UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

_____, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. CHEMBIO DIAGNOSTICS, INC., RICHARD L. EBERLY, and GAIL S. PAGE, Defendants.	CIVIL ACTION NO. CLASS ACTION **COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** JURY TRIAL DEMANDED

Plaintiff, _____ ("Plaintiff"), by his attorneys, on behalf of himself and all others similarly situated, brings this class action complaint for violation of federal securities laws ("Complaint") against Chembio Diagnostics, Inc. ("Chembio" or the "Company"), Richard L. Eberly, and Gail S. Page (collectively with Chebio, "Defendants"), based upon, *inter alia*, the investigation conducted 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's public filings with the United States ("U.S.") 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.

INTRODUCTION

1. This is a federal securities class 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 March 12, 2020 through June 16, 2020, inclusive (the "Class Period").

2. Chembio is a Nevada corporation headquartered in the State of New York. Chembio develops diagnostic solutions and offers products for treatment, detection, and diagnosis of infectious diseases. The Company claims to have developed and patented a new and innovative technology called the Dual Path Platform ("DPP®"), which allows for rapid diagnostic testing of a variety of chemical substances. On its website, the Company maintains 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 [point-of-care] testing faster, more accurate, and more cost effective."

3. In March 2020, the Company entered into a worldwide strategic partnership with LumiraDx Limited, a company focused on developing, manufacturing, and commercializing industry-leading point-of-care diagnostic platforms, with the aim of developing a diagnostic test for the detection of the COVID-19 virus and IgM and IgG antibodies on both of their DPP® platforms (the "DPP COVID-19 Test"). On this news, Chembio's shares jumped 65% during pre-market trading.

4. Throughout the Class Period, Defendants touted its progress in developing the DPP COVID-19 Test, representing that the test successfully aided in determining current or past exposure to the COVID-19 virus, that it provided high sensitivity and specificity, and that it was 100% accurate. Defendants' overly positive progress updates convinced some entities to place purchase order for Chembio's DPP COVID-19 Tests worth millions of dollars. These events, further boasted the price of Chembio shares, including on March 20, 2020, when Chembio common shares rose 54%. The Company's representations ultimately drove the Company's stock from a closing price of $3.10 per share on March 11, 2020, to a Class Period high of $15.54 per share on April 24, 2020, an increase of more than 400%.

5. Defendants benefitted awesomely from 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.

6. 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 Test. In a public announcement, the FDA informed that its decision was "due to performance concerns with the accuracy of the test." More specifically, the FDA informed that the Company's DPP COVID-19 Test "generate[d] a higher than expected rate of false results and higher than that reflected in the authorized labeling for the device." As a result, the FDA concluded that the "test's benefits no longer outweigh its risks."

7. The next day, on June 17, 2020, the Company publicly acknowledged the receipt of FDA's June 16, 2020 letter and informed the public of FDA's revocation of its EUA. Immediately following the disclosure of the FDA's June 17 letter, at least five analysts downgraded Chembio stock.

8. Furthermore, 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 unusually heavy trading volume of over 25 million shares.

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

JURISDICTION AND VENUE

10. 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.

11. Venue is proper in this Judicial District pursuant to Section 27 of Exchange Act because during the Class Period Defendants conducted business in this Judicial District, and a significant portion of Defendants' activities in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District.

12. In connection with the acts alleged in this Complaint, Chembio, directly or indirectly, used the instrumentalities of interstate commerce, including interstate wires, U.S. Postal Service mail, wireless spectrum, and the national securities exchange.

THE PARTIES

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

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

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

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

17. 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 releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them but not to the public, each of these defendants knew that the adverse

facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false statements pled herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

CLASS ACTION ALLEGATIONS

18. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of a class of all persons and entities who purchased the publicly traded common stock of Chembio during the Class Period (the "Class").

19. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at the present time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds of members of the Class located throughout the United States. As of June 1, 2020, Chembio had over 20 million shares of common stock outstanding, which were actively traded on the NASDAQ in an efficient market.

20. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class have sustained damages because of Defendants' unlawful activities alleged herein. Plaintiff has retained counsel competent and experienced in class and securities litigation and intends to pursue this action vigorously. The interests of the Class will be fairly and adequately protected by plaintiff. Plaintiff has no interests which are contrary to or in conflict with those of the Class that plaintiff seeks to represent.

21. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

22. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;

(b) whether defendants misstated and/or omitted to state material facts in their public statements and filings with the SEC;

(c) whether Defendants participated directly or indirectly in the course of conduct complained of herein; and

(d) whether the members of the Class have sustained damages and the proper measure of such damages.

FALSE AND MISLEADING STATEMENTS

23. On March 12, 2020, Chembio issued a press release titled, "Chembio and LumiraDx Announce COVID-19 Strategic Partnership" that stated the following:

> Chembio Management to Discuss During Earnings Call on March 12, 2020
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> HAUPPAUGE, N.Y., March 12, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced that it has entered into a worldwide strategic partnership with LumiraDx Limited to develop point-of-care diagnostic tests for the detection of the COVID-19 virus and IgM and IgG antibodies on both the LumiraDx and Chembio DPP platforms.
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> "We are pleased to expand our relationship with Chembio as our partner given the company's expertise and speed in developing high-quality point-of-care assays. By joining forces and bringing together the best of these two companies, we believe we will become the chosen approach for the detection and monitoring of the COVID-19 virus, which has become a worldwide pandemic," stated Ron Zwanziger, LumiraDx's Chairman and Chief Executive Officer.
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> "We are very excited to join with LumiraDx in this strategic partnership, ***which demonstrates our scientific expertise and the versatility of our DPP platform,"*** stated Gail Page, Chembio's Interim Chief Executive Officer. "Through our joint efforts, ***we expect the new products to provide comprehensive solutions to the new demands surrounding the worldwide testing needs for COVID-19."*** [1]

[1] Here, as throughout, all emphasis is added, unless otherwise noted.

Chembio's management team will discuss the strategic partnership during the conference call previously scheduled to review financial results for the fourth quarter and full year 2019. The conference call will begin at 4:30 p.m., Eastern Time, on Thursday, March 12, 2020. Investors interested in listening to the conference call may do so by dialing 877-407-0778 from the US or 201-689-8565 from outside the US or by accessing www.chembio.com/investors/calendar-of-events/. A replay of the call will be available by dialing 877-481-4010 from the US or 919-882-2331 from outside the US (using passcode 33460) or by accessing www.chembio.com/investors/calendar-of-events/.

24. Also on March 12, 2020, Chembio issued a press release titled, "Chembio Diagnostics Reports Fourth Quarter and Full Year 2019 Financial Results" that stated, in part, the following:

HAUPPAUGE, N.Y., March 12, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today reported financial results for the quarter and year ended December 31, 2019.

Recent Accomplishments & Highlights

- Achieved full year 2019 product revenue of $28.8 million and total revenue of $34.5 million, an increase of 3.3% and decrease of 0.3%, respectively compared to 2018
- Achieved fourth quarter 2019 product revenue of $5.5 million and total revenue of $6.9 million representing a decrease of 5.9% and 11.8%, respectively, compared to the prior year period
- Announced a worldwide strategic partnership with LumiraDx to develop and commercialize COVID-19 tests on the DPP and LumiraDX platforms
- Appointed Richard Eberly as Chief Executive Officer
- Received $1.5 million dollar UNICEF order for Multiplex Zika Systems
- Completed acquisition of Orangelife to diversify and expand our market penetration in Brazil and support Bio-Manguinhos, one of our major customers
- Received WHO Prequalification approval for both the HIV Self-Test and the Malaysia production facility
- Initiated production on our fully automated DPP manufacturing line and took delivery of our second and third automated lines for our other product platforms
- Continued collaborative work with the FDA on reproducibility study requirements for the HIV-Syphilis System PMA following acceptance of the syphilis and pregnant women data

"Though we were disappointed with the reduced rate of growth in our product revenues vs. prior years, our U.S. and European businesses were up, but they were mitigated by the shortfalls in Africa and Asia. We believe this is in large part due to the

> timing of annual tenders. As we examined our total revenue shortfall, it became apparent that it was principally driven by the decrease in R&D and grant revenue, which relates to the cadence of our collaboration work with customers such as AstraZeneca and Takeda." said Gail Page, Chembio's Interim Chief Executive Officer.
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> Ms. Page continued, "Reflecting on 2019, we accomplished several milestones that position the company favorably for future growth. These include multiple global product approvals and registrations, the acquisition of Orangelife that will enhance our commercial efforts in the largest infectious disease testing market, advancing development agreements with world-class partners, scaling production capacity through automation and an additional WHO prequalified facility, and strengthening the balance sheet."
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> ***"As we look to 2020, we are very excited to partner up with LumiraDx and combine our collective scientific expertise to develop point-of-care tests for COVID-19. We are confident our combined solutions will be the preferred approach for healthcare providers to detect and monitor this pandemic.*** In addition, we are pleased to have appointed Richard Eberly as CEO to lead the next phase of Chembio's growth. He is a diagnostics industry veteran who brings to the company years of experience commercializing and growing many product platforms. We are confident we have the right team and technology to extend our leadership in point-of-care diagnostics, grow revenues, and create long-term shareholder value."

25. Later in the day on March 12, 2020, Chembio held an investor conference call to discuss its partnership with LumiraDx and the Company's Fourth Quarter and Full Year 2019 Financial Results. At the outset of the call, Defendant Page reiterated earlier Company press release statements on the expansion of the DPP platform for COVID-19 testing, stating, in part, the following:

> We entered into a worldwide strategic partnership with LumiraDX Limited to develop point-of-care diagnostic tests for the detection of the COVID-19 virus as well as IgM and IgG antibodies on both the LumiraDX and Chembio DPP platforms. This expands and strengthens our existing relationship with LumiraDX and further ***demonstrates our scientific expertise and the versatility of our DPP platform***. Through our joint efforts, **we expect the new product to provide comprehensive solutions to the new demand surrounding the worldwide testing needs for COVID-19**.

26. During the question and answer session of the investor call, an analyst from Craig-Hallum Capital Group LLC asked Company representatives how the relationship with LumiraDx was structured. Defendant Page responded, stating:

That's the largest question. I need to be careful here because how we interact, what we do with Lumira, we want to respect their confidentiality, if you will. What I can say is that, if you'll notice that this is an entirely new agreement. This is a strategic partnership. This is one where both boxes will have the test, but Lumira will be selling the DPP as well as their own box. There's a lot more in this agreement that, again, properly incentivizes and rewards both of us for getting the test to the market in a very expeditious manner. ***But also, again, to point out that we're all very focused taking all the intelligence of LumiraDX and all the intelligence here to make sure we have something that's commercially viable. It's just like years ago, we had to get a test for the flu, right?*** So sometimes you go to doctor, you need to know, do I have the flu or don't I, right? There's all kinds of new viruses. And that goes back to, well, why do you need to know, what you need to know where they say stay home and you don't get on the plane, if you got the flu or you don't, whatever. ***So I think that we have a lot of expertise in bringing these types of things to the market. We have the platform,*** they have the collective intelligence. So I think it's -- we're very optimistic, and we're sorting out all the details.

27. On March 31, 2020, after the market closed, the Company issued a press release titled "Chembio Announces Launch of DPP COVID-19 Serological Point-of-Care Test" that stated the following:

IgM/IgG Antibody Results in 15 Minutes from a Simple Finger Stick

HAUPPAUGE, N.Y., March 31, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced the U.S. launch of the rapid DPP COVID-19 serological point-of-care test for the detection of IgM and IgG antibodies. These results can be obtained within 15 minutes from a simple finger stick utilizing Chembio's MicroReader 1 and MicroReader 2 analyzers which are produced by Chembio Germany. ***The ability of the DPP platform to provide numerical results can aid clinicians in determining current or past exposure to the COVID-19 virus and monitoring infection progression, while avoiding the human interpretation errors associated with visual readings.***

The DPP COVID-19 test detects antibodies in the blood that are produced by the body in response to a novel coronavirus infection. Numerical readings of the IgM and IgG antibodies have the ability to assist clinicians in determining patients who have been exposed to the novel coronavirus, even among patients who exhibit mild to no symptoms. Detection of an acute infection phase, as determined by the level of IgM antibodies, helps determine if a patient may still be infectious and could possibility transmit the infection to another person. Further along in the infection progression, the body typically starts to produce IgG antibodies, which increase while IgM levels decrease until eventually only IgG antibodies are present, demonstrating prior infection without the ability to transmit the virus.

"The results and data from our DPP COVID-19 test can help improve clinical outcomes through the management of individual patients by enabling clinicians to understand the likelihood of past and present infection and to manage populations as a whole as a surveillance test," stated Richard Eberly, Chief Executive Officer of Chembio. "Our measured approach has positioned us to offer a viable and sustainable long-term solution for clinicians. We expect to begin shipping product in April 2020, and we will continue to work with our partner LumiraDx to provide DPP COVID-19 tests with the ability to scale based upon market demand."

"We are excited that, through diligent collaboration with the FDA, our test will be distributed as authorized by the FDA Notification process under the public health emergency guidance issued on March 16, 2020," stated Gail S. Page, Chembio director. "This is another example of Chembio's ability to respond in an expeditious manner to global pandemics with differentiated solutions, as demonstrated previously with Zika and Ebola." . . . .

Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases. ***The company's patented DPP technology platform, which uses a small drop of blood from the fingertip, provides highquality, cost-effective results in approximately 15 minutes.***

28. On April 15, 2020, Chembio issued a press release titled "Chembio Diagnostics Receives Emergency Use Authorization for DPP COVID-19 System for IgG and IgM Antibodies" that stated, as follows:

First Shipments of the COVID-19 Serological Test have been Released
HAUPPAUGE, N.Y., April 15, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced receipt of Emergency Use Authorization (EUA) for its DPP COVID-19 System. The DPP COVID-19 System is a serological test and analyzer that provides numerical readings for both IgM and IgG levels within 15 minutes from a simple finger stick drop of blood. Both Chembio's Micro Reader 1 and Micro Reader 2 analyzers are compatible with the test.

"We are very pleased with the continued progress our teams are making to address the market demands with our DPP COVID-19 serological system," stated Rick Eberly, Chembio's Chief Executive Officer. "The flexibility of having two analyzers and a system that provides high sensitivity and specificity that is generally consistent with the performance of Chembio's other DPP platform tests as part of our offering places us in a unique position to serve a variety of markets. Additionally, we are pleased to announce that our manufacturing team has produced and shipped our first lots of the COVID-19 Systems, and we look forward to providing further product within the US and abroad."

29. On May 4, 2020, the Company issued a press release reporting the Company's financial results for the quarter ended March 31, 2020, that stated, in part, the following:

> Recent Accomplishments & Highlights
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> - Attained FDA Emergency Use Authorization for the DPP COVID-19 IgM/IgG System serological test
> - Announced the U.S. launch and shipments to customers of the DPP COVID-19 System
> - Selected by Stony Brook Medicine as the testing solution to identify COVID-19 survivors for study on COVID-19 convalescent plasma therapy
> - Received a $4.0 million purchase order from Bio-Manguinhos for our DPP COVID-19 System . . . .
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> "During the first quarter, we refocused our business strategy to address the escalating need for COVID-19 diagnostic tests. In a short period of time, we developed a COVID-19 serological testing system, received FDA Emergency Use Authorization and began shipping tests to customers in the United States and Brazil in April. ***Our differentiated testing system offers numerical discrete detection of both IgM and IgG antibodies in approximately 15 minutes from a fingerstick. Then, in approximately 15 seconds, the DPP COVID-19 System reads the test to provide numerical results using the portable Micro Reader analyzers that are engineered and produced by our wholly owned subsidiary in Germany. Numerical results reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many other serological tests,"*** said Gail Page, Chembio's Executive Chair of the Board. "We are proud to be serving the needs of clinicians and the broader healthcare community in this time of crisis."
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> "It has been an extremely productive first few weeks in my new role as CEO. Amid these challenging circumstances, the skill and hard work of this team has enabled a successful strategic pivot as we prioritize manufacturing and commercialization of our DPP COVID-19 System," said Richard Eberly, Chembio's Chief Executive Officer. "Through efficient use of our resources and technical ability, we are scaling production of these tests due to the strong demand we are experiencing. We believe the features and benefits offered by our DPP COVID-19 System will make it a preferred solution."

30. Additionally on May 4, 2020, the Company conducted a conference call with investors to discuss its financial results for the quarter ended March 31, 2020, in which Defendants Eberly and Page participated. During the conference call, Defendant Eberly represented that the ***"accuracy of the DPP COVID-19 systems after 11 days post the onset of symptoms is 100% for total antibodies.*** This is based on our data that was submitted to and reviewed by the FDA for the EUA."

31. On May 11, 2020, the Company issued a press release titled "Chembio Diagnostics Announces Closing of Public Offering of Common Stock" that stated the following:

> HAUPPAUGE, N.Y., May 11, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI) ("Chembio"), a leading point-of-care diagnostic company focused on infectious diseases, announced today the closing of its previously announced public offering of 2,619,593 shares of its common stock, which included 281,125 shares issued pursuant to the partial exercise by the underwriters of their option to purchase additional shares, at a public offering price of $11.75 per share for gross proceeds of approximately $30.8 million. All shares of common stock sold in the offering were offered by Chembio.

32. On May 18, 2020 the Company issued a press release titled "Chembio Diagnostics Announces US Distribution Agreement to Expand Reach of DPP COVID-19 Serological Test with Thermo Fisher Scientific's Healthcare Channel" that stated the following:

> HAUPPAUGE, N.Y., May 18, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced it has signed a multi-year, nonexclusive agreement with Thermo Fisher Scientific's healthcare channel, to distribute Chembio's DPP COVID-19 System in the United States. The DPP COVID-19 System is a rapid serological test and analyzer that provides numerical readings for both IgM and IgG antibody levels within 15 minutes from a finger stick drop of blood. The DPP COVID-19 System can include either Chembio's Micro Reader 1 or Micro Reader 2 analyzer.
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> "We are pleased to announce our strategic supplier partnership with the Fisher Healthcare channel, which will significantly increase our commercial footprint by providing access to thousands of hospital and physician office moderately complex labs across the country," stated Rick Eberly, Chembio's President and Chief Executive Officer. "We have initiated a comprehensive training and marketing program for the Fisher Healthcare channel sales team, in order to expand the targeted coverage for this important segment of the market as soon as possible."

33. The statements referenced above in paragraphs 23-32 were materially false and/or misleading because Defendants misrepresented and failed to disclose that the Company's DPP COVID-19 Test did not provide high-quality results and there were material performance concerns with the accuracy of the Company's DPP COVID-19 Test. In truth, as set forth in the FDA's June 16, 2020 letter to the Company, the Company's DPP COVID-19 Test generates a higher than

expected rate of false results and higher than that reflected in the authorized labeling for the device, and was not effective in detecting antibodies against COVID-19. Indeed, the FDA determined that based on the data the Company submitted in support of its EUA, it was not reasonable to believe that the test may be effective in detecting antibodies against COVID-19 and that, as a result, there was a material risk to public health from the false test results.

THE TRUTH EMERGES

34. On June 16, 2020, after the market closed, the FDA issued a press release disclosing that it had revoked the Company's EUA for the Company's DPP COVID-19 Test:

> 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 COVID19.
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> "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."
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> 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.
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> As the FDA has learned more regarding the capability for performance of SARSCoV-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.

35. 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. . .
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> 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. . . .
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> 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.

36. As a result of the revocation of Chembio's EUA, Chembio shares declined from a closing price on June 16, 2020 $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 an unusually heavy trading volume of over 25 million shares.

37. 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.

LOSS CAUSATION/ECONOMIC LOSS

38. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated Chembio stock price and operated as a fraud or deceit on Class Period purchasers of Chembio stock by misrepresenting the efficacy of the

Company's DPP COVID-19 Test. Defendants achieved this by making false statements about Chembio's DPP COVID-19 Test, while they knew, or at least recklessly disregarded, that there were material performance concerns with its DPP COVID-19 Test, as alleged herein. Later, however, when Defendants' prior misrepresentations were disclosed and became apparent to the market, the price of Chembio stock fell precipitously as the prior artificial inflation came out of Chembio' stock price.

39. As a result of their purchases of Chembio stock during the Class Period, plaintiff and other members of the Class, suffered economic loss, i.e., damages under the federal securities laws.

40. As a direct result of the public revelations regarding the truth about the condition of Chembio's business and the negative adverse factors that had been impacting Chembio's business during the Class Period, the price of Chembio's stock materially declined. This drop removed the inflation from Chembio's stock price, causing real economic loss to investors who purchased the stock during the Class Period.

41. The decline in Chembio's stock price at the end of the Class Period was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of Chembio's stock price declines negate any inference that the loss suffered by plaintiff and other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to the defendants' fraudulent conduct.

FRAUD-ON-THE-MARKET DOCTRINE

42. At all relevant times, the market for Chembio's common stock was an efficient market for the following reasons, among others:

(a) The Company's common stock met the requirements for public listing and was listed and actively traded on the NASDAQ, a highly efficient market;

(b) As a regulated issuer, the Company filed periodic public reports with the SEC; and

(c) The Company regularly issued press releases which were carried by national news wires. Each of these releases was publicly available and entered the public marketplace.

43. As a result, the market for the Company's publicly traded common stock promptly digested current information with respect to Chembio from all publicly available sources and reflected such information in the price of the Company's common stock. Under these circumstances, all purchasers of the Company's publicly traded common stock during the Class Period suffered similar injury through their purchase of the publicly traded common stock of Chembio at artificially inflated prices and a presumption of reliance applies.

ADDITIONAL SCIENTER ALLEGATIONS

44. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issues or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Chembio, their control over, and/or receipt and/or modification of Chembio's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Chembio, participated in the fraudulent scheme alleged herein.

45. Defendants knew or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of the personnel at the highest level of the Company, including the Individual Defendants.

46. Defendants had the motive and opportunity to perpetrate the fraudulent scheme and course of business described herein because the Individual Defendants were the most senior officers of Chembio, issued statements and press releases on behalf of Chembio and had the opportunity to commit the fraud alleged herein. As alleged above, the Company closed a public offering of its common stock on May 11, 2020, at an artificially inflated price for approximately $30 million in gross proceeds.

NO SAFE HARBOR

47. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

48. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward looking statement was false, or the forward-looking statement was authorized and/or approved by an executive officer of Chembio who knew that those statements were false when made.

FIRST CLAIM FOR RELIEF

For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

49. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

50. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were materially false and misleading in that they contained material misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

51. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they: (a) Employed devices, schemes and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make statements made, in light of the circumstances under which they were made not misleading; or (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Chembio publicly traded common stock during the Class Period.

52. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Chembio's publicly traded common stock. Plaintiff and the Class would not have purchased Chembio common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

53. As a direct and proximate result of these Defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Chembio common stock during the Class Period.

SECOND CLAIM FOR RELIEF

For Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

54. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

55. The Individual Defendants acted as a controlling person of Chembio within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

56. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

57. As set forth above, Chembio and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions each as a controlling person, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Chembio's and the Individual Defendants' wrongful conduct, plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully demands relief as follows:

A. Certifying this lawsuit as a class action pursuant to Rule 23 of the Federal Rules of

Civil Procedure, certifying Plaintiff as Class Representative;

B. Awarding damages in favor of Plaintiff and members of the Class against Chembio and Individual Defendants, jointly and severally, for all damages sustained as a result of Chembio's wrongdoing, in an amount to be proven at trial;

C. Awarding Plaintiff and members of the Class their costs of suit, including reasonable attorneys' fees and expenses, and including expert fees, as provided by law;

D. Awarding Plaintiff and members of the Class pre- and post-judgment interest at the maximum rate allowable by law; and

E. Directing such further relief as it may deem just and proper.

DEMAND FOR JURY TRIAL

58. Plaintiff demands a trial by jury as to all issues triable by a jury.