UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

SERGEY CHERNYSH, on behalf of himself and all others similarly situated, Plaintiff, v. CHEMBIO DIAGNOSTICS, INC., RICHARD L. EBERLY, and GAIL S. PAGE, Defendants.	CASE NO. 20-cv-2706 JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff, Sergey Chernysh, by his attorneys, on behalf of himself and all others similarly situated, alleges the following based upon the investigation by plaintiff's counsel, except as to allegations specifically pertaining to plaintiff, which are based on personal knowledge. The investigation by counsel included, among other things, a review of Chembio Diagnostics, Inc.'s ("Chembio" or the "Company") public filings with the United States Securities and Exchange Commission ("SEC"), press releases issued by the Company, public conference calls, media and news reports about the Company, and publicly available trading data relating to the price and volume of Chembio common stock.

I. INTRODUCTION

1. This action is a securities fraud action brought under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder by the SEC brought by Plaintiff on behalf of a class of all persons and entities who purchased the publicly traded common stock of Chembio during the period April 1, 2020

through June 16, 2020, inclusive (the "Class Period").

2. Chembio purports to be a leading point-of-care (POC) diagnostics company focused on detecting and diagnosing infectious diseases. The Company claims its patented Dual Path Platform (DPP) technology platform, which uses a small drop of blood from the fingertip, provides high-quality, cost-effective results in approximately 15 minutes.

3. Furthermore, the Company asserts that its products "meet the highest standards for accuracy and superior performance to help prevent the spread of infectious diseases" and that its "innovative solutions, like the Chembio Dual Path Platform (DPP®), make POC testing faster, more accurate, and more cost effective."

4. In light of the COVID-19 pandemic, the Company focused on the development and commercialization of a serological or antibody test. Chembio's antibody test was one of the first antibody tests authorized by the FDA during the COVID-19 public health emergency.

5. Throughout the Class Period, Defendants represented that its DPP COVID-19 serological POC test for the detection of IgM and IgG antibodies aided in determining current or past exposure to the COVID-19 virus, that its test provides high sensitivity and specificity, and was 100% accurate. Test sensitivity is the ability of a test to correctly identify those with the disease (true positive rate), whereas test specificity is the ability of the test to correctly identify those without the disease (true negative rate).

6. Based on Defendants representations, during the Class Period the Company's stock increased from a closing price on March 31, 2020, the day before the Class Period begins, of $5.12 per share, to a Class Period high of $15.54 per share on April 24, 2020.

7. Defendants took advantage of Chembio's inflated stock price. On May 11, 2020, the Company reported that it closed the public offering of approximately 2.6 million shares of Chembio stock at $11.75 per share for gross proceeds of approximately $30.8 million.

8. Then, on June 16, 2020, after the market closed, the U.S. Food and Drug Administration ("FDA") issued a press release disclosing that it had revoked the Company's Emergency Use Authorization ("EUA") for the Company's DPP COVID-19 Igm/IgG System:

> Today, the U.S. Food and Drug Administration revoked the emergency use authorization (EUA) of the Chembio Diagnostic System, Inc. (Chembio) DPP COVID-19 IgM/IgG System, a SARS-CoV-2 antibody test, **due to performance concerns with the accuracy of the test.** Antibody tests, a type of serological test, can help provide information on a person's and population's exposure to COVID-19.
>
> "Since the beginning of the COVID-19 public health emergency, the FDA has balanced the urgent need for access to diagnostic and antibody tests with providing a level of oversight that helps to ensure accurate tests are being deployed," said Jeff Shuren, M.D., director of FDA's Center for Devices and Radiological Health. "By continuing to monitor authorized tests and emerging scientific evidence, we are able to make changes when appropriate – **including taking action when a test's benefits no longer outweigh its risks**. Through these efforts, we are able to help assure that FDA-authorized tests meet the needs of the American public."
>
> The Chembio antibody test was one of the first antibody tests authorized by the FDA during the COVID-19 public health emergency. At the time of authorization, based on the information that Chembio submitted to the FDA at that time, the agency concluded that the test met the statute's "may be effective" standard for emergency use authorization, and that the test's known and potential benefits outweighed its known and potential risks.
>
> As the FDA has learned more regarding the capability for performance of SARS-CoV-2 serology tests during the pandemic, and what performance is necessary for users to make well-informed decisions—through both the continued review and authorization of serology tests as well as through a research partnership with the National Institutes of Health's National Cancer Institute (NCI)— the FDA was able to develop general performance expectations for these tests, which are listed in our serology templates.
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> **Data submitted by Chembio as well as an independent evaluation of the Chembio test at NCI showed that this test generates a higher than expected**

> **rate of false results and higher than that reflected in the authorized labeling for the device. Under the current circumstances of the public health emergency, it is not reasonable to believe that the test may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the test outweigh the known and potential risks of the test, including the high rate of false results.** Moreover, the risk to public health from the false test results makes EUA revocation appropriate to protect the public health or safety. As such, the FDA decided to revoke the emergency use authorization of the Chembio test, and this test may not be distributed.

(Emphasis added).

9. On June 17, 2020, the Company filed a report with the SEC on Form 8-K that acknowledged receipt of the FDA's June 16, 2020 letter and stated, in part, the following:

> On June 16, 2020, we received a letter from the U.S. Food and Drug Administration, or FDA, notifying us that the FDA was revoking the Emergency Use Authorization, or EUA, granted in April 2020 with respect to our DPP COVID-19 System, which consists of our serological test for COVID-19 and one of our Micro Reader analyzers. As a result of this decision by the FDA, we may no longer distribute the DPP COVID-19 System. . .
>
> In its letter of June 16, 2020, the FDA stated that it had decided to revoke the EUA for the DPP COVID-19 System due to performance concerns regarding the sensitivity and specificity of our test system. . . .
>
> We intend to continue working with the FDA with respect to the modification of the DPP COVID-19 System and of the revocation of the EUA for our test system.

10. As a result of disclosure of the FDA letter, Chembio shares declined from a closing price on June 16, 2020 of $9.93 per share to close at $3.89 per share on June 17, 2020, a decline of $6.04 per share, or over 60%, on heavier than usual volume of over 25 million shares.

11. Also on June 17, 2020, Bloomberg published a report titled "FDA Reversal on Chembio Antibody Test Sends Stock Down 63%" that noted that, in light of the FDA revocation of the Company's EUA, five analysts downgraded Chembio stock.

12. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common stock, Plaintiffs and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

13. The claims asserted arise under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Jurisdiction is conferred by Section 27 of the Exchange Act. Venue is proper pursuant to Section 27 of Exchange Act because during the Class Period defendant Chembio and the Individual Defendants conducted business in, and wrongful conduct took place in, this District.

III. THE PARTIES

14. Plaintiff purchased Chembio's publicly traded common stock as detailed in the attached Certification and was damaged thereby.

15. Defendant Chembio is incorporated in Nevada and its current principal executive offices are located at 555 Wireless Boulevard, Hauppauge, New York 11788.

16. Defendant Richard L. Eberly ("Eberly") has been the Company's President and Chief Executive Officer, and a director since March 16, 2020.

17. Defendant Gail S. Page ("Page"), has been the executive chair of the Company's board of directors since July 2017.

18. Defendants Eberly and Page are referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Chembio's quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company's reports and press

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