United States District Court
District of Massachusetts

In re: Karyopharm Therapeutics Inc., Securities Litigation	)	**Civil Action No. 19-11972-NMG**

MEMORANDUM & ORDER

GORTON, J.

This is a putative securities fraud class action brought by lead plaintiff Dr. Myo Thant ("Dr. Thant" or "plaintiff") on behalf of himself and other similarly situated investors against Karyopharm Therapeutics Inc. ("Karyopharm" or "defendant") and several Karyopharm directors and executive officers ("the Individual Defendants") (collectively, "defendants"). Dr. Thant alleges that Karyopharm investors have been harmed because they purchased the company's common stock at prices that were artificially inflated by defendants materially misleading statements and omissions about selinexor, its leading drug candidate for the treatment of certain advanced cancers.

Pending before the Court is defendants' motion to dismiss the second amended complaint ("the SAC") for failure to state a

claim. For the reasons that follow, that motion will be allowed and the SAC will be dismissed without prejudice.

I. Background

The following summary is based upon the factual allegations stated in the second amended complaint which are accepted as true for the purpose of the pending motion to dismiss. Karyopharm is a Massachusetts-based, commercial-stage biopharmaceutical company that develops and commercializes treatments for cancer and other serious diseases. Plaintiff is a Maryland resident who supposedly purchased and retained Karyopharm securities in or traceable to the public offerings of the company's common stock conducted in or about April, 2017, and May, 2018. He contends that the purchase price of those securities was artificially inflated because Karyopharm executives made several misrepresentations and omissions with respect to the safety and efficacy of selinexor between March 2, 2017, and February 22, 2019 ("the Class Period").

Also during that period, i.e. in August, 2018, Karyopharm submitted to the Food and Drug Administration ("the FDA") a new drug application ("NDA") for selinexor in combination with dexamethasone for the treatment of multiple myeloma in adults who have received at least three prior cancer treatments or therapies. Six months later, on or about February 22, 2019, the FDA publicly released a briefing document ("the February

briefing document"), apparently revealing a long history of toxicity and limited efficacy of selinexor. Karyopharm's stock price subsequently plummeted from a closing price of $8.97 per share on February 21, 2019, to $5.07 per share the next day. Four days after that, the FDA convened its Oncologic Drug Advisory Committee ("ODAC") which voted to delay the approval of selinexor pending additional data from the company's Phase 3 clinical trial, BOSTON, causing Karyopharm's stock price to fall farther to $4.13 per share.

Thereafter, Karyopharm amended its NDA for selinexor, narrowing the group of potential patients to those suffering from multiple myeloma who have received at least four (rather than three) prior lines of treatment, a population for which there was no approved therapy. In July, 2019, the FDA approved selinexor for that indication and, by the time this lawsuit was filed in September, 2019, the price of the company's common stock had risen to $11.67 per share.

A. The Clinical Trials and Alleged Misleading Statements

1. Phase 1

The company initiated Phase 1 clinical testing for selinexor in 2012, primarily evaluating the toxicity, safety and tolerability of the drug in patients with multiple myeloma and acute myeloid leukemia ("AML"), among other types of cancer. The trial consisted of several study-arms and cohorts, three

arms of which studied the drug with respect to patients with multiple myeloma who had received at least three prior lines of cancer treatment or therapy. Patients received selinexor either alone (monotherapy) or in combination with different doses of dexamethasone, a steroid often used in combination with cancer treatments.

During Phase 1, several patients had to discontinue treatment with selinexor prematurely due to adverse reactions caused by the drug's toxicity. Furthermore, as to the 56 multiple myeloma patients receiving monotherapy, only one responded to the treatment, i.e. 55 out of 56 patients showed no signs of effective treatment. Karyopharm, nonetheless, proceeded to Phase 2 testing for selinexor, commencing the SOPRA trial in June, 2014, and STORM in May, 2015.

2. SOPRA

SOPRA (Selinexor in Older Patients with Relapsed/Refractory AML) was designed primarily to treat patients 60 years or older suffering from AML who were ineligible for standard intensive chemotherapy and/or transplantation. Trial participants received either a fixed dose of selinexor twice per week or standard treatment from their physicians. According to the FDA, the trial data reported a median overall survival rate for selinexor-treated patients of 94 days, compared to 170 days for patients receiving standard care. It also purportedly showed

that 100% of the evaluable patients who received the drug experienced some adverse event ("AE"), 80% experienced a serious AE and 20% suffered from an AE that resulted in death.

Thus, on March 2, 2017, Karyopharm announced in a press release that it would be terminating the SOPRA trial ("the SOPRA press release"). The disclosed reasons for the termination were not the drug's toxicity but, instead, that the study did not reach statistical significance on its primary endpoint, i.e. superiority of overall survival ("OS") on selinexor as compared to standard treatment. In that press release, the company added that,

> since selinexor-treated patients that achieved a complete response (CR) showed a substantial OS benefit as compared with the physician's choice (PC) arm, Karyopharm and the [independent Data Safety Monitoring Board ("DSMB")] agreed that patients would be permitted to continue on the selinexor arm or the PC arm, as applicable, following discussion between the patient and their treating physician . . .
>
> . . . Among patients on the selinexor arm, 13% demonstrated a CR with or without full hematologic recovery (CRi) compared to 3% of patients on the PC control arm. Some patients remained on selinexor for over one year, but this did not result in a statistically superior OS compared to the PC arm. The DSMB found no new clinically significant AEs in the patients receiving selinexor. Importantly, rates of sepsis and febrile neutropenia, or FN, were lower on the selinexor arm (sepsis 4.9%, FN 14.7%) compared to the PC arm (sepsis 6.1%, FN 36.4%). As expected, the most common selinexor-related adverse events were nausea, anorexia, fatigue, vomiting, and thrombocytopenia.

The press release added that "60mg of single-agent selinexor dosed twice per week was well-tolerated".

The SAC does not contend that those reported statistics are false but, instead, avers that the statements, as a whole, are materially misleading because they omit material information and apparently contradict the trial data which plaintiff alleges shows a lack of efficacy, high toxicity and worse overall survival with selinexor compared to patients receiving standard care.

3. STORM

STORM (Selinexor Treatment of Refractory Myeloma), on the other hand, tested the safety and efficacy of selinexor in combination with low-dose dexamethasone for the treatment of heavily pre-treated patients with penta-refractory myeloma. In contrast to SOPRA, STORM was a single-arm study in that its data was not compared to a control-group arm. Nor did it evaluate selinexor when used by itself.

Upon receipt of the STORM study data, Karyopharm expressed to its investors confidence in the results. In an April 30, 2018, press release discussing Phase 2b of the study ("the STORM press release"), for instance, the company stated that,

> [o]ral selinexor demonstrated a predictable and manageable tolerability profile, with safety results that were consistent with those previously reported from Part 1 of this study . . . and from other selinexor studies. As anticipated, the most common adverse events (AEs) were nausea, vomiting, fatigue and reduced appetite and were primarily low grade and manageable with standard supportive care and/or dose modification . . .

The next day, Karyopharm hosted a conference call, during which an executive officer represented that

> [t]he success of the STORM study is an important milestone for Karyopharm. And these data represent a significant step in establishing the efficacy and safety of selinexor as a new treatment option for patients with myeloma . . . We look forward to submitting detailed STORM study results for presentation in an upcoming medical oncology meeting.

Karyopharm submitted its NDA to the FDA soon thereafter, based primarily on the STORM study, and filed its final study report in October, 2018. One month later, however, the FDA convened a post mid-cycle meeting to share its concern that STORM, as a single-arm trial, could not support approval of selinexor. In the following months, the FDA continued to review the STORM data and, in February, 2019, announced in a briefing document the conclusion that selinexor was "associated with significant toxicity" which caused all STORM patients, of which there were 202, to experience at least one treatment emergent adverse event ("TEAE"), with nearly 60% experiencing a serious AE and more than 25% permanently discontinuing the drug due to TEAEs. Moreover, there were approximately 42 on-study deaths, of which 18 were attributable to selinexor. Four days later, the agency announced that it would delay the approval of selinexor until the FDA could review results from the BOSTON trial.

Plaintiff now asserts that defendants' positive, public representations with regard to STORM were materially misleading because the STORM trial data "demonstrated a highly toxic drug with a safety record evidencing extremely poor tolerability" and was unlikely to support FDA approval.

4. BOSTON

In June, 2017, Karyopharm commenced its BOSTON trial which was designed to test selinexor in combination with low doses of both dexamethasone and Velcade, another cancer treatment drug, in patients with multiple myeloma who had received one to three prior lines of cancer treatment. That study tested the three drugs together against the use of just Velcade and dexamethasone.

B. Real World Data

In June, 2018, Karyopharm discussed with the FDA at a pre-NDA meeting the various data it intended to submit in support of its NDA, including real world data ("RWD"). At that meeting, Karyopharm affirmed that any use of RWD would include details regarding selection criteria, handling of missing data and elimination bias and be used for supportive analysis only. In an August, 2018, conference call, a Karyopharm executive also represented to the public that the company would be "following the FDA guidance with what [it] include[s] in the NDA". Despite

those representations, Karyopharm's NDA included a RWD study that was not pre-specified or reviewed by the FDA.

In subsequent conference calls and press releases, Karyopharm executives discussed with its investors its interpretation of the RWD study, reporting that the data showed that the range for overall survival of highly refractory multiple myeloma patients in the real world was three to four months, whereas patients receiving selinexor-related treatment had a median overall survival of 8.6 months. The FDA subsequently adjusted the data based on perceived methodological errors, however, and determined that the median overall survival in the real world was actually 12.6 and for STORM patients, it was 10.4.

In December, 2018, the FDA sent Karyopharm a written request for additional information concerning the RWD study, finding the comparability of the real-world patients to selinexor-treated patients in the STORM study inadequate. Karyopharm modified the analysis of the RWD study in response, relying on a smaller subset of real-world patients that were more similar to the patients in the STORM study in an effort to reduce the potential for confusing or overly optimistic conclusions. The FDA reviewed those modifications but ultimately refused to consider the results of the RWD due to the continued lack of comparability between the two studies.

A. The Procedural History

On July 23, 2019, the Allegheny County Employees' Retirement System initiated a lawsuit in this Court against Karyopharm, its officers and directors and certain underwriters that participated in Karyopharm offerings ("the Allegheny Action"). That same day, notice of the putative securities fraud class action was published pursuant to the Private Securities Litigation Reform Act of 1995 ("the PSLRA") on PR Newswire, a national business-oriented press release distribution service. 15 U.S.C. § 78u-4(a)(3)(A)(i).

In September, 2019, Heather Mehdi filed this nearly-identical putative class action against Karyopharm and certain of its officers and directors in this Court. A week later, Dr. Thant moved for appointment as lead plaintiff in the Allegheny action but that case was voluntarily dismissed in March, 2020. Shortly thereafter, he filed a motion for appointment as lead plaintiff and approval of counsel in the instant case which this Court allowed in April, 2020. In June, 2020, plaintiff filed his first amended complaint and, after a motion to dismiss was fully briefed, plaintiff filed the second amended complaint ("the SAC") with leave of Court in October, 2020.

The Second Amended Complaint alleges that, during the class period, defendants made materially misleading statements about the efficacy and safety of selinexor in violation of Sections 11

and 15 of the Securities Act of 1933 ("the Securities Act"), 15 U.S.C. §§ 77k & 77o (Counts I and II), Sections 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 (Counts III and IV). It adds that, as a result of that decline in market value, investors who purchased Karyopharm stock in reliance on those false and/or misleading statements suffered significant losses.

Defendants filed the pending motion to dismiss for failure to state a claim in November, 2020.

II. Discussion

A. Legal Standard

To survive such 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).

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). A court also may not disregard properly pled factual allegations even if actual proof of those facts is improbable. Ocasio-Hernandez, 640 F.3d at 12. 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.

B. The Securities Exchange Act

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 implements that provision and similarly makes it unlawful

> [t]o make any untrue statement of 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).

Thus, 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, 563 U.S. 27, 37-38 (2011) (internal citation omitted); 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)). Although, "the mere possession of material[,] nonpublic information does not create a duty to disclose it", a company that chooses to speak must provide enough facts "so that what was revealed would not be so incomplete as to mislead". Hill v. Gozani, 638 F.3d 40, 57 (1st Cir. 2011) (brackets in original) (internal citation omitted).

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, a plaintiff 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, a plaintiff 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). Such a showing is often supported by direct evidence, including admissions, internal records or other "smoking guns" suggesting that the defendants "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); see Tellabs, 551 U.S. at 324.

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. 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).

C. The Parties Arguments

At the crux of plaintiff's complaint is the contention that defendants knew selinexor is and has always been severely toxic and extremely limited in terms of efficacy but they, nevertheless, told investors that the drug resulted in better overall survival for refractory multiple myeloma patients than those who were not treating with it. As a result of the representations, plaintiff contends that he and other class

members purchased the company's stock at an artificially inflated price and consequently suffered losses.

The SAC identifies more than 10 statements made by Karyopharm executives in which material facts were allegedly either omitted or misrepresented. Because the challenged statements are numerous and largely duplicative, the Court will refer to them cumulatively or by general groupings. See In re Parametric Tech. Corp. Sec. Litig., 300 F. Supp. 2d 206, 213 (D. Mass. 2001) (grouping together for consideration closely related statements). Broadly, the challenged statements fall into categories regarding 1) the safety and efficacy of selinexor in the context of the SOPRA trial 2) the same in the context of the STORM trial and 3) the inclusion of the RWD study in the NDA and the conclusions drawn therefrom. Plaintiff avers that the challenged statements were misleading and 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 Karyopharm or the individual defendants made actionable, false or misleading statements or omissions because all material information was disclosed to investors. Defendants further contend that 1) their factual statements were accurate, 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 Safety and Efficacy of Selinexor

1. The SOPRA Trial

Plaintiff's contention that Karyopharm made materially misleading statements with respect to the SOPRA trial is contradicted by the timely disclosures that the company did make. With respect to the SOPRA press release, for instance, defendants expressly stated that Karyopharm was canceling that clinical trial because the results showed it would "not reach statistical significance for overall survival (OS), the study's primary endpoint". 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."). Defendants thus disclosed to investors that selinexor-treated patients, in general, showed a worse overall survival rate as compared to standard care patients. See In re Biogen Sec. Litig., 179 F.R.D. 25, 39 (D. Mass. 1997) (explaining that, if "the most relevant and disappointing aspect of the [results]—the failure to reach the primary endpoint" had been disclosed, "any additional disclosure

. . . would not have altered the total mix of information available").

To the extent plaintiff asserts that the press release represented the opposite, quoting the company's statement that "selinexor-treated patients . . . showed a substantial OS benefit as compared with the [control]", the Court is unpersuaded. Plaintiff, ironically, misleads this Court by truncating that statement and separating it from its context. See Gerneth v. Chiasma, Inc., No. 16-cv-11082, 2018 WL 935418, at (D. Mass. Feb. 15, 2018) (considering the context of a statement to determine its materiality). He omits from it 1) Karyopharm's qualification that the only selinexor-treated patients who showed an OS benefit were those who "achieved a complete response" and 2) the company's concession that only 13% selinexor patients achieved that response. Read in that context, however, no reasonable investor would have understood the SOPRA press release to be claiming that the trial showed a better overall survival rate for selinexor-treated patients. See also Corban v. Sarepta Therapeutics, Inc., No. 14-cv-10201, 2015 WL 1505693, at *6 (D. Mass. Mar. 31, 2015) ("That the company . . . cast its trial results in a positive light does not detract from [its] disclosure[s], as a defendant does not have a duty to cast the descriptions of its business in the most negative light" (internal quotation marks omitted)).

Furthermore, the press release was not rendered incomplete for failure to disclose 1) that the median overall survival for patients receiving selinexor was 94 days as compared to 170 days for patients receiving standard care and/or 2) that 100% of the evaluable patients who received selinexor experienced adverse events, 80% experienced serious AEs and 20% experienced AEs leading to death. First, Karyopharm has no affirmative duty to disclose every piece of information in its possession in which an investor may have an interest. See Hill, 638 F.3d at 56-57 ("[T]he mere possession of material[,] nonpublic information does not create a duty to disclose it." (internal citation omitted)).

Second, the information the company shared adequately provided its investors with an overall picture of the safety and efficacy of selinexor in the context of the SOPRA trial. See id. at 60 n.5 ("[W]e have not required complete disclosure of all the details when the overall risk is disclosed."). In fact, Karyopharm disclosed not only that most selinexor-treated patients in SOPRA failed to demonstrate a superior overall survival rate but also that selinexor was associated with AEs, the most common of which included nausea, anorexia, fatigue, vomiting and thrombocytopenia. The company also provided the specific rates of incidence on both arms of the trial for sepsis and febrile neutropenia, two other AEs. Nothing in the SAC thus

permits the reasonable inference that the omitted SOPRA toxicity and efficacy data would have substantially altered the total mix of information available to investors. See In re Biogen Sec. Litig., 179 F.R.D. at 39.

Instead, the reasonable inference supported by the factual allegations is that the defendants genuinely believed that the available data could support FDA approval for selinexor. Even after terminating SOPRA, the company continued to invest in clinical trials for the drug and ultimately filed an NDA. See Local No. 8 IBEW Retirement Plan & Trust v. Vertex Pharm., Inc., 838 F.3d 76, 81 (1st Cir. 2016) (noting that a company's investment in clinical trial design and performance of a clinical study suggests that the company "must have thought that positive results were possible"). Moreover, the FDA eventually approved the drug, in combination with dexamethasone, for the treatment of multiple myeloma patients who have received four prior cancer treatments or therapies and did so without a "black-box" warning. In re Biogen Idec, Inc. Sec. Litig., No. 05-cv-10400, 2007 WL 9602250, at *3 (D. Mass. Oct. 25, 2007) (describing a black-box warning as "the strictest FDA warning that the agency employs"). Thus, selinexor was able to meet the requisite safety and efficacy standards, validating Karyopharm's proclaimed views of it. See 21 C.F.R. § 314.105(c) ("FDA will

approve an application after it determines that the drug meets the statutory standards for safety and effectiveness.").

2. The STORM Trial

Plaintiff further maintains that Karyopharm misrepresented the safety and efficacy data from the STORM trial by stating that "selinexor demonstrated a predictable and manageable tolerability profile" yet omitting that 100% of the enrolled patients experienced AEs, nearly 60% experienced a severe AE, more than 25% of patients permanently discontinued the drug due to its side effects and approximately 18 on-study deaths were attributed to it. Given the circumstances of the STORM-related disclosures, the Court finds that position well-taken.

Unlike the SOPRA-related statements which announced the termination of that trial due to selinexor's failure to demonstrate a superior overall survival rate, the statements discussing STORM announced that the trial was a success and "an important milestone for Karyopharm" with respect to obtaining FDA approval for the drug. In that context, knowledge of selinexor's toxicity plausibly would have altered the total mix of information available to investors which was otherwise "skewed to present a rosy picture". Cf. Hill, 638 F.3d at 61 (concluding that a disclosure was not incomplete because the total mix of statements "was not skewed to present a rosy picture"). Karyopharm's disclosure of the most common AEs,

namely, nausea, vomiting, fatigue and reduced appetite, plausibly falls short of rendering its representation of STORM not misleading.

Noteworthy, the FDA apparently found STORM's toxicity data significant in that the agency suggested as much in the February briefing document and delayed its decision with respect to the approval of selinexor until the STORM data could be supplemented by Karyopharm's ongoing BOSTON trial. Accordingly, at this stage, the Court concludes that defendants' STORM-related disclosures were arguably incomplete for failing fully to reveal the drug's toxicity.

E. The Real World Data

Plaintiff finally proclaims that Karyopharm's disclosures relating to the real-world data were misleading, in violation of federal securities law. First, plaintiff challenges as false and/or materially misleading defendants' statement that the company was following FDA guidance as to the safety information it included in its NDA because Karyopharm included a RWD study that was not pre-specified and purportedly had methodological errors. One major fallacy of that challenge, however, is that the FDA and Karyopharm agreed at a pre-NDA meeting that the company could submit RWD for supportive analysis and plaintiff fails to allege any other purpose for which Karyopharm included the RWD study in its NDA.

Furthermore, as defendants aver, any technical non-compliance with FDA guidance in connection with the RWD was of no consequence because the FDA ultimately accepted, reviewed and approved Karyopharm's NDA. In any event, defendants' broad representation that they were "following the FDA guidance" constitutes an immaterial "generic assertion[]" regarding compliance. Cf. Singh v. Cigna Corp., 918 F.3d 57, 63-64 (2d Cir. 2019).

With respect to the differing real-world survival rates calculated by the defendants and the FDA, the discrepancy constitutes a non-actionable scientific disagreement. Although the FDA interpreted the RWD study results differently (adjusting for alleged methodological errors) and defendants' view of the data may have been erroneous, those facts alone do not render their opinions actionable. See Harrington v. Tetraphase Pharm. Inc., No. 16-cv-10133, 2017 WL 1946305, at *5 (D. Mass. May 9, 2017) (noting that "courts have been clear that scientific opinions are just that: opinions"); see also In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015) (noting that "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)).

Nowhere in the SAC does plaintiff allege plausibly that the defendants knew the conclusions they reported from the RWD were false. Nor does plaintiff proffer factual allegations to support its position that, when defendants submitted the NDA, they knew the real-world data on which they relied contained methodological errors. See Harrington, 2017 WL 1946305, at *5 ("An opinion is only actionable . . . if it is without any reasonable basis or objectively false" (internal citation and marks omitted)). Accordingly, plaintiff has failed to plead any actionable statement regarding the RWD study. See ACA Financial Guaranty Corp., 512 F.3d at 62 (rejecting pleadings of "fraud by hindsight").

F. Scienter

To the extent plaintiff plausibly alleges an actionable statement or omission, he fails adequately to plead scienter. 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 [investors] or a high degree of recklessness". Id. (internal quotation marks omitted). Under the PSLRA, a plaintiff must "state with particularity facts giving rise to a strong inference" of scienter. 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.

Here, plaintiff's allegations of scienter are based primarily upon the accounts of four former Karyopharm employees ("FEs") alleging various instances where company executives attempted to conceal from or minimize to the FDA adverse events related to selinexor. Importantly, none of those accounts shows a desire of defendants to mislead investors. Fire and Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 231 (1st Cir. 2015) ("Not all claims of wrongdoing by a company make out a viable claim that the company has committed securities fraud."). In fact, of the approximately 55 scienter-specific allegations, not one mentions investors and the one that mentions "the price of stock" refers to statements that were released well-before the commencement of the Class Period. Furthermore, only two FE accounts discuss events taking place during the Class Period and, as defendants contend, neither

> alleges any contact with the Individual Defendants, or anyone else alleged to have had any involvement in preparing any of the challenged statements.

Citing Southland Sec. Corp. v. INSpire Ins. Solutions Inc., 365 F.3d 353, 366 (5th Cir. 2004) (stating that corporate scienter

looks only "to the state of mind of the individual corporate official or officials who make or issue the [challenged] statement").

The SAC also fails to demonstrate that defendants' STORM-related omissions were reckless. To establish scienter by recklessness, a plaintiff must show that defendants made

> a highly unreasonable omission, involving not merely simple, or even inexcusable, negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it.

City of Dearborn Heights, 632 F.3d at 757 (citation omitted).

In this case, plaintiff has failed to demonstrate that defendants' omission of the STORM toxicity data was highly unreasonable. First, defendants offer a plausible, nonculpable explanation for not disclosing that data, i.e. they believed that such a disclosure was unnecessary to render their representations of selinexor's safety profile not misleading. Defendants plausibly contend that the market knew that any treatment tailored to a "very ill patient cohort" such as its multiple myeloma patients would result in high numbers of AEs and, therefore, understood that any representation as to the safety and tolerability of such a treatment was relative to that context. As a result, no reasonable investor would interpret their statement that selinexor's safety profile was

"predictable" and "manageable" to mean the drug was benign. Second, it was not "so obvious" that Karyopharm's STORM-related disclosures posed a danger of misleading the market. To the contrary, a contemporaneous analyst report "acknowledge[d that] the drug's toxicity profile could impact its overall adoption", demonstrating that defendants' disclosures were adequate.[1]

In any event, defendants also made several informative disclosures to investors which point against scienter. When the FDA placed Karyopharm's clinical trials on hold in March, 2017, for purportedly withholding certain AEs from selinexor's safety database, for instance, the company readily disclosed that event as it unfolded. See Mehta v. Ocular Therapeutix, Inc., 955 F.3d 194, 208 (1st Cir. 2020) ("[D]isclosures about the nature and consequences of [an FDA investigation] undercut any inference that defendants intentionally or recklessly misled investors"); In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 42 (1st Cir. 2014) ("[Informative disclosures] undercut any inference of fraudulent intent on the part of defendants"). Moreover, in its 2016 and 2017 Annual Reports, the company cautions investors that "drug development [such as with selinexor] entails a high risk of failure" because 1) it is hard to predict when or if a drug

[1] See In re Zyprexa Prod. Liability Litig., 549 F. Supp. 2d 496 (E.D.N.Y. 2008) (taking judicial notice of published analyst reports in determining what the market knew).

candidate will prove effective and 2) results of its trials "could reveal an unacceptably high severity and prevalence of [selinexor-related] side effects" that may cause the FDA to reject its NDA. See Ezra Charitable Trust v. Tyco Intern., Ltd., 466 F.3d 1, 8 (1st Cir. 2006) ("[A]ttempts to provide investors with warnings of risks generally weaken the inference of scienter"). Such voluntary disclosures "are not the actions of a company bent on deceiving investors". See Abiomed, 778 F.3d at 243-44.

G. Section 20(a)

The SAC also asserts a claim for control person liability pursuant to Section 20(a) of the Exchange Act against the individual defendants. Section 20(a) imposes joint and several liability on any person who, "directly or indirectly, controls any person liable" under Section 10(b) and Rule 10b-5. 15 U.S.C. § 78t(a). Because the SAC fails to allege an underlying violation of the federal securities laws, the amendment with respect to plaintiff's Section 20(a) claim is also futile. See Greebel, 194 F3d at 207.

H. The Securities Act

Finally, defendants contend that plaintiff has failed to state claims under the Securities Act because those allegations also fall short of Rule 9(b)'s heightened pleading standard and, with respect to Section 11 in particular, plaintiff has not

established that he has standing to sue. Plaintiff rejoins that no heightened pleading standard applies to Sections 11 and 15 of the Securities Act. As to standing, plaintiff asserts that he has alleged sufficient facts to plausibly suggest that the shares of Karyopharm stock he purchased are traceable to the public offerings.

Section 11 is an "enforcement mechanism[] for the mandatory disclosure requirements of the Securities Act". Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996). It imposes liability on the issuer of a security, as well as any person who signs the registration statement or serves as a director, if the registration statement (1) contains an untrue statement of material fact, (2) omits a material fact required to be included or (3) omits a material fact necessary to make the statements therein not misleading. 15 U.S.C. § 77k(a).

Section 11 differs from § 10(b) of the Securities Exchange Act because the former does not include a scienter or reliance requirement and neither the heightened pleading standard of Fed. R. Civ. P. 9(b) nor the PSLRA applies unless a § 11 claim sounds in fraud. Thus, to state a claim under Section 11, a plaintiff need only allege plausibly

> (1) the existence of either a misstatement or an unlawful omission; and (2) materiality.

Pension Trust v. J.Jill, Inc., 360 F. Supp. 3d 17, 22 (D. Mass. 2018) (quoting In re Morgan Stanley Info Fund Secs. Litig., 592 F.3d 347, 359 (2d Cir. 2010)).

An action under Section 11, however,

> may be maintained only by those who purchase securities that are the direct subject of the prospectus and registration statement.

Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp., 632 F.3d 762, 768 n.5 (1st Cir. 2011) (citation omitted). That requires the plaintiff to have purchased shares either in the offering or to be able to trace their shares back to it. In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 755 (1st Cir. 2016).

That standing inquiry becomes complicated where, as here, "the company has issued shares under multiple registration statements". Id. Under such circumstances, a plaintiff must plead plausibly that his "shares were issued under the allegedly false or misleading registration statement", rather than another statement. Id.

Here, the SAC fails to set forth sufficient facts to permit the reasonable inference that the shares purchased by plaintiff were issued as part of or traceable to the April, 2017, and May, 2018, public offerings. First, the SAC does not allege that plaintiff purchased his shares directly in the secondary offerings themselves. Second, his allegations with regard to

the traceability of his purchases are unavailing. Plaintiff contends that "upon information and belief" his shares "are traceable and/or were purchased pursuant to" the secondary offerings. The allegations he offers to support that belief, however, do not exclude the possibility that he purchased common stock from the pool of previously issued shares. See In re Ariad Pharm., Inc., 842 F.3d at 756 ("Indeed, the obvious alternative explanation is that the[purchased stock] could instead have come from the pool of previously issued shares."). In fact, 41,887,829 shares of Karyopharm stock were already outstanding prior to the April, 2017, offering (which issued only 3,902,430 shares) and 49,670,328 were outstanding prior to the May, 2018, offering (which issued only 9,152,543 shares).

Furthermore, none of plaintiff's purchases of Karyopharm stock took place on the day of either secondary offering and the price per share paid by him never matched the offering prices. The public offering price for the April, 2017, shares was $10.25 per share and the price per share for the May, 2018, offering was $14.75. Not one of the purchases proffered by plaintiff was at either price. See In re Ariad Pharm., Inc., 842 F.3d at 756 (noting the timing and price of the stock purchases). Accordingly, plaintiff lacks standing to bring claims under the Securities Act and, for that reason, Counts I and II will be dismissed.

ORDER

For the foregoing reasons, defendants' motion to dismiss the second amended complaint (Docket No. 44) is **ALLOWED.** Plaintiff's second amended complaint is hereby **DISMISSED without prejudice.**

So ordered.

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

Dated July 21, 2021