UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NICHOLAS SKIADAS, *individually and on behalf of all others similarly situated*, Lead Plaintiff,	1:19-cv-6137-GHW
-against-	MEMORANDUM OPINION AND ORDER
ACER THERAPEUTICS INC., CHRIS SCHELLING, and HARRY PALMIN, Defendants.	

GREGORY H. WOODS, United States District Judge:

Defendant Acer Therapeutics Inc. ("Acer") is a small biotechnology company. It sought Food and Drug Administration ("FDA") approval for a drug called celiprolol, or EDSIVO, to treat Vascular Ehlers-Danlos Syndrome ("vEDS"), a rare genetic connective tissue disorder. The FDA has approved no drugs to treat vEDS. So if the FDA approved EDSIVO, Acer, and its corporate officers—including Defendant Chris Schelling, Acer's CEO, and Defendant Harry Palmin, Acer's CFO—stood to generate massive profits.

But Acer needed financing before it was ready to submit EDSIVO for FDA approval, so it turned to the capital markets. Before Acer solicited investment, it filed disclosure documents with the Securities and Exchange Commission (the "SEC"). One set of those documents represented that "[i]n September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. At that meeting, the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) [New Drug Application ("NDA")] for EDSIVO™ for the treatment of vEDS." Later, Acer filed another set of documents with a similar, though different, disclosure about what the FDA "agreed to" at its September 2015 meeting. After Acer raised money from investors, it submitted its NDA to the FDA.

The FDA rejected Acer's NDA for EDSIVO. An Acer press release conceded that the FDA's rejection letter stated that "that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS." Nicholas Skiadas sued, and the Court appointed him as Lead Plaintiff. He argues that Defendants misled investors about what the FDA "agreed to" at the September 2015 meeting. Skiadas has plausibly alleged that Defendants' statements about the FDA's agreement were false or misleading and that Defendants deliberately or recklessly misled investors, so Defendants motion to dismiss is mostly DENIED. But Skiadas has failed to allege that some of the statements that he challenges here were false or misleading, so the motion is GRANTED as to those statements.

I. BACKGROUND

A. Facts[1]

1. Statutory and Regulatory Background

Every drug sold in the United States since 1938 has been the subject of a New Drug Application ("NDA"). SAC ¶ 72. An NDA proposes that the FDA approve a new drug for sale and marketing in the United States. *Id.* According to the FDA, "the goals of the NDA are to provide enough information to permit [the] FDA reviewer to reach the following key decisions:

- whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks;
- whether the drug's proposed labeling (package insert) is appropriate, and what it should contain; and

[1] The facts are drawn from the second amended complaint ("SAC"), Dkt No. 43, and are assumed true for this motion to dismiss. *See, e.g.*, *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002). But "[t]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

- whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity."

Id. (quoting New Drug Application, FDA, https://www.fda.gov/drugs/types-applications/new-drug-application-nda).

An NDA "is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged." *Id.* ¶ 73 (quoting New Drug Application, FDA, https://www.fda.gov/drugs/types-applications/new-drug-application-nda). Skiadas alleges that the FDA does not review an NDA substantively until a sponsor submits it. *Id.* ¶ 74-75.

The Prescription Drug User Fee Act provides for a "priority review" designation. *Id.* ¶ 77. The priority review designation enables applicants submitting NDAs meeting certain criteria to receive a decision within six months, instead of the standard ten months. *Id.* According to the FDA, "[a] Priority Review designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications." *Id.* (quoting Priority Review, FDA, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approvalpriority-review/priority-review).

After the FDA completes its review of an NDA, it issues a decision by letter. If the FDA rejects or denies the NDA, it issues a CRL. The CRL must contain "all of the specific deficiencies that the agency has identified." 21 C.F.R. § 314.110(a)(1). But "[i]f FDA determines, after an application is filed or an abbreviated application is received, that the data submitted are inadequate

to support approval, the agency might issue a complete response letter without first conducting required inspections and/or reviewing proposed product labeling." *Id.* § 314.110(a)(3).

2. Acer and vEDS

Acer is a "development-stage pharmaceutical company focused on the acquisition, development, and commercialization of therapies for serious, rare and life-threatening diseases with significant unmet medical needs." SAC ¶ 32. Schelling is the founder of Acer and served as its President and CEO. *Id.* ¶ 19. Palmin was Acer's CFO. *Id.* ¶ 20.

Acer was founded in 2013. *Id.* ¶ 32. It was a private company until September 2017, when Acer completed a reverse merger with a publicly traded corporation called Opexa Therapeutics, Inc. *Id.* ¶ 33. Reverse mergers allow companies to access private capital without undergoing a traditional Initial Public Offering. *Id.* Three months after the reverse merger deal closed, Acer raised $12.56 million in a secondary stock offering. *Id.* ¶ 127. Acer raised another $46 million from investors in another stock offering in August 2018. *Id.* ¶ 134.

vEDS is a rare and severe inherited connective tissue disorder that affects about 2,000 to 5,000 people in the United States. *Id.* ¶ 39. It causes abnormal fragility in blood vessels, which can have life-threatening consequences. *Id.* There are no drugs approved to treat vEDS, either in the United States or internationally. *Id.* ¶ 40. But some drugs called "beta-blockers" are prescribed to manage vEDS "off-label."[2] *Id.* One such beta-blocker is celiprolol. *Id.* Celiprolol was approved by the European Union ("EU") to treat hypertension in 1984. *Id.* The FDA has not approved celiprolol for any purpose. *Id.* But patients can import it for personal use through online pharmacies. *Id.* Acer hoped to get FDA approval for celiprolol and market it under the name EDSIVO. *Id.* ¶ 43.

[2] A drug is prescribed "off-label" when a doctor prescribes it for a condition for which it was not approved by a regulatory agency. *Id.* ¶ 4 n.2. A drug's manufacturer cannot market a drug for off-label use, but doctors can prescribe it for an unapproved use. *Id.*

Skiadas alleges that doctors in the United States often prescribe beta-blockers like celiprolol off-label to treat patients with vEDS in the United States. *Id.* ¶ 41. There are at least two such generic (and so low-cost) drugs available in the United States. *Id.* There is no evidence that celiprolol generates better outcomes for patients than these other generic beta-blockers. *Id.* ¶¶ 41-42.

But because the FDA has never formally approved any drugs to treat vEDS, Acer saw an opportunity. *Id.* ¶ 43. If Acer could obtain FDA approval for EDSIVO to treat vEDS, it would quality for Orphan Drug Exclusivity. *Id.* Orphan Drug Exclusivity is an FDA designation designed to promote investment into the research and development of new drugs to treat rare diseases. *Id.* ¶ 44. If the FDA approved EDSIVO for treatment of vEDS and Orphan Drug Exclusivity, Skiadas alleges that Acer could charge each patient more than $100,000 per year for the drug. *Id.* ¶ 47. The FDA approved Orphan Drug Exclusivity for EDSIVO in January 2015. *Id.* ¶ 43. So if Acer could show that EDSIVO treated vEDS, it stood to profit handsomely.

3. The Ong Trial

Rather than conduct its own clinical trial into the effectiveness of EDSIVO as treatment for vEDS, Acer licensed data from a study completed in 2004 called the "Ong Trial." *Id.* ¶ 44. The Ong Trial was a years-long randomized controlled trial to assess the effect of celiprolol on patients with vEDS that began in 2004. *Id.* ¶ 45.

The Ong Trial showed positive results for EDSIVO. The second amended complaint alleges that "[a]ccording to Acer's filings with the SEC," the treatment group's risk of an "arterial event" fell 64 percent on celiprolol as compared to the control group. *Id.* ¶ 54. "[B]ecause significant differences were recorded between the treatment group and the control group after 64 months," the relevant stakeholders ended the study early. *Id.* Results from the Ong Trial were published in The Lancet, a peer-revised medical journal, in October 2010. *Id.* ¶ 45.

In a December 2016 press release, Acer announced that it signed an agreement with Assistance Publique—Hôpitaux de Paris, Hôpital Européen Georges Pompidou ("AP-HP"), a hospital in France. The agreement granted Acer exclusive rights to access and use data from the Ong Trial. *Id.* ¶ 44. In a September 2017 press release, Acer explained that it had conducted a "retrospective source verified analysis" of the data from the Ong Trial. *Id.* ¶ 46. And in the same press release, Acer trumpeted the Ong Trial as a "robust clinical study" that had "achieved statistical significance." *Id.* ¶ 54.

But Skiadas alleges that the Ong Trial suffered from several "obvious" methodological flaws. *Id.* ¶ 55. For one, the Ong Trial enrolled only 53 participants. *Id.* ¶ 54. Skiadas also alleges that more than one-third of the Ong Trial's participants did not have the genetic mutation that causes vEDS. *Id.* ¶ 55. And the treatment and control groups were unbalanced: 12 of the 25 (almost half) of the patients in the treatment group did not have the mutation, while 8 out of 28 patients in the control group did not have that genetic mutation. *Id.*

Skiadas alleges the Ong Trial's results were unreliable because of these flaws. The imbalance of participants with generic mutations between the treatment and the control group allegedly created a bias for celiprolol. *Id.* ¶ 56. If a higher percentage of the treatment group than the control group never had vEDS, it isn't hard to understand why the Ong Trial was more likely overstate the effectiveness of celiprolol. And Skiadas alleges that a trial with 53 participants—even if all the participants had the genetic mutation that caused vEDS—was not large enough to show differences between the treatment and control groups. *Id.* ¶ 60. Skiadas also alleges that in early 2019, a journal called Pharmaceutical Technology published an article on its website entitled "[w]hy experts say Acer is unlikely to get FDA nod for vEDS drug." *Id.* ¶ 64. That article quoted medical experts who contended that the FDA would not approve EDSIVO because the Ong Trial was too small and otherwise inadequate. *Id.* The authors of this article allegedly contacted senior management at Acer. *Id.*

Skiadas also alleges that the FDA would have identified other "red flags" in the Ong Trial. *Id.* ¶ 56. He alleges that the FDA expects its researchers to conduct trials under 21 C.F.R. § 312 and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Standards. *Id.* ¶ 61. But because a high percentage of study subjects did not have the genetic mutation that causes vEDS, Skiadas alleges that the Ong Trial did not comply with those standards. *Id.* And the FDA allegedly would have considered the Ong Trial to be a retrospective study because Acer knew the results of the study before filing with the FDA. *Id.* ¶ 62. Skiadas alleges that the FDA frowns on that practice because a drug's sponsor can shop around for a study with a positive result. *Id.*

4. Acer's Offering Documents

After the reverse merger with Opexa, Acer sought to access financing from public capital markets. To that end, Acer filed a Form 10-Q for the third quarter of fiscal year 2017 (the "2017 Q3 Form 10-Q"). *Id.* ¶ 119. In that filing, Acer acknowledged that "[t]here is substantial doubt about the Company's ability to continue as a going concern within one year." *Id.* Acer also filed a Preliminary Prospectus Supplement and Prospectus Supplement with the SEC in December 2017 (the "2017 Offering Documents"). In the 2017 Offering Documents, Skiadas alleges that Defendants represented that Acer "met with the FDA to discuss the existing clinical data for EDSIVO." *Id.* ¶ 50. At that meeting, "the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS." *Id.* In its Form 10-K for the fiscal year 2017 (the "2017 Form 10-K"), Acer wrote that "[i]n September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. At that meeting, the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS." *Id.*

Note that these descriptions are subtly different. The 2017 Offering Documents stated that the FDA agreed that "additional clinical *development*" was unnecessary. But the 2017 Form 10-K

stated that the FDA agreed that "an additional clinical *trial*" was unnecessary. Acer also slipped in a qualifier: Rather than representing that additional development was unnecessary, full stop, the 2017 Form 10-K stated that the FDA told it that additional development was "not *likely* needed."

In its Form 10-Q for the first quarter of 2018 (the "2018 Q1 Form 10-Q"), Acer reiterated that there was substantial doubt about its ability to continue as a going concern. *Id.* ¶ 130. So in late July and early August 2018, Acer filed a Preliminary Prospectus Supplement and Prospectus Supplement (the "2018 Offering Documents" and together with the 2017 Offering Documents, the "Offering Documents") for another secondary offering. *Id.* ¶ 52. That document repeated the revised description of Acer's September 2015 meeting with the FDA. *Id.* That is, Acer represented that the FDA told them that an "additional clinical trial" was "not likely needed." *Id.*

5. Acer's Meetings with the FDA

Skiadas alleges that it is standard practice for drug sponsors like Acer to meet with the FDA several times before filing an NDA. *Id.* ¶ 80. The sponsor's senior management team usually represents it at these meetings. *Id.* ¶ 81. The FDA allegedly prepares minutes of the meeting and sends them to the sponsor to ensure that the Sponsor does not misunderstand the FDA's decision. *Id.* ¶ 82.

Skiadas alleges that Acer's SEC filings reflect this standard practice. Acer met with the FDA three times in September 2015, May 2017, and June 2018 to discuss data about EDSIVO. *Id.* ¶¶ 84-87. In Acer's 2017 Form 10-K, Defendants disclosed that "[i]n September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO." *Id.* ¶ 84. In the same document, Defendants reported that Acer management met with the FDA "to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting." *Id.* ¶ 85. At that meeting, the FDA advised Acer "on the expected presentation of the existing clinical data for EDSIVO to support the NDA filing." *Id.* And Defendants noted that they "plan[ned] to have a pre-NDA meeting" with the FDA. *Id.* After

the pre-NDA meeting, Defendants expected to submit an NDA for EDSIVO to treat vEDS by mid-2018. *Id.* In preparation, Defendants announced that Acer hired additional employees to continue "build[ing] out the commercial team and add other core personnel." *Id.* ¶ 96. In a March 2018 press release, Defendants informed investors that they planned to discuss the "positive results" from Acer's "retrospective source-verified analysis" of the Ong Trial "during a pre-NDA meeting with the FDA in the second quarter of 2018." *Id.* ¶ 86.

Skiadas alleges that "it is near certain" that FDA officials discussed the concerns with the Ong Trial data discussed above. *Id.* Because the problems with the Ong Trial were allegedly obvious, Skiadas alleges that the FDA did not agree that EDSIVO did not need additional clinical development. *Id.* ¶ 89. Skiadas also alleges that the FDA gives feedback about the clinical trials and data supporting a sponsor's submission before the sponsor submits an NDA. *Id.* ¶ 90. It is allegedly the FDA's "general practice" to state concerns before a Sponsor submits an NDA. *Id.* So Skiadas alleges that the FDA's statements before a sponsor submits an NDA focus on whether the FDA is likely to approve the NDA, not on whether the sponsor can submit an NDA. *Id.*

6. Acer's NDA for EDSIVO

Acer submitted its NDA for EDSIVO in October 2018. *Id.* ¶ 99. In the press release announcing its submission, Acer noted that it had "requested Priority Review, which if granted, could result in a six-month review period[.]" *Id.* In a December 2018 press release, Defendants announced that the FDA had accepted Acer's NDA for EDSIVO. *Id.* ¶ 100. The press release also announced that the FDA granted priority review of the NDA and set a target action date for June 25, 2019. *Id.*

In an April 2019 press release, Defendants announced that a long-term observational study of vEDS patients had been published. *Id.* ¶ 101. The April 2019 press release described the long-term observational study as publishing medical outcomes for 144 vEDS patients between the years 2000 and 2017. *Id.* According to the press release, one of the study's clinical investigators stated

that there was a "higher overall survival in patients treated with celiprolol in this long-term study" of vEDS patients. *Id.* That higher survival rate, the researcher noted, "appears to correlate with the significant event-free survival advantage that was reported in the [Ong Trial] of celiprolol treatment in vEDS patients." *Id.*

As its name suggests, the long-term observational study was not a randomized controlled trial. The researchers of the long-term observational study noted that "[i]t is difficult to formally assess this beneficial effect (the benefit of celiprolol on survival) in the absence of a placebo-controlled prospective trial, because other confounders might have influenced this observation." *Id.* ¶ 103. In other words, the long-term observational study found a correlation between celiprolol and positive health outcomes. But that correlation does not necessarily mean that celiprolol caused the positive outcomes. To make causal claims, researchers needed to conduct a randomized controlled trial. Two vEDS researchers not affiliated with the long-term observational study made this point in an April 2019 article. *Id.*

In June 2019, Defendants disclosed that the FDA had issued a CRL rejecting its NDA for EDSIVO. *Id.* ¶ 104. The press release noted that "[t]he CRL states that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS." *Id.* ¶ 116. On the day of the press release, the per-share price of Acer common stock fell 79 percent. *Id.* ¶ 117. And Defendants announced in a press release shortly thereafter that Acer had fired more than half of its employees. *Id.* ¶ 105.

B. Procedural History

This case began in July 2019. Dkt No. 1. The Court appointed Nicholas Skiadas as Lead Plaintiff. Dkt No. 24. Skiadas amended the complaint twice. Dkt Nos. 28, 43. The second amended complaint alleges two claims for relief. First, Skiadas alleges violations of section 10(b) of the Exchange Act and rule 10b-5. SAC ¶¶ 151-59. Second, Skiadas alleges a claim for control person liability in violation of section 20(a) of the Exchange Act. *Id.* ¶¶ 160-65.

Defendants moved to dismiss the second amended complaint. Dkt No. 49-51. Skiadas opposed the motion, Dkt No. 52, and Defendants replied, Dkt No. 53. Defendants also submitted a declaration supporting their motion to dismiss. Declaration of Jamie A. Levitt in Support of Defendants Motion to Dismiss, Dkt No. 51. On a motion to dismiss, a court may ordinarily "consider only the complaint, any written instrument attached to the complaint as an exhibit, any statements or documents incorporated in it by reference, and any document upon which the complaint heavily relies." *In re Thelen LLP*, 736 F.3d 213, 219 (2d Cir. 2013). But the Court may take judicial notice of under Federal Rule of Evidence 201, and thus consider, documents filed with the SEC. *See Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991). Exhibits A, B, C, and E to that declaration attach portions of Acer's SEC filings, so the Court has considered those documents.

Exhibit D to the Levitt Declaration purports to be FDA draft guidance from December 2017. The Court has not considered that document. Defendants argue that the Court may take judicial notice of this draft guidance. The Court is unpersuaded. There is, at least, a question of fact about whether that guidance applied during the events alleged in the second amended complaint. Indeed, the very fact that the document is labeled as "draft" guidance strongly suggests that the document had no legal effect. So the Court has declined to consider it.

II. LEGAL STANDARD

A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). If a complaint fails to meet this pleading standard, a defendant may move to dismiss it for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at

556). It is not enough for a plaintiff to allege facts consistent with liability; the complaint must "nudge[]" claims "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. "To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.'" *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Twombly*, 550 U.S. at 555).

Determining whether a complaint states a plausible claim is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679 (citation omitted). The court must accept all facts alleged in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *Burch v. Pioneer Credit Recovery, Inc.*, 551 F.3d 122, 124 (2d Cir. 2008) (per curiam). But

> "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." A complaint must therefore contain more than "naked assertions devoid of further factual enhancement." Pleadings that contain "no more than conclusions . . . are not entitled to the assumption of truth" otherwise applicable to complaints in the context of motions to dismiss.

DeJesus v. HF Mgmt. Servs., LLC, 726 F.3d 85, 87-88 (2d Cir. 2013) (brackets omitted) (quoting *Iqbal*, 556 U.S. at 678-79). So a complaint that offers "labels and conclusions" or "naked assertions" without "further factual enhancement" will not survive a motion to dismiss. *Iqbal*, 556 U.S. at 678 (brackets omitted) (citing *Twombly*, 550 U.S. at 555, 557).

Securities fraud claims are also subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). Rule 9(b) requires that "in alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To satisfy this requirement, the complaint 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 (citation omitted). "Allegations that are conclusory or unsupported by factual assertions are insufficient." *Id.* (citation omitted). Under the PSLRA,

plaintiffs must also 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, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). A plaintiff must therefore "do more than say that the statements . . . were false and misleading; [she] must demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004).

III. DISCUSSION

Skiadas has plausibly alleged that Defendants' statements violated federal securities laws. Under Section 10(b) and Rule 10b-5, it is unlawful to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading[.]" 17 C.F.R. § 240.10b-5(b); *see also* 15 U.S.C. § 78j(b). To survive a defendant's motion to dismiss a Section 10(b) claim, a plaintiff must plausibly 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) (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)) (alterations omitted). Defendants challenge the first and second elements.

A. False or Misleading Statements

1. Legal Standard

Both affirmative misrepresentations and omissions can be actionable under section 10(b). "A statement is misleading if a reasonable investor would have received a false impression from the statement." *Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 180 (S.D.N.Y. 2010) (citation omitted). In other words, the subjective intent of the person or entity making the statement is irrelevant; what matters is how a reasonable investor would have interpreted the statement. When a company does not have an obligation to speak but does so anyway, it assumes "a duty to be both

accurate and complete." *Caiola v. Citibank, N.A., N.Y.*, 295 F.3d 312, 331 (2d Cir. 2002); *see also In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 366 (2d Cir. 2010) (explaining that once a corporation makes "a disclosure about a particular topic, whether voluntary or required, the representation must be complete and accurate" (quotation omitted)). And "literally true statements" are actionable if they "create a materially misleading impression." *SEC v. Gabelli*, 653 F.3d 49, 57 (2d Cir. 2011), *rev'd and remanded on other grounds*, 568 U.S. 442 (2013).

Omissions can also be actionable under section 10(b). An omission is actionable if the omitted information was subject to "an affirmative legal disclosure obligation" or the omitted information is "necessary to prevent existing disclosures from being misleading." *Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 715-16 (2d Cir. 2011). The key is the "presence of a prior statement that otherwise is or will become materially misleading" because of the omission. *DoubleLine Capital LP v. Construtora Norberto Odebrecht, S.A.*, 413 F. Supp. 3d 187, 206 (S.D.N.Y. 2019).

To incur liability, misrepresentations or omissions must also be material. "At the pleading stage, a plaintiff satisfies the materiality requirement of Rule 10b-5 by alleging a statement or omission that a reasonable investor would have considered significant in making investment decisions." *Caiola*, 295 F.3d at 329 (quotation omitted). "To be actionable, a misrepresentation must be one of existing fact, and not merely an expression of opinion, expectation, or declaration of intention." *In re Moody's Corp. Sec. Litig.*, 599 F. Supp. 2d 493, 507 (S.D.N.Y. 2009) (quotation omitted). "Statements of 'hope, opinion, or belief about the company's future performance' are not actionable." *Id.* (quoting *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d 801, 811 (2d Cir. 1996)). But optimistic statements "may be actionable upon a showing that the defendants did not genuinely or reasonably believe the positive opinions they touted . . ., or that the opinions imply certainty." *Lapin v. Goldman Sachs Grp., Inc.*, 506 F. Supp. 2d 221, 239 (S.D.N.Y. 2006) (citation omitted).

2. Application

Skiadas has plausibly alleged that Defendants' statements about what the FDA "agreed to" were false or misleading. In the 2017 Offering Documents, Defendants stated that "the FDA agreed" at a September 2015 meeting that "additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS." SAC ¶ 106. Similarly, in its 2017 Form 10-K, Defendants stated that "the FDA agreed" at the September 2015 meeting "that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS." *Id.* ¶ 108. And in the 2018 Offering Documents, Defendants repeated the statement from the 2017 Form 10-K. *Id.* ¶ 112.

The parties disagree about whether these statements were false or misleading because they disagree what these statements represent the FDA "agreed to." Skiadas argues that a reasonable investor would have understood these statements to represent that the FDA agreed that no additional clinical development was necessary for the FDA to *approve* the EDSIVO NDA. Defendants argue that a reasonable investor would have understood these statements to concern only whether Acer could *submit* the EDSIVO NDA.

The challenged statements are ambiguous. Skiadas argues that the challenged statements are unqualified. Defendants stated that the FDA agreed that "an additional clinical trial is not likely needed[,]" full stop. And while the second clause of these sentences discuss submission, the first and second clauses are joined by the word "and." That "and" does not unambiguously suggest a logical relationship between the two clauses. To see why "and" might be insufficient, imagine that allegedly false statements included a "so." Then the above statement would have read that the FDA agreed "that an additional clinical trial is not likely needed and *so* stated that we may submit a 505(b)(2) NDA for EDSIVO." That "so" would have signified that the second clause logically

related to the first. Because the FDA agreed, Acer could submit its NDA. So, Skiadas argues, that the second clause of these sentences focuses on submission is largely irrelevant.[3]

Consider another example. Imagine that a friend tells you "John has arrived, and I need to go to the grocery store." Does the fact that John has arrived tell you anything about your friend's planned food-shopping trip? And conversely, does the fact that your friend needs to go to the grocery store tell you anything about John's arrival? The answer to both questions is no. Your friend just chose to express two unrelated ideas in the same sentence. Skiadas argues that the same is true here.

Skiadas also argues that subsequent events bolster the argument that a reasonable investor would have interpreted Defendants' statements as referring to EDSIVO approval, not submission. When the FDA issued its CRL stating that a clinical trial was necessary for EDSIVO approval, Acer's stock price nosedived. *Id.* ¶ 11. Skiadas urges the Court to infer that investors expected the FDA to approve EDSIVO without another expensive clinical trial and that the Offering Documents contributed to this misimpression.

Yet Defendants argue that a reasonable investor would have understood the challenged statements as about NDA submission, not approval. Defendants lean heavily on the second half of these statements, both of which focus on submission. *See, e.g.*, *id.* ¶ 108 (alleging that the FDA told Defendants "that an additional clinical trial is not likely needed and *stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS*" (emphasis added)). As noted above, the second half of the sentence is not dispositive. But Defendants are correct that this context weighs in favor of construing the statements to be about submission, not approval.

[3] To be sure, the mere fact that a disclosure could be redrafted to be clearer does not itself render the initial statement ambiguous. Statements can almost always be redrafted to be clearer with the benefit of hindsight. The Court offers this example to illustrate that the first half of the challenged statement, as drafted, does not unambiguously refer to submission.

Because the challenged statements are ambiguous, the Court cannot dismiss Skiadas' claims based on those statements as a matter of law. At the motion to dismiss stage of a securities fraud action, "the court reads ambiguities" in challenged statements "in [the plaintiff's] favor." *Umbach v. Carrington Inv. Partners*, No. 3:08CV484 (EBB), 2009 WL 413346, at *6 (D. Conn. Feb. 18, 2009). That is simply an application of the maxim that a court must draw all reasonable inferences in the plaintiff's favor on a motion to dismiss. Defendants' statements were ambiguous, so the Court must construe them as referring to EDSIVO approval, not submission, at this stage.

Construing the challenged statements to be about EDSIVO approval—as the Court must—Skiadas has plausibly alleged that the statements were false or misleading. Skiadas alleges that the FDA did not, in fact, agree that no further clinical development was necessary before it would approve EDSIVO. And the FDA rejected Acer's NDA in a CRL and noted that Acer would need to conduct a well-designed clinical trial before it would consider approving EDSIVO. The FDA's statement in the CRL makes plausible the allegation that the FDA never agreed that no further clinical development was necessary before it would approve EDSIVO. So Skiadas has satisfied his burden to plead that Defendants' statements about what the FDA "agreed to" were false or misleading.

Skiadas also alleges that Defendants' statements in their 2017 Form 10-K and 2018 Offering Documents that the "FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing" was false or misleading. SAC ¶¶ 110, 114. Skiadas alleges that these statements were false or misleading because they "led investors to believe that the Ong Trial data were sufficient to support FDA approval." *Id.* ¶¶ 111, 115. But that is not so. No reasonable investor could interpret the statement that the FDA "provided . . . guidance on the expected presentation of existing clinical data" to mean that the FDA had indicated that the Ong Trial data were adequate to assure FDA approval of EDSIVO. And Skiadas has alleged no facts to suggest that the FDA did not provide Acer "guidance" on its

expected presentation. That the FDA ultimately rejected the Acer's NDA for EDSIVO Skiadas does not suggest that the FDA did not provide Acer with guidance about how to present existing data. Skiadas has thus failed to allege that the statements were false or misleading.

B. Scienter

1. Legal Standard

A plaintiff alleging securities fraud must allege "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). The Supreme Court has explained that the "PSLRA requires plaintiffs to state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, i.e., the defendant's intention to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) (quotation omitted). The question "is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* at 322-23. "In addition to intent, recklessness is a sufficiently culpable mental state for securities fraud in this circuit." *ECA Local 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009) (citation omitted).

In the Second Circuit, a plaintiff may plead scienter either "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Kalnit v. Eichler*, 264 F.3d 131, 138 (2d Cir. 2001) (quotation omitted). A plaintiff need not rely exclusively on one of these theories. Indeed, *Kalnit* held that absent allegations of motive, "the strength of the circumstantial [evidence] must be correspondingly greater." *Id.* at 142 (quotation omitted). That accords with the Supreme Court's admonition to consider "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter." *Tellabs*, 551 U.S. at 323.

Reckless conduct is "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the

defendant or so obvious that the defendant must have been aware of it." *In Re Carter-Wallace Sec. Litig.*, 220 F.3d 36, 39 (2d Cir. 2000) (quotation omitted). But a plaintiff alleging recklessness must allege "conscious recklessness—*i.e.*, a state of mind approximating actual intent, and not merely a heightened form of negligence." *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 106 (2d Cir. 2015) (quotation omitted). "Securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements." *Kalnit*, 264 F.3d at 142 (quotation omitted). "Under such circumstances, defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." *Id.* (quotation omitted).

An "inference of scienter 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. If an inference of fraudulent intent is not "at least as compelling" as a contrary inference, it is inadequate, even in a "close case." *Slayton v. American Exp. Co.*, 604 F.3d 758, 777 (2d Cir. 2010). An inference of scienter need not be "irrefutable, i.e., of the 'smoking-gun' genre, or even the most plausible of competing inferences." *Tellabs*, 551 U.S. at 324 (quotation omitted); *see also City of Pontiac Gen. Emps.' Ret. Sys. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 372 (S.D.N.Y. 2012) ("[A]t the motion to dismiss stage, a tie on scienter goes to the plaintiff."). In sum, "[t]he inquiry on a motion to dismiss is as follows: 'When the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?'" *In re Scottish Re Grp. Sec. Litig.*, 524 F. Supp. 2d 370, 383 (S.D.N.Y. 2007) (quoting *Tellabs*, 551 U.S. at 326).

2. Application

Skiadas has plausibly alleged that Defendants acted with scienter. As noted above, although Defendants' statements about what the FDA "agreed to" are ambiguous, the Court must assume that they concerned EDSIVO approval, not submission, at this stage. And "case law addressing

misstatements relating to FDA approval lends support to Plaintiffs' use of these statements to demonstrate scienter." *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 811 (C.D. Cal. 2011). As in *Mannkind*, "Defendants' statements concerning 'approval' . . . by the FDA 'necessarily implied that there would be no serious impediments to timely FDA approval.'" *Id.* (quoting *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1130 (C.D. Cal. 2005)). "The natural effect of these statements would be to create the impression for investors that . . . 'it was in the bag' [that is,]—that there was a minimal chance of failure because the . . . studies had been specifically approved or agreed to by the very agency that would be reviewing them." *Id.* at 811-12. Because "FDA approval was the *sin[e] qua non*" for Acer's "success," statements "pertaining to the chances of such approval and the speed with which it would be secured were absolutely essential to the company's prospects." *Id.* at 812. So "Defendants' statements concerning 'approval' by or an 'agreement'" themselves are probative evidence of "a strong inference of scienter." *Id.*

Skiadas has also alleged other indicia of scienter. Skiadas has alleged that Defendants revised their representation of what the FDA "agreed to." Recall that in the 2017 Offering Documents, Skiadas alleges that Defendants wrote that "the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS." SAC ¶ 49. Later, Defendants allegedly wrote that "the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS." *Id.* ¶ 50. Defendants are wrong that the two statements are "substantively identical." Mem. at 23. The first is unqualified; the second is hedged. Any competent speaker of the English language could tell you that a statement that something is "not needed" is different from a statement that it is "not *likely* needed." Defendants' decision to alter the wording of their public statements suggests that the first statement was inaccurate. The altered wording thus supports an inference that in the 2017 Offering Documents, Defendants misstated, either consciously or recklessly, what the FDA "agreed to" in its September 2015 meeting with Defendants.

The inference of scienter is also bolstered by the fact that Defendants admitted in their SEC filings that they needed to raise funds for Acer to remain viable. In its 2017 Q3 Form 10-Q, Acer acknowledged that "[t]here is substantial doubt about the Company's ability to continue as a going concern within one year." SAC ¶ 119. Acer reiterated that sentiment in its 2018 Q1 Form 10-Q. *Id.* ¶ 130. That concern meant that Defendants had an incentive to gamble that the FDA would approve EDSIVO by misrepresenting what the FDA "agreed to." If Acer did not raise funding, its SEC filings represented that it would run out of money and Defendants would have had no chance to bring EDSIVO to market. Better to say what was necessary to raise the money and hope that the FDA would eventually approve EDSIVO.

Granted, as a general matter, "[t]he absence of stock sales by insiders, or any other evidence of pecuniary gain by company insiders at shareholders' expense, is inconsistent with an intent to defraud shareholders." *In re N. Telecom Ltd. Secs. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000). That is because allegations that defendants had "[m]otives that are generally possessed by most corporate directors and officers do not suffice" to support a strong inference of scienter. *Kalnit*, 264 F.3d at 139. But courts have found allegations of motive adequate where the company's needed to fundraise to survive. *See, e.g.*, *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 350 (E.D. Pa. 2014) (holding that a plaintiff adequately alleged scienter when the plaintiff alleged that a defendant was "sufficiently short on cash at the time of the alleged misrepresentations that it could not afford to finance an additional clinical trial as the FDA had recommended, heightening its need for a lucrative stock sale"). That makes sense: An executive at a company that will go belly up if it fails to fundraise has different incentives from a generic corporate insider. One salient difference is that the former executive has a stronger incentive to bet the farm in a reckless gamble because the alternative is certain failure. And Skiadas has alleged that Defendants had that incentive in this case. That allegation supports Skiadas' theory of scienter.

One of Defendants' central arguments against the conclusion that Skiadas has plausibly alleged scienter is that its statements about what the FDA "agreed to" were about EDSIVO submission, not approval. *See* Mem. at 23 (arguing that Skiadas' allegations of conscious misbehavior or recklessness "fail[] for the same reason that Plaintiff's falsity allegations fail"). But as noted above, those statements are ambiguous and the Court construes them as referring to EDSIVO approval, at least at this stage. Indeed, it is another point in favor of Skiadas that he has alleged that Defendants had access to information that contradicted the challenged statements. *See Kalnit*, 264 F.3d at 142 ("Securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements." (quotation omitted)).

Defendants also argue that Skiadas' allegations are fundamentally illogical. Defendants argue that it does not make sense that they would lie about whether the FDA had approved EDSIVO because, eventually, they would have to submit EDSIVO to the FDA for approval. If the FDA did not approve, then investors would uncover the scheme when the FDA ultimately rejected Acer's NDA for EDSIVO. That is precisely what happened.

This argument has some bite, but it is ultimately unpersuasive. True, "[c]ourts often refuse to infer scienter, even on a recklessness theory, when confronted with illogical allegations." *In re GeoPharma, Inc.*, 411 F. Supp. 2d 434, 446 n.83 (S.D.N.Y. 2006) (collecting cases). But Skiadas' allegations are not wholly illogical. Skiadas' allegations support the inference that Defendants rationally (though recklessly) gambled that the FDA would ultimately approve EDSIVO, even though the FDA had never "agreed" that it would approve EDSIVO without additional clinical development. As Judge Posner explained,

> [t]he fact that a gamble—concealing bad news in the hope that it will be overtaken by good news—fails is not inconsistent with its having been a considered, though because of the risk a reckless, gamble. It is like embezzling in the hope that winning at the track will enable the embezzled funds to be replaced before they are discovered to be missing.

Makor Issues & Rights, Ltd. v. Tellabs Inc., 513 F.3d 702, 710 (7th Cir. 2008). Skiadas has plausibly alleged that Defendants deliberately or recklessly misrepresented that the FDA agreed that it would approve EDSIVO to keep the company afloat. Viewing the totality of Skiadas' allegations, the inference that Defendants had an intent to defraud is at least as compelling as any alternative inference.[4]

IV. CONCLUSION

Skiadas has plausibly alleged a claim for securities fraud based on Defendants' statements about what the FDA "agreed to," so Defendants motion to dismiss is DENIED in part. But because Skiadas has not plausibly alleged that any other of Defendants' statements were false or misleading, so the motion is GRANTED in part.

The Clerk of Court is directed to terminate the motion pending at Dkt No. 49.

SO ORDERED.

Dated: June 16, 2020

GREGORY H. WOODS
United States District Judge

[4] Defendants challenged Skiadas claim for control person liability only on the grounds that he had not adequately alleged a section 10(b) or rule 10b-5 claim. *See Wilson v. Merrill Lynch & Co.*, 671 F.3d 120, 139 (2d Cir. 2011) (affirming the dismissal of a section 20(a) claim because the plaintiff "failed to state a claim for any primary violation of the securities laws"). Because Skiadas has plausibly alleged a primary violation, his section 20(a) claim also survives.