UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NEUROTROPE, INC. SECURITIES LITIGATION

17 Civ. 3718 (LGS)

OPINION AND ORDER

LORNA G. SCHOFIELD, District Judge:

Lead Plaintiffs Sean Hinshaw and Daniel Hovasse, individually and on behalf of all other persons similarly situated, bring this putative class action against Defendants Neurotrope, Inc. ("Neurotrope" or the "Company"), Susanne Wilke and Daniel Alkon (collectively, the "Individual Defendants"), alleging violations of § 10(b) and § 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). Defendants move to dismiss the First Amended Complaint (the "Complaint") pursuant to Federal Rule of Civil Procedure 12(b)(6). For the following reasons, the motion is granted.

I. BACKGROUND

The following facts are taken from the Complaint and accepted as true for the purposes of this motion. *See Doe v. Columbia Univ.*, 831 F.3d 46, 48 (2d Cir. 2016).

A. Background

Neurotrope is a clinical stage biopharmaceutical company that specializes in developing therapeutic drugs for neurodegenerative disease, such as Alzheimer's Disease ("AD" or "Alzheimer's"). Bryostatin-1 ("Bryostatin") is Neutrotrope's lead drug candidate for AD treatment. Neurotrope claims that Bryostatin promotes protein kinase C isozyme epilson ("PKC

protein"), which may have a role in growing synapses and in preventing synaptic loss that may correlate with the cognitive impairments associated with AD.

At all relevant times, Neurotrope has employed only about five individuals, including Defendant Wilke, its Chief Executive Officer ("CEO"), and Defendant Alkon, who has been Chief Scientific Officer ("CSO") since August 2013 and President since September 2016.

Before presenting a new drug to the United States Food and Drug Administration (the "FDA"), pharmaceutical companies are required to engage in three phases of clinical trials, each phase growing in sample size and complexity. 21 C.F.R. § 312.21; *see also* The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective, https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last visited April 24, 2018). Phase 1 studies typically include 20 to 80 subjects and are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and early evidence on effectiveness. 21 C.F.R. § 312.21(a)(1). Phase 2 studies are designed to evaluate the effectiveness, common short-term side effects and risks associated with the drug. *Id.* at § 312.21(b). Phase 2 studies' usually include no more than several hundred subjects. *Id.* Phase 1 and 2 studies are conducted to obtain preliminary evidence of effectiveness. *See id.* at § 312.21(c). Phase 3 studies are expanded controlled and uncontrolled trials, designed to gather additional information about effectiveness and safety to evaluate the benefit-risk relationship of the drug and provide a basis for physician labeling. *Id.* Phase 3 studies usually include several hundred to several thousand subjects. *Id.*

The medical industry standard for statistical significance is $p < 0.05$,[1] and one-sided tests are uncommon because they do not address whether the test drug is actually worse than the control.[2]

B. Events Prior to the Class Period

On March 17, 2015, Neurotrope issued a press release announcing that it had completed its Phase 2a study that preliminarily evaluated Bryostatin's safety, tolerability, and efficacy, as reflected by the correlation between PKC protein levels and Bryostatin plasma levels.

On January 7, 2016, Neurotrope issued a press release announcing that it had initiated its Phase 2b study to further evaluate the safety, tolerability, and efficacy of Bryostatin. The press release stated that the study would evaluate two different doses of Bryostatin (20 or 40 µg) versus placebo, with two efficacy end points: the primary efficacy endpoint based on Severe Impairment Battery ("SIB") scale, a benchmark used in severe Alzheimer's drug trials; and the secondary efficacy endpoints based on Activities of Daily Living ("ADL"), Neuropsychiatric Inventory ("NPI") and Mini-Mental State Exam ("MMSE").

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[1] "p-value" refers to the probability that the same results would be found if the null hypothesis of the study in question were true. *See* Federal Judicial Center, Reference Manual on Scientific Evidence 250 (3d 2011). For example, $p < 0.1$ means that the probability that the same results would be found if the null hypothesis of the study were true is less than 10%. $p < 0.05$ means that that probability is less than 5%. In practice, statistical analysts typically use $p < 0.05$ or $p < 0.01$. *Id.* at 251

[2] One- and two-sided tests refer to different methods of computing the statistical significance of a parameter inferred from a data set. *See* Federal Judicial Center, Reference Manual on Scientific Evidence 321 (3d 2011). In assessing a linear association between an independent and dependent variable, a two-sided test is appropriate where the alternative hypothesis is either positive or negative compared to the null hypothesis. *Id.* A one-sided test is appropriate where the alternative hypothesis is either positive or negative, but not both, compared to the null hypothesis. *Id.* For example, one would more likely use a one-sided test if he or she strongly believes that the independent variable's effect on the dependent variable is either zero or positive, but not negative. *Id.*

On November 22, 2016, Neurotrope issued a press release announcing that it had completed the enrollment for the Phase 2b study. Shortly thereafter, Neurotrope received the clinical results from the study. The clinical results showed that, compared to the placebo group, patients on the 40 µg dose did not show a statistically significant increase on SIB, neither at $p < 0.1$ nor at $p < 0.05$. Those on the 20 µg dose, in contrast, showed a mean increase on SIB of 1.5, compared to a decrease in the placebo group of -1.1. This improvement was statistically significant at $p < 0.1$, but not at $p < 0.05$. The Phase 2b study was a one-sided test.

C. The Alleged Material Omissions and Misrepresentations

During the period from January 30, 2017 to July 18, 2017 (the "Class Period"), Plaintiffs acquired Neurotrope's securities. Plaintiffs allege that Defendants made material omissions and misrepresentations on five occasions during the Class Period: (1) at the Noble Financial Capital Markets' 13th Annual NobleCON Conference for investors on January 30, 2017; (2) at the 2017 BIO CEO & Investor Conference on February 13, 2017; (3) in a March 24, 2017, press release and (4) in a May 1, 2017, press release.

The Complaint's allegations of material omissions and misstatements fall into three categories. The first category -- which makes up the majority of the alleged misleading statements -- consists of instances where Defendants failed to disclose that the Phase 2b study used a one-tailed test with $p < 0.1$ for statistical analysis, instead of the alleged industry norm of two-tailed test with $p < 0.05$. The Complaint alleges that this nondisclosure rendered misleading Defendants' statements touting positive results based on a showing of "statistically significant" efficacy in the Phase 2b study. For example, on January 30, 2017, the beginning of the Class Period, at the Noble Financial Capital Markets' 13th Annual NobleCON Conference for investors, Defendant Wilke announced that the Company had preliminary clinical and

compassionate use patient data from the Phase 2b study, and that they saw "remarkable results in the reversal of [AD]." Similarly, on February 13, 2017, at the 2017 BIO CEO & Investor Conference, Neurotrope announced that: "[w]e have extensive preclinical data, clinical data, and compassionate use data that leads us to believe that our mechanism of action can be very effective in reversing [AD]." And on May 1, 2017, Neurotrope's press release stated, "The results of this relatively small randomized, double-blind, placebo controlled study of Bryostatin-1 shows that Bryostatin-1 has the potential to positively impact the lives of these severely debilitated patients with moderate to severe AD."

The second category of alleged misstatements and omissions consists of Defendants' failure to disclose until November 22, 2016, that the Phase 2b study using a 40 µg dose did not show a statistically significant result. The Complaint alleges that the May 1, 2017, press release about the result of the Phase 2b study was misleading as a result of this omission.

The third category consists of instances where Defendants allegedly misrepresented Bryostatin's ability to reverse AD. For example, on March 24, 2017, Neurotrope issued a press release stating that "Bryostatin-1 has demonstrated the potential to prevent neuronal death as well as the well-known brain pathologies, amyloid plaques and neurofibrillary tangles" and touted "Bryostatin's multiple efficacies."

D. Reliance and Loss Causation

Following the January 30, 2017, statement, Neurotrope's share price increased from $9.75 per share on January 27, 2017, to $11.58 per share on January 30, 2017, on unusually heavy trading volume. And following the February 13, 2017, statement, the stock price increased from $13.35 per share on February 10, 2017, to $15.00 per share on February 13, 2017.

The May 1, 2017, press release disclosed, for the first time, that the study was one-sided and that "[a]mong the patients who completed the protocol (n = 113), the patients on the 20 µg dose at 13 weeks showed a mean increase on the SIB of 1.5 vs. a decrease in the placebo group of -1.1 (improvement of 2.6) ($p < 0.07$) (n = 80)." On this news, Neutrotrope's share price fell from $11.84 to $6.97, or approximately 63%.

On July 17, 2017, Neurotrope issued a press release disclosing that the Phase 2b study at 40 µg Bryostatin showed "no therapeutic signal." On this news, Neurotrope's share price fell approximately 24%, to close at $5.80 on July 20, 2017. The alleged Class period ends July 2017.

E. Scienter

The Complaint alleges scienter based on inferences from the facts summarized above. In addition, the Complaint alleges that the Individual Defendants knew all material information about Bryostatin, by virtue of their senior executive positions at Neurotrope, which had only five employees.

The Complaint also relies on two articles. On May 3, 2017, an article was published in *Seeking Alpha*,[3] titled "A Neurotrope Stock Promotion Scheme is Underway, but Who's Paying for It?" The Complaint speculates that "Neurotrope insiders" were responsible for the article's report that unknown persons paid to have articles by a sell-side analyst turned into paid promotional press releases distributed over a newswire service. On May 4, 2017, an analyst who goes by a pseudonym published an article in *Seeking Alpha* titled "Behind Neurotrope, Clear and Overwhelming Links to Fraudsters," which further describes how Neurotrope promoted its own stock price. The articles are not attached to the Complaint and no longer appear to be available on the *Seeking Alpha* website.

[3] *Seeking Alpha* is an online, crowd-sourced content service about the U.S. stock market.

II. STANDARD

To survive a motion to dismiss under Rule 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 has 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.* (citing *Twombly*, 550 U.S. at 556). It is not enough for a plaintiff to allege facts that are consistent with liability; the complaint must "nudge[]" claims "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. "To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.'" *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). On a Rule 12(b)(6) motion, "all factual allegations in the complaint are accepted as true and all inferences are drawn in the plaintiff's favor." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59 (2d Cir. 2016) (quoting *Littlejohn v. City of N.Y.*, 795 F.3d 297, 306 (2d Cir. 2015)). "In adjudicating a motion to dismiss, a court may consider only the complaint, any written instrument attached to the complaint as an exhibit, any statements or documents incorporated in it by reference, and any document upon which the complaint heavily relies." *ASARCO L.L.C. v. Goodwin*, 756 F.3d 191, 198 (2d Cir. 2014) (quoting *In re Thelen L.L.P.*, 736 F.3d 213, 219 (2d Cir. 2013)).

"Any complaint alleging securities fraud must satisfy the heightened pleading requirements of [the Private Securities Litigation Reform Act (the "PSLRA")] and Fed. R. Civ. P. 9(b) by stating with particularity the circumstances constituting fraud." *Emps.' Ret. Sys. of Gov't of the V.I. v. Blanford*, 794 F.3d 297, 304 (2d Cir. 2015) (quoting *ECA, Local 134 IBEW*

Joint Pension Tr. of Chi. v. JP Morgan Chase Co., 553 F.3d 187, 196 (2d Cir. 2009)). Under Rule 9, "[a] securities fraud complaint [based on misstatements] must (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." *Charles Schwab Corp. v Bank of Am. Corp.*, 883 F.3d 68, 94 (2d Cir. 2018) (internal quotation marks omitted) (quoting *Blanford*, 794 F.3d at 305). The PSLRA similarly requires a pleading to allege "the reason or reasons why the statement is misleading, and if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all the facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1)(B).

III. DISCUSSION

Plaintiffs assert a claim of securities fraud under § 10(b) of the Exchange Act and its implementing rule, Rule 10b-5. That rule makes it unlawful "[t]o 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). The Complaint also asserts a claim of control person liability under § 20(a) of the Exchange Act.

Principally at issue on this motion is whether the Complaint sufficiently pleads three of the six elements of securities fraud -- a material misrepresentation or omission, scienter and loss causation.[4] Because the Complaint fails to allege a material misrepresentation or omission, and scienter, the loss causation issue is not addressed.

[4] "To state a claim for violation of [§ 10(b) and Rule 10b-5], a plaintiff must allege '(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.'" *Charles Schwab*

A. Section 10(b) Violation

1. Material Omissions and Misrepresentations

As noted above, the first element of a Rule 10b-5 violation is that the defendant made an omission or misstatement of material fact. "[Section] 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. Sircusano*, 563 U.S. 27, 44 (2011) (internal quotation marks omitted) (quoting Rule 10b-5, 17 C.F.R. § 240.10b-5(b); *accord In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 239 (2d Cir. 2016) ("*Vivendi*"). "[O]nce a company speaks on an issue or topic, there is a duty to tell the whole truth, even where there is no existing independent duty to disclose information on the issue or topic." *Id*. at 258 (internal quotation marks omitted); *see also Caiola v. Citibank, N.A., N.Y.*, 295 F.3d 312, 331 (2d Cir. 2002) (when a party chooses to speak on a subject, it has a "duty to be both accurate and complete").

A statement or omission is material 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" to the market. *IBEW Local Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scot. Grp., P.L.C.*, 783 F.3d 383, 390 (2d Cir. 2015) (internal quotation marks and citations omitted).

"[A] sincere statement of pure opinion is not an untrue statement of material fact, regardless whether an investor can ultimately prove the belief wrong." *Omnicare, Inc. v.*

Corp., 883 F.3d at 92 (quoting *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2407 (2014)).

Laborers Dist. Council Const. Indus. Pension Fund, 135 S. Ct. 1318, 1327 (2015) (internal quotation marks omitted). "An opinion statement . . . is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way. Reasonable investors understand that opinions sometimes rest on a weighing of competing facts." *Id.* at 1329. However, "[§ 10(b)] liability for making a false statement of opinion may lie if either 'the speaker did not hold the belief she professed' or 'the supporting fact she supplied were untrue.'" *Tongue v. Sanofi ("Sanofi II")*, 816 F.3d 199, 210 (2d Cir. 2016) (quoting *Omnicare*, 135 S. Ct. at 1327). "[O]pinions, though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information whose omission makes the statement misleading to a reasonable investor." *Id.* (citing *Omnicare*, 135 S. Ct. at 1332).

A statement is not actionable if it is mere puffery. *Vivendi*, 838 F.3d at 244. Puffery encompasses "statements that are too general to cause a reasonable investor to rely upon them, and thus cannot have misled a reasonable investor. They are statements that lack the sort of definite positive projections that might require later correction." *Id.* at 245 (internal citations and quotation marks omitted).

a. Failure to Disclose the Phase 2b Statistical Analysis

The Company's failure to disclose -- between January and April 2017 -- that the Phase 2b study results were analyzed using a one-tail test with $p < 0.1$ is not a material omission. As in this case, in *Kleinman v. Elan Corp., P.L.C.*, 706 F.3d 145 (2d Cir. 2013) the plaintiffs brought a securities fraud action against defendants for statements announcing positive results on their phase 2 clinical study of an Alzheimer's drug. *Id.* at 147. The press release at issue in *Kleinman* stated that, although "the study did not attain statistical significance on the primary efficacy endpoints in the overall study population, post-hoc analyses did show statistically significant and

clinically meaningful benefits in important subgroups." *Id.* at 149. The plaintiffs alleged that this statement was misleading in part because the defendants had failed to disclose that the post-hoc analysis had changed the statistical modeling from linear to curvilinear. *Id.* at 154. The court rejected the plaintiff's argument, stating, "[t]he press release simply stated that a post-hoc analysis was used without specifying the methodology; nothing about this is misleading." *Id.*

Similarly in this case, Defendants stated that Bryostatin showed positive results without stating the methodology. This statement is not misleading because Bryostatin at 20 µg, compared to the control group, actually showed a positive correlation with PKC protein level.[5] Plaintiffs argue that the statement was misleading because the positive correlation was meaningful only because of the measure of statistical significance used. The Second Circuit rejected a similar argument: "Kleinman's real complaint is that Defendants were able to tout positive results only because they deviated from the established protocol (which called for a linear analysis) and changed the metrics by which data was analyzed." *Id.* The Court in *Kleinman* held that the omission was not actionable. *Id.* at 155.

Plaintiffs indirectly ask the Court to opine on the proper p-value and hold that the use of a p-value other than < 0.05 is so anomalous that the resulting statistical modeling is fraudulent if the p-value is not disclosed. It is not the Court's job to determine an appropriate p-value for

[5] The fact that Defendants did not adopt the alleged industry measure of statistical significance -- i.e., p-value of < 0.05 -- does not make Defendants' statement about Bryostatin's efficacy any less true, because "[s]tatistical significance is determined *by reference* to the p-value". *Davidson v. Ventrus Bioscis., Inc.*, No. 13 Civ. 3119, 2014 WL 1805242, at *8, n. 7 (S.D.N.Y. May 5, 2014) (emphasis added); *see also* Federal Judicial Center, Reference Manual on Scientific Evidence 250 (3d 2011). The p-value is a *standard* for determining whether the test result is considered statistically significant (e.g. the probability of that result occurring in the placebo population). The p-value can be set at any point. "[p-values] of 5% and 1% have become icons of science and the legal process. In truth, however, such levels are at best *useful conventions*. Because the term 'significant' is merely a label for a certain kind of p-value, significance is subject to the same limitations as the underlying p-value." *Id.* at 252 (emphasis added).

pharmaceutical studies. Defendants have not cited any FDA guideline or requirement that Defendants use a particular p-value in its Phase 2 clinical trials. *See generally In re Columbia Labs. Inc., Sec. Litig.*, 602 F. App'x 80, 82 (3d Cir. 2015) ("the FDA guidelines for single-trial studies -- incorporated by reference in the complaint -- do not require a 0.01 p-value for a new drug to be approved and do not identify any particular p-value for 'statistical significance.'"). The Second Circuit in *Kleinman* similarly reasoned:

> Our job is not to evaluate the use of post-hoc analysis generally in the scientific community; the FDA has already done so. Instead, we look to see whether the statements made were misleading or rendered misleading due to an omission. The June press release accurately disclosed that the only positive results from the entirety of the Phase 2 study stemmed from the use of post-hoc analysis.

Kleinman, 706 F.3d at 154–55. In the present case, Defendants accurately stated that the results of the study were positive but preliminary.[6]

In addition, the alleged omission of the statistical methodology -- a one-tail test with $p < 0.1$ -- did not make the statements made misleading. The full transcript of the January 30, 2017, conference reveals that while reporting that Bryostatin showed promising results in reversing AD, in response to an audience question about the trial results, Defendant Wilke clarified that it "was a trial of nine patients. [The sample size w]as very small, indeed." A reasonable investor would have understood that regardless of the methodology, the positive results were preliminary, based on a very small sample size, and required additional investigation. "[I]n the light of the circumstances under which they were made," *Matrixx*, 563 U.S. at 44, Defendants' failure to disclose how the study results were analyzed did not make Defendants' statement about

[6] Plaintiffs' reliance on *In re Decalth Sys. Inc., Sec. Litig.*, 36 F. Supp. 3d 320 (S.D.N.Y. 2014) ("*Decalth*") is inapposite. In *Decalth*, Defendants allegedly omitted results that cast a more negative light on their statements about the safety of the drug. *Id.* at 327-329. The information omitted in in this case, in contrast, was the methodology employed to interpret the results, and not the results themselves.

Bryostatin's effect misleading. *See, e.g.*, *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 586–87 (S.D.N.Y. 2016) (finding that the defendant's failure to disclose that the FDA requested evidence that the defendant's drug was superior to its components at comparable doses did not make the defendant's statement that the FDA requested "additional information" misleading, because the defendant had disclosed that it failed to receive the FDA approval of a drug, that the drug approval application included the full set of results from the drug study, and that the defendant planned to respond to the FDA's request for more information); *In re MELA Scis., Inc. Sec. Litig.*, No. 10 Civ. 8774, 2012 WL 4466604, at *12 (S.D.N.Y. Sept. 19, 2012) (finding that the defendant's failure to disclose the study's numerous flaws did not make the defendant's statement about the FDA granting an expedited review of their drug application misleading because the defendant disclosed that the review had been extended 180 days, that the FDA was convening a panel meeting to conduct and publish its initial review of the drug, and that the defendants were trying to address the FDA's concerns in a timely manner).[7]

b. Failure to Disclose failed the 40 µg Dose Result

Defendants' failure to disclose the results of the 40 µg dose study until July 17, 2017, is not a material omission. A similar allegation was made and rejected in *Kleinman.* The Second Circuit concluded that the defendant's failure to disclose that a "higher dose did not correlate with better results," was not misleading because "[n]othing in that June press release . . . discussed whether there was a dose response or whether one was expected. The absence of a dose response may be of interest to a reasonable investor, but that circumstance alone does not

[7] The Court is in receipt of the parties supplemental letters citing *Hoey v. Insmed Inc.*, et al. No. 16 Civ. 4323, 2018 WL 902266 (D.N.J. Feb. 15, 2018). The case is not binding precedent and is factually distinguishable because it deals with alleged omissions regarding the design and structure of a Phase 2 trial, and not the methodology used to interpret its results. To the extent those issues are comparable, the case is consistent with Defendant's position and this Opinion.

necessitate its disclosure." 706 F.3d at 150, 154 (internal quotation marks omitted). Similarly here, Neurotrope's May 1, 2017, press release made no reference to a dose response or whether one was expected. Also, that Defendants did not find a statistically significant correlation between PKC protein level and Bryostatin at 40 µg does not make statements about Bryostatin's potential efficacy at 20 µg necessarily misleading. The different results at these two different doses may merely reflect that Bryostatin's optimal dose for AD treatment is closer to 20 µg, rather than 40 µg. *See Matrixx*, 563 U.S. at 44 ("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.") (internal quotation marks omitted).

c. Bryostatin's Ability to Reverse AD

Defendants' statement about Bryostatin's ability to reverse AD is not misleading "in the light of the circumstances under which they were made." *Matrixx*, 563 U.S. at 44 (internal quotation marks omitted). The Complaint mischaracterizes Defendants' statement; Defendants did not claim that Bryostatin had the ability to reverse AD. The March 24, 2017, and the May 1, 2017, press releases both refer only the drug's "*potential*" to "reverse moderate to severe Alzheimer's" and "rejuvenate synaptic network." The full transcript of the January 30, 2017, conference reveals that Defendant Wilke stated that there was "some limited cognitive enhancement," that the Phase 2 study "was a trial of nine patients. Was very small, indeed," and that "[the study] led in the right direction." A reasonable investor would have understood those statements to mean that Bryostatin showed positive preliminary results that required further investigation, not that Bryostatin has unequivocally demonstrated an ability to reverse AD.

In addition, several statements identified as allegedly misleading are examples of corporate optimism and puffery that are not actionable:

- The February 13, 2017, statement that Neurotrope is "pretty excited about [its] upcoming Phase 2 top-line data in April 2017."
- The March 24, 2017, statement that "Bryostatin-1 has demonstrated the potential to prevent neuronal death" and that "Bryostatin's multiple efficacies, collectively provide an unprecedented opportunity to treat [AD]."
- The May 1, 2017, statement that "[t]hese results, which show improvement in patients with moderate to severe Alzheimer's disease, . . . provide exciting evidence of a new therapeutic approach potentially could rejuvenate synaptic networks in the brain."

These statements reflect Neurotrope's excitement and hope about Bryostatin's future and are "too general to cause a reasonable investor to rely upon it." *Scott v. Gen. Motors Co.*, 605 F. App'x 52, 54 (2d Cir. 2015); *see, e.g.*, *In re Fairway Grp. Hldgs. Corp. Sec. Litig.*, No. 14 Civ. 0950, 2015 WL 4931357, at *13 (S.D.N.Y. Aug. 19, 2015) (finding that the defendants' statements that they are "well positioned to support growth," and that they "continue to be very excited about [the company's] growth prospects" are inactionable corporate puffery); *In re eSpeed, Inc. Sec. Litig.*, 457 F. Supp. 2d 266, 286 (S.D.N.Y. 2006) (finding that the defendant's statement that "[they']re excited about [Price Improvement's] prospects. So far, so good. Everyone has been anxiously using it and learning how to use the technology" is an expression of corporate optimism.).

2. Scienter

The Complaint fails for the additional reason that it does not sufficiently plead scienter as to either of the Individual Defendants. The PSLRA requires a plaintiff to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state

of mind." 15 U.S.C. § 78u-4(b)(2)(A). "This standard requires courts to take into account 'plausible opposing inferences.'" *Matrixx*, 563 U.S. at 48 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007)). "For an inference of scienter to be strong, 'a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged.'" *ATSI*, 493 F.3d at 99 (quoting *Tellabs*, 551 U.S. at 324) (alterations and emphasis in original). In making this determination, a court must review "all the allegations holistically." *Tellabs*, 551 U.S. at 326.

A plaintiff may satisfy the scienter requirement by "alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 106 (2d Cir. 2015) (quoting *ATSI*, 493 F.3d at 99). Conscious misbehavior "requires a showing of deliberate illegal behavior," *Gould v. Windstar Commc'ns, Inc.*, 692 F.3d 148, 158 (2d Cir. 2012) (internal quotation marks and citation omitted), whereas recklessness includes "conscious recklessness" or "a state of mind approximating actual intent, and not merely a heightened form of negligence," *S. Cherry St., L.L.C. v. Hennessee Grp. L.L.C.*, 573 F.3d 98, 109 (2d Cir. 2009); *accord Fries v. N. Oil & Gas, Inc.*, No. 16 Civ. 6543, 2018 WL 388915, at *8 (S.D.N.Y. Jan. 11, 2018). A plaintiff adequately pleads recklessness by alleging that the defendant: (1) knew facts or had access to information contradicting its public statements; or (2) failed to review or check information that it had a duty to monitor. *Blanford*, 794 F.3d at 306. "[W]here 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); *accord Fries*, 2018 WL 388915, at *10.

A complaint may satisfy the scienter requirement as to a corporation "by pleading facts sufficient to create a strong inference either (1) that someone whose intent could be imputed to the corporation acted with the requisite scienter or (2) that the statements would have been approved by corporate officials sufficiently knowledgeable about the company to know that those statements were misleading." *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Secs., L.L.C.*, 797 F.3d 160, 177 (2d Cir. 2015) (internal quotation marks omitted).

Here, the Complaint does not plead facts supporting an inference of conscious misbehavior or recklessness. The allegedly misleading statements are all based on the non-disclosure of the statistical methodology used to conclude that the clinical trial yielded positive results. Plaintiffs can establish recklessness by adequately alleging that "defendants knew facts or had access to non-public information contradicting their public statements" and therefore "knew or should have known they were misrepresenting material facts." *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 76 (2d Cir. 2001) (citing *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000)). However, an inference of scienter does not follow from the mere fact of non-disclosure of relevant information. *In re Sanofi Sec. Litig. ("Sanofi I")*, 87 F. Supp. 3d 510, 534 (S.D.N.Y. 2015), *aff'd sub nom. Sanofi II*, 816 F.3d 199.

The section of the Complaint called "Additional Scienter Allegations" focuses on the knowledge of the Individual Defendants and their likely familiarity with the clinical trial and the p-value used to interpret the data, as well as the p-value "that is mostly widely accepted and used in the clinical-stage medical research industry." The Complaint sufficiently pleads that both of the Individual Defendants were in a position to know, and likely were familiar with, the results of the clinical trial and its significance. However, even though the Individual Defendants, by virtue of their senior positions and the Company's small size, may have had the opportunity to

defraud investors about the results of the trial, the Complaint fails to allege motive to do so sufficient to plead scienter.

The Complaint's sole allegation of motive rests on the assertion that "Bryostatin was Neurotrope's only drug product candidate, so the success of the Company hinged on the clinical success of this product." This allegation is insufficient because it does not allege that the Individual Defendants "benefitted in some concrete and personal way from the purported fraud," *Novak*, 216 F.3d at 307-08, and because it merely reflects the desire common to corporate insiders for their company to be successful and profitable. "[T]he 'motive' showing is generally met when corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit," but "[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. Accordingly, the Complaint fails to allege that the Individual Defendants possessed a motive sufficient to plead the element of scienter. *See, e.g.*, *Jackson v. Halyard Health, Inc.*, No. 16 Civ. 5093, 2018 WL 1621539, at *8 (S.D.N.Y. Mar. 30, 2018) (holding, inter alia, that Defendants' desire "to take advantage of the Ebola pandemic scare" was insufficient to allege motive because the statement merely reflected corporate insiders' common desire that the company appear profitable and maintain its stock price); *Gregory v. ProNAi Therapeutics Inc.*, No. 16 Civ. 8703, 2018 WL 1358387, at *30 (S.D.N.Y. Mar. 13, 2018) (holding that the desire to have a successful IPO and raise enough money to purchase another drug candidate if company's sole drug candidate failed, provided insufficient motive to show scienter); *Fialkov v. Alcobra Ltd.*, No. 14 Civ. 09906, 2016 WL 1276455, at *7 (S.D.N.Y. Mar. 30, 2016) (holding that the complaint fails to plead scienter where its sole allegation supporting scienter is that the

drug is the company's sole drug candidate and the complaint does not allege that defendants sold any shares during the class period).

The two *Seeking Alpha* articles published in May 2017 add nothing to support an inference that the Individual Defendants acted with scienter. First, *Seeking Alpha* is not authoritative or reliable. It is a crowd-sourced content service, which describes itself as providing content that "includes curated news, research, opinion and discussions from our editorial team of 47 in addition to 15,300+ individual and corporate contributors." The second article cited in the Complaint is written by an "analyst" who goes by a pseudonym. The articles are no longer available on the *Seeking Alpha* website and are not attached to the Complaint. Second, the articles as summarized in the Complaint do not mention the Individual Defendants. Third, the articles are vague and speculative. The first asks who is paying for Neurotrope's paid promotional press releases being distributed over a newswire, and the second anonymously identifies Neurotrope as that sponsor. These articles do not describe with "sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Cf. Blanford*, 794 F.3d at 305 (describing the standard for a complaint's reliance on a confidential source who is not named in the complaint).

Because the Complaint fails to allege scienter as to the Individual Defendants, it also fails to allege scienter as to Neurotrope. *See Teamsters*, 531 F.3d at 195.

B. Section 20(a) Violation

Section 20(a) imposes joint and several liability on control persons for underlying violations of the Exchange Act. *See* 15 U.S.C. 78t. To state a claim under § 20(a), a plaintiff must allege both a primary violation of the Exchange Act and control over the primary violator.

See Carpenters Pension Tr. Fund of St. Louis v. Barclays P.L.C., 750 F.3d 227, 236 (2d Cir. 2014). Because the primary claim fails, the Section 20(a) claim is dismissed as well.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is GRANTED in full.

Plaintiffs have requested leave to replead in the event the motion is granted. In light of the deficiencies in the Complaint discussed above, the Court believes that a second amended complaint would be futile and could not survive a motion to dismiss. Nevertheless, if Plaintiffs believe otherwise and seek to file another amended complaint, by June 25, 2018, they shall file a letter not to exceed three pages single-spaced, along with their proposed new pleading marked to show changes from the First Amended Complaint. The letter shall explain how the proposed complaint cures the deficiencies identified in this Opinion. Defendants shall respond by one week after the filing of Plaintiffs' letter.

The Clerk of Court is respectfully directed to close the motion at Docket Number 32.

Dated: June 4, 2018
New York, New York

LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE