CHEMBIO DIAGNOSTICS, INC.
Form 8-K
November 30, 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): November 30, 2012

CHEMBIO DIAGNOSTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	0-30379	88-0425691
(State or other jurisdiction of Incorporation)	(Commission File Number)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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.

The Company desires that the following information be available:

Chembio wishes to clarify that Chembio currently markets two of its own lateral-flow, finger-stick, whole-blood rapid HIV tests in Africa, both of which are FDA PMA-approved. Chembio has an additional test, which incorporates its patented DPP® technology and which is pending FDA PMA approval. The two FDA PMA-approved products are currently marketed under the Chembio brands of HIV 1/2 STAT PAK® and SURE CHECK® HIV 1/2, and are distributed in various markets in Africa as well as in South and Central America, and Asia. Chembio is reiterating these facts in order to correct certain public statements made by another party which indicate that there is only one FDA-approved HIV rapid test being marketed in Africa, and that test is not Chembio's.

The Company also wishes to clarify statements made by another party that suggest that Chembio's share of the US rapid HIV test market is estimated to be $8 million. However, that figure does not include the substantial portion of customer revenues from US sales of Chembio's HIV rapid tests that are realized by Alere, Inc. ("Alere"), which has the exclusive U.S. marketing rights to these products pursuant to a 10-year agreement executed in 2006 and under which Alere markets the products in the U.S. professional diagnostics market under its Clearview brand, as Clearview HIV 1/2 STAT-PAK and Clearview Complete HIV 1/2. As a result, using the amount of Alere's sales of Chembio US HIV point-of-care products would result in a substantially larger market share calculation for these Chembio products sold by Alere.

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.

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.

November 30, 2012 Chembio Diagnostics, Inc.

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