

CHEMBIO DIAGNOSTICS, INC.  
Form 8-K  
October 05, 2006

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UNITED STATES  
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): September 29, 2006

Chembio  
Diagnostics,  
Inc.

(Exact name of registrant as specified in its charter)

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| <u>Nevada</u>   | <u>333-85787</u>               | <u>88-0425691</u>                          |
| (State or other<br>jurisdiction<br>of<br>incorporation) | (Commission<br>File<br>Number) | (IRS<br>Employer<br>Identification<br>No.) |

**3661 Horseblock Road, Medford, NY 11763**

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (631) 924-1135

**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 (see General Instruction A.2. below):

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 1.01. Entry into a Material Definitive Agreement**

On September 29, 2006, the Registrant entered into the material agreements described below.

#### HIV Barrel License, Marketing and Distribution Agreement

This agreement is a three way agreement among Chembio Diagnostic Systems, Inc. (“Chembio”), Inverness Medical Innovations, Inc. (“Inverness”) and StatSure Diagnostic Systems, Inc. (“StatSure”). This agreement covers Chembio’s FDA-approved SURE CHECK(R) HIV 1/2 (“SURE CHECK”), a lateral flow rapid HIV test employing a proprietary barrel system that is a convenient, safe, accurate and integrated single-use rapid HIV antibody detection screening test. Some terms of the agreement are:

- o Inverness will market the SURE CHECK product under Inverness brands globally [subject only to certain existing international agreements Chembio and StatSure may keep in place for up to one year].
- o Inverness will exclusively market SURE CHECK under the agreement as well as any new HIV products in the “barrel field” that are developed, and may not compete with any products in this field worldwide as defined.
- o Chembio and StatSure have each granted Inverness exclusive rights to their intellectual property in the HIV barrel field
- o Inverness has a first right to negotiate any agreements to market and distribute any new Chembio HIV antibody detection tests, including products that may incorporate Chembio’s patent-pending Dual Path Platform (DPP(TM))

#### HIV Cassette License, Marketing and Distribution Agreement

This agreement is between Chembio and Inverness. This agreement covers Chembio’s FDA-approved STAT-PAK(TM) HIV 1/2 (“STAT-PAK”), a lateral flow rapid HIV test employing a cassette system that is a convenient, safe, accurate and a single-use rapid HIV antibody detection screening test. Some terms of the agreement are:

- o Inverness will market this product in the US market only; Chembio has a non-exclusive license under the Inverness lateral flow patents to continue to market the product under Chembio’s brand in the rest of the world
- o Inverness may bring a competitive HIV cassette product to the US market, but in that event Chembio would expand its lateral flow license for this product to the US and have other options under the agreement.

#### Non-Exclusive License, Marketing and Distribution Agreement

This agreement is between Chembio and Inverness. This agreement covers Chembio’s FDA-approved STAT-PAK(TM) HIV 1/2 (“STAT-PAK”), a lateral flow rapid HIV test employing a cassette system that is a convenient, safe, accurate and a single-use rapid HIV antibody detection screening test. Some terms of the agreement are:

- o Chembio has received a non-exclusive license under the Inverness lateral flow patents for its HIV 1/2 Dipstick for marketing outside the United States
- o Chembio has also received a worldwide non-exclusive license to manufacture and market a number of other Chembio-branded products including all Chembio’s rapid tests for human and veterinary and tuberculosis, Chagas disease, and tests for other defined emerging and neglected diseases.
- o Inverness has the right to market each of these products (except the HIV 1/2 STAT PAK Dipstick) under an Inverness brand pursuant to an agreed-upon pricing and margin sharing formula similar to the other agreements.

General to the three Agreements above

The agreements with Inverness contain margin sharing formulae that are designed to provide Inverness, Chembio and StatSure with reasonable profit margins after deduction for certain unit costs of the products. Based on their Joint HIV Barrel Product Commercialization Agreement, outlined below, StatSure and Chembio will share 50-50 in the net sales to Inverness of SURE CHECK after these deductions. Chembio will receive all of the net selling price to Inverness in the Cassette Agreement.

Chembio has the exclusive right and duty to manufacture the products marketed by Inverness under all the agreements, and it has the right to subcontract manufacturing, but not sublicense or subcontract its rights or obligations.

Joint HIV Barrel Product Commercialization Agreement and Settlement Agreement with StatSure

Chembio and StatSure have entered into a Settlement Agreement pursuant to which all matters in their litigation regarding StatSure' barrel patent and other matters have been settled. As stated in the second preceding paragraph above, the Joint JIV Barrel Product Commercialization Agreement provides that the parties will equally share in the profits relating to SURE CHECK after reimbursement to Chembio of its manufacturing and related costs, as defined, and that they will act jointly in the HIV barrel field. The settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to Chembio of its barrel patent for all HIV applications, thereby ensuring Chembio's exclusive right to manufacture, as well as Inverness' right to market though the marketing license StatSure grants Inverness under the 3-way Agreement.

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**ITEM 7.01. REGULATION FD DISCLOSURES**

(a) On October 5, 2006 the Registrant issued the press release titled "Inverness Medical Innovations, Chembio Diagnostics, Inc. and StatSure Diagnostic Systems, Inc. Announce Agreements to Market Rapid HIV and Other Tests" included herein as Exhibit 99.1.

(b) On October 5, 2006 the Registrant issued the press release titled "StatSure and Chembio Agree to End Litigation and Enter Agreement to Commercialize HIV Barrel Technology" included herein as Exhibit 99.2.

**ITEM 8.01 OTHER EVENTS**

Also on September 29, 2006, Inverness Medical Innovations, Inc. participated in a private placement of securities of Chembio. See Press Release filed as Exhibit 99.1 and Item 3.02 to a separate form 8-K filed with the U.S. Securities and Exchange Commission on October 5, 2006 by Chembio.

**ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS**

(d) Exhibits

**10.1** HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure.

**10.2** HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness.

**10.3** Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness.

**10.4** Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure.

**10.5** Settlement Agreement, dated September 29, 2006, between the Registrant and StatSure.

**99.1** Press Release titled "Inverness Medical Innovations, Chembio Diagnostics, Inc. and StatSure Diagnostic Systems, Inc. Announce Agreements to Market Rapid HIV and Other Tests" issued October 5, 2006

**99.2** Press Release titled "StatSure and Chembio Agree to End Litigation and Enter Agreement to Commercialize HIV Barrel Technology" issued October 5, 2006

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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 5, 2006 CHEMBIO DIAGNOSTICS, INC.

By: /s/ Lawrence A. Siebert

Lawrence A. Siebert  
Chief Executive Officer

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