

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): October 8, 2008 (October 2, 2008)



**CHEMBIO DIAGNOSTICS, INC.**

(Exact name of registrant as specified in its charter)

**Nevada**  
(State or other jurisdiction  
of Incorporation)

**0-30379**  
(Commission File Number)

**88-0425691**  
(IRS Employer  
Identification Number)

**3661 Horseblock Road**  
**Medford, NY 11763**  
(Address of principal executive offices)  
**631-924-1135**  
(Registrant's Telephone Number)

**N/A**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**ITEM 7.01. Regulation FD Disclosures.**

On October 2, 2008, the Company issued the press release titled “Chembio and Oswaldo Cruz Foundation Sign Agreement for DPP® Oral Fluid-Whole Blood HIV Test” included herein as Exhibit 99.1.

On October 8, 2008, the Company also issued a press release entitled “Chembio Receives FDA Approval For Extended Age Range for HIV Rapid Tests” included herein as Exhibit 99.2.

**ITEM 9.01. Financial Statements and Exhibits**

Exhibits.

99.1 Press Release titled “[Chembio and Oswaldo Cruz Foundation Sign Agreement for DPP® Oral Fluid-Whole Blood HIV Test](#)” issued October 2, 2008.

99.2 Press Release titled “[Chembio Receives FDA Approval For Extended Age Range for HIV Rapid Tests](#)” issued on October 8, 2008.

In accordance with General Instruction B.2 of Form 8-K, the information disclosed in Item 7.01 of, and Exhibit 99.1 and Exhibit 99.2 attached to, this Current Report on Form 8-K shall not be deemed “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing. This Current Report on Form 8-K does not constitute a determination of whether any information included herein is material.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: October 8, 2008

Chembio Diagnostics, Inc.

By: /s/ Lawrence A. Siebert  
Lawrence A. Siebert  
Chief Executive Officer

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## **ChemBio and Oswaldo Cruz Foundation Sign Agreement for DPP® Oral Fluid-Whole Blood HIV Test**

*Will Aid Expansion of Prevention Efforts in Brazil*

**MEDFORD, N.Y. and RIO DE JANEIRO, BRAZIL (October 2, 2008) – ChemBio Diagnostics, Inc. (OTC BB: CEMI)** (“ChemBio” or the “Company”) and the Oswaldo Cruz Foundation of Brazil (“FIOCRUZ”) today announced the completion of a technology transfer supply and license agreement for ChemBio’s DPP® HIV 1-2 rapid test for use with oral fluid or whole blood samples. This product has been developed by ChemBio with its patented Dual Path Platform (DPP®) technology. As previously announced in January, ChemBio and FIOCRUZ also executed similar agreements for DPP® rapid tests for Leishmania and Leptospirosis, and a third agreement for a multiplex DPP® test for the confirmation of HIV-1 that could be performed at the point of care. FIOCRUZ, which is affiliated with the Brazilian Ministry of Health, is its leading supplier for therapeutics, vaccines and diagnostic tests.

ChemBio’s DPP® test platform was selected for these public health programs because of the high levels of sensitivity and specificity of prototypes evaluated by Bio-Manguinhos. The separate sample application strip and direct binding of HIV antibodies to immobilized HIV antigens enabled by DPP® results in improved sensitivity based upon studies conducted by ChemBio comparing its product to other FDA-approved rapid HIV tests. ChemBio’s United States patent was issued in 2007 and patent protection for this technology is pending in a number of other countries, including Brazil. This screening test will help increase the reach and accessibility of HIV testing in Brazil, already a world leader in HIV prevention and treatment efforts, by means of a less invasive oral fluid test.

ChemBio is currently finalizing pre-clinical studies with this same product before commencing clinical trials in support of an FDA PMA application and also plans to seek inclusion of this product in major international programs such as the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR).

Under the terms of the agreement with FIOCRUZ, a minimum of 2.5 million of these tests will be purchased for a period of time, followed by an additional period during which components for tests will be purchased, followed by royalties for a period of five years. The total purchases by FIOCRUZ from ChemBio will ultimately be determined by the demand for the product by the national program, the pace of the technology transfer, and FIOCRUZ’s manufacturing capacity. Sales are anticipated to begin during 2009 once the products are approved for sale in Brazil, at which time a technology transfer fee will be payable to ChemBio. ChemBio’s 2004 agreement with FIOCRUZ for ChemBio’s lateral flow rapid HIV test for use with whole blood samples, HIV 1-2 STAT PAK®, has been very successful, thus providing the parties with a mutually strong preexisting relationship for this latest agreement and the agreements entered in January.

Dr. Akira Homma, Director of Bio-Manguinhos commented: “We believe that it is important to have more sensitive and specific tests that are simple to use and non-invasive based on oral fluid. This will allow us to complement and expand our program that exists as a result of the 2004 whole blood rapid HIV test agreement we entered with ChemBio”.

Javan Esfandiari, Senior Vice President of ChemBio, “This latest agreement reflects the strong collaborative relationship that we have continued to grow with FIOCRUZ, allowing us to bring innovative technologies to serve global public health needs.”

Lawrence Siebert, ChemBio’s Chairman and CEO, commented “We are pleased to launch this important new product based upon our proprietary DPP® technology with such an outstanding partner as we have with FIOCRUZ. The option for oral fluid HIV testing is one which we think should be made available globally and Brazil is obviously a very important market to begin this effort, particularly with a leading public health organization of this kind. I appreciate the efforts of all parties to bring this agreement to fruition.”

### **ABOUT BIO-MANGUINHOS/FIOCRUZ**

Bio-Manguinhos/FIOCRUZ is the largest immuno-biological producer (vaccines, kits for diagnosis of infectious and parasitic diseases, and biopharmaceuticals, such as erythropoietin and interferon) in Latin America. With a physical infrastructure comprising nearly 600,000 square feet and a workforce of approximately 1,000, Bio-Manguinhos was created in 1976. The unit is capable of processing over 120 million doses of vaccines per year, supplying up to 30 million doses per year of yellow fever vaccine alone to meet Brazilian and export requirements. In 2006, FIOCRUZ was awarded the Prize for Best Public Health Institution in the world granted by the World Federation of Public Health. Up to 2.5 million kits are produced each year through agreements with the Health Surveillance Secretariat and the National Program on Sexually Transmitted Diseases and Aids, both from the Ministry of Health. In 2004, Bio-Manguinhos entered into a technology transfer, supply and license agreement with ChemBio for one of ChemBio’s rapid HIV tests, and in January 2008, entered into similar agreements for DPP® rapid tests for Leishmania and Leptospirosis, and a third agreement for a multiplex DPP® test for the confirmation of HIV-1 that could be performed at the point of care.

### **ABOUT CHEMBIO DIAGNOSTICS**

ChemBio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing \$5 billion point-of-care testing market. ChemBio’s two FDA PMA-approved, CLIA-waived, rapid HIV tests are marketed in the U.S. by a third party company. ChemBio markets its HIV STAT-PAK® line of rapid HIV tests internationally to government and donor-funded programs directly and through distributors. ChemBio also has rapid tests for veterinary tuberculosis and chagas disease. In 2007 ChemBio received a U.S. patent for its 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 100 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 the audit of those results. Actual revenue 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, 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.*

**Contacts:**

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# ChemBio Receives FDA Approval For Extended Age Range for HIV Rapid Tests

*Approval for 13 Year-Olds and Above Fully Meets CDC Recommendations for Routine HIV Testing*

**MEDFORD, N.Y. (October 8, 2008) – ChemBio Diagnostics, Inc. (OTC BB: CEMI)** (“ChemBio” or the “Company”) has obtained approval from the United States Food and Drug Administration to extend the testing age range for its HIV rapid point-of-care tests to individuals 13 years of age and older. Lowering the testing age claim from 18 years of age to 13 is consistent with the latest United States Centers for Disease Control (“CDC”) recommendations that routine screening for HIV be performed on all patients 13 to 64 years of age.

A clinical study was designed to evaluate the performance of the company’s FDA-approved rapid tests, marketed exclusively in the United States by Inverness Medical Innovations, Inc. as Clearview® COMPLETE HIV 1/ 2 and Clearview® HIV 1/ 2 STAT-PAK®. The Laboratory of Viral Diagnostics, University of Maryland School of Medicine, performed the study for ChemBio on four separate specimen matrices from each study participant: fingerstick capillary whole blood, venous whole blood, serum and plasma. The participants each had a confirmed, known HIV positive status. Based upon the results of the studies and other related information provided to the FDA, the PMA supplement was approved to expand the indications of use section to include the pediatric sub-population 13-17 years of age.

Of the more than 1 million adults and adolescents estimated to be living with HIV infection in the United States, approximately 232,700 (21%) are unaware of their infection. In 2006, 56,500 (5%) of the people living with HIV were between the ages of 13 and 24.<sup>1</sup> These individuals cannot receive appropriate treatment for their HIV disease and may unknowingly continue to transmit the virus to others. In September 2006, the US Centers for Disease Control (CDC) changed its recommendations to include that all people in the United States between the ages of 13 and 64 years be routinely tested for HIV in healthcare settings. This testing can be performed in primary care facilities, emergency rooms, and clinics for substance abuse and pregnant women. Several states have now begun to implement these recommendations. Embracing these recommendations, California recently enacted a law that will require (as of January 1, 2009) private health insurance companies in the state to cover the cost of HIV testing regardless of whether the testing is related to a primary diagnosis.

From a public health perspective, the shift in the CDC recommendations from risk-based to routine "opt-out" testing is anticipated to lower the rate of new HIV infections. For individuals, early testing is essential to provide earlier access to care with a greatly improved prognosis. The objectives of the recommendations are many and include increasing HIV screening of patients, fostering earlier detection of infection, identifying and counseling persons with HIV infection and connecting them to clinical and prevention services, and further reducing transmission of HIV in the United States.<sup>2</sup>

Lawrence Siebert, ChemBio’s Chairman and CEO, commented, “We are pleased that our rapid HIV tests can now be used for the full range of individuals that should be routinely tested for HIV as recommended by the CDC. This will increase the opportunity for testing and early diagnosis and could subsequently lower infection rates as patients become aware of their HIV status.”

<sup>1</sup>CDC. HIV/AIDS Surveillance Report, 2006. Vol. 18. Atlanta: US Department of Health and Human Services, CDC; 2008. <http://www.cdc.gov/hiv>

<sup>2</sup>CDC. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings. MMWR 2006; 55:1-17.

## ABOUT CHEMBIO DIAGNOSTICS

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