UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 11163 / March 2, 2023

ADMINISTRATIVE PROCEEDING
File No. 3-21320

In the Matter of **Chembio Diagnostics, Inc.** **Respondent.**	**ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER**

I.

The Securities and Exchange Commission ("Commission") deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 ("Securities Act"), against Chembio Diagnostics, Inc. ("Chembio" or "Respondent").

II.

In anticipation of the institution of these proceedings, Chembio has submitted an Offer of Settlement (the "Offer"), which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission's jurisdiction over it and the subject matter of these proceedings, which are admitted, Chembio consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 8A of the Securities Act of 1933, Making Findings, and Imposing A Cease-and-Desist Order ("Order"), as set forth below.

III.

On the basis of this Order and Chembio's Offer, the Commission finds that:

Summary

1. This matter involves a material misrepresentation made by Chembio concerning the performance of a COVID-19 antibody test the company developed and marketed during the spring of 2020 ("COVID-19 Test"). Specifically, in a May 8, 2020 prospectus supplement filed with the Commission in connection with a Chembio stock offering, Chembio falsely stated that the COVID-19 Test was 100% accurate when used more than eleven days after the onset of symptoms. This statement was based on a subset of early performance data about the test, but was at odds with the results of a recent independent evaluation as well as Chembio's ongoing internal analysis, which indicated that the test generated a notable rate of false negative results. Although the prospectus supplement was reviewed by Chembio's senior executives before it was filed, no one from the company's research and development or regulatory divisions had been requested to review the statement about the test's accuracy. Chembio raised over $30 million in the stock offering, which closed on May 11, 2020.

2. Based on the foregoing and the conduct described below, Chembio violated Sections 17(a)(2) and 17(a)(3) of the Securities Act.

Respondent

3. Chembio is incorporated in Nevada, with principal offices located in Hauppauge, New York. Chembio's primary business is designing, manufacturing, and selling medical diagnostic tests for use in the United States and other countries. Chembio's common stock is registered with the Commission pursuant to Section 12(b) of the Securities Exchange Act of 1934 ("Exchange Act"), and is listed on the Nasdaq Capital Market under the ticker CEMI.

Facts

Chembio's COVID-19 Antibody Test

4. Since at least 2009, Chembio has focused on the development and sale of medical diagnostic tests in the United States and other countries. Prior to 2020, Chembio had received regulatory approvals from the FDA and regulatory agencies in other countries to market certain tests for various infectious diseases, including HIV and Zika virus.

5. Starting in February 2020, the United States Food and Drug Administration ("FDA") began to issue emergency orders related to the COVID-19 pandemic. In order to rapidly address the health crisis, these orders created processes by which companies like Chembio could develop and market COVID-19 diagnostic tests after undergoing a significantly expedited regulatory review. As the pandemic continued, the FDA issued several updates to its guidance and expectations for tests through a series of policy announcements.

6. In February and March 2020, shortly after the COVID-19 pandemic began in the United States, Chembio developed the COVID-19 Test. After evaluating the COVID-19 Test with an initial set of blood samples in March 2020, Chembio determined that the COVID-19 Test had a sufficiently high efficacy rate to warrant seeking regulatory approval for the test in the United States.

7. On April 5, 2020, Chembio submitted an application to the FDA for an Emergency Use Authorization ("EUA"), which would allow Chembio to market and distribute the test in the United States during the COVID-19 public health emergency. Chembio's EUA application included, among other things, tables of performance data related to the COVID-19 Test. One of these data tables indicated that the test correctly detected COVID-19 antibodies for all seventeen patients in the sample set who had provided exactly one blood sample eleven days or more after first experiencing COVID-19 symptoms.

8. On April 14, 2020, the FDA issued a letter granting Chembio's EUA application. The letter stated that the FDA had determined it was reasonable to believe the COVID-19 Test was effective at diagnosing COVID-19 based on the scientific evidence available at that time. The FDA's letter also included several conditions for the EUA. One of those conditions required Chembio to submit the COVID-19 Test for independent evaluation by the National Cancer Institute ("NCI"). Additionally, the FDA's letter referred to statutory authority by which the EUA could be revoked if, at a later time, it was no longer reasonable to believe the COVID-19 Test was effective or if the risks of the COVID-19 Test outweighed its potential benefits.

9. Soon after the EUA was granted, Chembio mailed tests to the NCI for evaluation. The NCI's evaluation involved, in part, using the COVID-19 Test on blood samples that were already known to contain COVID-19 antibodies to assess the rate at which the test produced false negative results.

10. On April 30, 2020, a representative of the FDA emailed a report documenting the NCI's evaluation to a member of Chembio's research and development department. In that email, the FDA representative requested that Chembio not share or distribute the report. The results, which Chembio believed to be preliminary, showed that the COVID-19 Test failed to detect COVID-19 antibodies in several positive samples, all of which were collected nineteen or more days after symptom onset. Overall, the NCI's evaluation found that the COVID-19 Test correctly detected COVID-19 antibodies in only 75% of the positive samples used in the NCI's evaluation. Chembio requested additional data from the FDA to better understand the results of the NCI's evaluation.

11. Later that day, after receiving the results of the NCI's evaluation, members of Chembio's research and development and regulatory departments compiled additional data that had been collected concerning the COVID-19 Test's performance since February 2020. This data set included information from Chembio's internal assessments as well as data provided by two hospitals that had recently been using the test in real-world settings. Overall, the data indicated that

the COVID-19 Test correctly detected antibodies in 88.1% of samples positive for COVID-19 that had been collected eleven or more days after symptom onset.

12. On May 4, 2020, the FDA issued revised guidance for companies seeking an EUA for antibody tests related to COVID-19, including identifying expected performance thresholds. On May 6, 2020, the FDA stated in a public briefing that it was imposing new expectations for the performance of COVID-19 antibody tests in connection with EUAs. Most notably, the FDA stated that tests would be expected to demonstrate that they could correctly detect the presence of COVID-19 antibodies at a rate of 90% or higher.

13. The results of the NCI's evaluation and Chembio's internal analysis both indicated that the COVID-19 Test did not correctly detect COVID-19 antibodies in all positive samples collected eleven days or more after the onset of symptoms. However, this information was not communicated to Chembio's senior executives in a sufficient level of detail to convey that the test was not meeting the FDA's current performance expectations, or to explain that recent data were not consistent with the performance data used to apply for the EUA.

Chembio's May 2020 Stock Offering and Material Misstatement about the Test

14. In mid-April 2020, shortly after the FDA approved Chembio's EUA application, Chembio's senior executives began to plan a $30 million offering of common stock that would give the company the necessary capital to expand its ability to manufacture, market, and distribute the COVID-19 Test.

15. In late April and early May 2020, Chembio's senior executives, along with various third parties, participated in due diligence efforts in connection with the offering. However, the due diligence process did not include a review of Chembio's own updated internal analysis of the COVID-19 Test or of documents related to the NCI's evaluation.

16. On May 8, 2020, Chembio filed a prospectus supplement in connection with the offering. Despite the results of the NCI's evaluation and the company's recent internal analysis regarding efficacy of the COVID-19 Test, the prospectus supplement stated, "The accuracy of the COVID-19 System after 11 days post the onset of symptoms is 100% for total antibodies." Though the prospectus supplement was reviewed by Chembio's senior executives, no one from Chembio's research and development or regulatory divisions were requested to review this statement before the prospectus supplement was filed.

17. On May 11, 2020, Chembio announced that the offering closed at a price of $11.75 per share, and had generated proceeds of approximately $30.8 million.

The FDA's Revocation of the Emergency Use Authorization

18. On June 16, 2020, the FDA announced that it was revoking the EUA for the COVID-19 Test. The FDA explained that information from the NCI's evaluation and other recent performance data demonstrated that the COVID-19 Test did not perform as well as described in Chembio's EUA application and could not meet the FDA's current clinical performance

expectations. As a result of the revocation, Chembio was no longer authorized to market or distribute the test in the United States.

19. On June 17, 2020, Chembio's stock price closed at $3.89, a 60% decline from the prior day's closing price of $9.93.

20. As a result of the conduct described above, Chembio violated Section 17(a)(2) of the Securities Act, which makes it unlawful, in the offer or sale of securities, to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and Section 17(a)(3) of the Securities Act, which, in the offer or sale of securities, proscribes any transaction, practice or course of business which operates or would operate as a fraud or deceit upon a purchaser of securities.

Chembio's Cooperation and Remedial Efforts

21. In determining to accept the Offer, the Commission considered remedial acts promptly undertaken by Respondent and cooperation afforded the Commission staff.

IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Chembio's Offer.

Accordingly, it is hereby ORDERED that**:**

A. Pursuant to Section 8A of the Securities Act, Chembio cease and desist from committing or causing any violations and any future violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act.

B. Chembio shall, within ten days of the entry of this Order, pay a civil money penalty in the amount of $500,000 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. § 3717.

Payment must be made in one of the following ways:

(1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;

(2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at http://www.sec.gov/about/offices/ofm.htm; or

(3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying Chembio as a respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Jason J. Burt, Regional Director, Division of Enforcement, Securities and Exchange Commission, 1961 Stout Street, Suite 1700, Denver, CO 80294.

C. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within thirty days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

By the Commission.

Vanessa A. Countryman
Secretary