UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

STEVEN EMERSON, individually and on behalf of all others similarly situated, SHELDON GRONER, BARRY HEANY, MARK HANESS, SCOTT HARTMANN, SATYA KUNAPULI, LIRIO FIOCCHI, RAUL ZAMUDIO, and OMER YUKSEL, Plaintiffs,	)	Civil Action No. 17-12137-PBS
v.	)	
GENOCEA BIOSCIENCES, INC., WILLIAM D. CLARK, JONATHAN POOLE, and SETH HETHERINGTON. Defendants.	)	

MEMORANDUM AND ORDER

December 6, 2018

Saris, C.J.

I. INTRODUCTION

Plaintiffs bring this class action against Genocea Biosciences, Inc. and three of its corporate officers alleging violations of Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 (Count I). The suit also brings derivative claims against the officers, President and Chief Executive Officer William D. Clark, Chief Financial Officer Jonathan Poole, and Chief Medical Officer Seth Hetherington, under Section 20(a) of the Exchange Act (Count II). Plaintiffs allege that Defendants violated the Exchange Act

and Rule 10b-5 by making materially misleading statements to investors about its clinical test results for a genital herpes immunotherapy treatment called GEN-003.

Before the Court are (1) Defendants' motion to dismiss all counts for failure to state a claim (Docket No. 59) and (2) Plaintiffs' motion to strike certain exhibits and documents submitted in support of Defendants' motion to dismiss (Docket No. 69). For the reasons stated below, after hearing, Defendants' motion to dismiss is **ALLOWED**. Because the Court only relied on the uncontested documents, the Court need not rule on the motion to strike the other documents.

II. FACTUAL BACKGROUND

Facts are drawn from Plaintiffs' consolidated amended complaint ("Compl.")(Docket No. 49), as well as documents uncontested by Plaintiffs.[1] At this stage of the litigation, the Court must "accept all factual allegations in the complaint as true." See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007).

A. Genital Herpes Simplex Virus

Genocea is an early-stage biopharmaceutical company based in Cambridge, Massachusetts, that researches, develops, and seeks to bring to market T cell vaccines to treat infectious

[1] See discussion of Plaintiffs' motion to strike in Section III, below.

diseases. Compl. ¶¶ 2, 20. Throughout the proposed Class Period – March 31, 2016 through September 25, 2017 – Genocea's only product candidate in active clinical development was a genital herpes immunotherapy treatment called GEN-003. Id. ¶¶ 1, 3.

The genital herpes simplex virus (HSV-2) is an incurable disease. Id. ¶ 30. After a patient is initially infected, the herpes virus can remain latent in the body until it periodically and sporadically reactivates; such reactivation is highly variable in individual patients. Id. ¶¶ 30–31. While the virus is active, it travels to a patient's skin and mucus membrane in a process known as "viral shedding." Id. ¶ 30. During active periods a patient may also develop genital lesions – sometimes referred to as "outbreaks" – because of the virus. The virus can be sexually transmitted during viral shedding even if the patient appears "asymptomatic" *i.e.*, does not appear to have genital lesions. Id. ¶ 31.

At the time GEN-003 was in clinical trials, there were already products on the market to treat genital herpes, either through a daily pill to decrease the risk of transmission and outbreaks or through pills that patients take once an outbreak occurs to lessen the pain and discomfort. Id. ¶ 3. One drug, acyclovir, is very effective in minimizing genital lesion outbreaks and is "dirt cheap." Id. ¶ 30. Defendants were developing GEN-003 as a therapeutic vaccine, which could be

administered every six to twelve months, rather than daily, to patients already infected with the virus. Id. ¶¶ 3, 27–28.

B. The Phase 2b Clinical Trial

Beginning in 2012, Genocea tested GEN-003's efficacy in three phased clinical trials – Phase 1/2a, Phase 2, and Phase 2b. Id. ¶ 4. During each of the phases, participants were randomly assigned to receive either a dose of the vaccine or a placebo. Id. ¶ 5. To establish a baseline viral shedding rate for each patient, Genocea instructed trial participants to swab their genital areas twice-daily for 28 days before receiving any treatment. Id. ¶ 36. Participants then received three injections at 21-day intervals of either the vaccine or placebo. Id. ¶ 42. Immediately following the last injection, each participant swabbed his or her genital areas again twice-daily for 28 days ("immediately post-dosing"). Participants then swabbed again for 28 days at six months post-dosing, and twelve months post-dosing. Id. ¶¶ 36, 42. Participants submitted their swabs for viral shedding analysis, as well as forms with self-reported lesion recurrences for analysis of genital lesion rates. Id. ¶36.

In anticipation of commercialization, Genocea announced a Phase 2b trial which would test a modified version of GEN-003. Id. ¶ 53. Up until this point, GEN-003 had been manually formulated; the modified GEN-003 would be manufactured using a

commercial, scalable process. Id. ¶ 53. The goal of Phase 2b was to ensure that the new formulation remained safe and effective, and the primary end point for the phase was the reduction in viral shedding rates immediately post-dosing. Id. ¶¶ 53-54. Secondary endpoints of the Phase 2b trial included viral shedding rate reductions at six and twelve months post-dosing and reductions in genital lesion recurrence. Id. ¶¶ 54. The Phase 2b trial contained two dose groups and one placebo control group. Id. ¶ 55. The two doses were a 60 µg per protein/50 µg of Matrix-M2 dose ("60/50 dose"), and a 60 µg per protein/75 µg of Matrix-M2 dose ("60/75 dose"). Id. ¶ 55.

On September 29, 2016, Genocea revealed results for the study's primary endpoint, the Phase 2b viral shedding results for immediately post-dosing. Id. ¶ 73. The company found that the 60/50 dose produced a 40% reduction in viral shedding and was statistically significant compared to both the baseline and placebo. Id. ¶ 73. The 60/75 dose showed a 27% decrease in viral shedding, but that result was not statistically significant against either the baseline rate or placebo control group. Id. ¶ 73. The press release stated, in part:

> The study achieved its primary endpoint, with GEN-003 demonstrating a statistically significant reduction of 40 per cent in the rate of viral shedding in the 60 µg per protein/50 µg of Matrix-M2 dose group compared to both baseline and placebo. The viral shedding rate reduction for this dose was consistent with its

> performance at the same time point in a prior Phase 2 trial.

Id. ¶ 73. On an earnings call held the same day, CMO Hetherington emphasized that GEN-003's viral shedding rate reduction results for Phase 2b were "consistent with the statistically significant 41% reduction that we observed for this dose group in the prior Phase 2 trial, this gives us great confidence that the effect is robust and replicable." Id. ¶ 75.

On November 3, 2016, CEO Clark announced that the six month post-dosing viral shedding results for Phase 2b would be released "later in the first half of 2017." Id. ¶ 76. The six month viral shedding results would not be released with the six month genital lesion results; this differed from the reporting schedule used previously in Phase 2. Id. ¶ 76.

On January 5, 2017, Genocea released the Phase 2b six month post-dosing genital lesion results. Id. ¶ 57. At six months post-dosing, two different GEN-003 doses produced statistically significant reductions in genital lesion rates both against participants' baseline and the placebo control group. Id. ¶ 57. The press release announced, "Positive 6-Month Results from GEN-003 Phase 2b Clinical Trial – Trial meets statistical significance vs. placebo for multiple clinical endpoints through six months." Id. ¶ 78. The release did not mention the Phase 2b six month post-dosing viral shedding results. Id.

According to two confidential witnesses, at a company-wide meeting following the announcement of the six month genital lesion results, Clark announced that there was "no interest" from potential funding partners in sponsoring the planned Phase 3 trials for GEN-003. Id. ¶ 60. Clark stated the company was going to focus more heavily on its oncology program. Id. A confidential witness also noted that layoffs occurred after the meeting. Id.

SEC filings in February reiterated that the "viral shedding rate reduction data at six months post dosing [was] expected in the first half of 2017." Id. ¶¶ 83-84.

On May 5, 2017, Genocea filed its first quarter 10-Q, which summarized the genital lesion data that Genocea announced in January 2017, describing it as "positive." 5/5/2017 Form 10-Q, Q1 2017 at 21. The company still did not disclose the Phase 2b six month viral shedding results, but stated "viral shedding rate reduction data at six-months and twelve-months post dosing is expected in the middle of 2017." Id. The form also reassured investors that Genocea continued "to expect that GEN-003 will be Phase 3-ready in the fourth quarter of 2017." Compl. ¶ 85.

At a July 2017 internal "all hands" meeting, Clark announced the Phase 2b twelve month post-dosing results for both viral shedding and genital lesions. At twelve months post-dosing, GEN-003 showed statistically significant reductions in

genital lesions for patients against the baseline rate as well as the placebo control group. Id. ¶ 57. However, the viral shedding results were not positive. Participants in the 60/50 dose saw a 42% reduction in viral shedding; while this was statistically significant against the baseline rate, it was not statistically significant against the placebo group, which saw a 52% decrease in viral shedding. Id. ¶ 88. The placebo group had performed better than the GEN-003 dose group in reducing viral shedding rates. Id. ¶ 61.

Outraged by the results, company scientists questioned Clark about the still undisclosed six month viral shedding results. Id. According to a confidential witness present at the meeting, scientist Scott Munzer asked Clark how the twelve month placebo result "was even possible." Id. Clark stated that he did not have the answers and that Hetherington was better positioned to answer. Id. Hetherington responded that such results had happened in other trials and that he would be looking into it more. Id.

On July 24, 2017, the company issued a press release announcing the Phase 2b twelve month post-dosing results. The press release stated that the 60/50 dose of the Phase 2b clinical trial had shown a statistically significant reduction in the median genital lesion rate and that "[o]ther clinical endpoints for this dose improved or were consistent with

previously reported positive data." Id. ¶ 87. The press release language was silent as to the twelve month viral shedding results; however, the chart included with the press release disclosed the negative twelve month viral shedding results and the placebo effect.

Slides distributed for the July 24, 2017 analyst call announced: "GEN-003 Phase 3 on Track to Start by End of 2017," and "GEN-003 Strongly Positioned Ahead of Phase 3," with a footnote on each slide stating "[s]ubject to obtaining capital." Id. ¶ 89. Defendant Clark started the analyst call by stating: "I am delighted to be sharing the most important readout from our Phase 2b trial and maybe the most important data in Genocea's history as we look ahead to Phase 3." Id. ¶ 90. On the call, Hetherington explained the placebo effect seen in the twelve month viral shedding data, stating:

> We know that GEN-003 works by reducing viral shedding and believe that variability in shedding data is a consequence of the sporadic nature of shedding in the small number of subjects provided [sic] data at this time point. We do not expect that this will be a factor in Phase 3 studies, given the much larger sample size.

Id. ¶ 91. On July 24, 2017, after the announcement of the Phase 2b twelve month results, Genocea's stock price increased to over $6.00/share. See Docket No. 60 at 32.

During the proposed class period, Clark and Hetherington did not sell any of their Genocea stock. Poole made two sales of

Genocea common stock – the first on May 8, 2017 and the second on July 24, 2017, the same day Genocea issued the Phase 2b twelve month post-dosing results. Id. ¶¶ 101–102. Until the summer of 2017, Poole had not sold any of the stock he had acquired since joining the company in April 2014. Id. ¶ 100. On May 8, Poole sold 6,213 shares of common stock. 5/10/17 Poole Form 4. On May 10, 2017, Poole entered into a 10b5-1 plan authorizing his broker to sell shares when Genocea's stock price hit $6.00/share. Ex. W, Rule 10b5-1 Trading Plan Between Jonathan Poole and E*TRADE Securities LLC.

Finally, on September 25, 2017, after financial markets had closed, Genocea issued a press release announcing that it would not be moving forward with the planned Phase 3 clinical trial of GEN-003. Instead, the company stated that it was "exploring strategic alternatives for GEN-003, and "ceasing GEN-003 spending and activities and reducing its workforce by approximately 40 percent." Compl. ¶ 95. The next day, Genocea's share price fell $4.08, or 76.5%, to close at $1.25. Id. ¶ 96.

The Phase 2b six month post-dosing viral shedding results have, to this date, never been publicly disclosed.

III. PLAINTIFFS' MOTION TO STRIKE

Defendants filed over fifty exhibits and other documents in support of their motion to dismiss. In response, Plaintiffs moved to strike thirty-three of those documents. Ordinarily when

ruling on a motion to dismiss under Rule 12(b)(6), "a court may not consider any documents that are outside of the complaint, or not expressly incorporated therein, unless the motion is converted into one for summary judgment." Alt. Energy, Inc. v. St. Paul Fire & Marine Ins. Co., 267 F.3d 30, 33 (1st Cir. 2001). However, there are "narrow exceptions" to this rule "for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claims; or for documents sufficiently referred to in the complaint." Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993); accord Miss. Pub. Employees' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 86 (1st Cir. 2008).

Plaintiffs do not contest thirty documents filed by Defendants.[2] The uncontested documents include various press releases, SEC filings, transcripts of investor calls and published scientific articles referred to in the complaint. Accordingly, the Court considered these documents for the

[2] Plaintiffs do not contest fifteen documents which they agree are relied on in the complaint: Exhibits E, H, I, L, M, P, Q, R, T, U, Y, Z, BB, and the May 5, 2017 and August 9, 2017 Form 10-Qs. Docket No. 70 at 1 n.1. The other unchallenged documents include Exhibit W, a medical dictionary definition (Docket No. 60 at 4 n.3), Genocea's stock chart price (Docket No. 60 at 32-33), and selected Form 4s for Defendants Poole, Hetherington, and Clark, as well as other Genocea leadership from April 12, 2014 through July 24, 2017. A summarized list of these documents can be found in Appendix A to Defendants' opposition to Plaintiffs' motion to strike. See Docket No. 77-1, "Appendix A". Defendants also filed three exhibits with their reply brief which Plaintiffs did not have an opportunity to contest. The Court also does not consider these exhibits – Exhibits GG, HH, and II - when ruling on the motion to dismiss.

purposes of Defendants' motion to dismiss. See Shaw v. Dig. Equip. Corp., 82 F.3d 1194, 1220 (1st Cir. 1996) superseded by statute on other grounds (holding a court "may properly consider the relevant entirety of a document integral to or explicitly relied upon in the complaint, even though not attached to the complaint, without converting the motion into one for summary judgment"). The Court did not consider other, contested exhibits and documents Defendants submitted in ruling on the motion to dismiss, so need not rule on the motion to strike.

IV. DEFENDANTS' MOTION TO DISMISS

A. Standard of Review

Plaintiffs alleging violations of Section 10(b) must plead "(1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) in connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 40 (1st Cir. 2014). Rule 9(b) requires a plaintiff "alleging fraud or mistake" to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Additionally, under the Private Securities Litigation Reform Act ("PSLRA") the complaint must "specify each statement alleged to have been misleading" as well as the "reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). The PSLRA also requires plaintiffs to "state with particularity facts

giving rise to a strong inference that the defendant acted with" scienter. 15 U.S.C. § 78u-4(b)(2)(A); see also ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008) (describing the PSLRA's pleading standard for scienter as "rigorous"). However, while the "pleading requirements under the PSLRA are strict, they do not change the standard of review for a motion to dismiss." Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002) (citation omitted); see also Tellabs, 551 U.S. at 322.

Defendants moved to dismiss the complaint in its entirety based on Plaintiffs' failure to allege any material misstatements or omissions, failure to allege facts supporting a strong inference of scienter, and failure to sufficiently plead loss causation. Plaintiffs' case rests largely on the allegation that Defendants knowingly or recklessly omitted the Phase 2b six month post-doing viral shedding test results, thereby causing members of the class to purchase Genocea's stock at an artificially inflated price.

B. Material Misrepresentation or Omission

Plaintiffs argue that Defendants' failure to disclose the Phase 2b six month post-dosing viral shedding results was a material omission that would have altered the total mix of information available in light of Genocea's positive statements about other Phase 2b results, the overall importance of viral

shedding results, and GEN-003's expected marketability. At the hearing, Plaintiffs directed the Court to three specific instances in which they allege Defendants made misleading statements due to the omission of the six month viral shedding data: January 5, 2017, May 5, 2017, and July 24, 2017.[3]

An omission is materially misleading when there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231–32 (1988) (internal quotation omitted). However, "it bears emphasis that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information. Disclosure 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." Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011) (internal quotation

[3] The complaint also alleges another category of misstatements related to Defendants' touting "statistically significant," "consistent," and "positive" clinical trial results. See Compl. ¶¶ 62-72. At the September 25, 2018 hearing before the Court, Plaintiffs' counsel acknowledged that allegations related to swabbing protocol and the Poisson statistical model were "more icing on the cake and not misstatements." Docket No. 86 at 18. Plaintiffs' counsel also stated at the hearing that the "heart of this case" rests on three instances – January 5, 2017, May 5, 2017, and July 24, 2017 - when Defendants' statements were allegedly misleading due to their failure to disclose the Phase 2b six month post-dosing viral shedding results. See id. This Court focuses on the material omission of the Phase 2b six month post-dosing viral shedding results in ruling on Defendants' motion to dismiss.

omitted). Importantly for this case, "[a] statement cannot be intentionally misleading if the defendant did not have sufficient information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it." N. J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 45 (1st Cir. 2008).

Plaintiffs do not know the contents of the Phase 2b six month viral shedding results, but urge the Court to infer that Genocea had the six month viral shedding results as early as January 2017, and that the results were negative. Plaintiffs suggest that Defendants had the six month viral shedding results in January 2017 because (a) Genocea had a pattern of releasing genital lesion and viral shedding data at the same time, and (b) Clark stated at a company-wide meeting on January 5, 2017 that there was "no interest" from potential funding partners in sponsoring the planned Phase 3 trial. Compl. ¶¶ 60, 72. Neither fact supports this inference.

Defendants alerted investors before January 2017 that the six month viral shedding results would not be released on the same timeline as the genital lesion results. On the September 2016 investor call, Hetherington stated that the release of the six month viral shedding results "may not be simultaneous [with genital lesion results] because . . . those assays have to be

run." Ex. P, 9/26/16 Investor Call, at 6. He was "hopeful" the viral shedding results would be "available around the first quarter of next year," but that it was unclear exactly when the results would be available "based on the sample acquisition and running of the assays." Id. Clark stated on November 3, 2016 that the six month post-dosing viral shedding results would be released "later in the first half of 2017." Compl. ¶ 76; accord Ex. R, Transcript of November 3, 2016 Genocea Biosciences, Inc. Q3 2016 Investor Call, at 2. Whether "first quarter" or "first half," investors were alerted that the viral shedding results were not expected at the same time as the genital lesion results for this Phase. Additionally, SEC filings in February and May of 2017 reiterated that the six month post-dosing viral shedding data was expected in the "first half of 2017." Compl. ¶ 84; 5/5/2017 Form 10-Q, Q1 2017 at 21. Without more, the Court cannot reasonably infer that the Defendants had the six month viral shedding results in January 2017. The only inference that can be drawn is that Defendants had the six month results by the time they released the twelve month post-dosing results in July 2017.

Clark's January 2017 statement also provides little support for the inference. According to two confidential witnesses, at a company-wide meeting in January 2017, Clark announced that there was "no interest" from potential funding partners in sponsoring

the planned Phase 3 trials and that the company was going to focus more heavily on its oncology program. Compl. ¶ 60. Plaintiffs argue there was "no interest" because Defendants must have had the negative six month viral shedding results at that point, which must have scared off potential funders. This is farfetched because there are no factual allegations or even a reasonable inference that Defendants told potential funders about the six month viral shedding results that they allegedly knew at the time. Plaintiffs speculate as to why there was "no interest" from funders and then ask the Court to infer Defendants had the six month results in January 2017 based on that speculation. The Court, without more, cannot reasonably draw such an inference. See Rodriguez-Vives v. P. R. Firefighters Corps of P. R., 743 F.3d 278, 286 (1st Cir. 2014) (noting that the "bareness of the factual allegations" may "make[] clear that the plaintiff is merely speculating about the fact alleged and therefore has not shown that it is plausible that the allegation is true").

Drawing all reasonable inferences in Plaintiffs' favor, the Court infers that Defendants had the Phase 2b six month post-dosing viral shedding results in July 2017 and that these results were not positive. If they had been positive, then Defendants would have released them.

Accordingly, the Court only considers the allegedly material misstatements made on July 24, 2017. On that date, Defendants announced the Phase 2b twelve month post-dosing results for both genital lesions and viral shedding. The company's press release declared "Genocea Reports Positive Top-Line 12-Month Phase 2b Data for GEN-003 in Genital Herpes." In the release, the company announced that at twelve months post-dosing, the 60/50 dose demonstrated a statistically significant reduction in the medial genital lesion rate and that "[o]ther clinical endpoints for this dose improved or were consistent with previously reported positive data." Compl. ¶ 87. The second page of the release included a chart disclosing that at twelve months post-dosing, GEN-003 did not produce a statistically significant reduction in viral shedding compared to the placebo group. The press release's language made no mention of the twelve month viral shedding results that were disclosed and was silent about the undisclosed six month viral shedding results.

Slides distributed for an analyst call that same day declared "GEN-003 Phase 3 on Track to Start by End of 2017," and "GEN-003 Strongly Positioned Ahead of Phase 3," with a footnote on each slide stating "subject to obtaining capital." Compl. ¶ 89. On the analyst call, Clark declared the twelve month results were "the most important readout from [the] Phase 2b trial and

maybe the most important data in Genocea's history as we look ahead to Phase 3." Compl. ¶ 90. In response to a question about the placebo effect seen for the twelve month viral shedding results, Hetherington stated:

> We know that GEN-003 works by reducing viral shedding and believe that variability in shedding data is a consequence of the sporadic nature of shedding in the small number of subjects provided [sic] data at this time point. We do not expect that this will be a factor in Phase 3 studies, given the much larger sample size.

Id. ¶ 91. Plaintiffs allege that each of these statements was rendered materially misleading because Defendants omitted the Phase 2b six month post-dosing viral shedding results. Id. ¶¶ 87-91.

The question is whether the six month viral shedding results were material facts "necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). Plaintiffs do not clearly explain why the disclosure of the negative six month viral shedding results in July would significantly alter the total mix of information available to investors who, at that point, had the negative twelve month results. Plaintiffs point to Clark's statement that the twelve month results were the "most important readout" from the Phase 2b trial, Compl. ¶ 90. Plaintiffs also argue that Hetherington's statement to investors was misleading because he sought to "explain away" the negative

twelve month viral shedding results. However, Plaintiffs do not allege facts to indicate that this was not the most important readout or that the placebo effect was not "a consequence of the sporadic nature of shedding in the small number of subjects [who] provided data" at that point. Compl. ¶ 91.

Relying on In re Delcath Systems, Inc. Securities Litigation, Plaintiffs argue that it is materially misleading to disclose one set of results without disclosing sufficient facts to "to allow a reasonable investor to make an accurate assessment of the disclosures that were made." 36 F. Supp. 3d 320, 332 (S.D.N.Y. 2014) (holding that disclosing a 7% mortality rate from the treatment group but not disclosing that there were zero deaths from the control group mislead investors about the safety of the tested medical device). By July 2017, Defendants had disclosed from the Phase 2b trial the positive viral shedding results from immediately post-dosing, positive genital lesion results from six months post-dosing, positive genital lesion results from twelve months post-dosing, and the negative viral shedding results from twelve months post-dosing.

Defendants persuasively argue that the viral shedding six month results could not have been material to investors given the positive market response to the negative twelve month viral shedding results in July 2017. Genocea's stock price rose on July 24, 2017, following the release of the negative Phase 2b

twelve month viral shedding results. Since Genocea's stock price did not drop when the company released the negative twelve month viral shedding results, the absence of the six month results is likely not material to investors who focused more on the genital lesion results. The release of the negative twelve month viral shedding results without consequence is fatal to Plaintiffs' allegations.

C. Scienter

Plaintiffs ask this Court to find a strong inference of scienter from the omission of the six month viral shedding results in July 2017. They argue that Defendants knew, or were reckless in not realizing, that failing to disclose the six month viral shedding results would mislead investors about the prospects for GEN-003 and the Phase 3 clinical trials. Scienter is a "mental state embracing intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976). At the pleading stage, the PSLRA requires that a complaint state with particularity specific facts giving rise to a "strong inference," 15 U.S.C. § 78u-4(b)(2)(A), that "defendants consciously intended to defraud, or that they acted with a high degree of recklessness." Aldridge, 284 F.3d at 82. Recklessness is "a highly unreasonable omission, involving not merely simple, or even inexcusable, negligence, but an extreme departure from the standards of ordinary care, and which

presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it." Greebel v. FTP Software, Inc., 194 F.3d 185, 198 (1st Cir. 1999). "Even if plaintiffs wish to prove scienter by 'recklessness,' they still must allege, with sufficient particularity, that defendants had full knowledge of the dangers of their course of action and chose not to disclose those dangers to investors." Maldonado v. Dominguez, 137 F.3d 1, 9 n.4 (1st Cir. 1998).

"There is no set pattern of facts that will establish scienter; it is a case-by-case inquiry." ACA Fin., 512 F.3d at 66. But whatever facts are alleged, they must "present a strong inference of scienter. A mere reasonable inference is insufficient to survive a motion to dismiss." Greebel, 194 F.3d at 196. For an inference of scienter to be strong, "a reasonable person would [have to] deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. The First Circuit has:

> found this exacting standard satisfied where the complaint "contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so."

In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 751 (1st Cir. 2016) (quoting In re Boston Scientific Corp. Securities

Litigation, 686 F.3d 21, 31 (1st Cir. 2012)). Additionally, "a plaintiff 'may combine various [other] facts and circumstances indicating fraudulent intent,' including those demonstrating 'motive and opportunity,' to satisfy the scienter requirement." Brennan v. Zafgen, Inc., 853 F.3d 606, 614 (1st Cir. 2017) (quoting Aldridge, 284 F.3d at 82).

Genocea's own disclosure of the negative twelve month viral shedding results weakens any showing of scienter. See Brennan, 853 F.3d at 617–18 (1st Cir. 2017)(finding that where defendants disclosed some but not all adverse events, and disclosed that they would not report all adverse events as they occurred, a strong competing inference to scienter was that defendants disclosed what they considered to be, at the time, the most relevant information about the clinical trials).

Plaintiffs assert a "core operations" theory - that Defendants intentionally withheld the Phase 2b six month viral shedding results because GEN-003 was core to Genocea's viability as a company. Again, Plaintiffs' core-operations theory is weakened because Defendants released the negative twelve month viral shedding results in July 2017. If Plaintiffs' theory was true, Defendants would have had a similar motive to withhold the twelve month viral shedding results as they did the six month viral shedding results.

Plaintiffs also draw the Court's attention to Poole's stock sales, but these sales do not bolster a strong inference of scienter. "Insider trading cannot establish scienter on its own, but it can be used to do so in combination with other evidence. Insider trading in suspicious amounts or at suspicious times may be probative of scienter." Bos. Sci., 523 F.3d at 92 (citations omitted). Even weak insider trading allegations may provide some support for scienter, but the "vitality of the inference to be drawn depends on the facts, and can range from marginal to strong." Greebel, 194 F.3d at 197-98 (citation omitted).

As an initial matter, Clark and Hetherington did not sell any stock during the proposed class period. See generally various defendant officers' Form 4s. During the summer of 2017, Poole made two sales of Genocea common stock: the first on May 8, 2017 and the second on July 24, 2017, the same day Genocea publicly released the twelve month results. Compl. ¶¶ 101-102. The May sale cannot be evidence of scienter as there are insufficient allegations that Defendants had the six month post-dosing viral shedding results at that time. The July 24, 2017 sale was actually executed by a stock broker based on a 10b5-1 plan Poole filled out on May 10, 2017. See Ex. W, Rule 10b5-1 Trading Plan. The trading plan occurred before the Court can reasonably infer Defendants had the six month viral shedding results. Additionally, the existence of a Rule 10b5-1 trading

plan "generally rebuts an inference of scienter and supports the reasonable inference that stock sales were pre-scheduled and not suspicious." In re Smith & Wesson Holding Corp. Sec. Litig., 604 F. Supp. 2d 332, 345 (D. Mass. 2009) (internal quotation omitted). Therefore, while this evidence of insider trading is a concern, standing alone, it does not support a strong inference of scienter with respect to the six month data. [4]

D. Count II - Section 20(a) Claims

Since Plaintiffs fail to allege a primary violation of Section 10(b), their Section 20(a) control person claims fail as a matter of law and are also dismissed. See Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 453 n.4 (1st Cir. 2017) (explaining that the derivative control person claim under Section 20(a) was properly dismissed where the district court dismissed the Section 10(b) claim).

ORDER

The motion to dismiss (Docket No. 59) is **ALLOWED**. The motion to strike (Docket No. 69) is moot considering the Court's ruling.

/s/ PATTI B. SARIS
Patti B. Saris
Chief United States District Judge

[4] The Court does not reach the issue of loss causation because Plaintiffs already fail to sufficiently allege necessary elements of a claim under Section 10(b) of the Exchange Act.