

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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KENNETH GORDON, Individually and
On Behalf of All Others Similarly
Situated,

Plaintiff,

-against-

VANDA PHARMACEUTICALS INC.,
MIHAEL H. POLYMERPOULOS,
JAMES P. KELLY, GIAN PIERO
REVERBERI, AND THOMAS E.
GIBBS,

Defendants.

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Appearances:

For the Plaintiff:

MICHAEL G. CAPECI, ESQ.
Robbins Geller Rudman & Dowd LLP
58 South Service Road, Suite 200
Melville, NY 11747

For the Defendant:

AUDRA J. SOLOWAY, ESQ.
Paul, Weiss, Rifkind, Wharton &
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BLOCK, Senior District Judge:

The plaintiffs in this securities-fraud action claim that Vanda Pharmaceuticals Inc. (“Vanda”) and company executives Mihael Polymeropoulos, James Kelly, Gian Piero Reverberi, and Thomas Gibbs knowingly made statements in violation of the Securities Exchange Act of 1934 (“Exchange Act”) and SEC Rule 10b-5. The defendants move to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) on

the grounds that the plaintiffs have not adequately alleged scienter, material misrepresentations or omissions, or loss causation. For the following reasons the motion is granted in part and denied in part.

I.

The following facts are taken from the amended complaint. For present purposes, the Court accepts them as true and draws all reasonable inferences in favor of the plaintiffs. *See, e.g., Gamm v. Sanderson Farms, Inc.*, 944 F.3d 455, 458 (2d Cir. 2019).

Vanda is a biopharmaceutical company that markets and sells two drugs. *See Am. Compl.* ¶ 2. Fanapt is FDA approved to treat schizophrenia in adults. *Id.* Hetlioz is FDA approved to treat Non-24, a rare circadian rhythm disorder that occurs almost exclusively in blind individuals. *Id.* For a consumer, the average monthly price of Hetlioz in February 2019 was \$18,600, for a yearly total of \$223,200. *See Am. Compl.* ¶ 160.

The complaint alleges that defendants made materially false and misleading statements and omissions regarding an off-label promotion scheme in which Fanapt and Hetlioz were marketed to treat disorders for which the drugs were not FDA-approved. *See Am. Compl.* ¶ 3. This allegedly involved, for example, promoting sales of Fanapt to children with schizophrenia – rather than adults – in a manner that was inconsistent with the FDA’s authorization. *See Am. Compl.* ¶ 120. According

to plaintiffs, Hetlioz was promoted off-label for conditions other than Non-24, including mundane sleep issues in individuals who are not blind (or otherwise suffering from the condition).¹ These allegations were revealed to the public in a highly critical report issued by short seller Aurelius Value (“Aurelius Report”) on February 11, 2019, causing Vanda’s stock to “drop[] precipitously.” Am. Compl. ¶ 9.²

The complaint further alleges that company executives Polymeropoulos, Kelly, Reverberi, and Gibbs made materially false or misleading public statements and prepared false and misleading investor reports. *See* Am. Compl. ¶ 25.

II.

“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.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when “the plaintiff pleads factual

¹ According to one expert, “[t]here have been fewer than 100 cases of sighted people with Non-24 sleep-wake disorder reported in the scientific literature.” Am. Compl. ¶ 148.

² Plaintiff also alleges that the defendants made materially false and misleading statements concerning Tradipitant – a drug in clinical trials – because Vanda failed to disclose to investors that the FDA believed it would need to conduct a nine-month non-rodent study to ensure the drug is safe for humans. Am. Compl. ¶ 6. This prompted Vanda to sue the FDA. Am. Compl. ¶ 9. Because the defendant’s motion to dismiss fails as to Vanda and individual defendant Polymeropoulos under the off-label drug promotion theory, as a practical matter the Court will not analyze this claim.

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).

To state a claim under Section 10(b) of the Exchange Act, a plaintiff must establish (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation. *In re Petrobras Sec.*, 862 F.3d 250, 275 (2d Cir. 2017).

III.

To adequately plead scienter, a complaint must “state with particularity facts giving rise to a strong inference that the defendant acted with” the intent to deceive, manipulate, or defraud. 15 U.S.C. § 78u-4(b)(2)(A); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). Under this heightened pleading standard, “[a] complaint will survive ‘only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.’” *Setzer v. Omega Healthcare Inv'rs, Inc.*, 968 F.3d 204, 212 (2d Cir. 2020) (quoting *Tellabs*, 551 U.S. at 324).

According to plaintiffs, the complaint establishes that the individual defendants each participated in the off-label marketing scheme and the individual defendants’ scienter is imputed to Vanda. Since Fanapt and Hetlioz were the only

two revenue generating drugs sold by Vanda, the plaintiffs contend that the defendants are presumed to be knowledgeable about the off-label sales scheme.

The second amended complaint repeats factual allegations that were also conveyed in a Washington D.C. qui tam suit. That case was recently dismissed. *See United States ex rel. Gardner v. Vanda Pharm., Inc.*, No. 17-CV-00464 (APM), 2020 WL 2542121, at *1 (D.D.C. May 19, 2020) (“dismiss[ing] all of Relator's claims” with the “opportunity to amend”). The defendants contend that unproven allegations from a qui tam action cannot establish securities fraud, and that dismissal of the qui tam action undercuts its reliability. Alternatively, defendants argue even if Vanda’s agents encouraged off-label use of Fanapt and Hetlioz, it does not necessarily follow that those same agents intended to deceive shareholders.

The Court agrees that, even with the heightened pleading standard, plaintiffs have adequately pled corporate scienter as to individual defendant Polymeropoulos, and that such intent can be imputed to Vanda Pharmaceuticals. *See Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 195 (2d Cir. 2008). Specifically, the complaint sufficiently alleges that Polymeropoulos actively participated in trainings where Vanda’s salesforce was directed to market Hetlioz and Fanapt to individuals who did not suffer from diseases those drugs were approved to treat.

By contrast, the Court disagrees that the plaintiffs have met the heightened pleading standard with respect to defendants Kelly, Reverberi, and Gibbs. In the Second Circuit, plaintiffs must supply “connective tissue” between the corporate misconduct and the alleged false statements. *Jackson v. Abernathy*, 960 F.3d 94, 99 (2d Cir. 2020). Complaints that leave the Court to “guess what role those employees played in crafting or reviewing the challenged statements and whether it would otherwise be fair to charge the Corporate Defendants with their knowledge” must be dismissed. *Jackson*, 960 F.3d at 99. The amended complaint lacks sufficient factual information establishing the involvement of Kelly, Reverberi, and Gibbs in the dissemination of false statements about off-label marketing. Therefore, the Court dismisses the plaintiffs’ claims as to defendants Kelly, Reverberi, and Gibbs.

IV.

Section 10(b) and Rule 10b-5 prohibit corporate officers from making “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). “[V]eracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather than mislead prospective buyers.” *Kleinman v. Elan Corp.*, 706 F.3d 145, 153 (2d Cir. 2013) (internal citations omitted). Even

“[s]tatements of literal truth ‘can become, through their context and manner of presentation, devices which mislead investors.’” *Kleinman*, 706 F.3d at 153 (citing *McMahan & Co. v. Warehouse Entm't, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990)).

The defendants contend the complaint fails to establish false or misleading statements related to the alleged off-label marketing activities because (1) companies are not obligated to disclose unadjudicated, unproven allegations like the qui tam action; and (2) plaintiffs principally allege omissions, which are not actionable except in limited circumstances.

The Court finds that the plaintiffs have alleged omissions which are material, in that there is a “substantial likelihood” disclosure “would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011); *see also Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019) (“An alleged misrepresentation is material if there is a substantial likelihood that a reasonable person would consider it important in deciding whether to buy or sell shares of stock.”). The complaint alleges Polymeropoulos made affirmative statements regarding the company’s marketing practices which failed to convey the company’s suspect drug promotion activities. *See Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250-51 (2d Cir. 2014) (“Even when there is no existing independent duty to disclose information, once a company speaks on an issue or

topic, there is a duty to tell the whole truth.”). Specifically, Polymeropoulos stated that “Fanapt . . . will be a drug that will be used once patients switch from another medication,” “Fanapt is considered in the US a second line treatment,” and “[o]ur sales team continues making progress in introducing Fanapt as an additional option in treating adult patients with schizophrenia.” Am. Compl. ¶¶ 265, 278, 302. These statements did not communicate that Vanda appears to have been actively promoting and marketing Fanapt off-label, as a first-line treatment. Materiality is established because Fanapt accounted for between forty to sixty percent of revenues during the class period – cumulatively amounting to hundreds of millions of dollars.

V.

Unlike scienter, loss causation is governed by the traditional “short and plain statement” rule laid out in Rule 8. Fed. Rule Civ. Proc. 8(a)(2); *see also Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 346 (2005). A securities fraud complaint is sufficient if it sets forth what the “relevant economic loss” and “causal connection might be.” *Dura Pharm.*, 544 U.S. at 347.

The amended complaint alleges that the February 11, 2018 revelations in the Aurelius Report produced unusually high levels of trading activity and caused Vanda’s stock to decline over five percent. Am. Compl. ¶¶ 434-35.

The defendants argue the complaint fails to adequately plead loss causation because the Aurelius Report described allegations of off-label marketing that had been previously disclosed a week earlier, upon unsealing of the qui tam action.

Media reports and other similar public disclosures are adequate to establish loss causation in this context. *See In re Winstar Commc'ns*, No. 01 CV 11522, 2006 WL 473885, at *14 (S.D.N.Y. Feb. 27, 2006) (finding short seller's report of alleged fraud sufficient to establish loss causation at the motion to dismiss stage). Contrary to the defendant's contentions, the fact that the qui tam action was unsealed a few days before the Aurelius Report does not defeat the plaintiffs' claims, especially in this procedural posture. The "effect of [an] intervening event on plaintiff's theory of loss causation 'is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to dismiss.'" *In re Sequans Commc'ns S.A. Sec. Litig.*, No. 17CV4665FBSJB, 2019 WL 4805072, at *3 (E.D.N.Y. Sept. 30, 2019) (citing *Emergent Capital Inv. Mgmt., LLC v. Stonepath Grp., Inc.*, 343 F.3d 189, 197 (2d Cir. 2003)).

CONCLUSION

For the foregoing reasons, the defendants' motion to dismiss is granted with respect to the claims against James Kelly, Gian Piero Reverberi and Thomas Gibbs and otherwise denied.

SO ORDERED.

/S/ Frederic Block
FREDERIC BLOCK
Senior United States District Judge

Brooklyn, New York
March 10, 2021