IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Southern Division

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EMPLOYEES' RETIREMENT SYSTEM OF THE CITY OF BATON ROUGE AND PARISH OF EAST BATON ROUGE,

*

Plaintiff, **Case No.: GJH-19-2713**

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v.

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MACROGENICS, INC., *et al.*,

*

Defendants.

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MEMORANDUM OPINION

This is a securities fraud case arising from Defendants' statements regarding the clinical trials of their cancer treatment product, "Margetuximab." Lead Plaintiff Employees' Retirement System of the City of Baton Rouge and Parish of East Baton Rouge ("CPERS" or "Plaintiff") brings this putative class action against Defendants MacroGenics, Inc., CEO and President Scott Koenig, and CFO and Treasurer James Karrels (collectively "Defendants"), for purported violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("the Exchange Act") and Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 (the "Securities Act"). Presently pending before the Court is Defendants' Motion to Dismiss, ECF No. 37. No hearing is necessary. *See* Loc. R. 105.6 (D. Md. 2016). For the following reasons, Defendants' Motion to Dismiss is granted.

I. BACKGROUND[1]

Resolving this case on a motion to dismiss, the Court takes Plaintiff's factual allegations in the Amended Complaint as true. MacroGenics is a clinical-stage biopharmaceutical company that trades on the NASDAQ under the symbol "MGNX." ECF No. 34 ¶¶ 22, 28. MacroGenics is developing Margetuximab, a treatment for patients with certain metastatic breast cancers. *Id.* ¶ 2. Plaintiffs are individuals who purchased common stock in MacroGenics between February 6, 2019 and June 4, 2019 (the "Class Period").

A. The SOPHIA Study

During the relevant time, MacroGenics was developing Margetuximab. ECF No. 34 ¶ 2. Margetuximab is an antibody developed for patients who had previously undergone cancer treatments but had achieved only sub-optimal results. *Id.* Margetuximab is the first of MacroGenics' product candidates to be tested in a Phase III clinical trial and is a "critically important product" to MacroGenics. *Id.*[2]

The SOPHIA Study, MacroGenics' Phase III trial, compared the performance of drugs in patients with HER2-positive[3] metastatic breast cancer who had previously been treated with anti-HER2-targeted therapies. ECF No. 34 ¶ 31. The study compared Margetuximab in combination

[1] Pin cites to documents filed on the Court's electronic filing system (CM/ECF) refer to the page numbers generated by that system.

[2] This Court has previously explained the drug approval process in *Lerner v. Nw. Biotherapeutics*, 273 F. Supp. 3d 573, 579 (D. Md. 2017). As part of the drug approval process, a drug sponsor is responsible for designing clinical trials and submitting their results to the FDA. *Id.* (quoting 21 U.S.C. § 355(b)(1)). "The sponsor, rather than the FDA, is responsible for designing the clinical trials. A sponsor generally conducts clinical trials in three phases. Phase I 'includes the initial introduction of an investigational drug into humans' and determines 'the metabolism and pharmacologic actions of the drug in humans.' Phase II involves studies that are 'typically well-controlled,' to determine the effectiveness of the drug on 'patients with the disease or condition under study.' Phase III includes 'expanded controlled and uncontrolled trials' intended to 'gather additional information about effectiveness and safety' and 'evaluate the overall benefit-risk relationship.'" *Id.* (quoting 21 C.F.R. § 312.21(a)-(c)).

[3] "HER2 is a protein found on the surface of some cancer cells that promotes growth and is associated with aggressive disease and poor prognosis." ECF No. 34 ¶ 29.

with chemotherapy against the performance of Trastuzumab and chemotherapy. *Id.* Trastuzumab has already received FDA Approval and is "the market-leading, standard biologic treatment for breast cancer." *Id.* ¶ 3.

The SOPHIA trial enrolled 536 patients at 200 trial sites across the world. ECF No. 34 ¶ 31. Patients were either assigned to a treatment of Margetuximab and chemotherapy or Trastuzumab and chemotherapy. *Id.* The trial endpoints were two-fold. First, the trial attempted to establish a "meaningful benefit"[4] to patients taking Margetuximab as opposed to Trastuzumab in terms of "progression free survival" ("PFS"). *Id.* ¶ 3. PFS measures how long patients enrolled in a specific treatment survive post-enrollment without progression of disease. *Id.* Second, the SOPHIA trial attempted to establish a "meaningful benefit" to patients taking Margetuximab compared to Trastuzumab in terms of "overall survival" ("OS"). *Id.* OS measures how long patients survive without regard to if they experienced post-enrollment progression of disease. *Id.* The objective of SOPHIA was to show that Margetuximab delivered "meaningfully superior PFS and OS results compared to the Trastuzumab-based treatment." *Id.* ¶ 33.

OS is a "critically important endpoint" in evaluating a new treatment for a disease with a high mortality rate. *Id.* ¶ 35. Although showing a superior OS rate to existing drugs is not necessary for FDA Approval, "showing such superior OS results substantially increases the likelihood of FDA approval." *Id.* Importantly, showing superior OS results is also "critical to the commercial prospects of a drug like Margetuximab" because oncologists are more likely to prescribe treatment that can produce results that are "meaningfully superior" to results from existing "standard of care" drugs. *Id.*

[4] A "meaningful benefit" seems to denote a "statistically significant" favorable difference between the performance of Margetuximab and Trastuzumab. *See* ECF No. 34 ¶ 72.

B. Summary of Events During the Class Period

The Class Period extends from MacroGenics' February 6, 2019 release of initial data until June 4, 2019, when MacroGenics presented at the annual meeting of the American Society of Clinical Oncologists (the "ASCO Conference").

Plaintiff alleges that MacroGenics conducted an initial analysis of the SOPHIA data and then began to "selectively" and "misleadingly" release positive aspects of the study while suppressing negative aspects during the Class Period. ECF No. 34 ¶ 4. On February 6, 2019, MacroGenics released results from its initial review of the SOPHIA Trial. *Id.* The analysis used October 10, 2018 as the "cut-off" date for the review.[5] In a press release, MacroGenics announced that the data showed a statistically significant PFS benefit to Margetuximab treatment but stated only that the OS data was still "maturing." *Id.* ¶ 5. The stock price of the Company "skyrocketed" by 130% (from $11.11 to $25.60) on that same day. *Id.* MacroGenics then announced that it would be holding a secondary public offering on February 13, 2019 at an offering price of $20.00 per share. *Id.* ¶ 6. The Company raised $126.5 million in gross proceeds from that secondary offering. *Id.* Over the next few months, MacroGenics continued to tout its positive PFS data while "declining to comment" on its OS data, except to say that the data was still "not mature." *Id.* ¶ 7.

Given that the data set was locked as of October 2018, Plaintiff alleges that the Company did have negative information regarding its interim OS data that it "chose not to disclose to investors." ECF No. 34 ¶ 8. Because the PFS analysis had already been put together using the

[5] Study data is "sequentially assessed over time" as of pre-specified "cut-off" points. *See* ECF No. 34 ¶ 33. A "cut-off" point is when the data is "effectively locked for analytical purposes[.]" *Id.* ¶ 5 n.1. Therefore, no new data was collected after October for that particular review. However, "results from SOPHIA continue to be reported to this day." *Id.* ¶ 33.

same data, Plaintiff alleges that the OS analysis was likely also put together as well, as "it is virtually certain that by the time that analysis of the SOPHIA data (as of a given cut-off date) was unmasked for PFS purposes[,] . . . the same data would have also been available and subjected to basic statistical analysis by the same time (if not well before) for OS purposes." *Id.* ¶ 38.

On May 15, 2019, MacroGenics disclosed initial interim OS data for the first time. ECF No. 34 ¶ 8. The Company disclosed that the median OS was "was prolonged by 1.7 months in patients treated with Margetuximab and chemotherapy compared to patients treated with trastuzumab and chemotherapy" and that OS "was prolonged by 6.8 months for the subset of patients that carried the CD16A 158F allele." *Id.*[6]

On June 4, 2019, MacroGenics presented interim SOPHIA data at the ASCO Conference. ECF No. 34 ¶ 9. As the Company previously disclosed, the PFS data showed "statistically significant improvement in PFS" for patients treated with Margetuximab and chemotherapy as compared to patients treated with Trastuzumab and chemotherapy. *Id.* ¶ 64. MacroGenics also announced that its interim analysis showed that median OS data for patients in the Margetuximab arm was 18.9 months versus 17.2 months in the Trastuzumab arm. *Id.* ¶ 66. In addition, the pre-specified exploratory subpopulation showed a median OS of 23.6 months in the Margetuximab arm versus 16.9 months in the Trastuzumab arm. *Id.* Because the data was "cut-off" at an early stage, the OS data was not expected to, and did not reach, statistical significance but "the results

[6] "SOPHIA also had a pre-specified 'exploratory objective' of evaluating the effect of an allelic variation (known as the CD16A 158F variation) on Margetuximab activity. Approximately 85% of the overall human population, as well as approximately 85% of patients enrolled in the SOPHIA study, carry the CD16A 158F allele[.]" ECF No. 34 ¶ 33 n.4.

existed and were (obviously) deemed sufficiently important to be presented at ASCO's annual meeting[.]" *Id.* ¶ 65.

More critically for Plaintiff, for the first time, MacroGenics also presented graphs that plotted the OS data in the form of Kaplan-Meier curves. ECF No. 34 ¶ 10.[7] Kaplan-Meier curves are linear graphs that "help assess whether observed differences are genuinely significant or are the result of only short-term effects." *Id.* Because a Kaplan-Meier curve "plots the observed OS rate over time," it allows observers to "better assess whether and to what extent the OS data – and particularly early and still 'maturing' OS data – is in fact 'on track' to show that OS differences between two treatment groups are actually statistically significant." *Id.* ¶ 70.

Kaplan-Meier curves are plotted with basic information. ECF No. 34 ¶ 69. To generate the curves, "one need only know: (a) the number of patients originally enrolled in each arm of the trial" and "(b) whether those patients were still alive or had died as of a particular cut-off date[.]" *Id.* Because doctors and patients will want to know which treatment has a higher OS rate after two years, as opposed to just a few months, "it is highly material to know whether the plotting of OS data over time . . . *consistently* shows a favorable difference" between the two treatments and "shows that the *size* of the difference is increasing over longer periods of time[.]" *Id.* ¶ 72 (emphasis in original). This information is particularly important when OS data is still not fully mature, as was the case here. *Id.* Curves that steadily widen are seen as "highly positive" in a cancer trial while curves that grow close together, cross each other, or reverse are unfavorable because "they constitute a clear indication that the OS data is not 'on track' to

[7] Plaintiff provided the graphs in the Amended Complaint. *See* ECF No. 34 ¶ 67.

generate a meaningful or statistically significant OS result when the data is fully 'matured[.]'" *Id.* ¶ 73. Curves that grow together, cross, or reverse are a "'red flag' for investors." *Id.*[8]

To Plaintiff's dismay, the Kaplan-Meier curves of the Margetuximab OS data "crossed" in several places and "separated late[.]" ECF No. 34 ¶ 10. The curves therefore "showed that SOPHIA was *not* on track to show that Margetuximab would result in a meaningfully higher overall survival rate than Trastuzumab once the study's OS data had fully 'matured.'" *Id.* ¶ 74 (emphasis in original). The curves "either overlapped or "crossed" at multiple points or "began to separate favorably to Trastuzumab and *unfavorably* against Margetuximab after roughly 24 months." *Id.* (emphasis in original). Plaintiff alleges that the overlapping and crossing of the two arms, as well as the fact that Trastuzumab was "producing much better OS results than Margetuximab after 24 months were materially adverse facts that were not disclosed to the public. . . but were known to Defendants throughout the Class Period." *Id.*

Over the next two days after the ASCO Conference, the price of MacroGenics stock fell more than 21% from trading at $18.71 on June 3, 2019 to closing at $14.66 on June 5, 2019. ECF No. 34 ¶ 11. This drop was also a decline of 43% of the stock's Class Period high on February 6, 2019 and of 27% from its February 2019 Offering price. *Id.*

C. MacroGenics' Public Statements

Plaintiff alleges Defendants made false and misleading representations and omissions in statements about Margetuximab during the Class Period. Plaintiff alleges that these wrongful statements and omissions caused them to buy MacroGenics stock at "artificially inflated prices"

[8] OS rates inevitably decline over time. The best that can be hoped for is a flat line between any two months because that would indicate that there were no new patient deaths. Thus, showing a consistent difference between the two curves that increases over time is important for assessing the success of a drug like Margetuximab against an industry standard drug. *See* ECF No. 34 ¶ 71.

and to suffer losses after the "full truth" about the study emerged. ECF No. 34 ¶ 12. The statements are, in relevant part, as follows:

1. On February 6, 2019, MacroGenics issued a press release titled "MacroGenics Announces Positive Results from Pivotal Phase 3 SOPHIA Study of Margetuximab."

   The press release stated, in relevant part:

   > The SOPHIA clinical trial met the primary endpoint of prolongation of progression-free survival (PFS) in patients treated with the combination of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy. Patients in the margetuximab arm experienced a 24% risk reduction in PFS compared to patients in the trastuzumab arm (HR=0.76, p=0.033). Notably, approximately 85% of patients in the study were carriers of the CD16A (FcγRIIIa) 158F allele, which has been previously associated with diminished clinical response to HERCEPTIN [the trade name for Trastuzumab] and other antibodies.
   >
   > In this pre-specified subpopulation, patients in the margetuximab arm experienced a 32% risk reduction in PFS compared to patients in the trastuzumab arm (HR=0.68, p=0.005). Results of the SOPHIA study are being prepared for submission for publication and presentation later this year at a major scientific conference. Follow-up for determination of the impact of therapy on the sequential primary endpoint of overall survival (OS) is ongoing, as pre-specified in the study protocol and recommended by the trial's independent Data Safety Monitoring Committee. MacroGenics anticipates submitting a Biologics License Application (BLA) to the U.S. Food and Drug Administration in the second half of 2019. . . .
   >
   > "We are pleased with the SOPHIA clinical results and are especially grateful to the patients, their caregivers, trial investigators and site personnel who participated in the study. I would also like to thank the entire MacroGenics team and our business partners who worked diligently to bring margetuximab to the clinic and execute the SOPHIA study," said Scott Koenig, M.D., Ph.D., MacroGenics' President and CEO. "Our Fc-engineered, immune-enhanced molecule has demonstrated a superior outcome in a head-to-head study against HERCEPTIN [Trastuzumab].
   >
   > We look forward to additional opportunities to develop Margetuximab in other HER2-positive breast and gastric cancer

populations.

ECF No. 34 ¶¶ 80, 132 ("February 6 Press Release").

2. The February 6, 2019 press release was then filed with the SEC as part of MacroGenics' Form 8-K. *Id.* ¶ 133.

3. MacroGenics held a conference call later on February 6, 2019 in which both Defendants Koenig and Karrels participated. Defendant Koenig stated:

> The results of the SOPHIA study are being prepared for submission – for publication and presentation later this year at a major scientific conference. Follow-up for determination of the impact of therapy on the sequential primary endpoint of overall survival is ongoing as prespecified in the SOPHIA study protocol and recommended by the Data Safety Monitoring Committee.
>
> Let me remind listeners that there are currently no approved therapies for the treatment of metastatic breast cancer patients who were previously treated with HERCEPTIN [Trastuzumab], Perjeta and Kadcyla. In this study, MacroGenics demonstrated a superior outcome in a head-to-head study against HERCEPTIN, and we're anticipating submitting a BLA to the U.S. FDA in the second half of 2019.
>
> [G]iven that this is a highly overtreated population and we're still seeing positive results, the ability to now move this up the line of therapy for breast cancer as well as for other HER2-positive tumors, I think provides us with greater upside opportunity for a commercial market for Margetuximab.

Id. ¶ 81 ("February 6 Call").

4. Later on February 6, 2019, Defendant Koenig stated in a call with an analyst that "trending for OS has been positive in the direction of Margetuximab, but we just don't have enough events to be able—to have significance here." *Id.* ¶ 82 ("February 6 Discussion").

5. The Offering Documents, which include the Registration Statement, the Prospectus and the Supplemental Prospectus, and which incorporated by reference the February 6 Press Release and the Form 8-K, stated, in pertinent part:

> In February 2019, we announced positive results from SOPHIA, our Phase 3 clinical trial of margetuximab in HER2- positive metastatic breast cancer patients. Margetuximab is an investigational immune-enhancing monoclonal antibody derived from our proprietary Fc Optimization technology platform. The SOPHIA clinical trial met the trial's first primary endpoint of prolongation of progression-free survival (PFS) in patients treated with the combination of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy. Patients in the margetuximab arm experienced a 24% risk reduction in PFS compared to patients in the trastuzumab arm (HR=0.76, p=0.033) . . . .
>
> Results of the SOPHIA study are being prepared for submission for publication and presentation later this year at a major scientific conference. Follow-up for determination of the impact of therapy on the sequential second primary endpoint of overall survival (OS) is ongoing, as pre-specified in the study protocol and recommended by the trial's independent Data Safety Monitoring Committee. We anticipate submitting a Biologics License Application (BLA) to the U.S. Food and Drug Administration for Margetuximab on the basis of the PFS results in the second half of 2019.
>
> The SOPHIA study enrolled 536 patients at approximately 200 trial sites across North America, Europe and Asia. The study evaluated margetuximab in a Phase 3 clinical trial in patients with advanced HER-2+ breast cancer who had received at least two prior lines of antiHER-2 directed therapy in the metastatic setting, or in the case of having received (neo)adjuvant pertuzumab, at least one prior line of antiHER-2 directed therapy in the metastatic setting, and who have received at least one and no more than three prior lines of therapy overall in the metastatic setting. Patients were treated with either margetuximab or trastuzumab in combination with one of four chemotherapy agents (capecitabine, eribulin, gemcitabine or vinorelbine). All study patients had previously received trastuzumab and pertuzumab, and approximately 90% had previously received ado-trastuzumab emtansine. The combination of margetuximab and chemotherapy demonstrated acceptable safety and tolerability, comparable overall to that of trastuzumab and chemotherapy.

Id. ¶¶ 84, 136 ("Offering Documents").

6. The Offering Documents also contained a recitation of risks:

> We may publicly disclose topline or interim data from time to time, which is based on preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to a particular study or trial. For example, we recently announced top line data for the SOPHIA trial of margetuximab for the treatment of certain metastatic breast cancer patients.
>
> We make assumptions, estimations, calculations and conclusions as part of our analysis of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.
>
> Top line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. In addition, the achievement of one primary endpoint for a trial does not guarantee that additional co-primary endpoints or secondary endpoints will be achieve.
>
> For example, the achievement by Margetuximab of its co-primary endpoint for progression-free survival events in the SOPHIA trial does not indicate whether the co-primary endpoint of overall survival will be achieved.

Id. ¶¶ 86, 139 ("Risk Factors").

7. Also under Risk Factors, MacroGenics stated that the "stock price is likely to be volatile" and that "some of the factors that may cause the market price of our common stock to fluctuate or decrease below the price paid in this offering" include "results and timing of our clinical trials." *Id.* ¶ 140.

8. On February 26, 2019, MacroGenics filed its Annual Report on Form 10-K, and Defendants Koenig and Karrels each signed it. *Id.* ¶ 88. In the 2018 10-K,

MacroGenics repeated statements made in the February 6 Press Release and the Offering Documents. *See id.*

9. On February 26, 2019, MacroGenics held a conference call. Defendants Koenig and Karrels participated in the call. Defendant Koenig stated, "As noted in our earlier announcement, it is too early to evaluate the sequential secondary primary endpoint to overall survival, as OS events continue to accrue in the study population." *Id.* ¶ 89 ("February 26 Call").

10. On May 1, 2019, MacroGenics issued a press release entitled "MacroGenics Provides Update on Corporate Progress and First Quarter 2019 Financial Results." The press release stated in part:

> In February, we reported topline results from SOPHIA showing that in the Phase 3 trial, progression-free survival was prolonged following treatment with margetuximab and chemotherapy compared to trastuzumab with chemotherapy. We look forward to presenting detailed results [at] ASCO. . . .
>
> An abstract containing data from SOPHIA was selected for presentation in an oral session to be held on Tuesday, June 4, 2019 at the American Society of Clinical Oncology (ASCO) Annual Meeting.

Id. ¶ 90 ("May 1 Press Release").

11. Defendants Koenig and Karrels participated in a call later that day. Defendant Koenig stated that "[a]n abstract describing the SOPHIA results has been accepted for an oral presentation at the annual meeting of the American Society of Clinical Oncology, or ASCO, to be held in June," and added that "we believe that the Phase III results in metastatic HER2-positive breast cancer . . . provide clinical validation of our Fc-optimization platform." *Id.* ¶ 91 ("May 1 Call").

12. On May 15, 2019, MacroGenics issued a press release entitled "MacroGenics Announces Positive Results from Phase 3 SOPHIA Study of Margetuximab in Patients with HER2-Positive Metastatic Breast Cancer." *Id.* ¶ 93. The Company stated that SOPHIA had met its "first sequential primary endpoint" of showing superior PFS in a "head-to-head" study against Trastuzumab. *Id.* The Company also disclosed that "[t]he median PFS of patients treated with Margetuximab and chemotherapy was 5.8 months compared to 4.9 months in patients treated with trastuzumab and chemotherapy," an improvement of 0.9 months. *Id.* The press release also stated that MacroGenics had performed an "interim" analysis on the OS data that it had as of the October 10, 2018 cut-off:

> At the time of the primary PFS analysis, overall survival (OS) data based on 158 events were immature. The median OS at that time was prolonged by 1.7 months in patients treated with margetuximab and chemotherapy compared to patients treated with trastuzumab and chemotherapy. For the exploratory subpopulation of patients carrying the CD16A 158F allele, the median OS was prolonged by 6.8 months in the margetuximab arm compared to the trastuzumab arm.

Id. ¶ 93 ("May 15 Press Release").

13. Defendant Koenig also added in the May 15 Press Release:

> The activity observed to date in SOPHIA is promising. Of note, this is the first randomized Phase 3 study that was designed to examine the potential benefit of Fc modification and the role of Fc-gamma receptor genotypes on anti-HER2 antibody efficacy. For overall survival, we anticipate the preliminary positive trend in favor of Margetuximab to continue, although subsequent results could fluctuate as additional events accrue.

Id. ¶ 94.

D. Procedural History

Former Lead Plaintiff Todd Hill commenced the action by filing the original Complaint on September 13, 2019. ECF No. 1. On November 12, 2019, CPERS filed a Motion to Appoint itself as Lead Plaintiff, ECF No. 19, which was granted on August 17, 2020, ECF No. 32. Plaintiff filed the Amended Complaint on October 16, 2020, alleging five claims. ECF No. 34. Plaintiff's first two claims allege violations of Sections 10(b) and 20(a) of the Exchange Act against MacroGenics, Defendant Koenig, and Defendant Karrels. *Id.* at ¶ 14. Plaintiff also alleged claims of strict liability and negligence in connection with MacroGenics' February 2019 Offering under Sections 11, 12(a)(2), and 15 of the Securities Act. *Id.* at ¶ 15. Plaintiff asserts that this Court has jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act and Section 22 of the Securities Act. *Id.* at ¶¶ 18, 121.

Defendants filed their Motion to Dismiss Lead Plaintiff's Amended Complaint for Failure to State a Claim pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) on November 30, 2020. ECF No. 37. Plaintiffs filed a Response in Opposition on January 29, 2021. ECF No. 46. Defendants filed a Reply on February 26, 2021. ECF No. 47. The Motion to Dismiss is now ready for review.

II. STANDARD OF REVIEW

Defendants "may test the adequacy of a complaint by way of a motion to dismiss under Rule 12(b)(6)." *Maheu v. Bank of Am., N.A.*, No. 12-cv-508-ELH, 2012 WL 1744536, at *4 (D. Md. May 14, 2012) (citing *German v. Fox*, 267 F. App'x 231, 233 (4th Cir. 2008)). To overcome a Rule 12(b)(6) motion, a complaint must allege enough facts to state a plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is plausible when "the plaintiff pleads factual content that allows the Court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

In evaluating the sufficiency of the Plaintiffs' claims, the Court accepts factual allegations in the Amended Complaint as true and construes the factual allegations in the light most favorable to the Plaintiff. *See Albright v. Oliver*, 510 U.S. 266, 268 (1994); *Lambeth v. Bd. of Comm'rs of Davidson Cty.*, 407 F.3d 266, 268 (4th Cir. 2005). The court should not grant a motion to dismiss for failure to state a claim for relief unless "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *GE Inv. Private Placement Partners II v. Parker*, 247 F.3d 543, 548 (4th Cir. 2001) (internal quotations and citations omitted). However, the Complaint must contain more than "legal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement[.]" *Nemet Chevrolet, Ltd v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 255 (4th Cir. 2009).

Several heightened pleading standards apply to this litigation. First, in claims "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) requires "that a plaintiff alleging fraud must make particular allegations of the time, place, speaker, and contents of the allegedly false acts or statements." *Adams v. NVR Homes, Inc.*, 193 F.R.D. 243, 249–50 (D. Md. 2000); *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (describing the "who, what, when, where, and how of the fraud claim").

Second, the Private Securities Litigation Reform Act ("PSLRA") imposes "additional pleading requirements on plaintiffs in securities fraud actions." *Shah v. GenVec, Inc.*, No. 12-cv-0341-DKC, 2013 WL 5348133, at *9 (D. Md. Sept. 20, 2013). The PSLRA requires Plaintiffs to "specif[y] the statements alleged to have been misleading and the reasons why they were misleading" and to "support a reasonable belief that the statements were in fact misleading." *Id.* (quoting *Teachers' Retirement System of LA v. Hunter*, 477 F.3d 162, 174–75 (4th Cir. 2007)).

"These heightened pleading standards exist because Congress recognized the potential for abuse in the securities fraud context, including 'nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests and manipulation by class action lawyers.'" *Plymouth Cty. Ret. Ass'n v. Primo Water Corp.*, 966 F. Supp. 2d 525, 538 (M.D.N.C. 2013) (citing *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006)). Accordingly, the Court should "be vigilant in preventing meritless securities fraud claims from reaching the discovery phase of litigation." *Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 623 (4th Cir. 2008).

III. DISCUSSION

A. Exchange Act Claims

1. Count I: Section 10(b) of the Exchange Act

Plaintiff's First Count alleges that Defendants violated Section 10(b) of the Exchange Act and Rule 10b–5. ECF No. 34 ¶ 111. Section 10(b) prohibits "any person" from "us[ing] or employ[ing], in connection with the purchase or sale of any security registered on a national securities exchange[,] . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Its implementing regulation, SEC Rule 10b–5, provides:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,
> (a) To employ any device, scheme, or artifice to defraud,
> (b) To 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, or
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b–5. To state a claim under § 10(b), the complaint must set forth facts showing:

> (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 (that is, the economic loss must be proximately caused by the misrepresentation or omission).

Shah, 2013 WL 5348133, at *10 (internal quotations and citations omitted); *see also Stoneridge Inv. Partners, LLC v. Scientific–Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). Defendants contend that Plaintiff has failed to allege any materially false or misleading statements or omissions and that Plaintiff has failed to allege facts giving rise to an inference of scienter, as required by the PSLRA. For the reasons below, the Court finds that Plaintiff has not alleged actionable misrepresentations or omissions nor has alleged facts supporting an inference of scienter.

a. Actionable Misrepresentation or Omission

To establish a misleading statement or omission, the amended complaint 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, . . . state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1). A challenged statement or omission must also be "'*factual*' i.e., 'one that is demonstrable as being true or false'; it 'must be *false*, or the omission must render public statements *misleading*;' and 'any statement or omission of fact must be *material*.'" *Shah*, 2013 WL 5348133, at *11 (quoting *Longman v. Food Lion, Inc.*, 197 F.3d 675, 682 (4th Cir. 1999)) (emphasis in original).

A statement or omission is "material" if there is a "substantial likelihood that a reasonable purchaser or seller of a security (1) would consider the fact important in deciding

whether to buy or sell the security or (2) would have viewed the total mix of information made available to be significantly altered by disclosure of the fact." *Shah*, 2013 WL 5348133, at *12 (quoting *In re PEC Solutions. Inc. Sec. Litig.*, 418 F.3d 379, 387 (4th Cir. 2005)). However, "Section 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). Instead, "the inquiry is whether, read as a whole, the statements or omissions would have misled a reasonable investor about the nature of the securities." *Shah*, 2013 WL 5348133, at *12 (internal quotations and citations omitted); *see also In Re Constellation Energy Group, Inc. Sec. Litig.*, 738 F. Supp. 2d 614, 624–25 (D. Md. 2010).

Plaintiff alleges that the statements identified in the Amended Complaint were "materially untrue, incomplete and misleading, and omitted material adverse information" because then-existing analysis of the October 2018 cut-off data showed that the data was "(a) not on track to support an ultimate finding that Margetuximab provided a statistically significant improvement in OS compared to Trastuzumab; (b) not on track to show that Margetuximab would meet one of the SOPHIA study's two primary endpoints . . . [and] (c) the prospects for relatively broad use and commercialization of Margetuximab, and the Company's ultimate revenue, net sales, and net income (profit) prospects . . . were materially less (and materially more uncertain) than a reasonable investor would have believed absent disclosure of the adverse information." *Id.* ¶ 83

The statements can be grouped into the following categories for analysis: statements about PFS results; statements of "superior outcome" or "positive results"; cautionary statements and Risk Factors; and statements about the interim OS data.

1. *Statements about PFS results*[9]

Plaintiff claims that when Defendants released information regarding the PFS results in the months before the ASCO Conference, they had a duty to disclose information about the OS results. *See* ECF No. 34 ¶¶ 4, 5. According to Plaintiff, the release of information about the PFS results altered the "total mix" of information available to investors, thus leaving them with a false impression of Margetuximab's success. *See* ECF No. 46 at 30, 33. In response, Defendants argue that they had no duty to simultaneously release first interim OS safety data, that investors were repeatedly told that, unlike the PFS results, analysis of the OS data would not be released until months later, and that any statements made about the PFS data did not imply that the OS results were "on track" to achieve statistical significance, let alone commercial success. *See* ECF No. 37-2 at 23, 25.

"Silence, absent a duty to disclose, is not misleading under Rule 10b–5." *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988). "Disclosure is required . . . only when necessary 'to make statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives, Inc.*, 563 U.S. at 44 (internal quotations omitted). To be sure, "'once a company speaks on an issue or topic, there is a duty to tell the whole truth.'" *Singer v. Reali*, 883 F.3d 425, 440 (4th Cir. 2018) (quoting *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250 (2d Cir. 2014)). But in these statements, MacroGenics did not "speak" on the OS data just by virtue of releasing results about its PFS data. *See, e.g.*, *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 879 n.7 (9th Cir. 2012) ("Section 10(b) and Rule 10b–5 do not categorically

[9] This category includes statements reporting PFS results in the February 6 Press Release, the Offering Documents, the May 1 Press Release, and the May 15 Press Release. *See, e.g.*, ECF No. 34 ¶ 80 ("The SOPHIA clinical trial met the trial's first primary endpoint of prolongation of progression-free survival (PFS) in patients treated with the combination of Margetuximab plus chemotherapy compared to Trastuzumab plus chemotherapy."); *id.* ¶ 93 (stating that SOPHIA had met its "first sequential primary endpoint" of showing superior PFS results in a "head-to-head" study against Trastuzumab).

prohibit statements that are incomplete or that report cumulative figures instead of detailed breakdowns of the underlying data or subcategories of data."); *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 569 (E.D. Pa. 2009) (no duty to disclose data about different patient subgroups because "Defendants consistently stated that they would only discuss the top-line results of each study"); *In re Amarin Corp. PLC Sec. Litig.*, 2021 WL 1171669, at *15 (D.N.J. Mar. 29, 2021) ("Merely announcing that results would be presented in the future does not put those results in play either. Additionally, dissemination of top-line results does not trigger a duty to disclose the full results of a study.").

Looking at the "total mix of information" available to investors during the class period, *see Shah*, 2013 WL 5348133, at *12, this Court does not find that a reasonable investor, upon hearing of the PFS results, would then be left with a mistaken impression that OS results were definitely "on track" and that Margetuximab was ensured to reach its secondary endpoint.

Therefore, because Defendants had no "duty" to simultaneously disclose OS results while reporting on their PFS results, the statements contained here are not actionable.

2. *Statements of "superior outcome" or "positive results"*[10]

Plaintiff objects to Defendants' statements that "we believe that" the SOPHIA results provide "clinical validation," ECF No. 34 ¶ 91, that the data is "promising," *id.* ¶ 94, and shows "positive results," *id.* ¶¶ 80, 93.

"While opinion or puffery will often not be actionable, in particular contexts when it is both factual and material, it may be actionable." *Longman*, 197 F.3d at 683. But "corporate

[10] This category includes statements from the February 6 Press Release, the February 6 Call, the February 6 Discussion, and the May 15 Press Release. The Offering Documents, and the 2018 10-K also incorporated the statements from the February 6 Press Release by reference. *See, e.g.*, ECF No. 34 ¶ 80 ("[Margetuximab] has demonstrated a superior outcome in a head-to-head study against [Trastuzumab]."); *id.* ¶ 81 ("[W]e're still seeing positive results"); *id.* ¶ 91 ("[W]e believe that" the SOPHIA results "provide clinical validation" of Margetuximab); *id.* ¶ 93 (press release entitled "MacroGenics Announces Positive Results"); *id.* ¶ 94 ("The activity observed to date in SOPHIA is promising.").

officials need not present an overly gloomy or cautious picture" so long as "public statements are consistent with reasonably available data." *In re Pfizer, Inc. Sec. Litig.*, 538 F. Supp. 2d 621, 631 (S.D.N.Y. 2008) (quoting *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000)).

Even if Defendants put an "unjustifiably positive spin on data available at the time[,]" such statements are "puffing" and are not actionable. *Shah*, 2013 WL 5348133, at *15 (terms such as "encouraging" and "bullish" considered puffing); *see also In re USEC Sec. Litig.*, 190 F. Supp. 2d 808, 822 (D. Md. 2002), *aff'd and remanded sub nom. Cohen v. USEC, Inc.*, 70 F. App'x 679 (4th Cir. 2003).

Plaintiff comes closer to the mark when arguing that MacroGenics' statements that the drug has "demonstrated a superior outcome in a head-to-head study against [Trastuzumab]," *see* ECF No. 34 ¶ 80, or that MacroGenics had released "positive results," *id.* ¶ 88, could be misleading because such statements are more capable of being "factual." But Margetuximab did display positive PFS results, and these statements are also broad enough as to be "puffing" or often came with accompanying caveats that "determination of . . . OS is ongoing[.]" *Id.* ¶¶ 80, 88.

"Defendants are not required to adopt [plaintiff's view of the data]. [They] may take issue with Defendants' researchers and scientists, but where a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement." *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013) (citing *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966–67 (D. Md. 1995)). Looking at the "total mix" of information available to investors, this Court cannot say that these statements were materially false or misleading. Therefore, they are not actionable.

3. Cautionary language and Risk Factors[11]

Plaintiff argues that Defendants' cautionary statements and Risk Factors warnings were materially false and misleading because they warned of a risk that they knew had already come to pass—that the OS data was not on track and, therefore, Margetuximab's prospects for achieving the OS endpoint, broad use, and commercialization had already diminished. *See* ECF No. 34 ¶¶ 87, 95.

First, "'[a] generic warning of a risk will not suffice when undisclosed facts on the ground would substantially affect a reasonable investor's calculations of probability.'" *Singer*, 883 F.3d at 442 (quoting *Meyer*, 761 F.3d at 251). Here, the Offering Documents included a detailed Risk Factors section warning that MacroGenics might release interim results that are subject to change—far from the "general warnings" of risk that the Fourth Circuit has found misleading. *See Singer*, 883 F.3d at 442. Investors were well-warned of the risks of investing in a drug where studies were ongoing. Defendants' repeated cautionary statements would not cause a reasonable investor to conclude the opposite—that there were no risks associated and that the preliminary positive results would continue. Instead, the Risk Factors "warned investors of the very risks Plaintiff claims were not disclosed." *Recupito v. Prudential Sec., Inc.*, 112 F. Supp. 2d 449, 457 (D. Md. 2000).

Second, it is true that some courts have held that a warning of future risk that has already come to fruition can be misleading. *See In re Van Der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 400 (S.D.N.Y. 2005). But if the risk warned of has not actually "transpired" or

[11] The Risk Factors warning in the Offering Documents states, "We may publicly disclose topline or interim data from time to time, which is based on preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to a particular study or trial…[T]he topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated." ECF No. 34 ¶ 86. Similarly, in the May 15 Press Release, Defendant Koenig warned that OS "results could fluctuate as additional events accrue." *Id.* ¶ 94.

made a "near certainty," then it is not misleading. *See In re FBR Inc. Sec. Litig.*, 544 F. Supp. 2d 346, 362 (S.D.N.Y. 2008) (finding that cautionary statements were not materially misleading because, inter alia, "[a]t the time that the cautionary statements were made, the risk that … would actually cause a loss to the company or its shareholders had neither 'transpired' nor become a 'near certainty.'")

Here, it is not sufficiently clear that, even assuming that Defendants had full access and knowledge of the OS data and associated Kaplan-Meier curves, failure had become a "near certainty" for Margetuximab such that MacroGenics' repeated cautionary statements were materially misleading.[12] Thus, the cautionary statements and risk warnings are not actionable.

4. *Statements about interim OS data*[13]

Plaintiff next argues essentially that, because the OS data was "vitally important" to investors, it was material and required to be disclosed. *See* ECF No. 46 at 26, 30.

"'Disclosure of an item of information is not required . . . simply because it may be relevant or of interest to a reasonable investor.'" *Lerner*, 273 F. Supp. 3d at 588 (quoting *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002)). This Court does not doubt that Plaintiff and other investors were eager to know full details of the SOPHIA Study, but, as explained above, Defendants made no statements implying that successful PFS results meant that successful OS

[12] As Defendant explains, failure to achieve the OS endpoint "cannot be assessed until the pre-specified number of deaths in the study occur." ECF No. 47 at 14 n.14. The interim OS data was "cut-off" as of October 10, 2018 when only 158 OS events (or 41% of the total needed) had happened. ECF No. 37-2 at 12 n.4. Therefore, MacroGenics would not be able to assess the "failure" of the endpoint until a point in the future—let alone be ensured failure in its commercial prospects.

[13] This category includes statements in the February 6 Press Release, the February 6 Call, the 2018 10-K, the Offering Documents, and the May 15 Press Release. *See, e.g.*, ECF No. 34 ¶ 80 ("Follow-up for determination of the impact of therapy on [OS] is ongoing[.]"); *id.* ¶ 82 (stating that "trending for OS has been positive in the direction of Margetuximab, but we just don't have enough events to … have significance here"); *id.* ¶ 94 ("For overall survival, we anticipate the preliminary positive trend in favor of Margetuximab to continue, although subsequent results could fluctuate as additional events accrue.").

results were guaranteed. Instead, Defendants simply reported accurately on the PFS data while reminding investors that, in comparison, the OS data would not be released until later. *See* ECF No. 34 ¶¶ 84, 91. Investors were well-aware that they did not have a clear picture of the OS data.

Plaintiff next objects to Defendants' characterizations of the OS data as trending "positive" or showing a "preliminary positive trend" that they "anticipate[d]" would continue. ECF No. 34 ¶¶ 82, 94. Plaintiff does not allege that the May 15 disclosure of interim OS data, which indeed shows an early positive trend, is false. *See id.* ¶ 93. As explained previously, if there is a "reasonable basis for Defendants' expressions of optimism," *Shah*, 2013 WL 5348133, at *14, such statements are not materially false or misleading. Further, these statements were accompanied by warnings that "subsequent results could fluctuate," *id.* ¶ 94, and that "we just don't have enough events" for significance, *id.* ¶ 82. The risk that Margetuximab might never reach the OS endpoint "was a known risk to investors." *Shah,* 2013 WL 5348133, at *14.[14] These statements are not actionable.

Finally, Plaintiff argues that Defendants' failure to release the accompanying Kaplan-Meier curve data until the June conference was itself a material omission. *See* ECF No. 34 ¶¶ 10, 95. Mere disagreement with a defendant's "methodology, interpretation of the data, or expressions of optimism" does not make a securities violation. *Lerner*, 273 F. Supp. 3d at 592. "'Defendants, like any other company wishing to publicly discuss the results of a scientific study, had to make a judgment as to which specific bits of information about the study and its conclusions to disclose.'" *Id.* at 590 (quoting *Padnes v. Scios Nova Inc.*, 1996 WL 539711, at *5

[14] In addition, as Defendants claim, *see* ECF No. 37-2 at 31, the statement that "we anticipate" a positive trend to continue is also protected as a "sincere statement of pure opinion" under *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 186 (2015) ("[A] sincere statement of pure opinion is not an 'untrue statement of material fact,' regardless whether an investor can ultimately prove the belief wrong.").

(N.D. Cal. Sept. 18, 1996)). Plaintiff has failed to show an actionable misrepresentation or omission because investors are not entitled to several forms of data or data in a preferred form.[15]

b. Scienter

To succeed on its Exchange Act claims, Plaintiff must also establish scienter, which requires Plaintiff to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind[.]" *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321 (2007) (citing 15 U.S.C. § 78u–4(b)(2)). The "strong inference" standard of the PSLRA "unequivocally raised the bar for pleading scienter." *Id.* (internal citations omitted). The Supreme Court and Fourth Circuit have made clear "that an inference of scienter can only be strong—and compelling, and powerful—when it is weighed against the opposing inferences that may be drawn from the facts in their entirety." *Cozzarelli*, 549 F.3d at 624 (citing *Tellabs, Inc.*, 551 at 323).

In resolving this inquiry, "[a] court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 885 (4th Cir. 2014) (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009)). Hence, "when the facts as a whole more plausibly suggest that the defendant acted innocently—or even negligently—rather than with intent or severe recklessness, the action must be dismissed." *Cozzarelli*, 549 F.3d at 624 (4th Cir. 2008). Additionally, "'[i]f the defendant is a corporation, the plaintiff must allege facts that support a strong inference of scienter with respect to at least

[15] Further, Defendants continue to disagree with Plaintiff that the OS data was negative. Defendants contend that first interim safety data "showed patients receiving Margetuximab had in fact lived longer—an disputably positive trend[.]" ECF No. 37-2 at 8 (emphasis omitted). Defendants aver that the delayed separation of the Kaplan-Meier curves "is typical for immune-oncological treatments." *Id.* at 19 (emphasis omitted).

one authorized agent of the corporation, since corporate liability derives from the actions of its agents.'" *Proter v. Medifast, Inc.*, No. 13-720-GLR, 2013 WL 1316034, at *9 (D. Md. Mar. 28, 2013) (quoting *Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 184 (4th Cir. 2007)).

Plaintiff alleges different variations of scienter. First, Plaintiff alleges that Defendants had the "motive and opportunity to commit fraud[.]" ECF No. 34 ¶ 98. Plaintiff alleges that, by issuing false and misleading statements about the SOPHIA study, Defendants intended to "deceive[] the investing public[,]" "artificially inflate[] the price of MacroGenics common stock[,]" and "cause[] Plaintiff and other members of the Class to purchase MacroGenics common stock at artificially inflated prices." *Id.* ¶ 97. Plaintiffs point to the 130% increase in stock price and the $126 million in gross proceeds during MacroGenics' second public offering as proof. *Id.* ¶ 98.

Plaintiff cannot establish scienter under this argument. Even if Plaintiff's allegations were true, it does not follow that "defendant acted with the required state of mind" to defraud investors. *Tellabs, Inc.*, 551 U.S. at 321 (2007). "We decline . . . to infer fraud from financial motivations common to every company." *Yates*, 744 F.3d at 891. "[T]he motivations to raise capital or increase one's own compensation are common to every company and thus add little to an inference of fraud." *Cozzarelli*, 549 F.3d at 627.

Plaintiff next argues that Defendants Koenig and Karrels, by virtue of their positions in MacroGenics, had "actual knowledge" that their statements were misleading because the previously undisclosed Kaplan-Meier data was likely "prepared and internally unblinded" no later than the Company's February 6, 2019 announcement. ECF No. 34 ¶ 100. According to Plaintiff, it "defies credulity" that Defendants Koenig and Karrels, "as the Company's CEO and CFO, respectively," would not have been aware of such "basic and materially adverse

information" shortly after preparation given that Margetuximab is MacroGenics' most important product. *Id.* ¶¶ 99, 100.

As this Court has explained, corporate executives' access to information and internal affairs is not enough to demonstrate scienter under the PSLRA. *Lerner*, 273 F. Supp. 3d at 593; *see also In re Criimi Mae, Inc. Sec. Litig.*, 94 F. Supp. 2d 652, 661 (D. Md. 2000). Rather, Plaintiffs must show "additional detailed allegations establishing the defendants' actual exposure" to the subject of the fraud. *Yates*, 744 F.3d at 890. This Plaintiffs have not done.

Overall, upon weighing competing inferences, this Court cannot find that Plaintiff's argument of "nefarious intent" is more "cogent and at least as compelling" as Defendants' argument of an innocent one. *See Tellabs*, 551 U.S. at 314; *Cozzarelli*, 549 F.3d at 626. While Plaintiff asserts that statements that OS data was "immature" or "accruing" were misrepresentations intended to hide that the OS data was adverse, "it is just as plausible, indeed more so, to infer that they only offered vague details about the study because it was ongoing." *In re Hum. Genome Scis. Inc. Sec. Litig.*, 933 F. Supp. 2d 751, 761 (D. Md. 2013). Indeed, that innocent inference is even more plausible here where Defendants made repeated statements that more data from the SOPHIA Study would be available in just a few months at the ASCO Conference. *See* ECF No. 34 ¶ 90. Conversely, it is implausible that Defendants hid the OS results for only a few months before, by their own choice, participating in the ASCO Conference and releasing the "truth" about the OS results.

"All investments carry risk, particularly in a field like biopharmaceuticals." *Cozzareli*, 549 F.3d at 627. "If we inferred scienter from every bullish statement by a pharmaceutical company that was trying to raise funds, we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation—exactly what Congress sought to avoid by enacting the

PSLRA." *Id.* Because Plaintiff does not meet the heavy burden to establish scienter, Count I is dismissed.

2. Count II: Section 20(a) of the Exchange Act

Plaintiff's Second Count alleges that Defendants Koenig and Karrels are liable pursuant to Section 20(a) of the Exchange Act. ECF No. 34 ¶ 115. Defendants contend that because Plaintiff has failed to allege the underlying violation of Section 10(b), Plaintiff's claim against the control persons fail as well. ECF No. 37-2 at 41.

Section 20(a) provides:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). A "claim for controlling person liability under section 20(a) must be based upon a primary violation of the securities laws[.]" *Svezzese v. Duratek, Inc.*, 67 F. App'x 169, 174 (4th Cir. 2003). Thus, because Plaintiff's claim under Section 10(b) is dismissed, the claim under Section 20(a) is dismissed as well. *See id.*; *Cozzarelli*, 549 F.3d at 628.

B. Securities Act Claims

The rest of Plaintiff's claims are pursuant to the Securities Act. The claims arise out of MacroGenics' February 13, 2019 secondary public offering. ECF No. 34 ¶ 117.

"Sections 11 and 12(a)(2) of the Securities Act apply to registration statements and prospectuses for securities, respectively. Both provisions prohibit materially false statements or omissions, although proof of scienter is not required." *Cozzarelli*, 549 F.3d at 628 (citing 15

U.S.C. §§ 77k, 77l)). The Amended Complaint alleges Section 11 and Section 12(a)(2) claims against MacroGenics and against Defendants Koenig and Karrels. ECF No. 34 ¶ 15. In addition, Defendants Koenig and Karrels are named as "control persons" liable under Section 15 of the Securities Act. *Id.*; *see* 15 U.S.C. §§ 77o.

The parties disagree as to a key preliminary issue. First, Plaintiff avers that the Securities Act claims are governed by Federal Rule of Civil Procedure 8(a) and require only "a short and plain statement of the claim showing that the pleader is entitled to relief." ECF No. 46 at 23. Defendant asserts that the heightened pleading requirement of Federal Rule of Civil Procedure 9(b) applies instead. *See* ECF No. 37-2 at 22.

The heightened pleading requirements of Federal Rule of Civil Procedure 9(b) apply to claims "alleging fraud or mistake[.]" Fed. R. Civ. P. 9(b). This Circuit, like several others, has held that Rule 9(b)'s heightened pleading requirements also apply to allegations under Section 11 or Section 12(a)(2) that "sound in fraud." *Cozzarelli*, 549 F.3d at 629. When a plaintiff alleges that the false statements are "part of a single, coordinated scheme to defraud investors" and the plaintiff's allegations that statements under the Securities Act are misleading for the same reasons that the statements are identified as fraudulent under the Exchange Act, the allegations "sound in fraud." *Id.* Even if a plaintiff's complaint expressly disclaims any allegations that could be construed as fraud, "a conclusory disclaimer cannot alter the substance of plaintiffs' allegations[.]" *Id.* (citing *California Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 160 (3d Cir. 2004); *Wagner v. First Horizon Pharm. Corp.*, 464 F.3d 1273, 1278 (11th Cir. 2006)).

While Plaintiff here takes care to keep its allegations under the Securities Act separate and expressly disclaims "intentional or reckless misconduct or that Defendants acted with

scienter or fraudulent intent[,]" ECF No. 34 ¶ 116, here, the same statements in the Offering Documents identified by Plaintiff in the Exchange Act claims are also identified in the Securities Acts claims as being "misleading" and containing "material misstatements and omissions," *see id.* ¶¶ 136, 139, for the same reason that they are alleged to be fraudulent under the Exchange Act claims, *see id.* ¶¶ 84, 86.

Thus, to survive this Motion to Dismiss, Plaintiff must "state with particularity the circumstances constituting fraud or mistake" for the Section 11 and Section 12(a)(2) claims. *See* Fed. R. Civ. P. 9(b).

1. Count III: Section 11 of the Securities Act[16]

Plaintiff brings the Third Count pursuant to Section 11 of the Securities Act. 15 U.S.C. §77k. Section 11 of the Securities Act provides that a "person acquiring [a] security" has a civil cause of action when a registration statement "contain[s] an untrue statement of a material fact or omit[s] to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a).

"Section 11 thus creates two ways to hold issuers liable for the contents of a registration statement—one focusing on what the statement says and the other on what it leaves out. Either way, the buyer need not prove (as he must to establish certain other securities offenses) that the defendant acted with any intent to deceive or defraud." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 179 (2015) (citing *Herman & MacLean v. Huddleston*, 459 U.S. 375, 381–382 (1983)).

[16] Defendant contends that Plaintiff has also failed to establish standing for the Section 11 claim. *See* ECF No. 37-2 at 39. Standing under Section 11 "is limited to those who purchased shares that were the direct subject of the registration statement that contained the actionable statement or omission." *In re 2U, Inc. Sec. Class Action*, No. 19-cv-3455-TDC, 2021 WL 3418841, at *25 (D. Md. Aug. 5, 2021) (citing *In re Ariad Pharms., Inc. Sec. Litig.*, 842 F.3d 744, 755 (1st Cir. 2016); *Krim v. pcOrder.com, Inc.*, 402 F.3d 489, 495 (5th Cir. 2005)). Because Plaintiff has alleged that it purchased its shares directly in the February 2019 offering, *see* ECF No. 34 ¶ 124, it has adequately pleaded standing.

Plaintiff contends that the Registration Statement was "inaccurate and misleading, contained untrue statements of material facts, omitted facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein." ECF No. 34 ¶ 150. For the reasons discussed above, Plaintiff has failed to show a materially misleading statement or omission.

Plaintiff also alleges claims under Items 303 and 503 of SEC Regulation S-K. ECF No. 34 ¶ 143, 145; *see* 17 C.F.R. § 229.303; 17 C.F.R. § 229.105.[17] "[A]n actionable Section 11 omission may arise when a registration statement fails to comply with Item 303 or 503 of SEC Regulation S–K." *Silverstrand Invs. v. AMAG Pharms., Inc.*, 707 F.3d 95, 102 (1st Cir. 2013) (citation omitted). To plausibly plead a claim under either, a complaint must allege (1) a registrant knew about an uncertainty or risk factor before or at the time of an offering; (2) that the known uncertainty or risk factor was "reasonably likely to have material effects on the registrant's financial condition or results of operation" or adversely affect "present or future business expectations"; and (3) that the offering documents failed to disclose the known uncertainty or risk factor. *Id.* at 103.

Far from issuing an impermissibly "generic or boilerplate" risk warning statement, *see Silverstrand*, 707 F.3d 95 at 103, Defendants did issue a thorough Risk Factors statement that, among other warnings, cautioned that "the topline results that we report may differ from future results of the same studies," "achievement by Margetuximab of its co-primary endpoint for progression-free survival events in the SOPHIA trial does not indicate whether the co-primary endpoint of overall survival will be achieved," and that "the results and related findings and conclusions are subject to change." ECF No. 34 ¶¶ 86, 139. Further, the Risk Warnings section

[17] Item 503 was recently re-codified as Item 105. *See Jaroslawicz v. M&T Bank Corp.*, 962 F.3d 701, 705 (3d Cir. 2020), *cert. denied*, 141 S. Ct. 1284, 209 L. Ed. 2d 19 (2021).

also stated that "[o]ur stock price is likely to be volatile" and "some of the factors that may cause the market price of our common stock to fluctuate or decrease below the price paid in this offering" include "results and timing of our clinical trials." *Id.* ¶ 140. These are precisely the uncertainties and risks that Plaintiff complains of.

"Securities Act claims cannot succeed in the absence of misleading statements." *Cozzarelli*, 549 F.3d at 630 (internal quotation omitted). As discussed above, Plaintiff has failed to plead that any of the statements were false or misleading, so the Section 11 claim fails.

2. Count IV: Section 12(a) of the Securities Act[18]

Plaintiff brings the Fourth Count pursuant to Section 12(a)(2) of the Securities Act. Section 12(a)(2) of the Securities Act provides that a "person purchasing [a] security" has a civil claim when a prospectus "includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements . . . not misleading." 15 U.S.C. § 77l(a)(2). Because Plaintiff has failed to establish that any of the statements are materially false or misleading, Plaintiff's Section 12(a)(2) claim fails as well.

3. Count V: Section 15 of the Securities Act

[18] Defendants also contend that Plaintiff has failed to establish standing for the Section 12 claim. ECF No. 37-2 at 39. Plaintiff counters that the Amended Complaint alleges that Defendants Koenig and Karrels "solicited the purchase [of shares]" and that the MacroGenics, a securities issuer, is a "statutory seller for Section 12(a)(2) purposes regardless of the form of underwriting." ECF No. 46 at 43, 44. First, as to Plaintiff's claims against MacroGenics, standing has been adequately alleged because an issuer can be a "seller" for the purposes of Section 12(a)(2) regardless of the underwriting method used to sell the issuer's securities. *See Citiline Holdings, Inc. v. iStar Fin. Inc.*, 701 F. Supp. 2d 506, 512 (S.D.N.Y. 2010) (citing 17 C.F.R. § 230.159A); *see also In re 2U, Inc. Sec. Class Action*, No. 19-cv-3455-TDC, 2021 WL 3418841, at *27 (D. Md. Aug. 5, 2021) (collecting cases to show that "numerous other courts have found issuers who sold their securities through a firm commitment offering liable under Section 12(a)(2) based on Rule 159A."). Second, for solicitors other than the immediate seller, "liability extends only to the person who successfully solicits the purchase, motivated at least in part by a desire to serve his own financial interests or those of the securities owner." *Pinter v. Dahl*, 486 U.S. 622, 647 (1988); *see also Citiline Holdings, Inc.*, 701 F. Supp. at 512. Plaintiff has alleged that Defendants Koenig and Karrels "solicited the purchase of securities motivated at least in part by a desire to serve their own financial interests," ECF No. 34 ¶ 166, and thus has adequately pleaded standing.

Plaintiff brings its Fifth Count pursuant to Section 15 of the Securities Act. Plaintiffs allege that Officer Defendants Koenig and Karrels as "control persons" are liable because of "the power and authority to control the contents of MacroGenics' quarterly reports, press releases, and presentations[.]" ECF No. 34 ¶ 26.

Section 15 provides that "[e]very person who . . . controls any person liable under sections 77k or 77l of this title…shall also be liable jointly and severally with and to the same extent as such controlled person[.]" 15 U.S.C. § 77o. Claims made against individual defendants under Section 15 "are, essentially, dependent derivatives of their parent statutes, and are thus properly dismissed if the parent statutes fail to state a claim upon which relief may be granted." *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 656 n.7 (4th Cir. 2004). Because this is a derivative claim, it fails as well.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss shall be **GRANTED**. A separate Order follows.[19]

Dated: September 29, 2021

/s/
GEORGE J. HAZEL
United States District Judge

[19] In a footnote, Plaintiff requested leave to amend should this Motion to Dismiss be granted. *See* ECF No. 46 at 44 n.19. However, this Court finds that "in light of the fundamental deficiencies in [P]laintiffs' theory of liability," further amendment would be futile. *Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 630 (4th Cir. 2008).