January 3, 2012

Chembio Provides Business Update

MEDFORD, N.Y., Jan. 3, 2012 /PRNewswire/ -- **Chembio Diagnostics, Inc.** (OTC.PK: CEMI and OTC.QB: CEMI), which develops, manufactures, markets and licenses point-of-care diagnostic tests, is providing this update regarding 2011 developments in the fourth quarter and an updated outlook for 2012.

1. 2011 Revenues - Chembio once again achieved record revenues based on record product shipments during the second half of the year. Audited financial results will be reported in March.
2. 2012 Outlook - We are starting off 2012 with a very strong backlog. We have received the 2012 forecasted demand from the Oswaldo Cruz Foundation (FIOCRUZ) of Brazil. Based on that, combined with conservative assumptions for the rest of our business, we anticipate that our 2012 revenues will increase significantly over those of 2011.
3. DPP® HIV Clinical Study - We are encouraged by the results we have had, as they continue to support approval on oral fluid, finger-stick whole blood, venous whole blood, serum and plasma samples. However, we are about three months behind our previously anticipated schedule. This is primarily due to delays that occurred because our final clinical trial sites did not receive their Internal Review Board (IRB) approvals when they were expected and because of the slower pace of recruitment of known positive pediatric patients. As a result, the recruitment and testing of approximately 200 patients in our 3,000-patient study did not occur by year-end as we had previously anticipated. Instead, we now expect the clinical trials to be completed by the end of the first quarter of 2012. Therefore our anticipated timeline, based on this delay, is now that we can submit our Module III to the FDA during the second quarter and, based on statutory FDA timetables, we could get FDA approval sometime between the fall of 2012 and early 2013. We would then immediately apply for CLIA waiver, which is expected to take between 1 and 3 months to be granted.
4. Syphilis - As a result of our having received a CE Mark for the product in Q3'11 and our business development efforts during Q4'11, we have established several European distributors for this product. We expect to start to see some revenues from these distributors as we get further into 2012 and local evaluations and business plans are established by each distributor. For the US market, we have decided to restart the clinical study in Q1'12 incorporating the use of a reader which we believe will enable more consistent determination of testing results. We expect to complete the clinicals in Q3'12, and make the 510(k) submission in Q4'12. Therefore we expect FDA 510(k) clearance would be in Q1 or Q2 of 2013, followed by commercial launch in the US.
5. SURE CHECK HIV OTC Study - We have made progress toward completing the requirements for submitting an IDE application. We believe that this year (2012) there will be external events that will help us to better define the market opportunity. This principally includes a meeting of the FDA's Blood Products Advisory Committee (date not determined yet) that is likely to result in a final recommendation concerning a competitor's application for OTC use of its HIV test. Assuming it is recommended, and the product is actually launched, we will be able to assess the market approach and its reception by their targeted consumers. This information will help us before we commit additional significant sums to this program. We can do this knowing that we are the only company other than this competitor that has a device that is qualified to begin the studies necessary to gain OTC approval. In the meantime we are participating in a field study that will provide us with additional data that will be useful in conducting the trials.
6. Other Opportunities in Chembio's Pipeline - We are working on potential new opportunities to expand our target markets, and product offerings, and will provide updates as available. No binding commitments have been made concerning any of these potential opportunities; and there is no assurance that any of them will occur.

We are most grateful for the hard work of our employees during 2011 and for the support of our investors, and we look forward to an exciting year in 2012.

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 140 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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SOURCE Chembio Diagnostics, Inc.