United States District Court
District of Massachusetts

Caryl Hull Leavitt, individually and on behalf of all others similarly situated	)	
Plaintiff,	)	**Civil Action No. 18-12433-NMG**
v.	)	
Alnylam Pharmaceuticals, Inc. et al,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

This putative securities fraud class action is brought by lead plaintiff Tunc Toker ("Toker") on behalf of himself and other similarly situated investors against Alnylam Pharmaceuticals, Inc., its Chief Executive Officer, its Chief Financial Officer and other executives (collectively "Alnylam" or "defendants"). Toker alleges that defendants made false and/or misleading statements regarding the efficacy and marketability of its therapeutic injection for the treatment of hereditary ATTR amyloidosis during the class period.

Toker brings this purported class action asserting claims against Alnylam and certain Alnylam executives pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934

("the Exchange Act"). Pending before this Court is the defendants' motion to dismiss. For the following reasons that motion will be allowed.

I. Facts

Alnylam is a biopharmaceutical company incorporated in Delaware with its principal place of business in Cambridge, Massachusetts. The company develops and commercializes treatments for hereditary transthyretin-mediated amyloidosis ("hATTR amyloidosis" or "hATTR"), a gene mutation that causes a potentially harmful build-up of certain proteins in the body's nerves and organs. hATTR amyloidosis manifests in two ways: damage affecting the nerves (polyneuropathy) and damage impacting the heart (cardiomyopathy). Patients often exhibit both manifestations. Alnylam develops its therapeutics based on RNA interference ("RNAi") which inhibits the formation of those disease-causing proteins.

In December, 2017, based on study data from their clinical trial, Phase 3 APOLLO ("APOLLO"), Alnylam submitted to the Food and Drug Administration ("the FDA") a new drug application and marketing authorization application for patisiran (trade name Onpattro) ("Onpattro" or "patisiran") for the treatment of both the polyneuropathy and cardiomyopathy manifestations of hATTR.

APOLLO was designed primarily to evaluate the efficacy and safety of Onpattro for hATTR amyloidosis patients with

polyneuropathy. Accordingly, the study's primary endpoint was to determine the efficacy of patisiran for such patients. APOLLO's secondary endpoints sought to measure the efficacy of patisiran on various other metrics, including cardiac health. In addition to primary and secondary endpoints, the study included several exploratory endpoints, also including cardiac assessments.

Because hATTR causes both polyneuropathy and cardiomyopathy, often in the same patients, the trial included patients with the cardiac manifestation of the disease known as the cardiac sub-population. Within that sub-population, APOLLO contained metrics to evaluate patisiran's efficacy for cardiomyopathy.

In September, 2017, Alnylam received data from APOLLO and, while discussing the study on a conference call with investors, announced that APOLLO met its primary and secondary efficacy endpoints. Following that announcement, Alnylam's stock (which trades on the NASDAQ Stock Exchange) rose from $75.04 to $113.84 per share, a 51% increase. The Amended Complaint alleges that, simultaneously, Alnylam claimed that APOLLO supported an FDA approval for cardiomyopathy. Shortly thereafter, an investigator in the study presented the full dataset at an hATTR meeting in Paris. In November and December, 2017, Alnylam submitted a New Drug Application ("NDA") to the FDA, using the

results from APOLLO, and seeking approval of the drug for all manifestations of hATTR.

In August, 2018, the FDA approved patisiran for the treatment of polyneuropathy caused by hATTR amyloidosis but did not approve the drug for treatment of cardiomyopathy. Further, the FDA approval did not include any labeling with respect to cardiomyopathy. In contravention of the FDA, however, the European Medicines Agency ("the EMA") approved Onpattro for all manifestations of hATTR (in patients with polyneuropathy) and included cardiac data on the drug label.

After the FDA's announcement that patisiran would not be approved for cardiomyopathy, Alnylam's stock price fell by almost 6% from $97.38 to $90.95. The price subsequently rebounded, however, and by September 11, 2018, had risen to $100.35 per share.

On September 12, 2018, the FDA released a report discussing its review of paisiran and the approval process ("the FDA report"). That day several securities analysts reported that the FDA report revealed a greater risk with respect to certain trials of Onpattro and a more limited market opportunity for the drug than previously thought. The analysts' reports suggested that the FDA was concerned by cardiac deaths in patients treated with Onpattro and that Alnylam did not provide sufficient cardiac efficacy data to support approval. After the FDA report

was published, Alnylam's price per share fell by over 5% from $100.35 to $94.75.

The Amended Complaint alleges that between February 15, 2018, and September 12, 2018 ("the Class Period"), defendants made materially misleading statements about the cardiac efficacy and safety of patisiran and APOLLO's results in violation of Section 10(b), SEC Rule 10b-5 and Section 20(a) of the Exchange Act. It alleges that, as a result of that decline in market value, investors who purchased Alnylam stock during the Class Period in reliance on defendants' false and/or misleading statements suffered significant losses.

II. Procedural History

In September, 2018, Carol Leavitt filed her Complaint in the United States District Court for the Southern District of New York. Shortly thereafter, notice of this putative securities fraud class action was published pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA") on GlobeNewswire, a global business-oriented press release distribution service with substantial operations in North America. 15 U.S.C. § 78u-4(a)(3)(A)(i).

In late November, 2018, the case was transferred to this Court. A few days later, putative class members Toker, Leavitt, Edwards and Iappini filed their respective motions to be appointed lead plaintiff pursuant to the PSLRA. Id. In May,

2019, this Court allowed the motion of Tunc Toker for appointment as lead plaintiff and approval of counsel. In July, 2019, plaintiff filed an Amended Complaint.

III. Motion to Dismiss

A. Legal Standard

To survive a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), a complaint must contain "sufficient factual matter" to state a claim for relief that is actionable as a matter of law and "plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 667 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible if, after accepting as true all non-conclusory factual allegations, the court can draw the reasonable inference that the defendant is liable for the misconduct alleged. Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011). A court may not disregard properly pled factual allegations even if actual proof of those facts is improbable. Id. Rather, the relevant inquiry focuses on the reasonableness of the inference of liability that the plaintiff is asking the court to draw. Id. at 13.

When rendering that determination, a court may not look beyond the facts alleged in the complaint, documents incorporated by reference therein and facts susceptible to

judicial notice. Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011)

B. Securities Fraud in Violation of the Exchange Act

1. Legal Standard

Section 10(b) of the Exchange Act makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security...any manipulative device or contrivance." 15 U.S.C. § 78j(b). SEC Rule 10b-5 similarly 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).

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must adequately plead six elements:

> 1) a material misrepresentation or omission; 2) scienter, or 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.

Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1317-18 (2011); see also ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008) (citing Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005)).

A claim for securities fraud must also comply with Fed. R. Civ. P. 9(b) and satisfy the exacting requirements of the PSLRA.

Rule 9(b) requires a party to state "with particularity the circumstances constituting fraud" including the time, place, and content of the alleged false or fraudulent representations. Fed. R. Civ. P. 9(b).

The PSLRA imposes two heightened pleading requirements on federal securities fraud claims beyond those enumerated in the Federal Rules of Civil Procedure. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 313 (2007). First, to support allegations of misleading statements or omissions, plaintiffs must

> 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). Second, to plead scienter adequately, plaintiffs must state "with particularity facts giving rise to a strong inference" that the defendant acted recklessly or with the intent to deceive, manipulate, or defraud. 15 U.S.C. § 78u-4(b)(2); Greebel v. FTP Software, Inc., 194 F.3d 185, 199 (1st Cir. 1999).

Ruling on a motion to dismiss a securities fraud claim therefore requires a district court to assess the strength of competing inferences. When there are equally strong inferences for and against scienter, "the draw is awarded to the plaintiff." City of Dearborn Heights Act 345 Police & Fire Ret.

Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011). Moreover, "scienter should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations." ACA Fin. Guar. Corp., 512 F.3d at 59.

In addition to heightened pleading requirements, the PSLRA contains safe-harbor provisions for forward-looking statements. See 15 U.S.C. § 78u-5. As defined by the statute, forward-looking statements are those "that speak predictively of the future." In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 195 (1st Cir. 2005). Forward-looking statements are not actionable if they are 1) identified and accompanied by meaningful cautionary language; 2) immaterial or 3) the plaintiff fails to prove that the statement was made "with actual knowledge" that it was false or misleading. Id. (quoting 15 U.S.C. § 78u-5(c)(1)).

C. The Parties' Arguments

At the crux of plaintiffs' complaint is the contention that APOLLO 1) was never designed to test the efficacy of patisiran for cardiomyopathy and 2) provided no cardiac efficacy data to the FDA. Plaintiffs maintain that FDA approval of patisiran for cardiomyopathy was, therefore, impossible and defendants' public statements which forecast approval were intentionally false and misleading. Plaintiffs submit that because an Alnylam clinical trial for a different hATTR drug, Revuisran, failed, the

defendants were motivated to inflate patisiran's potential fraudulently.

The Amended Complaint (which prolongs to 110 pages) identifies 38 public statements made by defendants which plaintiffs contend were intentionally false or misleading ("the challenged statements"). Because the challenged statements are numerous and verbose the Court will refer to them cumulatively or by general groupings. Broadly, the challenged statements fall into categories regarding 1) the prospects of FDA approval for all manifestations of hATTR amyloidosis and the resulting scope of the drug label and 2) results and data from the APOLLO clinical trial. Plaintiffs aver that the challenged statements were false statements of fact, not opinions, were not subject to any PSLRA safe harbor provision and were made with the requisite scienter.

Defendants counter that the complaint fails to state a claim on multiple, independent and dispositive grounds. They assert that plaintiff has not pled any particularized facts which demonstrate that Alnylam made actionable false or misleading statements/omissions because all material information was disclosed to investors. Defendants further rejoin that 1) Alnylam's projections were forward-looking statements accompanied by meaningful cautionary language and thus were protected by the PSLRA's safe harbor, 2) their statements

interpreting clinical trial results were non-actionable opinions and 3) plaintiff's allegations do not give rise to the strong inference of scienter necessary to state a claim for securities fraud under the PSLRA.

D. The Design of the APOLLO Study

Plaintiffs' contention that APOLLO was never intended to evaluate efficacy for cardiomyopathy is contradicted by the study design and its corresponding statistical analysis plan. As set out by the clinical study protocol, APOLLO was intended primarily to evaluate the efficacy and safety of patisiran in patients with hATTR amyloidosis with polyneuropathy. Its primary endpoint matched that goal. APOLLO did, however, contain a number of measures designed to test for cardiac efficacy and included secondary endpoints designed to test the efficacy of patisiran on measures of cardiac function on the cardiac sub-population. APOLLO also included several exploratory endpoints which incorporated cardiac assessments. Although exploratory endpoints are not the focal point of a clinical trial and are less likely to show an effect, they are nevertheless included to investigate novel hypotheses and can lead to data inclusion on drug labels.

The study design as disclosed in the clinical study protocol, therefore, refutes plaintiff's principal contention that FDA approval was impossible and that any statements that

defendants made with respect to cardiomyopathy were therefore misleading. See In re The First Marblehead Corp. Sec. Litig., 639 F. Supp. 2d 145, 155 (D. Mass. 2009). (noting that "a plaintiff fails to plead an actionable § 10(b) claim predicated on the concealment of information if that information was, in fact, disclosed.") Approval for cardiomyopathy may have been significantly less likely than approval for polyneuropathy but the available evidence indicates it was plausible.

Moreover, in 2019, the EMA approved patisiran and included APOLLO cardiac efficacy data in the label. The EMA's approval and inclusion of data on the label contradicts the plaintiffs' claims that FDA approval or a broad label was impossible. See In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 544 (S.D.N.Y. 2015).

The exploratory endpoints and the measures for cardiac efficacy were disclosed in the clinical study protocol. The EMA included cardiac efficacy data on the drug's label. That the FDA ultimately did not approve patisiran for cardiomyopathy does not demonstrate that such approval was out of the question or that the study was never designed to evaluate cardiomyopathy. In light of those facts, allegations that defendants made materially misleading statements with respect to FDA approval are unavailing. See Ganem v. InVivo Therapeutics Holdings Corporation, 845 F.3d 447 (1st Cir. 2017). Plaintiffs have not

pled specific facts to demonstrate that the defendants either knew FDA approval was impossible or fraudulently mischaracterized the purpose or potential of APOLLO.

E. Results of APOLLO

Plaintiffs further maintain that because Alnylam failed to submit cardiac efficiency data to the FDA, approval was unachievable. That contention is, however, contradicted by the FDA Report and the actions of the EMA. Alnylam provided the FDA with data intended to demonstrate cardiac effectiveness and told investors that it believed that data was significant and could support a broad label. After reviewing the data, the FDA apparently disagreed, but just because it came to a different conclusion does not mean there is merit in plaintiffs' claims that no data was presented or that the challenged statements constituted securities fraud. Notably, the EMA included cardiac data on the drug label it approved signifying that Alnylam must have collected and submitted at least some relevant data.

Moreover, the challenged statements which discussed APOLLO results and cardiac data were non-actionable opinions. Although the FDA interpreted trial results differently and defendants' opinions may have been erroneous, those facts alone do not render the statements fraudulent or misleading. Without specific allegations of falsity, opinions interpreting the results of a clinical study are not actionable. See Harrington

v. Tetraphase Pharm. Inc., No. CV 16-10133-LTS, 2017 WL 1946305, at *5 (D. Mass. May 9, 2017) (noting "courts have been clear that scientific opinions are just that: opinions"); see also In re Sanofi Sec. Litig., 87 F. Supp. 3d at 543 (noting "courts have repeatedly held publicly stated interpretations of the results of various clinical studies to be opinions because reasonable persons may disagree over how to analyze data and interpret results and neither lends itself to objective conclusions.")(internal quotations omitted.)

That Alnylam presented its data in a positive light and made optimistic statements before FDA review, without more, does not make those statements materially misleading. See Corban v. Sarepta Therapeutics, Inc., No. 14-CV-10201-IT, 2015 WL 1505693, at *6 (D. Mass. Mar. 31, 2015).

F. Cardiac Safety Data

Plaintiffs further contend that the defendants knowingly misrepresented the safety of patisiran because the true safety profile portended the agency's non-approval of the drug. Although Alnylam disclosed the frequency of death in the patisiran and placebo branches of the study, plaintiffs claim that Alnylam did not disclose that cardiac-related deaths in patisiran-treated patients occurred at a higher frequency (7 times) than in placebo patients (once) (a 3.5 to 1 drug to placebo death ratio after accounting for the fact that there

were twice as many patisiran patients as placebo patients in APOLLO). Plaintiffs note that a 4:1 ratio was enough to scuttle an earlier trial for Revusiran, an alternative hATTR drug intended to treat cardiomyopathy. Further, plaintiffs claim that the FDA disagreed when Alnylam reclassified certain deaths from cardiac to non-cardiac related. Plaintiffs submit that defendants knowingly made statements claiming patisiran was safe despite data which showed serious safety concerns.

Defendants rejoin that the FDA report, published after review of APOLLO data, refutes those claims on several grounds. Alnylam explains that the FDA concluded that those cardiac related deaths were 1) not caused by patisiran, 2) constitute too small a sample from which to draw a conclusion, 3) included patients with gene mutations associated with higher mortality. Overall, the FDA purportedly concluded that patisiran was safe.

As Alnylam points out, the FDA review of Onpattro supports their contentions. The FDA concluded that although concerning, the small numbers of deaths did not merit description in labeling. It also noted that the "small numbers of cardiac deaths...make this finding difficult to interpret." The FDA's risk assessment concluded that the deaths in patients given patisiran included those with gene mutations associated with a higher mortality. According to the report, there was no

imbalance between the patisiran and placebo groups and deaths were considered unrelated to study treatment.

In light of the FDA's safety evaluation and findings, particularly the data analysis limitations inherent in a small sample size, defendants' challenged statements regarding safety were not material misrepresentations or misrepresentation by omission.

G. PSLRA Safe Harbor

1. Forward-Looking Statements Regarding the Prospects of FDA Approval

In addition to their contention that their statements were not materially misleading, defendants identify 15 of the 38 challenged statements (all relating to FDA approval) that they claim are protected by the PSLRA's safe harbor provision.

To be protected by the PSLRA, those forward-looking statements must have been accompanied by meaningful cautionary language that was "substantive and tailored to the specific future projections, estimates or opinions ... which plaintiffs challenge." Isham v. Perini Corp., 665 F. Supp. 2d 28, 39 (D. Mass. 2009) quoting In re Smith & Wesson Holding Corp. Sec. Litig., 604 F.Supp.2d 332, 340 (D. Mass.2009). Disclaimers which are "vague or boilerplate are insufficient" to garner the protection. In re Sepracor, Inc. Sec. Litig., 308 F.Supp.2d 20, 34 (D. Mass. 2004). Moreover, if a forward-looking

statement is accompanied by meaningful cautionary language the defendant's state of mind is wholly irrelevant. See Stone & Webster, 414 F.3d at 212 (noting that as long as a forward-looking statement is accompanied by meaningful cautionary language, the PLSRA creates "a surprising rule that the maker of knowingly false and willfully fraudulent forward-looking statements, designed to deceive investors, escapes liability for fraud.").

The challenged statements, made on conference and earnings calls, which discussed potential FDA approval, are typical forward-looking statements. They anticipated a hoped-for future event, FDA approval, and fit squarely within the PLSRA's safe harbor. See In re Sanofi Sec. Litig., 87 F. Supp. 3d at 535 (noting that statements about FDA approval "are classically forward-looking – they address what defendants expected to occur in the future.").

Those challenged statements were accompanied by adequate meaningful cautionary language. At the outset of each conference call, a statement was read which included a paragraph addressing forward-looking statements and referred investors to Alnylam's quarterly report on file with the SEC. Alnylam's quarterly report ("10-Q") detailed over 25 pages of risk factors and included sections on risks related to development, clinical

testing and regulatory approval of product candidates and detailed statements about APOLLO and patisiran.

Furthermore, many of the conference calls were accompanied by slides which noted a variety of risk factors similar to those included in the SEC filings. Among other risks, the slides identified action by regulators, clinical results and efficacy and safety of product candidates as factors that could cause results to differ from Alnylam's forward-looking statements.

In addition to formalistic warning statements and slides, the challenged statements themselves were generally accompanied by a specific, if more abbreviated, summation of the principal risk inherent in developing novel pharmaceutical drugs, i.e., that FDA approval was not guaranteed. For instance, in a November, 2017, conference call defendant Dr. Vaishnaw cautioned investors with respect to the scope of the potential label that "the regulators need to weigh in" and "ultimately, of course, they [the FDA] have to adjudicate on that."

Statements made at healthcare conferences contained similar warnings with regard to the risk that the FDA might not approve Onpatro. For instance, in January, 2018, Dr. Maraganore stated that:

> we've asked for hATTR amyloidosis as the indication statement for patisiran and we think the data supports that. And we are very happy to have a dialogue and we'll have a dialogue with the FDA around that label. I think

> that if you look at the spectrum, that's a win, that's our ask that we think is supported by the data. The other extreme might be limited to polyneuropathy patients okay?

That statement is largely representative. The risk that patisiran was subject to FDA approval and could be limited was properly described by defendants in meaningful and specific terms sufficient to trigger the safe harbor. See Isham 665 F. Supp. 2d at 39-40.

During each of the conference calls, by virtue of opening statements, reference to SEC filings, presentation text and in the challenged statements themselves, Alnylam warned investors about specific risks including deficient clinical trial results and the prospect of the FDA declining to approve the drug. Such warnings are not mere boilerplate and were sufficient to invoke the safe harbor and as such are non-actionable. See Harrington 2017 WL 1946305, at *9 (D. Mass. May 9, 2017); In re Smith & Wesson Holding Corp. Sec. Litig., 604 F. Supp. 2d at 341.

H. Scienter

Although the Court has concluded that plaintiffs have failed to state an actionable claim, for the sake of completeness, it briefly turns to the allegations of scienter. The Court finds that the plaintiffs have not properly alleged scienter under the heightened pleading standard required by the PLSRA.

Scienter is "'a mental state embracing intent to deceive, manipulate, or defraud.'" ACA Fin. Guar. Corp., 512 F.3d at 58 (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n. 12, (1976)). It requires a showing that the defendant acted with "either conscious intent to defraud or a high degree of recklessness." Id. (internal quotation marks omitted). Under the PSLRA, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the requisite state of mind." 15 U.S.C. § 78u–4(b)(2). The Supreme Court has instructed that, to qualify as "strong",

> 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.

As explained further by the First Circuit Court of Appeals, a complaint which properly pleads scienter,

> often contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so.

In re Boston Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012).

Plaintiffs allegations of scienter are based on their familiar contention that defendants knew that 1) APOLLO was never intended to test or secure FDA approval for cardiomyopathy

and 2) APOLLO efficacy and safety data did not support approval. Plaintiffs also point to what they declare to be suspiciously timed stock sales and certain business incentives (for instance the desire to increase Alnylam's stock price ahead of a secondary public offering) to support their allegations of scienter.

1. Insider Trading

Plaintiffs allege that suspiciously-timed, insider trading by the individual defendants leads to the strong inference that they sought to defraud investors for personal gain. Defendants rejoin that 1) their stock sales were not unusual or suspicious; 2) all challenged stock sales were executed pursuant to Rule 10b5-1 trading plans and 3) the temporal delay between the stock sales and the market-moving announcement defeats an inference of scienter.

Although insider trading on its own cannot establish scienter, trading in "suspicious amounts or at suspicious times may be probative of scienter." Mississippi Pub. Employees' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 92 (1st Cir. 2008). In order to support an inference of scienter, the trading must be "unusual, well beyond the normal patterns of trading by those defendants." Greebel, 194 F.3d at 198. The plaintiff bears the burden of showing that insider sales were suspicious and must provide a complete picture of the defendant's trading, both

before and after the class period. See Lenartz v. Am. Superconductor Corp., 879 F. Supp. 2d 167, 186 (D. Mass. 2012).

During the Class Period, four of the five individual defendants sold their Alnylam stock in the aggregate amount of $66 million. Plaintiffs argue that such sales were executed before negative news about APOLLO reached the market when share prices were high.

Sole reliance on proceeds from insider trading is insufficient to establish a strong inference of scienter. Plaintiffs do not provide the necessary evidence or context surrounding the trades that would allow the Court to draw the strong inference required. For instance, the complaint makes no mention of the percentage of the holdings of each defendant that were sold during the Class Period. See Fire & Police Pension Ass'n of Colorado v. Abiomed, Inc., 778 F.3d 228, 246 (1st Cir. 2015). Moreover, a review of the individual defendants' trading patterns suggests that their trades during the Class Period were not significantly unusual or sufficient for the court to draw a strong inference of scienter.

Considered in context, defendants trades do not appear particularly suspicious. Defendant Mr. Soni did not trade at all, a fact that, while not dispositive, undercuts the inference of scienter for the other named defendants. See Acito v. IMCERA Grp., Inc., 47 F.3d 47, 54 (2d Cir. 1995). Dr. Greensreet, who

joined Alnylam in September, 2016, was ineligible to trade prior to the Class Period because her options had not yet vested. In fact, she acquired more stock than she sold during the Class Period. See Fire & Police Pension Ass'n of Colorado 778 F.3d at 246 (noting that a defendant who increases her holdings during the Class Period negates an inference of scienter). Dr. Maraganore's trading corresponded closely with stock options that were set to expire and remained relatively consistent before, during and after the Class Period. He sold approximately 10% of his shares in 2015, 8% in 2016, 12% in 2017 and 4% in 2018. Those fluctuations do not go "well beyond" his normal pattern of trading. Greebel, 194 F.3d 185 at 198.

Although defendants Mr. Green and Dr. Vaishnaw sold a higher percentage of their shares during the Class Period than in prior years, their trading does not rise to the level of unusual or suspicious. During the Class Period Green sold about 22% of his holdings, an increase of 16% from the previous year. Vaishnaw sold 47% of his holdings during the Class Period but in the year prior to the Class Period, he sold 33%. Again, those increases do not go "well beyond" normal patterns of trading. Greebel, 194 F.3d 185 at 198.

Furthermore, that all trading was pre-scheduled pursuant to Rule 10b-5 trading plans negates an inference of scienter. See Emerson v. Genocea Biosciences, Inc., 353 F. Supp. 3d 28, 42 (D.

Mass. 2018)(noting that the existence of a Rule 10b5-1 trading plan "generally rebuts an inference of scienter and supports the reasonable inference that stock sales were pre-scheduled and not suspicious.")(internal citations and quotations omitted). The plaintiffs' claim that defendants entered into 10b-5 plans knowing that the APOLLO would not support regulatory approval is, as previously explained, unpersuasive.

Overall, plaintiffs have failed to establish a strong inference of scienter. They have presented no direct evidence of scienter and "their circumstantial case is not compelling" Simon v. Abiomed, Inc., 37 F. Supp. 3d 499, 524 (D. Mass. 2014). Accordingly, the complaint does not actionably plead scienter and fails to state a claim.

I. Section 20(a)

Violations of Section 20(a) of the Exchange Act require an underlying violation of the Exchange Act. See ACA Fin. Guar. Corp., 512 F.3d at 67–68. Accordingly, because there is no primary violation of the Exchange Act, plaintiff's 20(a) claim will be dismissed.

IV. Dismissal without prejudice

The PSLRA does not "require that all dismissals be with prejudice," ACA Fin. Guar. Corp., 512 F. 3d at 56, and, in this case, the Court will afford the plaintiffs one last chance to amend. See Isham 665 F. Supp. 2d at 41 (noting that "although

the Court's findings do not rest entirely on pleading deficiencies, it will dismiss the case without prejudice, in an abundance of caution, and allow plaintiffs leave to amend once more."). If plaintiff chooses to file a second amended complaint and that complaint is deemed deficient, it will be dismissed with prejudice. See Suna v. Bailey Corp., 107 F.3d 64, 66 (1st Cir.1997) (affirming dismissal after the district court "'reluctantly grant[ed] plaintiffs leave to file a second amended complaint' ... but cautioned that if 'the second complaint fail [ed] to satisfy the pleading requirements, the action [would] then be dismissed with prejudice'").

ORDER

In accordance with the foregoing, the defendants' motion to dismiss (Docket No. 59) is **ALLOWED** and the Amended Complaint is **dismissed without prejudice.**

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated March 23, 2020