the data.

DPP® Syphilis Screen & Confirm -- We are engaged in a number of activities oriented to commercializing this product. Training, contracts and IRB approvals are in place to commence clinical trials in support of a 510(K) clearance of this product. We anticipate the trials to be substantially completed during 2011 and FDA 510(K) clearance during 2012. We have also submitted a CE Mark application to our notified body for this product, which we anticipate receiving within a few months. This will facilitate our efforts to start commercializing this product outside the United States. There has been an increasing debate in the public health community concerning the recommended sequence of tests used to screen and confirm for active Syphilis, which currently requires two separate, time-consuming laboratory tests. We believe our patented DPP® Screen & Confirm Treponemal-Non-Treponemal test will be a welcome solution for addressing this important public health problem.

CE Mark for FDA approved HIV tests -- The final studies for the CE Marking requirements for our Chembio-labeled HIV 1/2 STAT PAK® AND SURE CHECK® HIV 1/2 are complete and we will be submitting this data during August.

SURE CHECK® HIV 1/2 for Home Use -- The Company has initiated studies required for submission of an Investigational Device Exemption (IDE) to the Food and Drug Administration for its SURE CHECK ® HIV 1/2 rapid test as the first step toward over-the-counter (OTC) product approval. Chembio believes that a market study of the intended users and an additional "Flex" Study are required to complete the IDE submission. Both of these studies have been initiated and Chembio plans to complete both of these studies and submit an IDE to the FDA during the latter part of this year. Chembio has requested a meeting with the FDA to confirm and further clarify the process prior to submitting an IDE.

DPP® Influenza Immunity Test -- Based upon the evaluation of our prototypes from the initial contract development work performed in 2010, in July we submitted a new proposal pursuant to a request from the same government contractor we performed the work for in 2010 related to additional research and development activities.

Conference Call

Chembio has scheduled a conference call and webcast for 10:00 a.m. Eastern time on Thursday, August 4, 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 August 11, 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 #: 376049. The conference call may also be accessed via the internet at http://www.investorcalendar.com/IC/CEPage.asp?ID=165190. 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, 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.

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, and actual results may differ materially

from those anticipated in this press release. Such statements 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.

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

	For the three months ended		For the six months ended	
	June 30, 2011	June 30, 2010	June 30, 2011	June 30, 2010
Net product sales	$ 2,974,379	$ 2,335,665	$ 5,989,442	$ 4,550,562
License and royalty revenue	71,468	317,472	100,322	338,968
R&D, milestone and grant revenue	568,304	1,096,305	1,160,068	1,643,328
TOTAL REVENUES	$ 3,614,151	$ 3,749,442	$ 7,249,832	$ 6,532,858
GROSS MARGIN	$ 2,050,278	$ 2,094,966	$ 3,976,620	$ 3,401,340
Research and development expenses	$ 1,164,872	$ 791,596	$ 2,455,014	$ 1,592,354
Selling, general and administrative expenses	$ 688,259	$ 680,014	$ 1,463,630	$ 1,341,862
NET INCOME FROM OPERATIONS	$ 197,147	$ 623,356	$ 57,976	$ 467,124
NET INCOME	$ 194,839	$ 621,917	$ 52,542	$ 464,591
Basic net income per share	$ 0.00	$ 0.01	$ 0.00	$ 0.01
Weighted average number of shares outstanding, basic	63,060,582	62,070,736	62,675,073	62,028,450

Chembio Diagnostics, Inc.
Summary of Balance Sheets

	June 30, 2011	Dec 31, 2010
	(Unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,139,329	$ 2,136,351
Accounts receivable, net of allowance for doubtful accounts of $20,000 and $35,000 for 2011 and		

2010, respectively	1,642,749	3,946,398
Inventories	2,917,473	1,349,161
Prepaid expenses and other current assets	214,626	204,824
TOTAL CURRENT ASSETS	6,914,177	7,636,734
FIXED ASSETS, net of accumulated depreciation	778,123	813,214
OTHER ASSETS		
Deposits on equipment	156,536	-
License agreements and other assets	586,226	636,226
	$ 8,435,062	$ 9,086,174
TOTAL CURRENT LIABILITIES	$ 2,078,676	$ 3,076,457
TOTAL OTHER LIABILITIES	159,697	200,773
TOTAL LIABILITIES	2,238,373	3,277,230
TOTAL STOCKHOLDERS' EQUITY	6,196,689	5,808,944
	$ 8,435,062	$ 9,086,174

Chembio Diagnostics, Inc.
Summary of Cash Flow

	For the six months ended (Unaudited)	
	June 30, 2011	June 30, 2010
Net cash provided by (used in) operating activities	$ 926,164	$ (431,648)
Net cash used in investing activities	(288,402)	(144,345)
Net cash provided by (used in) financing activities	(634,784)	254,606
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ 2,978	$ (321,387)

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