

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): February 4, 2008 (January 29, 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 January 29, 2008, the Company issued the press release titled “Chembio in Additional Technology Pacts with Oswaldo Cruz Foundation” included herein as Exhibit 99.1.

ITEM 9.01. Financial Statements and Exhibits

Exhibits.

99.1 Press Release titled “[Chembio in Additional Technology Pacts with Oswaldo Cruz Foundation](#)” issued January 29, 2008.

In accordance with General Instruction B.2 of Form 8-K, the information disclosed in Item 7.01 of, and Exhibit 99.1 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.

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: February 4, 2008

Chembio Diagnostics, Inc.

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



CHEMBIO IN ADDITIONAL TECHNOLOGY PACTS WITH OSWALDO CRUZ FOUNDATION

Company's DPP™ Technology Licensed for Screening Programs Funded by Brazil's Ministry of Health

MEDFORD, N.Y. and RIO DE JANEIRO, BRAZIL (January 29, 2008) – Chembio Diagnostics, Inc. (OTC BB: CEMI) ("Chembio" or the "Company") and the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil today announced the completion of three new technology transfer, supply and license agreements for products being developed by Chembio with its patented Dual Path Platform (DPP™) technology. Previously, in 2004, Bio-Manguinhos and Chembio entered into a similar agreement concerning one of Chembio's HIV rapid tests.

Two of the products being developed by Chembio will be used in screening programs funded by Brazil's Ministry of Health for the control and eradication of Leishmaniasis and Leptospirosis, respectively, which are both blood-borne infectious diseases that are endemic in Brazil. A third test being developed is for the confirmation of HIV-1 in patients who have tested positive with a screening test. Bio-Manguinhos, also known as the Immunobiological Technology Institute, is the largest producer of vaccines and kits for diagnosis of infectious and parasitic diseases in Latin America.

Chembio's DPP™ test platform was selected for the screening programs because of its high sensitivity and specificity of prototypes evaluated by Bio-Manguinhos and because of the unique multiplexing capabilities of DPP™ for the confirmatory assay. The DPP™ point-of-care screening tests will complement the current Bio-Manguinhos national program, which currently only uses laboratory-based technologies. The HIV confirmatory test will allow for the simultaneous binding and uniform delivery of samples to multiple HIV antigens printed in the detection zone, providing results equivalent to Western blot in a simple point-of-care format that provides results within 20 minutes.

Under the new agreements, once the products meet mutually agreed-upon performance specifications and are approved for sale in Brazil, Chembio will receive a minimum purchase order for at least one million tests within a one year period. Thereafter, the agreement allows for production of the products to be transferred to Brazil, subject to certain royalty payments. This is similar to Chembio's 2004 agreement with Bio-Manguinhos for one of the Company's rapid HIV tests.

Dr. Akira Homma, founder and Director of Bio-Manguinhos commented: "The DPP™ is an important evolution in Rapid Test technology and is going to be an important technological platform for Bio-Manguinhos production of reagents for diagnosis tests. No doubt, the creation of an instrument that provides results in a few minutes, in the field or laboratories, will be very valuable for Brazilian Public Health. Chembio is an important partner in this area and we hope to strengthen this partnership for developing new products that are necessary for Brazilian Public Health." The full text of the Bio-Manguinhos press release can be viewed at the following link: <http://www.fiocruz.br/bio/cgi/cgilua.exe/sys/start.htm?infoid=608&sid=227>.

Javan Esfandiari, Senior Vice President of Chembio, said, "We are very pleased to be building on our relationship with Bio-Manguinhos and to be continuing to demonstrate the value of DPP™ technology in screening for infectious diseases. Our internal and external studies have demonstrated high sensitivity and specificity for our DPP™ assays for Leishmania, Leptospirosis and HIV 1 confirmatory tests in comparison with conventional rapid lateral flow technology."

Lawrence Siebert, Chembio's Chairman and CEO, commented, "We are pleased to expand our relationship with Bio-Manguinhos. This agreement also serves to advance the scale up of our DPP™ production capability for future DPP™ collaborations."

ABOUT LEISHMANIA AND LEPTOSPIROSIS

Leishmaniasis is transmitted by the bite of a tiny (2-3 millimeter) insect vector, *the phlebotomine sandfly*. Visceral leishmaniasis – also known as kala azar – is characterized by irregular bouts of fever, substantial weight loss, swelling of the spleen and liver, and anemia (occasionally serious). If left untreated, the fatality rate in developing countries can be as high as 100% within two years. Over the past 10 years, endemic regions have been spreading further and there has been a sharp increase in the number of recorded cases of the disease. As declaration is compulsory in only 32 of the 88 countries affected by leishmaniasis, a substantial number of cases are never recorded. In fact, 2 million new cases (1.5 million for CL and 500,000 for VL) are considered to occur annually, with an estimated 12 million people presently infected worldwide. Brazil has also experienced a sharp increase in the number of cases. Dogs habitually kept in the domestic environment are the principal animal reservoir, and children under the age of 15 years are the most severely affected age group. Current eradication programs in Brazil are therefore focused on this vector canine population. As such, currently-used, laboratory-based diagnostic technologies are impractical for determining whether dogs are infected.

Leptospirosis, also known as Weil's disease, is an emerging infectious disease caused by spirochetes of the genus *Leptospira* that affects humans and a wide range of animals, including mammals, birds, amphibians and reptiles. It is considered the most widespread zoonotic disease in the world. Human disease is acquired primarily through contact with water contaminated with the urine of infected wild or domestic animals. There are as many as 500,000 severe human cases worldwide each year. With few laboratories equipped to perform the antiquated microagglutination test upon which diagnosis now depends, it is well recognized that human leptospirosis is an under-recognized disorder. Leptospirosis is recognized as an emerging infectious disease in the U.S., where flooding and fresh water recreation has caused extensive outbreaks of the disease. In less developed countries, leptospirosis is a major public health problem causing substantial morbidity and mortality among subsistence farmers and urban slum dwellers.

Rapid testing will allow early diagnosis of Leptospirosis infection (IgG and IgM antibodies in blood) in acute phase in the field or community setting and treatment can be initiated immediately when it is the most effective. Furthermore, an accurate diagnostic test will help to rule out other infections similar to leptospirosis such as dengue.

ABOUT BIO-MANGUINHOS

Bio-Manguinhos, also known as the Immunobiological Technology Institute, is the largest producer of vaccines and kits for diagnosis of infectious and parasitic diseases in Latin America. With a physical infrastructure comprising nearly 600,000 square feet and a workforce of approximately 1,000, Bio-Manguinhos was created by Dr. Akira Homma, its current Director, in 1976. The unit is capable of processing over 200 million doses of vaccines per year, supplying up to 100 million doses per year of yellow fever vaccine alone to meet Brazilian and export requirements. In 2006, the unit 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 signed a technology transfer, supply and license agreement with Chembio for one of Chembio's rapid HIV tests.

ABOUT CHEMBIO DIAGNOSTICS

Chembio Diagnostics, Inc., a developer and manufacturer of proprietary rapid diagnostic tests, participates 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 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 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 currently available 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, N.Y. 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.

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