

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) **November 30, 2004**

CHEMBIO DIAGNOSTIC, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction
of Incorporation)

333-85787

(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 8.01. Other Events.

Chembio Diagnostics, Inc. ("CDI") has received a \$708,050 purchase order from Bio-Manguinhos to supply HIV 1/2 Stat-Pak components to manufacture rapid tests for the domestic Brazilian marketplace. Bio-Manguinhos, a significant Brazilian manufacturer of vaccines and an affiliate entity of the Brazilian Ministry of Health, will assemble these rapid tests, which detect HIV antibodies, and provide them to the Brazilian HIV/AIDS agency (DST/AIDS) as part of the Prevention of Mother to Child Transmission (PMTCT) program. Chembio is scheduled to complete this order for Bio-Manguinhos by the end of the year.

This purchase order follows from the recent approval of the Bio-Manguinhos branded version of HIV 1/2 Stat-Pak by the Brazilian National Monitoring Agency (Agencia Nacional de Vigilancia Sanitaria) ANVISA for use and distribution in Brazil. In February, Chembio Diagnostics Systems, Inc., a subsidiary of CDI, signed a 13-year technology transfer and supply agreement ("Agreement") with Bio-Manguinhos. The Agreement supports the request from the Brazilian Ministry of Health and National AIDS Control Organization to provide the Brazilian population with a domestically manufactured HIV rapid test.

During the first three years of this Agreement, Chembio will transfer technology and provide training to enable Bio-Manguinhos to produce Chembio's HIV rapid test product locally. The Agreement includes a commitment to purchase at least one million of Chembio's HIV 1/2 Stat-Pak rapid tests for the public health market in Brazil. Over the following 10-year period, Chembio will receive royalties based on sales of the product. With this current order, the contractual commitment for the first year of the contract has been met.

ITEM 9.01. Financial Statements and Exhibits

- 99.1 Press Release Dated November 29, 2004 and released on the same day.
99.2 Press Release Dated December 1, 2004 and released on the same day.

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: December 1, 2004

Chembio Diagnostics, Inc.

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

For Additional Information:

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CHEMBIO STRENGTHENS QUALITY AND REGULATORY TEAM

***Dr. David Gates appointed as Vice President of
Regulatory Affairs, Quality Assurance and Quality Control***

Medford, NY - November 29, 2004 - Chembio Diagnostics, Inc. announced today a restructure that adds key capabilities and depth to its regulatory affairs, quality assurance and quality control organization. Initiated by recently appointed Dr. David Gates, Vice President of Regulatory Affairs, Quality Assurance and Quality Control, these changes reflect the company's commitment to establishing a first class regulatory organization.

"Chembio is delighted to have appointed a seasoned executive to manage this crucial area. Under his leadership, we have also established full time positions in our Quality Assurance and Quality Control department," commented Lawrence A. Siebert, Chembio's President and CEO. "The company has worked hard to bolster this crucial aspect of our operation as we prepare for our HIV, Mad Cow and other regulatory submissions."

As an initial step last year, Chembio engaged New World Regulatory Solutions, Inc. and a former senior official from the USDA as part-time consultants to the company. The recent appointment of Dr. Gates further strengthens Chembio's internal team by offering day-to-day operating expertise onsite, while retaining access to its existing third party consulting team when needed.

Dr. Gates joined Chembio in August 2004. His background includes almost 20 years of in-vitro diagnostic and medical device experience in R&D, process development, regulatory affairs and quality management. During that time, he has held vice president level positions at Metragenix, director level positions in quality management and regulatory compliance at BD Diagnostic Systems and a broad range of senior management positions at Difco Laboratories. Dr. Gates earned his Regulatory Affairs Certification in 1991 and served as an Industrial Representative to the FDA Microbiology Advisory Panel from 1996 to 2000. He has a Ph.D from the University of Tennessee in Microbiology. Dr. Gates also held a post-doctoral fellowship at the State University of New York at Stony Brook in Molecular/Cellular Biology.

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About Chembio Diagnostics, Inc.

Chembio Diagnostics, Inc. possesses expertise in the development and manufacturing of rapid test products for various infectious diseases including HIV, Tuberculosis and Mad Cow Disease. As part of Chembio's strategy to provide its HIV rapid tests to millions of people worldwide through governmental and non-governmental agencies and through selected distributors and strategic partners, Chembio Diagnostics, Inc. (through its subsidiary Chembio Diagnostic Systems Inc.) has recently participated in numerous evaluations of its HIV rapid tests with leading agencies and companies around the world. Chembio is currently completing clinical trials in the United States for two of its HIV rapid tests, Sure Check and HIV Stat-Pak, in support of a planned submission to the FDA for US regulatory approval, which is anticipated in 2005. Chembio signed a technology transfer agreement with the Oswaldo Cruz Institute in February 2004 for one of its HIV tests and is a supplier to Prionics AG for a new rapid test for Mad Cow Disease that has been developed and is awaiting regulatory clearance in Europe. Chembio's headquarters are located at 3661 Horseblock Road, Medford, NY 11763. Chembio's telephone number is 631-924-1135. Email can be directed to info@chembio.com. Additional information can be found at <http://www.chembio.com>.

About New World Regulatory Solutions

New World Regulatory Solutions, Inc. was founded in 2002 with the mission of helping domestic and international companies gain regulatory approval for innovative medical devices. Headed by Maureen Garner, MS, MT (ASCP) the company's team of professionals offers decades of collective experience spanning regulatory affairs, FDA and ISO compliant quality systems, clinical trials management, product development and technical and scientific affairs. Maureen can be contacted at (732) 929-4803 or info@soop.us. Additional information is available at <http://www.soop.us>.

Forward Looking Statements

This release contains forward-looking statements regarding Chembio's future plans and expected performance that are based on assumptions and expectations that Chembio believes are reasonable. A number of risks, uncertainties and other factors could cause any of the assumptions and expectations to be incorrect and could cause actual results to differ materially from those reflected in the forward-looking statements. Some of these risks, uncertainties and other factors include, but are not limited to, the demand for our products, our ability to obtain our products from our suppliers, our ability to maintain commercially feasible margins given significant competition, and other factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date hereof. Chembio undertakes no obligation to publicly revise these forward-looking statements to reflect events or circumstances that arise after the date hereof. Readers should carefully review the risks described in other documents that Chembio files from time to time with the Securities and Exchange Commission, including its Registration Statement on Form SB-2, a copy of which is located at www.sec.gov.

For Immediate Release

For Additional Information:

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CONGRESSMAN TIM BISHOP TO VISIT CHEMBIO ON WORLD AIDS DAY

Congressman to support local manufacturer in the fight against HIV/AIDS worldwide

Medford, NY - December 1, 2004 - Chembio Diagnostics, Inc. (OTCBB:CEMI), a leading developer and manufacturer of rapid diagnostic tests, today announced that Congressman Tim Bishop, the Democratic representative for Suffolk County, New York, is visiting the company's headquarters on World AIDS Day, the annual international day of action on HIV/AIDS. Congressman Bishop will lend his support to Chembio as a local manufacturer, employing 55 people. During this visit, he will learn more about Chembio's rapid HIV tests and how they are a key component in the fight against the spread of HIV/AIDS.

"It is an honor to have Congressman Bishop visit our facilities," said Lawrence A. Siebert, President of Chembio Diagnostics, Inc. "As one of the few domestic companies to produce rapid HIV tests, Chembio is well-positioned as a supplier to the President's Emergency Plan for AIDS Relief (PEPFAR)."

To control the spread of HIV/AIDS, it is critical for individuals to know their status. Chembio's rapid tests, including the Sure Check™ HIV and HIV 1/2 Stat-Pak, deliver results within minutes without the need for special equipment or training, allowing HIV positive patients to begin effective treatment sooner and learn about prevention measures. The company's proprietary rapid tests are designed to detect HIV antibodies in finger stick whole blood, serum or plasma. Currently, Chembio is completing its U.S. clinical trials in support of its FDA PMA submission for Sure Check HIV and HIV 1/2 Stat-Pak rapid tests.

"On World AIDS Day, it is important to recognize the impact that a local manufacturer, such as Chembio, is making on a national and international level," said Congressman Bishop. "It is critical that the U.S. government supports domestic producers of rapid HIV tests because they play a crucial role in the battle against HIV/AIDS."

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