PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 21-2238

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

Plaintiff - Appellant,

and

TODD HILL,

Plaintiff.

v.

MACROGENICS, INC.; SCOTT KOENIG; JAMES KARRELS,

Defendants - Appellees.

Appeal from the United States District Court for the District of Maryland, at Greenbelt. George Jarrod Hazel, District Judge. (8:19-cv-02713-GJH)

Argued: December 6, 2022 Decided: March 2, 2023

Before GREGORY, Chief Judge, WILKINSON, Circuit Judge, and John A. GIBNEY, Jr., Senior United States District Judge for the Eastern District of Virginia, sitting by designation.

Affirmed by published opinion. Chief Judge Gregory wrote the opinion, in which Judge Wilkinson and Judge Gibney joined.

ARGUED: William C. Fredericks, SCOTT+SCOTT ATTORNEYS AT LAW LLP, New York, New York, for Appellant. Nina Fran Locker, WILSON SONSINI GOODRICH & ROSATI, P.C., Palo Alto, California, for Appellees. **ON BRIEF:** Thomas L. Laughlin, IV, Donald A. Broggi, Rihana L. Swartz, New York, New York, Jacob B. Lieberman, SCOTT+SCOTT ATTORNEYS AT LAW LLP, Colchester, Connecticut; Steven J. Toll, Jan E. Messerschmidt, COHEN MILSTEIN SELLERS & TOLL PLLC, Washington, D.C., for Appellant. Jeremy W. Gagas, Wilmington, Delaware, Laurie B. Smilan, Steffan N. Johnson, John B. Kenney, WILSON SONSINI GOODRICH & ROSATI, P.C, Washington, D.C., for Appellees.

GREGORY, Chief Judge:

In this securities class action suit, the Employees' Retirement System of the City of Baton Rouge and Parish of East Baton Rouge represents the class of persons and entities who acquired shares of common stock in MacroGenics, Inc. ("MacroGenics") between February 6, 2019 and June 4, 2019 (the "Class Period"). Plaintiffs initiated this action against MacroGenics, its president and CEO—Scott Koenig , and its senior vice president and CFO—James Karrels, (collectively "Defendants") for alleged violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, Securities and Exchange Commission ("SEC") Rule 10b–5, and sections 11, 12(a), and 15 of the Securities Act of 1933.

In their Amended Complaint, Plaintiffs alleged that after purchasing MacroGenics' stock, they experienced economic harm proximately caused by Defendants' material misrepresentations, misleading statements, or omissions concerning MacroGenics' clinical trial drug, Margetuximab. The district court granted Defendants' motion to dismiss after concluding that Plaintiffs had failed to sufficiently allege any actionable misrepresentations or omissions that would give rise to Defendants' duty to disclose, and that most of Defendants' statements were also immunized from suit. This appeal followed.

Finding the district court's analysis persuasive, we affirm.

I.

A.

MacroGenics is a public, clinical-stage biopharmaceutical company that trades under the ticker symbol "MGNX." Striving to advance new and improved treatments, the

company developed Margetuximab, an antibody treatment for patients with metastatic breast cancer. MacroGenics designed Margetuximab to target the HER2 oncoprotein, which is found on the surface of some cancer cells and causes tumors to grow. The HER2 oncoprotein is often associated with an aggressive form of the disease and a poor prognosis for patients. Margetuximab was the company's first treatment to progress to the crucial Phase 3 clinical trial, named "SOPHIA." The SOPHIA clinical trial was intended to compare how Margetuximab (in addition to chemotherapy) performed against the current standard-of-care therapeutic antigen, Trastuzumab (in addition to chemotherapy) in HER2-positive metastatic breast cancer patients who had previously undergone anti-HER2-targeted therapy treatments.

SOPHIA's clinical trial required two primary "endpoints," which are pre-determined key measures of the study's success. SOPHIA's two endpoints were: (1) prolongation of the progression free survival ("PFS") and (2) prolongation of the overall survival ("OS") of patients. PFS evaluates "how long patients enrolled in a given treatment arm of a clinical trial continue to survive, post-enrollment, without progression of the disease." J.A. 17. In other words, it tracks how many months "during and after the treatment of . . . breast cancer[] that a patient survives with the disease without the disease getting worse." J.A. 26. OS, on the other hand, measures "how long such patients survive for any reason and without regard to whether they experienced any post-enrollment progression of their disease[]." J.A. 17. More specifically, its focus is on "the length of time from either the date of diagnosis or the start of treatment for . . . breast cancer[] that patients diagnosed with the disease are still alive." J.A. 26. Beginning in 2016, SOPHIA enrolled 536

patients—i.e., the intent-to-treat ("ITT") population—who were divided into two arms of the trial: (1) Margetuximab with chemotherapy or (2) Trastuzumab with chemotherapy. MacroGenics' primary objective "was to . . . show that the Margetuximab-based treatment delivered meaningfully superior PFS and OS results compared to the Trastuzumab-based treatment." J.A. 26.

In a February 6, 2019 press release (the "February 6 Press Release"), which was published prior to the market's opening, MacroGenics revealed that, as of October 10, 2018, SOPHIA had reached its first PFS-related endpoint (having hit 265 PFS events[1]) and stated that:

> 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* . . . .
>
> "We are pleased with the SOPHIA clinical results . . ." said Scott Koenig . . . "Our Fc-engineered, immune-enhanced molecule *has demonstrated a*

[1] Post-enrollment in the SOPHIA trial, the PFS endpoint will be satisfied when 265 patients—or events—will survive without progression of their metastatic breast cancer. Whereas the OS endpoint will be fulfilled when 385 patients—or events—will, inevitably, pass away.

> *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."

J.A. 28–29 (emphasis added)

Later that same day, MacroGenics held a conference call to discuss the results (the "February 6 Call"). There, Koenig reiterated that the endpoint data for OS was "ongoing." J.A. 29. He also expressed that the results from the SOPHIA study were being prepared "for publication and presentation later this year at a major scientific conference," as "MacroGenics demonstrated a superior outcome in a head-to-head study against HERCEPTIN, and [they were] anticipating submitting a BLA to the U.S. FDA in the second half of 2019." J.A. 29–30. The "major scientific conference" referred to the upcoming June 2019 American Society of Clinical Oncology ("ASCO") Conference. The deadline to submit abstracts for presentations for this conference was February 12, 2019.

Also on the February 6 Call, after being asked about the progression of OS, Koenig explained that although filing with the FDA was not dependent on this data, "the 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." J.A. 30. Due to the February 6 Press Release and Call, Plaintiffs allege that MacroGenics' common stock ascended from $11.11 to $15.49 in one day.

On February 12, 2019, MacroGenics announced that it would conduct another public common stock offering. The following day, the Company sold 6.325 million shares of common stock at an offering price of $20 per share. The Amended Complaint posits

that investors paid over $126 million to acquire these shares and MacroGenics' net proceeds approximated $118.7 million. After the offering, MacroGenics filed a Prospectus Supplement (the "Prospectus"), to their Form S-3 Registration Statement and initial prospectus filed on November 2, 2016 with the SEC. Plaintiffs refer to these documents collectively as the "Offering Documents." The language found in the Offering Documents incorporated the February 6 Press Release, detailed above. The Offering Documents also disclosed a "Risk Factors" Section which emphasized:

> We may publicly disclose topline or interim data from time to time, which is based on a 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 the 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 analyses 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 achieved.* 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.*

J.A. 64 (emphasis added). In its Annual Form 10-K ("2018 10-K") submitted to the SEC on February 26, 2019, MacroGenics incorporated language previously detailed and further asserted that:

> In February 2019, we announced positive results from SOPHIA, our Phase 3 clinical trial of margetuximab in HER2-positive metastatic breast cancer patients . . . Results of the SOPHIA study *have been submitted* for

> 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 prespecified in the study protocol and recommended by the trial's independent Data Safety Monitoring Committee.

J.A. 33 (emphasis added). The same day, the Company held a conference call ("February 26 Call") where Koenig and Karrels discussed SOPHIA's PFS endpoint results and, in passing, the interim OS results:

> 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*. We plan to meet with the FDA in the first half of 2019 and anticipate submitting a biologics licensing application to the FDA on the basis of the PFS results in the second half of 2019. *We have already submitted an abstract containing previously disclosed as well as additional results to the ASCO meeting in June*. In this regard, we are currently reviewing options and strategies for commercialization, assuming margetuximab receives FDA approval in this indication.

J.A. 34 (emphasis added). MacroGenics then issued a press release on May 1, 2019 ("May 1 Press Release") which noted, in relevant part, that the PFS results were prolonged with Margetuximab in comparison to Trastuzumab, and that these results were to be presented at the ASCO Conference where an "abstract containing data from SOPHIA was selected for presentation." J.A. 34. Also on May 1, MacroGenics held its quarterly earnings conference call ("1Q2019 Call") where Koenig and an analyst had the following dialogue:

> [Analyst:] Can you please help set investor expectations ahead of the ASCO update, and specifically what sort of data will be presented, and will you have *survival data* in the ASCO presentation?
>
> [Koenig:] . . . Obviously *we're very excited about being able to disclose additional data from the SOPHIA trial*. There will be obviously an abstract coming out in mid-May, and this will be followed up obviously with a presentation on the morning of June 4. Our expectation is obviously to provide a recapping of the data we presented on the intent-to-treat population, on

> various subset populations, particularly looking at the F allele 158 population where we've seen the significant response rate. *And we will likely present the OS data at that point, which was disclosed or examined at the time of February 5 when we had our initial data*. There will be analysis of different subsets that were defined as secondary endpoints. And I presume that — that data presentation has not obviously been put together yet, but it should be very revealing in terms of where we think the promise of this drug is.

J.A. 35 (emphasis added). Koenig also asserted that "*it is too early to evaluate the second sequential primary endpoint of overall survival* as OS events *continue to accrue* in the study population." *Id*. (emphasis added).

On May 15, 2019, after the markets closed, MacroGenics issued a subsequent press release ("May 15 Press Release"), which discussed—for the first time in detail—the OS data that was accumulated from the October 10, 2018 cut-off date, the same day SOPHIA achieved its PFS endpoint. The May 15 Press Release declared:

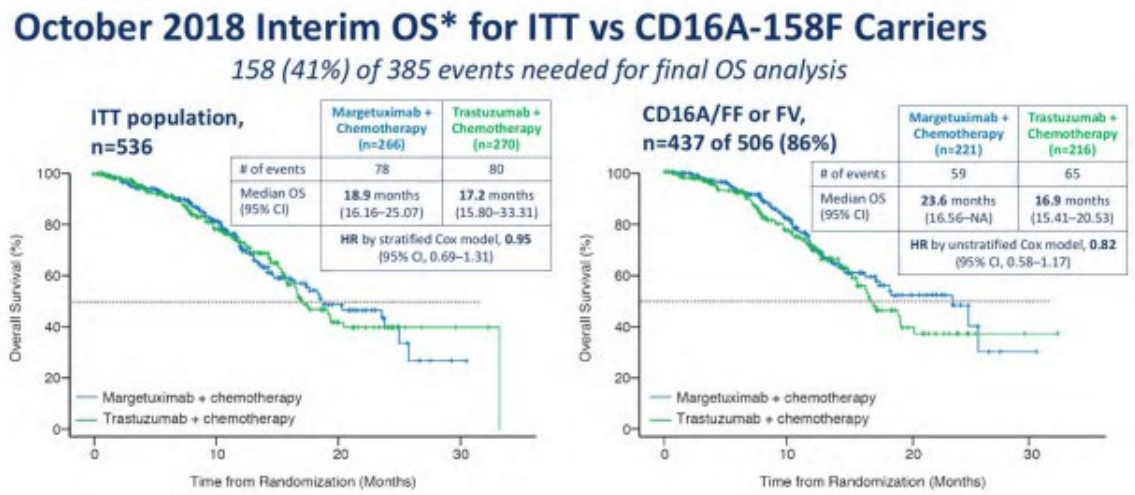
> At the time of the primary PFS analysis, *overall survival (OS) data based on 158 events were immature*. *The median OS at that time was prolonged by 1.7 months in patients treated with margetuximab and chemotherapy* compared to patients treated with trastuzumab and chemotherapy. For the exploratory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

J.A. 36 (emphasis added). These 158 OS events—or deaths—encompassed only forty-one percent of the overall population, and the data was premature given the early stage of the

data cut-off. The OS data were *interim*, and therefore not complete, as they had not yet reached their second endpoint.

Following the May 15 press release, MacroGenics witnessed a successive surge in its stock, which increased from $16.25 per share at the close of May 15 to $18.00 on May 16 and $18.71 on May 17. This raise "represented a one-day increase of $1.73 (or more than 10.6%) and a two-day increase of $2.44 (or 15.0%)." J.A. 36.

On June 4, 2019, MacroGenics presented the SOPHIA data from the October 10, 2018 cut-off at the ASCO Conference. The company declared the data depicted a "statistically significant improvement in PFS" for the patients in the Margetuximab cohort compared to the Trastuzumab cohort of the ITT population. J.A. 36–37. MacroGenics also presented a visual depiction of the interim OS data plotted on this Kaplan-Meier curves graph[2]:



[2] The Amended Complaint asserts that "[t]o graph Kaplan-Meier curves, one simply needs to have the study data concerning the number of ITT patients who, over a relevant time interval, have either survived or died." J.A. 39. For the SOPHIA trial's Kaplan-Meier curves specifically, Plaintiffs further allege that "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.*

J.A. 38. Dr. Rugo—one of the SOPHIA trial's independent investigators who presented this data at the ASCO Conference—expressed that the Kaplan-Meier curve graph demonstrated "the median OS was 18.9 months in the Margetuximab arm versus 17.2 months in the Trastuzumab arm" and "in the . . . subpopulation of patients carrying the CD16A 158F allele, the median OS was 23.6 months in the Margetuximab arm versus 16.9 months in the Trastuzumab arm." J.A. 37–38. Plaintiffs allege that, as the Kaplan-Meier curves graph shows, the "curves that grow closer together" or "cross" are "*unfavorable*, as they constitute a clear indication that the OS data is not on track to generate a meaningful or statistically significant OS result when the data is fully matured and a red flag for investors." J.A. 41 (internal quotation marks omitted). Specifically, Plaintiffs claim that

> (a) the curves either overlapped or "crossed" at multiple points in time as one moves left-to-right along the x-axis; and (b) the curves not only crossed, but began to separate favorably to Trastuzumab and unfavorably against Margetuximab after roughly 24 months (two years). Both 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 until the June 2019 ASCO Conference, but were known to Defendants throughout the Class Period.

J.A. 41–42. Following the ASCO Conference, and multiple analyst reports and articles[3], MacroGenics' stock plummeted, representing a "two-day decline of nearly 22%." J.A. 43.

[3] Plaintiffs focus on the following: Evercore ISI's analyst report describing SOPHIA's OS data as "underwhelming . . . so far," J.A. 42; Cowen Inc.'s analyst report commenting "[w]e believe the stock weakness after the presentation was due to investor concern about the magnitude of PFS benefit and initial OS signal, which only included 41% of required events[,]" *Id.*; and a *Vantage* article stating "[t]he sting in this case came in the form of survival curves . . . [which] separated relatively late in the analysis and crossed several times," J.A. 43.

B.

Plaintiffs brought this securities class action against Defendants on September 13, 2019. They later filed an Amended Complaint which asserted violations of § 10(b) of the Exchange Act and Rule 10b-5 (Count I); § 20(a) of the Exchange Act (Count II); § 11 of the Securities Act (Count III); § 12(a) of the Securities Act (Count IV); and § 15 of the Securities Act (Count V).

Defendants filed a motion to dismiss for failure to state a claim pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) on November 30, 2020. Defendants asserted that the class had failed to allege any materially false or misleading statements or omissions that give rise to an inference of scienter, as required by the Private Securities Litigation Reform Act ("PSLRA"). In support of this argument Defendants attached twenty exhibits to their motion to dismiss, which they claimed were either referenced in Plaintiffs' Amended Complaint or served as explanatory tools for their motion.

The district court granted Defendants' motion to dismiss. In determining whether Defendants' statements contained misleading representations or omitted material information and whether they had a duty to disclose, the court analyzed the statements in four groups: (1) statements about PFS results; (2) statements of "superior outcome" or "positive results"; (3) cautionary statements and Risk Factors; and (4) statements about the interim OS data.

Under the first bucket, the court held that, looking at the "total mix of information" given to investors during the Class Period, reasonable investors "upon hearing of the PFS results, would [not] be left with a mistaken impression that OS results were definitely 'on

track' and that Margetuximab was ensured to reach its secondary endpoint." J.A. 468. As to the second category, the court determined that these positive statements were mere puffery and not actionable. Concerning the third set of statements, the court concluded that the cautionary statements and Risk Factors were not misleading because it was unclear whether or not failure was inevitable, even if Defendants had full access and knowledge of the OS interim data. Finally, the court concluded that the statements about the interim OS data put investors on notice "that [MacroGenics] did not have a clear picture of the OS data." J.A. 472. Further, the court characterized Plaintiffs' frustration with Defendants' belated release of the Kaplan-Meier curves as a "mere disagreement with [the] defendant's methodology, interpretation of the data, or expressions of optimism," rather than a securities violation. *Id*. (internal citations omitted).

The court then determined that Plaintiffs failed to sufficiently plead scienter, the required second step for prevailing on Exchange Act claims, because Defendants did not have the state of mind necessary to defraud investors. The district court thus dismissed Count I. And because Count II, Plaintiffs' derivative § 20(a) claim, required "a primary violation of the securities laws," *Svezzese v. Duratek, Inc.*, 67 F. App'x 169, 174 (4th Cir. 2003), the district court also dismissed this claim.

The court also dismissed Plaintiffs' §§ 11 and 12(a) Securities Act claims (Counts III and IV), finding that they rested on the same Exchange Act assertions as Counts I and II. Finally, the district court dismissed Plaintiffs' derivative § 15 claim (Count V), which could not survive after the dismissal of Counts III and IV. Plaintiffs' timely appeal followed.

II.

We review de novo a district court's decision to dismiss a plaintiff's complaint under Federal Rule of Civil Procedure 12(b)(6). *In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 387 (4th Cir. 2005). In order to survive a motion to dismiss, Plaintiffs' "private securities fraud actions must clear the hurdle of the PSLRA," which imposes a heightened pleading standard. *Id.* (cleaned up). This Court must "accept all factual allegations in the complaint as true" and "consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

III.

A.

Section 10(b) of the Securities Exchange Act prohibits any individual from the "us[ing] or employ[ing], in connection with the purchase or sale of any security, . . . any manipulative or deceptive device or contrivance 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). Rule 10b–5, which incorporates § 10(b), provides that, in connection with the sale of a security, it is unlawful "[t]o employ any device, scheme, or artifice to defraud," "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading" or "[t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon

any person." 17 C.F.R. § 240.10b–5. We have explained that the purpose of the Exchange Act and its accompanying regulations is to ensure companies' disclosure of "the information necessary for investors to make informed investment decisions." *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 884 (4th Cir. 2014).

In order for Plaintiffs' claims to prevail under § 10(b) and Rule 10b–5, they must sufficiently allege: "(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; (6) and loss causation." *Stoneridge Inv. Partners, LLC v. Scientific–Atlanta, Inc.*, 552 U.S. 148, 157 (2008).

To establish a "misrepresentation" (misleading statement) or "omission," under the PSLRA's heightened pleading requirement, Plaintiffs' 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"—"that is, one that is demonstrable as being true or false"; "the statement must be false, or the omission must render public statements misleading"; and "any statement or omission of fact must be material." *Longman v. Food Lion, Inc.*, 197 F.3d 675, 682 (4th Cir. 1999).

For a fact to be considered material, there must be 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." *SEC v. Pirate Inv'r LLC*, 580 F.3d 233, 240 (4th Cir. 2009). Although Rule 10b–5 "prohibit[s] any misrepresentation of a fact deemed material" it does not "prohibit any misrepresentation—no matter how willful, objectionable, or flatly false—of immaterial facts, even if it induces reactions from investors that, in hindsight or otherwise, might make the misrepresentation appear material." *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 656 (4th Cir. 2004) (cleaned up). "Ultimately, the inquiry is whether, *read as a whole*, the statements or omissions would have misled a reasonable investor about the nature of the securities." *Lerner v. Nw. Biotherapeutics*, 273 F. Supp. 3d 573, 586–87 (D. Md. 2017) (quoting *Shah v. GenVec, Inc.*, No. DKC 12–0341, 2013 WL 5348133, at *12) (D. Md. 2000) (emphasis added).

B.

On appeal, Plaintiffs allege that their claims meet this heightened pleading standard for two reasons. First, they argue that Defendants' February 2019 written statements referencing SOPHIA's PFS results put the study's interim OS results "in play," and their subsequent oral and written statements that positively characterized SOPHIA's OS data triggered a duty to disclose because they contained either materially false and misleading statements or omissions. Second, they posit that none of Defendants' statements contained immaterial puffery, inactionable opinion, or risk warnings which would immunize them from liability. We address each argument in turn.

1.

In analyzing the "total mix of information" available to investors, the district court determined that MacroGenics' release of the PFS data did not address the interim OS results by releasing the PFS data, and that a reasonable investor could not have received from MacroGenics' statements the mistaken impression that the interim OS results would inevitably satisfy the OS endpoint based solely on the PFS results. Plaintiffs posit that the district court erroneously narrowed Defendants' written statements to the PFS data, rather than SOPHIA trial's *overall* progress. Plaintiffs also contend Defendants' positive oral statements concerning the interim OS results unambiguously put the data in play. Finding these arguments unpersuasive, we agree with the district court.

a.

To begin, we consider whether Defendants' written and oral statements concerning the SOPHIA trial's PFS results—prior to the May 15 Press Release—put the trial's interim OS results "in play," thereby triggering Defendants' duty to disclose the OS Kaplan-Meier curves graph.

A company's duty to disclose all material information may emerge when it "chooses 'to speak about a material subject to investors.'" *In re Amarin Corp. PLC Sec. Litig.*, No. 21-2071, 2022 WL 2128560, at *3 (3d Cir. June 14, 2022) (quoting *City of Edinburg Council v. Pfizer, Inc.*, 754 F.3d 159, 174 (3d Cir. 2014)). Further, a company is required to disclose under § 10(b) and Rule 10b–5 when "necessary to make statements made, in light of the circumstances under which they were made, not misleading." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (cleaned up).

Defendants did not have a duty to disclose the interim OS results because their written and oral statements prior to the May 15 Press Release, did not "speak" about the OS data. In these statements, Defendants primarily focused on the SOPHIA trial's success in reaching its first PFS endpoint. Any language concerning the OS endpoint was preliminary and focused on the ongoing nature of the OS data's accumulation. For instance, in the February 6 Press Release, Defendants mentioned that SOPHIA had "met the primary endpoint of prolongation of [PFS]," then proceeded to offer an overview of the PFS's endpoint results. J.A. 28–29. In brief reference to the OS endpoint, the Press Release explicitly stated that "[f]ollow-up for determination of the impact of . . . (OS) is *ongoing*." J.A. 29 (emphasis added). Reading this statement "as a whole," *Shah*, 2013 WL 5348133, at *12, this clearly indicated to all reasonable investors that, although the *PFS* results experienced success, one could not (and should not) draw a conclusion on the OS data's performance as MacroGenics continued to track OS performance.

Plaintiffs attempt to rebut this by shifting focus to the February 6 Press Release's title, "MacroGenics Announces Positive Results from Pivotal Phase 3 SOPHIA Study of Margetuximab." J.A. 28. They contend that the title, along with Koenig's statement that Defendants were "pleased with the SOPHIA clinical results," put *all* of SOPHIA's results in play. Opening Br. at 25. Not so.

In re Amarin Corp., which bears stark similarities to the case at bar, is instructive. That Third Circuit case concerned the Phase 3 trial of "REDUCE-IT," which evaluated whether Vascepa—a drug intended to treat heart disease—could reduce major adverse cardiac events. 2022 WL 2128560, at *1. After announcing topline results through a press

release and a subsequent conference call, the company's shares skyrocketed; it further informed the public that the full conclusive results of the trial would be disclosed at a conference later that year. *Id.* After Amarin revealed the full results, a group of health field professionals expressed concerns that the mineral oil placebo utilized in the trial was not inert, which, if true, could have significantly inflated REDUCE-IT's results and Vascepa's efficacy. *Id.*

Following these comments and the Corporation's disclosure of the full trial data, Amarin's stock plummeted. *Id.* Plaintiffs then pursued a class action suit alleging violations of §§ 10(b) and 20(a) of the Exchange Act, asserting that Amarin's press release and conference call announcing REDUCE-IT's topline results were materially misleading. *Id.* They further alleged that Amarin had a duty to disclose information surrounding the mineral oil placebo because discussion of the topline results put this information in play. *Id.* at *2. The Third Circuit determined that even though Amarin referenced the placebo group in its discussion of the topline results, the Corporation did not put the full trial data or information regarding the mineral oil placebo in play because it did not express "any affirmative characterizations regarding the effectiveness of the mineral oil placebo." *Id.* at *3.

So too, here. Although the title of the MacroGenics February 6 Press Release did not qualify that the positive results were specifically related to PFS, that much was delineated by the text of the press release. *See Kleinman v. Elan Corp., PLC*, 706 F.3d 145, 153 (2d Cir. 2013) (holding that "given the context of the statements, no reasonable investor could have understood the headline to mean anything other than the positive subgroup results"). Even more, a company's mere *reference* to full trial data in a discussion

of top-line results "does not trigger a duty to disclose the full results of a study." *In re Amarin Corp. PLC Sec. Litig.*, No. 3:19-cv-06601, 2021 WL 1171669, at *15 (D.N.J. Mar. 29, 2021). Thus, Defendants' reference to the accumulation of OS data when announcing the PFS top-line results did not put this interim information in play.

b.

Next, Plaintiffs allege that Defendants' oral statements (made during the initial February 6 Call and other occasions up to and including the May 15 Press Release) characterizing the OS data positively, unambiguously put the OS data in play and thereby triggered a duty to disclose the "material adverse facts." Opening Br. at 26. We disagree.

Defendants did not have a duty to disclose the Kaplan-Meier curves graph because they orally communicated the OS interim data prior to the graph's inaugural appearance at the June ASCO Conference. "Where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study." *Lerner*, 273 F. Supp. 3d at 587–88. It would be a stretch for us to find the existence of false or misleading statements where "a defendant's competing analysis or interpretation of data is itself reasonable," regardless of Plaintiffs' disagreement with the study's "researchers and scientists." *Kleinman*, 706 F.3d at 154.

Plaintiffs do not challenge the OS interim data itself, but they contest Defendants' *interpretation* of it. According to Plaintiffs, the Kaplan-Meier curves graph was inconsistent with Defendants' positive statements. But as indicated by the graph's depiction, and despite the Plaintiffs' stressed importance on the graph's visual crossing, Defendants accurately interpreted the OS interim data. The message of the May 15 Press

Release and the graph was the same: of the 158 events (41% of the OS population) collected at the October 2018 cut-off, Margetuximab exhibited a prolongation of life over Trastuzumab. Though the Kaplan-Meier curves graph was not presented alongside the May 15 Press Release, the data was consistent; the only difference is how and when the information was provided. At bottom, the Kaplan-Meier curves graph was not a fact contrary to Defendants' positive statements. Because Defendants' positive OS-related statements were not false or misleading, or an omission of the interim OS data, we cannot conclude that they had a duty to disclose the graph itself.

Assuming—without deciding—that Defendant's statements were material, the graph's depiction of the OS data was not a material fact requiring disclosure. Defendants distinguish a handful of cases where we, and the Supreme Court, have found that material adverse facts properly triggered a duty to disclose.

In *Matrixx*, the Supreme Court determined that disclosure was required where a manufacturer informed the market of specific revenue projections and was cognizant of, but denied, the causal link between defendant's drug and the significant risk of losing the sense of smell. 563 U.S. at 44–47. Unlike the defendant in *Matrixx*, Defendants here did not offer any specific revenue projections and clearly informed the public of all risks associated with purchasing MacroGenics' stock based on the interim results of the SOPHIA trial.

Turning to our precedent, in *Zak v. Chelsea Therapeutics International, Ltd.*, 780 F.3d 597, 609 (4th Cir. 2015), we concluded that disclosure was necessary when defendant's public statements conflicted with its awareness of non-public information concerning a new

drug's application status and the FDA's expectation for additional, successful efficacy studies prior to the drug's approval. Contrary to *Zak*, here, Defendants' alleged awareness of the Kaplan-Meier curves graph did not conflict with their public statements. Instead, Defendants accurately depicted the data the graph later illustrated while also warning that these results were not indicative of Margetuximab's overall success.

Finally, in *Singer v. Reali*, 883 F.3d 425, 440 (4th Cir. 2018), we determined that defendants' disclosure was crucial when they had chosen to inform the market that they were training surgeons on how to obtain reimbursements but failed to disclose that it was doing so through a fraudulent reimbursement scheme operation. Here, Plaintiffs failed to allege that Defendants acted deceptively in issuing the positive OS-related statements. Rather, based on the facts pleaded, Defendants' optimism appears to have been warranted given how the Margetuximab cohort's PFS endpoint and OS interim results out-performed the Trastuzumab cohort. Given this instructive precedent, we conclude that Defendants did not have a duty to disclose the Kaplan-Meier curves graph prior to the ASCO Conference.

2.

We also agree with the district court that a handful of Defendants' statements, some of which have been previously discussed, are also inactionable as a matter of law because they amount only to puffery or inactionable opinion, warrant protection under the PSLRA's Safe Harbor Provision, or are sufficiently hedged with cautionary statements and risk warnings.

a.

We start with puffery. Although a statement of "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. Yet, "expressions of puffery and corporate optimism" generally do not constitute securities violations. *Kleinman*, 706 F.3d at 153.

Defendants' statements on the February 6 Call, May 1 Call, and in the May 15 Press Release, respectively, vocalized: "trending for OS has been positive in the direction of margetuximab," J.A. 30; "we're very excited about being able to disclose additional data from the SOPHIA trial," J.A. 35; and "[t]he activity observed to date in SOPHIA is promising" and "[f]or [OS] we anticipate the preliminary positive trend in favor of Margetuximab to continue," J.A. 36. These statements are nothing more than expressions of optimism. Defendants' use of the words "positive," "excited," and "promising" are textbook examples of puffing statements that reasonable investors cannot rely upon in the hopes of a grand slam, when the bases aren't even fully loaded.

Also, Plaintiffs have failed to demonstrate how these positive statements misrepresented the interim OS data. Much of their assertions rest on the belief that the Kaplan-Meier curves graph was "objective, adverse data that materially undercut" Defendants' positive statements. Opening Br. at 34. However, and as discussed, Plaintiffs have failed to demonstrate with specificity how or why they arrived at this crossroad. And without specific allegations to support their position, we cannot reasonably infer it is correct. Indeed, Plaintiffs' Amended Complaint failed to sufficiently allege *when* the Kaplan-Meier curves graph was created and known to Defendants. Even more, Defendants' May 15 Press Release accurately portrayed the interim OS data that was later displayed on the Kaplan-Meier curves graph. At bottom, Defendants' words were merely

"soft, puffing statements," *Longman*, 197 F.3d at 686, that were supported by their interpretation of the OS interim data.

Moreover, Defendants consistently qualified their expressions of optimism with warnings that the OS endpoint could still fail. *See* J.A. 29 ("[f]ollow-up for determination of the impact of therapy on the sequential primary endpoint of [OS] is ongoing"); J.A. 30 ("the 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"); J.A. 35 ("it is too early to evaluate the second sequential primary endpoint of [OS] as OS events continue to accrue in the study population"). In short, each of Defendants' statements was hedged with guarded and restrained positivity. Looking at these statements in full, a reasonable investor could not have exclusively clung to these statements when deciding to purchase MacroGenics' stock. *See Longman*, 197 F.3d at 685–86.

b.

Defendants' positive statements about the interim OS data can also be classified as inactionable opinions, affording them further protection from suit. Unlike statements of fact, statements of opinion do not "express[] certainty about a thing." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 183 (2015). "Opinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." *Pfizer*,754 F.3d at 170; *see also Lerner*, 273 F. Supp. 3d at 591 (holding that statements of opinion can be actionable only if they were "both false and not honestly believed when they were made."). For purposes of this subsection, we will focus on Defendants' February 6 Call and May 15 Press Release.

Plaintiffs' negative interpretation of the Kaplan-Meier curves graph is merely a difference of opinion, which is insufficient to establish a securities law violation. "Interpretations of clinical trial data are considered opinions." *Pfizer*, 754 F.3d at 170. As explained, Plaintiffs' claims boil down to their interpretation of the Kaplan-Meier curves graph and Defendants' alleged failure to disclose it prior to the ASCO Conference. In Plaintiffs' eyes, the Kaplan-Meier's crossing curves were unfavorable to Margetuximab and demonstrated that the OS ultimately was not on track to be superior to the standard-of-care drug, Trastuzumab. However, Defendants' interpretation resides on greener pastures. Standing by their May 15 Press Release, Defendants appropriately assert that the Kaplan-Meier curves graph demonstrate the superior interim OS results for the Margetuximab cohort. There, they stated that "[t]he median OS at the time was prolonged by 1.7 months in patients treated with margetuximab and chemotherapy compared to patients treated with trastuzumab and chemotherapy." J.A. 36. Also that, "[f]or 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.* This was accurately demonstrated on the Kaplan-Meier curves graph which presented "for the ITT patient population, the median OS was 18.9 months in the Margetuximab arm versus 17.2 months in the Trastuzumab arm" and "of patients carrying the CD16A 158F allele, the median OS was 23.6 months in the Margetuximab arm versus 16.9 months in the Trastuzumab arm." J.A. 37–38.

In their motion to dismiss, Defendants directly refuted that the initial crossing of the Kaplan-Meier curves was typical for the delayed immunological effect of Margetuximab.

J.A. 93. As the district court correctly noted, the May 15 Press Release did "indeed show[] an early positive trend." J.A. 472. Just because Plaintiffs looked to and relied upon research disparaging the crossing curves of a Kaplan-Meier graph, it does not follow that Defendants' statements were materially misleading or contained omissions. It is much to the contrary, as the Kaplan-Meier curves graph undoubtedly portrayed the data that provided the basis for the positive opinions the company expressed in the May 15 Press Release.

We cannot instruct the district court to proceed with this case due to a difference of opinion because "[s]ecurities law is simply not a vehicle through which courts will police disagreements in the cancer research community or the parameters of clinical trials." *Zagami v. Cellceutix Corp.*, No. 15 Civ. 7194 (KPF), 2016 WL 3199531, at *13 (S.D.N.Y. June 8, 2016). Thus, Plaintiffs' allegation that Defendants' positive statements were material misrepresentations of current facts fails because the statements were inactionable opinions based on accruing data.

Plaintiffs have failed to sufficiently allege that Defendants did not believe their general positivity and enthusiasm about the results of the interim OS data. Even so, for the reasons stated above, Defendants' interpretation of the interim OS data displayed on Kaplan-Meier curves graph was accurate. This was indicated on the graph itself, which effectively transferred Defendants' verbal statements to a visual aid.

The mere fact that Plaintiffs interpreted the data in the graph differently does not make Defendants' statements actionable. An opinion "is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." *Omnicare*, 575 U.S. at 189. Thus, in considering the facts in the light most favorable to Plaintiffs and

assuming that Defendants had possession of the Kaplan-Meier curves graph when they issued the May 15 Press Release, we still cannot conclude that Defendants were obligated to disclose this visual representation.

Biopharmaceutical clinical trial drug companies constantly find themselves in the hot seat. Not only does their longevity depend on the creation of ground-breaking, experimental drugs designed to combat the world's deadliest illnesses, i.e. Cancer, but also a significant portion of their success turns on the amount of capital raised to explore these unchartered waters, making investors an integral part of the equation. Therefore, we cannot admonish these companies for issuing positive and accurate opinions while "weighing . . . competing facts," and must remind investors to "not expect that *every* fact known to an issuer supports its opinion statement." *Id.* at 190. It would be a great disservice to stifle biopharmaceutical companies' pursuit of medical advancements by failing to safeguard against an inundation of lawsuits alleging securities-law violations.

With that in mind, Plaintiffs have failed to allege that Defendants' Kaplan-Meier curves graph did not support its previous vocalization of the interim OS data. As stated, this contention demonstrates little more than a difference of opinion of the data and does not present any falsity or lack of reasonable basis. Further, apart from a brief historical discussion and a self-developed analogy, the Amended Complaint fails to allege *why* the Kaplan-Meier curves graph is the preferred method of analysis. Thus, Defendants' positive opinions are not material misrepresentations or omissions for which suit can be brought because "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." *Lerner*, 273 F. Supp. 3d at 590.

c.

Defendants' May 15 Press Release statement is further shielded from liability as a forward-looking statement under the PSLRA's "Safe Harbor" provision.

Forward-looking statements under the PSLRA include, *inter alia*, "projections of future performance, plans and objectives for future operations, and assumptions underlying statements about future financial, economic or operational performance." *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 279 (3d Cir. 2010). Future performance projections that are not phrased "as guarantees are generally not actionable" under § 10(b) and Rule 10b–5 claims. *Raab v. Gen. Physics Corp.*, 4 F.3d 286, 290 (4th Cir. 1993) (quoting *Krim v. Banctexas Grp., Inc.*, 989 F.2d 1435, 1446 (5th Cir. 1993)). Forward-looking statements will be protected by the Safe Harbor if (1) they are "accompanied by meaningful cautionary language," or (2) if "Plaintiffs have failed to plead that the speaker had actual knowledge of the statements' falsity at the time the statements were made." *In re DXC Tech. Co. Sec. Litig.*, No. 1:18cv01599, 2020 WL 3456129, at *5 (E.D. Va. June 2, 2020) (citing 15 U.S.C. § 78u–5(c)(1)); *see also Slayton v. Am. Express Co.*, 604 F.3d 758, 765–66 (2d Cir. 2010).

MacroGenics' statement "anticipat[ing] the preliminary positive trend [of OS] in favor of Margetuximab to continue," J.A. 36, is covered by the projection-of-future-performance bucket, as this forward-looking statement articulated the Company's expectation that the OS data would continue to show longevity in the Margetuximab cohort over the Trastuzumab cohort. Moreover, Defendants' statement cannot be interpreted as a

representation of present facts, which is not covered by the Safe Harbor provision. *See In Re Aetna*, 617 F.3d at 279–80. Although Defendant's statement uses "anticipate" in the present tense, the verb itself has a forward-looking definition. *See Anticipate, Merriam-Webster Online Dictionary*, https://www.merriam-webster.com/dictionary/anticipate (last viewed Feb. 17, 2023) (defining the term as "to speak or write in knowledge or expectation of *later* matter") (emphasis added). The same analysis applies to the statement's present tense use of "continue." This word, meaning "to remain in existence," *Continue*, *Merriam-Webster Online Dictionary*, https://www.merriam-webster.com/dictionary/continue (last viewed Feb. 17, 2023) offers the perception of a state that is currently occurring. But, looking at the full context of the phrase allows us to infer that the word "continue" is reliant upon the Defendants' hope that the current positive results will remain the same as time elapses. This present tense portion of Defendants' statement does not prohibit the Safe-Harbor Protection from applying because it cannot "meaningfully [be] distinguished from" Defendants' goals: to reach the OS endpoint with Margetuximab's superiority over the standard of care drug, Trastuzumab. Thus, the statement—read in its entirety—is forward-looking.

d.

Finally, Plaintiffs argue that Defendants' warnings were independently actionable misstatements that also omitted material information concerning the interim OS data (i.e., the Kaplan-Meier curves graph). We reject Plaintiffs' argument and agree with the district court's holding that Defendants' statements are immune from liability because they contained ample cautionary statements and Risk Warnings. Here, we consider all oral and

written statements from the February 6 Call through the May 15 Press Release, including Defendants' Offering Documents and the 2018 10-K filing.

As this Court has held, "[a]ll investments carry risk, particularly in a field like biopharmaceuticals." *Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 627 (4th Cir. 2008). Investors must, when making reasonable investment decisions, "read[] each statement, . . . whether of fact or of opinion, in light of all its surrounding text, including hedges, disclaimers, and apparently conflicting information." *Omnicare*, 575 U.S. at 190. However, "[a] generic warning of a risk will not suffice when disclosed facts on the ground would substantially affect a reasonable investor's calculations of probability." *Singer*, 883 F.3d at 442.

Each of Defendants' statements—when read in full and alongside any accompanying language—included a breadth of cautionary statements and risk warnings. For example, the Offering Documents (which incorporated the February 6 Press Release), had their own Risk Factors Section stating: "results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial"; "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"; and the topline results "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 achieved." J.A. 64. And, most relevant to Plaintiffs' allegations, "the achievement by margetuximab

of its co-primary endpoint for [PFS] events in the SOPHIA trial does not indicate whether the co-primary endpoint of [OS] will be achieved." *Id.*

Risk warnings and cautionary statements were either found in Defendant's statements or sufficiently crystalized in follow-up remarks. Take, for instance, the 2018 10-K the company filed on February 26, 2019 with the SEC. There, Defendants cautioned investors that the OS interim data was "ongoing." Later that same day, they emphasized on the February 26 Call that "it [was] too early to evaluate the sequential secondary primary endpoint to overall survival, as OS events continue[d] to accrue in the study population." J.A. 34. Similar cautionary statements are apparent in the February 6 Call, the May 1 Press Release and 1Q2019 Call, and the May 15 Press Release. Ultimately, Defendants' statements sufficiently warned investors and the public that the interim OS data was not final and had not reached (and may never reach) its predetermined endpoint, and that it was far too early to draw conclusions of Margetuximab's overall superiority over Trastuzumab.

Because Defendants did not omit the interim OS data (as previously determined) and their warnings were "extensive, specific and tailored" to the "very complaints" Plaintiffs raise, they are not actionable under the relevant securities laws. *See Paradise Wire & Cable Defined Benefit Pension Plan v. Weil*, 918 F.3d 312, 319 (4th Cir. 2019).

* * *

In sum, Plaintiffs' Amended Complaint has failed to sufficiently allege any actionable false, misleading material statements, misrepresentations, or omissions from Defendants. Given that, Defendants did not have a duty to disclose the interim OS data or its accompanying Kaplan-Meier curves graph. In so holding, we agree with the district

court and affirm their dismissal of Plaintiffs' suit. Because it is sufficient to affirm on these grounds alone, we decline to address the district court's finding that Plaintiffs' Amended Complaint failed to support a strong inference of scienter.[4]

In affirming the district court's dismissal of Plaintiffs' § 10(b) and Rule 10b–5 claims, we must also affirm its dismissal of Plaintiffs' derivative § 20(a) claims. *See Svezzese*, 67 F. App'x at 174 (observing that § 20(a) claims "must be based upon a primary violation of the securities laws").

C.

Finally, we assess the remainder of Plaintiffs' claims arising under §§ 11, 12(a), and 15 of the Securities Act and Items 303 and 105[5] of SEC Regulation S-K.[6]

The district court determined that these claims failed because Plaintiffs failed to plead sufficient facts showing that Defendants made materially false or misleading statements or omissions. On appeal, Plaintiffs devote little attention to challenging the dismissal of their § 11 and § 12(a) claims. Instead, they narrowly argue that Defendants

[4] Plaintiffs briefly argue that the district court could not consider the twenty exhibits attached to Defendants' motion to dismiss because the exhibits were not integral to the Amended Complaint. We decline to address this issue because we need not rely on the exhibits to affirm the district court's dismissal of the Plaintiffs' claims.

[5] When the district court issued its decision, Item 503(c) remained active. In an attempt to modernize, the SEC has since adopted Item 105 to replace Item 503(c)'s risk factors disclosure requirement.

[6] These claims arise from MacroGenics' second public offering on February 13, 2019. J.A. 57. Plaintiffs brought the §§ 11 and 12(a) claims against all Defendants, and the § 15 claim solely against Koenig and Karrels.

violated the Securities Act by "breaching their independent 'duty to speak' under Items 303 and 105 of SEC Regulation S-K." Opening Br. at 53.

Finding Plaintiffs' arguments unpersuasive, we affirm the district court's decision dismissing their Securities Act claims.

1.

Plaintiffs have insufficiently pled Defendants' alleged violation of §§ 11 and 12(a) of the Securities Act. The "basic purpose" of the Securities Act of 1933 is "to provide greater protection to purchasers of registered securities." *Yates*, 744 F.3d at 894 (quoting *Herman & MacLean v. Huddleston*, 459 U.S. 375, 383 (1983)). "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)).

Section 11 specifically provides that "any person acquiring such 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). It "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." *Omnicare, Inc.*, 575 U.S. at 179 (citing *Huddleston*, 459 U.S. at 381–82). Section 12(a) asserts 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).

As we have explained, Plaintiffs have not adequately pled a misrepresentation or omission of material facts concerning Defendants' Offering Documents. Here, Plaintiffs reiterated the Offering Documents' "Risk Factors" section, as well as the documents' incorporation of the February 6 Press Release. Their Amended Complaint also restated their belief that these statements were materially untrue, misleading, or were omissions because Margetuximab was not on track to superiority and the risks Defendants sought to warn about "had already come to pass." Opening Br. at 65. However, for the reasons discussed at length above, Plaintiffs have failed to demonstrate any materially false, misleading representations or omissions in Defendants' statements. Because Plaintiffs' §§ 11 and 12(a)(2) claims are inextricably intertwined with the alleged misstatements and omissions raised under their Exchange Act claims, their Securities Act claims cannot prevail.

2.

Plaintiffs' assertion under Item 303 meets the same fate.[7] The purpose of Item 303 is to "provide material information relevant to an assessment of the financial condition and results of operations of the registrant." 17 C.F.R. § 229.303(a). The Item requires disclosure of "any known trends . . . events or uncertainties that will result in or that are reasonably likely to result in the registrant's liquidity increasing or decreasing in any material way." 17 C.F.R. § 229.303(b)(1)(i). To assert that Defendants failed to comply with Item 303's disclosure provisions, Plaintiffs must allege that (1) "a registrant knew about [a trend, event, or uncertainty] before an offering"; (2) "the known [trend, event, or

[7] The Plaintiffs rightly point out that the district court conflated its Item 303 and 105 analyses. Yet, Plaintiffs' assertions nevertheless fail under proper consideration.

uncertainty] is reasonably likely to have material effects on the registrants' financial condition or results of operation"; and (3) "the offering documents failed to disclose the known [trend, event, or uncertainty]." *Silverstrand Inv. v. AMAG Pharm., Inc.*, 707 F.3d 95, 103 (1st Cir. 2013) (internal quotation marks omitted).

The allegations in the Amended Complaint do not plausibly meet this test, failing at the first step. Although the Amended Complaint informs us that Defendants' interim OS data was cut off in October 2018 when SOPHIA accomplished its PFS endpoint, we cannot infer that Defendants believed SOPHIA's interim OS data created an overall "trend" that forecasted "uncertainty" about the OS data's final results. Actually, it is quite the opposite. At the time, Defendants did disclose the only trend of which they were aware. They were excited because—per their analysis—the interim OS data did demonstrate a *positive trend of longevity* over Trastuzumab at that time. Therefore, it appears that no "uncertainty" surrounded the results of the *interim* OS data.

However, despite their satisfaction with these interim results, Defendants clearly disclosed in the February 6 Press Release (which was later incorporated into the Offering Documents) that "uncertainty" remained concerning whether the OS endpoint would ever reach full fruition. The Press Release stated: "The SOPHIA clinical trial met the trial's first primary endpoint of [*PFS*] in patients treated with . . . margetuximab . . . [f]ollow-up for determination of the impact of therapy *on the sequential second primary endpoint of [OS] is ongoing*." J.A. 62 (emphasis added). Thus, Plaintiffs' do not prevail under their Item 303 claim.

3.

Plaintiffs' Item 105 claim reaches the same dead end. Under Item 105, "a discussion of the material factors that make an investment in the registrant or offering speculative or risky," when appropriate, should be provided under a section entitled "Risk Factors." 17 C.F.R. § 229.105(a). It also provides that the "discussion must be organized" to discuss each risk factor individually, with a concise explanation indicating "how each risk affects the registrant or the securities being offered." 17 C.F.R. § 229.105(a)–(b). Since the Risk Factors should describe how such risks would impact the offered securities, "generic or boilerplate discussions" will not inform investors "how the risks may affect their investment." *Silverstrand*, 707 F.3d at 103. To prevail under an Item 105 claim, a plaintiff's complaint must allege that, at the time of the offering in question, the registrant knew "(1) a risk factor existed; (2) the risk factor could adversely effect [sic] the registrant's present or future business expectations; and (3) the offering documents failed to disclose the risk factor." *Id.* For the sake of efficiency, we focus only on the third step.

Looking at the Amended Complaint, it is evident that the Offering Documents clearly asserted the risk factors associated with the SOPHIA trial, particularly the OS data and its related secondary endpoint. As the district court properly held, Defendants' Risk Factors were appropriately "thorough" and went beyond being "generic or boilerplate." J.A. 479. In its Offering Documents' Risk Factors Section, Defendants specifically stated:

- "we recently announced top line data for the SOPHIA trial . . . We make assumptions, estimations, calculations and conclusions as part of our analyses of data, and *we may not have received or had the opportunity to fully and carefully evaluate all data*," J.A. 64 (emphasis added);

- "results and related findings and conclusions *are subject to change* following a more comprehensive review of the data," also, "the achievement of one primary endpoint for a trial *does not guarantee that* . . . secondary endpoints will be achieved," for instance, "the achievement by margetuximab of its co-primary endpoint for [PFS] events in the SOPHIA trial *does not indicate whether the co-primary endpoint of [OS] will be achieved*." *Id.* (emphasis added); and

- Defendants also transparently referred to the volatility of its stock price, which they believed was determined by the "*results* and timing of" their clinical trials. J.A. 65.

Plaintiffs' allegation that these warnings are generic enough to apply to any pharmaceutical company is misplaced. Defendants' risk warnings are explicit and directly relevant to Margetuximab's SOPHIA trial. We cannot infer otherwise.[8]

4.

Because Plaintiffs' §§ 11 and 12(a)(2) claims fail, we also affirm the dismissal of its § 15 claim. Much like the Exchange Act's § 20(a), § 15 of the Securities Act is a derivative claim that depends on parent statutes (§§ 11 and 12(a)(2)), and § 15 claims are "properly dismissed if the parent statutes fail to state a claim upon which relief may be granted." *Greenhouse*, 392 F.3d at 656 n.7. Because Plaintiffs have failed to plead a primary violation of the Securities Act, they have consequently failed to plead a § 15 violation.

[8] In passing, Plaintiffs further assert that Defendants' risk warnings were insufficient because their cautionary language could not combat events that had already occurred. This argument is unavailing. We cannot reasonably infer from the Amended Complaint that, at the time of the February 2019 offering, adverse events were in swing. Rather, Defendants were pleased with how the interim OS data sat. It was not until 2021, two years after the offering in question, that the failure to achieve the final OS endpoint could be assessed, after the pre-specified number of deaths had occurred. *See* J.A. 86, 471 n.12.

IV.

Plaintiffs ask us, in the alternative, to grant leave to amend "any matters . . . pled with insufficient particularity." Opening Br. at 56. Much like we witnessed in *Cozzarelli*, Plaintiffs failed to file a motion for leave to amend before the district court, only making their request in a footnote in response to Defendants' motion to dismiss, and did not present the district court with a proposed amended complaint. *See Cozzarelli*, 549 F.3d at 630; *see also Willner v. Dimon*, 849 F.3d 93, 114 (4th Cir. 2017) (finding no abuse of discretion in district court's denial of leave to amend where Plaintiff made no formal move and failed to file any indication of the specific amendments sought). Because Plaintiffs have not met the requirements for filing a request for leave to amend under Federal Rules of Civil Procedure 7(b) and 15(a), the district court did not abuse its discretion in denying their request.

For the reasons provided herein, the district court's decision to dismiss Plaintiffs' Amended Complaint is

AFFIRMED.