In the
United States Court of Appeals
For the Second Circuit

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AUGUST TERM, 2019

ARGUED: OCTOBER 21, 2019
DECIDED: JULY 13, 2020

No. 19-642-cv

TREVOR ABRAMSON, Individually and on behalf of all others similarly situated,
Plaintiff,

MICHAEL NGUYEN, Individually and on behalf of all others similarly situated, KELLY NGUYEN, Individually and on behalf of all others similarly situated
Lead Plaintiffs-Appellants,

v.

NEWLINK GENETICS CORPORATION, CHARLES J. LINK, JR., NICHOLAS N. VAHANIAN,
Defendants-Appellees.

JOHN B. HENNEMAN, III, GORDON H. LINK, JR.,
Defendants.

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Appeal from the United States District Court
for the Southern District of New York.

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Before: KEARSE, WALKER, and LIVINGSTON, *Circuit Judges.*

Plaintiffs Michael Nguyen and Kelly Nguyen brought this class action under S.E.C. Rule 10b-5, 17 C.F.R. 240.10b-5, following the failure of Defendant NewLink Genetics Corporation's ("NewLink") Phase 3 clinical trial for a novel pancreatic cancer drug and the resulting decline in the market value of NewLink shares. On appeal, Plaintiffs argue that the district court (William H. Pauley III, *Judge*) erred in dismissing pursuant to Fed. R. Civ. P. 12(b)(6) their Rule 10b-5 claims alleging that NewLink and its leadership (collectively, "Defendants") materially misrepresented the efficacy of their pancreatic cancer drug, scientific literature on pancreatic cancer, and the design of their Phase 3 clinical trial, and these misrepresentations caused Plaintiffs financial losses. We conclude that Defendants' statements about the efficacy of their pancreatic cancer drug were puffery, not material misrepresentations. We conclude, however, that Plaintiffs plausibly pled material misrepresentation and loss causation for Defendants' statements about the scientific literature and the design of their clinical trial. We therefore AFFIRM the district court's dismissal of Plaintiffs' Rule 10b-5 claim regarding the 2013–2016 Assessments, VACATE the district court's dismissal of Plaintiffs' Rule 10b-5 claims regarding the September, March, and Enrollment statements, and REMAND for further proceedings consistent with this opinion.

KIM E. MILLER, Kahn Swick & Foti, LLC, New York, NY (J. Ryan Lopatka, Kahn Swick & Foti, LLC, New York, NY; Lewis S. Kahn and Craig J. Geraci, Kahn Swick & Foti, LLC, New Orleans, LA, *on the brief*), *for Plaintiffs-Appellants*.

SARAH M. LIGHTDALE, Cooley LLP, New York, NY (David H. Kupfer, Cooley LLP, New York, NY; Samantha A. Kirby, Cooley LLP, Palo Alto, CA, *on the brief*), *for Defendants-Appellees*.

JOHN M. WALKER, JR., *Circuit Judge*:

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BACKGROUND

Charles J. Link and Nicholas N. Vahanian are the co-founders of NewLink, a pharmaceutical company that develops cancer treatments. At the time of the events giving rise to the present litigation, Link was Chairman and Chief Executive Officer of NewLink, and Vahanian was President and Chief Medical Officer.

Because of the huge demand for efficacious cancer drugs, in particular those that can successfully treat the most intractable cancers, the market in shares of firms that can potentially treat intractable cancers is highly sensitive to developments in trials to establish a drug's effectiveness and gain the Food and Drug Administration's ("FDA") approval. Generally, the FDA requires three phases of human clinical trials. After the completion of the phase 1 trial, investigators are required to submit their data for approval to the FDA before continuing to the next phase and launching a larger trial. The same process applies when a drug candidate moves from a phase 2 trial to a larger phase 3 trial. If the phase 3 trial results are sufficiently strong, investigators can submit a new drug application and receive FDA approval to manufacture and sell the drug. The results of each trial and the success or failure of each phase are closely watched by the market, and the market reacts accordingly.

The present litigation stems from statements made and market losses incurred during trials related to NewLink's development of algenpantucel-L, or HyperAcute Pancreas, a potential treatment for pancreatic cancer following a patient's resection (surgery to remove a tumor).[1] In 2010, NewLink completed

[1] The facts described herein are from the second amended complaint, which we take to be true in our review of the district court's Rule 12(b)(6) dismissal. *See Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 161 (2d Cir. 2000).

enrollment for a Phase 2 trial for HyperAcute Pancreas. One of the criteria for enrollment in that trial was that subjects had to have an "[e]xpected survival [greater than or equal to] 6 months."[2] Individuals with either Stage I or Stage II pancreatic cancer were eligible to enroll. The Phase 2 trial did not have a control group, and it was not a double-blind study. In June 2012, after at least 24 months of follow-up with each patient, NewLink ended the Phase 2 trial and assessed that those treated with HyperAcute Pancreas had a "survival rate," or median life expectancy, of 24.1 months.

On September 27, 2013, roughly one year after the end of the Phase 2 trial and during NewLink's more rigorous Phase 3 trial for HyperAcute Pancreas, Vahanian gave a presentation before prospective investors at a biotech conference highlighting industry "Newsmakers."[3] At that conference, Vahanian discussed the Phase 2 trial for HyperAcute Pancreas and referred to its 24.1-month survival rate as "remarkable."[4] After noting that patients with other cancers like melanoma have survival rates as high as "30 months or 40 months," he compared, in the "September Statement," the low survival rates for resected pancreatic cancer allegedly reported in the relevant literature:

> 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

[2] *Vaccine Study for Surgically Resected Pancreatic Cancer*, CLINICALTRIALS.GOV (June 26, 2015), https://clinicaltrials.gov/ct2/show/NCT00569387.

[3] App'x at 974.

[4] *Id*. at 975.

> want to make that distinction—survival rates come between 15 to 19, 20 months. That's it.[5]

Shortly before making this comment, Vahanian had referenced in his presentation a paper by Manuel Hidalgo that identified survival rates of 15.4 months and 12.7 months for Stage IIA and IIB pancreatic cancer patients. Although not mentioned by Vahanian at the conference, the same Hidalgo paper presented survival rates of 24.1 months and 20.6 months for Stage IA and IB patients.[6]

In addition to Vahanian's conference statement, NewLink and Vahanian made several statements between 2013 and 2016 ("2013–2016 Assessments") that expressed confidence in the Phase 2 trial results. In one public filing, NewLink referred to the "encouraging interim data from [its] Phase 2 clinical trial."[7] In other filings, NewLink claimed that the Phase 2 trial saw "improvement in both disease-free and overall survival."[8] On an investor call, Vahanian claimed that the Phase 2 trial results "really exceeded any expectation that experts in the field had

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[5] *Id.* at 978.

[6] Manuel Hidalgo, *Pancreatic Cancer*, 362 NEW ENG. J. MED. 1605, 1610 (2010) (citing data from Bilimoria *et al.*, *Validation of the 6th Edition AJCC Pancreatic Cancer Staging System*, 110 CANCER 738, 741 (2007) (reviewing outcomes, as reported in the National Cancer Database, for 21,512 resected pancreatic cancer patients)).

[7] App'x at 748.

[8] *Id.* at 749.

for what would happen in terms of one-year survival" and that the interim results from the Phase 2 trial were "a very strong efficacy signal."[9]

Roughly contemporaneous with the September Statement, NewLink purportedly completed enrollment of subjects for its Phase 3 trial for HyperAcute Pancreas. The Phase 3 trial did not have a six-month expected survival enrollment criterion, although NewLink still sought to enroll individuals with either Stage I or Stage II pancreatic cancer. Unlike the Phase 2 trial, the Phase 3 trial had a control group and was double-blind. On September 17, 2013, NewLink published a press release ("Enrollment Statement") stating that the Phase 3 trial "accrual goal of 722 subjects with surgically resected pancreatic cancer ha[d] been met."[10] The Phase 3 trial would publish results in three waves: after 222 "events" (*i.e.* deaths of trial subjects), after 333 events, and after 444 events.

On March 7, 2014, after 222 events, the first wave of results came in for the Phase 3 trial. The results showed that HyperAcute Pancreas had not satisfied the threshold for FDA approval. NewLink stock prices dropped. Four days later, Vahanian had a call with industry analysts. An analyst from Jefferies & Company asked him whether analysts should "assume that the control arm would be living beyond the low 20s" and asked what would happen to NewLink's statistical assumptions if analysts "ma[d]e the assumption that the control arm is living at 24 or 25 months."[11] Vahanian responded with the following "March Statement":

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[9] *Id.* at 744.

[10] *Id*. at 717.

[11] *Id*. at 723.

> Considering that it is our expectations, it is our belief that in our study today we don't have any reason to believe that median survival for these patients will be more than low 20s. Nevertheless, our study even though expectations were 18, 19 months, study is designed in the low 20s.[12]

After the call, NewLink stock prices rebounded. Between the first wave of results and the second wave, Vahanian and Link sold $5 million and $10 million of their NewLink holdings respectively.

On March 11, 2015, after 333 events and the release of the second wave of results, NewLink announced that HyperAcute Pancreas had again not satisfied the threshold for FDA approval. NewLink stock prices dropped again. The second wave of results showed a median survival rate of 28.5 months for both the control and test groups blended together. On a July 2015 earnings call, Vahanian reiterated NewLink's belief that the median months for survival in the "control arm [was] in the low 20s,"[13] After NewLink's reassuring statements, NewLink stock prices once again rebounded. Between the second and third waves of results, Vahanian and Link sold another $2 million and $9 million of their NewLink holdings respectively. They stopped trading before the announcement of the third wave of results.

On March 9, 2016, after 444 events and the end of the Phase 3 trial, NewLink announced that the Phase 3 trial had failed and HyperAcute Pancreas would not

[12] *Id.* at 724.

[13] *Id.* at 730.

satisfy the threshold for FDA approval. The price of NewLink stock dropped by 30.61%. The third wave of results showed a median survival rate of 27.3 months for the test group, which was *below* the 30.4-month survival rate for the control group.

Shortly before publication of the third wave of results, NewLink reported and Jefferies & Company highlighted in a "Flash Note" that one clinical site in the Phase 3 trial had been "non-compliant with certain [Good Clinical Practice ("GCP")] requirements."[14] NewLink identified the noncompliance as "a minor procedural issue involving one clinician."[15] The Flash Note stated that the clinical site at issue "only ha[d] 'a few' patients enrolled" and "in case any patients need to be excluded . . . exclusion of these patients should not have a material impact on the trial."[16] The price of NewLink stock dropped after the Flash Note was published. For the present litigation, Plaintiffs have identified a former NewLink Clinical Research Associate ("Confidential Witness") who claims to have "witnessed pervasive GCP violations" at NewLink, including the "acceptance of patients in the [Phase 3] trial that did not qualify."[17] The Confidential Witness did not specifically link the improper enrollments to the GCP noncompliance described in the Flash Note.

After the Phase 3 trial's failure, Plaintiffs brought this class action alleging that Defendants' 2013–2016 Assessments, the September Statement, the March

[14] *Id*. at 824.

[15] *Id*.

[16] *Id*.

[17] *Id*. at 733.

Statement, and the Enrollment Statement were materially false or misleading statements that amounted to securities fraud under S.E.C. Rule 10b-5. In challenging the 2013–2016 Assessments, September Statement, and March Statement, Plaintiffs highlighted a list of "major" studies of resected pancreatic cancer patients that was published in a 2011 medical journal by Vincent Picozzi, a pancreatic cancer researcher that NewLink had previously referred to as an authority on pancreatic cancer. Picozzi's list included six American studies that showed survival rates of 43.7, 25.4, 25, 21, 20.6, and 16.7 months. The district court dismissed Plaintiffs' claim regarding the 2013–2016 Assessments, September Statement, and March Statement, finding that Plaintiffs had not pleaded their falsity. It also dismissed Plaintiffs' claim regarding the Enrollment Statement, finding that Plaintiffs had alleged falsity but had failed to plead that their financial losses were caused by the false statement. Plaintiffs challenge each of these dismissals.

DISCUSSION

On appeal, Plaintiffs argue that they (1) adequately alleged falsity with respect to the 2013–2016 Assessments, September Statement, and March Statement and (2) adequately alleged falsity and loss causation with respect to the Enrollment Statement. We review the district court's dismissal of plaintiffs' claims for failure to state a claim *de novo*, "accepting all factual allegations in the complaint as true and drawing all reasonable inferences in the plaintiffs' favor."[18]

A. Whether Plaintiffs Have Adequately Alleged Falsity

[18] *Ganino*, 228 F.3d at 161.

The district court dismissed Plaintiffs' claims regarding the 2013–2016 Assessments, September Statement, and March Statement after finding that these statements were not plausibly alleged to be false or materially misleading. Specifically, the district court determined that the 2013–2016 Assessments were not misleading because they were "expressions of puffery and corporate optimism that do not . . . give rise to securities violations."[19] It then determined that the September and March statements were unactionable statements of opinion or disagreements with how Defendants "chose to interpret the historical data," rather than falsifiable statements of facts.[20] We agree with the district court's disposition of Plaintiffs' securities fraud claim based on the 2013–2016 Assessments but disagree with its conclusion regarding the September and March statements.

In assessing Plaintiffs' falsity arguments, we consider whether Plaintiffs have met the heightened pleading standards in the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Federal Rule of Civil Procedure 9(b). The PSLRA requires that plaintiffs "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief . . . all facts on which that belief is formed."[21] Similarly, Rule 9(b) requires that "a

[19] *Nguyen v. NewLink Genetics Corp.*, 297 F. Supp. 3d 472, 489 (S.D.N.Y. 2018) (internal quotation marks omitted).

[20] *Nguyen v. NewLink Genetics Corp. (Nguyen II)*, No. 16-cv-3545, 2019 WL 591556, at *5 (S.D.N.Y. Feb. 13, 2019) (internal quotation marks omitted).

[21] 15 U.S.C. § 78u-4(b)(1).

complaint . . . specify the statements that the plaintiff contends were fraudulent" and "explain why the statements were fraudulent."[22]

1. *2013–2016 Assessments*

We agree with the district court that Plaintiffs have not adequately pled the false or misleading nature of the 2013–2016 Assessments. Plaintiffs argue that these statements were false or misleading because the Phase 2 trial excluded individuals whose life expectancy was below six months, which "none of the other major pancreatic cancer studies" did.[23] Under Plaintiffs' theory, because the design of the Phase 2 trial would naturally lead to higher survival rates than those seen in other pancreatic cancer studies, Defendants could not honestly compare the Phase 2 results against other studies' results and say that the Phase 2 results were "encouraging," "an improvement," or suggestive of HyperAcute Pancreas's "efficacy." Plaintiffs' theory is untenable.

Generic, indefinite statements of corporate optimism typically are not actionable. We do not anticipate that reasonable investors place substantial reliance on generalizations regarding a company's health or the strength of a company's product.[24] And we have never required corporate officials to "present an overly gloomy or cautious picture of current performance and future

[22] *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004) (internal quotation marks omitted); *see also* Fed. R. Civ. Pro. 9(b).

[23] Appellants' Br. at 40.

[24] *See ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 206 (2d Cir. 2009).

prospects."[25] We have found "puffery"—like Defendants' descriptions of the Phase 2 results as "encouraging" and "an improvement"[26]—actionable only when the speaker "knew that the contrary was true."[27] Plaintiffs have not plausibly pled that Defendants believed the 2013–2016 Assessments to be false. As compared to the results of some studies of resected pancreatic cancer patients, the Phase 2 results arguably did show improvement. Although Vahanian and Link sold millions in NewLink stock during the pendency of the Phase 3 trial, this alone does not show that they disbelieved their generic, positive representations about HyperAcute Pancreas. Vahanian and Link reasonably could have been selling stock to hedge against the risk of the Phase 3 trial failing, despite their belief that HyperAcute Pancreas showed promise. Under these circumstances, we conclude that the 2013–2016 Assessments were unactionable puffery.

2. *September Statement*

The status of the September Statement, to the effect that "all the major studies" show survival rates of at most 20 months for resected pancreatic cancer patients, presents a more difficult question that requires discussion of the distinction between statements of opinion and statements of fact in our jurisprudence. Rule 10b-5 prohibits persons from (1) making "any untrue statement of a material fact" and (2) from "omit[ting] to state a material fact necessary in order to make [] statements made, in the light of the circumstances

[25] *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000).

[26] *See Kleinman v. Elan Corp., PLC*, 706 F.3d 145, 153 (2d Cir. 2013) (identifying "words like 'encouraging'" as "'expressions of puffery and corporate optimism' that do not generally 'give rise to securities violations'" (quoting *Rombach*, 355 F.3d at 174)).

[27] *Novak*, 216 F.3d at 315.

under which they were made, not misleading" in connection with the purchase or sale of any security.[28] The first part of this language unambiguously renders untrue statements of fact actionable. Although it has not always been appreciated in our jurisprudence, the second part of this language, which does not cabin "statements" with the modifier "of a material fact," renders both statements of fact *and* those of opinion actionable when such statements would be misleading without the contextualization of material facts.[29]

Before the Supreme Court decided *Omnicare, Inc. v. Laborers Dist. Council Const. Industry Pension Fund*,[30] our circuit paid little attention to this second part of Rule 10b-5 and recognized sparingly few circumstances in which a statement of opinion would be actionable. As now, plaintiffs alleging the falsity of a statement of fact merely had to plead that the statement was incorrect. But a district court's characterization of a statement as one of opinion rather than one of fact was all but fatal to the plaintiff's Rule 10b-5 claim. Plaintiffs challenging a statement of opinion had to plead "that the statement was both objectively false and disbelieved by the defendant at the time it was expressed."[31] This posed a substantial challenge for plaintiffs because statements of opinion, as defined in our

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[28] 17 C.F.R. § 240.10b-5(b).

[29] *See Omnicare, Inc. v. Laborers Dist. Council Const. Industry Pension Fund*, 575 U.S. 175, 187 n.4 (2015). *Omnicare* addressed § 11 of the Securities Act of 1933, which shares much of its relevant text with Rule 10b-5.

[30] *See generally id*.

[31] *Fait v. Regions Financial Corp.*, 655 F.3d 105, 110 (2d Cir. 2011) (internal quotation marks omitted).

jurisprudence, did not regard "objective factual matters,"[32] and it could be difficult for plaintiffs to locate evidence suggesting as plausible that a defendant's subjective beliefs conflicted with that defendant's stated opinion. The Supreme Court's *Omnicare* decision altered this calculus.

Analyzing § 11 of the Securities Act of 1933, which shares the relevant text concerning false and misleading statements with Rule 10b-5,[33] *Omnicare* rejected the proposition that there can be no liability based on a statement of opinion unless the speaker disbelieved the opinion at the time it was made. *Omnicare* established two principal ways of challenging statements of opinion that do not require plaintiffs to show that the speaker subjectively disbelieved the statement. First, plaintiffs can allege that a statement of opinion contained one or more embedded factual statements that can be proven false.[34] A statement structured, "I believe that x is so because y has occurred," contains the factual and falsifiable statement, "y has occurred." If y has in fact not occurred, the statement of opinion is actionable because an embedded but complete "statement of a material fact" under the first part of Rule 10b-5 can be proven false.

Second and relevant here, plaintiffs can allege that a statement of opinion, without providing critical context, implied facts that can be proven false. *Omnicare* used the statement, "We believe our conduct is lawful," as an example.[35] The

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[32] *Id*. at 111.

[33] *See* 15 U.S.C. § 77k(a) (creating liability for a registration statement that "contained an untrue statement of a material fact or omitted to state a material fact . . . necessary to make the statements therein not misleading").

[34] *Omnicare*, 575 U.S. at 185.

[35] *Id*. at 188.

Supreme Court explained that this statement implies, if investors are not informed otherwise, that the speaker has so concluded after investigating the governing law.[36] If the speaker in fact has not investigated the governing law, and has omitted this critical context, the statement of opinion, although literally true (assuming the speaker believed it) and thus not actionable under the first part of Rule 10b-5, may be misleading by omission and thus actionable under the second part of Rule 10b-5. In other words, when a statement of opinion implies facts or the absence of contrary facts, and the speaker knows or reasonably should know of different material facts that were omitted, liability under Rule 10b-5 may follow.

With respect to this second basis for challenging a statement of opinion, *Omnicare* held that the appropriate perspective for identifying whether a statement of opinion implies facts is that of the reasonable investor.[37] In assessing what a reasonable investor would expect, the Supreme Court stressed the importance of context, such as "the customs and practices of the relevant industry" and whether the opinion was expressed in a formal statement such as an S.E.C. filing or instead was a "baseless, off-the-cuff judgment[], of the kind that an individual might communicate in daily life."[38] Finally, *Omnicare* recognized that "[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts" and thus that a statement of opinion does not imply false information to a reasonable investor simply because there is "some fact cutting the other way" that the speaker omitted.[39] Returning to its example, "We believe our conduct is

[36] *Id*.

[37] *Id*.

[38] *Id*. at 190.

[39] *Id*. at 189–90.

lawful," the Court explained that this statement would not be misleading by omission if the speaker "did not disclose that a single junior attorney expressed doubts about a practice's legality, when six of his more senior colleagues gave a stamp of approval."[40]

Turning now to the September Statement, the district court characterized the statement as one of opinion rather than fact because "Vahanian was discussing studies that he believed to be 'major'" and was presenting his own analysis of data when he represented the findings of "all the major studies."[41] The district court, emphasizing that Plaintiffs had "fail[ed] to aver that the speaker did not hold the belief he professed" and concluding that Plaintiffs had not "misled investors," then had little difficulty dismissing Plaintiffs' Rule 10b-5 claim.[42] Plaintiffs first dispute the district court's characterization of the September Statement, arguing that it contravenes *Omnicare*'s dictate that courts should distinguish statements of opinion from those of fact by reference to the distinctions between the two that are "so ingrained in our everyday ways of speaking and thinking."[43] Ultimately, we need not decide whether the district court's classification and methodology for winnowing statements of fact from those of opinion ran afoul of *Omnicare*. By increasing the ability of plaintiffs to plead material omissions with respect to statements of opinion as described above, *Omnicare* reduced the significance of district courts' classification of statements as those of fact or opinion. The outcome

[40] *Id*. at 190.

[41] *Nguyen II*, 2019 WL 591556, at *4.

[42] *Id*. at *4 (internal quotation marks omitted).

[43] *Omnicare*, 575 U.S. at 183.

of Plaintiffs' Rule 10b-5 claim would not differ based on whether the September Statement was a statement of fact or one of opinion.

Plaintiffs also contend that the September Statement misled investors by implying that no credible studies have shown resected pancreatic cancer patients to have survival rates higher than 20 months. We agree that the September Statement plausibly would have conveyed this supposed fact to a reasonable investor. To start, the September Statement, whether one chooses to call it a statement of fact or opinion, was not framed like a statement of opinion. Vahanian did not couch his representation of survival rates with prefatory language like "I believe" or "In my estimation."[44] Instead, he flatly said, "Resected pancreatic cancer patients live 15 months, 19 months . . . . 20 months. That's it."[45] He then cited the results of "all the major [American] studies" from "the last 30 years" in direct support of this categorical proposition.[46] A jury could reasonably find that Vahanian was not, as the district court concluded, merely "discussing studies he believed to be 'major'" and his own subjective analysis,[47] but rather reassuring his audience of the depth of his knowledge and the accuracy of his apparently factual representation in case they doubted that survival rates actually "come between 15

[44] *Id*. at 187 (describing that a "reasonable person . . . . recognizes the import of words like 'I think' or 'I believe'" and that this prefatory language is relevant to our securities fraud analysis because it "convey[s] some lack of certainty as to the statement's content").

[45] App'x at 978.

[46] *Id*.

[47] *Nguyen II*, 2019 WL 591556, at *4.

to 19, 20 months."[48] This context, including the specificity of the representation[49] and the authority with which it was made, could lead "a reasonable person [to] think that a more detailed investigation lay behind the . . . statement"[50] and that no meaningful evidence existed to rebut the proposition that resected pancreatic cancer patients live between 15 and 20 months. Finally, Vahanian made his statement during NewLink's scheduled presentation at an important conference for biotech investors. Investors in attendance reasonably would not have interpreted his statement as a "baseless, off-the-cuff judgment[]"[51]; instead, they would have credited his statement as researched and intentional, part of a well-prepared professional presentation. A jury could find that Vahanian's statement, whether characterized as one of fact or opinion, would, absent clarification, lead a reasonable investor to the falsifiable conclusion that no study any knowledgeable person would find credible has shown the median survival rates of resected pancreatic cancer patients to be longer than 20 months.

Plaintiffs plausibly pled the false or misleading nature of this conclusion. Half of the American studies that Plaintiffs submitted—all of which Picozzi, an expert on pancreatic cancer, described outside the context of this litigation as "major"—preceded the September Statement and showed survival rates ranging

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[48] App'x at 978.

[49] *Omnicare*, 575 U.S. at 190, n.8 (explaining that "a reasonable investor generally considers the specificity of an opinion statement in making inferences about its basis").

[50] *Id*.

[51] *Id*. at 190.

from 25 months to 43 months.[52] While we accept that speakers may reasonably form opinions in spite of "some fact cutting the other way,"[53] and have no obligation to disclose *all* contrary facts irrespective of their significance, a jury could conclude that Vahanian's confident statement and his omission of noted studies' findings were a bridge too far. When omitted contrary facts substantially undermine the conclusion a reasonable investor would reach from a statement of opinion, that statement is misleading and actionable. Here, a jury could understand the September Statement to imply that no knowledgeable person could reasonably contest Vahanian's stated survival rates and characterization of prior pancreatic cancer research. A jury could therefore find that Vahanian could not truthfully and accurately represent to investors that no "major" studies showed survival rates in excess of 20 months, if in fact several studies, which Plaintiffs have plausibly alleged experts considered to be "major," did so. Accordingly, the district court erred in dismissing Plaintiffs' Rule 10b-5 claim based on the September Statement.

3. *March Statement*

Using the same framework established by *Omnicare*, we conclude that Plaintiffs have also plausibly pled the misleading nature of the March Statement. On appeal, Plaintiffs focus on the parts of the March call in which Vahanian responded to a question about whether analysts could "make the assumption that

[52] Furthermore, the Hidalgo paper that Vahanian cited at the biotech conference where he made the September Statement showed survival rates of 24.1 months and 20.6 months for Stage IA and IB resected pancreatic cancer patients. Plaintiffs did not plead this arguable inconsistency in their complaint, but their other pleadings are sufficient to allege that Vahanian's statement was misleading.

[53] *Omnicare*, 575 U.S. at 189.

the control arm is living at 24 or 25 months."[54] Vahanian first stated, "[I]t is our belief that in our study today we don't have any reason to believe that median survival for these patients will be more than low 20s."[55] This is plainly a statement of opinion. Vahanian then stated, "Nevertheless, our study . . . is designed" for the possibility that the control group survival rate is "in the low 20s."[56] This second statement is one of fact.

Both because of its posture as a response to a specific question and its categorical nature, Vahanian's statement of opinion conveyed, in much the same way as the September Statement, the supposed fact that resected pancreatic cancer patients have survival rates no greater than 20 months. A jury could find that, by saying that NewLink did not have "any reason" to believe that the control group could be living "at 24 or 25 months,"[57] Vahanian implied that there were no competing facts on survival rates, not that he had deemed competing facts less persuasive. As with the September Statement, the several studies showing survival rates above 20 months are plausibly more than "some fact cutting the other way."[58] A jury could conclude that the sheer volume of competing facts required Vahanian either to speak less confidently about the control group's survival rate or to disclose the existence of studies showing survival rates above 20 months. We therefore conclude that a jury could reasonably base liability on

[54] App'x at 723.

[55] *Id.* at 724.

[56] *Id.*

[57] *Id.*

[58] *Omnicare*, 575 U.S. at 189.

the March statement of opinion and that the district court erred in dismissing Plaintiffs' Rule 10b-5 claim.

By contrast, we conclude that the March statement of fact (that "our study . . . is designed" for the possibility that the control group survival rate is "in the low 20s") is not actionable because Plaintiffs have not adequately alleged its falsity. The only evidence Plaintiffs present of the statement of fact's falsity is the survival rate from NewLink's Phase 2 trial: 24.1 months. Plaintiffs argue that, based on this Phase 2 survival rate, NewLink could at most have designed the Phase 3 trial with an anticipated 20.1-month survival rate for the control group. But this does not rebut Vahanian's statement that NewLink designed the Phase 3 trial in anticipation of the trial's control group living "in the low 20s."[59] After all, 20.1 is a figure in the low 20s. Moreover, that Plaintiffs disagree with the methodology that Defendants purported to have selected for the Phase 3 trial does not mean that the methodology was not in fact selected. Although we find the statement of opinion in the March Statement actionable, we agree with Defendants that the statement of fact is not.

B. Whether Plaintiffs Have Adequately Alleged Loss Causation

With respect to the Enrollment Statement, the district court found that Plaintiffs had sufficiently alleged falsity but dismissed Plaintiffs' claim nonetheless because they had not plausibly alleged a causal link between the Enrollment Statement and their financial losses. Despite Defendants' protestations on appeal, we agree with the district court's falsity conclusion. Plaintiffs' Confidential Witness, allegedly a NewLink researcher with access to

[59] App'x at 724.

NewLink executives, claimed to have witnessed the enrollment of ineligible individuals and to have raised concerns about the "design" of the Phase 3 trial with Vahanian.[60] The Confidential Witness further claimed that Vahanian dismissed those concerns about the "design" of the Phase 3 trial and was "'really pushy'" about enrolling enough individuals within a particular timeframe.[61] At the pleading stage, these allegations of falsity are sufficiently particular and plausible.

We disagree, however, with the district court's conclusion that Plaintiffs failed to plausibly plead loss causation. The PSLRA "imposes on plaintiffs 'the burden of proving' that the defendant's misrepresentations 'caused the loss for which the plaintiff[s] seek[] to recover.'"[62] To establish loss causation, Plaintiffs must "demonstrat[e] that 'the *subject* of the fraudulent statement or omission was the cause of the actual loss suffered.'"[63] Plaintiffs must allege not only the but-for causation of their losses but also the proximate causation, or that the fraud "concealed something from the market that, when disclosed," would foreseeably and "negatively affect[] the value of the security."[64] Generally, plaintiffs sufficiently plead loss causation[65] when they allege that their share's "price fell

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[60] *Id*. at 716, 733.

[61] *Id*. at 716.

[62] *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 345–46 (2005) (quoting 15 U.S.C. § 78u-4(b)(4)).

[63] *In re Vivendi, S.A. Securities Litigation*, 838 F.3d 223, 261 (2d Cir. 2016) (quoting *Suez Equity Investors, L.P. v. Toronto-Dominion Bank*, 250 F.3d 87, 95 (2d Cir. 2001)) (emphasis in *Vivendi*).

[64] *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 173 (2d Cir. 2005).

[65] This case does not require us to decide whether Rule 9(b)'s heightened pleading standard applies to allegations of loss causation. *But see Oregon Public Employees Retirement Fund*

significantly after the truth became known" through an express, corrective disclosure[66] or "through events constructively disclosing the fraud" like the "materialization of [the] risk" concealed.[67] Here, Plaintiffs argue that the Jefferies & Company Flash Note about Defendants' GCP violations was a corrective disclosure that expressly revealed the falsity of the Enrollment Statement. In the alternative, they argue that the failure of the Phase 3 trial was "attributable to [the] concealed" improper design of the trial and that the failure therefore constructively disclosed the fraud.[68] We find Plaintiffs' alternative theory of loss causation persuasive.

Turning to Plaintiff's primary argument, we reject the contention that the Flash Note alone was a corrective disclosure. The Flash Note reported that the GCP noncompliance affected one clinical site with only "a few" subjects and that it was uncertain whether any patients from that site would have to be excluded.[69] The Flash Note did not mention improper enrollment. If anything, the Flash Note's uncertainty about whether patients would have to be excluded could be

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v. Apollo Group Inc., 774 F.3d 598, 604 (9th Cir. 2014) (characterizing the Second Circuit's pleading standard for loss causation as a "heightened" standard, insofar as it "requir[es] that plaintiffs show that the loss was both foreseeable and caused by the materialization of the risk concealed by the fraudulent statement"). Plaintiffs have pled "with particularity" how they believe the Enrollment Statement inflated the value of NewLink shares and how the falsity of the Enrollment Statement was publicly revealed, thereby causing Plaintiffs' financial losses. Thus, our review is focused on whether Plaintiffs' specific theories of loss causation are plausible.

[66] *Dura Pharmaceuticals, Inc.*, 544 U.S. at 347.

[67] *In re Vivendi, S.A. Securities Litigation*, 838 F.3d at 262.

[68] *Lentell*, 396 F.3d at 174.

[69] App'x at 824.

read to suggest that the GCP noncompliance was something other than improper enrollment. Because the Flash Note did not alert the public to the falsity of the Enrollment Statement, we agree with the district court that it cannot serve as a corrective disclosure.[70]

Plaintiffs' alternative argument, that the risk of Defendants' alleged improper enrollments materialized when the Phase 3 trial failed, is more compelling. In essence, Plaintiffs argue that the improper enrollment foreseeably caused the failure of the Phase 3 trial. We agree that a sufficient number of improper enrollments would naturally and predictably affect a trial's statistical integrity. And Plaintiffs' Confidential Witness reported "pervasive" GCP violations, including the enrollment of ineligible individuals.[71] That at the end the control group had a higher survival rate than the test group by three months suggests as plausible that the pervasive enrollment of ineligible individuals may have affected the trial results. This suffices because, at this early pleading stage, we do not require "conclusive proof" of the causal link between the fraud and Plaintiffs' loss.[72]

We find that Plaintiffs have "allege[d] sufficient facts to raise a reasonable inference that" the alleged improper enrollments concealed by the Enrollment Statement affected the Phase 3 trial's outcome, thereby "caus[ing] an ascertainable

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[70] *See In re Omnicom Group, Inc. Securities Litigation*, 597 F.3d 501, 511 (2d Cir. 2010) (requiring a corrective disclosure to "reveal some then-undisclosed fact with regard to the specific misrepresentations alleged in the complaint").

[71] App'x at 733.

[72] *Financial Guarantee Ins. Co. v. Putnam Advisory Co., LLC*, 783 F.3d 395, 404 (2d Cir. 2015).

portion of [Plaintiffs'] loss."[73] Thus, the district court erred in dismissing Plaintiffs' Rule 10b-5 claim based on the Enrollment Statement. Discovery will reveal the extent of the improper enrollment and allow the fact-finder to conclude whether the improper enrollment had an impact on the trial results.

CONCLUSION

For the reasons stated above, we AFFIRM the district court's dismissal of Plaintiffs' Rule 10b-5 claim regarding the 2013–2016 Assessments, VACATE the district court's dismissal of Plaintiffs' Rule 10b-5 claims regarding the September, March, and Enrollment statements, and REMAND for further proceedings consistent with this opinion.

[73] *Id*.