UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EVY GRU, Individually and on Behalf of All Others Similarly Situated, Plaintiff,	:	22 Civ. 3925 (LGS)
-against-	:	**OPINION AND ORDER**
AXSOME THERAPEUTICS, INC., HERRIOT TABUTEAU, NICK PIZZIE, MARK JACOBSON, CEDRIC O'GORMAN, and KEVIN LALIBERTE, Defendants.	:	

LORNA G. SCHOFIELD, District Judge:

Lead Plaintiff Evy Gru, individually and on behalf of all other persons similarly situated, bring this putative class action against Defendants Axsome Therapeutics, Inc. ("Axsome" or the "Company"), Herriot Tabuteau, Nick Pizzie, Mark Jacobson, Cedric O'Gorman and Kevin Laliberte. Plaintiff alleges securities fraud in violation of § 10(b) and § 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5 ("Rule 10b-5"). Defendants move to dismiss the Amended Complaint (the "Complaint") pursuant to Federal Rule of Civil Procedure 12(b)(6). For the following reasons, the motion is granted.

I. BACKGROUND

The following facts are taken from the Complaint, documents referenced in the Complaint or are matters of which judicial notice may be taken, including public filings. *See Dixon v. von Blanckensee*, 994 F.3d 95, 101-02 (2d Cir. 2021); *United States v. Am. Soc'y of Composers, Authors & Publishers*, 627 F.3d 64, 69 n.2 (2d Cir. 2010) (public filings).

A. The Parties

Defendant Axsome is a New York City-based biopharmaceutical company that is publicly traded on the NASDAQ and develops therapies for central nervous system ("CNS") disorders.

Plaintiff periodically purchased Axsome securities between January 3, 2020, and July 14, 2021. He sold all of those shares on August 16 and 17, 2021. The Complaint proposes a class period beginning December 30, 2019, and ending April 22, 2022 (the "Class Period"). Another Plaintiff purchased and sold Axsome securities from June 11, 2020, through April 13, 2022, but withdrew from the case for personal reasons.

Defendants Herriot Tabuteau, Nick Pizzie, Mark Jacobson, Cedric O'Gorman and Kevin Laliberte were officers of the Company in executive positions during part or all of the Class Period. Defendant Tabuteau has served as Axsome's Chief Executive Officer ("CEO") and Chairman of the Board of Directors since founding the Company in 2012. Defendant Jacobson has been employed at Axsome since April 2014 and has served as Axsome's Senior Vice President of Operations since September 2017 and Chief Operating Officer ("COO") since March 2020.

B. The Alleged Fraud and Ultimate Disclosure

This case concerns alleged securities fraud during Axsome's development of AXS-07, a drug designed for the acute treatment of migraines. AXS-07 is one of Axsome's core products from its CNS portfolio. The Complaint alleges material omissions and misstatements made during the Class Period in Axsome's: (1) Forms 10-Q and 10-K, (2) Forms 8-K and (3) conference calls with investors and analysts. The Complaint's allegations of material omissions and misstatements all center around Defendants' failure to disclose that Axsome

encountered manufacturing issues in the development of AXS-07. The Complaint alleges that as a result of this omission, statements discussing the timeline and prospect of FDA approval were false or misleading.

The Complaint alleges that Defendants made false and misleading statements beginning on December 30, 2019, the first day of the Class Period. That day, Axsome issued a press release announcing positive results from an AXS-07 efficacy trial called MOMENTUM and stating the Company's plans to file a new drug application ("NDA") with the U.S. Food and Drug Administration (the "FDA") "in the second half of 2020" based on these results. The press release also states that "[b]ased on FDA feedback, Axsome believes that MOMENTUM will be the only efficacy trial required to support an NDA filing for AXS-07 for the acute treatment of migraine." For the next ten months, Axsome continued to state its intentions to file an NDA in 2020 and the positive prospect of FDA approval through press releases, investor conference calls and forms filed with the U.S. Securities and Exchange Commission (the "SEC").

For example, on May 8, 2020, the Company publicly filed its 2020 first quarter results and issued a press release that states, "As we move towards the submission of two NDAs in the fourth quarter . . . one for AXS-07 in migraine, our commercial team is focused on launch-readiness activities to ensure successful commercial execution." During a conference call with investors and analysts that day, in response to a question about Axsome's chemistry, manufacturing and controls ("CMC") activities, Defendant Tabuteau stated:

> With regards to CMC activities, there are registration batches which are being manufactured now. A good thing for us is that we have been manufacturing our clinical trial supply at commercial scale and also at the same CMO that we're using for commercial production. So, there's no scale up that needs to be done. Now, with regards to manufacturing and any kind of science to it, there's always tweaks and experimentation, but I would say that there is no rate-limiting step and there is no extensive experimentation. This is simply manufacturing our registration batches for regulatory purposes.

On November 5, 2020, Axsome announced that it would delay the submission of its AXS-07 NDA to the FDA. Axsome's press release states, "Axsome now plans to submit the [AXS-07] NDA to the FDA in the first quarter of 2021, versus previous guidance of the fourth quarter of 2020, to allow for inclusion of supplemental manufacturing information to ensure a robust submission package." In response, Axsome's stock price fell about 7% on that day.

On Axsome's earnings call that day, in response to an analyst's request for Defendants to "provide more specifics on what manufacturing data . . . will be added for AXS-07," Defendant Tabuteau stated:

> Great. So with regards to the additional manufacturing information, this is a standard information when you manufacture additional batches. So we continue to manufacture additional batches of drugs. And while we already have very long-term stability data on other batches, we think that because of the unique nature of the delivery technology, this can only help to make the submission robust and assure that there are no hiccups during review.

In response to a similar question from another analyst, Defendant Jacobson stated, "So just want to be clear, this is not the result of the manufacturing or stability issue or anything like that." Axsome ultimately submitted its NDA for AXS-07 to the FDA in June 2021.

Some of the Complaint's allegations are based on information from a confidential witness ("CW 1"), a former Axsome employee who was a Senior Clinical Trial Manager from July 2019 to February 2022. In early 2021, Axsome tasked CW 1 with starting to manage a new study, slated to begin at the end of April 2021, to provide additional data for AXS-07 to support the drug's marketing. Axsome delayed this study until August 2021, and then delayed it again to November 2021 and then early 2022 because Axsome did not have a sufficient supply of the drug to conduct the study. AXS-07 has two main active ingredients that contribute to the drug's claimed effect, meloxicam and rizatriptan. According to CW 1, Axsome used one vendor to

supply meloxicam, a second vendor to supply rizatriptan and a third vendor to combine the two products to make AXS-07. Around August 2021, CW 1 was told that Axsome's third vendor was unable to manufacture the drug because of issues with the equipment used to combine the two ingredients. In early 2022, CW 1 was told that the manufacturer was still having equipment problems. Based on CW 1's information, the manufacturing problems persisted from at least April 2021 through February 2022 and had not been resolved when CW 1 left the Company.

Axsome publicly disclosed AXS-07's manufacturing problems on Monday, April 25, 2022 -- shortly after Friday, April 22, 2022, the last day of the Class Period. Axsome announced that the FDA had informed the Company that CMC issues were unresolved, and that the Company expected to receive the FDA's complete response letter on or around April 30, 2022. CMC requirements ensure that the manufacturing process produces a safe and effective drug even when the production is scaled up for commercial sale following FDA approval. In response to this news, Axsome's stock price dropped approximately 22% that day. On May 2, 2022, Axsome announced that that it had received the FDA response, which identified the need for additional CMC data pertaining to AXS-07 and the manufacturing process.

C. Procedural History

Plaintiff Evy Gru commenced this putative class action on May 13, 2022, as the sole named plaintiff. By stipulation, a second Plaintiff, Santoshanad Thakkar, was added, and both Gru and Thakkar were appointed co-lead Plaintiffs. The Complaint naming both Plaintiffs was filed October 7, 2022.

On January 11, 2023, Plaintiff Thakkar moved to withdraw, and the motion was granted. The instant motion to dismiss was filed before Mr. Thakkar withdrew but had not yet been fully

briefed. Because of the withdrawal and its possible impact on the motion, Defendants were granted additional pages in their reply, and Plaintiff was granted a surreply.

II. STANDARD

To survive a motion to dismiss under Rule 12(b)(6), "a complaint 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)); *accord Kaplan v. Lebanese Canadian Bank, SAL*, 999 F.3d 842, 854 (2d Cir. 2021). It is not enough for a plaintiff to allege facts that are consistent with liability; the complaint must "nudge[]" claims "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570; *accord Bensch v. Est. of Umar*, 2 F.4th 70, 80 (2d Cir. 2021). To survive dismissal, a complaint's "factual allegations must be enough to raise a right to relief above the speculative level." *Melendez v. Sirius XM Radio, Inc.*, 50 F.4th 294, 306 (2d Cir. 2022).[1] On a Rule 12(b)(6) motion, "all factual allegations in the complaint are accepted as true and all inferences are drawn in the plaintiff's favor." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59 (2d Cir. 2016); *accord Francis v. Kings Park Manor, Inc.*, 992 F.3d 67, 72 (2d Cir. 2021). However, a court does not consider "conclusory allegations or legal conclusions couched as factual allegations." *Dixon*, 994 F.3d at 101.

"A complaint alleging securities fraud must also satisfy heightened pleading requirements set forth in Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 (PSLRA)." *Set Cap. LLC v. Credit Suisse Grp. AG*, 996 F.3d 64, 75 (2d Cir. 2021). "Rule 9(b) requires litigants to state with particularity the circumstances constituting fraud." *Id.*

[1] Unless otherwise indicated, in quoting cases, all internal quotation marks, alterations, emphases, footnotes and citations are omitted.

"To do so, a plaintiff 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." *Id.* "The PSLRA, in turn, requires a plaintiff alleging securities fraud to (1) specify each misleading statement, (2) set forth the facts on which a belief that a statement is misleading was formed, and (3) state with particularity facts giving rise to a 'strong inference' that the defendant acted with scienter -- the required state of mind." *Id.* (quoting 15 U.S.C. § 78u-4(b)(2)(A)). "A complaint may rely on information from confidential witnesses if they are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Emps.' Ret. Sys. of Gov't of the V.I. v. Blanford*, 794 F.3d 297, 305 (2d Cir. 2015).

III. DISCUSSION

Plaintiff asserts a claim of securities fraud under § 10(b) of the Exchange Act and its implementing rule, Rule 10b-5. That rule makes it unlawful "[t]o 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 the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). Plaintiff also asserts a claim of control person liability under § 20(a) of the Exchange Act. Both claims are dismissed.

A. Section 10(b) Violation

The Complaint fails to state a claim of securities fraud because it does not plead facts that, if true, would satisfy the required element of loss causation. Gru, the only remaining Plaintiff, sold all of his Axsome securities before any corrective disclosure of the alleged fraud. He therefore sold his shares at a price still inflated by the fraud and suffered no loss as a result of the fraud.

1. Pleading Requirements for a 10(b) Violation

To support a claim for securities fraud, "a plaintiff must plead: (1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance on the misrepresentation or omission, (5) economic loss, and (6) loss causation." *Noto v. 22nd Century Grp., Inc.*, 35 F.4th 95, 102 (2d Cir. 2022). "The first two elements must be pled with heightened specificity pursuant to the Private Securities Litigation Reform Act of 1995 and Federal Rule of Civil Procedure 9(b)." *Id.* at 102-03. Principally at issue on this motion is whether the Complaint sufficiently pleads three of the six elements of securities fraud -- loss causation, a material misrepresentation or omission, and scienter.

2. Loss Causation

The Complaint does not sufficiently plead loss causation. Loss causation is the "causal connection between the material misrepresentation and the loss." *Ret. Bd. of Policemen's Annuity & Benefit Fund of Chi. on behalf of Policemen's Annuity & Benefit Fund of Chi. v. FXCM Inc.*, 767 F. App'x 139, 141 (2d Cir. 2019) (summary order). The Second Circuit has not resolved which pleading standard applies to the issue of loss causation -- the heightened pleading requirements of Rule 9(b) or the "short and plain statement of the claim" standard of Rule 8(a)(2). *See Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 179 n.65 (2d Cir. 2020). In this case, the Complaint does not meet even the lower Rule 8(a)(2) standard.

To plead loss causation, a complaint must allege "that the subject of the fraudulent statement or omission was the cause of the actual loss suffered." *Abramson*, 965 F.3d at 179; *see also Lea v. TAL Educ. Grp.*, 837 F. App'x 20, 27 (2d Cir. 2020) (summary order) (holding that loss causation requires the complaint to plead "that the loss was foreseeable and caused by the

materialization of the risk concealed by the fraudulent statement"). A complaint must allege "not only the but-for causation of [one's] 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." *Abramson*, 965 F.3d at 179. "Generally, plaintiffs sufficiently plead loss causation when they allege that their share's price fell significantly after the truth became known through an express, corrective disclosure or through events constructively disclosing the fraud like the materialization of the risk concealed." *Id.*

3. The April 2022 Corrective Disclosure

Here, the Complaint does not plead facts to show that Plaintiff suffered a loss caused by the alleged fraud. The factual foundation for the fraud claim is the allegation that Axsome experienced significant problems in the manufacturing process for its new drug, AXS-07, and what these problems presaged for the timing and prospect of FDA approval. The alleged fraudulent conduct is Defendants' failure to disclose these manufacturing problems, and Defendants' resulting misleading statements about when Axsome would file an NDA and the prospect of FDA approval.

Plaintiff purchased his shares of Axsome stock between January 2020 and July 2021 -- i.e., after December 30, 2019, when Axsome allegedly began making false statements about the prospects and plans for AXS-07. He sold his shares at various times, but had completely divested his holdings by August 17, 2021, at a time when Axsome still allegedly was making false statements about its new drug. Plaintiff thus purchased and sold all of his shares at an inflated market price before the depressing effect of the bad news about the new drug's manufacturing problems.

Eight months after Plaintiff's last sale, on April 25, 2022, Axsome disclosed the manufacturing issues with the announcement that the FDA's response to the NDA was that CMC issues were unresolved. Only then did the stock price reflect public knowledge of the manufacturing issues, causing Axsome's stock price to drop approximately 22% that day. Plaintiff Gru, having long since sold his shares, does not dispute that the fraud revealed through this April 2022 "corrective disclosure" caused him no loss.

4. The November 2020 Partial Disclosure

Plaintiff asserts that the requirement for loss causation is satisfied because an earlier "partial corrective disclosure," at a time when he still held the stock, also caused the stock price to drop. This argument fails because this earlier disclosure was not "corrective." On November 5, 2020, Axsome announced that it planned to postpone the submission of its NDA to the FDA from the fourth quarter of 2020 to the first quarter of 2021, "to allow for inclusion of supplemental manufacturing information to ensure a robust submission package." The stock price fell 7% that day, but not because the Company disclosed AXS-07's manufacturing problems. As the Complaint alleges, Defendants "continued to mislead investors" about the alleged CMC issues. There was no corrective disclosure about manufacturing issues. *See Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 175 n.4 (2d Cir. 2005) (plaintiffs' allegations did not amount to a corrective disclosure because they did "not reveal to the market the falsity of the prior" statements). The Complaint itself states that the November 5, 2020, announcement "did not give any indication that there were actual problems with the manufacturing process for AXS-07" and "did not reveal to investors the nature or extent of the CMC problems that Axsome was having with AXS-07." Since the announcement did not disclose any manufacturing issues, the

7% drop in Axsome's stock price must have resulted from the announcement that the NDA submission was delayed.

Plaintiff argues that he suffered a loss on account of the fraud because the stock price dropped on November 5, 2020, because of "materialization of the risk concealed" -- i.e., that the price drop resulted from the announcement of the delayed NDA submission, which in turn resulted from the undisclosed manufacturing issues. Even if this theory could support loss causation, it is factually incorrect and not supported by the Complaint. The Complaint does not support the inference that, by November 5, 2020, there were significant manufacturing issues or that Defendants were aware of any. For example, the first alleged misstatement occurred on December 30, 2019, the beginning of the Class Period. The Company "misrepresented the timeline for filing an NDA for AXS-07, and the likelihood of success of that NDA, *in light of the CMC problems that plagued the development of AXS-07*." (Emphasis added.) The Complaint makes similar allegations about the Company's public statements and filings throughout 2020. But the Complaint provides no factual basis for the conclusory assertion that, in late 2019 and throughout 2020, Axsome was "plagued" with CMC problems.

To the contrary, the Complaint suggests that serious manufacturing problems had not emerged or were not yet understood until the second quarter of 2021. The Complaint alleges that, in early 2021, an inside source, CW1, was tasked with managing a new study, scheduled to begin in April 2021. In early 2021, Axsome needed its supplier to manufacture more AXS-07 for the study, as the drug Axsome had on hand was nearing its expiration date. But the study was delayed repeatedly until August and then November 2021 because sufficient quantities of AXS-07 for the study could not be manufactured. All of this suggests that in early 2021 Axsome believed that sufficient quantities of AXS-07 could be manufactured for the scheduled April

2021 study. CW 1 confirmed this conclusion; despite having worked at Axsome since July 2019, CW1 asserted only that CMC issues "persisted at least from April 2021 through when CW 1 left the Company in February 2022."

Whether the Complaint's deficiency is characterized as no loss causation, no misstatement or omission, or no scienter, the Complaint does not allege facts to suggest that a serious manufacturing problem had emerged and was known to Defendants in November 2020 when the Company announced that it would briefly delay of the submission of the NDA into the next quarter. This November 5, 2020, announcement was made almost half a year before CW 1's study was first delayed. The drop in share price following the November 2020 announcement was not caused by any "realization" of an intentionally hidden fact, as Plaintiff argues.

B. Section 20(a) Violation

Section 20(a) imposes joint and several liability on control persons for underlying violations of the Exchange Act. *See* 15 U.S.C. § 78t. To state a claim under § 20(a), a plaintiff must allege both a primary violation of the Exchange Act and control over the primary violator. *See Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 236 (2d Cir. 2014). Because the primary claim fails, the § 20(a) claim is dismissed as well.

IV. CONCLUSION

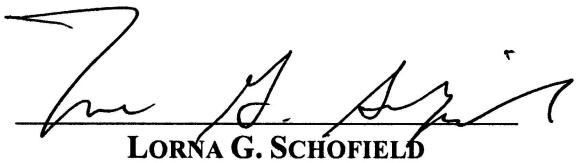
For the foregoing reasons, Defendants' motion to dismiss is **GRANTED**. Plaintiff's request for oral argument is **DENIED** as moot.

Plaintiff has requested leave to replead in the event the motion is granted. If Plaintiff seeks to file another amended complaint, by **October 13, 2023**, he shall file a letter not to exceed three pages single-spaced, along with his proposed Second Amended Complaint marked to show

changes from the First Amended Complaint. The letter shall explain how the proposed amended complaint cures the deficiencies identified in this Opinion, as well as the scienter issues raised by Defendants and the need for individual allegations as to each Defendant. Defendants shall respond, with the same page limitation, by one week after the filing of Plaintiff's letter.

The Clerk of Court is respectfully directed to close the motion at Dkt. 41.

Dated: September 25, 2023
New York, New York



LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE