UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CARL D. CACHIA, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

-against-

BELLUS HEALTH INC., ROBERTO BELLINI, FRANÇOIS DESJARDINS, DR. CATHERINE BONUCCELLI, DR. JACKY SMITH, JEFFERIES LLC, COWEN AND COMPANY, LLC, GUGGENHEIM SECURITIES, LLC, ROBERT W. BAIRD & CO. INCORPORATED and BLOOM BURTON SECURITIES INC,

Defendants.

MEMORANDUM DECISION AND ORDER

21 Civ. 02278-GBD

GEORGE B. DANIELS, United States District Judge:

Lead Plaintiff Carl Cachia ("Plaintiff" or "Cachia") brings this class action against BELLUS Health Inc. ("BELLUS" or the "Company"), Roberto Bellini ("Bellini"), François Desjardins ("Desjardins"), Dr. Catherine Bonuccelli ("Dr. Bonuccelli"), Dr. Jacky Smith ("Dr. Smith"), Jefferies LLC ("Jefferies"), Cowen and Company, LLC ("Cowen"), Guggenheim Securities, LLC ("Guggenheim Securities"), Robert W. Baird & Co. Incorporated ("Baird") and Bloom Burton Securities Inc. ("Bloom") (collectively, "Defendants") for alleged misrepresentations Defendants made to investors. (*See* First Amended Complaint ("FAC"), ECF No. 33.) Specifically, Plaintiff complains that Defendants committed fraud-based violations under Sections 10(b) and 20(a) of the 1934 Securities Exchange Act and strict liability violations under sections 11, 12(a)(2), and 15 of the 1933 Securities Act. (*See* FAC at ¶¶ 1, 233-282.) Now Defendants BELLUS, Bellini, Desjardins, Dr. Bonuccelli (collectively, "BELLUS Defendants"), and Dr. Smith move to dismiss the FAC pursuant to Federal Civil Rule 12(b)(6). (BELLUS Defs.'

Mot. to Dismiss, ECF No. 54; Dr. Smith's Mot. to Dismiss, ECF No. 63.) The motions to dismiss are GRANTED for Plaintiff's failure to state a claim.

I. BACKGROUND

Since we assume the Plaintiff's factual allegations to be true, the following facts are from the FAC and any documents it relies upon unless otherwise noted.[1]

A. The Parties

BELLUS is a biopharmaceutical company that is currently developing BLU-5937, a drug to treat chronic cough (defined as a cough lasting at least eight weeks. (FAC at ¶¶ 2, 3.) BLU-5937 is BELLUS' sole drug product it plans to introduce into the market. (*See Id.* at ¶ 13.) The company is incorporated in Canada, but has been trading on the U.S. stock exchange in the NASDAQ marketplace since September 5, 2019. (*See Id.* at ¶¶ 22, 23). The individual Defendants are company executives: Defendant Bellini is the President and Chief Executive Officer ("CEO") of BELLUS; Defendant Desjardins is the Senior Vice President; and Defendant Bonuccelli is the Chief Medical Officer. (*Id.* at ¶¶ 24-26.) Defendant Dr. Smith plays a unique role in which she is not an employee of the company, but serves as the Chairman of the Clinical Advisory Board to advise BELLUS in its development of BLU-5937. (*See Id.* at ¶ 32.) Plaintiff is an investor who purchased BELLUS securities during the Class Period.[2] (*Id.* at ¶ 20.) He brings this action on behalf of "all persons and entities who purchased or otherwise acquired (a) common stock pursuant or traceable to the IPO Documents issued in connection with the Company's IPO and/or (b)

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[1] The Court "may also '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.'" *Kleinman v. Elan Corp*, 706 F.3d 145 (2d Cir. 2013) (quoting *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir.2007)).

[2] The Class Period is September 5, 2019 to July 6, 2020. (FAC ¶ 1.)

BELLUS securities between September 5, 2019 and July 6, 2020 (the "relevant period" or "Class Period"). (*Id.* at ¶¶ 1, 227.)

B. Competitors' Clinical Trials

BELLUS is competing against pharmaceutical companies Merck & Co. ("Merck"), Shionogi, and Bayer AG ("Bayer") to develop a treatment for chronic cough. (*See* FAC at ¶¶ 3, 76, 88, 91.) These pharmaceutical companies are in the process of developing a drug to target what are known as P2X3 receptors, which play an important role in our cough reflexes. (*Id.* at ¶¶ 61-62.) Currently, there is no FDA approved drug that targets P2X3 receptors. (*Id.* at ¶ 63.)

To obtain FDA approval, generally a drug must go through four phases of clinical trials (Phase I-IV) to assess the drug's benefits, efficacy, and safety. (*Id.* at ¶¶ 66-72.) Merck's drug, Gefapixant, is the most advanced in the FDA approval process. By March 2018, Merck had successfully completed two different Phase 2 clinical trials. (*See Id.* at ¶ 4.) Both Phase 2 trials were randomized, double-blind, and placebo-controlled, with dose escalation (50 mg, 100mg, 150mg and 200mg) occurring every 4 days over the course of 16 days. (*See Id.* at ¶ 78.) Importantly, the enrollment criteria in the two Merck trials required, *inter alia*, patients to have chronic cough for over a year with a certain cough severity score, but did not include a minimum coughs per hour (c/h) threshold requirement. (*See* FAC at ¶¶ 77-80.) On May 18, 2016, Merck announced that its first Phase 2b trial for Gefapixant demonstrated effectiveness (significant reduction in awake cough frequency), which had 29 patients with a baseline mean awake cough frequency of 56.9 c/h. (*See Id.* at ¶ 80.) A year later, on May 22, 2017, Merck announced that a second, larger Phase 2b trial for Gefapixant was successful, which consisted of 253 patients with a mean baseline awake cough frequency at 40.3 c/h. (*See* FAC at ¶¶ 84.) However, and

importantly, in both clinical trials patients experienced a loss in taste as a side effect of the drug. (*Id.* at ¶¶ 80, 86.)

Shionogi and Bayer were not far behind Merck in the development of their drug targeting P2X3 receptors. On March 14, 2019, Shionogi described and provided results on their Phase 2 clinical trial. (*Id.* at ¶ 88.) The trial was also randomized, double-blind, and placebo-controlled. (*Id.*) Enrollment in the trial required patients to have chronic cough for at least 6 months, but did not include a minimum c/h threshold. (FAC at ¶ 88.) The trial showed that Shionogi's drug was able to "significantly reduce cough while having the least amount of taste disturbances." (*Id.* at ¶ 90.) Shionogi's March announcement did not include a report on participants' ultimate baseline c/h average or mean. But on September 22, 2019 Shionogi disclosed that the successful trial consisted of patients with a baseline cough frequency of 56 c/h. (*Id.* at ¶ 110.) On July 25, 2019, Bayer announced that it ran a successful Phase 2 clinical trial that did not include a minimum c/h threshold eligibility requirement for participating patients. (*Id.* at ¶ 91.) Bayer ostensibly did not release the mean baseline cough frequency of its participating patients.

C. BELLUS' Clinical Trial and Public Statements

While BELLUS was seemingly behind its competitors, it was in the process of developing its chronic cough treatment drug BLU-5937. This drug was not only supposed to treat chronic cough, but limit the taste disturbance side effect associated with competitors' treatments. (FAC at ¶ 94-95.) In November 2018, BELLUS had a successful Phase 1 human clinical trial in which none of the 24 participants reported loss of taste. (*See Id.* at ¶ 74.) On July 30, 2019, BELLUS announced that it had designed RELIEF—its Phase 2 clinical trial for BLU-5937. (*See Id.* at ¶ 96 n.25.) Like its competitors, BELLUS accounted that RELIEF was a double-blind, placebo-controlled, and dose-escalation (25, 50, 100 and 200 mg) trial. (*See Id.*) RELIEF's enrollment

criteria were also similar to its competitors in that participants were required to have unexplained chronic cough for at least a year and a certain cough severity. (*See* Defs.' Mem. of Law in Support of Mot. to Dismiss, ECF No. 55, at 5.) But importantly, the clinical trial differed in one respect: participants were required to meet a minimum threshold of 10 c/h. (*See Id.*; FAC at ¶ 124.) In its July 30, 2019 announcement, BELLUS stated that it had enrolled its first patient in the trial and expected 65 patients to enroll in total. (FAC at ¶¶ 96-97.) BELLUS announced that it finished enrolling patients in RELIEF on March 19, 2020. (*See Id.* at ¶156.) On April 6, 2020, BELLUS announced that ultimately 52 patients completed the RELIEF trial. (*Id.* ¶159.)

At the time BELLUS first designed the RELIEF trial in July 2019, the Company was not publicly trading on the NASDAQ yet. To generate investor support for RELIEF and in advance of BELLUS' initial public offering ("IPO"), BELLUS made numerous public announcements "presenting BLU-5937 as poised to dominate the untapped ~$10 billion market for chronic cough – riding the coattails of competitors." (*Id.* at ¶100.) On September 3, 2019, BELLUS filed "a preliminary prospectus supplement (the "Supplement") to its short form base shelf prospectus, dated July 26, 2019 (the "Base Prospectus") in connection with a proposed $60 million IPO of its common shares…on the NASDAQ." (FAC at ¶101.) BELLUS also filed additional accompanying public documents related to its IPO. (*Id.* at ¶101-102.) The IPO documents discussed how the RELIEF trial for BLU-5937 followed the same design and parameters as Merck's clinical trials, and referenced the success of competitors' trials to support BELLUS' expressed expectations of its Phase 2 clinical trial and the efficacy of BLU-5937. (*Id.* at ¶¶ 102, 138-139.) However, the Prospectus provided conditional language demonstrating next steps *only if* RELIEF was successful, informed investors that FDA approval "may never occur," and warned that the clinical effectiveness of BLU-5937 is not yet supported by data. (*See* Prospectus Form

Supp., ECF No.56-3, at S-4, S-10, S-12 S-37, S-44.) The IPO eventually raised $70 million. (FAC at ¶ 103.) BELLUS began trading on the NASDAQ in September 2019.

After the IPO, and throughout the relevant time period, BELLUS continued to make public statements and presentations touting the anticipated success of RELIEF and the efficacy of BLU-5937. These public statements continued to reference data from its competitors' successful Phase 2 trials, especially Merck's clinical trials, to demonstrate the potential effectiveness of a drug that targets P2X3 receptors and BELLUS' belief in its own Phase 2 trials. (*See Id.* at ¶¶ 104-108, 146-147, 151, 153-154, 161, 164, 166-168, 170.) For instance, in a February 27, 2020 press release, BELLUS stated, "The P2X3 receptor in the cough reflex pathway is a rational target for treating chronic cough, and it has been validated in multiple clinical trials with different P2X3 antagonists." (*Id.* at ¶ 151.) At a May 12, 2020 conference, Defendant Bellini stated that BELLUS feels "very comfortable around the power of [its] trial, considering it's the largest that's been completed with *this* design." (*Id.* at ¶ 162.) This design was in direct reference to the design of competitors' Phase 2 trials. BELLUS continued to make similar public statements before BELLUS had a chance to complete enrolling patients in RELIEF. BELLUS stated its strong belief in RELIEF up until July 2020.

On July 6, 2020 BELLUS provided the unfortunate news that RELIEF was unsuccessful. (*See* FAC at ¶199.) Experts attributed the unsuccessful trial to the "unusually low baseline cough counts compared to competitive trials…" (See, *e.g., Id.* at ¶ 202.) However, RELEIF did demonstrate a statistically significant reduction in cough frequency for all patients at or above baseline median cough frequency of 32.4 c/h. (*Id.* at ¶ 199.) The BELLUS stock tanked in response to this news. (*Id.* at ¶ 197.)

D. Procedural Background

Several months after the BELLUS stock crashed, Cachia filed an amended complaint against the Defendants alleging that through its IPO documents and public statements, the Defendants misled investors about RELIEF's design, enrollment, and ability to demonstrate the efficacy of BLU-5937. (*See* the FAC.) The BELLUS Defendants and Dr. Smith moved to dismiss the FAC for failure to state a claim. (ECF No. 54; ECF No. 63.)

II. LEGAL STANDARD

For a complaint "[t]o survive a motion to dismiss, [it] must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). To state a facially plausible claim requires the plaintiff to demonstrate "more than a sheer possibility that a defendant has acted unlawfully" by pleading facts that enable the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citation omitted). The factual allegations pled must therefore "be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555 (citation omitted). In examining the complaint, a district court strikes any conclusory statements and then considers whether the plaintiff's remaining well-pleaded factual allegations, assumed to be true, "plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679; *see also Targum v. Citrin Cooperman & Co., LLP*, No. 12 Civ. 6909 (SAS), 2013 WL 6087400, at *3 (S.D.N.Y. Nov. 19, 2013). In deciding the 12(b)(6) motion, the court must also draw all reasonable inferences in the non-moving party's favor. *See N.J. Carpenters Health Fund v. Royal Bank of Scot. Grp., PLC*, 709 F.3d 109, 119–20 (2d Cir. 2013).

Allegations of fraud, including securities fraud under the 1934 Securities Exchange Act must satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) by "stat[ing] with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b); *see ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007). A complaint alleging securities fraud under the 1934 Securities Exchange Act must also meet the requirements of the Private Securities Litigation Reform Act ("PSLRA"). 15 U.S.C. § 78u–4(b). The PSLRA "expand[s] on the Rule 9(b) standard," requiring that "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[s] acted with the required state of mind." *Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98, 108 (2d Cir. 2012). Claims under the 1933 Securities Act that are premised on the same allegations of fraud alleged under the 1934 Securities Exchange Act are also subject to Rule 9(b)'s heightened pleading standards. *See Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004).

III. PLAINTIFF'S COMPLAINT FAILS TO PLEAD A CLAIM

Plaintiff, on behalf of a class, brings securities fraud claims under Sections 10(b) and 20(a) of the 1934 Securities Exchange Act and its accompanying SEC Rule 10b-5, and sections 11, 12(a)(2), and 15 of the 1933 Securities Act.[3] However, Plaintiff's securities fraud theories fail because he does not identify a single false statement or omission that makes any statement misleading. For this reason alone, the complaint is dismissed. The complaint is also dismissed for a failure to plausibly allege any of the other elements of securities fraud.

[3] The same standards apply under either statute because the allegations challenge the same set of misstatements. *See Rombach*, 355 F.3d at 175 ("We analyze the allegations regarding the registration statement in light of the Section 10(b) claims as well, because the Section 10(b) count incorporates as though fully set forth therein the allegations contained in the Section 11 count.").

To sufficiently allege a violation of Section 10(b) and Rule 10b-5, a plaintiff must plead "(1) a material misrepresentation (or omission); (2) scienter, i.e., a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance ...; (5) economic loss; and (6) loss causation[.]" *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 152 (2d Cir. 2013) (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336 (2005)). To plausibly allege a violation of Section 11, 12, or 15, a plaintiff must plead that the material misrepresentation or omission was in registration statements filed with the SEC, and does not need to plead the scienter or reliance elements of a 10b-5 claim.[4] *See In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 358 (2d Cir. 2010); *Rombach*, 355 F.3d at 169 n.4.

A. Plaintiff Failed to Plead a Material Misrepresentation

The FAC alleges that BELLUS "misled investors regarding the RELIEF trial's design, enrollment, and prospects for success" by misrepresenting that BELUSS was following "the design of competitors' successful trials and, therefore, that there was a high likelihood of BELLUS." (Pl.'s Mem. of Law in Opp. to Mot to Dismiss, ECF No. 67, at 13.) The FAC claims that certain public statements contained in registration documents with the SEC and other public comments were in fact false for failing to disclose that the company disregarded the correlation between patients' high cough frequency in competitors' Phase 2 clinical trials and the efficacy of the competitor's respective drug. (*See, e.g.*, FAC at ¶¶ 140.) Contrary to Plaintiff's assertions, the pleaded statements are not actionable false statements.

A material misrepresentation or omission can be a statement that is prima facie not true or omits facts that make the statement misleading. *See Kleinman*, 706 F.3d at 152 ("Untrue

[4] The difference between the sections is based on who is liable. *See In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d at 358.

statements must be identified and, if applicable, so must the omitted facts that are necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading.) (quotations omitted). The "veracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather than mislead prospective buyers." *Operating Local 649 Annuity Trust Fund v. Smith Barney Fund Mgmt.*, LLC, 595 F.3d 86, 92 (2d Cir.2010). In fact, "[s]tatements of literal truth can become, through their context and manner of presentation, devices which mislead investors." *See Kleinman*, 706 F.3d at 153 (quotations omitted). Certain statements in fact cannot ever be the proper basis for fraud, such as statements about how clinical trials are designed or managed. *See Zagami v. Cellceutix Corp.*, No. 15 CIV. 7194 (KPF), 2016 WL 3199531, at *12 (S.D.N.Y. June 8, 2016) ("What is more, neither is a proper basis for a claim of fraud. Put simply, securities law is not a tool to second guess how clinical trials are designed and managed.") (quotations omitted).

Furthermore, simply because a certain fact was omitted from a statement does not necessarily mean there was a material misrepresentation or omission. Put differently, "[d]isclosure of an item of information is not required…simply because it may be relevant or of interest to a reasonable investor." *Kleinman*, 706 F.3d at 152-53. Instead, an omission becomes a material misrepresentation only when the "omitted fact makes a statement, in the light of the circumstances under which they were made…misleading." *Id.* at 153. Additionally, as the Supreme Court made clear, when a representation is an opinion, it "is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way" of its opinion. *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175, 190 (2015). Securities law only requires Defendants to make statements that "fairly align with the information in the [Defendant]'s possession at the time." *Id.* at 189.

Plaintiff argues that Defendants misled investors because despite contrary representations, it was not following the "critical aspect" that "competitors had tested their drugs on more patients with higher cough frequencies." (ECF No. 67 at 13.) The BELLUS Defendants and Dr. Smith argue that this is simply not true and that they truthfully disclosed the specifics of the trial and believed in the strength of the trial's design to prove the efficacy of BLU-5937. (*See* ECF No. 55 at 1-2.) The Defendants are right and the FAC does not demonstrate that any statement made by the Defendants were false or misleading.

First, as a matter of law, Plaintiff cannot use hindsight and securities law as tools "to second guess how clinical trials [were] designed and managed." *Zagami*, 2016 WL 3199531, at *12. The design of the clinical trial is essentially what Plaintiff challenges. Their argument is simply that the design of RELIF, particularly the 10 c/h threshold, resulted in patients with a lower cough frequency, which is why RELEIF was unsuccessful.[5] This second guessing a clinical trial's design and enrollment criteria is not permitted under securities law. *Id.* Plaintiff tries to circumvent this prescription by arguing that he is not challenging the design of RELIEF, but challenging the portrayal of RELEIF as similar to its competitors and a failure to inform investors that RELIEF was in fact enrolling patients with a lower awake cough frequency. This leads to the second reason why Plaintiff has failed to allege a misrepresentation.

Factually, nothing Defendants said in the Base Prospectus, Supplement, other IPO documents, and additional public statements were false or omitted facts making its statements

[5] For instance, certain statements by the Defendants were alleged to be false because "Defendants Smith and Bonucelli failed to disclose that BELLUS had disregarded, in designing its P2X3 Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck's studies had demonstrated. Specifically, the Company's Phase 2 trial had a low cough frequency threshold of 10 coughs per hour to enroll patients, which had resulted in a low number of severe cough patients being enrolled. This design flaw in BELLUS's Phase 2 trial meant there was a high risk it would not meet its designated primary endpoint for efficacy." (FAC ¶ 174.)

misleading. As stated in press releases, RELEIF was in fact similar to its competitors' trials – it tested a drug that targeted P2X3 receptors in a randomized, double-blind, and placebo-controlled trial. (*See* FAC ¶¶ 78, 96 n.25.) This was very similar to Merck's, Shionogi's, and Bayer's trials. The only difference was the fact that RELEIF required patients to have a baseline awake cough frequency of 10 c/h. Defendants did not omit this enrollment requirement when disclosing the parameters of RELIEF, but specifically disclosed this fact to investors. (*See Id.* at ¶ 124.) Therefore, Plaintiff incorrectly relied on the inapposite case, *In re World Wrestling Ent., Inc. Sec. Litig.*, 180 F. Supp. 3d 157, 183–84 (D. Conn. 2016), to contend that Defendants had a duty to disclose the enrollment criteria of their clinical trial compared to the criteria of another trial when they made a "critical change." (ECF No. 67 at 12.) Defendants did in fact publicly disclose this difference, notwithstanding whether the difference was critical or not. This public disclosure "precludes the . . . claim of a nondisclosure rendering other statements actionably misleading." *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372, 411 (S.D.N.Y. 2018), *aff'd*, 757 F. App'x 35 (2d Cir. 2018). Investors had the information to discern the differences between the trials and determine whether investing in BELLUS was prudent. Any second guessing now by a reasonable investor of RELIEF'S design strength with the benefit of hindsight is not permitted.

Third, the statements about the anticipated results of RELEIF were pure speculation, and thus, nonactionable statements of opinion. *See Omnicare*, 575 U.S. at 189-90; *Arkansas Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 355 (2d Cir. 2022). Defendants are only asked to make statements that "fairly align with the information in the [Defendant]'s possession at the time." *Omnicare*, 575 U.S. at 189. BELLUS qualified all of its expectations by stating that the efficacy of BLU-5937 was not yet proven, no matter its comparisons to competitors' drugs. (*See* ECF No.56-3 at S-12 ("The clinical effectiveness of BLU-5937 is not

yet supported by clinical data.").) Therefore, any forward-looking statements about the success of RELIEF are nonactionable statements of opinion. *See Arkansas Pub. Emps. Ret. Sys.*, 28 F.4th at 355 ("All of the statements identified by the Investors were made on earnings calls or in presentations in which the relevant risk--that the trial may fail to reach its primary endpoint… And although they claim that Bristol-Myers had an obligation to disclose why the trial might fail… they cite no law to support such an argument.").

However, such statements may not even be needed: it would contradict rationale to assume statements about expectations of a not yet tested drug or not yet run clinical trial to be true. BELLUS hired experts and used the trials of its competitors to design RELEIF, but that is as best as one can get without running tests. At the time of the trial design, there were in fact no existing facts indicating that a 10 c/h threshold would result in an unsuccessful trial or that the threshold needed to be higher. Only Merck had released its results before the press release outlining the design of RELEIF. Merck's Phase 2 clinical trial did not have a cough frequency threshold, which implies a threshold may only increase the mean frequency. No fact existed demonstrating that BELLUS definitively knew its trial would fail. In fact, BELLUS would not even know the mean awake cough frequency of participants in RELEIF until enrollment was complete in March of 2020. Only then, was there maybe a fact cutting against BELLUS' belief in the anticipated success of RELIEF. However, this still did not give rise to a required disclosure. *See Arkansas Pub. Emps. Ret. Sys.*, 28 F.4th at 355 ("Although the Investors argue at length that the trial was riskier than the Investors (with hindsight) believe was necessary, they make no claim (and allege no facts indicating) that these statements of opinion were false.").

Plaintiff specifically argues that Defendants' statements were misrepresentations because they failed to disclose the fact that as patients enrolled in RELEIF, BELLUS knew it was not

enrolling patients with a mean cough awake cough frequency at least as high as the mean in Merck's trial. However, even if Defendants did know this fact, it "is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." *Omnicare*, 575 U.S. at 190. Here, there still was no definitive proof that such a high mean awake cough frequency was necessary to prove the efficacy of BLU-5937. Simply put, the alleged statements were statements about BELLUS' expectations. They may have been grounded in science, but a reasonable investor knows that a belief in the potential success of a clinical trial is only a hypothesis, research-based opinions, until tested and proven otherwise. As such, Plaintiff has failed to put forth any allegation that Defendants made public misrepresentations.

B. Plaintiff Failed to Plead Scienter

Scienter is only required for Plaintiff's 10(b) and 10b-5 claims under the Exchange Act. Plaintiff is required to "plead with particularity facts giving rise to a strong inference that the defendant[s] acted with the required state of mind," which is "an intent to deceive, manipulate, or defraud." *ECA, Local 134 IBEW Joint Pension v. JP Morgan Chase*, 553 F.3d 187, 198 (2d Cir. 2009). Scienter is pled by showing either (1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." *Id.* at 198; *see also In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 529 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

Even if Defendants' statements were misleading, Plaintiff has failed to demonstrate that Defendants had a motive to commit fraud. Plaintiff argues "[w]ithout FDA approval of BLU-5937, BELLUS will likely not survive," and in order to get FDA approval BELLUS needed funding through its IPO. (ECF No. 67 at 32.) "Courts have found allegations of motive adequate where the company's needed to fundraise to survive." *Skiadas v. Acer Therapeutics Inc.*, No. 1:19-

cv-6137-GHW, 2020 WL 3268495, at *11- *12 (S.D.N.Y. June 16, 2020) However, the Defendant in *Skiadas* was waiting for a decision from the FDA and needed liquidity to stay afloat in the short term. *Id.* at *10-11. This created a very specific need for survival, which in turn demonstrates a strong motive to commit fraud. Here, BELLUS was not even awaiting a decision from the FDA. They were not even close – only at a Phase 2 clinical trial. FDA approval at the very least requires 4 phases of clinical trials.[6] Any purported need for survival based on FDA approval was attenuated: BELLUS still needed to have investors float the company not only through Phase 2 clinical trials, but Phases 3 and 4. Plaintiff's contention about BELLUS's need for fundraising was general in nature. *See In re OSG Sec. Litig.*, 971 F. Supp. 2d 387, 408 (S.D.N.Y. 2013) (allegation that offering was "critical to [the company's] very survival" was "too generalized a motive to plead securities fraud"). In fact, Plaintiffs acknowledge that BELLUS "spent years and millions of dollars" investing in BLU-5937. Such an investment despite being considerably removed from any FDA approval in the near future makes any motive to lie illogical. *See Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d at 600-01.

There are also no factual allegations supporting the proposition that Defendants consciously or recklessly knew any statements were misleading. As discussed above, there is no indication that RELEIF's cough frequency threshold was going to result in a lower mean awake cough frequency of its patients. There was also no indication that a higher awake cough frequency was in fact necessary to demonstrate efficacy. Therefore, Defendants were in their right to believe the clinical trial was still going to be successful even if after full enrollment it knew it had a lower awake cough frequency than its competitors' Phase 2 clinical trials. As such, there was no

[6] *See* FAC ¶¶ 66-72

conscious or reckless disregard that any statements about the anticipated success of RELEIF were misleading. Plaintiff has not sufficiently pled scienter.

IV. LEAVE TO AMEND IS DENIED

Plaintiff, in the alternative, seeks leave to amend the FAC. (Mot. for Leave to Amend FAC, ECF No. 76.) Courts should freely permit Plaintiff's leave to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2). By its terms, this rule is not absolute, and "district court[s] have the discretion to deny leave if there is a good reason for it." *Brown v. Quiniou*, 467 F. App'x 13, 15 (2d Cir. 2012) (quoting *Jin v. Metro. Life Ins. Co.*, 310 F.3d 84, 101 (2d Cir. 2002)). For instance, "[i]t is well established that leave to amend a complaint need not be granted when amendment would be futile." *Kim v. Kimm*, 884 F.3d 98, 106 (2d Cir. 2018) (quoting *Ellis v. Chao*, 336 F.3d 114, 127 (2d Cir. 2003)). A proposed amendment is futile when "it could not withstand a motion to dismiss pursuant to Rule 12(b)(6)." *Long v. Parry*, 679 F. App'x 60, 63 (2d Cir. 2017) (citing *Dougherty v. N. Hempstead Bd. of Zoning Appeals*, 282 F.3d 83, 88 (2d Cir. 2002)).

Plaintiff's proposed amendments to the FAC are futile and fails to cure the deficiencies in the FAC. None of the amendments cure the fact that BELLUS never made a misrepresentation about RELEIF. Its statements were factually true and there were no omissions that made its representations misleading. The proposed amendments do not add a single representation that changes the analysis above. While that failure is a ground alone to deny further leave to amend, the proposed amendments also fail to support any plausible scienter allegations. Plaintiff merely doubles down on and tries to bolster the same arguments that failed for Plaintiff above. For the foregoing reasons, the PSAC would be futile. Therefore, the motion for leave to amend is denied.

V. CONCLUSION

Defendants' motion to dismiss is GRANTED. Plaintiff's motion for leave to amend is DENIED. Plaintiff's claims are dismissed in their entirety. The Clerk of Court is directed to close the pending motions, (ECF Nos. 54, 63, and 76), and close the case.

Dated: SEP 21 2022
September, 2022
New York, New York

SO ORDERED.

George B. Daniels

GEORGE B. DANIELS
UNITED STATES DISTRICT JUDGE