UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

WILLIAM H. PAULEY III, United States District Judge:

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

BACKGROUND

The allegations of the Complaint are presumed true for purposes of this motion. This securities fraud action arises from a failed clinical trial designed to test the efficacy of a pancreatic cancer immunotherapy. The central issue is whether NewLink Genetics Corporation's ("NewLink") clinical trial was built on faulty assumptions, outdated clinical studies, and a compromised patient pool for the purpose of misleading investors into believing that NewLink's immunotherapy product would be a commercial success.

Importantly, NewLink and its officers and directors were blinded to the results of the clinical trial. At each clinical trial milestone, an independent monitoring committee analyzed data to determine whether the overall survival of trial participants receiving NewLink's

immunotherapy exceeded that of a separate group of participants treated with standard chemotherapy. Although NewLink and its co-founders, Charles Link and Nicholas Vahanian, presented an optimistic outlook on the product's success, that assessment was belied by each interim report concluding that the immunotherapy had not yielded a statistically significant improvement in overall survival. Ultimately, the clinical trial terminated on news that NewLink's product not only failed to increase overall survival rates, but underperformed the standard chemotherapy treatment, with patients in the latter group living three months longer.

Over the nearly three year trial period, NewLink's stock price vacillated between interim reports of the immunotherapy's middling performance and Defendants' continued assurances that the product would achieve the trial objectives. The trial's final report sounded the death knell for NewLink's plans to commercialize the product and sent its stock price tumbling. Shortly thereafter, Plaintiffs commenced this action against NewLink, Link, and Vahanian, for violations of Section 10(b), Section 20(a), and Section 20A of the 1934 Exchange Act.

I. NewLink, HyperAcute Pancreas, and Phase 2 Clinical Trial

NewLink is a clinical stage biopharmaceutical company that specializes in developing cellular immunotherapeutic products to treat cancer. (Complaint, ECF No. 38 ("Compl."), ¶ 1.) The product at issue in this action is algenpantucel-L, also known as HyperAcute Pancreas, a therapeutic vaccine intended to treat pancreatic cancer. (Compl. ¶ 2.) As NewLink's most advanced treatment candidate, HyperAcute Pancreas is designed to stimulate the human immune system to recognize and attack cancer cells. (Compl. ¶ 2.)

In February 2010, NewLink completed its 70-patient Phase 2 clinical trial for HyperAcute Pancreas in surgically-resected (surgically removed) pancreatic cancer patients.

Phase 2 focused on earlier stage, resected pancreatic cancer patients with better prognoses than later stage patients. Phase 2 was designed as an open label, non-randomized trial in which two separate groups of patients were given HyperAcute Pancreas in doses of either 100 million or 300 million cells, respectively, twice a month for six months in combination with a standard chemotherapy-based treatment. (Compl. ¶ 31.)

Phase 2 did not contain a control group—that is, every patient in the trial received HyperAcute Pancreas with dosage amount as the only variant. (Compl. ¶ 32.) Out of the 70 patients, 26 were prescribed a high dose and 44 received a low dose. The trial resulted in a one-year survival rate of 96% for the high dose group and 79% for the low dose group, though these results did not conclusively establish that HyperAcute Pancreas improved disease-free and overall survival of resected pancreatic cancer patients. (Compl. ¶ 32.)

II. Initial Public Offering and Phase 3 Clinical Trial

In May 2010, based on "encouraging interim data" from the Phase 2 trial, NewLink initiated Phase 3. (Compl. ¶ 33.) Shortly thereafter, NewLink submitted a registration statement with the SEC, signaling its intent to become a public company. In November 2011, NewLink issued its prospectus, sold 6.2 million shares of stock at $7 per share, and raised $43.4 million in capital. (Compl. ¶ 33.)

Phase 3 was designed as an open-label, randomized, and controlled trial evaluating 722 patients with Stage I and Stage II surgically resected pancreatic cancer with no detectable disease by CT scan. (Compl. ¶ 34.) Half the participants were enrolled into the control group and received only the standard chemotherapy based treatment (the "Control Group"). The other half received standard adjuvant therapy with 300 million cells of HyperAcute Pancreas (the "Treatment Group"). (Compl. ¶ 34.) The trial's primary endpoint

was to achieve overall survival with secondary goals of disease-free survival, safety, toxicity, and immunological responses. In other words, the trial would only be considered a success if the Treatment Group lived longer than the Control Group, the latter of which Defendants said had a life expectancy of "18, 19 months to low 20s at best." (Compl. ¶ 34.)

The Phase 3 trial was conducted under a Special Protocol Assessment with the Food and Drug Administration ("FDA"), which meant the trial's design, clinical endpoints, and statistical analyses were declared acceptable for FDA approval despite the fact that the trial had yet to be completed. (Compl. ¶ 35.) Further, because HyperAcute Pancreas was designed to address an unmet medical need and counter a rare medical condition in pancreatic cancer, the FDA granted the Phase 3 trial a Fast Track designation for expedited review and an Orphan Drug designation, which carried exclusive marketing rights, clinical tax research incentives, and filing fee exemptions. (Compl. ¶ 35.)

A. Patient Enrollment

Phase 3 had four major milestones. The first consisted of enrolling 722 qualified patients. The criteria for enrolling patients in the trial were very strict. (Compl. ¶ 40.) During the enrollment period, a former NewLink clinical research associate employed from January 2012 through December 2014 ("Confidential Witness") said that Vahanian was concerned about getting enough patients for the trial, and pushed to complete patient enrollment within a narrow time frame. As a result of Vahanian's pressure to enroll patients quickly, the Confidential Witness explained that NewLink flouted eligibility rules by registering unqualified patients. (Compl. ¶ 42.) By September 17, 2013, NewLink announced that it had reached the "accrual goal of 722 subjects with surgically resected pancreatic cancer." (Compl. ¶ 44.) According to the Complaint, Vahanian pushed for expedited enrollment because his and Link's 2013 year-end

bonuses were tied to completing Phase 3 patient enrollment. (Compl. ¶ 43.) In total, Vahanian and Link received bonuses of $189,000 and $297,440, respectively, and also obtained vested stock for their "extraordinary performance in 2013." (Compl. ¶ 43.)

B. Interim Analyses

The second, third, and fourth milestones of the Phase 3 trial were periodic reviews—or interim analyses—of trial data by an independent Data Safety Monitoring Committee (the "Data Committee"). (Compl. ¶ 36.) The first interim analysis occurred after 222 patient deaths were reported. If the data revealed that there was a 99.5% likelihood that the overall survival of the Treatment Group exceeded that of the Control Group, NewLink could stop the trial and apply for marketing approval. Achieving this benchmark meant that the Treatment Group had an approximately 45% improvement in overall survival over the Control Group. (Compl. ¶ 36.)

If the data in the first interim analysis did not show such an improvement, the study would continue until 333 patient deaths were reported. In the second interim analysis, if the data showed that there was a 98% likelihood that the overall survival of the Treatment Group eclipsed that of the Control Group, NewLink could proceed immediately to market its product. Passing this threshold meant that the Treatment Group had a 30% improvement in overall survival over the Control Group. (Compl. ¶ 37.)

The third and final interim analysis occurred after 444 patient deaths were reported. At this point, if the data failed to show about a 95.5% likelihood that the Treatment Group patients were outliving the Control Group patients—or a 20% improvement in overall survival between the two groups—the study would be disbanded. (Compl. ¶ 38.)

i. First Interim Data Results

From September 2013 to February 2014, NewLink's stock price tripled in value to $53.48 per share. During this six-month period, Link sold 181,000 shares and Vahanian sold 177,162 shares, making millions of dollars in profit. (Compl. ¶ 46.) In March 2014, NewLink announced that the Data Committee had completed its first interim analysis following 222 patient deaths and recommended continuing the trial. (Compl. ¶ 47.) In response to this deflating news, Defendants remarked that the first interim results were an "anticipated outcome," and Vahanian added that they "look[ed] forward to continuing the study and to gathering additional, more mature data in support of [NewLink's] mission to provide improved treatment options for patients with pancreatic cancer." (Compl. ¶ 47.)

Some investment analysts began questioning whether NewLink had made faulty assumptions about the Control Group's overall survival rate. Defendants assured them that their initial estimates were well-founded, and that the first interim results did not affect their expectations regarding Phase 3's success. (Compl. ¶ 48.) For example, when asked whether it was his "expectation [ ] that the [Control Group] is performing as [he] would have figured it in this statistical plan at this point in time based on when [he] know[s] patients were enrolled in the trial," Link answered that the "statistical plan [ ] would easily tolerate a [Control Group] in the low 20[] [months]," and that there was no "fundamental change that has occurred in the United States that is suddenly going to jump the survival of pancreatic cancer patients in the [Control Group] by five or six months." (Compl. ¶¶ 48–49.)

While news of the first interim results caused NewLink's stock price to drop, Defendants' statements comforted investors and analysts, and revived the stock to its pre-announcement price. (Compl. ¶ 52–53.) Between March 2014 and May 2015, as the stock price

rebounded, Link sold approximately 300,000 shares for a $10 million profit. Vahanian sold 100,000 shares for $5 million, including a conspicuously large transaction involving 60,000 shares in March 2015, which netted him $3 million. (Compl. ¶ 55.)

ii. Second Interim Data Results

In May 2015, NewLink announced that the Data Committee had again concluded that the trial data did not warrant market approval. (Compl. ¶ 56.) To offset the negative implications associated with this news, Defendants parroted statements signaling their expectation of HyperAcute Pancreas's clinical and commercial success. (Compl. ¶ 56.) To that end, Defendants cited the trial's "fast-track status, orphan drug designation," and previewed their steps to prepare for the product's regulatory approval and commercialization. (Compl. ¶ 56.) According to Plaintiffs, however, Defendants "continued to mislead investors to believe that the final results from the [Phase 3 trial] would be sufficiently positive to proceed to commercialization." (Compl. ¶ 56.)

After announcing the second interim results, the stock price plunged from $52.14 to $36.55 per share in one day. To repair this damage, Defendants again issued materially false and misleading statements to instill confidence in the product. (Compl. ¶ 58.) For example, Defendants showcased their plans to "expand [their] manufacturing capabilities," and promised "additional details around [their] manufacturing progress and commercial supply" for the product as they "move[d] closer to the potential launch." (Compl. ¶ 59.) Despite the persistent questions surrounding the accuracy of the Control Group's survival rate, Defendants maintained that the "median months for overall survival from randomization in the [Control Group] is in the low 20s." (Compl. ¶ 59.)

After the release of second interim results, questions swirled around NewLink's compliance with certain clinical requirements pertinent to the trial. Specifically, in a March 2016 report, an investment analyst raised concerns about a note in NewLink's 10–K report that "a clinical site involved in the [Phase 3 trial] was discovered to be non-compliant with certain Good Clinical Practice (GCP) requirements." (Compl. ¶ 62.) Defendants responded that the problem was "procedural in nature and only a minor issue," and because the "site in question only has 'a few' patients enrolled . . . exclu[ding] these patients should not have a material impact on the trial." (Compl. ¶ 62.) But according to the Confidential Witness, non-compliance issues were not an isolated problem. The Confidential Witness observed pervasive violations of Good Clinical Practice standards regarding the "handling of client data, clinical report forms, and acceptance of patients in the [Phase 3] trial that did not qualify." (Compl. ¶ 63.) Other issues plagued the integrity of the trial: "numerous regulatory documentation errors," no "quality control documentation in place before the trials began," no employees with regulatory experience, and insecure storage of confidential patient information. (Compl. ¶ 63.)

Despite Defendants' misrepresentations and omissions regarding the facts underlying the Phase 3 trial, the stock price recovered, allowing Link and Vahanian to make "one final push to sell off their NewLink holdings." (Compl. ¶ 64.) Between May 2015 and May 2016, Link sold 260,000 shares for $9 million. Vahanian sold 43,000 shares for over $2 million. (Compl. ¶ 64.)

iii. Third Interim Data Results

In May 2016, NewLink reported that the Phase 3 study "for patients with resected pancreatic cancer did not achieve its primary endpoint." (Compl. ¶ 65.) NewLink's press release fleshed out the details: "[o]verall survival from time of randomization was 29.3 months

for both groups combined. There was no statistically significant difference between the two groups. The median survival was 30.4 months and 27.3 months for the [Control Group] and [Treatment Group], respectively." (Compl. ¶ 65.) Plaintiffs theorize that this harrowing news supported the market's suspicion that the Control Group's estimated survival rate had been understated from the outset to create a false appearance that study participants were living longer because of HyperAcute Pancreas. In reality, however, with Treatment Group patients living three months less than those in the Control Group, the final results suggested that NewLink's product had "harmed the patients and shortened their lives." (Compl. ¶ 66.)

These revelations precipitated a 30% drop in the stock's value, from $16.50 to $11.45 per share on May 9, 2016. Over the next few days, the share price continued to slide, closing at $9.71 per share on May 12, 2016. Before the stock's precipitous decline, however, Link and Vahanian had collectively managed to sell a little more than one million NewLink shares, representing 81% and 252% of their overall holdings, respectively, for insider trading profits of approximately $36.4 million.

DISCUSSION

I. Standard

A. Rule 12(b)(6) Motion

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 Trust 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). "A court may also take judicial notice of news articles discussing the conduct raised in the complaint." In re Smith Barney Transfer Agent Litig., 765 F. Supp. 2d 391, 397 (S.D.N.Y. 2011) (citing In re Salomon Analyst Winstar Litig., 2006 WL 510526, at *4 (S.D.N.Y. Feb. 28, 2006)).

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 Rule 9(b) by stating with particularity the circumstances constituting fraud. ECA, 553 F.3d at 196. Rule 9(b) requires a party to "state with particularity the circumstances constituting fraud or mistake." 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." Romach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004).

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) that one or more plaintiffs relied upon such misstatement or omission; and (5) that 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 three of those elements: (1) that the Complaint does not adequately plead materially false statements or omissions of fact; (2) that the Complaint fails to establish the requisite level of scienter; and (3) that the Complaint falls short of alleging loss causation.

A. Material Misstatements and Omissions of Fact

The Complaint identifies four discrete categories of misrepresentations: (1) Phase 3 patient enrollment; (2) Control Group survival rates; (3) Phase 2 efficacy; and (4) NewLink's commercialization efforts. This Court addresses each category in turn.

i. Patient Enrollment

Plaintiffs allege that the representations regarding patient enrollment in the Phase 3 trial were false because the trial consisted of patients who did not meet the stringent criteria under the Special Protocol Assessment. (Compl. ¶¶ 39, 81.) Without 722 qualified patients, Plaintiffs assert that Phase 3 was premised on an incomplete and tainted pool of study participants. (See, e.g., Compl. ¶ 81.) Specifically, Plaintiffs cite the testimony of the Confidential Witness, who explained that Vahanian was "really pushy" about enrolling patients and that NewLink had trouble enrolling qualified patients. With pressure mounting, the Confidential Witness said that NewLink disregarded certain guidelines to expedite patient enrollment. Moreover, in March 2016, when New Link was asked about a Phase 3 clinical site that had failed to comply with Good Clinical Practice standards, Defendants downplayed the problem, minimizing the non-compliant site's impact on Phase 3. Defendants represented that because the "site in question only has 'a few' patients enrolled," it would not have a material impact on the trial. (Compl. ¶ 62.) However, that statement, according to Plaintiffs, was materially false in view of the Confidential Witness's observations about "pervasive GCP violations at New Link with regard to the handling of client data, clinical report forms, and acceptance of patients" who did not qualify under Phase 3's rigorous guidelines. (Compl. ¶ 63.)

Defendants attack the patient enrollment allegations on two grounds. First, they claim that the Confidential Witness statements cannot be credited because the witness did not have access to trial screening or patient enrollment information. Second, even if this Court took the Confidential Witness statements at face value, Defendants contend that the inclusion of "several" ineligible patients would not have materially impacted the trial since only 680 patients were required to ensure the trial's statistical integrity. (Memo. of Law in Supp. of Mot. to

Dismiss, ECF No. 52 ("Mot."), at 10–11.) In other words, the Phase 3 trial expressly built in a buffer that accounted for the possibility of ineligible patients.

"Information presented through Confidential Witnesses in a complaint is allowed as long as the witnesses are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess [ ] the information alleged." Cornwell v. Credit Suisse Grp., 689 F. Supp. 2d 629, 637 (S.D.N.Y. 2010). It is not enough that the witness was involved in the Phase 3 trial in some capacity; Plaintiffs must allege whether that witness "actually communicated with management or [perceived] management's reaction to" the patient enrollment figures. Glaser v. The9, Ltd., 772 F. Supp. 2d 573, 589 (S.D.N.Y. 2011). While a confidential witness's direct contact with the individual defendants makes it more likely that the witness's observations about the alleged misstatements are truthful and credible, a plaintiff is not required to allege specific contact. "[T]here is no baseline requirement of such contact in order to allege sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." Plumbers & Pipefitters Nat'l Pension Fund v. Orthofix Int'l. N.V., 89 F. Supp. 3d 602, 615–16 (S.D.N.Y. 2015). A plaintiff need only plead the "probability that [the confidential witness] know[s] what [he or she] is talking about." In re EVCI Colleges Holding Corp. Sec. Litig., 469 F. Supp. 2d 88, 97 (S.D.N.Y. 2006).

Here, the Complaint alleges with sufficient particularity the Confidential Witness's position at New Link and the witness's communications with Vahanian. The Confidential Witness was a NewLink Clinical Research Associate from January 2012 through December 2014—a period leading up to NewLink's announcement that it had completed patient enrollment. The Confidential Witness "spoke personally with Defendant Vahanian about the

design of [the Phase 3 trial]," which necessarily included the criteria under which patients were enrolled. (Compl. ¶ 42.) Plaintiffs further allege that the Confidential Witness observed "pervasive [Good Clinical Practice] violations at New Link with regard to the handling of client data, clinical report forms, and acceptance of patients in the [Phase 3 trial] that did not qualify under the" required terms. (Compl. ¶ 63 (emphasis added).)

The Confidential Witness noticed that Vahanian became "pushy" and recalls that he was only concerned about expediting trial enrollment. The urgency surrounding patient enrollment is not, by itself, unusual given the high stakes of a long awaited clinical trial. But when that is coupled with the Confidential Witness's recollection that "NewLink had a difficult time finding eligible patients for the [Phase 3 study] within the required time frame," the Complaint establishes enough of a basis to conclude that the Confidential Witness probably possessed relevant information about this particular set of allegations. (Compl. ¶ 42.)

Defendants demand more details about the Confidential Witness's communications with Vahanian, how the Confidential Witness knew Vahanian's "pushiness" led to enrollment of ineligible patients, what rules were disregarded, and when and how many violations occurred. But on a motion to dismiss, all that is necessary is that the Confidential Witness, by virtue of his position at NewLink and interaction with Vahanian, probably possessed the information underlying Plaintiffs' allegations about patient enrollment. Of course, the Confidential Witness's knowledge and credibility regarding the relevant information can be tested in discovery. At the pleadings stage, "Plaintiff[s] [are] only required to show that the source of the belief is someone in a position to have had personal knowledge." Levy v. Maggiore, 48 F. Supp. 3d 428, 443 (E.D.N.Y. 2014).

Further, Defendants' argument that enrollment of ineligible participants would not have affected the trial's statistical integrity is not persuasive at this stage. Defendants improperly presume that the number of ineligible participants consisted of less than the margin of error—42 patients—and would not have compromised the integrity of the trial. (Mot. at 11.) This Court cannot dismiss the possibility that a material cohort of ineligible patients were enrolled, especially since the eligibility criteria were "exceptionally important" and "designed to correlate with prior pancreatic cancer studies, so that the overall survival estimate for the control group was estimable and based on prior data." (Compl. ¶ 41.) Moreover, when analysts reported that one of the trial sites violated Good Clinical Practice standards, invoking a concern that unqualified patients had been enrolled, Defendants characterized the issue as an isolated incident affecting "a few" patients. (Compl. ¶ 62.) While that assurance propped the stock price, it contradicted confidential testimony that Good Clinical Practice violations were "pervasive." (Compl. ¶ 63.) And if true, ineligible patient enrollment not only meant there was a tainted pool of participants but that NewLink's representations about achieving Phase 3's first milestone—in spite of the highly selective and stringent design of the study—were false. (Compl. ¶¶ 36, 39–40, 80.)

The Complaint therefore pleads enough at this juncture to show that NewLink's representations about patient enrollment were false and how they were false. The potential inclusion of ineligible patients in the Phase 3 trial is something that is not "so obviously unimportant to a reasonable investor" that it should be disregarded on a motion to dismiss. N.J. Carpenters Health Fund v. Royal Bank of Scot. Grp., PLC, 709 F.3d 109, 126 (2d Cir. 2013).

ii. Control Group Survival Rates

Plaintiffs also allege that NewLink understated the Control Group's survival rate anywhere from 15 to 20 months (Compl. ¶¶ 74, 90) to mislead investors into believing "that patients receiving [HyperAcute Pancreas] were living longer than the [C]ontrol [G]roup." (Memo. of Law in Opp. of Mot. to Dismiss, ECF No. 54 ("Opp."), at 6.) This is important, Plaintiffs argue, because it created the impression that the extended patient survival in the Phase 3 trial was directly attributable to the efficacy of HyperAcute Pancreas. (Opp. at 6–7.) In reality, however, the Control Group had a median survival rate of 30.4 months while the Treatment Group lasted only 27.3 months. (See e.g., Compl. ¶¶ 51, 65.)

Defendants counter that Plaintiffs' allegations are essentially a criticism of Phase 3's methodology which, as a matter of law, does not make a statement misleading. Moreover, Defendants contend that NewLink based its Control Group survival rates on specific, well-publicized data from prior studies. (Compl. ¶¶ 48 (RTOG–9704 trial was 18.6 months survival), 49 ("referencing a recent study that was published by Johns Hopkins Group which demonstrated 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"), 90 ("The benefit of GEM/Abraxane combination in metastatic studying up front is 1.7 months" which would "move the needle from 18, 19 months to low 20s at best.").) Thus, while Plaintiffs take issue with Link and Vahanian's insistence that their estimates were an accurate reflection of the Control Group's survival rate—even doubling down on those projections after receiving abysmal interim results—Defendants argue that these statements were substantiated by credible studies documenting decades-long survival rates of pancreatic cancer patients.

Given the shocking revelation that the actual median survival rate of the Control Group hovered around 30 months—ten months more than what NewLink represented—it is easy to understand why Plaintiffs seek to characterize Defendants' statements as false and misleading. Even more telling, the market learned that the Control Group lived three months longer than the Treatment Group, and the Complaint suggests that HyperAcute Pancreas may have harmed Treatment Group patients and shortened their lives. (Compl. ¶¶ 65–66.) Understandably, one investment analyst remarked that "NewLink deserves to be investigated for this disastrous pancreatic trial result." (Compl. ¶ 68.) But disaster is not necessarily a product of fraud.

The most salient fact belying Plaintiffs' theory is that Defendants were blinded to the trial results. Plaintiffs concede this incontrovertible fact. (Compl. ¶ 113; see also Compl. ¶¶ 117, 126–127.) Defendants did not have access to survival rates until May 2016, when they learned, together with the market, that the Phase 3 trial failed. That Defendants remained blind to Phase 3's results throughout the duration of the trial undermines the allegation that they misrepresented the Control Group's survival rates in the interim.[1]

More plausibly, Defendants' statements about the Control Group's survival rates stem from their interpretation of previously published studies. "[I]nterpretations of the results of various clinical studies . . . are essentially no different than opinions," because "[r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions." In re Sanofi-Aventis Sec. Litig., 774 F. Supp. 2d 549, 567 & n.20

[1] After the first interim results were released, Plaintiffs claim that Defendants' statement that Phase 3's continuation was "an anticipated outcome" was misleading because it was material information they withheld from investors. (Compl. ¶ 47 (that Defendants expected Phase 3 to fall short of achieving the first milestone was "material information that they never conveyed to investors leading up to the first interim result announcement, and material information that they traded on at great personal profit").) But Defendants did disclose the possibility that the first interim results would not achieve a statistically significant overall survival rate such that Phase 3 would continue on to the next milestone. (Declaration of Sarah M. Lightdale in Supp. of Defs. Mot. to Dismiss, ECF No. 53, Exs. G at 7–9; H at 5 (investor analyst noting that "[t]he bar to stop the study early for efficacy is really high").)

(S.D.N.Y. 2011). Thus, Defendants' survival rate estimates are non-actionable opinions so long as they are reasonably supported by data. Gillis v. QRX Pharma Ltd., 197 F. Supp. 3d 557, 598 n.30 (S.D.N.Y. 2016).

Here, Link cited the "RTOG–9704 trial which was 18.6 months if you include all the patients in that trial," as support for his opinion that Defendants' estimates "remain[ed] the same as [they've] had all along," and that no "fundamental change [ ] has occurred in the United States that is suddenly going to jump the survival of pancreatic cancer patients in the control arm by five or six months. [They] don't believe that." (Compl. ¶ 48 (emphasis added).) In a similar vein, Vahanian relied on a Johns Hopkins Group study "which demonstrated that for the last three decades . . . the survival expectancy of pancreatic cancer was 19.2 months," to formulate his opinion that the estimated survival rate of Control Group participants was "in the low 20s." (Compl. ¶ 49.) None of the statements referenced in the Complaint suggest that either Link or Vahanian lacked a sincere opinion about the estimated survival rates; to the contrary, the studies they relied on provided a reasonable foundation from which they developed their estimates regarding the Control Group's overall survival.

But "[l]ike objective statements of material fact, subjective statements of opinion can be actionable as fraud." Gillis, 197 F. Supp. 3d at 577. Plaintiffs must allege with particularity "provable facts to demonstrate that the statement of opinion is both objectively and subjectively false." Sanofi-Aventis, 774 F. Supp. 2d at 568. Put another way, Plaintiffs must show both that Defendants "did not actually hold the belief or opinion stated, and that the opinion stated was in fact incorrect." Sanofi-Aventis, 774 F. Supp. 2d at 568 (emphasis original). The Complaint fails to allege this. At best, Plaintiffs say that Defendants should have known better than to represent the Control Group's survival rate at such low figures because the

interim updates suggested that "patient deaths were occurring at a slower than expected rate." (Compl. ¶ 51.) But this allegation does not undermine the well-founded basis for Defendants' belief that standard chemotherapy patients would survive at the rates they initially disclosed to the market. And nothing in the Complaint suggests, even on information and belief, that Defendants' "publicly expressed opinions were different than or contradicted by the[ir] true opinions." Sanofi-Aventis, 774 F. Supp. 2d at 568. "Plaintiffs cannot premise a fraud claim upon a mere disagreement with how [Defendants] chose to interpret" the historical data. Sanofi-Aventis, 774 F. Supp. 2d at 568.

To further support their claim, Plaintiffs rely heavily on the stark disparity between the estimated survival rates ascribed to the Control Group and the actual survival rates reported at the conclusion of the trial. But this is tantamount to alleging fraud by hindsight, a pleading strategy that courts have roundly rejected. "A securities fraud action may not rest on allegations that amount to second-guesses of defendants' opinions about" the Control Group's survival rate—"second-guesses made all too easy with the benefit of hindsight." Podany v. Robertson Stephens, Inc., 318 F. Supp. 2d 146, 154 (S.D.N.Y. 2004). Even if Defendants re-assessed their estimates during the course of the trial based on the interim results, the Complaint "contains insufficient allegations to infer that it was a foregone conclusion that . . . adverse consequences would ensue." In re EDAP TMS S.A. Sec. Litig., 2015 WL 5326166, at *11 (S.D.N.Y. Sept. 14, 2015) (internal quotation marks and citations omitted).

Finally, to the extent that Plaintiffs take issue with Defendants' reliance on historical studies reporting survival rates at 18 to 20 months in designing the Phase 3 trial, their argument fails as a matter of law because it is essentially a criticism of the trial's methodology.[2]

[2] While the Complaint does not reference alternatives to the studies NewLink used to estimate the Control Group survival rate, Plaintiffs offer two studies reporting longer survival periods in their opposition brief. (Opp. at

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, Inc. Sec. Litig., 2014 WL 585658, at *7 (S.D.N.Y. Feb. 14, 2014) (citing Kleinman v. Elan Corp., 706 F.3d 145, 154–55 (2d Cir. 2013)).

iii. Phase 2 Statements

Plaintiffs assert that Defendants misrepresented Phase 2 data in primarily two ways. First, they contend that Defendants' interpretation of Phase 2 data—namely, that only one patient in the high dose group had died—improperly concluded that Phase 2 achieved efficacy. (Compl. ¶ 86.) Second, Defendants' statement that they initiated Phase 3 based on "encouraging Phase 2 data that suggest[ed] improvement in both disease-free and overall survival" is misleading, Plaintiffs argue, because Phase 2 data did not demonstrate such metrics. (See, e.g., Compl. ¶¶ 5–6, 33, 53, 76, 94, 96; Opp. at 9.) At the heart of Plaintiffs' claim is that NewLink touted the efficacy of its drug based on the results of a previous trial that was not designed to test efficacy. Defendants counter that these statements about Phase 2's results amount to nothing more than expressions of optimism. They also argue that these statements reflected earnestly held opinions interpreting Phase 2 results. (Mot. at 14.)

Defendants' statement that one-year patient survival was "a very strong efficacy signal for the trial in the high-dose group" was not misleading. The market knew that Phase 2 lacked a control group, so no reasonable investor could have credited the view that HyperAcute Pancreas, after Phase 2, had demonstrated actual efficacy. In a March 2014 call, for example,

6, 23.) But aside from the fact that these studies do little to undermine the basis on which Defendants formulated the Control Group survival rate, they are inapposite because a reasonable investor would have appreciated that other studies, however many or few, would have been considered by NewLink when designing the Phase 3 trial.

Link expressly noted that "the Phase 2 data didn't have a no-treatment arm so the Phase 2 data was limited." (Compl. ¶ 86.) Moreover, these Phase 2 statements are opinions. They are couched with phrases like "suggests potential," and "we felt," and are reasonable extrapolations of Phase 2 data. In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015).

In any event, Phase 2 trials may provide preliminary information regarding efficacy. In re Delcath Sys., Inc. Sec. Litig., 36 F. Supp. 3d 320, 325 (S.D.N.Y. 2014) ("Phase II clinical trials are conducted in a limited patient population . . . to assess and evaluate the drug's appropriate dosages, safety profile, and preliminary efficacy."); 21 C.F.R. § 312.21(b). Here, it was certainly true that a higher dose of HyperAcute Pancreas demonstrated greater efficacy relative to a lower dose. Defendants' specific statement makes clear that Phase 2 showed a "strong efficacy signal" for the high-dose group. (Compl. ¶ 86 (emphasis added).)

As for Defendants' statements regarding the effect of Phase 2 data on Phase 3, many of those statements are puffery. "[E]xpressions of puffery and corporate optimism do not give rise to securities violations. Up to a point, companies must be permitted to operate with a hopeful outlook: People in charge of an enterprise are not required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage." Rombach, 355 F.3d at 174 (citations omitted). On the other hand, pollyannaish statements couched as rosy corporate-speak may be actionable if they contradict facts known to a defendant. See Novak v. Kasaks, 216 F.3d 300, 315 (2d Cir. 2000) (statements describing retailer's inventory as "in good shape" and "under control" were not puffery when defendants allegedly knew the opposite was true). Although there is no definitive test to determine how vague a statement must be to qualify as puffery, courts have focused on the imprecision of statements and

whether such statements relate to future expectations. See Lasker v. N.Y. State Elec. & Gas Corp., 85 F.3d 55, 59 (2d Cir. 1996); In re Virtus Inv. Partners, Inc. Sec. Litig., 195 F. Supp. 3d 528, 538 (S.D.N.Y. 2016).

As an initial matter, NewLink's statements that it was "confident" in Phase 2's study design and "encouraged" (Compl. ¶ 70) by its progress are "the type of expressions of puffery and corporate optimism that do not generally give rise to securities violations." Kleinman, 706 F.3d at 153; Virtus, 195 F. Supp. 3d at 538. Here, NewLink's comments about its Phase 2 data are adorned with optimistic language, but nothing about those statements is misleading. They are "too general to cause a reasonable investor to rely upon them." City of Westland Police & Fire Ret. Sys. v. MetLife, Inc., 129 F. Supp. 3d 48, 77 (S.D.N.Y. 2015).

Additionally, while Plaintiffs argue that NewLink improperly utilized Phase 2 data to extrapolate Phase 3's success, no reasonable investor would have credited that inference. Plaintiffs object to these statements on the ground that Phase 2 data "had no bearing whatsoever on the potential efficacy of" HyperAcute Pancreas nor could they "demonstrate improvement in overall and disease-free survival." (Opp. at 9.) But that argument overlooks the market's knowledge of Phase 2's design and purpose, and the market's awareness that Phase 2's results did not directly bear on Phase 3's intended objectives. Phase 2 was perceived as a success—NewLink achieved its primary and secondary objectives relating to disease-free and overall survival. (See Declaration of Sarah M. Lightdale in Supp. of Defs. Mot. to Dismiss, ECF No. 53 ("Lightdale Decl."), Ex. A at 11.[3]) And based on Phase 2's strong results, Defendants merely expressed their confidence in the next step of marshaling HyperAcute Pancreas to market.

[3] This Court takes judicial notice of public disclosure documents required by law to be filed with the SEC. Kramer v. Time Warner Inc., 937 F.2d 767, 774 (2d Cir. 1991). In resolving a motion to dismiss, a court may consider "any written instrument . . . incorporated into the complaint by reference, legally required public disclosure documents filed with the S.E.C., and documents possessed by or known to the plaintiff upon which it relied in

Moreover, the relevant FDA guidelines make clear that Phase 2 and Phase 3 trials investigate different attributes of a proposed drug. "The purpose of Phase II is to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study" and often focuses on a smaller group of subjects. Failkov v. Alcobra Ltd., 2016 WL 1276455, at *1 (S.D.N.Y. Mar. 30, 2016) (citing 21 C.F.R. § 312.21(b)). "Phase III studies gather additional information about the drug's safety and effectiveness by testing it on a much larger group of subjects than in the prior phases." Failkov, 2016 WL 1276455, at *1 (citing 21 C.F.R. § 312.21(c)). That Phase 2 and Phase 3 tested different metrics and embodied different objectives were distinctions that a reasonable investor could make. (Compl. ¶ 31 ("[E]very patient in the Phase 2 trial received [HyperAcute Pancreas], and the only distinguishing characteristic between the two groups involved in the trial was the dosage amount."); Lightdale Decl. Exs. A at 11–12, F at 20.)

Finally, Defendants' statements regarding Phase 2 results are non-actionable opinions. Simply put, Defendants interpreted Phase 2 data in a positive light, finding that starting Phase 3 was justified. (Compl. ¶ 97 ("We initiated these trials based on encouraging Phase 2 data . . .").); City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 170 (3d Cir. 2014) ("These allegations show a difference of opinion within Wyeth about whether the Phase 2 interim results—together with the seriousness of Alzheimer's disease and the totality of what the companies had learned from their immunotherapy programs—justified initiating a Phase 3 trial."). The Complaint also does not allege that Link or Vahanian disbelieved their opinions, or withheld facts that they knew contradicted their statements. Tongue v. Sanofi, 816 F.3d 199,

bringing the suit." ATSI, 493 F.3d at 98. And this Court may take notice of not only the fact that these documents exist but also consider their substance, including even those from SEC filings that were not specifically cited in the Complaint. Malin v. XL Capital Ltd., 499 F. Supp. 2d 117, 132–33 (D. Conn. 2007).

209–10 (2d Cir. 2016). At the time "the statement was made, [NewLink] had moved on to Phase 3 of the clinical trials—a step that can only be taken after there have been positive Phase 2 results sufficient to satisfy both business and regulatory interests. [There is thus] no reason to think (nor is one alleged) that Defendants' statements were not honestly believed." Kleinman, 706 F.3d at 153.

iv. Regulatory Approval and Commercialization of HyperAcute Pancreas

The Complaint alleges that Defendants' statements about HyperAcute Pancreas's commercial viability were false and misleading. Plaintiffs assert that "Defendants misleadingly conveyed to investors that they expected" the drug to be "approved for marketing and commercialization" despite interim results casting doubt on whether HyperAcute Pancreas would be approved and marketed. (Compl. ¶ 83.) After receiving the first interim results, for example, Link commented, "[a]s we approach the second interim analysis we will continue our commercialization strategy and planning efforts including building the infrastructure needed to support an independent launch in the US market for [HyperAcute Pancreas] as a treatment for patients with resected pancreatic cancer." (Compl. ¶ 82; see also Compl. ¶¶ 56 ("[HyperAcute Pancreas] has the potential to be the first and only FDA approved drug for resected pancreatic cancer . . . we are thoughtfully preparing for regulatory filings and commercial activities associated with a potentially positive outcome of the trial"); 104 ("We are preparing to commercialize this innovative immunotherapy . . . starting to lay the commercial groundwork that will allow us to accelerate access to [HyperAcute Pancreas], if approved by the FDA.").) Defendants counter that these statements constitute forward-looking statements that qualify for protection under the PSLRA's safe harbor.

The PSLRA provides that a defendant "shall not be liable" with respect to any forward-looking statement that is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u–5(c)(1). All safe harbor categories require the statements to be forward-looking. In relevant part, the PSLRA defines forward-looking statements to include: (1) statements regarding the "plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;" and (2) "any statement of the assumptions underlying or relating to" such plans or objectives. 15 U.S.C. § 78u–5(i)(1)(B), (D).

Many of the allegations pertaining to commercialization or regulatory approval qualify for protection under the PSLRA safe harbor because they are "classically forward-looking—they address what [D]efendants expected to occur in the future." Sanofi, 87 F. Supp. 3d at 535. (See e.g., Compl. ¶¶ 80, 82, 84, 102, 126.) Moreover, they are accompanied by meaningful cautionary language. In assessing whether language is sufficiently cautionary, courts must "first identify the allegedly undisclosed risk and then read the allegedly fraudulent materials—including the cautionary language—to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist." In re Delcath, 36 F. Supp. 3d at 333. NewLink's Form 10–Q for the quarterly period ending September 30, 2013 is illustrative. There, NewLink warned investors that its "ability to obtain FDA approval of HyperAcute Pancreas depends on, among other things, completion of [the] Phase 3 clinical trial," and that the "final results of [the] Phase 3 clinical trials of HyperAcute Pancreas may not meet the FDA's requirements to approve the product for marketing." (Lightdale Decl. Exs. F at 20; Q at 3 ("If we meet the [Phase 3] trial endpoints we

will execute our regulatory strategy with the FDA, continue to build our U.S. commercialization plans and explore partnering [HyperAcute Pancreas] outside the U.S.") (emphasis added).)

Defendants provided investors with "substantive information about the risk that ultimately materialized"—Phase 3's failure and NewLink's inability to market its product—leaving no doubt that a reasonable investor would not have believed that such risks did not exist. Sanofi, 87 F. Supp. 3d at 537; Gregory v. Pronai Therapeutics Inc., 2018 WL 1358387, at *22 (S.D.N.Y. Mar. 13, 2018) ("Here, [defendant] warned that its specific drug, PNT2258, might fail to prove effective. Its cautionary statements were thus not, as plaintiffs claim, mere boilerplate."). Nor have Plaintiffs alleged that the cautionary language failed to disclose a risk that Defendants knew about (i.e., statements that were made with actual knowledge that they were false or misleading) because all of the parties involved were blinded to Phase 3's data.

Some of the other statements, however, as Plaintiffs point out, are not exclusively forward-looking. In such instances, "it is well recognized that even when an allegedly false statement has both a forwardlooking aspect and an aspect that encompasses a representation of present fact, the safe harbor provision of the PSLRA does not apply." In re SLM Corp. Sec. Litig., 740 F. Supp. 2d 542, 556 (S.D.N.Y. 2010) (citation omitted). Some of Defendants' statements are strictly representations of present or historical fact. For example, in an 8–K filed in the fourth quarter of 2014, Defendants commented that it was "preparing to commercialize this innovative immunotherapy in the United States ourselves, and are starting to lay the commercial groundwork that will allow [them] to accelerate access to [HyperAcute Pancreas], if approved by the FDA." (Compl. ¶ 104 (emphasis added); see also Compl. ¶¶ 112, 116.) Other statements are laced with both a present and future element: "We are working to expand our manufacturing capabilities. We will provide additional details around our manufacturing

progress and commercial supply . . . as we move closer to the potential launch." (Compl. ¶ 112.) Plaintiffs argue that these statements "drop anchor nowhere near the PSLRA's safe harbor," and instead deceived the market into believing that Phase 3's success would inevitably result in commercializing HyperAcute Pancreas. (Opp. at 14.)

"It is true that misrepresentation of present or historical facts cannot be cured by cautionary language, but [Plaintiffs] here ha[ve] failed to posit that the present or historical fact in these statements w[ere] false, thus rendering the forward-looking portions of any statement false." NECA–IBEW Health & Welfare Fund v. Pitney Bowes, 2013 WL 1188050, at *18 (D. Conn. Mar. 23, 2013) (alteration and citation omitted). Because "statements about present or historical facts, whose accuracy can be determined at the time they were made, are not forward-looking statements," this Court must determine whether their "misleading nature can be verified at the time they are made." In re Vivendi Universal, S.A. Sec. Litig., 765 F. Supp. 2d 512, 569 (S.D.N.Y. 2011).

Defendants' present and historical statements regarding the regulatory approval or commercial viability of HyperAcute Pancreas were not false or misleading at the time they were made. In essence, Plaintiffs argue that Defendants put the cart before the horse by elaborating on NewLink's efforts to lay the groundwork for HyperAcute Pancreas's commercialization even though the drug had yet to clear Phase 3 or obtain FDA approval. Doing so, Plaintiffs argue, misleadingly signaled to the market that the drug was effective (i.e., that it would clear Phase 3) and commercially viable. (Compl. ¶ 117.) But the present or historical facts underlying Defendants' statements are not false, and therefore do not render the accompanying forward-looking statements false. Defendants may have been blinded to Phase 3's results, but Link and Vahanian modeled their statements on an earnestly held view that the "HyperAcute

immunotherapy program has the potential to improve treatment options." (Compl. ¶ 116 (emphasis added).) Link and Vahanian had a good faith basis to express their "confidence to extend [NewLink's] manufacturing capabilities." (Compl. ¶ 116.) It was also true that Phase 3, despite its second interim results, "remain[ed] under SPA with the FDA and ha[d] open drug and fast track status." (Compl. ¶ 116.)

At base, Defendants' statements amount to nothing more than an expression about their calculated business decision to forge ahead on developing what they believed was a promising drug. Against the clear cautionary language outlining the risks attendant to a failed clinical trial, Defendants made it clear that they were "making very large strategic investments in expanding [their] manufacturing capabilities . . . strategies for commercialization and marketing." (Compl. ¶ 112 (emphasis added).) These are merely investments NewLink made in anticipation of HyperAcute Pancreas's success. Although this business decision did not yield the result NewLink and its investors hoped for, such an outcome does not suddenly make Defendants' previous statements of present or historical fact any less true. In re Merck & Co., Inc. Sec., Derivative & ERISA Litig., 2012 WL 3779309, at *7 (D.N.J. Aug. 29, 2012); Schaffer v. Horizon Pharma PLC, 2018 WL 481883, at *9 (S.D.N.Y. Jan. 18, 2018) ("Plaintiffs fail to allege that any of the statements made by [defendant] were misrepresentations of present or historical facts.").

B. Scienter

The PSLRA requires a plaintiff to plead with particularity facts giving rise to a strong inference of scienter, i.e., an intent to deceive, manipulate, or defraud. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 313 (2007). The inference must be "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing

inference of nonfraudulent intent." Tellabs, 551 U.S. at 314. Scienter may be established in two ways: (1) showing that defendants had the motive and opportunity to commit fraud; or (2) furnishing circumstantial evidence of conscious misbehavior or recklessness. ATSI, 493 F.3d at 99.

As an initial matter, it is undisputed that Defendants had an opportunity to commit fraud. Link and Vahanian are co-founders of NewLink. Link was Chairman and Chief Executive Officer, and Vahanian served as President and Chief Marketing Officer of the company. (Compl. ¶¶ 24–25.) With these allegations, this Court presumes that "corporations, corporate officers, and corporate directors would have the opportunity to commit fraud if they so desired." Pension Comm. of. Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC, 446 F. Supp. 2d 163, 181 (S.D.N.Y. 2006). Thus, the only question is whether the Complaint adequately pleads "motive."

i. Stock Sales

Plaintiffs cite Link and Vahanian's Class Period stock sales as evidence of their motive to commit fraud. "[M]otive can be shown . . . when corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit." In re Citigroup Inc. Sec. Litig., 753 F. Supp. 2d 206, 233 (S.D.N.Y. 2010). Nonetheless, the "mere fact that insider stock sales occurred does not suffice . . . plaintiffs must [instead] establish that the sales were 'unusual' or 'suspicious.'" In re Gildan Activewear, Inc. Sec. Litig., 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009). Whether trading is unusual or suspicious turns on a number of factors: (1) the amount of net profits realized from the sales; (2) the percentages of holdings sold; (3) the change in volume of insider defendant's sales; (4) the number of insider defendants selling; (5) whether sales occurred soon after statements defendants are alleged to have known were misleading;

(6) whether sales occurred shortly before corrective disclosures or materialization of the alleged risk; and (7) whether sales were made pursuant to trading plans such as Rule 10b5–1 plans. Glaser, 772 F. Supp. 2d at 587. Plaintiffs bear the burden of demonstrating that Defendants' stock sales are unusual. Acito v. IMCERA Grp., 47 F.3d 47, 54 (2d Cir. 1995).

The Complaint depicts the glaring disparity in Link and Vahanian's trading activity between the Class Period and the months preceding and following the Class Period (the "Control Period"). (Compl. ¶ 44.) Link sold 753,001 shares for approximately $24.4 million during the Class Period, which Plaintiffs claim represented 81% of the shares he held at the outset of the Class Period. By contrast, Link sold only 430,000 shares for a total of $6.59 million during the Control Period. (Compl. ¶ 137.) Vahanian, on the other hand, sold 325,173 shares for about $12 million during the Class Period, representing 252% of his stock holding when the Class Period first began. During the Control Period, however, Vahanian sold only 22,000 shares for $398,000. (Compl. ¶ 138.)

The mere fact that Link and Vahanian sold a large quantity of stock during the Class Period, by itself, is insufficient to establish an inference of motive. City of Brockton Ret. Sys. v. Shaw Grp., 540 F. Supp. 2d 464, 475 (S.D.N.Y. 2008). These sales must be analyzed in context to ascertain whether they comprised a significant proportion of Link and Vahanian's total holdings, and whether they were timed to occur prior to the announcement of bad news or after certain misstatements were made. The stock sales must also be viewed against pre- and post-Class Period sales, and whether they occurred in the regular course under a non-discretionary trading plan. Considering all of these context-specific factors, this Court concludes that Plaintiffs have pled enough to raise a strong inference of scienter that is "at least as

compelling as any opposing inference one could draw from the facts alleged." Tellabs, 127 S. Ct. at 2510.

Link and Vahanian jettisoned a significant percentage of their stock holdings during the Class Period. NewLink's stock began trading on November 11, 2011, after its initial public offering. In the 676 days between the initial public offering and the start of the Class Period, Link and Vahanian engaged in modest trading. (Compl. ¶ 133.) Defendants note that Link and Vahanian were both subject to extensive lock-up periods—a period of six months immediately after the initial public offering and another three months after a follow-on offering in January 2013. Though these lock-up periods minimize the time frame in which Link and Vahanian could have traded, their trading activity even in the limited Control Period bears no resemblance to the pattern or frequency of their Class Period trading. (Compl. ¶ 135.) Before the Class Period, Link sold 430,000 shares for approximately $6.5 million. But during the Class Period, he sold 323,000 more shares and reaped about $17.8 million in gross profits. (Compl. ¶ 134.) Similarly, Vahanian sold only 22,000 shares for $398,000 before the Class Period. But during the Class Period, he disposed of 325,000 shares for about $12 million. (Compl. ¶ 134.) Even if this Court accounts for the lock-up periods, Link and Vahanian's trades are unusual because they traded "in amounts dramatically out of line with prior trading practices." In re Glenayre Techs., Inc. Sec. Litig., 1998 WL 915907, at *4 (S.D.N.Y. Dec. 30, 1998). Moreover, Link and Vahanian did not make a single trade in the 175 days between the end of the Class Period and the commencement of this action.

This Court also considers whether Link and Vahanian's trades during the Class Period were suspiciously timed, made either on the heels of a misrepresentation designed to inflate NewLink's stock price or right before the disclosure of bad news. Link and Vahanian's

use of Rule 10b5–1 trading plans informs this Court's assessment of their trades. Ordinarily, the use of a non-discretionary trading plan that sells fixed quantities of stock on pre-scheduled dates undermines any inference of scienter. In re Lululemon Sec. Litig., 14 F. Supp. 3d 553, 585 (S.D.N.Y. 2014). But "where (as here) 10b5–1 trading plans are entered into during the class period, they are not a cognizable defense to scienter allegations on a motion to dismiss." George v. China Auto. Sys., Inc., 2012 WL 3205062, at *9 (S.D.N.Y. Aug. 8, 2012); Freudenberg v. E*Trade Fin'l Corp., 712 F. Supp. 2d 171, 201 (S.D.N.Y. 2011). This is because a "clever insider might maximize their gain from knowledge of an impending price drop over an extended amount of time, and seek to disguise their conduct with a 10b5–1 plan." Freudenberg, 712 F. Supp. 2d at 199 (citing In re Immucor Inc. Sec. Litig., 2006 WL 3000133, at *18 n.8 (N.D. Ga. 2006)). The Complaint alleges that Vahanian adopted a trading plan on October 28, 2013—during the Class Period—just three days before he made his first trade. (Compl. ¶ 143.) Link entered into his first trading plan three months before the Class Period, but subsequently entered into two new trading plans during the Class Period. (Compl. ¶ 148.)

While the mere adoption of a trading plan during the Class Period may give rise to an inference of scienter, that inference becomes stronger when trades executed pursuant to a trading plan are sporadic. Here, Vahanian "sold irregular amounts of shares at irregular intervals under his first 'plan,' including 8,000 shares on November 11, 2013; 4,000 shares just four days later; 2,200 shares a week later on November 18, 2013; 3,800 shares the next day on November 19, 2013; 4,500 shares 8 days later on November 27, 2013; 7,500 shares two days later on November 29, 2013; 30,000 shares three days later on December 2, 2013; 27,162 shares a month later on January 3, 2014; 10,000 shares ten days later on January 13, 2014; 35,000 shares the next day on January 14, 2014; 20,000 shares 20 days later on February 3, 2014; and 25,000

shares the next day on February 4, 2014." (Compl. ¶ 144.) Just a month before the first interim results were announced, Vahanian stopped trading altogether. (Compl. ¶ 145.) After several months, in January 2015, Vahanian instituted a new plan once the stock price recovered and traded in the $40 dollar range, and began selling shares erratically. (Compl. ¶ 145.) Shortly after NewLink released news of the second interim trial results, Vahanian amended his trading plan. (Compl. ¶ 145.)

Link's sales under his trading plans were irregular. After initiating his first trading plan three months before the Class Period, Link entered into two other plans during the Class Period, with each plan covering hundreds of thousands of shares. (Compl. ¶ 148.) In January 2016, Link amended his final trading plan, authorizing only two trades in March 2016 and one in April 2016 before ceasing all activity prior to the May 2016 announcement of the final Phase 3 results. (Compl. ¶ 148.)

On balance, that Link and Vahanian adopted and amended their trading plans during the Class Period at conveniently opportune times supports an inference of scienter. In re Gentiva Sec. Litig., 971 F. Supp. 2d 305, 328 (E.D.N.Y. 2013) (10b5–1 plan was "strategically amended [ ] to take advantage of an inflated stock price or insider information"). Non-discretionary trading plans designed to sell shares at pre-determined dates and quantities diminishes the likelihood that a defendant would exploit a felicitous period during a fraudulent scheme when the stock price is artificially inflated. But the Complaint suggests that Link and Vahanian exercised enough control to institute new plans on their terms. And because the Complaint alleges that Link and Vahanian were aware of the compromised patient enrollment figures at the time they adopted their trading plans, the "fact that there might be an innocent explanation for the timing of [their] sale is not enough to defeat the inference of scienter that

arises" from the Complaint's allegations. Freudenberg, 712 F. Supp. 2d at 200–01 (citing In re EVCI, 469 F. Supp. 2d at 100).

On that score, Defendants note that many of Link and Vahanian's trades were not suspiciously timed—that is, they were not made near dates on which allegedly false statements or negative news were released. See In re Keyspan Corp. Sec. Litig., 383 F. Supp. 2d 358, 385 (E.D.N.Y. 2003); In re Take–Two Interactive Sec. Litig., 551 F. Supp. 2d 247, 279 (S.D.N.Y.2008) (lapse of "approximately four months between these substantial sales and the revelation of the alleged falsity[ ] inescapably attenuates any inference of scienter"). Thus, as Defendants argue, the trades are not suspicious and may have occurred for innocuous reasons unrelated to the alleged fraud. (Mot. at 20–21.)

That the Complaint does not tether every single trade to a fraud-related event is not fatal to an inference of scienter. Plaintiffs sufficiently allege that Link began trading two weeks after NewLink announced it had completed patient enrollment (Compl. ¶ 147) during a period in which the stock price was rising and the market was optimistic about the trial's prospective success. Plaintiffs also note that Link stopped trading altogether after his April 7, 2016 trade (Compl. ¶ 148), about a month before the disclosure of the final results tanked the stock price. These events are sufficiently close enough in time to shroud Link's actions in suspicion, especially in view of his decision to amend and then terminate his trading plan. In re Oxford Health Plans, Inc., Sec. Litig., 187 F.R.D. 133, 139 (S.D.N.Y. 1999) ("In late August 1997, two months before the devastating October 27, 1997 press release . . . all of the Individual Defendants except Sullivan sold shares of Oxford common stock . . . The timing of these trades is 'suspicious' enough, along with other evidence, to support a strong inference of scienter.").

On the other hand, Vahanian unloaded a substantial cache of stock in November 2013, about a month and a half after the stock price began rising on news of Phase 3 patient enrollment. (Compl. ¶ 144.) Crediting the Complaint's allegations regarding patient enrollment as true, Vahanian's sale of nearly 30,000 within a month of touting the completion of Phase 3 enrollment is suspicious. Further, Vahanian "abruptly" stopped trading under one of his trading plans about a month before the first interim results were disclosed, avoiding a stock price drop of over 25%. (Compl. ¶ 145.) And Vahanian did not start trading again until he was sufficiently assured that the stock price had rebounded to a level propped up by Defendants' misrepresentations in the weeks leading up to the second interim results. (Compl. ¶ 145.)

Finally, the Complaint's allegations detailing the number of shares sold as a percentage of total holdings militates in favor of inferring scienter. A "sale amounting to a large percentage of an individual's holdings may be sufficient." In re SLM Corp., 740 F. Supp. 2d at 558; In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 75 (2d Cir. 2001) (selling 80 percent of holdings sufficient to establish motive). Here, Plaintiffs assert that Link liquidated 81%, and Vahanian 252%, of the stock they held as of the start of the Class Period. (Compl. ¶¶ 137–138.) Defendants counter that if this Court accounts for the exercisable stock options Link and Vahanian received as compensation, the disparity between their stock sales in proportion to total holdings diminishes significantly. (Mot. at 19.)

The parties dispute whether stock options may be considered for purposes of demonstrating stock sales as a percentage of total holdings. This Court sees no compelling reason why exercisable stock options should be treated any differently than disposable stock. While the Second Circuit has yet to opine directly on this issue, most courts have expressed an inclination to include exercisable stock options. In re eSpeed, Inc. Sec. Litig., 457 F. Supp. 2d

266, 291 (S.D.N.Y. 2006); see Rothman v. Gregor, 220 F.3d 81, 94 (2d Cir. 2000) ("Taking into account [defendant's] vested options, he held more shares at the end of the [class period] than at the beginning."). Other Circuits have taken more definitive positions. The Ninth Circuit has held that "[s]tock options should be considered in calculating the percentage of shares sold unless the insider could not have exercised them." Ronconi v. Larkin, 253 F.3d 423, 435 n.25 (9th Cir. 2001) (considering the "total number of shares and options"). The First Circuit, most recently in Brennan v. Zafgen Inc., 853 F.3d 606, 615–16 (1st Cir. 2017), found that "[a]fter accounting for [defendant's] vested options, he retained" the majority of his stock holdings. See also City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 760–61 (1st Cir. 2011) ("[I]t is appropriate to consider not only the shares of stock that [defendants] held prior to their sales, but also the shares that they could have sold through the exercise of options.").

While this Court has identified two cases in this District declining to factor stock options in evaluating stock sales, neither case assumed an authoritative position on the issue. Plaintiffs rely principally on In re Oxford, which ignored vested options because the court could not "evaluate the true value of the options exercised by the Individual Defendants." 187 F.R.D. at 140. But the In re Oxford court also conceded that the defendants "may have exercised options to buy at a very low price per share, in which case the shares would have been valuable to the defendants even after the stock plummeted." In re Oxford, 187 F.R.D. at 140. Thus, the court's decision to exclude vested options was not based on a fundamental belief that vested options are not representative of a party's trading potential. And in In re EVCI, the court expressed in dicta that it was inclined to follow In re Oxford, but found that "regardless of which side of [the stock options] debate one comes down on," the defendant there "sold far too much

stock," with or without stock options, "to wriggle out from a fair inference of motive and opportunity." 469 F. Supp. 2d 88, 100 (S.D.N.Y. 2006) (comparing 41% counting stock options and 80% without).

When evaluating stock sales, the number of shares sold by an insider compared with the number he could have sold is more probative on the question of whether Class Period sales are unusual or suspicious. Vested, or exercisable,[4] stock options are like ordinary shares except they have a designated strike price that obligates the option holder to pay that price before receiving stock. To incentivize employees to share in the company's success, the strike price of a stock option is usually fixed at a lower figure, allowing the employee to profit on the difference between the strike price and current market price. Once a party exercises a vested stock option at the designated strike price, it becomes a share that may be sold immediately. In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 986–87 (9th Cir. 1999) ("[W]e see no reason to distinguish vested stock options from shares because vested stock options can be converted easily to shares and sold immediately."). In some instances, parties may exercise the option on a cashless basis—where transaction costs are covered by a concurrent sale of existing shares—making the transaction even more seamless and immediate. Thus, "[a]ctual stock shares plus exercisable stock options represent the owner's trading potential more accurately than the stock shares alone," and "a sale involving a significant portion of an insider's actual shares, but only a small portion of his shares and options combined, is less suspicious than were the insider to hold no options." Silicon Graphics, 183 F.3d at 987 (emphasis added).

[4] Not all stock options are created equal. "Many courts draw a distinction between options that are vested (and thus immediately exercisable) and those that are not." In re eSpeed, 457 F. Supp. 2d at 291. The relevant SEC filings distinguish between Link and Vahanian's exercisable and unexercisable stock options.

This Court, however, cannot entirely credit Defendants' contention that Link's total holdings only decreased by 22% if his exercisable options are included. (Mot. at 19.) The relevant SEC filings reveal that many of the stock options—though characterized as "exercisable"—did not vest immediately. For example, a proxy statement filed on April 6, 2016 for the period ending May 20, 2016 enumerates a dizzying array of stock options awarded to Link and Vahanian at various points during their employment. Some stock options were granted as early as June 2007 with a strike price of $0.80, and others were granted as late as January 2015 with a strike price of $43.65. (Lightdale Decl. Ex. X at 37.[5]) But a number of those grants are subject to varying conditions. Some "vest over a five-year period, with 20% of the options vesting on the first anniversary of the vesting commencement date and the remaining 80% of the options vesting in equal monthly installments thereafter over the next four years." (Lightdale Decl. Ex. X at 39.) Others "vest in equal monthly installments over 47 months." (Lightdale Decl. Ex. X at 39.)

Therefore, some stock options may not have been exercisable at the time Link and Vahanian chose to sell their stock because they had not yet vested. Further, while it appears that many of the options were granted at strike prices far less than the average market price during the Class Period, a portion could have been characterized as "out of the money" because their strike price exceeded the market price at the time Link and Vahanian sold. Although the number of exercisable options is useful in evaluating stock sales, this Court cannot determine with certainty whether the options awarded to Link and Vahanian expanded their holdings so significantly that Link's sales only decreased his holdings by 22% (as opposed to the 81% alleged in the Complaint). In any event, this is an issue that can be calculated more precisely by

[5] The page numbers to Exhibit X specifically correlate to the pagination of the PDF file.

the parties in discovery and re-assessed at summary judgment. At this stage, this Court cannot determine whether including options would negate an inference of scienter.

ii. Executive Compensation

"Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud." Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001). Thus, as a general matter, "incentive compensation can hardly be the basis on which an allegation of fraud is predicated." ECA, 553 F.3d at 201. "If scienter could be pleaded solely on the basis that defendants were motivated [to commit fraud] because an inflated stock price or improved corporate performance would increase their compensation, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions." ECA, 553 F.3d at 201; Penn. Pub. Sch. Emps. Ret. Sys. v. Bank of Am. Corp., 874 F. Supp. 2d 341, 357–58 (S.D.N.Y. 2012) ("A desire to increase executive compensation to retain qualified executives is plainly common to most corporate officers.").

However, the Complaint does not merely allege that Link and Vahanian were motivated to inflate NewLink's stock price for the purpose of earning substantial bonuses. Patel v. L–3 Commc'ns Holdings, Inc., 2016 WL 1629325, at *12 (S.D.N.Y. Apr. 21, 2016) ("[T]he existence, without more, of executive compensation dependent upon stock value does not give rise to a strong inference of scienter.") (emphasis original). Rather, their bonuses were tied to a specific goal—enrollment of 722 patients before the end of 2013. (Compl. ¶ 149 (bonus targets for 2013 specifically "pertained to enrollment in the HyperAcute Pancreas Phase 3 clinical trial, which was given a weight of 40%").) Crediting these allegations as true, Link and Vahanian had a specific motive to lie about or manipulate patient enrollment numbers since doing so would

allow them to reap a concrete benefit in the form of bonuses amounting to nearly 60% and 49% of their base salaries, respectively. (Compl. ¶ 149.)

Moreover, the bonus program incentivized a specific form of misconduct which, if true, threatened the foundational integrity of the Phase 3 trial. In re Take–Two, 551 F. Supp. 2d at 295 ("Although the desire to improve a company's earnings in order to bolster one's income . . . may be a 'generalized' desire . . . the desire to inflate a company's earnings in order to hide options backdating is a much more particularized desire specific to participants in the backdating scheme."). While a court cannot sustain "the plaintiffs' claims on the basis of motive if scienter rests solely on the fact that individual defendants stood to benefit by way of employment incentives," In re Wellcare Mgmt. Grp., Inc. Sec. Litig., 964 F. Supp. 632, 639 (N.D.N.Y. 1997), the allegations regarding Link and Vahanian's specific motives to obtain outsized bonuses may certainly be considered as part of the calculus in assessing whether there is a strong inference of scienter. In re Cornerstone Propane Partners, L.P., 355 F. Supp. 2d 1069, 1092 (N.D. Cal. 2005) (cases involving allegations of scienter based on executives' general motive to increase compensation inapposite because "they do not involve programs which specifically and directly tied executive bonuses to the very instrument used to commit the alleged fraud"); In re Cardinal Health Inc. Sec. Litig., 426 F. Supp. 2d 688, 737–38 (S.D. Ohio 2006) ("By presenting specific facts tying the Individual Defendants' compensation to company performance, Plaintiffs do more than just present 'bare allegations' of motive and opportunity.").

Plaintiffs' allegations regarding Defendants' stock sales and executive compensation establish a basis from which this Court can infer a strong inference of scienter underlying Defendants' false and misleading statements about patient enrollment. Accordingly, because the Complaint "plead[s] facts rendering an inference of scienter at least as likely as any

plausible opposing inference" through Defendants' motive and opportunity to commit fraud, Tellabs, 551 U.S. at 328 (emphasis added), this Court need not consider the additional circumstantial evidence of conscious misbehavior or recklessness. China Auto. Sys., 2012 WL 3205062, at *7 (with regard to motive and opportunity or strong circumstantial evidence of conscious misbehavior or recklessness, "plaintiffs need only show one or the other—not both").

Nevertheless, it is worth noting that at least with respect to Defendants' representations regarding patient enrollment, "[c]onscious misbehavior or recklessness . . . can be established by showing, inter alia, that defendants knew facts or had access to information suggesting that" their announcement touting the achievement of Phase 3's first milestone was "not accurate." In re Centerline Holding Co. Sec. Litig., 380 F. App'x 91, 93 (2d Cir. 2010) (citation omitted). The Complaint sufficiently alleges Link and Vahanian's responsibilities and incentives associated with completing patient enrollment. Coupled with the Confidential Witness's observations about Vahanian's push to complete patient enrollment and the Company's inability to recruit qualified patients, the Complaint sufficiently alleges strong circumstantial evidence of scienter.

C. Loss Causation

In view of the conclusory allegations tying Plaintiffs' economic loss to the disclosure of the fraud, the Complaint fails to sufficiently plead 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, a plaintiff 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, 586 F. Supp. 2d at 163 (citation omitted).

The Complaint in its current form alleges that in May 2016, the market learned of the fraud through a press release announcing that Phase 3 "did not achieve its primary endpoint," and that the overall survival rate of the Control Group exceeded that of the Treatment Group by three months. (Compl. ¶ 128.) The Complaint's loss causation allegations are predicated on a corrective disclosure theory—that "the available public information regarding the company's financial condition [was] corrected, and [ ] the market reacted negatively to the corrective disclosure." Carpenters Pension Trust Fund of St. Louis v. Barclays PLC, 750 F.3d 227, 223 (2d Cir. 2014). In advancing this theory, Plaintiffs broadly allege that upon "revelation of these previously undisclosed facts," NewLink's stock "plummeted 30.61% on heavy trading volume." (Compl. ¶¶ 129, 160.) More specifically, Plaintiffs assert that Defendants "misrepresent[ed] the viability of [HyperAcute Pancreas] and its likelihood of success in the [ ] Phase 3 trial," and when their "prior misrepresentations came to be revealed to investors, shares of NewLink declined precipitously." (Compl. ¶ 159.)

But without showing how NewLink's May 9, 2016 press release announcing the final results of the Phase 3 trial constituted a corrective disclosure—i.e., revealed that previous statements or omissions were false—the Complaint, at best, advances a narrative in which NewLink's stock price dropped on the disappointing news that a highly promising cancer therapy failed to clear its clinical trial. In re Gentiva, 932 F. Supp. 2d at 385 ("[L]oss causation is not adequately pled simply by allegations of a drop in stock price following an announcement

of bad news if the news did not disclose the fraud."); Fort Worth Emp'r Ret. Fund v. Biovail Corp., 615 F. Supp. 2d 218, 228–29 (S.D.N.Y. 2009). Indeed, it is unclear which misrepresentations or omissions were corrected or exposed by the May 9, 2016 disclosure. Because the press release focuses on the actual survival rates of each patient group, one implication is that it corrected Defendants' misrepresentation about the Control Group's estimated survival rate. But this Court has already concluded that those allegations do not sufficiently allege falsity. And with the one category of representations that this Court found to be sufficiently alleged, the Complaint does not establish a nexus between Defendants' statements about patient enrollment and the drop in stock price.

Nor have Plaintiffs sufficiently alleged loss causation under a materialization of risk theory. Loss causation alternatively may be alleged "by showing that the loss was foreseeable and caused by the materialization of the risk concealed by the fraudulent statement." Omnicom Grp., 597 F.3d at 513 (citation omitted). Thus, "[w]here the alleged misstatement conceals a condition or event which then occurs and causes the plaintiff's loss, a plaintiff may plead that it is the materialization of the undisclosed condition or event that causes the loss." Initial Pub. Offering Sec. Litig., 544 F. Supp. 2d 277, 289 (S.D.N.Y. 2008). Here, though news of Phase 3's failure caused the loss, Defendants repeatedly cautioned investors about a litany of risks—the inability to achieve the trial's primary endpoint, obtain FDA approval, or commercialize the drug—that could lead to a significant drop in stock value. In other words, the risk that materialized was disclosed by Defendants and known by investors.

Of course, allegations of loss causation "are not subject to the heightened pleading requirements of Rule 9(b) and the PSLRA. Rather, courts in this district have made it clear that if the complaint connects the Defendants' fraud with Plaintiffs' purported loss within

the short and plain statement standard of Rule 8(a)," then nothing further is needed at this stage of the litigation. Bristol Myers Squibb, 586 F. Supp. 2d at 163 (alterations, quotation marks, and citations omitted); In re SLM Corp., 740 F. Supp. 2d at 560 (all that is required is modest showing that share price decline followed alleged corrective disclosures revealing fraud). Thus, this Court will afford Plaintiffs another opportunity to amplify their loss causation allegations.

In view of this Court's dismissal of Plaintiffs' Section 10(b) claim, their Section 20(a) claim is also dismissed. Shah v. Stanley, 2004 WL 2346716, at *14 n.12 (S.D.N.Y. Oct. 19, 2004) (Section 20(a) is dependent on the viability of a Section 10(b) claim). Further, to state a claim under Section 20A, plaintiffs must properly plead an independent cause of action for insider trading under Section 10(b). DeMarco v. Robertson Stephens Inc., 318 F. Supp. 2d 110, 126 (S.D.N.Y. 2004). "Since a Section 10(b) claim has not been stated against [Link or Vahanian], it follows that a Section 20A claim has not been stated." In re LaBranche Sec. Litig., 405 F. Supp. 2d 333, 364 (S.D.N.Y. 2005).

III. Amendment of the Complaint

Plaintiffs seek leave to amend their Complaint in the event this Court grants Defendants' motion. Under Rule 15, this Court has broad discretion to grant such leave "freely" and "when justice so requires." Fed. R. Civ. P. 15(a)(2). This Court is mindful of the Stipulation and Order memorializing a scheduling order for amended pleadings. (ECF No. 33.) Although granting leave under Rule 15 must be balanced against the strictures of Rule 16 when a scheduling order is in place, this Court finds that there is good cause to modify the schedule. Moreover, allowing the amendment of the pleading at this stage of the litigation will not prejudice the defendants, especially where activity in this case has largely been limited to briefing the present motion to dismiss. Fresh Del Monte Produce, Inc. v. Del Monte Foods, Inc.,

304 F.R.D. 170, 175 (S.D.N.Y. 2014). This Court shall afford Plaintiffs a final opportunity to cure the deficiencies identified in this Opinion & Order, and fortify their allegations through an amended complaint.

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is granted and the Complaint is dismissed without prejudice. Plaintiffs shall file any amended complaint by May 4, 2018. The Clerk of Court is directed to terminate the motion pending at ECF No. 51.

Dated: March 29, 2018
New York, New York

SO ORDERED:

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