UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 11209 / July 5, 2023

SECURITIES EXCHANGE ACT OF 1934
Release No. 97836 / July 5, 2023

ACCOUNTING AND AUDITING ENFORCEMENT
Release No. 4428 / July 5, 2023

ADMINISTRATIVE PROCEEDING
File No. 3-21514

In the Matter of **CO-DIAGNOSTICS, INC.** **Respondent.**	**ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933 AND SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, 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") and Section 21C of the Securities Exchange Act of 1934 ("Exchange Act"), against Co-Diagnostics, Inc. ("Co-Diagnostics" or "Respondent").

II.

In anticipation of the institution of these proceedings, Respondent 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, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 8A of the Securities Act of 1933 and Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order ("Order"), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds[1] that:

SUMMARY

1. These proceedings concern Co-Diagnostics's issuance of misleading press releases on February 6 and 10, 2020 concerning a screening test it had developed to detect the novel coronavirus, later named COVID-19 by the World Health Organization. Specifically, the press releases misleadingly suggested that the test could be used by consumers to detect COVID-19, when in fact, at that time, the test was intended for Research Use Only ("RUO"), which meant it could not be sold for clinical diagnostic purposes.

2. Co-Diagnostics offered and sold securities to investors after it issued the February 6 and 10, 2020 press releases.

3. In addition, Co-Diagnostics failed to disclose related party transactions involving the family members of the company's Chief Executive Officer ("CEO") and then-Chief Financial Officer ("CFO"), Secretary, and General Counsel in its annual reports for the fiscal years ended December 31, 2018, 2019, and 2020 and in its definitive proxy statements filed in 2019, 2020, and 2021. Co-Diagnostics also failed to keep accurate books and records and failed to have disclosure controls and procedures designed to ensure the company disclosed related party transactions as required.

4. Based on this conduct, and as described in further detail below, Co-Diagnostics violated Sections 17(a)(2) and 17(a)(3) of the Securities Act and Sections 13(a), 13(b)(2)(A), and 14(a) of the Exchange Act, and Rules 12b-20, 13a-1, 13a-15(a) and 14a-3 thereunder. Negligence is sufficient to establish a violation of Sections 17(a)(2) and 17(a)(3) of the Securities Act. *Aaron v. SEC*, 446 U.S. 680, 696-97 (1980).

RESPONDENT

5. **Co-Diagnostics**, a Utah company with its principal executive offices in Salt Lake City, Utah, develops, manufactures, and sells reagents used for diagnostic tests, as well as polymerase chain reaction ("PCR") test kits used for diagnostic and research purposes. Co-Diagnostics's common stock is registered under Section 12(b) of the Exchange Act and trades on the Nasdaq under the ticker "CODX."

OTHER RELEVANT INDIVIDUALS

6. **Dwight H. Egan ("Egan")**, age 69, is a resident of Sandy, Utah. Egan has been the CEO of Co-Diagnostics, as well as the Chairman of its Board, since 2013.

[1] The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

7. **Reed L. Benson ("R. Benson")**, age 76, is a resident of Sandy, Utah. R. Benson was the CFO of Co-Diagnostics from 2014 to February 2021, its Secretary from 2014 to August 2021, and its General Counsel from April 2013 to September 2021. R. Benson was also a director of Co-Diagnostics from 2014 to 2017. R. Benson is an Inactive Emeritus Attorney in Utah and has an inactive CPA license.

8. **Andrew B. Benson ("A. Benson")**, age 44, is a resident of Salt Lake City, Utah. A. Benson has been Co-Diagnostics's Head of Corporate Communications and Investor Relations since 2014. A. Benson is also a co-owner and Managing Partner of a consulting company that provides services relating to public and investor relations. He is the son of R. Benson.

FACTS

Co-Diagnostics Issues Materially Misleading Press Releases on February 6 and 10, 2020

Background

9. Co-Diagnostics's business focuses on the development of molecular tools for the detection of infectious diseases, liquid biopsy for cancer screening, and agricultural applications. Prior to 2020, Co-Diagnostics designed and sold polymerase chain reaction ("PCR") diagnostic tests for diseases and pathogens such as tuberculosis, hepatitis B and C, Malaria, dengue, human papilloma virus, chikungunya, and Zika virus.

10. On July 2, 2019, Co-Diagnostics received a letter from the staff of Nasdaq informing the company that it was in danger of becoming de-listed because its stock had closed below $1.00 for the prior 30 consecutive business days. Per Nasdaq rules, to remain listed, Co-Diagnostics's stock had to close at or above $1.00 for 10 consecutive business days within the next 180 calendar days, and if it failed to regain compliance within that time Co-Diagnostics could be eligible for an additional 180 calendar day period to regain compliance.

11. As a result of this notice, Co-Diagnostics increased its public relations efforts in order to inform the public and its customers about the development of its testing products and to maintain its Nasdaq listing. These efforts included issuing frequent press releases, as well as using third-party consultants, including the firm co-owned by A. Benson, to disseminate those press releases and other information about the company.

12. On January 23, 2020, Co-Diagnostics announced that it had completed the principal design work for a PCR screening test for the novel coronavirus, which would later be named COVID-19 ("the Logix Smart Test"). At this time, this version of the Logix Smart Test was intended for research use only, which meant it could not be sold for clinical diagnostic purposes (*i.e.*, to actually diagnose a patient as having COVID-19) without receiving further authorization.

The February 6 and 10, 2020 Press Releases

13. On February 6, 2020, Egan and A. Benson worked on drafting a press release relating to the Logix Smart Test with the goal of issuing it sometime that day. Egan ultimately approved the final version of the press release for publication (the "February 6 Release").

14. As of February 6, 2020, Co-Diagnostics had not received authorization from the Food and Drug Administration ("FDA") or any other regulatory entity to sell or use its Logix Smart Test for diagnostic purposes. Co-Diagnostics later received approval to sell the Logix Smart Test for diagnostic purposes in the European Union and other places that accepted a CE marking on February 24, 2020, and Emergency Use Authorization from the FDA to sell the test for diagnostic purposes in the United States on April 3, 2020.

15. Yet, the February 6 Release announced that Co-Diagnostics's "research use only (RUO) CoPrimer Test for the 2019 n-Cov coronavirus [was] ready for sale to appropriate laboratories, hospitals and institutions in need of a solution to the current coronavirus epidemic." The press release further stated that Co-Diagnostics "believe[d] that the test's unique design [would] provide enhanced accuracy when detecting the presence of the coronavirus, including improved specificity over tests designed on a different platform."

16. Egan was also quoted in the release as stating, "[i]ncreased specificity is one of the hallmarks of tests built using [Co-Diagnostics's] patented CoPrimer platform."

17. The references to the "specificity" of the Logix Smart Test in the February 6 Release spoke to whether the Company's technology could differentiate COVID-19 from other viruses with similar genetic sequences in a patient (*i.e.*, to correctly identify as negative patients who do not have COVID-19).

18. On February 6, 2020, Co-Diagnostic's stock closed at $3.08, representing an 18.92% increase over the day prior on a volume of 10,909,200, a 48 % increase from the average daily volume for the prior thirty calendar days.

19. Co-Diagnostics used similar language to describe the Logix Smart Test in a February 10, 2020 press release (the "February 10 Release"). In the February 10 Release, Co-Diagnostics announced "sales of its screening test designed to identify the presence of the novel coronavirus" and quoted Egan as stating that the company was "pleased to be able to offer a product to this market that excels in being both sensitive and specific, the two benchmarks for accuracy in molecular diagnostics." The February 10 Release further quoted Egan as stating that the company believed it could be "most helpful in this ongoing situation . . . by providing diagnostic solutions that are affordable and accessible in any market in the world" and that the speed with which Co-Diagnostics had designed and commercialized its test was a "compelling proof-of-concept that the Company's unique process and patented technology could quickly and efficiently be applied to address the diagnostic needs associated with other emergencies, including potential mutations of the coronavirus."

20. Egan and A. Benson worked on drafting the February 10 Release, which Egan ultimately approved.

21. On February 10, 2020, Co-Diagnostics stock closed at $3.96, representing a 32% increase over the day prior, on a volume of 28,920,600.

The FDA Has Concerns About the Statements Made By Co-Diagnostics in the February 6 and 10, 2020 Press Releases

22. On February 11, 2020, a representative from the FDA contacted Co-Diagnostics's Head of Regulatory Affairs to inform Co-Diagnostics that the FDA had concerns with, among other things, the above-quoted language in the February 6 and 10 Releases.

23. With respect to the February 6 Release, the FDA said that the language in question implied that the Logix Smart Test could be used for diagnostic purposes, when it could not, and also impermissibly made claims about the test's performance given it had not yet been approved for diagnostic use. With respect to the February 10 Release, the FDA said that the language in question implied that the Logix Smart Test could be used for screening and diagnostic purposes, when it could not. The FDA requested that Co-Diagnostics take immediate action to resolve these issues and provide to the FDA a list of proposed corrective actions by February 14, 2020.

24. Three days later, on February 14, 2020, Co-Diagnostics sent the FDA a corrective and preventive action plan, signed by A. Benson and Co-Diagnostics's then-Head of Regulatory Affairs, which required the then-Head of Regulatory Affairs to review press releases relating to the Logix Smart Test going forward to ensure better accuracy.

25. The FDA again contacted Co-Diagnostics on February 26, 2020 with remaining concerns regarding the February 6 and 10 Releases, which were still accessible on Co-Diagnostics's website. In response, on or around February 28, 2020, Co-Diagnostics added a legend to the releases stating that the test was (1) for research use only and not intended for use in diagnostic procedures; and (2) not available for sale in the U.S. Thereafter, the February 6 and 10 Releases remained on Co-Diagnostics's website with the addition of this language.

26. Prior to the addition of the clarifying legend, the February 6 and 10 Releases were materially misleading because they implied that the Logix Smart Test was able to be sold and used to diagnose COVID-19 with accuracy when it had not yet received the appropriate regulatory approval to be utilized in this manner either in the United States or abroad.

27. A reasonable investor would have found the statements in the February 6 and 10 Releases about the purported ability of the Logix Smart Test to be shipped to "laboratories, hospitals and institutions in need of a solution to the current coronavirus epidemic" to be material, especially because these statements were made in the early stages of the pandemic when COVID-19 testing was scarce.

Co-Diagnostics Offers and Sells Securities

28. On or around February 13, 2020, Co-Diagnostics offered and sold 3,324,676 shares of the Company's common stock at a purchase price of $3.08 per share in a registered direct public offering, for gross proceeds of approximately $10.2 million. At the time of the offer and sale, Co-Diagnostics had neither retracted nor modified the materially misleading statements contained in the February 6 or 10 Releases.

Co-Diagnostics Fails to Report Transactions with the CEO's and CFO's Family Members

29. Item 404(a) of Regulation S-K requires an issuer to disclose "any transaction . . . in which any related person had or will have a direct or indirect material interest." The instructions to Item 404(a) define related person to include any immediate family member of a director or executive officer of the issuer, including children. Under Item 404(d), Co-Diagnostics, which made filings as a "smaller reporting company" in fiscal years 2018 through 2020, was required to disclose any transaction exceeding "the lesser of $120,000 or one percent of the average of the . . . company's total assets at year end for the last two completed fiscal years."

30. The relevant related-person reporting thresholds for Co-Diagnostics were $29,791 for fiscal year 2018, $31,077 for fiscal year 2019, and $18,842 for fiscal year 2020.

31. During this time, Co-Diagnostics employed Egan's son as the Director of Sales and Marketing. Egan's son was paid compensation totaling $91,352 in fiscal year 2018, $224,900 in fiscal year 2019, and $1,113,440 in fiscal year 2020.

32. Also during this time, Co-Diagnostics employed A. Benson, the son of then-CFO, Secretary, and General Counsel, R. Benson, as the Head of Corporate Communications and Investor Relations. A. Benson was paid compensation totaling $327,820 in fiscal year 2018, $218,959 in fiscal year 2019, and $1,109,303 in fiscal year 2020. In addition, Co-Diagnostics retained the services of the consulting company that A. Benson co-owned and paid that company $60,000 in fiscal year 2018, $78,500 in fiscal year 2019, and $20,000 in fiscal year 2020. Co-Diagnostics also issued 7,000 shares of Co-Diagnostics stock to the consulting company in fiscal year 2020.

33. These payments to Egan's son and to A. Benson constituted reportable transactions under Item 404 of Regulation S-K. They were not recorded in Co-Diagnostics's books and records as related party transactions, and Co-Diagnostics failed to disclose them in its annual reports on Form 10-K for the fiscal years ended December 31, 2018, 2019, and 2020 or in its definitive proxy statements filed in 2019, 2020, and 2021.

34. Egan signed the company's annual reports on Form 10-K for the fiscal years ended 2018, 2019, and 2020 and solicited proxies relating to the definitive proxy statements filed in 2019, 2020, and 2021. R. Benson signed the company's annual reports on Form 10-K for fiscal years ended December 31, 2018, and December 31, 2019.

35. During this time, Co-Diagnostics did not have any policies or procedures concerning related party transactions, including what constitutes a related party transaction or how such transactions should be disclosed by the company. Co-Diagnostics did not identify related party transactions in its books and records.

Violations

36. As a result of the conduct described above, Co-Diagnostics violated Sections 17(a)(2) and 17(a)(3) of the Securities Act, which prohibit any person in the offer or sale of securities from obtaining money or property by means of any untrue statement of material fact or any omission to state a material fact necessary in order to make statements made, in light of the circumstances under which they were made, not misleading, and from engaging in any practice or course of business which operates or would operate as a fraud or deceit upon the purchaser in the offer or sale of securities, respectively.

37. As a result of the conduct described above, Co-Diagnostics violated Section 13(a) of the Exchange Act and Rule 13a-1 thereunder, which require issuers with a class of securities registered pursuant to Exchange Act Section 12 to file such periodic and other reports as the Commission may prescribe and in conformity with such rules as the Commission may promulgate. The obligation to file such reports embodies the requirement that they be true and correct. In addition to the information expressly required to be included in such reports, Rule 12b-20 of the Exchange Act requires issuers to add such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made, not misleading. Co-Diagnostics violated Exchange Act Rule 12b-20.

38. As a result of the conduct described above, Co-Diagnostics violated Section 14(a) of the Exchange Act and Rule 14a-3 thereunder. Section 14(a) of the Exchange Act prohibits any person from acting in contravention of the Commission's rules and regulations "to solicit or to permit the use of his name to solicit any proxy . . . in respect of any security . . . registered pursuant to Section 12" of the Exchange Acts. Rule 14a-3 prohibits issuers with securities registered pursuant to Exchange Act Section 12 from soliciting proxies without furnishing proxy statements containing the information specified in Schedule 14A, including related party disclosures pursuant to Item 404.

39. As a result of the conduct described above, Co-Diagnostics violated Exchange Act Rule 13a-15(a), which requires issuers with a class of securities registered pursuant to Exchange Act Section 12 to maintain disclosure controls and procedures.

40. As a result of the conduct described above, Co-Diagnostics violated Section 13(b)(2)(A) of the Exchange Act, which requires issuers with a class of securities registered pursuant to Exchange Act Section 12 to make and keep books, records, and accounts which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets of the issuer.

Co-Diagnostics's Remedial Efforts

41. In determining to accept the Offer, the Commission considered remedial acts promptly undertaken by Respondent.

IV.

In view of the foregoing, the Commission deems it appropriate and in the public interest to impose the sanctions agreed to in Respondent Co-Diagnostics's Offer.

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

A. Pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, Respondent Co-Diagnostics 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 and Sections 13(a), 13(b)(2)(A), and 14(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-15(a), and 14a-3 thereunder.

B. Co-Diagnostics shall, within 30 days of the entry of this Order, pay a civil money penalty in the amount of $250,000 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 Co-Diagnostics 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 Steven G. Rawlings, Assistant

Regional Director, Division of Enforcement, New York Regional Office, Securities and Exchange Commission, 100 Pearl St., Suite 20-100, New York, NY 10004-2616.

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 30 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