

CHEMBIO DIAGNOSTICS, INC.

Form 8-K

December 05, 2012

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): December 4, 2012 (November 28, 2012)

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 DISCLOSURE.

On December 4, 2012, the Company issued a press release entitled "Chembio to Present at LD Micro V: Main Event Conference". A copy of the press release is furnished herewith as Exhibit 99.1.

On November 28, 2012, the Company was informed by the US Food and Drug Administration ("FDA") that its premarket approval ("PMA") application for the DPP(R) HIV 1/2 Assay lacked certain information needed to complete its FDA's review. The two issues that were cited involved manufacturing-related issues (validation on one piece of equipment and additional samples for in-process testing) and did not involve any clinical trial data. The Company has addressed the issue concerning samples for the in-process testing, and expects to complete the equipment validation today and submit them to the FDA by the end of this week. If the Company does not submit data satisfactory to the FDA by December 7, 2012, then the approval process can be delayed up to an additional 180 days. The Company believes this delay will not occur, and it will receive approval before the end of the year.

The information in this Item 7.01 of this Form 8-K is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Form 8-K also shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

Exhibits.

99.1 Press Release entitled "Chembio to Present at LD Micro V: Main Event Conference" dated December 4, 2012.

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.

December 4, 2012

Chembio Diagnostics, Inc.

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

EXHIBIT INDEX

| Exhibit Number | Description |
|-------------------|--|
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