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. POLYMEROPOULOS, JAMES P. KELLY, GIAN PIERO REVERBERI, AND THOMAS E. GIBBS,

Defendants.
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MEMORANDUM AND ORDER

Case No. 1:19-cv-01108-FB-LB

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.
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1285 Avenue of the Americas
New York, NY 10019

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.

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