IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MICHAEL J. ORTMANN, *individually and on behalf of all others similarly situated*,	*	
Plaintiff,	*	
v.	*	
AURINIA PHARMACEUTICALS, INC. *et al*,	*	Civil No. 22-1335-BAH
Defendants.	*	

* * * * * * * * * * * * * *

MEMORANDUM OPINION

Plaintiff Michael J. Ortmann ("Ortmann"), on behalf of himself and all others similarly situated, brought suit against Aurinia Pharmaceuticals, Inc. ("Aurinia"), Aurinia's Chief Executive Officer ("CEO") and President, Peter Greenleaf ("Greenleaf"), and Aurinia's Chief Financial Officer ("CFO"), Joseph Miller ("Miller" and, collectively, "Defendants") alleging violations of the Securities and Exchange Act of 1934 (the "Exchange Act"). ECF 1. The Court subsequently appointed Movant Skye Capital Partners ("Skye Capital" or "lead Plaintiff") as lead Plaintiff, ECF 44, and Skye Capital filed an amended complaint, ECF 54. Pending before the Court is Defendants' motion to dismiss the amended complaint. ECF 71. Skye Capital filed an opposition, ECF 72, and Defendants filed a reply, ECF 73. All filings include memoranda of law and exhibits, and Defendants also submitted a Joint Record of exhibits in support of their motion to dismiss in accordance with Judge Chuang's Case Management Order.[1] ECF 74. The Court has reviewed all

[1] The Court references all filings by their respective ECF numbers and page numbers by the ECF-generated page numbers at the top of the page.

relevant filings and finds that no hearing is necessary. *See* Loc. R. 105.6 (D. Md. 2023). Accordingly, for the reasons stated below, Defendants' motion to dismiss is **GRANTED**.

I. BACKGROUND[2]

Aurinia is a pharmaceutical company that specializes in "developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need." ECF 54, at 6 ¶ 19. In fact, Aurinia's flagship product—and its "sole commercial product"—is LUPKYNIS, which is a medication designed to treat adult patients with active lupus nephritis ("LN"). *Id.* The Food and Drug Administration ("FDA") approved LUPKYNIS in 2021, and Aurinia immediately began working to get LUPKYNIS into the market with as many patients as possible. *Id.* at 7 ¶ 22.

The proposed class in this case consists of those, like Skye Capital, who "purchased or otherwise obtained" Aurinia securities between May 7, 2021, and February 25, 2022. ECF 54, at 3 ¶ 1. According to Skye Capital, during this time period, Aurinia misled its investors about the success of LUPKYNIS and its future prospects. *Id.* at 4 ¶ 3. The amended complaint takes issue with Aurinia's touting of its success while failing to notify members of the class that (1) despite the fact that LN is "typically treated by nephrologists," Aurinia "mainly focused on engaging with rheumatologists"; (2) "the social and economic backgrounds of LN patients[] made them hard patients to reach"; (3) LN patients were often "non-compliant with their drug regimens"; (4) practitioners found the paperwork involved in initiating a prescription for LUPKYNIS to be "tedious" and believed that LUPKYNIS was "too expensive"; and (5) concerns over "insurance coverage limitations" deterred practitioners from prescribing LUPKYNIS. ECF 54, at 10–12 ¶¶ 35–41. The amended complaint highlights several specific statements alleged to be made

[2] In evaluating the merits of a motion to dismiss, the Court must "accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus,* 551 U.S. 89, 94 (2007).

misleading due to the omission of these pieces of information (the "key facts"). ECF 54, at 13–22 ¶¶ 46–64.

A. Defendants' May 6, 2021, Statements

On May 6, 2021, Aurinia issued a press release relating to its performance in the first quarter of 2021. ECF 54 at 13 ¶ 46. The amended complaint highlights the following section as misleading due to the omission of the above pieces of context:

> 2021 started with the FDA approval of LUPKYNIS, the first FDA-approved oral treatment for active lupus nephritis – a devastating complication of lupus . . . . Our pivotal decision and work to build a world-class commercial infrastructure prior to approval ultimately led to Aurinia being able to make LUPKYNIS immediately available to patients and physicians following approval. Since that time, the Aurinia team has been encouraged by the feedback we are receiving from physicians and patients and our confidence has only grown as we continue to understand the tremendous need and value of LUPKYNIS, and work to accelerate broader adoption across the underserved LN population.

Id.

That same day, Aurinia held an earnings call to explain its performance during the past quarter in more detail. ECF 54, at 13 ¶ 47. During this call, Greenleaf stated the following:

> So with respect to LUPKYNIS launch, as you all know by now, we were granted FDA approval around the end of January. And once we had the approval in hand, we got to work getting the therapy to patients. Max Colao is here today and he will provide [you] with more specifics in a few minutes. **But in short, we are executing the plan and I have a great deal of confidence in the team and in the trends that we are currently seeing during the first quarter and into second quarter.**
>
> We ended the first quarter with two months of hard data, which included 257 patients start forms and a solid albeit early conversion rate. These trends continue and have grown into the early part of Q2. Things are off to a good start and just like any novel drug launch, the back half of the year is going to be that much more important. As mentioned by one of our sell side analyst notes, most launches only realize a small percentage, give or take less than 5% or so, of first year sales in their initial launch quarter. We had just 60 days**. So when you look at this metric, we believe that we are right on trends and currently pointing in the right direction.**
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> . . . .

> [O]n the financial front, we ended the first quarter with just over $360 million which will support us and our efforts well into 2023. So we have a strong balance sheet to support our ongoing activities.

Id. at 13–14 ¶ 47 (emphasis and alterations in original).

B. Defendants' August 5, 2021, Statements

The next statements with which the amended complaint takes issue came on August 5, 2021. ECF 54, at 14–16 ¶¶ 49–51. On that day, Aurinia again both issued a press release and held an earnings call, this time regarding its second quarter performance and its overall performance during the first six months of 2021. *Id.* at 14–16 ¶¶ 49–50. Skye Capital highlights the following excerpt of the press release as misleading due to the omission of the five pieces of information listed above:

> **"Aurinia continues to make progress toward transforming the treatment of lupus nephritis (LN) by improving access to treatment and providing disease education and care for the long underserved LN patient community**," said Peter Greenleaf, President and Chief Executive Officer of Aurinia. "Our second quarter results demonstrate our momentum as COVID-related restrictions are loosened in parts of the United States with a significant increase in both revenue and patient start forms. **We are confident that with this year-to-date performance and a strong balance sheet, that we are well-poised for growth as we continue our work to expand the treatment of LN** and seek new opportunities that could address the needs of patients with serious autoimmune disorders."
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> Mr. Greenleaf further stated, "As we continue to expand patient access to LUPKYNIS across the United States, **we anticipate that annual net revenue for LUPKYNIS will be in the range of $40 to $50 million for 2021, setting Aurinia up for a very strong 2022 as we recognize the benefit of patients continuing on therapy** and hopefully achieving reductions in their proteinuria."
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> . . . .
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> Total revenue was $6.6 million and $29 thousand for the quarters ended June 30, 2021 and June 30, 2020, respectively. Total revenue was $7.5 million and $59 thousand for the six months ended June 30, 2021 and June 30, 2020, respectively. The increase for both periods was primarily the result of the commercial sales of LUPKYNIS following FDA approval in January 2021.

Id. at 14–15 ¶ 49 (emphasis in original). During the earnings call that day, Greenleaf made the following comments:

> So, here we are, we're well into the summer and just over five months into the LUPKYNIS launch. **I guess needless to say that we generated a lot of data points up to this point to supplement our prelaunch research and continue to learn more now that we actually have entered the real-world environment including lupus nephritis patient characteristics and healthcare professional attitudes and behaviors. With this ongoing understanding of the market and just under two quarters of commercial availability, our confidence with LUPKYNIS remains undiminished.**
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> . . . .
>
> **Next, let me walk you through our revenue performance for the quarter and provide some context because there is a positive message here as well.** In Q2, we generated $6.6 million in net sales. This number exceeded consensus expectations for the quarter **and shows the type of ramp we have expected** with the new drug and an indication that did not historically have an FDA-approved treatment. We believe this in combination with the prevailing wins [sic] of the COVID environment is a significant result.
>
> Okay, let's move on to some other positive trends. As of today, patient start forms are well north of 800 to-date and our conversion rate to patients on therapy continues to increase from what we last reported at the end of Q1. On the payer coverage front, LUPKYNIS is currently covered for over 110 million lives in the United States and we are continuing to pursue further coverage. To provide some added granularity behind that number, there are, as of today, at least 50 published LUPKYNIS clinical coverage policies.
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> Importantly, the prior authorization requirements across these policies are very much in-line with the package insert and in fact, the restrictions are less onerous than what we had originally expected. All are reasons to be optimistic. We believe this trend will continue to grow for the remainder of 2021 and drive down our time to starting therapy and drive up our overall conversion rates.
>
> **In addition, I can also report that the rate of prescription abandonment to date so far has been low** and so far, albeit it is early on in the launch, our rate of compliance is also exceeding our initial launch expectation. In the face of these results, we have also experienced some challenges and acted on many key inmarket [sic] learnings. The most prominent of these of course is the pandemic.

Id. at 15–16 ¶ 50 (emphasis in original).

C. Defendants' November 3, 2021, Statements

This pattern repeated itself in November 2021, when Aurinia issued a press release and held a conference call regarding its performance in the third quarter of 2021 as well as its performance in the first nine months of 2021 overall. ECF 54, at 16–20 ¶¶ 53–59. The press release stated the following:

> Aurinia achieved third quarter revenue of $14.7 million, with nine months ended September 30, 2021 revenue of $22.2 million and maintains its previously stated annual revenue estimate in the range of $40 to $50 million for 2021.
>
> "We are very pleased with Q3 results as we continue to execute on our LUPKYNIS commercialization strategies," said Peter Greenleaf, President and Chief Executive Officer of Aurinia. "Despite the challenge of the COVID-19 Delta variant and a slight seasonal slowdown, we saw steady increases in patient start forms and patients on treatment toward the end of the quarter and continue to see this upward momentum through October."
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> . . . .
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> **Third Quarter 2021 Highlights & Upcoming Milestones**:
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> - Aurinia has secured 412 patient start forms (PSFs) in the third quarter and as of November 3, 2021, Aurinia has secured a total of more than 1,265 PSFs.
> - PSF conversion rates continue to increase with more than 68% of PSFs converted to patients on therapy. Q2 conversion rates were 50%. Time to convert continues to decrease since launch: 30- and 60-day conversion rates have improved each month.
> - As of early October, Aurinia has confirmed coverage for LUPKYNIS through published payer policies for 65% of total lives in the market. Through patients gaining access to LUPKYNIS, the company now has confirmed coverage in plans covering 87% of total lives.

Id. at 17 ¶ 53 (emphasis in original). On the earnings call, Greenleaf's scripted remarks included the following:

> So let's start with our business performance related to the launch starting first with the quarter. In Q3, we generated $14.7 million in net sales, which exceeded analyst expectations and represents 122% increase over the prior quarter. Since the launch in late January, our total recognized revenue is $22.2 million. Based on our current metrics and anticipated year end results, we maintain our guidance in the range of $40 million to $50 million for 2021. In the third quarter, we added 412 patients, new patient star [sic] forms while COVID-19 challenges with the Delta variant and

> Southern states impacted per PSF prescribing early in the summer, it should be noted that we saw a steady increase in prescribing rates throughout September and continuing into October.
>
> As of this week, we have now logged a total of more than 1,265 patients star [sic] forms year-to-date and remain optimistic that this upward momentum will continue. We also continue to see improvements in movement from patient star [sic] forms to patients on therapy with a conversion rate in excess of 68% currently. This was up from approximately 50% in Q2. In addition, our time to convert is shrinking. Both 30 and 60 day conversion rates have continued to improve each month. On the payer coverage front, we continue to make progress, especially with regional and local plans.
>
> As of early October, we have confirmed LUPKYNIS coverage through published payer policies for 65% of total lives in the market. Through patients gaining access to LUPKYNIS, we have now confirmed coverage and plans covering 87% of total lives. While our goal is to ensure there are specific policies in place, healthcare professionals and patients are gaining access to LUPKYNIS through medical justifications and working in conjunction with Aurinia's personalized patient support resources. ***We continue to work to make access – the access process as seamless as possible for providers and patients, so that patients can quickly gain access and start our treatment.***
>
> ***Just over nine months post launch, we're not slowing down***. Our team continues to work tirelessly to educate professional in both professional and patient audience about LUPKYNIS and the urgent need to diagnose and treat lupus nephritis patients as quickly as possible. The most recent healthcare provider market research shows that LUPKYNIS awareness has increased significantly with both rheumatologists and nephrologists, and is on par with the competition, which by the way this competition has been on the market for over 10 years. LUPKYNIS is remarkable clinical results continue to differentiate our product and bolster this awareness and confidence in prescribing.

Id. at 17–18 ¶ 54 (emphasis in original).

Greenleaf also answered questions from attendees during this call. In particular, Greenleaf gave the following response to a question about seasonality in sales of LUPKYNIS:

> We've had north of 1,265 PSFs here to date. And if you just do the backwards math on that in the month of October alone, it's approximately 160 new patient start forms in the month of October alone. So I don't want anyone to take away that we've seen a slowing down at this business. We saw impact in – specifically in the Southeast as it was related to the Delta variant that was off target with what we've seen since the start of this launch. We still feel very confident in our prescription

> start form performance as it pertains to year-to-date and we don't know yet if the summer was something that's going to be a predictable seasonality. Sorry for the long-winded answer. Max, yes.

ECF 54, at 18 ¶ 55. When asked whether some providers or consumers were hesitant to use LUPKYNIS until more data was available, Greenleaf responded:

> Yes, Joe, I think, it's a great question. And I think the two biggest – in my mind, the two biggest swing factors that are hard to quantify for me today around the launch in the business, one has been the impact of COVID on our first year at a launch to quantify that for you would be difficult. I would say it definitely has, but to say whether it's 20% or 30%, we just don't know. The second – and by the way COVID decreasing and seeing lower virus rates, et cetera, we know we'll have a positive impact on our business, both with the physician access, patient access, access to care, patients staying on drug, we know that. The other thing we know that's hard to quantify is that obviously having three years worth of data both safety and tolerability data out to three years is better than having just one.
>
> And we know that it's going to help our business in lots of different ways. One, we're one of the only products that has data out this long in this patient population. So, that's an important thing to note. And with our drug in the class of CNIs, obviously we want to—while we're a new and differentiated new mechanism—a new drug, we want to continue to reinforce it, utilizing this drug over longer periods of time, doesn't compromise in any way the patient's kidney function, which we're hopeful that in three years we'll actually show that. We know that's going to have meaningful impact on both prescribing behavior and probably even more importantly how payers react to reimbursing the drug over longer periods of time when as you know our label today's safety and efficacy beyond one year has not been established. So hopefully that it's not a quant answer for you, and I apologize for that, but we think it's going to be really meaningful to both our patients, physicians and our efforts in getting the drug off the ground. And we will launch this data to the market in terms of what the outcomes are as if it were an extension of a pivotal trial, which it is.

Id. at 19 ¶ 56. Greenleaf also fielded a questions about the potential of an acquisition of Aurinia, responding to one of these questions as follows, after refusing to comment on an earlier question on the same topic:

> We have a business plan and we have a mission as a company. And that business plan is to get this drug to as many patients suffering from autoimmune disease and lupus nephritis as humanly possible.

> And we remain committed to doing that in a way that drives the most shareholder value, and we remain committed to exploring any and all avenues to complete that mission and do it in a way that is best for driving shareholder value. So I realized that that's a wide open answer, but I think if you read between the lines no one here at Aurinia has a boxed in way of thinking about how we both create value and expand access to this product more broadly, either in our hands or in someone else's or in partnership with someone, we remain open to all potential avenues.

Id. at 19–20 ¶ 57. Finally, Greenleaf answered another question by discussing issues with patient compliance:

> Yes, as we've said, it's early, so it's really hard to deduce what the trend will be going forward. We are watching both physician behavior here and patient behavior. Remember we have—***this patient population is a difficult one and can be pretty notoriously uncompliant. So we are looking very closely, not only at physician prescribing behavior, but at persistency as it pertains to the patient and staying compliant and staying on drug. And I just think, you know, we're not trying in any way walk away from this question. I just think you need more than six to nine months worth of data to say anything about the persistency of your drug.*** But over time, this is going to be one that we cannot speak about when you have a year's worth of data that's out there or more. And we, as we've said on previous calls, have every belief that we'll do that. ***So far things have looked good, but I don't want a false report that—compliance will be until I have a project—what I believe will be a projectable number and that's time.***

Id. at 20 ¶ 58 (emphasis in original).

D. A Dip in Aurinia's Stock Price

Aurinia's reports on its third quarter 2021 performance revealed a "mixed financial performance" with "earnings [that] lagged expectations." ECF 54, at 20 ¶ 60. The amended complaint alleges that this, combined with Aurinia's disclosure that LN patients are "notoriously uncompliant," resulted in a 5% drop in stock price on heavier than normal trading volume on the day that the third quarter results were reported. *Id.* at 20–21 ¶ 60. According to the amended complaint, the only reason this decrease in stock price was not more dramatic was due to Defendants' misleading statements and omissions "buoy[ing]" the price. *Id.* at 21 ¶ 61. In particular, the amended complaint alleges that Greenleaf's vague responses to questions about a

potential acquisition led investors to believe that an acquisition was "imminent," when in reality Defendants had already "received and rejected an offer to sell." *Id.* ¶ 62

E. Defendants' February 16, 2022, Statements

The final set of statements that the lead Plaintiff takes issue with were made by Greenleaf at a healthcare conference on February 16, 2022. ECF 54, at 21 ¶ 63. At that conference, Greenleaf was "asked a question regarding the Company's year-over-year sales trajectory" and responded by stating that "aggressive numbers will come from [Aurinia]," and that Defendants "want to come and show numbers that we think we can achieve, but at the same time that I'm sure we have a lot of ambition as to how we want to grow the business." *Id.* Again, the amended complaint alleges that these statements were misleading because they omitted the key pieces of information listed above. *Id.* ¶ 64.

F. Aurinia's Stock Price Crashes

"On February 8, 2022, Aurinia issued a press release announcing the Company's financial results for the fourth quarter and year ended December 31, 2021," which made clear that its 2022 revenue guidance was "far short of expectations." ECF 54, at 22 ¶ 65. According to a financial publication quoted in the amended complaint, investors had been expecting "the midway point of the company's 2022 revenue forecast to come in at around $178 million," but the actual revenue guidance for 2022 was between "$115 to $135 million." *Id.* at 22–23, ¶¶ 65–66. "On this news," the amended complaint alleges, "Aurinia's common share price plummeted $3.94 per share, or 24.26%, to close at $12.30 per share on February 28, 2022, on unusually heavy trading volume." *Id.* at 23 ¶ 67.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) governs dismissals for failure to "state a claim upon which relief can be granted." In considering a motion under this rule, courts discount legal

conclusions stated in a complaint and "accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus,* 551 U.S. 89, 94 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A court then draws all reasonable inferences in favor of the plaintiff and considers whether the complaint states a plausible claim for relief on its face. *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 253 (4th Cir. 2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

"The complaint must offer 'more than labels and conclusions' or 'a formulaic recitation of the elements of a cause of action[.]'" *Swaso v. Onslow Cnty. Bd. of Educ.*, 698 F. App'x 745, 747 (4th Cir. 2017) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). At the same time, a "complaint will not be dismissed as long as [it] provides sufficient detail about [the plaintiff's] claim to show that [the plaintiff] has a more-than-conceivable chance of success on the merits." *Owens v. Balt. City State's Att'ys Off.*, 767 F.3d 379, 396 (4th Cir. 2014).

Claims of violations of section 10(b) of the Securities and Exchange Act of 1934 and Rule 10b–5 promulgated thereunder are subject not only to the general Rule 12(b)(6) standard, but also to the heightened pleading requirements established by Rule 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). Fed. R. Civ. P. 9(b); 15 U.S.C. § 78u–4(b); *see also Stoneridge Inv. Partners, LLC v. Sci.-Atlanta*, 552 U.S. 148, 165 (2008) (noting that the PSLRA "imposed heightened pleading requirements and a loss causation requirement" on private actions "arising from the [] Exchange Act."). Rule 9(b) requires that a party alleging "fraud or mistake" is required to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Additionally, the PSLRA requires that, when a complaint alleges that a statement is misleading based on an omission, "the complaint shall specify each statement alleged to have been

misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4 (b)(1)(B). "Accordingly, 'unless plaintiffs in securities fraud actions allege facts supporting their contentions of fraud with the requisite particularity mandated by Rule 9(b) and the Reform Act [PSLRA], they may not benefit from inferences flowing from vague or unspecific allegations—inferences that may arguably have been justified under a traditional Rule 12(b)(6) analysis.'" *California Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 145 (3d Cir. 2004) (quoting *In re Rockefeller Ctr. Props., Inc.,* 311 F.3d 198, 224 (3d Cir. 2002)).

In evaluating a motion to dismiss, the Court may consider "documents attached to the complaint, 'as well as those attached to the motion to dismiss, so long as they are integral to the complaint and authentic.'" *Fusaro v. Cogan*, 930 F.3d 241, 248 (4th Cir. 2019) (quoting *Philips v. Pitt Cnty. Mem. Hosp.*, 572 F.3d 176, 180 (4th Cir. 2009)). A document is "integral" when "its 'very existence, and not the mere information it contains, gives rise to the legal rights asserted.'" *Chesapeake Bay Found., Inc. v. Severstal Sparrows Point, LLC*, 794 F. Supp. 2d 602, 611 (D. Md. 2011) (citation omitted) (emphasis omitted).

For example, "where a complaint in a fraud action references a document containing the alleged material misrepresentations, the referenced document may be considered part of the complaint." *Walker v. S.W.I.F.T. SCRL*, 517 F. Supp. 2d 801, 806 (E.D. Va. 2007); *Am. Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 367 F.3d 212, 234 (4th Cir. 2004) ("American Chiropractic explicitly referred to the [document], and its mail and wire fraud claims are based on the alleged misrepresentation made in that document."). "Similarly a newspaper article reporting allegedly fraudulent statements by a corporate officer may be considered part of the complaint in

a securities fraud action, [] and an allegedly libelous magazine article referred to in a complaint may be considered part of the complaint in a libel action based on that article." *Walker*, 517 F. Supp. 2d at 806. To be clear, the parties may dispute the facts contained within the "integral" document so long as the "authenticity of the document" is unquestioned. *Fusaro*, 930 F.3d at 248.

Here, the amended complaint bases its claims upon statements made in specific documents and as part of specific recorded phone calls. *See* ECF 54, at 13–23. Because these statements are the source of the claims in this case, the documents in which they are contained are integral to the amended complaint, even though they were not attached thereto. *See Sinnathurai v. Novavax, Inc.*, 645 F. Supp. 3d 495, 512 (D. Md. 2022) (considering as integral to the complaint in a securities fraud case documents submitted by the defendant on a motion to dismiss containing "transcripts or exhibits containing the specific alleged actionable statements"). Furthermore, Skye Capital does not object to the Court's consideration of Defendants' Exhibits 4, 7–12, 14–16, or 18–19.[3] ECF 72, at 16 ("[T]he Court should not consider Exhibits 1, 2, 3, 5, 6, 13, 17, 20."). As such, the Court will consider the exhibits in ECFs 74-7 through 74-12, ECFs 74-14 through 74-16, and ECFs 74-18 and 74-19, each of which is explicitly referenced in the amended complaint as containing the allegedly misleading statements. *See Iron Workers Loc. 16 Pension Fund v. Hilb Rogal & Hobbs Co.*, 432 F. Supp. 2d 571, 581–82 (E.D. Va. 2006) (considering documents submitted by defendant as attachments to motion to dismiss when those documents contained the allegedly misleading statements in securities fraud action).

[3] Exhibit 4 corresponds to ECF 74-4; Exhibit 7 to ECF 74-7; Exhibit 8 to ECF 74-8; Exhibit 9 to ECF 74-9; Exhibit 10 to ECF 74-10; Exhibit 11 to ECF 74-11; Exhibit 12 to ECF 74-12; Exhibit 14 to ECF 74-14; Exhibit 15 to ECF 74-15; Exhibit 16 to ECF 74-16; Exhibit 18 to ECF 74-18; and Exhibit 19 to ECF 74-19.

III. ANALYSIS

Defendants argue that the amended complaint should be dismissed for failure to state a claim because it "fails to plead a material misrepresentation or omission." ECF 71-1, at 20 (capitalization adjusted). Alternatively, Defendants argue that the amended complaint "fails to plead a strong inference of scienter," as required by the PSLRA. *Id.* at 33. Skye Capital argues the motion should be denied, first on procedural grounds, or, alternatively, because the amended complaint successfully states a claim. ECF 72, at 15–43. The Court first addresses Skye Capital's procedural arguments before turning to the question of whether the amended complaint states a cognizable claim.

A. The motion to dismiss will not be denied on procedural grounds.

Skye Capital argues that Defendants' motion to dismiss should be denied because it (1) includes a number of exhibits upon which it relies and (2) includes an attachment which Skye Capital claims is "plainly an end-run" around Court-order page limits. ECF 72, at 15–17 (taking issue with ECF 71-3, a nine-page exhibit entitled "Chart of Challenged Statements"). These arguments fail.

For the reasons explained above, the Court will properly consider the exhibits to Defendants' motion to dismiss which are integral to the amended complaint, i.e., those which contain the very statements upon which the amended complaint bases its claims. As such, the mere fact that Defendants submitted exhibits with their motion to dismiss—a very common practice in this Court —does not render their motion to dismiss procedurally flawed. And the Court's consideration of documents integral to the amended complaint does not convert this motion into one for summary judgment. *Fusaro*, 930 F.3d at 248.

Furthermore, the Court finds that the "Chart of Challenged Statements" attached as an appendix to Defendants' motion to dismiss merely summarizes the arguments contained in

Defendants' brief. As such, the Court need not rely on it at all, and it adds no additional argument to Defendants' motion. Because the Court finds that it can resolve the motion without considering the exhibit, Skye Capital's argument as to this exhibit is moot. The motion is not procedurally defective, and the Court proceeds to the merits of the motion.

B. The amended complaint fails to plead a material omission, and therefore fails to state a claim for a violation of Section 10(b) and Rule 10b–5.

The amended complaint alleges that Defendants violated Section 10(b) of the Securities and Exchange Act of 1934 and Rule 10b–5 promulgated thereunder as well as Section 20(a) of the Exchange Act. ECF 54, at 36–40 ¶¶ 119–136. The Court will begin with an analysis of the claims under Section 10(b) and Rule 10b–5. Section 10(b) prohibits the use of "any manipulative or deceptive device or contrivance" if employed "in connection with the purchase or sale of any security." 15 U.S.C. § 78j(a)(1) and (b). "SEC Rule 10b–5 implements this provision by making it unlawful to, among other things, '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.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (quoting 17 CFR § 240.10b–5(b)). "Deceptive acts include misstatements, omissions by those with a duty to disclose, manipulative trading practices, and deceptive courses of conduct." *S.E.C. v. Pirate Inv. LLC*, 580 F.3d 233, 240 (4th Cir. 2009) (citing *Stoneridge Inv. Partners, LLC,* 552 U.S. at 158). To state a claim for a violation of section 10(b) and Rule 10b–5, Skye Capital must plead "(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." *Stoneridge Investment Partners, LLC,* 552 U.S. at 157. The first element—a material misrepresentation or omission—is determinative in this case.

Though the amended complaint states that the identified statements made by Defendants were "materially false and misleading statements and omissions," the amended complaint never asserts that any particular statement was false; it asserts only that the statements were misleading because of important context that was omitted.[4] *See* ECF 54, at 16 ¶ 52 (explaining that identified statements "were materially false and misleading when made because Defendants knew, but omitted and/or minimized the significance" of key facts); *id.* at 21–22 ¶ 64 (same); *id.* at 14 ¶ 48 (same). As such, the Court will analyze the amended complaint solely from the view of alleging misrepresentation through omission. *See* Fed. R. Civ. P. 9(b) (requiring that fraud and misrepresentation be pled with "particularity").

When it comes to misrepresentation through omission, "it bears emphasis that § 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43–45 (2011) (citing 17 CFR § 240.10b–5(b)). This standard is often summarized as an inquiry into whether the omitted information would have "significantly altered the 'total mix' of information available" to investors and consumers. *Basic*

[4] The amended complaint appears to allude to a potential outright misrepresentation regarding the question of an acquisition of Aurinia. ECF 54, at 19–20 ¶ 57, 21 ¶¶ 61–62. However, Skye Capital specifies that the reason that statements related to a potential acquisition were misleading was due to the omission of the key facts mentioned above. ECF 54, at 21 ¶ 64 ("The statements referenced in ¶¶ 53-59 and 63 were materially false and misleading when made because Defendants knew but omitted and/or minimized the significance" of the key facts). Because of the heightened pleading requirements for securities fraud claims, the Court need not consider alternative theories of liability that were not pled. Defendants' statements regarding any potential acquisition were pled as misrepresentations solely based on a theory of omission under Section 10(b) and Rule 10b–5, and these statements will be analyzed only under this framework.

Inc. v. Levinson, 485 U.S. 224, 231–32 (1988) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).

Of course, this standard is easier recited than it is explained. It is best understood through illustrative examples. In *Matrixx Initiatives, Inc.*, the Supreme Court found that the omission of ongoing reports of serious adverse reactions to a medication was misleading. 563 U.S. at 45–47. There, the defendant sold a cold medicine, Zicam, which accounted for 70% of its total sales. *Id.* at 47. The defendant had reason to know that there was a "reliable causal link" between Zicam and a loss of smell, reported by multiple consumers, and a researcher was set to present a report on the link between the two at a national conference. *Id.* at 45–46. The Court found that "[c]onsumers likely would have viewed the risk associated with Zicam (possible loss of smell) as substantially outweighing the benefit of using the product (alleviating cold symptoms), particularly in light of the existence of many alternative products on the market." *Id.* at 47. Thus, the omission of that information constituted a material misrepresentation. *Id.*

Importantly, the materially misleading impact of an omission "can be 'negate[d]' by adequate warnings and disclaimers." *San Antonio Fire & Police Pension Fund v. Syneos Health Inc.*, 75 F.4th 232, 245 (4th Cir. 2023) (citing *Gasner v. Bd. of Supervisors*, 103 F.3d 351, 358 (4th Cir. 1996)). In order for such a warning to absolve a defendant of a claim of misrepresentation by omission, however, the warning must be "specific" and "tailored to address the alleged misrepresentation or omission." *Paradise Wire & Cable Defined Benefit Pension Plan v. Weil*, 918 F.3d 312, 319 (4th Cir. 2019). "The point is that the cautionary language stands in for the omitted information[.]" *San Antonio Fire & Police Pension Fund*, 75 F.4th at 246. And finally, a defendant cannot be liable for misrepresentation based on a theory of omission when the defendant did, indeed, disclose the allegedly omitted information. *See, e.g., Smith v. Cir. City*

Stores, Inc., 286 F. Supp. 2d 707, 721 (E.D. Va. 2003) (finding no misrepresentation through omission when allegedly omitted information was disclosed by company in, *inter alia*, public SEC filings).

Because Skye Capital bases its claims entirely on a theory of omission based on Defendants failing to communicate five specific pieces of information, no violation of Section 10(b) or Rule 10b–5 will sound if Defendants either (1) disclosed that information or (2) provided language of an adequate disclaimer for that omitted information. As explained below, the Court finds that the disclosures Defendants made were sufficient to notify investors of the allegedly omitted information, and that any additional disclosures relating to that information would not have "significantly altered the 'total mix' of information available." *Basic Inc.,* 485 U.S. at 232.

The material omissions that Skye Capital identifies are (1) despite the fact that LN is "typically treated by nephrologists," Aurinia "mainly focused on engaging with rheumatologists"; (2) "the social and economic backgrounds of LN patients' [] made them hard patients to reach"; (3) LN patients were often "non-compliant with their drug regimens"; (4) practitioners found the paperwork involved in initiating a prescription for LUPKYNIS to be "tedious" and believed that LUPKYNIS was "too expensive"; and (5) concerns over "insurance coverage limitations" deterred practitioners from prescribing LUPKYNIS. ECF 54, at 10–12 ¶¶ 35–41. Skye Capital has failed to plead that Defendants omitted this information in a way that misled investors, as a review of the amended complaint and the integral documents noted above reveal that the allegedly omitted information was actually disclosed. Indeed, the disclosures often came in the very documents in which the lead Plaintiff alleges misleading statements were made, beginning with the date of the very first allegedly misleading statement.

1. *Alleged omission number one: Despite the fact that LN is "typically treated by nephrologists," Aurinia "mainly focused on engaging with rheumatologists.*

Defendants repeatedly noted that they were engaging both rheumatologists and nephrologists, beginning on May 6, 2021, the date of the first allegedly misleading statement. ECF 74-8 at 5 ("Engaged with over 6,000 rheumatologists and nephrologists); *see also* ECF 74-9, at 8 (again referring to both rheumatologists and nephrologists). Defendants even specified exactly how they divided their efforts of targeting both types of specialists, explaining that they worked with roughly 50% nephrologists and 50% rheumatologists, again as early as May 6.[5] ECF 74-9, at 12. This disclosure about Defendants' work with both types of practitioners continued throughout the entire period of alleged wrongdoing identified by the purported class. *See* ECF 74-12, at 7 ("I would say rheumatologists are probably a little more aggressive on that curve than our nephrologist[s]."); ECF 74-16, at 9 ("Obviously, rheumatologists and nephrologists are different in the specialty and how they think about the disease. . . . our prescribing [sic] have actually pretty much split down the middle with half being nephrologists and half rheumatologists."). As such, it is hard to see how Defendants could have mislead investors through omitting this information when they openly and repeatedly discussed it throughout the relevant time period.

[5] Skye Capital argues in its opposition to Defendants' motion to dismiss that Defendants erred in targeting nephrologists and rheumatologists equally, since, according to Skye Capital, Defendants should have been targeting nephrologists more than they were targeting rheumatologists. ECF 72, at 27. But the wisdom of Defendants' marketing strategy is not before the Court. The relevant inquiry here is whether Defendants disclosed the manner in which they chose to work with rheumatologists and nephrologists, which they did. Nor has Skye Capital raised any argument that Defendants had an obligation to explain the intricacies of the differences of LN treatment practices between nephrologists and rheumatologists.

2. *Alleged omission number two: "The social and economic backgrounds of LN patients[] made them hard patients to reach."*

Defendants repeatedly emphasized that LN patients came from underserved and under-resourced communities beginning on May 6, 2021, and continuing throughout the purported class period. *See* ECF 74-8, at 5 (referencing "underserved LN population"). In the August 5, 2021, press release, Defendants again referenced the underserved nature of the community, explaining that they were seeking to "improve access" for the community, indicating, with the aid of simple logic, that the LN patient community was one currently without access. ECF 74-11, at 5. And on February 16, 2022, Defendants plainly stated that LN patients came from marginalized communities and that this "comes into play when [Defendants] think about [their] target audience," their marketing strategies, and their treatment adherence. ECF 74-18, at 4. Additionally, Defendants repeatedly acknowledged that LN patients were not receiving healthcare services at an appropriate level during the pandemic. *See* ECF 74-9, at 11 ("[P]atient visits in general and follow-up diagnostic patients for patients—or visits for patients with lupus are down almost 50% according to a very sizable patient survey done by the World Lupus Foundation.").

It is true that Defendants did not explicitly say that "[t]he social and economic backgrounds of LN patients[] made them hard patients to reach." ECF 54, at 10 ¶ 36. But this they were not required to do. Defendants were not required to state every obstacle facing them in the most specific language possible. Instead, they were obligated only to disclose as much information as was required to render reasonable and accurate the picture painted by the "total mix" of information available to investors. They did so when they made clear that the patient population with whom they worked was one that was "underserved" (i.e., generally did not receive adequate resources or supports), *see id.*, at 13 ¶ 46, and lacked "access" (i.e., did not have adequate information or supports to take advantage of what treatments might be available to them), *see id.*,

at 14 ¶ 49. This assessment was underscored by Defendants' frank disclosure that the Covid pandemic was hitting this group particularly hard, again indicating that this group lacked access to healthcare and resources. The picture painted by this information is very clearly one of patients who are "hard [] to reach." *See id.* at 10 ¶ 36. Thus, Skye Capital has failed to plead that this material was omitted.

3. *Alleged omission number three: LN patients were often "non-compliant with their drug regimens."*

As with alleged omission number two, Defendants did not overtly state that LN patients were often "non-complaint with their drug regimens" and did not expressly mention that this detracted from sales. ECF 54, at 10 ¶ 37. However, Defendants clearly indicated as much through the information they communicated about LN patients. Beginning on May 6, 2021 and continuing through the duration of the class period, Defendants continually referenced the fact that LUPKYNIS's target population is underserved and under-resourced, meaning that the target population is one that has difficulty accessing ongoing care. As with the second alleged omission, it takes only a minor critical thinking step to deduce that these specific details about the target population means that non-compliance with their drug regimens could be a problem. This was again underscored by the discussion of the impacts of Covid on this population, highlighted as early as May 6, 2021 with the disclosure that this population's attendance at doctor's appointments decreased by about half during the pandemic. *See* ECF 74-9, at 11. And of course, as Skye Capital acknowledges, on November 3, 2021, Defendants plainly stated that "this patient population is a difficult one and can be pretty notoriously uncompliant." ECF 74-16, at 14.

Furthermore, when Defendants referenced positive compliance indicators, they explicitly stated that the data was tentative, and that it should be taken as preliminary, as they could not offer reliable numbers on this point until LUPKYNIS had been in the field for a longer period of time.

See, e.g., ECF 74-12, at 12 ("But it's so early in the game that we have to watch that over time. Patients that —we have to see patients on drug for 6 months, a year, 1.5 years, 2 years before we really know what our ongoing persistency rate is going to be."). This ongoing transparency about the social background of patients coupled with cautionary language and disclaimers relating to positive compliance numbers yields the conclusion that the "total mix of information" relating to the compliance of LN patients was misleading.

4. *Alleged omission number four: Practitioners found the paperwork involved in initiating a prescription for LUPKYNIS to be "tedious" and believed that LUPKYNIS was "too expensive."*

Defendants repeatedly noted that some doctors expressed hesitancy about prescribing LUPKYNIS. On the May 6, 2021, call, Defendants noted that doctors believed the pricing of LUPKYNIS to be "within shouting distance of a fair cost effectiveness range," all but explicitly stating that doctors thought the product was too expensive (i.e., not quite "fair cost effective"). ECF 74-9, at 8. They also explained that physicians were "cautious" and that it could take 20 to 50 days for a prescription to be filled once a doctor had completed the start forms. *Id.* at 7, 16. On the August 5, 2021, call, Defendants again explained that it "takes time" to educate providers and get providers to "adopt [] new treatment approaches." ECF 74-12, at 6. Indeed, during this call, Defendants explicitly stated, "[T]he initial process for getting a patient on drug involves some paperwork and involves a prior [authorization] in most cases and that alone is an initial hurdle you need to get over." *Id.* at 11. Defendants were sufficiently explicit in their disclosure on this point. As such, Skye capital has failed to plead that Defendants omitted this information.

5. *Alleged omission number five: Concerns over "insurance coverage limitations" deterred practitioners from prescribing LUPKYNIS.*

Finally, Skye Capital has failed to plead that Defendants omitted the alleged fact that concerns over "insurance coverage limitations" deterred practitioners from prescribing

LUPKYNIS. ECF 54, at 11 ¶ 40. Defendants were clear from the outset that there were gaps in insurance coverage and that many of the insurance policies that did provide coverage for LUPKYNIS still had additional processing hurdles like prior authorization requirements. *See* ECF 74-9, at 8. The May 6, 2021, press release referred to "continual gradual expansion of payor coverage," indicating that insurance coverage was not yet widespread. ECF 74-8, at 5. On the call on that same day, Defendants explained that they were in the "early phase of establishing payer access" and that only "11 payers" had established insurance coverage. ECF 74-9, at 8. Defendants also acknowledged that some insurance providers had "step-through requirements" and that they had "had payer denials." *Id.* at 15. Defendants acknowledged the link between insurance coverage and physician buy-in, explaining that as they had "seen more policies coming online," that had "obviously increase[ed] [their] access with additional commercial and government providers." *Id.* at 6. Again, Defendants explained that providers were "cautious" and that it could take "anywhere from 20 to as many as 50 days" to fill a prescription after a doctor completed the start forms. *Id.* at 7, 16. On the August 5, 2021, conference call, Defendants again explained that many insurance policies required prior authorization before covering LUPKYNIS and that such requirements were a "hurdle" for providers. ECF 74-12, at 11. Finally, on November 3, 2021, Defendants explained that they were "still getting an understanding of how doctors are prescribing LUPKYNIS, and the number and time to discontinuation, persistence, patient and payer mix all of which really impact the actual net realizable revenue per patient per year going forward." ECF 74-16, at 11. As such, Plaintiffs have not pled that Defendants failed to address insurance obstacles or resultant physician hesitancy.

Because the very documents containing the allegedly misleading statements disclosed each of the allegedly omitted pieces of information (or included appropriate disclaimers relating to that

information), Skye Capital has failed to state a claim for a violation of Section 10(b) or Rule 10b–5.

C. Because Skye Capital's Section 10(b) claim fails, their Section 20(a) claim necessarily fails.

A "section 20(a) claim seeks to impose liability on the officers as control persons, with such liability being 'derivative of—and dependent upon—liability of a controlled person under section 10(b).'" *Amalgamated Bank as Tr. for LongView Collective Inv. Funds v. Maximus, Inc.*, 771 F. App'x 238, 239 (4th Cir. 2019) (per curium) (quoting *Singer v. Reali*, 883 F.3d 425, 438 (4th Cir. 2018)). As such, "[b]ecause the complaint is legally insufficient with respect to the § 10(b) claim, the § 20(a) claim must also fail." *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 894 n.8 (4th Cir. 2014) (citation omitted).

IV. CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss, ECF 71, is **GRANTED**. the amended complaint has failed to state a claim on either count and is dismissed with prejudice.

A separate implementing Order will issue.

Dated: August 13, 2024

/s/
Brendan A. Hurson
United States District Judge