

CHEMBIO DIAGNOSTICS, INC.  
Form DEFA14A  
August 02, 2012

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

SCHEDULE 14A INFORMATION  
Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant    
Filed by a Party other than the Registrant

Check the appropriate box:  
 Preliminary Proxy Statement  
 Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))  
 Definitive Proxy Statement  
 Definitive Additional Materials  
 Soliciting Material under Rule 14a-12

CHEMBIO DIAGNOSTICS, INC.

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(Name of Registrant as Specified in Its Charter)

Not Applicable

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(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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No fee required.

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Date Filed:



CHEMBIO DIAGNOSTICS, INC.  
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To Our Shareholders:

It is with great pleasure that I provide you with an update of Chembio's tremendous progress during the first half of 2012. It has been an extremely productive time for your Company that featured significant advances in a number of areas that are critical to building a sustainable growth enterprise, and that now put us in a stronger position to build further upon these successes.

Chembio has two rapid HIV tests that are approved by the U.S. Food and Drug Administration ("FDA") and are marketed in the U.S. and internationally. On the strength of these products, we have delivered strong top-line growth for several years with successive record profitability in each of the last three. We also reported record top- and bottom-line results in the first quarter of this year and remain optimistic about our full-year 2012 prospects.

Our HIV and other rapid tests provide healthcare professionals and their patients with vital information about disease status – simply, quickly, accurately and cost effectively – all at the point of care, when the patient already is present, and actions can be taken and information can be provided. Millions of our rapid HIV tests have been used in point-of-care settings around the world, and I am very proud to say that Chembio's products have helped to save or improve countless lives.

Moving forward, we are strengthening our rapid, HIV-test franchise, first with Chembio's new Dual Path Platform (DPP®) HIV 1/2 Assay, a rapid point-of-care test designed for use with oral fluid or blood samples. Earlier this year, in support of FDA approval, we completed a 3,000-patient clinical trial as part of a full Premarket Approval ("PMA") application for which data has been submitted to the FDA and is pending a determination. We expect that this determination will occur by the end of 2012. Second, we are uniquely positioned to participate in the HIV self-test, or over-the-counter, opportunity with our unitized Sure Check® HIV 1/2 finger-stick-whole-blood test. This test is FDA-approved for professional use and is well established in the U.S. by our domestic marketing partner, Alere, Inc., under the name "Clearview Complete HIV 1/2". Notably, our results show that this test is more sensitive than the existing competitive oral fluid test.

In order to begin the regulatory process toward an over-the-counter market approval for self-testing by consumers, a company must first have a product that is FDA-approved for the professional market, making Chembio the only current practical alternative to the recently-approved oral fluid self-test. As such, we are accelerating our development plans to bring our rapid, in-home HIV test to market. We are working toward filing an Investigation New Device application with the FDA by year-end and look forward to reporting to you on our progress with this program.

Most recently, we participated in AIDS 2012, the world's premier conference in the HIV field, where we exhibited our entire suite of HIV rapid, point-of-care diagnostic tests before an audience of the leading AIDS clinicians, policy makers and advocates.

In addition to our HIV franchise of rapid tests, Chembio has many new opportunities for its products and technologies both in the U.S. and around the world, as our pipeline features many other potential products, including rapid, point-of-care diagnostic tests for syphilis, hepatitis C, influenza and more.



In light of the recently released draft recommendations from the U.S. Centers of Disease Control and Prevention (“CDC”) to test all baby boomers in the U.S. for hepatitis C, we are accelerating the development of our point-of-care test for that virus. We were particularly pleased to announce the publication of independent data in the peer-reviewed Journal of Clinical Virology, which demonstrated Chembio’s DPP® HCV point-of-care assay, when used with blood samples, had acceptable sensitivity and specificity, and was comparable to conventional laboratory immunoassays currently in use. With approximately 4.1 million Americans estimated to have been infected with the hepatitis C virus, and with 45% to 85% unaware of their infection, the development of a rapid, point-of-care test is an important public health initiative, and is another emerging market where we believe Chembio is extremely well-positioned for leadership.

In addition, we recently signed a new development agreement providing for up to \$480,000 of research and development funds to Chembio as a follow-on to our previous successful initial development of a multiplex rapid point-of-care influenza immunity test utilizing our patented DPP® technology. As a result of pandemic planning activities, the U.S. Department Of Health And Human Services ("HHS") and the CDC identified point-of-care and high-throughput testing as a gap in influenza diagnostics. Rapid responses in the field, such as the vaccination, prophylactic treatment or isolation of patients, require on-site diagnostic tests for influenza infection and immunity. Ideally, these tests should be fast, portable, self-contained and non-technical. Development of these tests is especially critical for military forces, as evidenced by previous influenza outbreaks that spread rapidly through densely populated barracks and have killed thousands of soldiers. We are confident that these development efforts, which are supported by the CDC, will produce a rapid influenza immunity test that can be administered in the field or in an outpatient setting to determine a person's influenza immunity status.

Our patented technology, along with our manufacturing platform and expertise, continues to enable us to collaborate on new product opportunities with commercial partners to identify complementary technologies, and to begin to develop our Chembio and DPP® brand. Chembio is among the fastest-growing employers on New York’s Long Island, which is where we make all our products – made with pride in America!

In June, we were especially pleased to announce the listing of our common stock on the NASDAQ Capital Markets®. We are confident that this NASDAQ listing will provide Chembio with a significantly expanded market for its securities and will contribute to increased investor interest, which our Board of Directors believes will be in the best interests of all our shareholders.

In closing, we are proud of our achievements to date and remain confident in and excited about Chembio’s prospects moving forward. I thank all of our dedicated employees, our board of directors, business partners, and investors for their support and encouragement as we build Chembio into a world-leading diagnostic company.

Sincerely,

/s/ Lawrence Siebert  
Lawrence Siebert  
Chief Executive Officer  
August 2, 2012

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