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# 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) **June 13, 2007 (June 7, 2007)**



#### **CHEMBIO DIAGNOSTIC, 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))
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**ITEM 7.01. Regulation FD Disclosures.**

- (a) On June 7, 2007 the Registrant issued the press release titled “[Chembio Issued USDA License to Manufacture and Market Prima TB STAT-PAK Assay](#)” included herein as Exhibit 99.1.
- (b) On June 13, 2007 the Registrant issued the press release titled “[Chembio Issued U.S. Patent for Universal Rapid Test & Method in Detection of Tuberculosis in Multiple Host Species](#)” included herein as Exhibit 99.2.

**ITEM 9.01. Financial Statements and Exhibits**

- (c) Exhibits.

- 99.1 Press Release titled “Chembio Issued USDA License to Manufacture and Market Prima TB STAT-PAK Assay” issued June 7, 2007.
- 99.2 Press Release titled “Chembio Issued U.S. Patent for Universal Rapid Test & Method in Detection of Tuberculosis in Multiple Host Species” issued June 13, 2007.

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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: June 13, 2007

Chembio Diagnostics, Inc.

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

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# **ChemBio Issued USDA License to Manufacture and Market PrimaTB STAT-PAK® Assay**

## ***New Serological Assay for Rapid Detection of Tuberculosis (TB) in Non-Human Primates***

New York, June 7, 2007 - (OTCBB: CEMI) – The U.S. Department of Agriculture (USDA) has issued ChemBio Diagnostic, Inc. a license to manufacture and market a rapid diagnostic test developed by ChemBio for the detection of tuberculosis in non-human primates - specifically, Rhesus macaques and Cynomolgus macaques. The licensure is an important initial milestone for ChemBio, both for developing a line of veterinary tuberculosis products and for having been granted a USDA manufacturing facility license; the facility license could facilitate new veterinary product development, manufacturing and licensure opportunities.

The licensed test, PrimaTB STAT-PAK® Assay, is a rapid lateral-flow test for the detection of TB antibodies in nonhuman primates (NHP). The test employs a unique multi-antigen cocktail of carefully selected recombinant proteins of *Mycobacterium tuberculosis* and can use serum, plasma, or whole blood samples to provide “yes-or-no” results within 20 minutes. When used alone or in combination with tuberculin skin testing, ChemBio’s PrimaTB STAT-PAK can help reduce TB transmission.

TB is a zoonotic disease transmissible human to animal and vice versa as well as within species. The occurrence of TB in NHP can be devastating, spreading quickly and leading to increased fatalities within infected populations. Many of today’s NHPs are utilized in research and pharmaceutical studies where even a single loss can seriously compromise lengthy and expensive experimental data.

The tuberculin skin test (TST) is the only method currently accepted as a stand-alone test by the USDA and the U.S. Centers for Disease Control. The TST requires injection of the tuberculin into the animal’s eyelid. A positive (i.e., reactive) interpretation is indicated when the animal’s immune system produces a reaction that creates inflammation and swelling at the injection site. This type of positive response usually peaks within 3 days from the time of injection and then begins to rapidly dissipate. Repeat testing often is required to determine a true reactive response as well as to rule-out false positives or confirm a negative test.

Interpretation of TST is both difficult and subjective, resulting in potential false positives/negatives. Possible causes of false positives include impurities in the tuberculin, trauma resulting from poor injection technique, previous vaccination, or cross-reactivity with an atypical or saprophytic mycobacterium that share some of the antigens. Possible causes of false negatives include anergy due to major pulmonary tuberculosis infection, testing too early in the infection prior to the development of a hypersensitivity response, systemic fungal infection or viral infection concurrent vaccination (e.g. measles), immunosuppressive drugs, technical errors, or localized desensitization if the test is repeated at the same site.

TB infection in an NHP can mean the loss of an animal that costs several thousand dollars. Other NHPs that come in contact with the infected animal also have to be tested and have to be destroyed if found to be infected, thus wasting large sums of money, time, and resources.

Les Stutzman, VP of Marketing at ChemBio, commented, “I am pleased that we now have the regulatory approval needed for our manufacturing facility and for PrimaTB STAT-PAK®. This initial offering in ChemBio’s line of veterinary tests offers the primatology community access to a new technology that we believe not only improves on the performance of the current approaches to detecting tuberculosis in non-human primates, but is also significantly easier for the technician to perform and interpret, is less traumatic on the animal, and can be very cost effective”.

The global market potential for a more sensitive, rapid, and convenient assay like PrimaTB is currently estimated at 500,000 tests annually and extends across a widely diverse market segment from major pharmaceutical firms, academic research facilities, quarantine holding and breeding facilities to zoo and conservation centers.

As part of ChemBio’s PrimaTB STAT-PAK Assay licensing announcement, ChemBio is also pleased to announce successful conclusion of an exclusive multi-year North American distributor licensing agreement with Centaur Inc. (Overland Park, Kansas). Centaur will have exclusive distributorship of PrimaTB STAT-PAK Assay for North America (US, Canada, and Mexico). While ChemBio continues to develop its international distribution channels for PrimaTB STAT-PAK, it will continue to work directly with all interested customers for the product.

### **ABOUT CHEMBIO**

ChemBio Diagnostics, Inc., a developer and manufacturer of rapid diagnostic tests for infectious diseases, is on the frontlines of the global battle against the AIDS pandemic. The Company has received marketing approval from the FDA for its SURE CHECK® HIV 1/2 and HIV 1/2 STAT-PAK® rapid tests, marketed in the United States by Inverness Medical Innovations. The Company also manufactures rapid tests for veterinary Tuberculosis and Chagas Disease. In March 2007 ChemBio was issued a United States patent for the Dual Path Platform (DPP(TM)), a next generation lateral flow platform. DPP has demonstrated significant advantages over currently available lateral flow methods, including increased sensitivity, sample flexibility, and multiplexing capabilities.

For further information please visit [www.chembio.com](http://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, 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.*

**Contact:**  
Matty Arce - 631-924-1135 ext 123.

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## **ChemBio Issued U.S. Patent for Universal Rapid Test & Method in Detection of Tuberculosis in Multiple Host Species**

### ***Rapid Serological Screening for TB in Multiple Species***

New York, June 13, 2007- (OTCBB: CEMI) – ChemBio Diagnostic, Inc. (OTC BB: CEMI.OB – News) has been issued United States Patent Number 7,192,721 for a test and methodology to rapidly (in 20 minutes or less) detect Tuberculosis (“TB”) in multiple animal species.

TB is a zoonotic disease defined as transmissible from humans to animals and vice versa as well as within species. The occurrence of TB in cattle is commonly referred to as bovine TB (*Mycobacterium bovis*, which is part of the *Mycobacterium tuberculosis* complex). Bovine TB is infectious across most mammalian species and is spread primarily through the exchange of respiratory secretions between infected and uninfected animals. TB is a chronic disease in which most animals show little or no symptoms of infection. Where cattle are intended for consumption within the human food chain, slaughterhouse surveillance for the presence of indicative organ lesions is the routine post-mortem method employed. However, the sensitivity of post-mortem slaughterhouse surveillance for visible lesions to detect TB is reportedly less than 50%.

The tuberculin skin test (TST) is the conventional ante-mortem test used to screen for TB in most domestic and captive livestock species (*e.g.*, cattle, sheep, camels, deer, etc.) as well as those found in zoos and other exotic wildlife. Initial results from a TST requires a minimum of 3 days and often remains questionable until further confirmed by a repeat skin test, the addition of more complex testing, or at animal necropsy. Moreover, interpretation of TST is both difficult and subjective, resulting in a significant risk that the test will yield either false positive or false negative results.

ChemBio’s tests are designed to offer the zoological and agricultural markets a simple, rapid, reliable, and convenient animal-side test for the detection of TB antibodies. ChemBio’s current tests incorporate single path lateral flow technology in-licensed by ChemBio. Next generation tests will incorporate the company’s Dual Path Platform (DPP™) technology.

Les Stutzman, VP of Marketing at ChemBio commented, “Using our newly patented universal test method in combination with a unique set of recombinant antigens in a simple rapid test format, ChemBio is well positioned to commercialize a line of screening products under the company’s registered STAT-PAK® trademark. These assays will be submitted to USDA for full licensure and will include – ElephantTB STAT-PAK, CamelidTB STAT-PAK, CervidTB STAT-PAK and BovidTB STAT-PAK – for detecting active TB in various animal species. I am most appreciative to Javan Esfandiari, our Senior VP of ChemBio’s R&D team and Konstantin Lyashchenko, PhD., Director of Mycobacterial Immunology, for their respective roles in developing this proprietary product line.”

ChemBio estimates that the total commercial global market potential for a more sensitive, rapid, and convenient veterinary TB assay like STAT-PAK is \$50 million per year; this includes applications for slaughterhouse surveillance screening, programs that trap-test-cull livestock, and rapid import/export screening. ChemBio’s initial marketing efforts will seek to have the products used as a supplement to current TB screening methods in zoos, exotic species conservation centers, import and export quarantine testing facilities, and farms.

ChemBio is actively seeking agents or partners to assist in developing its domestic and international distribution channels for these products. During the interim ChemBio will continue to work directly with all interested customers for these products.

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