UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FRANK MICHOLLE, Individually and on Behalf of All Others Similarly Situated, Plaintiff, - against - OPHTHOTECH CORPORATION, DAVID R. GUYER, and SAMIR PATEL, Defendants.	No. 17-CV-210 (VSB) (**Consolidated**) **OPINION & ORDER**

Appearances:

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VERNON S. BRODERICK, United States District Judge:

In this putative class action, lead plaintiff Sheet Metal Workers' Pension Plan of Southern California, Arizona and Nevada claims that Defendants Ophthotech Corporation and Ophthotech co-founders David R. Guyer and Samir Patel violated Sections 10(b) and 20(a) of the Securities

Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and Rule 10b–5, 17 C.F.R. § 240.10b–5, by making materially false and misleading statements regarding the parameters and results of clinical studies for Fovista, a new drug developed by Ophthotech to treat macular degeneration. Before me are Defendants' motion to dismiss the Consolidated Amended Complaint for failure to state a claim, and Plaintiff's motion to strike certain documents Defendants submitted in connection with their motion to dismiss. For the reasons that follow, Defendants' motion to dismiss is DENIED, and Plaintiff's motion to strike is GRANTED IN PART and DENIED IN PART.

I. Background[1]

Defendant Ophthotech is a clinical-stage biopharmaceutical company which, during the proposed class period from March 2, 2015 through December 12, 2016 (the "Class Period"), was focused on developing the drug Fovista for the treatment of wet age-related macular degeneration ("Wet AMD"). (CAC ¶ 2.) "Wet AMD" is a degenerative eye disease that occurs when areas of abnormal blood vessels and abnormal tissue—commonly referred to as "CNV lesions" or simply "lesions," (*id.* ¶¶ 2, 5 n.2, 57 n.8)—form in the retina and leak fluid or blood, causing patients to experience blurred vision and blind spots in their visual field, (*id.* ¶ 2). During the Class Period, Defendant Guyer served as Ophthotech's Chief Executive Officer ("CEO") and Chairman of the Board of Directors, (*id.* ¶ 20), and Defendant Patel served as Ophthotech's President and Vice Chairman, (*id.* ¶ 21).

[1] The following factual summary is drawn from the allegations contained the Consolidated Amended Complaint for Violations of the Federal Securities Laws ("CAC" or "Complaint"), filed June 4, 2018. (Doc. 63.) I assume the allegations set forth in the Complaint to be true for purposes of this motion. *See Kassner v. 2nd Ave. Delicatessen Inc.*, 496 F.3d 229, 237 (2d Cir. 2007). My references to these allegations should not be construed as a finding as to their veracity, and I make no such findings.

Ophthotech designed Fovista to be used in combination with anti-vascular endothelial growth factor ("anti-VEGF") drugs, which are commonly used to treat wet AMD. (*Id.* ¶ 3.) Anti-VEGF agents—including the drug Lucentis—block proteins that bind to cells on the inner lining of the abnormal blood vessels associated with wet AMD, thereby inhibiting cell growth. (*Id.*) Fovista, by contrast, is an anti-platelet derived growth factor ("anti-PDGF") agent designed to block proteins that bind to cells on the outer lining of the abnormal blood vessels. (*Id.* ¶ 2.) Thus, in theory, Lucentis and Fovista would work together to block proteins on both the inner and outer lining of the abnormal blood vessels, thereby more effectively reducing the size of CNV lesions. (*Id.* ¶ 3.)

A. *Phase 2b of the Fovista Clinical Trials*

In order to secure approval from the U.S. Food and Drug Administration, a new drug must typically undergo three phases of clinical trials. (CAC ¶ 32 n.3.) Phase 1 involves the introduction of the drug to a small group of patients with the target disease. (*Id.*) Phase 2 evaluates the safety and efficacy of the drug on a larger group of patients and is sometimes subdivided, with Phase 2a assessing safety and Phase 2b assessing clinical efficacy. (*Id.*) Phase 3 expands the safety and efficacy assessment to a larger group of patients. (*Id.*)

In June 2012, Ophthotech completed a Phase 2b clinical trial of Fovista (the "Phase 2b Trial"), which evaluated the efficacy of Fovista administered in combination with Lucentis ("Fovista combination therapy"), as compared to Lucentis alone ("Lucentis monotherapy"). (*Id.* ¶¶ 4, 33, 36.) In selecting individuals to participate in the Phase 2b Trial, Defendants analyzed wet AMD patients' lesions using an imaging technique called fluorescein angiography ("FA"). (*Id.* ¶ 100.) Potential participants were divided into subgroups on the basis of whether their lesions contained "classic" or "occult" components, as measured by FA. (*Id.* ¶ 54.) "Classic"

refers to the portion of the lesion that is well-defined and typically located above the retinal pigment epithelium ("RPE") layer of the retina,[2] while "occult" refers to the portion of the lesion that is poorly defined and typically located below the RPE layer of the retina. (*Id.*) Classic and occult subtypes represent a spectrum, with "pure classic" lesions containing no occult components and "pure occult" lesions containing no classic components. (*Id.*) Between these extremes, "predominantly classic" lesions contain 50% or greater classic components, while "minimally classic lesions" contain less than 50% classic components. (*Id.*) Approximately 40% of wet AMD patients' lesions are classified as "pure occult." (*Id.*) Patients with "pure occult" lesions were not eligible to participate in the Phase 2b Trial. (*Id.*)

On June 13, 2012, Ophthotech announced the results of the Phase 2b Trial, which measured improvement in participants' visual acuity by counting the number of additional letters trial participants gained on an "Early Treatment Diabetic Retinopathy Study ('ETDRS') eye chart, a standardized chart used for vision testing," at the conclusion of the 24-week trial period. (*Id.* ¶¶ 33–34, 36.) A press release announcing the trial's results stated that those patients "receiving the combination of Fovista . . . and Lucentis gained a mean of 10.6 letters of vision on the ETDRS standardized chart at 24 weeks, compared to 6.5 letters for patients receiving Lucentis monotherapy[,] . . . representing a 62% additional benefit." (*Id.* ¶ 36.) The press release further stated that Fovista combination therapy resulted in a "robust benefit" over Lucentis monotherapy "across all subgroups including those analyzing baseline vision, lesion size and the proportion of patients gaining 1, 2, 3, 4 and 5 lines of vision (ETDRS standardized chart)." (*Id.*)

[2] "The RPE layer of the retina lies between the choroid and the neurosensory region of the retina." (CAC ¶ 54 n.7.)

The June 13, 2012 press release did not specify that at the start of the trial, those patients in the Lucentis monotherapy control group had lesions which, on average, were approximately 17% larger than the lesions of those patients in the Fovista combination therapy group. (*Id.* ¶ 51.) Specifically, in the Lucentis monotherapy group, the mean total lesion size was 1.8 disc areas, as compared to the 1.5 disc area mean total lesion size among patients in the Fovista combination group. (*Id.*)[3] These details were not disclosed until Ophthotech published the results of the Phase 2b Trial in *Ophthalmology*, the Journal of the American Academy of Ophthalmology on October 31, 2016. (*Id.* ¶ 117.) During a November 8, 2016 conference call with analysts and investors, a Morgan Stanley analyst inquired whether the "baseline imbalance [in] lesion size [might have] impact[ed] the strength of the Phase 2 data"; Defendant Patel responded that those concerns had "no validity." (*Id.* ¶ 119.)

B. *Phase 3 of the Fovista Clinical Trials*

Following the apparent success of the Phase 2b Trial, Ophthotech completed its initial public offering on September 30, 2013, raising hundreds of millions of dollars to finance the third phase of the Fovista clinical trials (the "Phase 3 Trial"). (CAC ¶¶ 4, 40.) Ophthotech launched the Phase 3 Trial in August 2013. (*Id.* ¶ 43.) Like the Phase 2b Trial, the Phase 3 Trial enrolled a group of patients who received Fovista combination therapy, as well as a control group of patients who received Lucentis monotherapy. (*Id.* ¶¶ 44, 46.)

Defendants publicly announced that certain changes were made to the parameters of the clinical trial between Phase 2b and Phase 3. First, the Phase 3 Trial enrolled a larger number of wet AMD patients than the Phase 2b Trial (1,891 as compared to 449), and measured

[3] Lesion size is measured in units called "disc area," which calculate the size of the area of the retina where a standard sized optic nerve emerges. (CAC ¶ 51 n.6.)

participants' change in visual acuity after 12 months, rather than 24 weeks. (*Id.* ¶¶ 33, 45, 48.) In addition, Ophthotech's 2014 Form 10-K—filed with the U.S. Securities and Exchange Commission ("SEC") on March 2, 2015—explained that Defendants "ha[d] modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for [the] Phase 3 clinical trials as compared to [the] Phase 2b clinical trial." (*Id.* ¶ 63.)

Specifically, as a result of advances in retinal imaging technology, FA imaging was being replaced by spectral domain optical coherence tomography ("SD-OCT") as the standard imaging technology. (*Id.* ¶ 57.)[4] Thus, for the Phase 3 Trial, Defendants elected to use SD-OCT rather than FA to analyze the characteristics of potential trial participants' lesions. (*Id.*) In addition, rather than categorizing patients based on the "classic" or "occult" components of their lesions and excluding any patients with pure occult lesions (as Defendants had done in the Phase 2b Trial), Defendants determined a patient's eligibility for the Phase 3 Trial based on the presence of sub-retinal hyper-reflective material ("SHRM"),[5] a type of abnormal tissue observable in some wet AMD patients. (*Id.* ¶ 55.)[6] Only SD-OCT—and not FA imaging technology—is capable of detecting the presence of SHRM, which may be found in patients whose lesions are

[4] SD-OCT utilizes scattered light to obtain high-resolution retinal tissue images, while FA involves injecting a dye and capturing its image during circulation through the retina. (CAC ¶ 57 n.8.)

[5] In describing "SHRM," Ophthotech stated, "the presence of [SHRM] is thought by many experts to indicate the presence of [a] CNV lesion. The subsequent resolution of [SHRM] is thought to correlate with regression of the CNV lesion." (CAC ¶ 56.)

[6] During a May 11, 2015 investor conference call, Defendant Patel explained the decision to shift from FA to SD-OCT as follows:

> Obviously when we started the Phase 3, the use of [FA], as you know, is quite unusual and rare nowadays. Virtually everybody uses [SD-OCT] and the [SD-OCT] is very high resolution, and its sensitivity and specificity has determined the location of the fluorelier vascularization with respect to the RPE, which is what you are really trying to do when you look at classic [and it] is better and more accurate. So it is for that reason we switched over to using SHRM. In essence, the definition for the use of the term classic refers to [FA]. Its equivalent component on [SD-OCT] is called SHRM.

(CAC ¶ 70.)

classified as either classic or occult. (*Id.* ¶¶ 57–58.) In connection with this change, Ophthotech's 2014 Form 10-K stated that while Defendants had "modified the methodology used to determine a patient's eligibility" for the Phase 3 Trial, they "ha[d] made no meaningful changes to the inclusion and exclusion criteria in these Phase 3 clinical trials from those [they] used in [their] Phase 2b clinical trial," and further stated that Defendants "expect[ed] that this w[ould] result in the enrollment of a patient population similar to the patient population enrolled in [their] Phase 2b clinical trial." (*Id.* ¶ 63.)

When subsequently asked about potential differences between Phase 2b and Phase 3, Defendant Patel assured investors during a February 10, 2016 conference that "as far as differences between the Phase IIB study and the Phase III, there really aren't any differences that are material or significant in any way." (*Id.* ¶ 90.) With regard to using the presence of SHRM to determine eligibility, he explained, "that's one change that we made, but it's actually no different in terms of the type of patients we are putting in." (*Id*.) During a September 13, 2016 conference, he stated that "the definition[] that is used for [SHRM] is the same as the presence of what the classic [subtype] conveys by [FA]. . . . And our definition[,] . . . using [] SD-OCT are the same group of patients." (*Id.* ¶¶ 113, 115.)

On December 12, 2016, Ophthotech announced the results of the Phase 3 Trial, and informed investors that "[n]o benefit [was] observed upon [the] addition of Fovista® to monthly Lucentis® regimen for the treatment of wet [AMD]." (*Id.* ¶ 149.) The price of Ophthotech common stock subsequently plummeted approximately 86%, from a closing price of $38.77 per share on Friday, December 9, 2016 to a closing price of $5.29 per share on Monday, December 12, 2016. (*Id.*) During the Class Period, both Defendants Guyer and Patel sold a majority

(66.3% and 82.2%, respectively) of their personally-held Ophthotech common stock, "for proceeds of" approximately $22.6 million and $22.9 million, respectively. (*Id.* ¶ 143.)

After announcing the results of the Phase 3 Trial, Ophthotech terminated its Fovista clinical program, and Defendants Guyer and Patel both stepped down from their positions at the company, although Guyer transitioned to a newly created Executive Chairman position. (*Id.* ¶¶ 127, 129–30.) As of the date of the filing of the CAC, Ophthotech common stock was trading below $3.00 per share. (*Id.* ¶ 132.)

II. Procedural History

On January 11, 2017, Plaintiff Frank Micholle filed a class action complaint (the "Micholle action"), alleging that Ophthotech and its officers and directors violated Sections 10(b) and 20(a) of the Securities Exchange Act (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a), as well as SEC Rule 10b–5. (Doc. 1.) Plaintiff Mark Wasson filed a similar complaint (the "Wasson action") on March 9, 2017. *See Wasson v. Ophthotech Corp.*, No. 17-cv-1758 (S.D.N.Y. Mar. 9, 2017), ECF No. 1. Subsequently, eight plaintiff groups filed motions requesting consolidation of the Micholle and Wasson actions, appointment of lead plaintiff, and approval of lead counsel. (Docs. 9, 12, 15, 18, 21, 28, 30, 35.)

On March 13, 2018, I issued an Opinion & Order consolidating the Micholle and Wasson actions and appointing Sheet Metal Workers' Pension Plan of Southern California, Arizona, and Nevada as lead plaintiff. (Doc. 56.) On June 4, 2018, Plaintiff filed a Consolidated Amended Complaint, naming Ophthotech, Guyer, and Patel as defendants. (Doc. 63.) On July 27, 2018, Defendants filed a motion to dismiss the CAC pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim on which relief can be granted. (Doc. 69.) Defendants also filed a memorandum of law, (Doc. 70), and the Declaration of Jeremy T. Adler ("Adler

Declaration" or "Adler Decl."), attaching 83 exhibits in support of their motion, (Doc. 71). Plaintiff filed its opposition to the motion to dismiss on October 12, 2018. (Doc. 74.) On the same date, Plaintiff moved to strike several of the exhibits attached to the Adler Declaration. (Docs. 75–77.) On November 19, 2018, Defendants filed a reply in further support of their motion to dismiss the CAC, (Doc. 83), as well as an opposition to Plaintiff's motion to strike, (Doc. 82). Plaintiff filed a reply in support of its motion to strike on December 10, 2018. (Doc. 86.)

III. Legal Standard

A. *Motion to Dismiss*

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim will have "facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* This standard demands "more than a sheer possibility that a defendant has acted unlawfully." *Id.* "Plausibility . . . depends on a host of considerations: the full factual picture presented by the complaint, the particular cause of action and its elements, and the existence of alternative explanations so obvious that they render plaintiff's inferences unreasonable." *L-7 Designs, Inc. v. Old Navy, LLC*, 647 F.3d 419, 430 (2d Cir. 2011).

In considering a motion to dismiss, a court must accept as true all well-pleaded facts alleged in the complaint and must draw all reasonable inferences in the plaintiff's favor. *Kassner v. 2nd Ave. Delicatessen Inc.*, 496 F.3d 229, 237 (2d Cir. 2007). A complaint need not make "detailed factual allegations," but it must contain more than mere "labels and conclusions" or "a

formulaic recitation of the elements of a cause of action." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted). Although all allegations contained in the complaint are assumed to be true, this tenet is "inapplicable to legal conclusions." *Id.*

B. *Securities Fraud – Section 10(b) Claims*

Rule 10b–5, promulgated under Section 10(b) of the Exchange Act, provides in pertinent part that it is unlawful to "make any untrue statement of a material fact or to omit 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(b). To state a claim for securities fraud under Section 10(b) and Rule 10b–5, a plaintiff must adequately plead: "(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." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148, 157 (2008).

"Securities fraud claims are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Federal Rule of Civil Procedure 9(b) requires a securities fraud claim to "state with particularity the circumstances constituting fraud or mistake." This standard requires that the complaint "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *ATSI*, 493 F.3d at 99. "Allegations that are conclusory or unsupported by factual assertions are insufficient." *Id.*

The Private Securities Litigation Reform Act ("PSLRA") also imposes a heightened pleading standard on securities fraud complaints. *See* 15 U.S.C. § 78u–4(b); *Lewy v. SkyPeople Fruit Juice, Inc.*, No. 11 Civ. 2700(PKC), 2012 WL 3957916, at *7 (S.D.N.Y. Sept. 10, 2012) ("Courts must dismiss pleadings that fail to adhere to the requirements of the PSLRA."). To satisfy the PSLRA, a securities fraud complaint must "'specify' each misleading statement"; "set forth the facts 'on which [a] belief' that a statement is misleading was 'formed'"; and "'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345 (2005) (quoting 15 U.S.C. § 78u–4(b)).

C. *Motion to Strike*

A district court is limited in the material it may consider in deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). "First, it may consider assertions made within 'the four corners of the complaint itself.'" *Russomanno v. Murphy*, No. 09 Civ. 8804(RJH), 2011 WL 609878, at *3 (S.D.N.Y. Feb. 16, 2011) (quoting *Gregory v. Daly*, 243 F.3d 687, 691 (2d Cir. 2001)). A court may also consider "any written instrument attached to [the complaint] as an exhibit or any statements or documents incorporated in [the complaint] by reference." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002) (quoting *Int'l Audiotext Network, Inc. v. A.T. & T. Co.*, 62 F.3d 69, 72 (2d Cir. 1995)). For a document to be considered "incorporated by reference," the complaint must contain a "clear, definite and substantial reference" to that document. *Helprin v. Harcourt*, 277 F. Supp. 2d 327, 330–31 (S.D.N.Y. 2003). "A mere passing reference or even references . . . to a document outside of the complaint does not, on its own, incorporate the document into the complaint itself." *Williams v. Time Warner, Inc.*, 440 F. App'x 7, 9 (2d Cir. 2011) (summary order). "Multiple references to,

and lengthy quotations from, an outside document have been considered sufficiently substantial to incorporate the document into the complaint by reference." *Allen v. Chanel Inc.*, No. 12 CV 6758(RPP), 2013 WL 2413068, at *5 (S.D.N.Y. June 4, 2013).

Where a document is not incorporated by reference, "the court may nevertheless consider it where the complaint 'relies heavily upon its terms and effect,' which renders the document 'integral' to the complaint." *Chambers*, 282 F.3d at 153 (quoting *Int'l Audiotext Network*, 62 F.3d at 72); *see also ATSI*, 493 F.3d at 98 (permitting courts to consider "documents possessed by or known to the plaintiff and upon which [the plaintiff] relied in bringing suit"). Finally, a court may consider any matters that are subject to judicial notice, including publicly filed documents. *See Cortec Indus., Inc. v. Sum Holdings L.P.*, 949 F.2d 42, 47 (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."); *see also ATSI*, 493 F.3d at 98. Adjudicative facts "not subject to reasonable dispute" because they are either "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned" may also be judicially noticed by the court. Fed. R. Evid. 201(b).

If a motion to dismiss introduces additional materials outside the pleadings, Federal Rule of Civil Procedure 12(d) specifies that a court may either exclude those materials or convert the motion to one for summary judgment.

IV. Discussion

Defendants argue that the CAC fails to sufficiently allege several of the elements required to establish a violation of Rule 10b–5. Specifically, Defendants argue that Plaintiff failed to plead (A) a false or misleading statement, (B) scienter, or (C) loss causation. I address each argument in turn.

A. *False or Misleading Statements*

Defendants first contend that the CAC fails to state a claim under Section 10(b) and Rule 10b–5 because it does not sufficiently allege that Defendants made any false or misleading statements with respect to the Fovista clinical trials. I disagree.

1. Applicable Law

A Section 10(b) plaintiff must assert that a challenged representation is false and "demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004); *accord Kleinman v. Elan Corp., plc*, 706 F.3d 145, 152–53 (2d Cir. 2013). 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." *Kleinman*, 706 F.3d at 153 (citation omitted). Statements that are literally true may become misleading based upon "their context and manner of presentation." *Id.* And "whether a statement is 'misleading' depends on the perspective of a reasonable investor: The inquiry . . . is objective." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2016).[7]

Section 10 "do[es] not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). Indeed, "[e]ven

[7] *Omnicare* analyzed the misleading nature of a statement under Section 11 of the Securities Act of 1933. The test for whether a statement is materially misleading under Section 11 is the same as the test under Section 10(b) of the Exchange Act. *See Rombach*, 355 F.3d at 178 n.11.

with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under section 10(b) and Rule 10b–5 by controlling what they say to the market." *Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711(PKC), 2013 WL 2399869, at *10 (S.D.N.Y. May 29, 2013) (internal quotation marks omitted). An omission is actionable under the securities laws "only when the [defendant] is subject to a duty to disclose the omitted facts." *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993). "Such a duty may arise expressly, pursuant to a statute or regulation, or implicitly as a result of the ongoing duty to avoid rendering existing statements misleading by failing to disclose material facts." *City of Westland Police & Fire Ret. Sys. v. MetLife, Inc.*, No. 12 cv 0256 (LAK), 2015 WL 5311196, at *9 (S.D.N.Y. Sept. 11, 2015) (internal quotation marks omitted); *see also In re MELA Scis., Inc. Sec. Litig.*, No. 10 CV 8774(VB), 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012) ("Disclosure is required under [Section 10] only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." (citing *Matrixx Initiatives*, 563 U.S. at 44)). Indeed, "once a party chooses to speak, it has a 'duty to be both accurate and complete.'" *Plumbers' Union Local No. 12 Pension Fund v. Swiss Reinsurance Co.*, 753 F. Supp. 2d 166, 180 (S.D.N.Y. 2010) (quoting *Caiola v. Citibank, N.A., N.Y.*, 295 F.3d 312, 331 (2d Cir. 2002)).

With respect to statements of opinion and belief, the Supreme Court has held that a plaintiff may demonstrate that such a statement is false by alleging that (1) the opinion or belief is itself a factual misstatement *or* (2) the opinion or belief is misleading due to the omission of a material fact. *Omnicare*, 135 S. Ct. at 1326–27. Even if a statement of opinion is literally accurate—i.e., it is honestly held—it may still be actionable if the opinion omits facts necessary to make the statement not misleading to a reasonable investor. *Id.* at 1327–28; *see also id.* at

1329 (requiring that the opinion "fairly align[] with the information in the [defendant's] possession at the time"). However, the Second Circuit has cautioned "against an overly expansive reading of this standard." *Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016). Specifically, the court has explained that "[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts," and that "[a] reasonable investor does not expect that every fact known to an issuer supports its opinion statement." *Id.* (quoting *Omnicare*, 135 S. Ct. at 1329). These cautions mean that "a statement of opinion 'is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way.'" *Id.* (quoting *Omnicare*, 135 S. Ct. at 1329). To establish that a statement of opinion was misleading on the basis of an omitted fact, a plaintiff must: (1) identify the omitted fact, (2) show that "the omitted fact would have been material to a reasonable investor," (3) establish that the omission rendered the opinion misleading to a reasonable investor, and (4) take into account the "statement's context," including relevant "hedges, disclaimers, or qualifications." *Omnicare*, 135 S. Ct. at 1333.

2. Application

The CAC's allegations of material misstatements and omissions essentially fall into two categories. First, Plaintiff alleges that Defendants' statements regarding the success of the Phase 2(b) Trial were misleading because Defendants failed to disclose that patients in the Lucentis monotherapy control group had larger lesions and poorer vision at the beginning of the trial than patients in the Fovista combination therapy group. Second, Plaintiff alleges that Defendants failed to disclose a material change in the patient enrollment criteria for the Phase 3 Trial. For the reasons that follow, I find that Defendants' statements related to the Phase 2(b) Trial are not

actionable, but that their statements related to the Phase 3 Trial are sufficient to support a securities fraud claim.

a. Statements Regarding Success of Phase 2(b) Trial

Plaintiff asserts that Defendants' assessment—as stated in a June 13, 2012 press release—that Phase 2b Trial participants who received a combination of Fovista and Lucentis saw a "62% additional benefit" in their improved visual acuity over those participants treated with Lucentis only is misleading. (CAC ¶ 36.) As previously explained, *see supra* Part I.A, the Phase 2(b) Trial measured improvement in visual acuity by counting the number of additional letters participants had gained on an ETDRS standardized vision chart at the conclusion of the trial period. (CAC ¶ 36.) Plaintiff does not appear to challenge the mathematical accuracy of the conclusion that, on average, participants in the Fovista combination therapy group gained 62% more letters on the vision chart than those in the Lucentis monotherapy group. Rather, Plaintiff contends that this figure was "not indicative of Fovista's efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group." (*Id.* ¶ 81.) The CAC alleges that the imbalance in baseline lesion size "skewed the results of the [Phase 2b] trial" as "larger lesions correlate with poorer visual acuity" and "patients with poorer vision are less likely to respond to treatment." (*Id.* ¶ 52.) According to Plaintiff, the failure to disclose the fact that the average baseline lesion size of patients in the Lucentis monotherapy group was larger than the average baseline lesion size of patients in the Fovista combination therapy group rendered Defendants' statements touting the results of the Phase 2b Trial materially misleading because those statements dramatically overstated the success of the trial. Plaintiff is incorrect, and I find that

there are multiple reasons why Defendants' comments regarding the Phase 2b Trial results are not actionable misstatements.

First, Defendants repeatedly disclosed in public SEC filings that patients in the Lucentis monotherapy control group had, on average, larger lesions than those patients in the Fovista combination therapy group. In Ophthotech's 2014 and 2015 Forms 10-K, Ophthotech explained that, "in our Phase 2b trial[,] . . . the Lucentis monotherapy group had a greater proportion of patients with large CNV sizes compared to the group treated with a combination of 1.5 mg of Fovista and Lucentis." (Adler Decl. Ex. 1 (2014 10-K), at 29; Ex. 5 (2015 10-K), at 29.)[8] Contrary to Plaintiff's assertion, Defendants were under no obligation to disclose precisely how much larger the lesions of those participants in the Lucentis monotherapy group were. *See, e.g.*, *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 879 n.7 (9th Cir. 2012) ("Section 10(b) and Rule 10b–5 do not categorically prohibit statements that are incomplete or that report cumulative figures instead of detailed breakdowns of the underlying data . . . ."); *cf. In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, No. 13 Civ. 755(KBF), 2014 WL 585658, at *11 (S.D.N.Y. Feb. 14, 2014) ("That plaintiffs would have preferred to have had more information regarding how the Phase 2 Trial was performed and how the results were analyzed is irrelevant to a determination of actionable falsity."). Plaintiff does not adequately explain with reference to controlling case law why Defendants' failure to specifically disclose the precise difference in lesion size renders their statements materially misleading.

I find both the Second Circuit's decision in *Kleinman v. Elan Corp.*, 706 F.3d 145, and Judge Castel's decision in *Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869, instructive on this point. In both *Abely* and *Kleinman*, plaintiffs asserted that defendants should have provided

[8] Ophthotech filed its 2014 Form 10-K on March 2, 2015, the first day of the Class Period. (*See* CAC ¶ 61.)

additional details regarding the specifics of clinical trials for new drugs "in order to provide context for the seemingly promising conclusions" of those trials. *Abely*, 2013 WL 2399869, at *11. In *Kleinman*, plaintiff alleged that defendants materially misstated and omitted information about the results of a Phase 2 trial for a drug designed to treat Alzheimer's by failing to disclose that one control group in the Phase 2 trial showed a "larger than expected cognitive decline." 706 F.3d at 154. According to plaintiff, the omission of this information from the press release announcing the study's results exaggerated the drug's efficacy. *Id*. The Second Circuit disagreed and concluded that defendants were not obligated to disclose this information—which, in any event, defendants disputed. *See id.* ("Defendants are not required to adopt [plaintiff's] view regarding the degree of difference [in cognitive decline] or its effect on the results."). Defendants' press release acknowledged that "there were 'imbalances in . . . characteristics at baseline between subgroups' in Phase 2," which disclosure the Second Circuit found sufficient to avoid liability under Section 10(b). *Id.*

Similarly, in *Abely*, plaintiff challenged defendants' decision to publish only the results for colorectal cancer patients treated with the trial drug at issue, and not for breast cancer patients treated with the same drug. 2013 WL 2399869, at *10. Judge Castel held that defendants had no obligation to disclose this information, explaining that "[t]he Phase 2 trial's findings as to breast cancer patients, and as to the overall patient population, may have been of interest to shareholders, or provided context to evaluate the findings on colorectal cancer, but relevance alone does not trigger the duty to disclose." *Id.*

Here too, the fact that information regarding the specific difference in baseline lesion size between the Fovista combination therapy group and the Lucentis monotherapy group "might have provided useful context for investors does not rise to the level of an actionable

omission." *Id.* at *11 (citing *Matrixx Initiatives*, 563 U.S. at 43–46). Nor were Defendants required to adopt Plaintiff's "view regarding the degree of difference [in lesion size] or its effect on the results." *Kleinman*, 706 F.3d at 154.

Moreover, Defendants *did* disclose the precise difference in average baseline lesion size during the Class Period, when they published the results of the Phase 2b Trial on October 31, 2016.[9] Those results reported that the average total lesion size for the 1.5 mg Fovista combination therapy group was 1.5 disc areas, compared to an average total lesion size of 1.8 disc areas for the Lucentis monotherapy control group. (*See* Adler Decl. Ex. 4, at 227; *see also In re Keryx*, 2014 WL 585658, at *10 (where "plaintiffs' allegations as to falsity amount to a desire to have known aspects of the methodology used in the Phase 2 trial earlier than such details were fully disclosed," those allegations "fail as a matter of law").)[10]

Plaintiff acknowledges the October 31, 2016 disclosure but asserts that Defendants "continued to mislead investors by downplaying its significance." (Pl.'s Opp'n 9.) When, during a November 8, 2016 conference call with investors, Defendant Patel was asked whether the baseline imbalance in lesion size may have impacted the results of the Phase 2b Trial,

[9] Among the exhibits to the Adler Declaration that Plaintiff seeks to strike are the published results of the Phase 2b Trial. (*See* Adler Decl. Ex. 4.) Although Plaintiff does not quote directly from these results, Plaintiff specifically references the contents of the publication, (*see, e.g.*, CAC ¶ 119), and I find that the results are integral to the CAC. Many of the statements that Plaintiff challenges in this lawsuit relate to Defendants' characterization of the results of the Phase 2b Trial and I therefore conclude that the CAC "relies heavily upon [the] terms and effect" of the published trial results. *Chambers*, 282 F.3d at 153; *see also Abely*, 2013 WL 2399869, at *22 (denying motion to strike and finding it "appropriate to review the versions of the [clinical] studies' designs as published" where plaintiff asserted that "defendants misstated and omitted material aspects of the Phase 2 and Phase 3 trials").

[10] Plaintiff claims that these details were made available to the public too late—only six weeks before the end of the Class Period—to be of real use to investors. (*See* Pl.'s Opp'n 23.) ("Pl.'s Opp'n" refers to Plaintiff's Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Consolidated Amended Complaint, filed October 12, 2018. (Doc. 74.).) For the reasons stated above, Defendants were not required to describe the results of the Phase 2b study at this level of specificity to render their statements regarding the success of the trial not false or misleading. In any event, the fact that the price of Ophthotech's common stock did not drop until December 12, 2016, *see supra* Part I.B, confirms that the October 31, 2016 disclosure regarding the average baseline lesion sizes in the Phase 2b Trial did not cause Plaintiff's loss. *See In re Keryx*, 2014 WL 585658, at *14 (dismissing Section 10(b) claim, in part, for failure to adequately plead loss causation, where defendants disclosed the information allegedly withheld from the market more than two weeks before stock prices dropped).

Defendant Patel "dismissed such concerns as having 'no validity.'" (CAC ¶ 119; *see also id.* ¶¶ 84–85 (challenging Defendant Patel's statement during a December 3, 2015 conference call that improvements observed in patients in the Fovista combination therapy group were "not really related to any baseline features that typically drive visual acuity . . . such as lesion size [or] baseline vision")[11].)

The CAC, however, contains no well-pleaded allegations suggesting that Patel's statements were false. The lone allegations on the topic—that patients with larger baseline lesions, and, in turn, "poorer visual acuity," are "less likely to respond to treatment," (*id.* ¶ 52), or that "larger lesions tend to be more chronic, severe, and difficult to treat," (*id.* ¶ 120)—are wholly unsupported, conclusory assertions, which without more are insufficient to satisfy the PSLRA's heightened pleading standards. Under the PSLRA, a Plaintiff must "provid[e] documentary evidence and/or a sufficient general description of the personal sources of the plaintiffs' beliefs." *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000). The CAC's allegations appear to be based on information and belief but they fail to satisfy the PSLRA's requirement that "where an allegation regarding a misstatement or omission is based on information and belief, the plaintiff 'state with particularity all facts upon which that belief is formed.'" *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, No. 02 Civ.8726(LAK), 2004 WL 616123, at *1 (S.D.N.Y. Mar. 30, 2004) (quoting 15 U.S.C. § 78u-4(b)(1)); *see also id.* ("The Complaint appears to base

[11] Plaintiff also seeks to strike the full transcript of the December 3, 2015 conference call. (*See* Adler Decl. Ex. 7.) The CAC quotes a portion of this call, (CAC ¶ 84), and I find it appropriate to take judicial notice of the entire transcript "to provide the full context in which the information was disclosed to the market." *Patel v. Parnes*, 253 F.R.D. 531, 547 (C.D. Cal. 2008) (taking judicial notice of full transcript of calls during which defendants allegedly made misleading statements). The fact that the CAC quotes an excerpt from this call confirms that "there was undisputed notice to plaintiff[] of [the call's] contents." *Cortec Indus.*, 949 F.2d at 48 (finding certain documents that plaintiffs "had either in [their] possession or had knowledge of and upon which they relied in bringing suit" were integral to the complaint). Plaintiff cannot on the one hand rely on a statement made during the call while at the same time seeking to ignore other statements made during the same call. Plaintiff's request to strike the transcript of the December 3, 2015 conference call is therefore denied.

these allegations [regarding defendants' past conduct] on information and belief, but it does not identify the basis for that belief. These allegations therefore are inadequate under both Rule 9(b) and the PSRLA . . . ."). Because the CAC's hypothesis that the larger baseline lesions in the Lucentis monotherapy group affected the success of the Phase 2b Trial is unsourced and unsupported, I find it to be wholly speculative. Plaintiff's hypothesis is also undermined by the published results of that trial, which explain that the "relative treatment benefit in the [Fovista] combination therapy arm was evident regardless of baseline [visual acuity] [or] lesion size." (Adler Decl. Ex. 4, at 230.) Plaintiff does not challenge the accuracy of these published results, which confirm that the Fovista combination therapy group demonstrated greater improvement in visual acuity than the Lucentis monotherapy group across all baseline lesion sizes.

For the foregoing reasons, I find that the CAC fails to satisfactorily allege that Defendants' statements regarding the success of the Phase 2b Trial were materially misleading.[12]

b. Statements Regarding Changes to Phase 3 Enrollment Criteria

With respect to Defendants' statements regarding the patient enrollment criteria for the third phase of the Fovista clinical trials, Plaintiff alleges that Defendants failed to disclose that they made a "critical change" to the enrollment criteria by requiring only the presence of SHRM in order for a patient to be eligible for the Phase 3 Trial, rather than categorizing patients by lesion subtype and then excluding all patients with pure occult lesions, as they had done in the Phase 2b Trial. (CAC ¶ 53.)[13] Plaintiff asserts that SHRM may be present in patients whose

[12] To the extent Plaintiff challenges additional statements by Defendants regarding the Phase 2b Trial—including descriptions of the trial as "well conducted," "robust," and having produced results of "statistical and clinical significance," (CAC ¶¶ 50, 106, 117)—these statements "constitute corporate puffery rather than actionable misrepresentations." *In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 354 (S.D.N.Y. 2011); *see also In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 370 (E.D.N.Y. 2013) (concluding that the terms "robust" and "best-of-class" "fall into the category of commonplace statements too general to cause reliance by a reasonable investor" (internal quotation marks omitted)).

[13] Plaintiff also moves to strike two academic papers, which address different methods for classifying wet AMD lesions. (*See* Adler Decl. Exs. 2, 3.) Defendants concede that these articles are neither integral to the CAC nor

lesions are categorized as either classic or occult, (*id.* ¶ 58), and that therefore, this modification materially impacted the enrollment criteria for the Phase 3 Trial. Whether Defendants' challenged statements on this topic are materially misleading is a close question; however, I find them sufficiently misleading in the context they were alleged to have been made to permit Plaintiff's claim to survive at this stage of the litigation.

Defendants concede that they modified the methodology for determining a patient's eligibility to participate in the Phase 3 Trial but assert that they communicated this change to investors. Ophthotech's 2014 Form 10-K states, "we have modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trials as compared to our Phase 2b clinical trial"—that is, Ophthotech had moved from FA imaging (which distinguishes between classic and occult subtypes) to SD-OCT imaging (which detects the presence of SHRM). (*Id.* ¶ 63; *see also* Adler Decl. Ex. 5, at 94 ("Our Phase 3 clinical program enrolls patients based on a specific definition of the presence of neovascularization with certain characteristics, including the presence of . . . SHRM, using the commonly employed modality of . . . SD-OCT.").) However, that very same sentence in Ophthotech's 2014 Form 10-K goes on to state that "we have made *no meaningful changes to the inclusion and exclusion criteria* in these Phase 3 clinical trials from those we used in our Phase

incorporated by reference therein; however, Defendants argue that I may take judicial notice of "definitions of particular medical terms" set forth in the articles—i.e., definitions of "classic" and "occult" lesions and "SHRM"—as these definitions are "helpful for understanding the allegations in the Complaint" and are found in sources "whose accuracy cannot reasonably be questioned." (Defs.' Mot. to Strike Opp'n 2, 6.) ("Defs.' Mot. to Strike Opp'n" refers to Defendants' Opposition to Plaintiff's Motion to Strike Exhibits Submitted with Defendants' Motion to Dismiss, filed November 19, 2018. (Doc. 82.).) Plaintiff's motion to strike these two exhibits is granted. The definition of these terms appears to be "subject to reasonable dispute," Fed. R. Evid. 201(b)—in fact, the CAC specifically alleges that "SHRM," in particular, "was a newly-discovered phenomenon that had not been thoroughly studied and was not fully understood." (CAC ¶ 7.) Moreover, one of Defendants' primary arguments in their motion to dismiss is that the presence of "SHRM" is essentially synonymous with "classic" lesion components—an assertion that Plaintiff vigorously disputes. For these reasons, I decline to take judicial notice of Defendants' purported definitions of these critical terms.

2b clinical trial. We expect that this will result in the enrollment of a patient population similar to the patient population enrolled in our Phase 2b clinical trial." (CAC ¶ 63 (emphasis added).) Plaintiff alleges that this statement was materially misleading because—contrary to Defendants' representations—the change in methodology significantly affected the trial's enrollment criteria in that patients with pure occult lesions who had been excluded from Phase 2b may have been eligible to participate in Phase 3. I find that to the extent Defendants' reference to the change in methodology constituted an adequate disclosure in isolation, Defendants' second statement effectively converted the earlier statement into an assertion that this change in methodology was not meaningful with regard to either end results or the patient population.

Courts have concluded that the term "meaningful" reflects a statement of opinion, which is false only where "the speaker did not hold the belief [it] professed" or where "the supporting fact[s] [it] supplied were untrue." *Tongue*, 816 F.3d at 210 (internal quotation marks omitted); *see also Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 598 (S.D.N.Y. 2016) (finding challenged statement of opinion not misleading where statement "was not inconsistent with the data known to [defendants]"). Here, as discussed in further detail below, there is evidence suggesting that Defendants' characterization of the altered methodology as having no "meaningful" impact on the trial's inclusion and exclusion criteria may well have been "inconsistent" with the data known to them.

Moreover, Defendants made several additional statements emphasizing that they had not altered the enrollment criteria for the Phase 3 Trial. At a November 17, 2015 conference, for instance, Defendant Guyer asserted that Defendants had "changed nothing" from Phase 2 to Phase 3. (*See* CAC ¶¶ 80, 82 ("You see too many companies make a lot of changes from Phase 2 to Phase 3, and you get surprises. So we were just being superstitious and changed nothing.").)

During another conference on December 8, 2015, Guyer described the Phase 3 Trial as "really similar in virtually every way" to the Phase 2b Trial. (*See id.* ¶ 86 ("[T]he Phase III program really is to just confirm the Phase II, really similar in virtually every way short of the regulatory time point of 12 months, which is needed for regulatory [approval], versus six months.").) When asked specifically about the change in methodology from enrolling patients with classic lesions to enrolling patients with SHRM, Defendant Patel assured investors at a February 10, 2016 conference that "that's one change that we made, but it's actually no different in terms of [] the type of patients we are putting in." (*Id.* ¶ 90; *see also id.* ("[A]s far as differences between the Phase IIB study and the Phase III, there really aren't any differences that are material or significant in any way.").) Defendant Patel provided the same assurances at a September 13, 2016 conference, when he stated that "the definition[] that is used for [SHRM] is the same as the presence of what the classic [subtype] conveys by [FA]. . . . And our definition[,] . . . using these SD-OCT are the same group of patients." (*Id.* ¶¶ 113, 115.) This statement appears to equate the presence of SHRM with the classic lesion subtype.

Unlike Plaintiff's claims regarding the Phase 2b Trial—which lacked any well-pleaded allegations suggesting that Defendants' description of the trial's success was inaccurate—documents undisputedly incorporated into the CAC by reference tend to contradict Defendants' repeated assertions that they made no significant changes to the inclusion and exclusion criteria between Phase 2b and Phase 3 of the Fovista clinical trials. *Cf. Novak*, 216 F.3d at 314 (noting that plaintiffs can satisfy the PSLRA's heightened pleading standard by "providing documentary evidence [supporting] the plaintiffs' beliefs"). Two passages from Ophthotech's 2014 and 2015 Forms 10-K, when read together, appear to acknowledge that at least 17% of all wet AMD patients would have been eligible to participate in the Phase 3 Trial but ineligible to participate in

the Phase 2b Trial. (*Compare* Adler Decl. Ex. 1 (2014 10-K), at 13 ("[T]he pure occult subtype accounts for approximately 40% of the cases . . . in the wet AMD patient population."), *with* Adler Decl. Ex. 5 (2015 10-K), at 94 ("[A] recent third-party retrospective analysis based on a . . . wet AMD population with relatively broad entry criteria in a National Eye Institute sponsored study showed that approximately 77% of patients in that study demonstrated the presence of SHRM.").)[14] These statements indicate that while 40% of wet AMD patients have lesions classified as "pure occult"—and therefore would have been ineligible to participate in the Phase 2b Trial—only 23% of wet AMD patients (i.e., those who do not demonstrate the presence of SHRM) would have been ineligible to participate in the Phase 3 Trial. While the full significance of these statements must await discovery, there appears by Defendants' own admission to be at least a 17% overlap between lesions classified as "pure occult" and those that demonstrate the presence of SHRM.[15] These statistics suggest that the pool of eligible participants did in fact change between Phase 2b and Phase 3 of the Fovista clinical trials, and that Defendants' assertions to the contrary did not "fairly align[] with the information in

[14] Although this information is contained in Defendants' public SEC filings, I cannot conclude that these disclosures—which "are set forth in two separate places, and use varying and vague terminology"—are sufficient as a matter of law to correct any misperception resulting from Defendants' repeated statements emphasizing that they had made no material changes to the enrollment criteria. *In re Alstom SA*, 406 F. Supp. 2d 433, 453 n.11 (S.D.N.Y. 2015); *see also id.* (rejecting defendant's arguments that its disclosures were adequate where the relevant information was "separated into two, non-consecutive footnotes" with language "mak[ing] it virtually impossible to discern what exactly the company [wa]s alluding to").

[15] I note that 17% may, in fact, be a conservative estimate because it assumes that all 23% of wet AMD patients who did not display SHRM overlapped with the 40% of patients with pure occult lesions. If any of the 23% of patients lacking SHRM instead had lesions with classic components, the overlap between pure occult lesions and the presence of SHRM would have been even greater. It is perhaps for this reason that the CAC alleges that the changed methodology resulted in all "40% of wet AMD patients with pure occult lesions [being] eligible to participate in the Phase 3 Trials." (CAC ¶ 64.) Given the other allegations in the CAC and the documents incorporated by reference therein, I suspect that Plaintiff's assertion may be exaggerated; however, this uncertainty only bolsters Plaintiff's allegation that, at the time Defendants launched the Phase 3 Trial, "SHRM was a newly-discovered phenomenon that had not been thoroughly studied and was not fully understood." (*Id.* ¶ 7.)

[Defendants'] possession" at the time their statements were made. *Omnicare*, 135 S. Ct. at 1329.[16]

Finally, although Defendants do not explicitly argue that their allegedly misleading statements regarding the similarity of the Phase 2b and Phase 3 enrollment criteria were immaterial to prospective investors, I note that I cannot make a materiality determination as a matter of law. Materiality is a fact-specific inquiry as to whether "there is a substantial likelihood that a reasonable shareholder would consider [the stated or omitted fact] important in deciding how to act." *Hutchison v. Deutsche Bank Sec. Inc.*, 647 F.3d 479, 485 (2d Cir. 2011) (quoting *Basic v. Levinson*, 485 U.S. 224, 231 (1988)). In other words, courts must determine whether a reasonable investor would have considered the statement or omission "significant in making investment decisions." *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 161 (2d Cir. 2000). The Second Circuit has held that a "complaint may not properly be dismissed on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *Ind. Pub. Ret. Sys. v. SAIC, Inc.*, 818 F.3d 85, 96 (2d Cir. 2016) (internal quotation marks omitted). I find that a prospective investor may well have considered the degree of similarity between the parameters of a new clinical trial and those of a recently completed—and purportedly very successful—clinical trial important in deciding whether to invest in a developmental drug.

[16] Therefore, the circumstances present here are not analogous to those Judge Paul Engelmayer confronted in *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557. In *Gillis*, Judge Engelmayer determined that defendants' characterization of the results of their clinical trial as having demonstrated a "meaningful" safety advantage over other treatments "was a matter on which reasonable minds could differ." *Id.* at 598. He rejected plaintiffs' fraud claim premised on defendants' comment, noting that defendants' view "was not inconsistent with the data known to them" and finding it important that "the information which the [complaint] faults defendants for omitting does not contradict [defendants'] statements. *Id.* at 597.

Ultimately, although Defendants disclosed a change in the "methodology" used to determine a patient's eligibility to participate in the Phase 3 Trial, they described this change in complex and opaque terms and then repeatedly insisted that, practically speaking, the modification had no material effect on the trial's enrollment criteria. This emphasis on the lack of a material effect diminishes the impact of Defendants' disclosure. Moreover, Plaintiff has identified evidence which calls Defendants' characterization into question and which suggests that the change in methodology may well have led to a corresponding change in the pool of individuals eligible to participate in Phase 3 of the Fovista clinical trials. I therefore find that the CAC satisfactorily alleges that Defendants' comparisons between the Phase 2b and Phase 3 enrollment criteria amount to actionable misrepresentations under Section 10(b) and Rule 10b–5.

B. *Scienter*

Having found that the CAC sufficiently alleges that Defendants made materially false or misleading statements with respect to the enrollment criteria for Phase 3 of the Fovista clinical trials, I next turn to the question of whether the facts alleged give rise to a "strong inference" of scienter. 15 U.S.C. § 78u–4(b). While I agree with Defendants that Plaintiff has not alleged sufficient facts to plausibly suggest that Defendants had the motive and opportunity to commit fraud, I find that Plaintiff does identify sufficient evidence of conscious misbehavior or recklessness to plead scienter.

1. Applicable Law

Pursuant to the PSLRA, a well-pleaded securities fraud claim must "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 requisite state of mind in a section 10(b) and Rule 10b–5 action is an intent 'to deceive, manipulate, or defraud.'" *ECA, Local 134 IBEW Joint*

Pension Tr. of Chi. v. JP Morgan Chase Co., 553 F.3d 187, 198 (2d Cir. 2009) (quoting *Tellabs*, 551 U.S. at 313). A strong inference of scienter[17] may arise where the complaint alleges that defendants "(1) benefitted in a concrete and personal way from the purported fraud; (2) engaged in deliberately illegal behavior; (3) knew facts or had access to information suggesting that their public statements were not accurate; or (4) failed to check information they had a duty to monitor." *Novak*, 216 F.3d at 311 (internal citations omitted). In the Second Circuit, scienter may be pleaded by alleging facts to show either (1) "that defendants had both motive and opportunity to commit fraud," or (2) "strong circumstantial evidence of conscious misbehavior or recklessness." *Id.* at 307 (quoting *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 52 (2d Cir. 1995)). "The inquiry . . . 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 323–24.

a. Motive and Opportunity to Defraud

In order to raise a strong inference of scienter through the "motive and opportunity" to defraud prong, a plaintiff must allege that the defendant "benefitted in some concrete and personal way from the purported fraud." *Novak*, 216 F.3d at 307–08. "General allegations that the defendants acted in their economic self-interest are not enough." *Ganino*, 228 F.3d at 170. Likewise, "[m]otives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute 'motive' for purposes of this inquiry." *ECA*, 553 F.3d at 198.

[17] The term "scienter," as applied to conduct necessary to give rise to an action for civil damages under the Exchange Act and Rule 10b-5, refers to "[a] mental state consisting in an intent to deceive, manipulate, or defraud." "Scienter," Black's Law Dictionary (11th ed. 2019).

A plaintiff may allege that a defendant benefitted from the purported fraud in a concrete way by selling a number of his or her shares during the class period. *See In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009). However, "[t]he mere fact that insider stock sales occurred does not suffice to establish scienter." *In re Bausch & Lomb Sec. Litig.*, 592 F. Supp. 2d 323, 344 (W.D.N.Y. 2008) (citation omitted). Rather, a plaintiff must establish that the stock sales during the class period were "unusual" or "suspicious." *See id.* (citing *Acito*, 47 F.3d at 54). "[C]ourts may use information from SEC filings regarding a defendant's stock sales to determine whether such sales were 'unusual' or 'suspicious.'" *In re Bear Stearns Cos. Sec., Derivative, & ERISA Litig.*, 763 F. Supp. 2d 423, 582 (S.D.N.Y. 2011). Insider stock sales qualify as unusual where, for instance, "the trading was in amounts dramatically out of line with prior trading practices and at times calculated to maximize personal benefit from undisclosed inside information." *In re Gildan*, 636 F. Supp. 2d at 270 (internal quotation marks omitted). Other factors relevant to the determination of whether insider stock sales were "unusual" include the amount of profit earned from the sales, the percentage of the defendant's overall holdings sold, and the number of insiders selling. *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 74–75 (2d Cir. 2001). "There is no *per se* rule, however, that sale of a particular monetary amount or percentage of total holdings is unusual." *In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430, 444 (S.D.N.Y. 2005) (citing *In re Scholastic*, 252 F.3d at 75).

b. Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness

As an alternative to pleading motive and opportunity to defraud, a plaintiff may raise a strong inference of scienter under the "strong circumstantial evidence" prong, which requires that a plaintiff plead allegations plausibly suggesting that a defendant either consciously

misbehaved or acted recklessly. *ECA*, 553 F.3d at 198. Conscious misbehavior "encompasses deliberate illegal behavior," while "securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements." *Novak*, 216 F.3d at 308. "Under such circumstances, defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." *Id*. "Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information." *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 196 (2d Cir. 2008) (quoting *Novak*, 216 F.3d at 309).

In *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, the Supreme Court expounded on the relevant considerations used to determine whether a complaint has alleged facts that give rise to the requisite "strong inference" of scienter:

> a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the "smoking-gun" genre, or even the most plausible of competing inferences. . . . Yet the inference of scienter must be more than merely "reasonable" or "permissible" . . . . A complaint will survive, we hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.

551 U.S. at 323–24 (internal citation and quotation marks omitted); *see also Van Dongen v. CNinsure Inc.*, 951 F. Supp. 2d 457, 472 (S.D.N.Y. 2013) ("The question before the Court with respect to scienter is, 'When the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?'" (quoting *ECA*, 553 F.3d at 198)); *City of Pontiac Gen. Emps.' Ret. Sys. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 372 (S.D.N.Y. 2012) ("[A]t the motion to dismiss stage, a tie on scienter goes to the plaintiff.").

2. Application

The CAC alleges scienter under both theories—that is, (1) that Defendants had motive and opportunity to defraud, and (2) that there is strong circumstantial evidence of Defendants' recklessness. Defendants argue that both sets of allegations are insufficient under the PSLRA. I address in turn the CAC's allegations with regard to each theory.

a. Motive and Opportunity to Defraud

The CAC alleges that Individual Defendants Guyer and Patel both sold the majority of their Ophthotech common stock during the Class Period, which—according to Plaintiff—demonstrates a motive to commit fraud. (CAC ¶¶ 143–45.) Specifically, Patel sold 82.2% of his personally held Ophthotech common stock during the Class Period, while Guyer sold 66.3% of his Ophthotech stock during the same period. (*Id.* ¶ 143.)[18] Each Defendant's sales generated over $22 million in proceeds. (*Id.*) Other than noting the percentage of Guyer's and Patel's holdings sold during the Class Period, however, Plaintiff alleges few of the additional facts courts have found relevant when considering stock sales by insiders. For example, Plaintiff "fail[ed] to allege any facts relating to the amount of profit the Individual Defendants garnered from their sales." *In re Gildan*, 636 F. Supp. 2d at 271 (finding plaintiffs failed to adequately allege motive and opportunity); *see also In re BISYS*, 397 F. Supp. 2d at 445 ("[G]ross proceeds, standing alone, tell us very little."). Plaintiff also has not alleged that the sales were suspiciously timed to occur soon after the allegedly misleading statements were made or shortly before any

[18] Although a "sale amounting to a large percentage of an individual's holdings may be sufficient " to infer scienter, *Nguyen v. New Link Genetics Corp.*, 297 F. Supp. 3d 472, 496 (S.D.N.Y. 2018) (citation omitted), Defendants' sale of a majority of their Ophthotech common stock during the Class Period is undercut by the fact that they followed the same trading pattern prior to the Class Period as well, *see infra*. *Cf. Ronconi v. Larkin*, 253 F.3d 423, 435–37 (9th Cir. 2001) (concluding that the fact that defendant sold 98% of her total shares failed to support an inference of scienter because plaintiffs did not "allege[] sufficient trading history for [the court] to conclude that her trading was dramatically out of line with prior trading practices" (internal quotation marks omitted)).

corrective disclosure or materialized risk. *See In re Gildan*, 636 F. Supp. 2d at 270. Indeed, the CAC contains a table summarizing Patel's and Guyer's Class Period sales, which demonstrates that they sold their Ophthotech shares at regular monthly intervals throughout the Class Period. (*See* CAC ¶ 145; *see also In re BISYS*, 397 F. Supp. 2d at 444–45 (finding that plaintiff failed to allege motive and opportunity when "Defendants' sales appear to have been distributed fairly evenly throughout the Class Period, not clustered at its end, when insiders theoretically would have rushed to cash out before the fraud was revealed and stock prices plummeted").)

Most importantly, the CAC "fail[s] to plead any facts that would suggest that defendants' sales during the Class Period deviated from their patterns of sales before [] the Class Period." *In re BISYS*, 397 F. Supp. 2d at 445. In fact, the CAC contains no reference to Defendants' stock sales prior to the Class Period. Defendants attach as exhibits to the Adler Declaration various SEC filings, (Adler Decl. Exs. 10–83), which reveal that Guyer's and Patel's Class Period trades were not "dramatically out of line with [their] prior trading practices," *In re Gildan*, 636 F. Supp. 2d at 270. I find it appropriate to take judicial notice of these documents. *See, e.g.*, *In re Sina Corp. Sec. Litig.*, No. 05 Civ. 2154(NRB), 2006 WL 2742048, at *11 (S.D.N.Y. Sept. 26, 2006) (explaining that "plaintiffs only list sales that occurred during the Class Period; they do not include previous sales, thus leaving the Court unable, from the face of the complaint, to determine if [defendants' trading] activities were truly 'unusual,'" and taking judicial notice of defendants' SEC filings).[19]

[19] Guyer's and Patel's SEC Forms 3 and 4 (submitted as Exhibits 10 to 83 of the Adler Declaration) are documents "required to be filed with the SEC under penalty of perjury, [and] are used by officers of public corporations to publicly disclose their transactions in company stock." *Malin v. XL Capital Ltd.*, 499 F. Supp. 2d 117, 133 (D. Conn. 2007), *aff'd*, 312 F. App'x 400 (2d Cir. 2009). I therefore find that they may be considered for the truth of their contents. *See id.* ("These documents are routinely accepted by courts on motions to dismiss securities fraud complaints and are considered for the truth of their contents."); *see also In re Bear Stearns*, 763 F. Supp. 2d at 583 ("The Forms 3, 4, and 5 are required SEC disclosures and may be considered for the truth of their contents."); *In re Sina*, 2006 WL 2742048, at *11 (granting motion to dismiss while taking judicial notice of defendants' SEC filings "to conclusively determine that the Individual Defendants' trading activity during the Class Period was not at all

The SEC filings of Defendants Guyer and Patel confirm that their trading practices during the Class Period were similar to their practices prior to the Class Period. For instance, both prior to and during the Class Period, Defendant Guyer acquired common stock on a monthly basis by exercising options that had vested, and sold all of those newly acquired shares the same day. (*See* Defs.' Br. App'x A.) Defendant Patel's stock sales followed a similar pattern: in the twelve months prior to the Class Period, Patel sold between 14,319 and 27,873 shares each month, while during the Class Period, he sold between 12,000 and 27,215 shares per month. (*See id.* App'x B.) In fact, Plaintiff appears to concede that Defendants' Class Period stock sales were in line with their earlier sales. (*See* Pl.'s Opp'n 31 ("Both prior to and during the Class Period, Guyer and Patel frequently sold *all* of their available Ophthotech stock . . . .").) Plaintiff does not adequately explain why this fact should not impact my analysis.

Defendants also argue that these sales were not suspicious because the trades were made pursuant to non-discretionary 10b5-1 trading plans. (*See* Defs.' Br. 29–30.) However, I decline to consider this argument at the motion to dismiss stage as the majority of Defendants' Class Period sales were carried out pursuant to 10b5-1 trading plans entered into during the Class Period. Although ordinarily "the use of a non-discretionary trading plan that sells fixed quantities of stock on pre-scheduled dates undermines any inference of scienter," where such a plan is entered into during the class period, it is "not a cognizable defense to scienter allegations

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unusual when compared with their prior activity"). Plaintiff's motion to strike these exhibits is denied.

Plaintiff's motion to strike the charts summarizing the information contained in Exhibits 10 to 83 of the Adler Declaration, (*see* Defs.' Br. App'x A, B), is also denied. ("Defs.' Br." refers to the Memorandum of Law in Support of Defendants' Motion to Dismiss the Consolidated Amended Complaint, filed July 27, 2018. (Doc. 70.).) I find that these appendices are properly considered as compilations of voluminous data "that cannot be conveniently examined in court" under Federal Rule of Evidence 1006. *See In re Bear Stearns*, 763 F. Supp. 2d at 582–83 (taking notice of "charts and tables [that] expressly summarize SEC Forms 3, 4, and 5"). I find it particularly appropriate to rely on these materials given that Defendants have also submitted the "underlying documents . . . for consideration." *Malin*, 499 F. Supp. 2d at 134.

on a motion to dismiss." *Nguyen v. New Link Genetics Corp.*, 297 F. Supp. 3d 472, 494 (S.D.N.Y. 2018) (internal quotation marks omitted). Setting aside the fact that Defendants traded pursuant to a non-discretionary trading plan, I conclude that the timing and amount of the underlying Class Period trades—in comparison to Defendants' prior trading activity—confirm that Defendants' trades during the Class Period were not "unusual or suspicious in timing or amount." *In re Keryx*, 2014 WL 585658, at *13. I therefore find that Plaintiff has not established a strong inference of scienter under the "motive and opportunity" prong.

b. Circumstantial Evidence of Misbehavior or Recklessness

I next analyze whether Plaintiff has identified strong circumstantial evidence indicating that Defendants either consciously misbehaved or acted recklessly. Because I have determined that the only actionable misstatements alleged in the CAC are Defendants' assertions that there was no material change in the enrollment criteria between Phase 2b and Phase 3 of the Fovista clinical trials, I will analyze only whether Plaintiff pleads facts indicating Defendants' conscious misbehavior or recklessness as to that category of alleged misstatements. I find that the CAC—and the documents it incorporates by reference—contain sufficient facts to support a strong inference that Defendants were aware that they lacked a reasonable basis for their repeated representations that the change in methodology following the Phase 2b Trial did not alter the pool of patients eligible to participate in the Phase 3 Trial.

Defendants insist that "[i]t defies reason that they would have changed the eligibility criteria in a way that would have undermined the Phase 3 Trials' chance of success." (Defs.' Br. 33.) As an alternative theory, Defendants argue that "the far more compelling inference is that Defendants believed that assessing eligibility . . . through SD-OCT (and its identification of SHRM), rather than through FA (and its identification of classic lesions) would actually improve

[Ophthotech's] ability to distinguish between various lesion subtypes, not that it would hinder the likelihood of success." (*Id.*) I find that while "defendants' characterization of events is certainly one inference that can be drawn from the alleged facts[,] . . . taking the facts in the light most favorable to [Plaintiff], this does not amount to a more compelling inference than that proffered by [Plaintiff]." *In re Ambac Fin. Grp., Inc. Sec. Litig.*, 693 F. Supp. 2d 241, 269 (S.D.N.Y. 2010). Plaintiff puts forth a credible theory that Defendants determined that the allegedly increased risk of failure resulting from the change in enrollment criteria was outweighed by certain benefits that would accompany broadening the pool of patients eligible to participate in the Phase 3 Trial. Specifically, Plaintiff points out that by changing the Phase 3 enrollment criteria to include patients with pure occult lesions, if the trial were successful, "[Defendants] would be more likely to secure broad approval of Fovista for all wet AMD patients, including the 40% of patients with pure occult lesions." (Pl.'s Opp'n 19 n.13.).

In any event, Defendants' argument that they would not have intentionally sabotaged the Phase 3 Trial's likelihood of success misses the mark. The CAC alleges that Defendants materially altered the Phase 3 enrollment criteria despite repeatedly representing that the changed methodology had not had this effect. Whether or not this alteration made the Phase 3 Trial more likely to fail is a question of causation—the proper scienter inquiry is whether Defendants "knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." *Novak*, 216 F.3d at 308. The fact that Defendants had in their possession information suggesting that there was an overlap between those patients whose lesions were classified as pure occult—and who therefore would have been *ineligible* to participate in Phase 2b—and those patients who demonstrated the presence of SHRM—and who therefore would have been *eligible* to participate in Phase 3, (*see* Adler Decl. Ex. 1, at 13; Ex. 5, at 94)—is

sufficient to demonstrate at the motion to dismiss stage of this litigation that Defendants were reckless in representing that they had "changed nothing" between Phase 2b and Phase 3, (*see* CAC ¶ 82; *see also Van Dongen*, 951 F. Supp. 2d at 473 ("The Court finds a strong inference of scienter because Lead Plaintiffs have adequately alleged that defendants were aware of information that contradicted their statements.")).

Thus, I find that the factual allegations set forth in the CAC are sufficient to draw the requisite "strong inference" of scienter.

C. *Loss Causation*

Finally, Defendants contend that the CAC fails to adequately allege loss causation. To the contrary, I find that Plaintiff satisfactorily alleges that the risk concealed by Defendants' misleading statements regarding the enrollment criteria for the Phase 3 Trial materialized, thereby causing Plaintiff's loss.

1. Applicable Law

To demonstrate loss causation under Section 10 and Rule 10b–5, a plaintiff must ultimately "prove the damages it suffered were a foreseeable consequence of the misrepresentation" alleged. *Suez Equity Inv'rs, L.P. v. Toronto-Dominion Bank*, 250 F.3d 87, 96 (2d Cir. 2001). At the pleading stage, a complaint must allege "facts that support an inference that [the defendant]'s misstatements and omissions concealed the circumstances that bear upon the loss suffered such that plaintiffs would have been spared all or an ascertainable portion of that loss absent the fraud." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 175 (2d Cir. 2005); *see also Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F3d 227, 232 (2d Cir. 2014) (explaining that a complaint must allege that "the subject of the fraudulent statement or omission was the cause of the actual loss suffered" (internal quotation marks omitted)).

Loss causation may be established either by demonstrating (1) that the defendant made a corrective disclosure revealing the earlier fraud or (2) that the risk concealed by the defendant's fraud subsequently materialized. *See Axar Master Fund, Ltd. v. Bedford*, 308 F. Supp. 3d 743, 760 (S.D.N.Y. 2018). "A plaintiff pleading that its economic loss was caused by the materialization of a concealed risk 'must allege that the loss was (1) foreseeable and (2) caused by the materialization of the concealed risk.'" *Id.* (quoting *In re Lehman Bros. Sec. & Erisa Litig.*, 799 F. Supp. 2d 258, 304 (S.D.N.Y. 2011)). If, however, "the connection is attenuated, or if the plaintiff fails to demonstrate a causal connection between the content of the alleged misstatements or omissions and the harm actually suffered, a fraud claim will not lie." *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 261 (2d Cir. 2016) (internal quotation marks omitted). "[T]he law is clear that Plaintiffs must do more than simply point to missed earnings forecasts or other 'bad news' to plead loss causation." *In re Francesca's Holdings Corp. Sec. Litig.*, No. 13-cv-6882 (RJS), 2015 WL 1600464, at *21 (S.D.N.Y. Mar. 31, 2015).

"The question of whether Rule 9(b) applies to loss causation has not yet been definitively addressed by the Second Circuit, but the vast majority of courts in this district have required that loss causation only meet the notice requirements of Rule 8." *Wilamowsky v. Take–Two Interactive Software, Inc.*, 818 F. Supp. 2d 744, 753 n.7 (S.D.N.Y.2011) (collecting cases); *see also Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 182–83 (2d Cir. 2015) (describing the question of whether a plaintiff must plead loss causation "with the specificity required by Rule 9(b)" as "an open one in our Circuit [] in the PSLRA context"); *see also Speakes v. Taro Pharm. Indus., Ltd.*, No. 16-cv-08318 (ALC), 2018 WL 4572987, at *10 (S.D.N.Y. Sept. 24, 2018) ("The Second Circuit Court of Appeals has yet to weigh in on this debate."). "Under either standard, however, the securities fraud plaintiff's burden is not a heavy

one" and requires only that a plaintiff "'provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind.'" *Speakes*, 2018 WL 4572987, at *10 (quoting *Dura*, 544 U.S. at 347).

2. Application

As Defendants assert, the "Loss Causation/Economic Loss" section of the CAC contains boilerplate causation allegations that, standing alone, would be insufficient to withstand a motion to dismiss. (*See, e.g.*, CAC ¶¶ 147–50 (alleging that Defendants' "misrepresentations and fraudulent conduct . . . . presented a misleading picture of Ophthotech's business and prospects," which "caused Ophthotech common stock to trade at artificially inflated levels" that plummeted when the fraud was "finally . . . revealed to investors" at the time the Phase 3 Trial results were announced).)

However, the crucial allegations that support a plausible claim that Defendants' misrepresentations caused Plaintiff's losses are found elsewhere in the CAC: Plaintiff alleges that "the changed enrollment criteria significantly impacted the Phase 3 Trials' prospects for success, because when images of patients' lesions were examined at the end of Ophthotech's phase 1 clinical trial of Fovista, *the occult components of the lesions appeared to be unaffected by treatment with Fovista.*" (*Id.* ¶ 60 (emphasis added).)[20] In short, Plaintiff contends first that Defendants' modifications to the enrollment methodology—i.e., determining eligibility for the Phase 3 Trial based on the presence of SHRM rather than the absence of pure occult lesions—

[20] Because I find that Plaintiff need only satisfy the more lenient Rule 8 pleading standard here, Plaintiff is not required—at this early stage of the litigation—to provide documentary evidence to support its claims that the inclusion of patients with pure occult lesions in the Phase 3 Trial increased the risk that the trial would fail. *Cf. Novak*, 216 F.3d at 314 (explaining that, in order to satisfy Rule 9(b)'s heightened pleading standard, plaintiffs must "provid[e] documentary evidence and/or a sufficient general description of the personal sources of the plaintiffs' beliefs"). Defendants attached the published results of the Phase 1Fovista clinical trial as an exhibit to the Adler Declaration, (*see* Adler Decl. Ex. 8), to challenge Plaintiff's factual assertions regarding the outcome of the Phase 1 trial; however, in response to Plaintiff's motion to strike, Defendants withdrew their request that I take judicial notice of the published Phase 1 results. (*See* Defs.' Mot. to Strike Opp'n 1 n.1, 7 n.7.)

significantly altered the pool of potential Phase 3 participants by allowing at least some individuals with pure occult lesions who would have been ineligible to participate in the Phase 2(b) Trial to participate in Phase 3. (*See, e.g.*, *id.* ¶ 8.) Plaintiff next argues that this change made the Phase 3 Trial more likely to fail because results from earlier clinical trials demonstrated that Fovista was less effective in treating the occult components of lesions. (*Id.* ¶ 60.) In other words, because occult lesions are less responsive to Fovista, by making changes to the Phase 3 enrollment criteria that resulted in the inclusion of patients with pure occult lesions in that trial, Defendants increased the risk that the trial would fail. Finally, Plaintiff argues that this risk ultimately materialized when Defendants announced in December 2016 that the Phase 3 Trial did not reveal a statistically significant improvement in visual acuity for those patients who received Fovista combination therapy, as compared to those who received Lucentis monotherapy. (*Id.* ¶ 121.)

While discovery may reveal that the failure of the Phase 3 Trial was unrelated to the allegedly altered enrollment criteria, it is a logical inference that changing a key variable in a subsequent iteration of a clinical trial increases the risk that the previous trial's results will not be replicated. And the fact that Defendants claimed to change so few variables between Phase 2b and Phase 3 only increases the likelihood that the changed enrollment criteria contributed to the failure of Phase 3. (*Cf. id.* ¶ 86 (quoting Defendant Guyer's statement that "the Phase III program really is to just confirm the Phase II, really similar in virtually every way short of the regulatory time point of 12 months, which is needed for regulatory [approval], versus six months").) At the motion to dismiss stage, it is sufficient that Plaintiff has plausibly alleged "a direct connection between the risk that is hidden from investors and the subsequent loss suffered by those investors." *Salvani v. ADVFN PLC*, 50 F. Supp. 3d 459, 465 (S.D.N.Y. 2014), *aff'd*

sub. nom. Salvani v. InvestorsHub.com, Inc., 628 F. App'x 784 (2d Cir. 2015). Moreover, "to prove loss causation, plaintiffs need not show that the alleged scheme was the *sole* cause of loss." *In re Initial Pub. Offering Sec. Litig.*, 227 F.R.D. 65, 115 n.378 (S.D.N.Y. 2004), *vacated and remanded on other grounds sub nom. In re Initial Pub. Offerings Sec. Litig.*, 471 F.3d 24 (2d Cir. 2006).

In sum, I find Plaintiff's allegations that Defendants' misrepresentations concealed an increased risk that the Phase 3 Trial would fail, followed by the actual failure of that trial, sufficient to plead loss causation at the motion to dismiss stage. *Cf. Lentell*, 396 F.3d at 175 (requiring plaintiff to allege that defendant had "misstated or omitted risks that [led] to the loss").[21]

V. Conclusion

For the foregoing reasons, Plaintiff's motion to strike is GRANTED IN PART and DENIED IN PART, and Defendants' motion to dismiss the CAC is DENIED.

[21] Defendants further contend that, because Plaintiff has failed to plead a violation of Section 10(b) of the Exchange Act, Plaintiff has also necessarily failed to plead a control person claim under Section 20(a). *See Ganino*, 228 F.3d at 170 ("To make out a prima facie case under § 20(a)[,] . . . a plaintiff must show a primary violation [here, the alleged violation of Section 10(b) and Rule 10b–5] by the controlled person . . . ." (internal quotation marks omitted)). Because (1) I have determined that the CAC adequately pleads a primary violation of the Exchange Act, and (2) Defendants cite no other ground for dismissing Plaintiff's Section 20(a) claim, Defendants' motion to dismiss that claim is denied.

The Clerk of Court is respectfully directed to terminate the motions pending at Docket Entries 69 and 75.

SO ORDERED.

Dated: September 18, 2019
New York, New York

Vernon S. Broderick
United States District Judge