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Chembio Files PMA Module II With FDA For DPP(R) HIV Test

ANVISA Approval of DPP(R) Leptospirosis Test; Shareholder Meeting Results

MEDFORD, NY, Oct 03, 2011 (MARKETWIRE via COMTEX) --

Chembio Diagnostics, Inc. (OTCQB: CEMI) (PINKSHEETS: CEMI), which develops, manufactures, markets and licenses point-of-care diagnostic tests, reports it has filed the second module of its Pre-Marketing Approval (PMA) application to the United States Food & Drug Administration for its DPP® HIV 1/2 Assay which contains the non-clinical data for the product. Chembio's DPP® HIV 1/2 Assay is a "yes/no" qualitative rapid test for the detection of antibodies to HIV 1 & 2 in oral fluid, finger-stick whole blood, venous whole blood, serum or plasma samples. The test is intended to be used as an aid in the diagnosis of HIV/AIDS in point-of-care settings such as public health and other clinics, hospital emergency rooms, and physicians' offices. The DPP® HIV 1/2 Assay delivers visual results within approximately 15 minutes, is simple to use, has a shelf life of 24 months, and does not require refrigeration. The product incorporates Chembio's patented Dual Path Platform technology as well as a proprietary sample collection system that enables certain unique product features.

In March 2011, Chembio received approval from the FDA to submit this PMA application as a Modular PMA. In a Modular PMA, the PMA is viewed as a compilation of sections, such as preclinical, clinical, and manufacturing, that together become a complete application. The process begins with a PMA Shell that lays out the plan for submission of the modules. The PMA Shell is an outline of modules and identifies information necessary to support the filing and approval of a product subject to the PMA requirements (such as an HIV test) through a combined IDE and PMA process. The FDA reviews each module separately as it is received, allowing manufacturers to receive timely feedback during the review process. A traditional PMA takes 180 days for the FDA to complete its initial review. A modular PMA takes the FDA 90 days to complete its review of each module. Thus the modular approach will allow the FDA to make a decision in half the time once all information to support the basis of approval is on file.

In April 2011, Chembio submitted the first PMA module, which contained the manufacturing information for the product. Chembio received a response from the FDA concerning the information that was contained in this first module and has submitted its reply to this FDA response.

The second module that Chembio has filed contains pre-clinical and non-clinical data such as the test's performance against sero-conversion panels and potentially interfering substances. The third and final PMA module will contain the clinical data which Chembio now anticipates being completed during the current fourth quarter, with the third module being filed with the FDA during January 2012, although there can be no assurance of this.

Lawrence Siebert, Chembio's CEO, commented, "Having completed the submission of the second PMA module, we look forward to completing the clinical trials by year end as well as completing the submission of all required information to the FDA in January, all of which are key steps in our ultimate goal in bringing our DPP® HIV 1/2 Assay to market."

ANVISA Approval of FIOCRUZ DPP® Leptospirosis Test

As previously reported in Chembio's Form 10-Q for the quarter ended June 30, 2011, in July 2011, the Oswaldo Cruz Foundation of Brazil, also known as FIOCRUZ, received approval from ANVISA, the Brazilian regulatory agency, for the DPP® Leptospirosis assay for use in Brazil. This approval triggered a milestone event payment of $100,000 to the Company, which will be recognized in the third quarter of 2011. Although as previously reported, the Company anticipates at least $3 million in revenues during 2011 from the other four DPP® products (Canine Leishmaniasis, HIV 1/2 Assay, HIV 1/2 Confirmatory Assay, and Syphilis Treponemal Assay), it has not yet received, and currently does not anticipate any orders or shipments of, the Leptospirosis product in 2011. The only remaining DPP® product under contract with FIOCRUZ that has not yet been submitted for approval is the Trep/Non-Trep Syphilis test.

Mr. Siebert commented, "All of the products we have submitted to ANVISA through FIOCRUZ have now been approved, a major milestone in our campaign to make Chembio's technology available to the public health needs in Brazil."

Shareholders Meeting Results

The Company held its Annual Meeting of Shareholders on September 22, 2011. As reported in its Form 8-K filing on the same date, each of the Company's recommended proposals was approved by the shareholders.

Mr. Siebert commented "We appreciate everyone's support and approval of the proxy proposals, which included electing the two recently-added independent board members whom I believe are strong additions to our board. In addition the approval of granting discretionary authority to the board to effect a reverse split within certain parameters, if and when the Board deems it in the Company's best interests, will give our board the needed flexibility to position the Company as needed in the future."

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., formerly named 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.

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, as the Company has not completed the preparation of its financial statements for those periods, nor has its auditor completed a review or audit of those results. 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, to obtain regulatory approvals in a timely manner and the demand for Chembio's products. In addition, actual revenue may differ materially from any amount referenced or otherwise anticipated in this press release. 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 set forth in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

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