UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

| | | |
|---|---|---|
| MICHAEL NGUYEN and KELLY NGUYEN, *individually and on behalf of all others similarly situated*, | : | |
| Plaintiffs, | : | 16cv3545 |
| -against- | : | OPINION & ORDER |
| NEW LINK GENETICS CORPORATION, *et al.*, | : | |
| Defendants. | : | |

WILLIAM H. PAULEY III, Senior United States District Judge:

Defendants NewLink Genetics Corporation ("NewLink"), Charles Link, and Nicholas Vahanian move to dismiss the Second Amended Class Action Complaint ("Complaint") in this securities fraud action. For the reasons that follow, Defendants' motion to dismiss is granted.

## BACKGROUND

In the wake of this Court's prior Opinion & Order, Nguyen v. New Link Genetics Corp., 297 F. Supp. 3d 472 (S.D.N.Y. 2018), NewLink cabined its motion to dismiss to falsity and loss causation, the two elements that Plaintiffs failed to adequately allege in the First Amended Complaint.

The allegations of the Complaint are presumed true on this motion. Plaintiffs claim NewLink made a series of misrepresentations regarding the development of its flagship pancreatic cancer drug, algenpantucel-L, also known as HyperAcute Pancreas. Through the Phase 2 and Phase 3 clinical trials, NewLink and its officers allegedly misrepresented the drug's

efficacy and misled the market into believing that the company would obtain Food and Drug Administration ("FDA") approval to market the drug. However, the drug failed to achieve the requisite markers in its clinical trial, foreclosing its chances for FDA approval.

With respect to falsity, the Complaint alleges three new misstatements or omissions. Two relate to the alleged underreporting of the historic survival rate of pancreatic cancer patients during Phase 3 testing, while the third relates to Phase 2 testing's efficacy. Plaintiffs' new allegations attempt to show that NewLink undersold the survival rate of the control group so that its Phase 3 results would look better than they were, and that NewLink inflated its Phase 2 results by excluding sicker patients. According to the Complaint, this painted a rosier picture for investors, who were misled into thinking the drug would obtain FDA approval.

As for loss causation, Plaintiffs now allege that three partial or corrective disclosures revealed the truth behind NewLink's alleged misrepresentations, in addition to the final disclosure that Phase 3 had failed. All were purportedly followed by dips in NewLink's stock price, which Plaintiffs claim were caused by the disclosures. (SAC ¶ 222.) NewLink counters that these disclosures were simply bad news that triggered dips in its stock price.

## DISCUSSION

### I. Standard

#### A. Rule 12(b)(6)

On a motion to dismiss, a court must accept the facts alleged as true and construe all reasonable inferences in plaintiff's favor. ECA, Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co., 553 F.3d 187, 196 (2d Cir. 2009). Nevertheless, a complaint must "contain sufficient factual matter . . . to state a claim to relief that is plausible on its face."

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "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. The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678.

A court may consider "any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." ATSI Commc'ns, Inc. v. Shaar Fund Ltd., 493 F.3d 87, 98 (2d Cir. 2007).

B. PSLRA and Rule 9(b)

A securities fraud complaint must also satisfy the heightened pleading requirements of the Private Securities Litigation Reform Act ("PSLRA") and Federal Rule of Civil Procedure 9(b) by stating with particularity the circumstances constituting fraud. ECA, 553 F.3d at 196. This pleading threshold gives a defendant notice of the claim and is designed to safeguard the defendant's reputation from "improvident" charges in strike suits. ATSI, 493 F.3d at 99. "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." ATSI, 493 F.3d at 99.

The PSLRA "expanded on the Rule 9(b) standard, requiring that securities fraud complaints specify each misleading statement; that they set forth the facts on which [a] belief that a statement is misleading was formed; and that they state with particularity facts giving rise

to a strong inference that the defendant acted with the required state of mind." Anschutz Corp. v. Merrill Lynch & Co., 690 F.3d 98, 108 (2d Cir. 2012). Plaintiffs must "do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004).

While falsity is subject to higher pleading standards, "[t]he Second Circuit has not resolved which pleading standard applies to the issue of loss causation . . . ." Cohen v. Kitov Pharm. Holdings, Ltd., 2018 WL 1406619, at *6 n.4 (S.D.N.Y. Mar. 20, 2018); see also Speakes v. Taro Pharm. Indus., Ltd., 2018 WL 4572987, at *10 (S.D.N.Y. Sept. 24, 2018) (same). However, "the vast majority of courts in this district have required that loss causation only meet the notice requirements of Rule 8." In re New Energy Sys. Sec. Litig., 66 F. Supp. 3d 401, 405 n.26 (S.D.N.Y. 2014) (quotation marks omitted); see Nguyen, 297 F. Supp. 3d at 500 (applying Rule 8's requirements to loss causation).

II. Section 10(b)

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must allege that (1) the defendant made a misstatement or omission of material fact; (2) the defendant did so with the requisite scienter; (3) the misstatement or omission was in connection with the purchase or sale of securities; (4) one or more plaintiffs relied upon such misstatement or omission; and (5) such reliance was the proximate cause of a plaintiff's loss. Lentell v. Merrill Lynch Co., 396 F.3d 161, 172 (2d Cir. 2005). Defendants' motion disputes the sufficiency of two of those elements: (1) that the Complaint does not adequately plead materially false statements or omissions of fact; and (2) that the Complaint falls short of alleging loss causation.

A. Falsity

Misstatements of fact and opinion are both actionable, albeit subject to different standards. "A fact is a thing done or existing or [a]n actual happening. An opinion is a belief[,] a view, or a sentiment which the mind forms of persons or things. . . . [A] statement of fact ('the coffee is hot') expresses certainty . . . , whereas a statement of opinion ('I think the coffee is hot') does not." Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 135 S. Ct. 1318, 1325 (2016) (quotation marks and citations omitted) (alterations in original). In distinguishing fact from opinion, courts note that "statements of opinion include subjective statements that reflect judgments as to values that [are] not objectively determinable." In re Aratana Therapeutics Inc. Sec. Litig., 315 F. Supp. 3d 737, 758 (S.D.N.Y. 2018) (quotation marks omitted) (alteration in original).

To be actionable, statements of fact must be false, or, through their "context and manner of presentation," likely to "mislead investors." Kleinman v. Elan Corp., 706 F.3d 145, 153 (2d Cir. 2013) (quotation marks omitted). Thus, "[e]ven a statement which is literally true, if susceptible to quite another interpretation by the reasonable investor[,] may properly be considered a material misrepresentation." Kleinman, 706 F.3d at 153 (2d Cir. 2013) (quotation marks omitted) (alteration in original).

Opinions, on the other hand, are analyzed under Omnicare. There, the Supreme Court held that where an investor alleges that an issuer omitted material information that rendered an opinion misleading, the "investor must identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." Omnicare, 135 S.

Ct. at 1332. Simply put, an opinion is false "if either the speaker did not hold the belief she professed or the supporting fact she supplied w[as] untrue." Tongue v. Sanofi, 816 F.3d 199, 209 (2d Cir. 2016) (quotation marks omitted). In addition, "opinions, 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." Tongue, 816 F.3d at 209.

But the Supreme Court "cautioned against an overly expansive reading of this standard, noting that [r]easonable investors understand that opinions sometimes rest on a weighing of competing facts, and . . . do[] not expect that every fact known to an issuer supports its opinion statement. . . . [Thus, a] statement of opinion is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." Tongue, 816 F.3d at 210 (quotation marks and citations omitted) (alterations in original).

Here, the alleged false statements and opinions fall into three categories, which are discussed in turn. However, this Court notes that it previously found that Plaintiffs adequately pled falsity in the First Amended Complaint for the alleged misstatement about NewLink's successful completion of Phase 3 patient enrollment.

1. Dr. Vahanian's September 27, 2013 Statement

Plaintiffs claim that Dr. Vahanian, a NewLink co-founder, falsely stated at a September 27, 2013 conference that "[r]esected pancreatic cancer[] patients live 15 months, 19 months. You can look at the last 30 years, all the major studies, pancreatic cancer survival – U.S-based studies, I want to make that distinction – survival rates between 15 to 19, 20 months. That's it." (Second Am. Compl., ECF No. 65 ("SAC"), ¶ 92.) Plaintiffs aver that this was either a false statement of fact (because major studies did not list the survival rates at 15-20 months) or

an opinion statement supported by false data or made in a misleading fashion (i.e., NewLink omitted and ignored major studies reporting longer survival rates). As support, Plaintiffs cite numerous studies purportedly listing higher survival rates, including non-U.S. studies. (SAC ¶ 56.) They also claim that no studies showed survival rates as low as 15 months. In addition, Plaintiffs claim the "RTOG-9704" study, which NewLink relied on to set its estimated control group survival rate, showed that some patients lived longer than 20 months. (SAC ¶ 53.) NewLink counters that whether a study is considered "major" is a matter of opinion and that the studies cited were those Dr. Vahanian and NewLink characterized as major. Further, NewLink argues that it sincerely believed these were the major studies. In addition, they argue that this statement is taken out of context and that their testing always assumed a survival rate in the low-20-month range.

As a threshold issue, this statement is one of opinion. Despite Plaintiffs' contention that this was a statement of fact because Dr. Vahanian said "all the major studies," his statement "reflect[s] judgments as to values that [are] not objectively determinable." In re Aratana, 315 F. Supp. 3d at 758 (quotation marks omitted) (alteration in original). Indeed, this Court cannot readily determine which of the slew of studies cited by both parties are "major," and a reasonable investor would understand that Dr. Vahanian was discussing studies that he believed to be "major." Moreover, these statements are opinions because "interpretations of the results of various clinical studies . . . are essentially no different than opinions," given that "[r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions." Nguyen, 297 F. Supp. 3d at 486 (alterations in original) (quotation marks omitted). Thus, Dr. Vahanian's statement of opinion is actionable only if (1) he did not sincerely believe it, (2) it was not reasonably supported by data, or (3) he omitted

information which rendered the statement misleading. See Tongue, 816 F.3d at 209; Gillis v. QRX Pharma Ltd., 197 F. Supp. 3d 557, 598 n.30 (S.D.N.Y. 2016). Plaintiffs do not adequately allege a misstatement under any of these approaches.

First, Dr. Vahanian explicitly noted that his statement was based on "U.S.-based studies, I want to make that distinction." (SAC ¶ 92.) And given that NewLink is a U.S.-based company, reliance on U.S. studies is not misleading. Thus, any non-U.S. studies relied on by Plaintiffs are immaterial. Next, the Second Circuit has explained that "[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts, and . . . do[] not expect that every fact known to an issuer supports its opinion statement. The[refore,] . . . a statement of opinion is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." Tongue, 816 F.3d at 210 (quotation marks and citations omitted) (alterations in original). NewLink's statement is precisely the type of statement contemplated by the Second Circuit.

Here, NewLink relied on several studies which support Dr. Vahanian's estimate of a 15-20-month survival rate. NewLink relied primarily on the RTOG-9704 study, which found a median overall survival rate of 18.6 months across both arms of the study. (Decl. of Sarah M. Lightdale in Supp. of Defs.' Mot. to Dismiss, ECF No. 75 ("Lightdale Decl."), Ex. J at 1319.) In addition, the Johns Hopkins Group study found a 19-month survival rate. (Lightdale Decl. Ex. W.) And Dr. Vahanian referenced a study published by "Hidalgo" that found a survival rate of approximately 15.4 months. (Decl. of Sarah M. Lightdale in Further Supp. of Defs.' Mot. to Dismiss, ECF No. 80 ("Suppl. Lightdale Decl."), Ex. X at 4.)

Third, Plaintiffs wrench Dr. Vahanian's statement out of context. Specifically, the full context of Dr. Vahanian's statement reads:

> Pancreatic cancer is significantly different than melanoma. When you are staging patients in melanoma and predicting survival, based on stages, can vary between 10 to 30 months or 40 months. In pancreatic cancer, that window is very narrow. Resected pancreatic cancer, patients live 15 months, 19 months. You can look at the last 30 years, all the major studies, pancreatic cancer survival – US-based studies, I want to make that distinction – survival rates come between 15 to 19, 20 months. That's it. So the flexibility in pancreatic cancer and predicting survival is much narrower than other diseases.

(Suppl. Lightdale Decl., Ex. X at 6.) In other words, Dr. Vahanian was illustrating that the survival window for pancreatic cancer was narrower compared to other forms of cancer, namely melanoma. (SAC ¶ 92.) Nothing in the Complaint suggests that Dr. Vahanian was referring to the control group survival rate. Indeed, only a few months later, Dr. Vahanian stated that "our study even though expectations were 18, 19 months, study is designed in the low 20s." (SAC ¶ 109.) Coupled with the fact that NewLink was blinded to Phase 3's results, Plaintiffs fail to adequately allege that Dr. Vahanian's statement was misleading as to control group survival rates. As the Second Circuit has explained, Plaintiffs must "do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." Rombach, 355 F.3d at 174.

Ultimately, Plaintiffs failed to allege that the 15-20-month statement was false in the First Amended Complaint, and all Plaintiffs have done to amplify their allegations is cite more contrary studies. But that fails to aver that "the speaker did not hold the belief []he professed[,] the supporting fact[s] []he supplied were untrue," or he misled investors. Tongue, 816 F.3d at 209 (quotation marks omitted). Accordingly, Plaintiffs fail to adequately allege that Dr. Vahanian's September 27, 2013 statement was false.

2. Dr. Vahanian's March 11, 2014 Earnings Call Statement

Plaintiffs claim that during a March 11, 2014 earnings call, Dr. Vahanian falsely stated that the results of a recent Johns Hopkins Group study found that "for the last three

decades going all the way back to the 1980s, 1990s and all the way up to 2011, the survival expectancy of pancreatic cancer was 19.2 months." (SAC ¶ 109.) Plaintiffs claim that the Johns Hopkins Group study does not support that assertion. Moreover, during that same earnings call, Dr. Vahanian stated that "we know historically in the United States the outcome for instance of the RTOG-9704 trial was 18.6 months if you include all the patients in the trial." (SAC ¶ 191.) Plaintiffs allege that this was misleading because the median survival rate of the gemcitabine adjuvant arm of the RTOG-9704 trial was approximately 20 months, and the 18.6-month figure only came after blending those patients with other patients in the trial. (SAC ¶ 191.) NewLink responds that Dr. Vahanian's statement was accurate because he offered the qualifier "if you include all the patients in the trial."

With respect to the Johns Hopkins Group study, Plaintiffs argue that Dr. Vahanian was referencing collaborative studies between Johns Hopkins and the Mayo Clinic from 2008-10, and the 19.2-month rate appeared only in the Mayo Clinic's data. (SAC ¶ 110.) Plaintiffs argue this is problematic because (1) the arm of the study with a 19.2-month survival rate in the Mayo Clinic study did not receive adjuvant therapy; (2) the Johns Hopkins study only went back to 1993, while the Mayo Clinic's study went back to the 1980s; and (3) NewLink excluded patients with visible tumors after surgery from its trial, unlike the Hopkins-Mayo study. NewLink counters that Dr. Vahanian was referencing a different article: a 2013 article published by Johns Hopkins Group physicians who studied patients from 1980 to 2011. Given that Dr. Vahanian's 2014 statement said the Hopkins study was recent and that the study spanned from 1980 to 2011, this Court finds it implausible that Dr. Vahanian was referring to the article Plaintiffs suggest. (Lightdale Decl. Ex. W.) Moreover, the article NewLink cites came to the conclusions Dr. Vahanian claimed it did—namely, that there was a 19-month median survival

rate for pancreatic cancer and that survival rates did not change over time from the 1980s to 2011. (See Lightdale Decl. Ex. W at 83.) While the study reported 19 months, not 19.2 months, that discrepancy means, if anything, that Dr. Vahanian overstated the control group, which belies Plaintiffs allegations.

Undeterred, Plaintiffs also argue that the Johns Hopkins Group study was misleading and irrelevant. That argument is unavailing because (1) it does not make Dr. Vahanian's statement about the results of that specific study false and (2) "Plaintiffs cannot premise a fraud claim upon a mere disagreement with how [NewLink] chose to interpret" the historical data. In re Sanofi-Aventis Sec. Litig., 774 F. Supp. 2d 549, 568 (S.D.N.Y. 2011). Moreover, this argument is a criticism of the trial's methodology, which is insufficient to state a claim for securities fraud. See Nguyen, 297 F. Supp. 3d at 487; In re Keryx Biopharmaceuticals, Inc. Sec. Litig., 2014 WL 585658, at *7 (S.D.N.Y. Feb. 14, 2014). Finally, it suffers from the same flaw as those about historical survival rates, because NewLink based its trial on a survival rate in the low-20-month range.

With respect to the RTOG-9704 study, Dr. Vahanian stated that the survival rate was 18.6 months "if you include all the patients in the trial." In that sense, his statement was accurate. However, "[e]ven a statement which is literally true, if susceptible to quite another interpretation by the reasonable investor[,] may properly be considered a material misrepresentation." Kleinman, 706 F.3d at 153 (quotation marks omitted) (alterations in original). Thus, the Complaint that NewLink's reference to "all patients in the trial" was misleading because the arm of the study Plaintiffs contend is a better comparator reported a survival rate of approximately 20 months. (SAC ¶ 104.) But this argument fails because Dr. Vahanian explicitly stated on that same earnings call that the NewLink study contemplated a

control arm in the low-20-month range. (SAC ¶ 109.) In addition, any qualms with NewLink's interpretation of historical data are insufficient to state a fraud claim. See In re Sanofi-Aventis Sec. Litig., 774 F. Supp. 2d at 568. Therefore, Plaintiffs do not adequately allege falsity with respect to Dr. Vahanian's statement on the March 11, 2014 Earnings Call.

3. Statements Regarding Phase II

Plaintiffs allege that NewLink excluded patients with short life expectancies from its Phase 2 trial, which artificially boosted the trial's results. (SAC ¶¶ 37, 95, 106.) Plaintiffs further allege that "[n]o other major study excluded such patients." (SAC ¶ 106.) Plaintiffs argue that this is especially important because Phase 2 did not use a control group, and thus compared its results to historical survival rates. (SAC ¶ 36.) NewLink asserts that it disclosed this criterion on the FDA's website, and thus did not make a misstatement. (See SAC ¶ 37 & n.2.) But Plaintiffs counter that this amounts to a truth-on-the-market defense, which "is intensely fact-specific and is rarely an appropriate basis for dismissing a § 10(b) complaint for failure to plead materiality." Ganino v. Citizens Utils. Co., 228 F.3d 154, 167 (2d Cir. 2000).

As a threshold matter, this Court need not reach the truth-on-the-market defense, which is meant to "rebut the presumption that [a company's] misrepresentations have affected the market price of its stock by showing that the truth of the matter was already known." Ganino, 228 F.3d at 167. "That is, 'a misrepresentation is immaterial if the information is already known to the market because the misrepresentation cannot then defraud the market.'" Gamm v. Sanderson Farms, Inc., 2018 WL 1319157, at *5 n.7 (S.D.N.Y. Jan. 19, 2018) (quoting Ganino, 228 F.3d at 167). Here, there was no misrepresentation to be made immaterial by disclosing the truth to the market. The only on point information publicly available was that

NewLink was excluding sicker patients from its study. In other words, the issue is not what the market knew, it is a disagreement over the methodology of excluding sicker patients.

Indeed, Plaintiffs argue that excluding shorter-living patients from NewLink's study was misleading. But that Plaintiffs "would have preferred the [D]efendants to have used a different drug trial methodology or found the [D]efendants' methodology to be lacking, [is] not sufficient to adequately allege falsity." In re Keryx Biopharmaceuticals, 2014 WL 585658, at *7 (citing Kleinman, 706 F.3d at 154–55); see Nguyen, 297 F. Supp. 3d at 487. And NewLink may have had good reason to exclude such patients—namely, so that patients would receive the drug for at least six months. (Oct. 19, 2018 Oral Arg. Tr., ECF No. 81 ("Oral Arg. Tr."), at 18:3–4.)

Finally, Plaintiffs argue that Phase 2's reported 24.1-month survival rate did not represent any increase over reported survival rates in historical studies, meaning that NewLink misled consumers regarding Phase 2's success. This argument overlaps with Plaintiffs' other arguments regarding historical survival rates and yields the same result.

B. Loss Causation

Loss causation is the "causal connection between the material misrepresentation and the loss." Dura Pharms. Inc. v. Broudo, 544 U.S. 336, 342 (2005). To plead loss causation, plaintiffs must "link the defendant's purported material misstatements or omissions with the harm ultimately suffered." In re Bristol Myers Squibb Co. Sec. Litig., 586 F. Supp. 2d 148, 163 (S.D.N.Y. 2008). If the relationship between the loss and the information concealed or misstated by the defendant is "sufficiently direct, loss causation is established, but if 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 Bristol Myers Squibb, 586 F. Supp. 2d at 163 (citation omitted). Specifically, Plaintiffs must

demonstrate that the "subject" of the misstatement or omission was "the cause of the actual loss suffered." In re Vivendi, S.A. Sec. Litig., 838 F.3d 223, 261 (2d Cir. 2016) (quotation marks omitted).

"[A] plaintiff can establish loss causation either by showing a 'materialization of risk' or by identifying a 'corrective disclosure' that reveals the truth behind the alleged fraud." In re Vivendi, 838 F.3d at 261. Plaintiffs' allegations rest solely on the corrective disclosure theory. (Oral Arg. Tr. at 29:12–15.) Under the corrective disclosure theory, Plaintiffs must demonstrate that "the available public information regarding the company's financial condition [was] corrected, and . . . the market reacted negatively to the corrective disclosure." Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC, 750 F.3d 227, 233 (2d Cir. 2014).

Plaintiffs enumerate three categories of corrective disclosures, which this Court discusses in turn. However, because loss causation is the "causal connection between the material misrepresentation and the loss," Plaintiffs are limited to alleging a corrective disclosure of the only actionable misstatement—that patients were successfully enrolled in Phase III. Dura Pharms., 544 U.S. at 342.

1. First and Second Corrective Disclosures

Plaintiffs allege that two interim analyses—which were to be released after Phase 3 reached certain patient-death benchmarks—constituted corrective disclosures of material misstatements regarding historical survival rates.

Plaintiffs claim the first corrective disclosure occurred on March 7, 2014, when NewLink issued a press release regarding its first interim analysis of Phase 3, after 222 patient deaths, showing that NewLink was not ready to seek marketing approval. (SAC ¶¶ 60, 206.) Plaintiffs allege that this revealed the truth behind misrepresentations about historical survival

rates and the success of Phase 2, "because, given the considerable length of time it took to record 222 patient deaths, it became clear to investors that the control arm of the study was living much longer than the 15 months that Defendants had stated, and began to suggest that [the drug] did not meaningfully increase survival time in patients." (SAC ¶ 206.) Plaintiffs point to questions posed during a March 11, 2014 call with analysts, who asked why they should not assume the control arm of the study was living beyond 20 months. (SAC ¶ 207.)

The second alleged corrective disclosure occurred on May 11, 2015, when NewLink issued a press release regarding the second interim analysis of Phase 3, which again showed that NewLink was not ready to seek marketing approval because "patients did not have a 30% increase in overall survival rate [as compared to] the control group." (SAC ¶¶ 69–70, 209.) While NewLink still expressed optimism that the drug would be approved, analysts were skeptical. (SAC ¶ 69.) For example, Jefferies stated that "[t]he company continues to insist the integrated survival rate is in the upper 20s," causing Jefferies "to become more cautious on the final analysis." (SAC ¶ 209.)

Because Plaintiffs have not sufficiently alleged falsity with respect to statements regarding historical survival rates, there can be no loss causation based on those alleged misstatements. See Dura Pharms., 544 U.S. at 342. And because these statements do not relate to Phase 3 enrollment, these alleged corrective disclosures fail.

2. Third Corrective Disclosure

As for the third corrective disclosure, Plaintiffs allege that NewLink filed a Form 10-K on February 29, 2016 disclosing that one of the "'clinical trial sites participating in the [Phase 3] trial may not [have] be[en] in compliance with certain [Good Clinical Practices ("GCP")] requirements,' after the site self-reported certain violations to the FDA." (SAC ¶ 213.)

The Form 10-K was highlighted in a "Flash Note" issued by Jefferies on March 1, 2016, which stated that NewLink management "described [the GCP violation] as a minor procedural issue involving one clinician," and that "there is a buffer in case any patients need to be excluded, and exclusion of these patients should not have a material impact on the trial." (SAC ¶ 79.) Plaintiffs contend this partially revealed the truth that Defendants had misstated that they satisfied all eligibility requirements for and completed Phase 3 enrollment. (SAC ¶¶ 81, 214.)

To make the connection, Plaintiffs cite statements from a confidential witness ("Confidential Witness"),[1] who observed "pervasive GCP violations" at NewLink, including that NewLink flouted enrollment eligibility rules. (SAC ¶¶ 47, 80.) NewLink announced that it had enrolled 722 subjects on September 17, 2013, while the Confidential Witness was still with the company. (SAC ¶ 49.) Plaintiffs claim these "pervasive GCP violations" demonstrate that NewLink did not meet Phase 3's eligibility requirements.

NewLink responds that the GCP violations reported in the 10-K and Flash Note were minor and had no effect on patient enrollment because there was a 42-patient "buffer" in case any patients needed to be excluded. It also contends that the Confidential Witness left NewLink more than a year prior to the alleged third corrective disclosure, and none of his allegations relate to the February 2016 disclosure. Simply put, NewLink argues that the GCP violations in the alleged corrective disclosure do not relate to Phase III patient enrollment. This Court agrees.

To date, NewLink has never disclosed that any patients were excluded from Phase 3 because of GCP violations. (See Oral Arg. Tr. at 8:2–10.) And nothing in the February 2016 Form 10-K or Flash Note suggests that Phase 3 patient enrollment was improper. Rather, the

[1] This Court previously found that Plaintiffs described the Confidential Witness with sufficient particularity. Nguyen, 297 F. Supp. 3d at 484.

disclosures suggest that one clinician may have committed a violation during the study and that the "worst case scenario" would be that "a few" patients would be excluded—but not enough to threaten the 42-patient buffer. (See Lightdale Decl. Ex. C.) Indeed, Phase 3 patient enrollment had been completed in September 2013, six months prior to the allegation that one clinician had committed GCP violations during the study. (SAC ¶ 49.) Ultimately, Plaintiffs alleged that the fraudulent statement was that Phase 3 had achieved full and adequate patient enrollment, and this alleged corrective disclosure did nothing to "reveal[] the truth behind the alleged fraud." In re Vivendi, 838 F.3d at 261.

3. Final Disclosure

On May 9, 2016, NewLink issued its final disclosure that Phase 3 had failed. (SAC ¶ 215.) Plaintiffs note that the results of Phase 3 revealed that the control group's survival rate was about 50% higher than what was conveyed by Defendants. (SAC ¶ 216.) They also allege that the final disclosure showed that the research and development on which the Phase 3 trial was based was not conducted properly. (SAC ¶ 218.)

These allegations merely parrot those already found to be insufficient in the First Amended Complaint. Ultimately, they are insufficient to allege loss causation because they merely show that the market reacted to adverse news. See Nguyen, 297 F. Supp. 3d at 500; In re Gentiva Sec. Litig., 932 F. Supp. 2d 352, 385 (E.D.N.Y. 2013). Nothing in this disclosure relates to the only actionable misrepresentation regarding Phase 3 enrollment. Accordingly, Plaintiffs fail to plead loss causation.

III. Remaining Claims

Section 20(a) and Section 20A claims are dependent on the viability of Section 10(b) claims. See Shah v. Stanley, 2004 WL 2346716, at *14 n.12 (S.D.N.Y. Oct. 19, 2004); In

re LaBranche Sec. Litig., 405 F. Supp. 2d 333, 364 (S.D.N.Y. 2005). Because Plaintiffs' Section 10(b) and Rule 10b-5 claims fail, these claims fail as well.

## CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss the Complaint is granted. The Clerk of Court is directed to terminate all pending motions and to mark this case closed.

Dated: February 13, 2019
New York, New York

SO ORDERED:

WILLIAM H. PAULEY III
U.S.D.J.