UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ERSTE-SPARINVEST KAPITALANLAGEGESELLSCHAFT MBH and OKLAHOMA LAW ENFORCEMENT RETIREMENT SYSTEM, Individually and On Behalf of All Other Persons Similarly Situated,	
Plaintiffs,	
v.	**Civil Action No. 16-11943**
SERES THERAPEUTICS, INC., ROGER J. POMERANTZ, and MICHELE TRUCKSIS,	
Defendants.	

MEMORANDUM AND ORDER

CASPER, J. **March 30, 2018**

I. Introduction

Plaintiffs Erste-Sparinvest Kapitalanlagegellschaft MBH ("ESK") and Oklahoma Law Enforcement Retirement System ("OLERS") (collectively, "Plaintiffs") have filed this lawsuit against Defendants Seres Therapeutics, Inc., Roger J. Pomerantz ("Pomerantz") and Michele Trucksis ("Trucksis") (collectively, "Seres") individually and on behalf of a proposed class of similarly situated persons alleging violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder (Count I), 15 U.S.C. § 78j; 17 C.F.R. 240.10b-5, and Section 20 of the Exchange Act (Count II), 15 U.S.C. § 78t. D. 32. Defendants have moved to dismiss. D. 43. For the reasons stated below, the Court ALLOWS the motion.

II. Standard of Review

On a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6), the Court must determine if the facts alleged "plausibly narrate a claim for relief." Schatz v. Republican State Leadership Comm., 669 F.3d 50, 55 (1st Cir. 2012) (internal citation omitted). Reading the complaint "as a whole," the Court must conduct a two-step, context-specific inquiry. García-Catalán v. United States, 734 F.3d 100, 103 (1st Cir. 2013). First, the Court must perform a close reading of the claim to distinguish the factual allegations from the conclusory legal allegations contained therein. Id. Factual allegations must be accepted as true, while conclusory legal conclusions are not entitled credit. Id. Second, the Court must determine whether the factual allegations present a "reasonable inference that the defendant is liable for the misconduct alleged." Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011). In sum, the complaint must provide sufficient factual allegations for the Court to find the claim "plausible on its face." García-Catalán, 734 F.3d at 103.

The Court will dismiss a pleading that fails to include "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "To avoid dismissal, a complaint must provide 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" García-Catalán, 734 F.3d at 102. "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" Id. (quoting Twombly, 550 U.S. at 557) (alteration in original). "In determining whether a [pleading] crosses the plausibility threshold, 'the reviewing court [must] draw on its judicial experience and common sense.'" García-Catalán, 734 F.3d at 103 (internal citations omitted).

III. Factual Background

A. The Parties

Seres is a start-up biopharmaceutical company focusing on developing products intended to restore the function of an imbalanced ("dysbiotic") human microbiome, the bacteria, fungi and viruses naturally present in the human gut. D. 32, ¶¶ 4, 25. Seres has its headquarters in Cambridge, Massachusetts, and its stock is traded publicly on NASDAQ. D. 32, ¶ 24. Pomerantz is Seres's Chairman, President and Chief Executive Officer ("CEO"). D. 32, ¶ 26. Trucksis is Seres's Chief Medical Office ("CMO") and Executive Vice President ("EVP"). D. 32, ¶ 27.

ES is an Austrian investment company responsible for managing fund assets. D. 32, ¶ 22. OLERS is a retirement plan responsible for managing assets for its members. D. 32, ¶ 23. ES and OLERS both purchased Seres stock during the alleged class period of June 25, 2015, to July 29, 2016 ("Class Period"), and ES and OLERS were appointed as lead plaintiffs on December 28, 2016. D. 32, ¶ 21.

B. Development of SER-109

Seres was developing SER-109 for regulatory approval and commercialization. D. 32, ¶ 32. SER-109 is a pill-based treatment that aims to prevent a particular kind of infection of the colon that causes severe and persistent diarrhea ("CDI"), in a manner that is less invasive and less harsh on the human microbiome than currently approved treatments. Id.

Seres conducted a Phase 1b/2 clinical study of SER-109 in 2013-2014 to evaluate its safety and efficacy. D. 32, ¶ 33. In September 2014, Seres announced the results of the Phase 1b/2 study. D. 32, ¶ 35. It announced that twenty-six of thirty patients across both enrolled groups in the Phase 1b/2 study (87%) had achieved the primary efficacy endpoint, measured by the patient being CDI-free eight weeks after treatment, and an overall "clinical cure rate" of 97%. Id. Three other patients

were CDI-free at the eight-week mark, but had experienced recurrences during the period of the study. Id. The Phase 1b/2 study was done without an investigational new drug application ("IND"), which would have allowed the FDA to review Seres's testing and manufacturing protocols. D. 32, ¶¶ 36-37.

In June 2015, Seres completed its IPO, and on June 26, 2015, became a publicly traded company on NASDAQ. D. 32, ¶¶ 55-56. At the time of the IPO, Seres's stock was $18 per share. D. 32, ¶ 56. On the first day of its listing on NASDAQ for public trading, the share price closed at $51.40 per share. Id.

Seres began a Phase 2 clinical study of SER-109. D. 32, ¶ 43. The FDA required Seres to conduct the Phase 2 study under an IND, meaning their manufacturing practices were subject to review and would have to be followed in the same manner as they would after the drug's approval, when the drug would be available commercially. Id. As a result, Seres transitioned the manufacture of SER-109 in-house for the Phase 2 study, whereas the drug had been manufactured by physicians at the clinical testing sites during the Phase 1b/2 study. D. 32, ¶¶ 44-45, 47. Seres also had to create a "new formulation" of SER-109 for the Phase 2 trial, eliminating any variations in dosing and strength. D. 32, ¶ 48.

The Phase 2 study measured the same primary efficacy endpoint as Phase 1b/2 – i.e., whether patients were CDI-free eight weeks after treatment. D. 32, ¶ 57. The Phase 2 study was, unlike Phase 1b/2, double-blinded and placebo-controlled. Id. It also included an "open label extension study," through which any patient who suffered from a recurrence of CDI during the Phase 2 study, from the placebo or SER-109 groups, would be able to receive an additional SER-109 treatment. D. 32, ¶ 65. Seres explained that this extension would encourage patient enrollment and provide "additional safety data and . . . greater understanding of the impact of a second dose

of SER-109." Id. The estimated "primary completion date" of Phase 2 was originally March 2016, anticipating a total of 87 test subjects, D. 32, ¶¶ 57, 71, although Seres had originally disclosed in June 2015 that it expected results to the Phase 2 trial sometime in the middle of 2016, D. 32, ¶ 83.

C. Phase 2 Interim Results

Plaintiffs allege, based on a confidential witness who was a senior executive in manufacturing and quality at Seres during the Class Period ("CW1"),[1] that Trucksis would have received updates and information regarding the Phase 2 study. D. 32, ¶ 68. Furthermore, despite the Phase 2 study being double-blinded, Plaintiffs allege that Defendants were receiving real-time updates about the interim results from medical monitors at the testing sites and clinics dealing with patients who had relapsed. D. 32, ¶¶ 67, 69. Plaintiffs' consulting expert, Ms. Chew ("Chew"),[2] who is referenced in the amended complaint, states that real-time synchronization of patient data with the company sponsoring the drug trial is an industry standard practice intended to allow companies to track safety data. D. 32, ¶ 70. Plaintiffs allege that this information would have been gathered and available in February 2016. D. 32, ¶ 71.

Plaintiffs also allege that Defendants were aware of negative interim results because patients in the Phase 2 study experienced a "high rate of serious adverse events" ("SAEs"), and patients in the SER-109 group experienced more SAEs than those in the placebo group. D. 32, ¶ 72.

[1] The parties dispute the reliability of CW1's allegations in the amended complaint. In resolving a motion to dismiss, however, the Court may assume the factual allegations in the amended complaint to be true, including CW1's statements.

[2] The parties also dispute the reliability of Chew's allegations in the amended complaint. For the same reasons explained above with respect to CW1, the Court may consider them for resolving the pending motion.

D. Phase 2 Results and Analysis

On July 29, 2016, Seres announced the eight-week results from the Phase 2 study. D. 32, ¶ 79. In a press release, Seres said that while patients taking SER-109 had a lower CDI recurrence rate than the control group, it did not achieve the primary endpoint with statistical significance. Id. The press release further stated that there had been no serious adverse events ("SAEs") in the Phase 2 study and there was no difference in other adverse event frequency or type between the SER-109 and control groups. D. 47-7. On that day, the price of Seres's stock dropped 72 percent. D. 32, ¶ 78.

Approximately six months later, on January 31, 2017, Seres issued another press release, announcing and summarizing its full analysis of the Phase 2 data, and held a conference call with a slide presentation. D. 47-8; see D. 32, ¶¶ 81, 120, 122. Although Seres had initially hypothesized that manufacturing-related issues may have impacted the Phase 2 study results, it ultimately concluded that any issues "regarding product quality or formulation" did not affect the results. D. 47-8 at 5. None of the SAEs reported during the Phase 2 trial were found to be drug-related. D. 47-8 at 5; D. 47-9 at 9. Seres identified two factors it believed to be critical in understanding the data from the Phase 2 study: (1) the polymerase chain reaction ("PCR") based method for testing study subjects for CDI; and (2) the dosage amount. D. 47-8 at 3. Seres stated that the PCR method may have caused overestimation of CDI recurrence among subjects, negatively affecting interpretation of the results. Id. Furthermore, Seres stated that previously unavailable technology indicated that subjects who received higher doses of SER-109 could, in essence, respond to the treatment more favorably than those who had received a lower dosage. Id. at 4. Seres believed testing again with an increased dosage of SER-109 could allow to advance through additional

clinical trials. D. 47-9 at 25. On March 16, 2017, Seres shared this information with the FDA and announced a new Phase 2 trial.

E. Statements about Phase 2

On June 25, 2015, Seres's Form S-1 Registration Statement (the "Registration Statement") filed with the SEC became effective. D. 32, ¶ 55. In the Registration Statement, Seres stated that it believed "the manufacturing formulation changes have resulted in a more pure form of SER-109 that, based on pre-clinical studies, is comparable in potency to that used in the Phase 1b/2 clinical study." Id. The Registration Statement also stated that Seres had "changed the manufacturing process" for the Phase 2 study. D. 32, ¶ 58. Pomerantz and Trucksis continued to reiterate these points in public statements in SEC filings, media appearances, shareholder conference calls, and public events such as health conferences – focusing investors on the purity of the new SER-109 formulation, the capacity of Seres's in-house manufacturing process, the methodological similarities between Phase 1b/2 and Phase 2 and, ultimately, Phase 2's high probability of success. See D. 32, ¶¶ 86-87, 89, 92, 94-96, 99, 106, 108-112.

IV. Procedural History

This action was instituted on September 28, 2016. D. 1. Plaintiffs were approved as the lead plaintiffs for the purported class on December 28, 2016. D. 28. Plaintiffs then filed an amended complaint. D. 32. Defendants have now moved to dismiss. D. 43. The Court heard the parties on the pending motion and took the matter under advisement. D. 59.

V. Discussion

A. Securities Exchange Act Section 10(b)

To state a claim under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated there under, a plaintiff must allege (1) a material misrepresentation or

omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 750 (1st Cir. 2016). The Private Securities Litigation Reform Act ("PSLRA") and Fed. R. Civ. P. 9(b) require a plaintiff alleging securities fraud to plead "with particularity" allegations showing a "plausible entitlement to relief." ACA Fin. Guar. Corp v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). Thus, a complaint alleging securities fraud must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). Section 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information." Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011). Rather, "[d]isclosure is required under these provisions only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" Id. (quoting 17 C.F.R. § 240.10b–5(b)).

1. Seres's Knowledge That the Phase 2 Study Would Fail

The parties agree that there is no duty to predict for investors what results the Phase 2 study would generate, but rather dispute whether Seres's alleged statements were false and misleading. Plaintiffs allege that Defendants knew certain facts that made the eventual negative results of the Phase 2 trial a foregone conclusion rather than merely uncertain. Defendants contend they were not aware of any facts that would have triggered a duty to disclose interim results from the Phase 2 study. Plaintiffs point to three allegations in the amended complaint inferring that Seres must have had knowledge about the prospective results.

a) Inference of Falsity from Open Label Extension

First, the amended complaint alleges Seres was aware of how many subjects enrolled in the open label extension of the study would receive an additional single dose of SER-109.

Defendants contend that the amended complaint contains no allegations about what it knew about the patients who enrolled in the open label extension and further that it was incapable of knowing any such information, because it was blinded as part of the study.

Plaintiffs allege that Seres was aware that test subjects were opting for an additional treatment in the open label extension, and nearly double the test subjects were taking SER-109 rather than the placebo, and, therefore, that they knew the Phase 2 results would be negative. D. 32, ¶¶ 66, 74. The amended complaint, however, does not allege that Defendants made any statements relating to the interim results of Phase 2 generally or participation in the open label extension specifically. At most, the amended complaint alleges that Defendants "touted . . . the high probability of success of Phase 2." D. 32, ¶ 60; see id., ¶ 170. But if Defendants did not make any "affirmative statement about the strength of the Phase 2 interim results nor characterized those results in any manner . . . . [Defendants] did not place the strength or nature of the Phase 2 interim results 'in play.'" City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 174 (3d Cir. 2014). Not only does this allegation fail as to specificity by failing to demonstrate plausibly why general optimism about Phase 2 was false or misleading because of the open label extension data, see ACA Fin. Guar. Corp., 512 F.3d at 58 ("[t]he PSLRA requires plaintiffs' complaint to 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading'" (quoting 15 U.S.C. § 78u-4(b(1)), it also fails to do more than "contrast a defendant's past optimism with less favorable actual results," which does not support a claim of securities fraud, id. at 62 (internal quotation marks and citations omitted). Accordingly, the open label extension does not create any inference that Defendants' statements were false or misleading and does not support a claim for securities fraud here.

b) Inference of Falsity from SAEs

Second, the amended complaint alleges Seres could have inferred "that Phase 2 was not going as planned" because of the number of SAEs experienced by subjects. D. 32, ¶¶ 72, 75. This allegation is insufficient, because Plaintiffs have not alleged that Seres knew the results or had access to the results of Phase 2 despite being double-blinded. Sponsors receive notice of SAEs that occur in their trials, see 21 C.F.R. § 312.64(b), but such notice does not "unblind" the patient, by revealing whether they were in the SER-109 or placebo groups, to report these SAEs to the FDA unless, in relevant part, the event relates to an endpoint of the study (e.g., CDI recurrence) and there is a "causal relationship between the drug and the event," 21 C.F.R. § 312.32(c)(5); see Fed. Drug Admin., Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA/BE Studies, at 16-17 (Dec. 2012), available at https://www.fda.gov/downloads/Drugs/Guidances/UCM227351.pdf (last visited March 30, 2018). Because none of the SAEs were found to be drug-related, D. 32, ¶ 116; D. 47-8 at 5; D. 47-9 at 9, even taking the allegations in the amended complaint as true, the high number of SAEs did not have any relationship to SER-109, and thus did not on its own diminish the probability of the Phase 2 study's success. Accordingly, the SAEs do not create an inference that Defendants' statements were false or misleading, and here do not support a claim for securities fraud.

c) Inference of Falsity from Expected Completion Date

Third, the amended complaint alleges that Seres would have been aware of the open label extension and SAE data in February 2016 because the expected completion date for the study was March 2016 according to a website post on clinicaltrials.gov. D. 32, ¶¶ 71, 75. However, this expected completion date was set in May 2015, with Seres later supplementing its disclosures to state that it estimated a later date of completion, D. 32, ¶ 71, and statements in both earnings calls

and public filings confirmed that Seres did not expect Phase 2 study results until mid-2016. See, e.g., D. 47-12 at 4; D. 47-13 at 3; D. 47-14 at 4. The only significance ascribed to February 2016 in the amended complaint is that by that time the Phase 2 study had reached full enrollment, D. 32, ¶ 73, but does not make any specific allegations about what data would have been collected or analyzed by then, or how many SAEs had occurred. Accordingly, the original expected completion date of March 2016 for Phase 2 does not create any inference that Defendants' statements were false or misleading, nor does it create any inference that Defendants had the knowledge necessary for such statements to be false, even considering the allegations regarding Chew.[3]

2. Failure to Disclose Material Differences between Phase 1b/2 and Phase 2

Plaintiffs allege that a series of statements by Seres relating to: (1) similarities and differences between the Phase 1b/2 study and the Phase 2 study were false or materially misleading with respect to SER-109's dosage or potency in Phase 1b/2 and Phase 2, D. 32, ¶¶ 7, 14, 15, 48, 53, 54, 55, 60; (2) changes in manufacturing and Seres's confidence in its ability to manage the pills' manufacture, D. 32, ¶¶ 7, 39-40, 42, 45, 47, 54, 58, 61, 82, 88, 92, 119; and (3) comparing

[3] The insufficiency of these allegations also undercuts Plaintiffs' allegation that after inferring the negative results in the Phase 2 study in February 2016, Pomerantz, Trucksis and other Seres executives sold their own Seres stock from March 2016 until the end of the class period, D. 32, ¶¶ 76, 124-37, and that these sales before disclosure of the Phase 2 results support an inference of scienter. While the plans were executed in February and March 2016, D. 32, ¶ 76, during the Phase 2 study, which in principle allowed them "to take advantage of an inflated stock price or insider information," George v. China Auto Sys., Inc., 2012 WL 3205062, at *9 (S.D.N.Y. Aug. 8, 2012), thus initially rebutting the trading plan defense, see Emps.' Ret. Sys. of Gov't of V.I. v. Blanford, 794 F.3d 297, 309 (2d Cir. 2015); In re Biogen Sec. Litig., No. 05-cv-10400-WGY, 2007 WL 9602250, at *14 (D. Mass. Oct. 25, 2007), as the Court has explained above, Plaintiffs have not plausibly alleged that Defendants knew of or had access to information that made their public statements materially misleading and false. In other words, because Plaintiffs have failed to establish the underlying misleading and false nature of Defendants statements, no inference of scienter can be drawn from the timing of their trading plans and stock sales.

Phase 2 to Phase 1b/2 as a similar study given the successful results in Phase 1b/2, D. 32, ¶¶ 16 (describing the trials as "highly similar," with the "main difference" being location of trial sites), 89 (same), 95-96 (describing Phase 2 as "like the first study"), 106 (describing changes relating to dosage as "minimal"), 170 (describing studies as "highly similar"), were false and materially misleading. In each case, Plaintiffs have failed to allege with specificity that these statements were false or misleading.

As to the strength of the drug, even crediting Plaintiffs' argument that potency is focused on the relative strength or efficacy of a drug rather than its quantity of a chemical content, Plaintiffs allege that this statement was false because the July 29, 2016 press release revealed that in the Phase 2 study, SER-109 had not achieved its primary endpoint, and in some portions of the patient population performed worse than a placebo. D. 32, ¶ 115. This statement does not mention either the chemical content or potency of SER-109, but rather discloses that Phase 2 had had disappointing outcomes. Seres did not make any statements linking the Phase 2 results to potency or dosage until the January 31, 2017 press release after the class period, D. 32, ¶ 81, and nothing in the amended complaint prior to that plausibly alleges that "this information was known to the defendants at the relevant time." ACA Fin. Guar. Corp., 512 F.3d at 62-63. The amended complaint characterizes Defendants' intention that purity would be improved and potency would remain consistent, and without imputing plausible knowledge to the contrary, seek to characterize this disappointment as fraud.

As to Seres's manufacturing capabilities, Plaintiffs allege that transitioning manufacturing operations for a drug in development to a new facility takes approximately eighteen to twenty-four months to be done successfully, but Seres moved its manufacturing of SER-109 to be used in Phase 2 in-house in only eight months. D. 32, ¶ 38. However, the amended complaint does not allege

that Defendants made any statements about the timeline of the in-house manufacturing processes. Instead, Plaintiffs' allegations amount to a theory that Seres's optimism about its in-house manufacturing was misleading because its struggles in ramping up production could not be corrected and made a successful Phase 2 study unlikely. These allegations amount to "fraud by hindsight" alleging that the outcome was assured because it in fact occurred, which is insufficient to support a claim for securities fraud. See Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 457 (1st Cir. 2017); ACA Fin. Guar. Corp., 512 F.3d at 62. Furthermore, even if the optimism was false, the amended complaint falls short in alleging that Defendants were aware of any information that the manufacturing process would risk affecting the Phase 2 results, rather than generalized struggles in ramping up the in-house manufacturing process. ACA Fin. Guar. Corp., 512 F.3d at 62-63.

As to the similarity of Phases 1b/2 and 2, Plaintiffs rely on their allegations concerning potency and manufacturing to argue that describing the two studies as particularly similar was misleading. As the Court explained above, those allegations do not plausibly show that such statements were false or misleading, or that Defendants knew the facts at the time that would make them so. Furthermore, these differences, which Defendants did not emphasize in comparing the studies, were disclosed. For example, the Phase 2 study, unlike the Phase 1b/2 study, would require Seres to manufacture SER-109 in-house, D. 32, ¶ 47, and this difference was disclosed on multiple occasions in public filings and statements, even if Defendants did not focus on it in attempting to compare the studies positively, see D. 32, ¶¶ 92, 99. Excluding issues concerning potency, dosage or manufacturing, each of the statements Plaintiffs allege were false or misleading specified the ways in which the studies would be similar, none of which Plaintiffs contend were false or misleading. For example, in the November 10, 2015 earnings call, Pomerantz, in

describing the studies as "highly similar," spoke about their desire to show the same results with a broader geographic scope of patients in the United States. D. 32, ¶ 89. At a conference on June 7, 2016, Pomerantz said that the primary endpoint would be the same in Phase 2 as it had been in Phase 1b/2, and in noting the "minimal" changes between the two studies, included references to alteration of the drug formula and moving manufacturing in-house. D. 32, ¶ 106.

Accordingly, Defendants' alleged statements comparing the Phase 1b/2 and Phase 2 studies were not false or misleading, and cannot support a claim for securities fraud.

3. Non-Actionable Statements

a) Statements by Third Parties

Defendants contend that several of the statements Plaintiffs allege were false or misleading, regardless, are not actionable. First, Defendants argues that several of the alleged statements were not made by Seres, but rather by third-party media figures and financial analysts assessing Seres's stock and business prospects. D. 32, ¶¶ 87, 91, 102-103, 108-112, 117. Plaintiffs argue that the analyst statements are entangled with statements made by Seres, and therefore are actionable. "[L]iability may attach to an analyst's statements where the defendants have expressly or impliedly adopted the statements, placed their imprimatur on the statements, or have otherwise entangled themselves with the analysts to a significant degree. . . . [T]he court will determine whether" the Plaintiffs' allegations "could establish a significant and specific, not merely a casual or speculative, entanglement between the defendants and the analysts." In re Cabletron Sys., Inc., 311 F.3d 11, 37-38 (1st Cir. 2002) (quoting Schaffer v. Timberland Co., 924 F. Supp. 1298, 1310 (D.N.H. 1996)). In other words, when the analysts are "mouthpieces" for the company, their statement's become the company's. Id. at 38.

The "entanglement test" also applies to analyst and other third-party statements by defendants that "intentionally foster a mistaken belief concerning a material fact." Id. (quoting Elkind v. Liggett & Myers, Inc., 635 F.2d 156, 163–64 (2d Cir. 1980), superseded by statute on other grounds, 15 U.S.C. § 78bb(a)(1)). Most relevant here, the First Circuit found that the defendants in In re Cabletron, 311 F.3d at 38, had intentionally fostered a mistaken belief by analysts when they told analysts, who in turn reported the information, that the defendants' products would "ship in volume in the second week of April" and were "ramping up according to plan." Id. The First Circuit noted that the purpose of the analysis is to "separate[] mere salesmanship from fraudulent misrepresentation." Id. For this reason, some of the third-party statements alleged by Plaintiffs are facially insufficient. See D. 32, ¶¶ 87 (responding to Pomerantz's description of Phase 1b/2 by saying "you are doing amazing things"), 108-114 (reporting "high confidence" in Phase 2 results based on dinner with Seres management), 117 (describing unexpected and disappointing Phase 2 results).

However, two statements by analysts alleged in the amended complaint could satisfy the entanglement test because they adopt expectations of the Phase 2 study's success based on Defendants' presentations of the successful Phase 1b/2 data. D. 32, ¶¶ 91, 102-103. Even if these statements were considered to be beyond mere salesmanship, they still cannot support a claim for securities fraud. In the first statement, an analyst responded to Pomerantz's presentation on the November 10, 2015 earnings conference call by concluding based on the primary endpoint data in Phase 1b/2 that "we expect Phase 2 to be positive." D. 32, ¶ 91. In the second statement, two analysts responded to information in the 2015 Form 10-K by describing the Phase 2 study as similar to Phase 1b/2 and concluding that the study had a high success rate. D. 32, ¶¶ 102-103. These statements included differences between the studies the analysts believed to be material,

and, in the case of one of them, included differences Plaintiffs have omitted from their reproduction of the statement in the amended complaint. See D. 32, ¶ 103 (describing "important differences that we believe will favor SER-109 highlighted below" where amended complaint does not reproduce those differences). The omissions Plaintiffs allege made the underlying statements misleading relate to the same allegations of potency and manufacturing distinctions, which as the Court previously explained were not misleading and were not made with any knowledge indicating they were false. Furthermore, these distinctions had already been disclosed prior to the conference call in the Registration Statement, see D. 32, ¶ 83, and in Seres's 2015 Form 10-K, respectively, see D. 32, ¶ 99.

b) Statements outside the Class Period

Second, Defendants argue that several of the alleged statements would have occurred outside the alleged class period, June 25, 2015 through July 29, 2016, D. 32, ¶ 171, and thus these statements could not have been considered, much less material, in the decision making of relevant shareholders deciding to purchase Seres stock. The statements Seres identifies occurred on August 11, 2016, and January 31, 2017. D. 32, ¶¶ 80-81, 119, 122. The Court must "limit [its] analysis of the [] plaintiffs' claims . . . to the statements allegedly made by defendants within the Class Period." Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1217 n.31 (1st Cir. 1996) (citing In re Clearly Canadian Secs. Litig., 875 F. Supp. 1410, 1420 (N.D. Cal.1995)), superseded by statute on other grounds, 15 U.S.C. § 78u–4(b)(1). Accordingly, these alleged statements may not be considered to support Plaintiffs' claim for securities fraud. See Rosenbaum Capital LLC v. Bos. Commc'ns Grp., Inc., 445 F. Supp. 2d 170, 173 n.1 (D. Mass 2006).

c) Optimistic Puffery Statements

Third and finally, Defendants argue that several of the alleged statements are generalized and optimistic puffery by Pomerantz and Trucksis. D. 32, ¶¶ 14, 87 (treatment for SER-109 "has one times ten to the eighth bacteria in spore form in there and . . . that's how we cured 97% of the people with CDI"); id., ¶¶ 16, 89, 95 (comparing the Phase 2 trial to the "amazing," "unprecedented," "remarkable" results of the Phase 1b/2 study); id., ¶ 92 (touting Seres's manufacturing as "what we do better than anybody"); id., ¶ 86 (claiming a high probability of success).

Statements that amount to "rosy affirmation" of a company's prospects or products are not actionable statements for a securities fraud claim. In re Viogen Inc. Sec. Litig., 193 F. Supp. 3d 5, 42 (D. Mass. 2016) (claiming that company sold a "terrific product that is going to perform very well in the market" was not actionable). But the statements must be "so vague, so general, or so loosely optimistic that a reasonable investor would find [them] unimportant to the total mix of information." In re Smith & Wesson Holding Corp. Sec. Litig., 604 F. Supp. 2d 332, 342 (D. Mass. 2009). Further, similarly to the safe harbor provision, only purely forward-looking statements are protected. Id.

Plaintiffs dispute the vagueness and generality of some of the statements. First, Plaintiffs contend that they specifically allege that the Pomerantz statement about high probability of success was qualified by stating that his belief was supported by clinical data he had seen that indicated a high probability of success. D. 32, ¶ 86. Second, when stating that Seres's manufacturing was "what we do better than anybody," Plaintiffs argue that this statement shouldn't be viewed as superlative in isolation, but rather in the context of a broader and more generic claim to analysts, stating again that Phase 2 had a high probability of success. Id., ¶ 92. Third, Plaintiffs argue that

any vague statements about purity or potency must also be read in context, because they allege that these statements were supported by reference to the 97% success rate in Phase 1b/2. Plaintiffs do not allege that these generic portions of the statements by Defendants were false and misleading, see, e.g., D. 32, ¶ 93 (explaining bases for claim that the statement in D. 32, ¶ 92, was false and materially misleading), and thus, Defendants' argument on this issue is moot. However, to the extent they are alleged to be false in context of and reference to specific claims concerning potency or in-house manufacturing, the Court has already found that those statements were not false and misleading, and that Plaintiffs have not plausibly alleged that Defendants knew them to be false and misleading when they were made.

B. Securities Exchange Act Section 20

Under Section 20(a) of the Securities Exchange Act, when any "person" has been found liable for violating another section of the Securities Exchange Act:

> "[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action."

15 U.S.C. § 78t(a). Count II, alleging control person liability, rises and falls with the derivative claim, Count I. See Hill v. Gozani, 638 F.3d 40, 70 (1st Cir. 2011). Accordingly, because Count I under Section 10(b) and Rule 10b-5 fails, so too must Count II.

VI. Conclusion

For the foregoing reasons, the Court ALLOWS Defendants' motion to dismiss, D. 43.

So Ordered.

/s/ Denise J. Casper
United States District Judge