UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re CHEMBIO DIAGNOSTICS, INC. SECURITIES LITIGATION	:	20-CV-2706 (ARR) (PK) (Consolidated)
This Document Relates To: ALL ACTIONS	:	**OPINION & ORDER**

ROSS, United States District Judge:

During the summer of 2020, four putative class actions were brought against Chembio Diagnostics, Inc. ("Chembio") and several of Chembio's senior executives and directors (collectively "Chembio defendants"), as well as Robert W. Baird & Co. Inc. ("Baird") and Dougherty & Company LLC ("Dougherty"), the underwriters of Chembio's May 7, 2020 secondary stock offering ("May Offering") (together, the "underwriter defendants"). These actions claimed violations of the Securities Act of 1933 ("Securities Act") and the Securities Exchange Act of 1934 ("Exchange Act") arising out of the May Offering and Chembio's then-flagship product, a COVID-19 antibody test. On December 29, 2020, these actions were consolidated into this current putative class action. Defendants now move to dismiss the Consolidated Amended Complaint ("Complaint") in its entirety for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6).[1] For the reasons set forth below, the motion is granted in part and denied only as to the Securities Act Sections 11 and 12(a)(2) claims against the underwriter defendants.

[1] The underwriter defendants moved to join the motion to dismiss and the reply on March 26, 2021, and April 30, 2021, respectively. I granted these motions along with this decision. *See* Minute

BACKGROUND

A. Factual Background[2]

Lead plaintiffs represent two proposed classes of investors in Chembio, a Nevada corporation headquartered in Hauppauge, New York that develops and sells diagnostic solutions and products for the treatment, detection, and diagnosis of infectious diseases. Consolidated Am. Compl. ¶¶ 1, 4, 34–36 ("CAC"), ECF No. 64. Chembio's diagnostic technology relies primarily on its Dual Path Platform® ("DPP") technology, which the company advertises as "mak[ing] testing faster, more accurate, and more cost effective." *Id.* ¶ 4.

On February 4, 2020, the Secretary of the Department of Health and Human Services determined, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, that the COVID-19 outbreak in the United States was a public health emergency with significant potential to affect national security or the health and security of United States citizens living abroad. CAC ¶ 141. Pursuant to this declaration, the Food and Drug Administration ("FDA") began granting emergency use authorizations ("EUAs") for COVID-19 diagnostic and antibody tests. *See id.* ¶¶ 145–46. An EUA is a temporary approval of a product relevant to the declared public health emergency and requires a less rigorous review process than the FDA's process for regular, long-term approval. *See id.* ¶¶ 147−48. While regular FDA approval is granted only once the Agency has determined that there is "substantial evidence," based on adequate and well-controlled investigations, that the product will have the effect it is intended to have, an EUA can be issued if "it is reasonable to believe that . . . the product *may* be effective." *Id.* ¶ 148

Entries, Feb. 23, 2022.

[2] At the motion to dismiss stage, I accept as true all facts pleaded by plaintiffs, as drawn from the Complaint and draw all reasonable inferences in plaintiffs' favor. *See Lundy v. Cath. Health Sys. of Long Island Inc.*, 711 F.3d 106, 113 (2d Cir. 2013).

(alteration and emphasis in original). The FDA assesses the potential effectiveness of possible EUA products on a case-by-case basis using a risk-benefit analysis. *Id.* The EUA will then last as long as the public health emergency declaration persists and, if sought by the FDA, additional testing confirms that the product meets the FDA's criteria. *See id.* ¶¶ 147–48.

On March 12, 2020, Chembio announced that it would leverage its DPP technology to create a COVID-19 antibody test. *Id.* ¶ 6. On March 31, 2020, Chembio announced the launch of its DPP COVID-19 IgM/IgG[3] System (the "Test"). *Id.* ¶¶ 6, 198. The Test is a single-use test of a blood, serum, or plasma sample to determine whether the person who provided that sample is infected—or has previously been infected—with COVID-19. *Id.* ¶¶ 172, 198.

Chembio applied to the FDA for an EUA for the Test. *See id.* ¶¶ 6, 198. Regarding the Test's ability to positively identify the presence of COVID-19 antibodies, Chembio represented to the FDA that the Test had a 77.4% rate for Immunoglobulin M (IgM), an 87.1% rate for Immunoglobulin G (IgG), and a 93.5% rate for combined IgM/IgG. *Id.* ¶ 174. Chembio further represented that the Test was 94.4% likely to correctly identify the *absence* of COVID-19 antibodies.[4] *See id.* ¶¶ 165, 174. On April 14, 2020, the FDA issued an EUA to use the Test solely in laboratory settings. *Id.* ¶¶ 10, 73. Chembio was one of the first companies to earn an EUA for a COVID-19 test. *Id.* ¶ 10. Chembio's stock rose from a closing price of $3.10 per share on March 11, 2020 to $15.54 per share on April 24, 2020. *Id.* ¶ 13.

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[3] Immunoglobulin G (IgG) and Immunoglobulin M (IgM) are the antibodies most likely to be found in the blood following a viral infection. IgM is the first antibody produced to fight a new infection and is commonly detectable after four to seven days; as it is short-lived, it may indicate that the virus is still present. IgG also protects against infections but is not produced until seven to fourteen days after infection, and remains detectable in the blood for months to years after infection. CAC ¶ 152.

[4] This data was also included in the product insert for the Test, which was available to investors and accompanied the product when it was distributed to the public. CAC ¶ 200.

After granting the EUA for laboratory settings, the FDA ordered further evaluations of the Test. *See* Sigismondi Decl. in Supp. of Mot. to Dismiss ("Sigismondi Decl."), Ex. B ("May 22 Email"), ECF No. 84-1. The Test was independently evaluated by the Department of Health and Human Services, the National Institutes of Health, and the National Cancer Institute (together referred to as "NCI evaluation"). CAC ¶ 17. Sometime between April 14 and May 15, 2020, Chembio also submitted a request to amend its EUA to allow use of the Test in point-of-care settings. May 22 Email. During a call on April 29, 2020 (the "April 29 call"), the FDA informed Chembio that the NCI evaluation demonstrated higher false negative and false positive rates than the data Chembio had submitted. CAC ¶ 181. According to a summary later sent by the FDA to Chembio, the Agency informed Chembio on the call that it "had concerns regarding the results of the NCI evaluation" and, because of these concerns, "would not be moving forward, at that time," with Chembio's amendment request. May 22 Email. The summary also states that the FDA provided Chembio with the complete NCI evaluation results on April 30, 2020, one day after the call. *Id.* Between April 29, 2020 and May 15, 2020, Chembio submitted to the FDA the results from additional studies of the Test.[5] *Id.*; *see* CAC ¶ 184.

After the April 29 call, Chembio held a series of events to promote the May Offering. On May 4, 2020, Chembio conducted a conference call with investors in which Richard L. Eberly, Chembio's Chief Executive Officer ("CEO") and President since March 16, 2020, and Gail S. Page, Chembio's Executive Chair of the Board and former interim CEO, participated. CAC ¶¶ 37, 39, 206. On the call, Mr. Eberly stated, "[t]he accuracy of the [Test] after [eleven] days post the onset of symptoms is 100% for total antibodies. This is based on our data that was submitted to

[5] The May 22 email identifies two additional studies: one independent study conducted by Richmond University Medical Center (RUMC) and one study performed by Chembio and Stony Brook University Hospital (SBUH). May 22 Email.

and reviewed by the FDA for the EUA." *Id.* ¶ 206. Mr. Eberly also stated, "we expect [the Test] to drive significant incremental revenue in the future and will be a main driver in the infectious disease vertical. . . . We are . . . confident in our ability to take [a] significant share in this market and sustain a leadership position for the long term." *Id.* In response to a question about future revenue, Mr. Eberly replied, "We're hopeful that demand will continue to grow. So . . . as our capacity expands, we'll be able to sell everything we make." *Id.* ¶ 208. In response to a question about Chembio's antibody testing competitors, Ms. Page said, since Chembio was "the only one with [a] finger-stick [test]," it was "very well positioned," and she thought a lot of other companies would "fall out." *See id.* ¶¶ 211−12. Ms. Page added, "[s]o I think that's really going to change and get rid of a lot of the noise that's in the market" and "that's very beneficial for people like us that we may not necessarily be first, but we intend to be the best in the market." *Id.* ¶ 211. In a press release issued the same day, Mr. Eberly was quoted:

> [T]he skill and hard work of this team has enabled a successful strategic pivot as we prioritize manufacturing and commercialization of our [Test]. 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 [Test] will make it a preferred solution.

Id. ¶ 215.

Chembio also engaged underwriter defendants Baird and Dougherty, both financial services firms, to assist with the May Offering. *Id.* ¶¶ 48–49, 90–99. Baird acted as "book-running manager" for the offering and Dougherty as "co-manager." *Id.* ¶ 90. Both served as underwriters of the May Offering and shared more than one million dollars in fees for their services. *Id.* ¶ 92. These underwriter defendants also assisted Chembio in planning the May Offering and allegedly participated in several meetings leading up to the May Offering, where, *inter alia*, the language to be used and disclosures to be made in the Prospectus (incorporated into the Registration Statement) were discussed. *Id.* ¶¶ 95−96, 110.

The Prospectus Supplement, dated May 7, 2020, updated the Prospectus and Registration Statement for the offering. Goldman Decl. in Supp. of Mot. to Dismiss ("Goldman Decl."), Ex. E, ECF No. 84-2; Goldman Decl. ¶ 3; CAC ¶ 110. The updated Registration Statement stated that in February 2020, Chembio had shifted its focus to developing COVID-19 testing, designating its other infectious disease products as "legacy products" from which Chembio "expect[ed] to generate [only] an immaterial amount of revenue" while the company continued to "focus on the manufacture and commercialization" of the Test. CAC ¶ 70. The Registration Statement warned that Chembio's finances could be negatively impacted by its focus on the Test: the virus was unpredictable, the health threat could dissipate, new regulations might hinder production, Chembio might be unable to meet demand, or the FDA could "revoke the EUA under which our [Test] is sold if it determines that the underlying health emergency no longer exists or warrants such authorization." *Id.* ¶¶ 73, 75. The Registration Statement also noted that the EUA permitted Chembio to sell the Test only to certified laboratories. *Id.* ¶¶ 73, 80. It added that Chembio was "working with the FDA to identify and understand the requirements and guidelines" for amending the EUA to permit sales to other types of customers. *Id.* ¶ 80. The Registration Statement did not mention the April 29 call or the results of the NCI evaluation. *Id.* ¶¶ 17–19.

The May Offering closed on May 11, 2020, with Chembio having sold approximately 2.6 million shares of Chembio stock at $11.75 per share. *Id.* ¶¶ 15, 218.

On May 18, 2020, Chembio issued a press release announcing an agreement with Thermo Fisher Scientific's healthcare channel for the latter to distribute the Test in the United States. *Id.* ¶ 219. The release quoted Mr. Eberly's prediction that the partnership "will significantly increase our commercial footprint by providing access to thousands of hospital and physician office . . . labs across the country." *Id.*

On May 22, 2020, the FDA emailed Chembio. *Id.* ¶ 20. Among other things, the email explained that Chembio had not made clear how the additional data it had submitted between April 29 and May 15, 2020 "address[ed] concerns" raised by the NCI evaluation results. The email also listed further concerns about that additional data. May 22 Email. In particular, the email noted that the Richmond University Medical Center ("RUMC") results showed a higher false negative rate than had been claimed for the Test, a rate that "incur[red] an unacceptable risk of clinically significant harm to patients." *Id.*; *see also* CAC ¶ 20. As for the Stony Brook University Hospital ("SBUH") results, the email noted three concerns: (1) while "some data may be supportive of the labeled performance" of the Test, Chembio had not "provided sufficient information on how this data was collected"; (2) the results included data "that suggests the performance is different, in a way that is clinically significant, from the labeled performance"; and (3) "the inconsistency between these data sets suggests significant variability." May 22 Email. The email invited Chembio to respond by May 25, 2020 "with information adequate to demonstrate that the health risks posed by [the Test] performing differently than the labeled performance can be adequately mitigated/addressed in a timely manner." *Id.* The FDA warned that if Chembio did not adequately allay its concerns by May 25, the Agency might "take steps and/or request that [Chembio] take additional actions to protect the public health as appropriate." *Id.*; CAC ¶ 20.

On May 24, 2020, Chembio proposed to the FDA a modification to the Test that they believed would address the Agency's concerns. CAC ¶ 21. On June 16, 2020, the FDA sent Chembio a letter rejecting this proposal and revoking the EUA for the Test. *Id.* ¶ 23; Sigismondi Decl., Ex. C ("June 16 Ltr."), ECF No. 84-1. The letter stated that Chembio's proposal was a "significant modification" prohibited by the EUA. June 16 Ltr.; CAC ¶ 187. The letter also stated, based on an analysis submitted by Chembio, that the proposal failed to "resolve[] the poor clinical

performance" of the Test. June 16 Ltr. Finally, the letter stated that, because the additional evaluations performed since the issuing of the EUA demonstrated that the Test's "performance may be both inconsistent and lower than that described in [Chembio's] original submission," the FDA had determined that "the criteria for issuance of emergency authorization. . . are no longer met" for the Test. *Id.* Specifically, the letter concluded that it was "not reasonable to believe the product may be effective in detecting antibodies against [COVID-19]" and that "other circumstances ma[d]e revocation appropriate to protect the public health or safety." *Id.*

The FDA announced its decision to revoke Chembio's EUA in a press release issued after the market closed on June 16, 2020. CAC ¶ 224. On June 17, 2020, Chembio publicly acknowledged its receipt of the FDA's letter and the revocation of its EUA. *Id.* ¶ 24. That same day, several market analysts downgraded Chembio stock. *Id.* ¶ 24. After an "unusually heavy trading volume" of 25 million shares sold that day, Chembio's share price declined over 60%, down to $3.89 per share on June 17, 2020. CAC ¶ 25.

Chembio has continued to suffer the financial consequences of the EUA revocation. Chembio's gross product margin for the first three quarters of 2020 was 92% lower than it had been in 2019. *Id.* ¶ 28. In the latest Form 10-Q cited in the Complaint, dated November 5, 2020, Chembio acknowledged that the revocation "preclud[ed] the sale of the [Test] within the U.S. during the third quarter of 2020, and also deferr[ed] certain customer opportunities . . . outside the U.S." *Id.*

B. Procedural Background

Plaintiffs filed four separate lawsuits against Chembio between June 18, 2020 and August 17, 2020. *Chernysh v. Chembio Diagnostics, Inc.*, No. 20-CV-2706; *Gowen v. Chembio Diagnostics, Inc.*, No. 20-CV-2758; *Bailey v. Chembio Diagnostics, Inc.*, No. 20-CV-2961; *Special Situations Fund III QP, L.P. v. Chembio Diagnostics, Inc.*, No. 20-CV-3753. On December

29, 2020, Magistrate Judge Arlene R. Lindsay granted the motions to consolidate and appoint lead counsel. Dec. 29, 2020 Op. & Order, No. 20-CV-2706, ECF No. 54. The Consolidated Amended Complaint ("Complaint") was filed February 12, 2021.

The Complaint identifies two proposed classes: (1) "[a]ll persons who purchased Chembio common stock directly in or traceable to the Company's May 7, 2020 offering . . . pursuant to Chembio's . . . Registration Statement and its Prospectus and Prospectus Supplement"; and (2) "[a]ll persons who purchased or otherwise acquired Chembio securities on the open market" during the class period, marked as between March 12, 2020 and June 16, 2020. CAC ¶ 1. The lead plaintiffs are Special Situations Fund III QP, L.P., Special Situations Cayman Fund, L.P., and Special Situations Private Equity Fund, L.P. (collectively the "Funds"), as well as Municipal Employees' Retirement System of Michigan ("MERS"). *Id.* at 1. Lead plaintiffs MERS and the Funds both allege that they purchased Chembio common stock during the class period and that the Funds collectively purchased 125,000 shares in the May Offering pursuant to the Registration Statement. *Id.* ¶¶ 34–35.

The Complaint names as defendants Chembio; the underwriter defendants; Mr. Eberly, Ms. Page, Mr. Esfandiari (Chembio's Executive Vice President and Chief Science and Technology Officer), and Mr. Goldman (Chembio's Executive Vice President and Chief Financial Officer) (collectively "officer defendants"); and three Chembio directors ("director defendants"). *Id.* ¶¶ 36–52.

Plaintiffs assert five causes of action:

1. Count I under Section 11 of the Securities Act against Chembio, the director defendants, and the underwriter defendants, as well as defendants Ms. Page and Mr. Goldman. *Id.* ¶¶ 106−18.
2. Count II under Section 12(a)(2) of the Securities Act against the same defendants. *Id.* ¶¶ 119−27.

3. Count III under Section 15 of the Securities Act against the director defendants, as well as defendants Ms. Page and Mr. Goldman. *Id.* ¶¶ 128−34.
4. Count IV under Section 10(b) of the Exchange Act and Rule 10b-5 against Chembio, the officer defendants, and the director defendants. *Id.* ¶¶ 277−80.
5. Count V under Section 20(a) of the Exchange Act against the officer defendants. *Id.* ¶¶ 281–85.

Defendants moved to dismiss the Complaint pursuant to Rules 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u–4, *et seq*. Defs.' Mem. in Supp. Mot. to Dismiss ("Defs.' Mem."), ECF No. 87.

LEGAL STANDARD

On a motion to dismiss under Rule 12(b)(6), I accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of the non-moving party. *Lundy*, 711 F.3d at 113. I will not, however, accept allegations in the complaint if they are clearly contradicted by relevant documents that I have authority to consider (*see* Discussion I, *infra*). *TufAmerica, Inc. v. Diamond*, 968 F. Supp. 2d 588, 592 (S.D.N.Y. 2013) (citation omitted) ("If a document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, control, and the court need not accept the allegations in the complaint as true."). Dismissal is proper "only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 69 (2d Cir. 2001) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

The Complaint's allegations "must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Indeed, only "a plausible claim for relief survives a motion to dismiss." *LaFaro v. N.Y. Cardiothoracic Grp., PLLC*, 570 F.3d 471, 476 (2d Cir.

2009). Courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

In securities fraud cases, the PSLRA requires a complaint to "specify each statement [or omission] alleged to have been misleading, the reason or reasons why the statement [or omission] is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1). Rule 9(b) of the Federal Rules of Civil Procedure, which applies to allegations of fraud, imposes a comparable requirement. *See* Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."). This particularity requirement does not, however, mandate "the pleading of detailed evidentiary matter." *In re Scholastic*, 252 F.3d at 72. Allegations that do not sound in fraud, however, need only meet the notice pleading standard of Federal Rule of Civil Procedure 8(a)(2).

DISCUSSION

I. Documents Considered.

The parties dispute whether I may consider the numerous documents attached to defendants' Motion to Dismiss. In ruling on a motion to dismiss a securities suit, I may look beyond the complaint and its attachments to documents incorporated into the complaint by reference, public disclosure documents filed with the Securities and Exchange Commission ("SEC"), *Gamm v. Sanderson Farms, Inc.*, 944 F.3d 455, 462 (2d Cir. 2019), and "documents that the plaintiffs either possessed or knew about and upon which they relied in bringing the suit," *Rothman v. Gregor*, 220 F.3d 81, 88 (2d Cir. 2000). A document is incorporated by reference if the complaint "make[s] a clear, definite and substantial reference to the documents." *Mosdos Chofetz Chaim, Inc. v. Vill. of Wesley Hills*, 815 F. Supp. 2d 679, 691 (S.D.N.Y. 2011) (citation omitted). "[L]imited quotation does not

constitute incorporation by reference." *Goldman v. Belden*, 754 F.2d 1059, 1066 (2d Cir. 1985).

SEC filings may be considered under Federal Rules of Evidence 201, which permits me to take judicial notice of, *inter alia*, facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2); *see also Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47–48 (2d Cir. 1991) ("[W]hen a district court decides a motion to dismiss a complaint alleging securities fraud, it may review and consider public disclosure documents required by law to be and which actually have been filed with the SEC, particularly where plaintiff has been put on notice by defendant's proffer of these public documents."). Courts consider SEC filings to ensure that securities fraud complaints do not evade dismissal by inaccurately quoting public documents. *See Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991) ("Were courts to refrain from considering such documents, complaints that quoted only selected and misleading portions of such documents could not be dismissed under Rule 12(b)(6) even though they would be doomed to failure."); *see also I. Meyer Pincus & Assocs., P.C. v. Oppenheimer & Co.*, 936 F.2d 759, 762 (2d Cir. 1991) (declining to "create a rule permitting a plaintiff to evade a properly argued motion to dismiss simply because [the] plaintiff ha[d] chosen not to attach the [document at issue] to the complaint or to incorporate it by reference"). In the motion to dismiss context, I take judicial notice of documents only "to determine what statements [the documents] contain[ ]," not for the truth of the matters asserted. *Time Warner*, 937 F.2d at 774.

Defendants attached twelve exhibits to their Motion to Dismiss. Exhibits A through C are the communications from the FDA to Chembio regarding its EUA for the Test. Sigismondi Decl., Exs. A–C, ECF No. 84-1. Exhibits D, J, and K are Chembio's routine public filings with the SEC. Goldman Decl., Exs. D, J, K, ECF No. 84-2. Exhibit E is a filing with the SEC regarding the May Offering, and Exhibit F is Chembio's Registration Statement, effective October 3, 2018. Goldman

Decl., Exs. E–F, ECF No. 84-2. Exhibits G through I are documents produced by Chembio: a March 12, 2020 press release, and transcripts of earnings calls with investors on March 12, 2020 and May 4, 2020. Goldman Decl., Exs. G–I.

I will consider Exhibits B through G, and I through K in deciding defendants' Motion to Dismiss. Plaintiffs clearly relied in massive part on Exhibit B—the May 22, 2020 email from the FDA to Chembio—in writing the Complaint; the email is the cornerstone of plaintiffs' factual narrative and is referenced throughout the pleading. Exhibit C—the June 17, 2020 letter revoking the EUA—is also referenced throughout. Exhibits D–F, J, and K are public filings with the SEC of which I can take judicial notice. And Exhibits G and I are significantly quoted in the Complaint, so have been incorporated by reference.

I cannot, however, consider Exhibits A and H. Exhibit A—the letter from the FDA granting the EUA for the Test—is not specifically or substantially referenced in the complaint and was not obviously relied upon by plaintiffs in drafting the complaint. Plaintiffs only briefly quote Exhibit H—the transcript of the March earnings call—in the Complaint, so the document is not incorporated by reference. Furthermore, neither document is publicly available in a manner that would allow me to take judicial notice.

II. Claims Under Exchange Act Section 10(b) and Rule 10b-5.

Exchange Act Class plaintiffs[6] allege that the Chembio defendants violated Section 10(b) of the Exchange Act and Rule 10b-5—the SEC's implementing rule, 17 C.F.R. 240.10b-5—by "disseminat[ing] or approv[ing] false statements, which they knew or recklessly disregarded were

[6] The Exchange Act Class is comprised of plaintiffs who allegedly purchased or otherwise acquired Chembio securities on the open market during the class period (March 12 through June 16, 2020). CAC ¶ 1.

misleading in that they contained 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." CAC ¶ 278. These statements include those made in the Registration Statement for the May Offering, as well as public disclosures—in press releases and conference calls—made after the April 29 call. [7] CAC ¶¶ 68−81, 206−20. Defendants respond, *inter alia*, that plaintiffs have failed to establish the scienter element required to succeed on their Exchange Act claims. Defs.' Mem. 34–45.[8]

A. Legal standard.

Section 10(b) makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . [,] any manipulative or deceptive device or contrivance in contravention of [SEC rules and regulations]." 15 U.S.C. § 78j(b). SEC Rule 10b-5 clarifies that Section 10(b) prohibits, *inter alia*, "mak[ing] any untrue statement of a material fact or [] omit[ting] to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5. Because a Section 10(b) claim sounds in fraud, it must meet the heightened pleading requirements of Federal Rule of Civil

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[7] The Complaint cites several statements and publications by Chembio and the individual Chembio defendants that precede April 29, 2020. *Id.* ¶¶ 191–205. However, plaintiffs have not pleaded how those statements were materially misleading, or how, before the FDA raised the data accuracy issue on the April 29 call, defendants could have made those statements with fraudulent intent. Defendants accordingly challenged the relevance of these statements to plaintiffs' legal claims and argued they should not be considered. Defs.' Mem. 24–25. Plaintiffs did not respond to this argument, arguing only that the statements after April 29 are actionable. Pls.' Opp'n to Defs.' Mot. to Dismiss ("Pls.' Opp'n"), ECF No. 88. Plaintiffs have therefore waived the argument. *Laface v. E. Suffolk BOCES*, No. 18-CV-1314 (ADS), 2019 WL 1959489, at *8 (E.D.N.Y. May 2, 2019) ("In the Second Circuit, a plaintiff's failure to respond to contentions raised in a motion to dismiss claims constitute an abandonment of those claims." (internal quotations and citation omitted)); *see also id.* (collecting cases). I accordingly focus on statements made after April 29, 2020.

[8] Defendants also argue that the statements at issue are non-actionable because they were immaterial, puffery, expressions of opinion, or future statements protected by the safe harbor of the PSLRA. Defs.' Mem. 17–24. Because I decide these claims on the issue of scienter, *see* Discussion II.B, *infra*, I do not need to reach these arguments regarding whether the statements were materially misleading.

Procedure 9(b) and of the PSLRA. *Fresno Cnty. Emps.' Ret. Ass'n v. comScore, Inc.*, 268 F. Supp. 3d 526, 535 (S.D.N.Y. 2017). Under Rule 9(b), plaintiffs must plead six elements in connection with their purchase of Chembio securities: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (citation omitted). "[A] defendant must actually make a false or misleading statement in order to be held liable under Section 10(b). Anything short of such conduct is merely aiding and abetting, and . . . not enough to trigger liability under Section 10(b)." *In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 641 (S.D.N.Y. 2007) (quoting *Wright v. Ernst & Young LLP*, 152 F.3d 169, 175 (2d Cir. 1998)). "[W]hen fraud is alleged against multiple defendants, a plaintiff must set forth separately the acts complained of by each defendant. A complaint may not simply clump defendants together in vague allegations." *Id.* at 641 (alteration in original) (citation omitted).

B. Plaintiffs fail to plead scienter for all statements at issue.

To adequately allege scienter, plaintiffs must plead facts that support a "strong inference" of a mental state "embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319; *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 110–11 (2d Cir. 2009). "[A]n inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.'" *Tellabs*, 551 U.S. at 314. For each allegedly violative act or omission, the PSLRA requires the complaint to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A). The inquiry, however, is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard."

Tellabs, 551 U.S. at 322–23 (emphasis in original). The inference "need not be irrefutable," *id.* at 324, and any "tie on scienter goes to the plaintiff," *City of Pontiac General Emps.' Ret. Syst. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 372 (S.D.N.Y. 2012).

1. Individual scienter

Plaintiffs can satisfy the scienter requirement for the officer and director defendants by pleading facts showing either (1) that these defendants had the motive and opportunity to commit fraud, or (2) "strong circumstantial evidence" of "conscious misbehavior or recklessness," *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 168–70, that is, "a state of mind approximating actual intent, and not merely a heightened form of negligence," *Novak v. Kasaks*, 216 F.3d 300, 312 (2d Cir. 2000) (internal quotations and citation omitted).

To plead motive with sufficient particularity, plaintiffs must allege that defendants "benefitted in some concrete and personal way from the purported fraud." *ECA, Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.* (*IBEW*), 553 F.3d 187, 198 (2d Cir. 2009) (internal quotations and citation omitted). It must be a "specific benefit that would inure to the defendants that would not be either generalized to all corporate directors or beneficial to all shareholders." *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001). Motives common to most corporate officers, including the desire for the corporation to appear profitable, to keep stock prices high to increase officer compensation, or even to enhance their own prestige do not suffice for scienter. *See, e.g.*, *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 54 (2d Cir. 1995) (finding allegations that the defendants were motivated by a desire to maintain or increase executive compensation insufficient for scienter); *Russo v. Bruce*, 777 F. Supp. 2d 505, 519 (S.D.N.Y. 2011) (finding allegation of executives' desire to "protect and enhance [their] executive positions and the substantial compensation and prestige obtained thereby" to all be "too general to support a strong inference of scienter" (alteration in

original)). For example, individual employees wanting a specific stock offering to be successful (but not profiting directly from the sale) is insufficient to infer scienter. *Russo*, 777 F. Supp. 2d at 520 (finding "a generalized motive to ensure the success of the issue and to raise as much money as possible" insufficient to infer scienter (internal quotations and citation omitted)). Instead, "the 'motive' showing is generally met when corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit." *IBEW*, 553 F.3d at 198.

Where plaintiffs do not allege that defendants had a motive to defraud the public, they must instead plead facts that support "a stronger inference of recklessness." *Kalnit*, 264 F.3d at 143. To qualify as reckless, defendants' conduct must have been "highly unreasonable" and "an extreme departure from the standards of ordinary care." *Novak*, 216 F.3d at 311 (citation omitted). Plaintiffs can establish recklessness by adequately alleging that "defendants knew facts or had access to non-public information contradicting their public statements" and therefore "knew or should have known they were misrepresenting material facts." *In re Scholastic*, 252 F.3d at 76 (citation omitted). Plaintiffs can sometimes successfully plead recklessness by alleging "facts demonstrating that defendants failed to review or check information that they had a duty to monitor." *Novak*, 216 F.3d at 308. An alleged "refusal to see the obvious, or to investigate the doubtful," however, must be "egregious" to be actionable. *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996) (citation omitted). The key to the analysis, ultimately, is "the honest belief of the management in the truth of information issued to the public. If the management knows that certain facts will necessarily prevent the regulatory approval . . . and conceals these facts from the investing public, then there is scienter." *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008), *aff'd sub nom. State Univ. Ret. Sys. of Ill. v. Astrazeneca PLC*, 334 F. App'x 404 (2d Cir. 2009) (summary order). If, on the other hand, "the management of the company releases positive reports about the drug to the public

along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud." *Id.*; *see also id.* (collecting cases).

Plaintiffs argue that they have sufficiently pleaded scienter by alleging that "by no later than April 29, 2020, the Chembio Defendants had access to material, contradictory information regarding the efficacy of the Test," and "the core importance of the Test's performance and prospects to Chembio's business." Pls.' Opp'n to Defs.' Mot. to Dismiss 41 ("Pls.' Opp'n"), ECF No. 88 (citing CAC ¶¶ 17–23, 176–88, 239–57). But plaintiffs fail to plausibly allege either motive or conscious recklessness on the part of any individual defendant.

For motive, plaintiffs appear to ask me to infer that Chembio and its executives concealed false information to raise Chembio's stock price. What is missing, however, is the necessary concrete, individualized benefit to officer and director defendants. Plaintiffs have pleaded that defendants were motivated by the company's financial prospects, CAC ¶ 253; Pls.' Opp'n 50, which is "precisely the sort of commonplace and hence unsuspicious motive that courts have routinely found insufficient to establish scienter," *In re Keyspan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 382 (E.D.N.Y. 2003); *see also Novak*, 216 F.3d at 307 (collecting cases). Plaintiffs also plead that the increased media exposure for the company from the seeming success of the Test was a sufficient motive. Pls.' Opp'n 50 (citing CAC ¶¶ 177, 245). Plaintiffs do not, however, cite any cases for this proposition. Moreover, media exposure for Chembio and its executives sounds more similar to the desire for prestige that courts have found insufficient for motive, *see supra*, than the concrete individual benefits, like stock sales, that have routinely been found to support motive.

Finally, the Complaint appears to advance a "bet the company" theory that, with all other products consigned to legacy status, Chembio's fate was dependent on the Test's success to a degree that should satisfy motive *See, e.g.*, CAC ¶ 240 ("The adverse developments at issue

impacted the most central aspect, or the core, of the Company's business, operations, and revenue."). Alleging a motivation of avoiding an event that would "threaten the survival of a company" is still "far too generalized (and generalizable) to allege the proper 'concrete and personal' benefit required by the Second Circuit," however. *In re PXRE Grp., Ltd., Sec. Litig.*, 600 F. Supp. 2d 510, 531–32 (S.D.N.Y. 2009), *aff'd sub nom. Condra v. PXRE Grp. Ltd.*, 357 F. App'x 393 (2d Cir. 2009). For this reason, similar theories have been rejected by courts in this Circuit. *See, e.g.*, *id.* at 533 ("[R]aising capital . . . to stave off a company's collapse . . . does not suffice [because] [s]uch a motive is too generalized."); *In re Ambac Fin. Grp., Inc. Sec. Litig.*, 693 F. Supp. 2d 241, 266 (S.D.N.Y. 2010) ("[T]he desire to maintain a high corporate credit rating is not enough to plead motive, even though Ambac's credit rating was fundamental to its business model."); *Zirkin v. Quanta Cap. Holdings Ltd.*, No. 07-CV-851 (RPP), 2009 WL 185940, at *12 (S.D.N.Y. Jan. 23, 2009) ("A motive to maintain a higher financial rating to protect the viability of the [c]ompany . . . is not enough [for scienter].").

Plaintiffs are therefore left to plead recklessness. As all reasonable inferences fall in favor of plaintiffs at the pleading stage, I must assume that the April 29 call with the FDA provided notice to defendants that the Test was not 100% accurate after 11 days. By April 29, Chembio was in possession of the RUMC data, which they sent to the FDA following their call, and the FDA had communicated the NCI data to them, sending the full data report on April 30, 2020. May 22 Email. Plaintiffs accordingly assert that officer and director defendants necessarily knew about the contradictory data by virtue of their senior roles at Chembio and the centrality of the Test to Chembio's business. CAC ¶¶ 244, 247, 256–57. Therefore, plaintiffs plead, those defendants were aware of the increased likelihood that the EUA would be revoked. *See, e.g.*, CAC ¶¶ 210, 220.

Even assuming, *arguendo*, that officer and director defendants did in fact know that the

Test was not 100% accurate, plaintiffs have still not sufficiently pleaded scienter. As noted above, a reckless state of mind approximates actual intent; pleading heightened negligence will not cross this high threshold. *See Novak*, 216 F.3d at 312. As applied to this case, the officer and director defendants' actions would have been reckless if defendants knew, but did not disclose, that it was inevitable that Chembio would lose its EUA for the Test. But the information that the Test might not be as accurate as they claimed did not put defendants on notice that the EUA *would* be revoked. The May 22 email summarizing the April 29 call does not say that revocation was discussed as a possibility on that call. *See* May 22 Email. Indeed, plaintiffs provide no basis to infer that the FDA mentioned taking any action on the Test's EUA (beyond denying Chembio's request for amendment) until the May 22 email, after the May Offering. *See, e.g.*, CAC ¶ 20.

Moreover, Chembio continued to submit data from further studies of the Test through May 15. In its May 22 email to defendants, the FDA even invited defendants to submit additional data by May 25. *See* May 22 email. To be sure, the NCI and RUMC data may have increased defendants' concerns about the likelihood of revocation. But it would be unreasonable to infer that the data necessarily notified defendants that revocation was inevitable when defendants continued to send more data to the FDA and receive feedback. The competing inference that defendants still believed—in the uncertain early months of the COVID-19 pandemic and with few competitor products on the market—that the FDA would maintain their EUA, is more compelling given the facts pleaded. Therefore, plaintiffs have not adequately pleaded that officer and director defendants were reckless in failing to warn that the EUA would be revoked.

Plaintiffs also advance a more limited recklessness argument, pleading that officer and director defendants were reckless in their statements about the Test's accuracy. *See, e.g.*, CAC ¶¶ 207, 212, 214, 216–17. This argument also fails, however, because plaintiffs have

insufficiently pleaded that these defendants knew about the contradictory NCI and RUMC data when they made the allegedly reckless statements. As noted above, plaintiffs proffer that because officer and director defendants were senior executives at the company, they necessarily knew about the contradictory data regarding their most important product. CAC ¶¶ 244, 247, 256–57. But circumstantial evidence of knowledge is insufficient to support recklessness without more: "all allegations going to scienter . . . must show that [the] individual defendants actually possessed the knowledge highlighting the falsity of public statements; conclusory statements that defendants 'were aware' of certain information, and mere allegations that defendants 'would have' or 'should have' had such knowledge is insufficient." *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 591 (S.D.N.Y. 2011); *see also, e.g.*, *Patel v. L-3 Commc'ns Holdings Inc.*, Nos. 14-CV-6038, 14-CV-6182, 14-CV-6939 (VEC), 2016 WL 1629325, at *8 (S.D.N.Y. Apr. 21, 2016) ("Lead [p]laintiffs do not allege with any particularity the who, what, and when of any of these events or any specificity as to what the [i]ndividual [d]efendants actually knew or should have known."). In particular, pleading access to information based on an individual defendant's executive position is insufficient to support an inference of scienter. *See, e.g.*, *Glaser*, 772 F. Supp. 2d at 588 ("[A]llegations that [the] information [at issue] was the sort of data that would have been reviewed by the [i]ndividual [d]efendants are too speculative to give rise to a strong inference of scienter." (internal quotations and citation omitted)); *In re Health Mgmt. Sys., Inc. Sec. Litig.*, No. 97-CV-1865 (HB), 1998 WL 283286, *6 (S.D.N.Y. June 1, 1998) ("[C]ourts have routinely rejected . . . attempt[s] to plead scienter based on allegations that because of defendants' board membership and/or their executive managerial positions, they had access to information concerning the company's adverse financial outlook."); *see also In re Sona Nanotech, Inc. Sec. Litig.*, No. 20-CV-11405 (MCS), 2021 WL 5504758, at *8 (C.D. Cal. Oct. 28, 2021) (finding "woefully insufficient"

plaintiffs' pleading that the individual defendants, because of their roles as corporate officers, knew that the company's statements about its COVID-19 test were incorrect "based on an apparent possession of contradictory information").[9] Nevertheless, plaintiffs cite nothing more concrete to support that officer and director defendants, who either made or signed the Registration Statement containing the statements at issue, knew about the contradictory data.[10] Accordingly, I find that plaintiffs' fail to sufficiently plead scienter on behalf of any of officer and director defendants.

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[9] Plaintiffs' pleadings sound in the core operations doctrine, the central theory of which is that "when contradictory facts of critical importance to the company either were apparent or should have been apparent, an inference arises that high-level officers and directors had knowledge of those facts by virtue of their positions with the company." *Wallace v. IntraLinks*, No. 11-CV-8861 (TPG), 2013 WL 1907685, at *8 (S.D.N.Y. May 8, 2013) (citation omitted). After the PSLRA, however, courts do not accept this pleading strategy as the *sole* evidence of scienter; such an inference can only be additional evidence of scienter. *Id.*; *see also In re Ferrellgas Partners, L.P., Sec. Litig.*, No. 16-CV-7840 (RJS), 2018 WL 2081859, at *19 (S.D.N.Y. Mar. 30, 2018) ("[W]hile allegations regarding core operations may factor into a court's holistic assessment of scienter allegations, they are not independently sufficient to raise a strong inference of scienter." (internal quotation marks omitted)), *aff'd*, 764 F. App'x 127 (2d Cir. 2019); *Tyler v. Liz Claiborne, Inc.*, 814 F. Supp. 2d 323, 343 (S.D.N.Y. 2011) ("[T]hat an allegedly fraudulent statement concerned 'core operations,' standing alone, is insufficient to support strong circumstantial evidence of scienter. Rather, the 'core operations doctrine' bolsters the strength of the inference of scienter when [the] plaintiff has already adequately alleged facts indicating that [the] defendants might have known their statements were false.").

[10] Plaintiffs cite *City of Pontiac General Employees' Retirement System v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359 (S.D.N.Y. 2012), to argue that Mr. Eberly and Ms. Page's statements about the Test's accuracy were "strong circumstantial evidence that [defendants] were receiving some form of specific information," *id.* at 372. But in citing *Lockheed Martin*, plaintiffs ignore the broader context of that court's conclusion. There, the court found relevant—*in combination*—pleadings (1) that the senior corporate defendants "made specific statements about the projections and performance" of the company (as plaintiffs argue here), *and* (2) that the defendants received their information from a co-defendant, as to whom the court had already found the complaint sufficiently alleged scienter. *Id.* at 371−73. Even faced with more substantial pleading than exists in plaintiffs' Complaint, however, the *Lockheed Martin* court still found that it was equally plausible that either (1) the defendants acted with scienter, or (2) their co-defendant misled them. *Id.* at 372−73. The *Lockheed Martin* plaintiffs prevailed only because a tie at the pleading stage goes to the plaintiff. *See id.* That the allegations in *Lockheed Martin* amounted only to a tie underscores the deficiency of plaintiffs' pleadings here.

2. Corporate scienter

To adequately plead scienter for Chembio, plaintiffs must plead facts that "create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter." *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Cap., Inc.*, 531 F.3d 190, 195 (2d Cir. 2008). While "the most straightforward way" to establish scienter for a corporate defendant "is to impute it from an individual defendant who made the challenged misstatement," that is not required. *Jackson v. Abernathy*, 960 F.3d 94, 98–99 (2d Cir. 2020) (internal quotations and citation omitted). "The scienter of the other officers or directors who were involved in the dissemination of the fraud may also be imputed to the corporation, even if they themselves were not the actual speaker." *Id.* at 99. Alternatively, "a shareholder need not . . . identify the individuals responsible for the fraudulent statement" where the statement is "so dramatic that collective corporate scienter may be inferred." *Id.* at 98−99 (internal quotations and citation omitted).

Plaintiffs argue that they have plausibly pleaded Chembio's corporate scienter by alleging the following: (1) with all other products relegated to legacy status, all Chembio defendants were focused on the Test, and thus "cannot reasonably dispute knowledge of and involvement in test-related FDA communications," Pls.' Opp'n 48; *see also* CAC ¶ 247; and (2) scienter can be imputed to Chembio from defendant Esfandiari, Pls.' Opp'n at 48–49, or non-defendant Dr. Louise M. Sigismondi, Research and Development Director of Regulatory Affairs at Chembio, who received the May 22 email and the June 16 letter, CAC ¶ 258; *see also* May 22 Email; June 16 Letter. Plaintiffs at different points identify Dr. Sigismondi and Mr. Esfandiari as the source of Chembio's scienter. The Complaint imputes scienter to Chembio from only Dr. Sigismondi. CAC ¶ 258. In their Motion to Dismiss, defendants criticize this aspect of plaintiffs' pleading as insufficient. Defs.' Mem. 41. Rather than defending Dr. Sigismondi as the source of corporate scienter, however, in their opposition, plaintiffs make no mention of Dr. Sigismondi; instead, they proffer Mr. Esfandiari as the

sole source of Chembio's scienter. Pls.' Opp. at 48–49. However, even if plaintiffs had adequately pleaded Mr. Esfandiari as the source of Chembio's scienter—which they did not—plaintiffs would not have adequately alleged Chembio's scienter. As discussed above, knowledge of an increased risk of revocation—the only knowledge that can be imputed to Dr. Sigismondi or Mr. Esfandiari—is not knowledge of *certain* revocation. *See supra*. I therefore find plaintiffs have not sufficiently pleaded an individual whose scienter can be imputed to Chembio.[11]

Ultimately, plaintiffs have not persuasively alleged with sufficient specificity an inference of fraudulent intent that is at least as compelling as competing inferences of non-fraudulent intent. I therefore do not need to reach the other elements of plaintiffs' Section 10(b) claim, which I dismiss.

III. Claims Under Securities Act Sections 11 and 12(a)(2)

The Securities Act Class plaintiffs[12] allege that Chembio, the underwriter defendants, Ms. Page, Mr. Goldman, and the director defendants violated Sections 11 and 12(a)(2) of the Securities Act. CAC ¶¶ 106–27. These provisions impose liability on those involved in preparing and publishing an offering's registration statement and prospectus, including all signatories, for untrue statements of material fact or misleading omissions contained in those documents. 15 U.S.C. § 77k. Issuers, like Chembio, "are subject to 'virtually absolute' liability" while Sections 11 and 12 hold other defendants potentially liable for negligence. *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 359 (2d Cir. 2010) (quoting *Herman*, 459 U.S. at 382). Ms. Page, Mr. Goldman, and the director defendants are named as signers of the Registration Statement. CAC ¶¶ 39–40, 44–46. The underwriter defendants

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[11] Plaintiffs have not attempted to identify a sufficiently dramatic statement that would support an inference of collective corporate scienter.

[12] The Securities Act Class is composed of the plaintiffs who allegedly purchased Chembio common stock directly in or traceable to the May Offering and pursuant to Chembio's offering documents. CAC ¶ 1.

are named for their alleged role in preparing the Registration Statement. *Id.* ¶¶ 50−52.

The Securities Act imposes "a stringent standard of liability," and plaintiffs "need only show a material misstatement or omission to establish [their] *prima facie* case." *Herman & MacLean v. Huddleston*, 459 U.S. 375, 381–82 (1983). An actionable misstatement or omission takes the form of "(1) a misrepresentation; (2) an omission in contravention of an affirmative legal disclosure obligation; [or] (3) an omission of information that is necessary to prevent existing disclosures from being misleading." *In re Morgan Stanley*, 592 F.3d at 360. Section 11 applies this standard to the registration statement, while Section 12(a)(2) applies it to, *inter alia*, prospectuses. *Id.* at 358–59; *In re XP Inc. Sec. Litig.*, 524 F. Supp. 3d 23, 29 (E.D.N.Y. 2021). Because the two sections are "Securities Act siblings with roughly parallel elements, courts typically analyze the two claims together." *City of Omaha Police & Fire Ret. Sys. v. Evoqua Water Techs. Corp.*, 450 F. Supp. 3d 379, 401 (S.D.N.Y. 2020) (internal quotations and citation omitted).

As a general rule, Sections 11 and 12(a)(2) claims do not require plaintiffs to plead scienter because "[f]raud is not an element or a requisite" of those claims. *Rombach v. Chang*, 355 F.3d 164, 171 & n.4 (2d Cir. 2004). A Securities Act plaintiff therefore typically needs to allege only that the statement or omission was materially misleading, which is a "fact-specific" inquiry that does not focus on whether statements are "literally true" but instead on whether the statements, "taken together and in context, would have misle[d] a reasonable investor." *In re Facebook, Inc. IPO Sec. & Derivative Litig.*, 986 F. Supp. 2d 487, 515 (S.D.N.Y. 2013).

Where Section 11 and/or Section 12(a)(2) claims are "premised on allegations of fraud," however, Rule 9(b)'s heightened pleading standard applies. *Rombach*, 355 F.3d at 171. It is not uncommon to analyze Sections 11 and 12(a)(2) claims under this standard: "The same course of conduct that would support a Rule 10b–5 claim may as well support a Section 11 claim or a claim

under Section 12(a)(2)." *Id.* at 171. For such claims, plaintiffs must plead the elements of fraud by "(1) specify[ing] the statements that the plaintiff contends were fraudulent, (2) identify[ing] the speaker, (3) stat[ing] where and when the statements were made, and (4) explain[ing] why the statements were fraudulent." *Id.* at 170 (internal quotations and citation omitted).

A. The appropriate pleading standard for the claims against the named Chembio defendants is fraud, while the standard for the claims against the underwriter defendants is negligence.

The parties dispute whether plaintiffs' claims under Sections 11 and 12 of the Securities Act sound in negligence or fraud, and therefore disagree as to the appropriate pleading standard. Defs.' Mem. 14–16; Pls.' Opp'n 11–16; Defs.' Reply in Supp. of Mot. to Dismiss 20–24 ("Defs.' Reply"), ECF No. 90. To determine whether Securities Act claims sound in fraud, courts must engage in a "case-by-case analysis of particular pleadings to determine whether 'the gravamen of the complaint is plainly fraud.'" *Refco*, 503 F. Supp. 2d at 32 (quoting *Rombach*, 355 F.3d at 172). Plaintiffs cannot evade Rule 9(b)'s heightened pleading standard by disclaiming any intent to plead fraud. *See, e.g.*, *Fresno Cnty. Emps.' Ret. Ass'n*, 268 F. Supp. 3d at 558 ("On their own, such disclaimers are insufficient to subject a complaint to [Federal] Rule [of Civil Procedure] 8, because '[p]laintiffs cannot evade the Rule 9(b) strictures by summarily disclaiming any reliance on a theory of fraud or recklessness.'" (alteration in original) (quoting *City of Roseville Emps.' Ret. Sys. v. EnergySolutions, Inc.*, 814 F. Supp. 2d 395, 424 (S.D.N.Y. 2011))). Plaintiffs must avoid language "classically associated with fraud," *Rombach*, 355 F.3d at 172, and "carefully couch[]" their claims "in the language of negligence." *Refco*, 503 F. Supp. 2d at 32. And while keeping separate the factual allegations supporting Securities Act and Exchange Act claims is helpful, separate pleadings will not remedy factual overlap of claims. *See, e.g.*, *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG* (*UBS*), 752 F.3d 173, 183 (2d Cir. 2014) (concluding that Section 11 claims sounded in

fraud where, *inter alia*, the claims were identical to the plaintiff's Section 10(b) claims); *In re HEXO Corp. Sec. Litig.*, 524 F. Supp. 3d 283, 299 n.17 (S.D.N.Y. 2021) (holding separation of Securities Act and Exchange Act claims did not prevent the court from finding the Securities Act claim sounded in fraud because both claims "rest[ed] on the same theory"). When "the only allegations supporting falsity are the plaintiffs' allegations relating to fraudulent intent," the fraud claims are "substantially intertwined" with the Section 11 claims, and the latter must also be pleaded according to Rule 9(b). *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 502 (S.D.N.Y. 2004).

1. Chembio defendants

Here, plaintiffs' Sections 11 and 12(a)(2) allegations against Chembio, the director defendants, Ms. Page, and Mr. Goldman sound in fraud. To be sure, plaintiffs disclaim any intent to plead fraud and insert the classic language of negligence pleading in their Section 11 claim. CAC ¶ 113 ("None of Defendants named herein made a reasonable investigation or possessed reasonable grounds to believe that the statements in the Registration Statement were complete, accurate or non-misleading."). Nevertheless, the gravamen of plaintiffs' factual claims is fraud. While plaintiffs ostensibly separate their Securities Act and Exchange Act pleadings, the two sections share a nucleus of operative facts: Chembio knew the Test's data were in doubt but did not disclose that fact. The only addition the Exchange Act pleading makes to the Securities Act pleading regarding the Registration Statement and the Prospectus is adding allegations of intent to deceive or defraud. *See* CAC ¶ 217 (incorporating by reference Securities Act pleadings from paragraphs 68 through 81 without pleading additional facts). Plaintiffs' Sections 11 and 12(a)(2) claims against the Chembio defendants are therefore substantially intertwined with their Exchange Act fraud claims.

This conclusion is supported by the overlap in defendants named in the claims and plaintiffs' use of language "classically associated with fraud," *Rombach*, 355 F.3d at 172, in its Securities Act

claims. For example, the Complaint alleges that management, who signed the Registration Statement, "knew that the FDA had expressed concerns about the reliability of the data it submitted with its EUA application and that there was an increased risk that its EUA for the [Test] would be revoked," CAC ¶ 72, yet did not include that information in the Registration Statement.

Plaintiffs cite *In re Refco, Inc. Securities Litigation*, 503 F. Supp. 2d 611 (S.D.N.Y. 2007) to support their argument that their Sections 11 and 12(a)(2) allegations sound in negligence. Pls.' Opp'n 13–14. Although a comparison of this case to *Refco*, which found that the plaintiffs' Securities Act claims sounded in negligence, is instructive, it works to plaintiffs' detriment. In *Refco*, all allegations supporting claims about the defendants' intent were framed in the language of negligence, and the defendants did not identify any allegations in the Securities Act section "that contain[ed] even a hint of fraud." 503 F. Supp. 2d at 631–32. Moreover, not only were the Securities Act and Exchange Act claims divided into separate sections, but also the *substance* of plaintiffs' allegations "kep[t] the distinction [] clear." *Id.* at 632. In the instant case, by contrast, although plaintiffs allege in their Securities Act claims that Chembio's corporate officers did not conduct a reasonable investigation of the statements contained in the Registration Statement (sounding in negligence), their factual pleadings supporting these claims allege that the corporate officers knew but did not disclose the risk of EUA revocation (sounding in fraud). *See, e.g.*, CAC ¶ 72 ("The Registration Statement . . . failed to disclose that, at the time of the May Offering, management *knew* that the FDA had expressed concerns about the reliability of the data it submitted with its EUA application and that there was an increased risk that its EUA for the [Test] would be revoked." (emphasis added)). Nor did plaintiffs here adhere to the clear division of pleading in *Refco*: their Exchange Act claims incorporate the Securities Act claims regarding the Registration Statement and Prospectus and add only a brief additional pleading regarding intent.

See CAC ¶ 217. In other words, the "substance of [plaintiffs'] allegations" does not "keep[] the distinction [] clear." *Refco*, 503 F. Supp. 2d at 632. I will therefore evaluate plaintiffs' Securities Act claims against the Chembio defendants under Rule 9(b)'s fraud pleading standard.

2. Underwriter defendants

Plaintiffs' Sections 11 and 12(a)(2) claims against underwriter defendants, by contrast, sound in negligence. *Cf., e.g.*, *Rombach*, 355 F.3d at 171-72 (finding the Section 11 claims against the corporate defendants sounded in fraud and the Section 11 claims against the underwriters sounded in negligence). Plaintiffs' only claim against the underwriters is that they failed to conduct a reasonable investigation into the statements contained in the Registration Statement and Prospectus. CAC ¶¶ 90–99. Moreover, no fraud claims have been brought against the underwriters.

I will therefore evaluate plaintiffs' Securities Act claims against the underwriters under Rule 8's notice pleading standard.

B. The motion to dismiss the Section 11 and 12(a) claims is granted as to the Chembio defendants and denied as to the underwriter defendants.

Section 11 holds liable issuers and other signatories of a registration statement that "contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). "Section 12(a)(2) imposes liability on any person who 'offers or sells' a security by means of a prospectus that 'includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements, in light of the circumstances under which they were made, not misleading.'" *In re Axis Cap. Holdings Ltd. Sec. Litig.*, 456 F. Supp. 2d 576, 596–97 (S.D.N.Y. 2006) (quoting 15 U.S.C. § 77l(a)(2)). These sections thus hold issuers liable not only for what a registration statement and prospectus say, but also what they leave out. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 179 (2015).

Whether a statement is misleading is contextual: "[e]ven if statements are not literally false, the veracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather than mislead prospective buyers." *City of Coral Springs Police Officers' Ret. Plan v. Farfetch Ltd.*, No. 19-CV-8720 (AJN), 2021 WL 4481119, at *8 (S.D.N.Y. Sept. 30, 2021) (internal quotations and citations omitted); *see also Lau v. Opera Ltd.*, 527 F. Supp. 3d 537, 551 (S.D.N.Y. 2021) ("An entirely truthful statement may provide a basis for liability if material omissions related to the content of the statement make it materially misleading." (citation and modifications omitted)); *In re Facebook*, 986 F. Supp. 2d at 515 ("The law is well settled that so-called 'half-truths'—literally true statements that create a materially misleading impression—will support claims for securities fraud." (citation and modification omitted)). Defendants are protected, however, if they have disclosed the exact risk at issue. *Rubinstein v. Credit Suisse Grp. AG*, 457 F. Supp. 3d 289, 296 (S.D.N.Y. 2020) ("A Section 11 claim fails as a matter of law when a registration statement warns of the exact risk that later materialized." (internal quotations and citation omitted)).

When pleaded in negligence, Section 11 is a strict liability scheme: "the buyer need not [plead] (as he must to establish certain other securities offenses) that the defendant acted with any intent to deceive or defraud." *Omnicare*, 575 U.S. at 179; *see also Herman*, 459 U.S. 381−82. When pleading in fraud, however, plaintiffs must allege intent to successfully plead a Section 11 claim. *See* Fed. R. Civ. P. 9(b); *UBS*, 752 F.3d at 183.

1. Chembio defendants

Plaintiffs assert that the Registration Statement—signed by the director defendants and defendants Page and Goldman, and incorporating the Prospectus—contained several materially misleading statements and material omissions. CAC ¶¶ 106–127. Because I have already found—in connection with plaintiffs' Section 10(b) Exchange Act claim—that based on insufficiently alleged

scienter, the statements in the Registration Statement and the Prospectus do not support a compelling inference of fraud, *see* Discussion II, *supra*, defendants' motion as to the Chembio defendants is granted.

2. Underwriter defendants

To successfully plead a Section 11 claim under the negligence standard, plaintiffs must allege that (1) the underwriter defendants were in fact underwriters under the Securities Act, (2) plaintiffs purchased the registered securities, and (3) that a material misrepresentation or omission was made in the Registration Statement. *See*; *In re Citigroup Inc. Bond Litig.*, 723 F. Supp. 2d 568, 587 (S.D.N.Y. 2010); *see also* 15 U.S.C. §§ 77b(a)(11), 77k(a). To successfully plead a Section 12(a)(2) claim, plaintiffs must allege that (1) the defendant is a 'statutory seller'; (2) the sale was effectuated 'by means of a prospectus or oral communication'; and (3) the prospectus or oral communication 'include[d] an untrue statement of a material fact or omit[ted] to state a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading.'" *In re Morgan Stanley*, 592 F.3d at 359 (alterations in original) (quoting 15 U.S.C. § 77l(a)(2)). Because the underwriter defendants argue only that there was no material misrepresentation or omission in the Registration Statement (including the Prospectus), only the third prongs of each standard—misleading statement or omission—are at issue here.[13] Without the

[13] The underwriter defendants in this case joined Chembio's Motion to Dismiss, Defs.' Joinder in Mot. to Dismiss, ECF No. 85, which challenged plaintiffs' Sections 11 and 12(a)(2) claims only as to the untrue statement/material omission prongs, *see* Defs.' Mem. 17–24. The underwriter defendants have therefore waived any objection to these claims on the grounds that the Complaint insufficiently alleges that plaintiffs purchased the securities or that defendants were in fact underwriters for this transaction. *See Laface v. E. Suffolk BOCES*, No. 18-CV-1314 (ADS), 2019 WL 1959489, at *8 (E.D.N.Y. May 2, 2019). Even absent waiver, however, the Complaint sufficiently pleads that the plaintiffs purchased the securities, *see* CAC ¶¶ 34–35, and that the underwriter defendants met the statutory definition by "market[ing] and underwr[iting] the May Offering and s[elling] Chembio common stock to investors," CAC ¶ 111; *see also* 15 U.S.C. § 77b(a)(11) (defining "underwriter").

heightened pleading standard, plaintiffs' pleadings need accord merely with Rule 8's notice pleading standard. *See In re Citigroup Inc. Bond Litig.*, 723 F. Supp. 2d at 586–87.

An untrue statement or an omitted fact is materially misleading if, in context, it is likely to mislead a reasonable investor. *In re Morgan Stanley*, 592 F.3d at 360. I analyze the allegedly fraudulent materials in their entirety, *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 357 (2d Cir. 2002), to determine whether "there is a substantial likelihood that the disclosure of the [untrue statement or] omitted material would have been viewed by the reasonable investor as having significantly altered the total mix of information already made available," *In re ProShares Trust Sec. Litig.*, 728 F.3d 96, 102 (2d Cir. 2013) (internal quotations, citation, and modifications omitted); *cf. Rubinstein*, 457 F. Supp. 3d at 295 (noting that a Section 11 claim may not be pleaded "with the benefit of 20/20 hindsight") (internal quotations and citation omitted). As materiality is a mixed question of fact and law, allegations of materiality are accepted at this stage, unless the alleged misstatements or omissions are "so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *ECA v. JP Morgan Chase Co.*, 553 F.3d 187, 197 (2d Cir. 2009) (internal quotations and citation omitted).[14] Therefore, the key question here is whether the statements were misleading.

Turning first to whether the Registration Statement and Prospectus contained a misleading statement, plaintiffs highlight the following two excerpts:

1. "We refer to our infectious disease products, other than the [Test], as our legacy products. We expect to generate an immaterial amount of revenue from our legacy products for the foreseeable future, while we continue to focus on the manufacture and commercialization of the [Test]."

[14] "The definition of materiality is the same for [sections 11 and 12(a)(2) of the Securities Act] as it is under section 10(b) of the Exchange Act." *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 360 (2d Cir. 2010).

2. "The speed with which we were able to develop a test for COVID-19 illustrates the DPP platform's applicability to new and emerging infectious diseases," and "illustrates our ability to expand our DPP technology into a broader range of tests."

CAC ¶¶ 70, 78–79. The first quote is a statement of opinion, which is actionable "only if the defendant's opinions were both false and not honestly believed when they were made." *Kleinman v. Elan Corp.*, 706 F.3d 145, 153 (2d Cir. 2013) (internal quotations and citation omitted). An opinion "is not misleading just because external facts show the opinion to be incorrect." *Omnicare*, 575 U.S. at 188. Plaintiffs do not allege that the signers of the Registration Statement (and incorporated Prospectus) did not believe this opinion and they have not pleaded any untrue statement of fact within this opinion. The second quote is insufficiently specific to be taken as a statement of fact. Rather, it is puffery, which describes "[s]tatements that are too vague or general to be relied upon" by a reasonable investor. *Okla. L. Enf't Ret. Sys. v. Papa John's Int'l, Inc.*, 444 F. Supp. 3d 550, 559 (S.D.N.Y. 2020); *see also Barilli v. Sky Solar Holdings, Ltd.*, 389 F. Supp. 3d 232, 251 ("Puffery is an optimistic statement that is so vague, broad, and non-specific that a reasonable investor would not rely on it, thereby rendering it immaterial as a matter of law." (internal quotations and citation omitted)). Therefore, neither of these statements is actionable.

Although plaintiffs have not adequately alleged that the Registration Statement and Prospectus contained a materially misleading affirmative statement, they have adequately alleged that these documents contained a material omission. "For an omission to be actionable, the securities laws must impose a duty to disclose the omitted information." *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002). This duty can arise in the presence of "information that is necessary to prevent existing disclosures from being misleading" or an affirmative legal disclosure obligation. *In re Morgan Stanley*, 592 F.3d at 360. For the former, "once corporate officers undertake to make statements, they are obligated to speak truthfully and to make such additional disclosures as are necessary to avoid rendering the statements made misleading." *In re Par Pharm.,*

Inc. Sec. Litig., 733 F. Supp. 668, 675 (S.D.N.Y. 1990); *Lau*, 527 F. Supp. 3d at 551 ("[O]nce a party chooses to speak, it has a 'duty to be both accurate and complete'" (quoting *Caiola v. Citibank, N.A.*, 295 F.3d 312, 331 (2d Cir. 2002)); *see also In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 268 (2d Cir. 1993) ("A duty to disclose arises wherever secret information renders prior public statements materially misleading[.]"). For the latter, plaintiffs point to the SEC's Regulation S-K—including Item 105—as relevant here. CAC ¶¶ 83–89. Item 105—formerly Item 503[15]—requires a corporation to "provide under the caption 'Risk Factors' a discussion of the material factors that make an investment" in a security "speculative or risky," and requires the discussion of each risk factor to "adequately describe[] the risk." 17 C.F.R. § 229.105.2. "Although there is scant caselaw on Item [105], the inquiry can be boiled down to whether the Offering Documents were accurate and sufficiently candid." *Panther Partners Inc. v. Jianpu Tech. Inc.*, No. 18-CV-9848 (PGG), 2020 WL 5757628, at *7 (S.D.N.Y. Sept. 27, 2020) (internal quotations and citation omitted). Plaintiffs must demonstrate "*actual* knowledge" of a risk to sufficiently allege an Item 105 violation. *Rubinstein*, 457 F. Supp. 3d at 300.

Plaintiffs plead that defendants made a material misstatement by declaring in the Registration Statement and Prospectus that the Test was 100% accurate after eleven days while omitting to disclose the other data in Chembio's possession that indicated a lower accuracy. *See, e.g.*, CAC ¶¶ 19, 74. Plaintiffs allege that despite "the [increasing] risk and uncertainty of having the EUA revoked . . . as a result of the FDA communication," defendants failed to disclose "that [the] data underlying Chembio's EUA application was overstated and inconsistent with that of

[15] Effective May 2, 2019, the SEC relocated former Item 503(c) to Item 105 "without substantively changing the underlying disclosure requirements." FAST Act Modernization and Simplification of Regulation S-K, 84 Fed. Reg. 12674-01, 12688, 12712.

independent evaluations." *Id.* ¶ 74. Defendants argue that plaintiffs' allegations about the accuracy of Chembio's data have no foundation. Defs.' Reply in Further Supp. Mot. to Dism. 12 ("Reply").

I find that, at this stage of the proceeding, plaintiffs have sufficiently pleaded that the NCI and RUMC data contradicted Chembio's claim that the Test was 100% accurate after eleven days, and that Chembio knew this on April 29. I reach this finding by comparing competing inferences. Plaintiffs infer that the gap between the aggregate numbers in Chembio's data and the aggregate numbers in the NCI and RUMC data make it more likely than not that the Test was not in fact 100% accurate after eleven days. Pls.' Opp'n at 21–23. Defendants counter that the gap in the aggregate numbers between the datasets has no bearing on the specific accuracy figures for eleven days. Reply at 12. The inference defendants appear to draw is that it is more plausible that, across the NCI and RUMC data, the accuracy of the Test remained 100% for eleven days, while the aggregate numbers were brought down by the Test's decreased accuracy on days before or after eleven days. At the motion to dismiss stage, I take all reasonable inferences in plaintiffs' favor. I must therefore assume that the provision of the NCI data to Chembio by April 30—and Chembio's possession of other data that the FDA said contradicted Chembio's initial data on the Test's accuracy—put Chembio on notice that it was incorrect to declare in its Registration Statement (including the Prospectus) that the accuracy of the Test was 100% after eleven days.

Applying the above to the Complaint, I find that plaintiffs have sufficiently pleaded an actionable failure to disclose under Item 105. This contradictory data clearly cast doubt on the future of the EUA.[16] Accordingly, the Registration Statement did not disclose one of the most

[16] Defendants cite *In re Tempur Sealy International, Inc., Securities Litigation*, No. 17-CV-2169 (LAK), 2019 WL 1368787 (S.D.N.Y. Mar. 26, 2019), where the court concluded that plaintiffs' allegations of defendants' knowledge would have required "clairvoyance and a secret window into the corporate thinking and workings" of the customer. Reply 25 (quoting *In re Tempur Sealy Int'l*

significant risks to Chembio's business: the potential loss of sales and marketing authorization in the United States for their flagship product.

Defendants argue that the Registration Statement contained sufficient cautionary language warning of the risk of the EUA being revoked. Defs.' Mem. 22–24. Defendants say it is generally known that an EUA can be revoked and point to the warning in the Registration Statement that "[t]he FDA has established certain conditions that must be met to maintain authorization under an EUA." Defs.' Mem. 8–9, 20 n.7. I find this cautionary language to be insufficient because the warnings do not directly address the risk of revocation of the EUA based on the accuracy of the Test coming into question. *See* CAC ¶¶ 72–77. Here, there was a particular reason to be concerned that the EUA might be revoked, a specific risk not covered by such a boilerplate warning, *see Barilli*, 389 F. Supp. 3d at 261 ("Adequate cautionary language must be 'tailored to the specific future projections, estimates or opinions in the [document] which the plaintiffs challenge,'" (quoting *Slayton v. Am. Express Co.*, 604 F.3d 758, 772 (2d Cir. 2010)); *see also City of Omaha*, 450 F. Supp. 3d at 399 (S.D.N.Y. 2020) ("[V]ague disclosures of general risks will not protect defendants from liability." (internal quotations and citation omitted)).

The motion to dismiss the Securities Act claims against the underwriter defendants is therefore denied.

IV. The Control Person Claims Are Dismissed.

Section 15 of the Securities Act and Section 20 of the Exchange Act both impose liability on entities or individuals who "controlled" those responsible for primary violations under their respective statutes. *See* 15 U.S.C. § 77o; 15 U.S.C. § 78t(a). As I have already found that plaintiffs have failed to

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Inc., Sec. Litig., 2019 WL 136787, at *8). No such x-ray vision was alleged or needed here. Defendants had in their possession information that supported a reasonable inference of a likely risk.

allege a primary violation by any of the Chembio defendants, there is no eligible primary violation to support a Section 15 or Section 20(a) claim. The motion to dismiss is granted on both claims.

CONCLUSION

Plaintiffs' Securities Act claims are therefore dismissed except as to the underwriter defendants. Plaintiffs' Exchange Act claims are dismissed in full. Plaintiffs request leave to amend. Pls.' Opp'n 53 n.18. I grant plaintiffs leave to replead their Securities Act claims, but not their Exchange Act claims. When claims are dismissed for failure to state a claim, it is customary to grant leave to replead unless to do so would be futile. *Cortec Indus.*, 949 F.2d at 48, 50; *see also* Fed. R. Civ. P. 15(a)(2) (stating leave to amend should be freely given "when justice so requires."). Repleading would be futile where, *inter alia*, the problems with the complaint are substantive. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 548–49 (citing *Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000)), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016). Here, the problems with the Exchange Act claims are not of pleading, but of substance. Plaintiffs' Exchange Act claims hinge on an alleged knowledge of a risk, not a knowledge of a certainty. Plaintiffs have not identified how repleading would allow them to remedy this scienter deficiency and I am not persuaded that repleading could do so. Plaintiffs' Exchange Act claims are therefore dismissed with prejudice. Plaintiffs' Securities Act claims against Chembio, the director defendants, Ms. Page, and Mr. Goldman are dismissed without prejudice as to repleading within fourteen days.

SO ORDERED.

/s/
Allyne R. Ross
United States District Judge

Dated: February 23, 2022
Brooklyn, New York