UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MARY HELEN YARBOROUGH et al.,	)	
Plaintiff,	)	
v.	)	Civil No. 24-12119-LTS
ARDELYX et al.,	)	
Defendants.	)	

ORDER ON MOTION TO DISMISS (DOC. NO. 32)

December 24, 2025

SOROKIN, J.

This is a putative class action alleging violations of the Securities Exchange Act of 1934 and Rule 10b-5 against Ardelyx, Inc. and various Ardelyx executives. Plaintiffs, who bring this suit on behalf of a class of similarly situated investors, contend that class members were harmed when they purchased Ardelyx's common stock at prices that were inflated by the company's false and misleading statements during the Class Period of February 22, 2024, through July 1, 2024. They additionally allege that two Ardelyx executives engaged in insider trading. Defendants moved to dismiss the amended complaint pursuant to Fed. R. Civ. P. 12(b)(6). Doc. No. 32.[1] For the reasons that follow, Defendants' motion to dismiss is ALLOWED.

[1] Citations to "Doc. No. __ at __" reference items filed on the electronic docket ("ECF") in the action that is the subject of this Order; pincites are to page numbers in the ECF header or, where applicable, to the paragraph numbering within the document.

I. BACKGROUND

A. Scope of Facts

Before summarizing the factual background of this case, the Court resolves the scope of the record, as each party requests that the Court consider documents beyond the complaint. At the dismissal stage, courts "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 322 (2007).

Here, both parties have asked the Court to consider several documents beyond the four corners of the amended complaint that they argue are incorporated by reference or subject to judicial notice. See Doc. No. 35; Doc. No. 39. Beginning with Defendants' request, they seek the consideration of sixteen exhibits attached to their motion to dismiss. Doc. No. 35. Upon examining the exhibits, the Court finds that Exhibits 1 to 3 and 5 to 14 are incorporated by reference because Plaintiffs quote from and rely upon these documents to shape their allegations in the complaint, and the authenticity of these documents is not challenged. See Beddall v. State St. Bank & Tr. Co., 137 F.3d 12, 17 (1st Cir. 1998) ("When . . . a complaint's factual allegations are expressly linked to—and admittedly dependent upon—a document (the authenticity of which is not challenged), that document effectively merges into the pleadings and the trial court can review it in deciding a motion to dismiss under Rule 12(b)(6)."); Clorox Co. P.R. v. Proctor & Gamble Com. Co., 228 F.3d 24, 32 (1st Cir. 2000) (quoting Shaw v. Digit. Equip. Corp., 82 F.3d 1194, 1220 (1st Cir. 1996)) ("[I]t is well-established that in reviewing the complaint, we 'may properly consider the relevant entirety of a document integral to or explicitly relied upon in the complaint, even though not attached to the complaint, without converting the motion into one for summary judgment.'"). Defendants' remaining documents, Exhibits 4, 15, and 16, are not

mentioned or referenced in the complaint and, therefore, are not incorporated.[2] Nonetheless, all three documents were publicly filed with the Securities and Exchange Commission ("SEC"), and Plaintiffs do not dispute their authenticity. Therefore, the Court takes judicial notice of these documents "at least with regard to the fact that [they] contain[] certain information, though not as to the truth of [their] contents." OrbusNeich Med. Co., BVI v. Bos. Sci. Corp., 694 F. Supp. 2d 106, 111 (D. Mass. 2010) (taking judicial notice of report publicly filed with SEC).

Plaintiffs ask the Court to consider six exhibits. Doc. No. 39. The Court finds that Exhibits 3 and 6 are incorporated by reference, because the allegations in the amended complaint reference and rely upon these documents.[3] Furthermore, Defendants make no authenticity objection to these two documents. Plaintiffs' remaining documents, Exhibits 1, 2, 4, and 5, are all publicly available documents, the authenticity of which is also not challenged. Thus, the Court takes judicial notice of these remaining documents for the fact that they exist and contain certain information but not for the truth of the facts asserted in them. Piper v. Talbots, Inc., 507

[2] Defendants assert that Exhibit Nos. 15 and 16 are incorporated by reference, but the Court disagrees with this assessment. Exhibit No. 15 contains copies of Defendant Grammer's Form 4s filed with the SEC on November 12, 2021 and June 8, 2022. Doc. No. 33-15. Exhibit No. 16 contains copies of Defendant Williams's Form 4s filed with the SEC on August 24, 2022 and November 23, 2022. Doc. No. 33-16. Defendants argue that these documents are incorporated by reference because "Plaintiffs rely on [Grammer's and Williams's] stock sales to support their theories of scienter." Doc. No. 35 at 6. However, Plaintiffs do not mention or reference the particular stock sales contained in these Form 4s anywhere in the amended complaint. Furthermore, Plaintiffs' theories of scienter rely on Grammer's and Williams's stock sales during the Class Period, whereas Exhibit Nos. 15 and 16 concern stock sales that occurred before the Class Period. While Plaintiffs mention Grammer's and Williams's Pre-Class Period stock sales on a broad level to argue that their sales during the Class Period were anomalous to their past trading activities, Doc. No. 25 ¶¶ 98-99, this level of generality is not sufficient to incorporate any or all Form 4s reflecting stock sales made by Grammer and Williams before the Class Period. Nonetheless, because Exhibit Nos. 15 and 16 represent documents publicly filed with the SEC, the Court takes judicial notice of these exhibits.

[3] One of these documents, Exhibit 3, is a declaration filed in a different lawsuit by Williams, a defendant in this lawsuit. No party has suggested these facts give rise to a bias affecting how the Court considers the document.

F. Supp. 3d 339, 343 (D. Mass. 2020) (taking judicial notice of documents from publicly accessible websites, where other party did not contest their authenticity).

B. Factual Background

The following facts are drawn from the amended complaint, Doc. No. 25, and the above-described documents that are incorporated therein or subject to judicial notice. Ardelyx is a pharmaceutical company. Id. ¶ 3. One of Ardelyx's two products is XPHOZAH, an oral drug that helps treat excess phosphorus in patients receiving dialysis. Id. Patients undergoing dialysis typically use a class of drugs called "phosphate binders" to control their phosphorus levels. Id. ¶ 4. XPHOZAH provides an alternative option for patients who cannot (1) manage their phosphorus levels with existing phosphate binders on the market, or (2) take phosphate binders due to an intolerance of that medication. Doc. No. 37-2 at 2. XPHOZAH reduces phosphorous levels not by binding to phosphorus, but rather by blocking phosphorus from entering the bloodstream. Doc. No. 37-4 at 2. Both XPHOZAH and phosphate binders are oral drugs (i.e., pills), Doc. No. 25 ¶ 6, with XPHOZAH offering a lower pill burden than phosphate binders, Doc. No. 37-4 at 2.

In October 2023, Ardelyx received approval from the FDA to sell XPHOZAH. Doc. No. 25 ¶ 4. At that point, orally administered drugs, including XPHOZAH and phosphate binders, were reimbursed by Medicare Part D. Id. ¶ 6. Under this reimbursement scheme, these drugs had a competitive advantage over drugs that fell within the predetermined "Bundle" payment made by Medicare Part B to dialysis centers. Id. ¶¶ 6, 82. This is because providers were separately reimbursed by Medicare Part D for prescribing these drugs instead of being forced to spend funds from their fixed Bundle payments to acquire the drugs. Id. ¶ 6. Furthermore, patients had the flexibility to receive Medicare Part D drugs from pharmacies, unlike Medicare Part B drugs that must be stocked and dispensed by dialysis centers. Id. ¶ 11.

Unfortunately for Ardelyx, this favorable reimbursement scheme was not set in stone. Medicare Part D coverage for oral-only drugs including XPHOZAH was scheduled to expire on January 1, 2025. Id. ¶ 7. Absent the passage of a Congressional bill or a regulation by the Centers for Medicare and Medicaid Services ("CMS") extending Medicare Part D coverage beyond January 1, 2025, XPHOZAH was fated to be added to the Bundle. Id. ¶¶ 7, 46-49. In the face of this uncertain regulatory future, Ardelyx initially proclaimed that it would apply for the Transitional Drug Add-on Payment Adjustment ("TDAPA") program should XPHOZAH be added to the Bundle. Id. ¶¶ 52-55. TDAPA is a CMS-run program, which provides a two-year temporary grace period for drugs newly added to the Bundle. Id. ¶ 50. During this two-year transition period, drugs continue to be separately reimbursed by Medicare, creating (at least in theory) a financial incentive to providers to prescribe those drugs. Id. CMS also tracks the drug's usage during the TDAPA period and uses this data to raise the Bundle payment by an amount determined by a CMS algorithm designed to cover any additional costs after the expiration of the TDAPA period. Id. ¶ 51. Thus, the TDAPA process theoretically helps to "ensure that Medicaid pays enough money to dialysis providers to allow them to administer the new drug to patients who need it even without separate reimbursement." Id.

According to Plaintiffs, Ardelyx portrayed TDAPA as "the cornerstone" of its strategy in the event efforts to change the law placing XPHOZAH into the Bundle on January 1, 2025, failed. Id. ¶ 52. Before the Class Period, Ardelyx executives repeatedly told investors that the company would apply for TDAPA should XPHOZAH be added to the Bundle. Id. ¶¶ 53-55. Market analysts subsequently believed that XPHOZAH could enter TDAPA if it were added to the Bundle, and Defendants perpetuated this belief throughout the Class Period. Id. ¶ 57. On February 22, 2024 (the first day of the Class Period), Ardelyx made the first of its four allegedly

false statements undergirding Plaintiffs' fraud claims. Ardelyx filed a 2023 10-K, in which it cautioned investors that "[t]here can be no assurances that CMS will determine XPHOZAH will qualify for TDAPA status," but did not raise the possibility of not applying for TDAPA in the first place. Id. ¶¶ 56, 127. It did, however, note various shortcomings of the TDAPA process, including that "revenue for sales of XPHOZAH could be significantly less in the TDAPA period than it would be if XPHOZAH is not bundled," that any post-TDAPA increase to the Bundle may not be "sufficient to adequately reimburse the dialysis facilities for XPOHZAH [sic] at a price that is profitable for us," and that "inclusion of XPHOZAH in the [Bundle] . . . will negatively and materially impact the revenue . . . on sales of XPHOZAH." Id. ¶ 127. On March 5, 2024, Ardelyx's then-Chief Commercial Officer Susan Rodriguez reiterated the possibility of entering the TDAPA program while speaking on a healthcare conference panel:

> Should the bundle not be delayed, despite everybody's best efforts and support, and the fact that it's bad medicine, it does move into this transition period. . . . So exactly how this will work in that transition during—TDAPA is really very hard to predict. But as an innovation focused company, we will be quite dedicated, very persistent, in doing everything we can to make sure that all patients who need XPHOZAH will have access to XPHOZAH.

Id. ¶ 129. Rodriguez's comment is the second allegedly false statement made by Defendants.

According to Plaintiffs, Ardelyx's plan to apply for TDAPA was all a lie. In fact, while Defendants "told investors that TDAPA offered a viable option," id. ¶ 10, Plaintiffs allege that they "had concluded otherwise," id. ¶ 11. Plaintiffs claim Ardelyx had already decided not to apply for TDAPA—a decision that the company hid from investors until July 2024. Id. ¶ 111. Ardelyx, per Plaintiffs, knew that TDAPA was not a viable option for XPHOZAH because it had witnessed other drugs fare poorly under the program. Id. ¶ 12. While concealing this conclusion from the public, Ardelyx allegedly revealed this information to CMS behind closed doors. Id. Plaintiffs point to a presentation that Ardelyx delivered to CMS on March 11, 2024, as part of

the company's lobbying efforts to persuade CMS to exclude XPHOZAH from the Bundle. Id. ¶ 62. During the presentation, which Ardelyx's Chief Medical Officer Lauren Williams and Chief Legal and Administrative Officer Elizabeth Grammer attended, Ardelyx mentioned four other drugs that had been placed in the Bundle on a slide entitled, "IMPACT/POTENTIAL IMPACT OF [THE BUNDLE]." Id. ¶¶ 63-67. Two of those drugs, Jesduvroq and Korsuva, were in their TDAPA periods at the time of the presentation. Id. ¶ 66. Two other drugs, Sensipar and Parsabiv, had already undergone their TDAPA periods. Id. ¶ 75. The presentation identified all four drugs as "Innovation Lost."[4] Id. ¶ 66. As Plaintiffs explain, all four drugs had "fared poorly either in the TDAPA period or immediately after it stopped." Id. ¶ 71. In particular, Korsuva, Sensipar, and Jesduvroq experienced low sales during their TDAPA period, whereas Parsabiv's "sales rose" during the TDAPA period but plummeted afterward. Id. ¶¶ 72-81.

On March 13, 2024, two days after the presentation to CMS, Ardelyx sent CMS a follow-up letter urging the exclusion of XPHOZAH from the Bundle. Id. ¶ 68. In that letter, Williams wrote: "Nephrologists and dialysis providers have observed that the addition of new drug therapies to the [Bundle] can produce negative effects, as exemplified by the limited access patients today have to effective calcimimetic therapy options and a new antipruritic drug (Korsuva)." Id. ¶¶ 68-69. Based on these communications to CMS in March 2024, Plaintiffs contend that Ardelyx and its executives knew that TDAPA had diminished patient access to other drugs and because of that, Ardelyx had "decided not to enter TDAPA based on the experience" of those other drugs. Id. ¶ 111.

[4] However, nowhere in the presentation did Ardelyx say it would not apply for TDAPA if CMS placed XPHOZAH in the Bundle.

Ardelyx's lobbying efforts to CMS proved unsuccessful. On April 29, 2024, CMS issued a guidance entitled, "Including Oral-Only Drugs in the . . . Bundled Payment." Doc. No. 37-1. The guidance affirmed CMS's plan to incorporate oral-only renal dialysis service drugs and biological products into the Bundle starting on January 1, 2025. Id. at 2. Additionally, CMS noted that it would treat phosphate binders differently from other renal dialysis drugs. The guidance explained that starting on January 1, 2025, CMS would continue separately paying providers for phosphate binders through the TDAPA program for at least two years. Id. After the TDAPA period, "CMS [would] then undertake rulemaking to modify the [Bundle] base rate to account for the cost and utilization of phosphate binders." Id. However, CMS clarified that it would "not [be] following this process for any other oral drugs or biological products." Id. For any "oral renal dialysis drug or biological product which is not a phosphate binder," the manufacturers would have to undergo "the existing TDAPA application process described at 42 CFR 413.234." Id. The guidance did not specify whether or not XPHOZAH would be grouped with the phosphate binders.

On May 2, 2024, Ardelyx filed its 10-Q for the quarter ending on March 31, 2024—the third allegedly false statement by Defendants. Doc. No. 25 ¶ 131. The 10-Q, which repeated verbatim Ardelyx's 10-K filed on February 22, 2024, expressed that "[t]here can be no assurances that CMS will determine that XPHOZAH will qualify for TDAPA status," but left open the possibility that XPHOZAH would undergo TDAPA "if deemed eligible by CMS." Id. Echoing the February 10-K, the 10-Q also detailed the same caveats about the TDAPA process. Id. (warning that "revenue for sales of XPHOZAH could be significantly less in the TDAPA period," that Bundle adjustments may not "adequately reimburse the dialysis facilities . . . at a

price that is profitable for us," and that inclusion of XPHOZAH in the Bundle "will negatively and materially impact the revenue . . . on sales of XPHOZAH").

That same day, Ardelyx's Chief Executive Officer Michael Raab held a call to discuss Q1 earnings, during which he stated, "[y]ou know currently, I think, as we've said, our intent is to enter TDAPA." Id. ¶ 133. He also noted that the "specifics" of the process would "play out over time" and mentioned Ardelyx's ongoing lobbying efforts to persuade Congress to delay the Bundle. Id. Raab concluded his comment by stating: "So the work continues and the specifics about how things come in and out based upon these next six months or more, . . . we'll get that to you as . . . we also learn." Id. Raab's call constitutes the last of Defendants' four allegedly false and actionable statements.

On May 13, 2024, CMS sent a letter to Ardelyx rejecting the company's request that CMS take action to exclude XPHOZAH from the Bundle. Doc. No. 37-2. In the letter, CMS confirmed that XPHOZAH would be placed in the Bundle beginning on January 1, 2025. Id. at 2. The letter identified XPHOZAH as a "renal dialysis service" used as an "add-on therapy in patients . . . who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy." Id. The letter also linked to the April 29 guidance, noting that "CMS has recently published operational guidance . . . in connection with the incorporation of phosphate binders into the ESRD PPS [the Bundle], which may provide helpful information to Ardelyx." Id. at 3. CMS concluded the letter by encouraging Ardelyx to submit a TDAPA application "as soon as possible to ensure a timely determination for potential TDAPA eligibility beginning January 1, 2025." Id.

Against this backdrop, Grammer and Williams made what Plaintiffs label "massive, unprecedented stock sales." Doc. No. 25 ¶ 94. Most of these sales arose from pre-established

Rule 10b-5 trading plans, but two of the largest sales were not made pursuant to those plans. Id. ¶ 97. On March 20, 2024, Grammer sold 86,000 shares (amounting to $664,780 in proceeds), which was pursuant to her Rule 10b-5 trading plan. Id. On May 3, 2024, Grammer sold 45,000 shares of stock (amounting to $405,000), and Williams sold 39,949 shares (amounting to $333,574)—stock sales pursuant to each executive's trading plans. Id. On May 6, 2024, Grammer sold 282,170 shares (amounting to $2,505,047)—a sale that was not disclosed in her trading plan. Id. ¶¶ 94, 97. On May 21, 2024, Grammer sold 6,927 shares (amounting to $54,100), in line with her trading plan. Id. ¶ 94. On May 23, 2024, Williams sold 4,794 shares (amounting to $37,441), which was in accordance with her trading plan. Id. On June 5, 2024, Williams sold 145,000 shares (amounting to $1,033,400)—a sale that was not included in her trading plan. Id. ¶¶ 94, 97. In total, Grammer and Williams respectively sold 37.6% and 33.7% of all the shares that were available for them to sell during the Class Period. Id. ¶ 101. For the May 6 and June 5 sales—which were not made pursuant to Grammer's and Williams's trading plans—neither executive declared any specific objective for these sales, such as satisfying tax obligations. Id. ¶ 97. Furthermore, Plaintiffs contend that Grammer and Williams had never engaged in sales of a similar magnitude before the Class Period. Id. ¶ 98. Plaintiffs do not claim that any other Ardelyx executives made any stock sales, let alone unprecedented or suspicious sales, during the Class Period.

On June 27, 2024, CMS issued a proposed rule in the Federal Register, which officially confirmed that XPHOZAH and all other oral-only drugs would be added to the Bundle effective January 1, 2025. Id. ¶¶ 109-110. The June 27 rule also made explicit that CMS was not treating XPHOZAH as a phosphate binder. See Medicare Program; End-Stage Renal Disease Prospective Payment System, 89 Fed. Reg. 55760-01 (July 5, 2024) (to be codified at 40 C.F.R.

pt. 123) [hereinafter "Prospective Payment System Proposed Rule"]. The rule reiterated that CMS would undertake a special TDAPA process for phosphate binders, as detailed in the April 29 guidance. Id. at 55796. On the other hand, "for any other oral-only drugs, such as XPHOZAH," CMS would apply the regular TDAPA process used "for all new renal dialysis drugs and biological products, consistent with § 413.234." Id.

When the July 1, 2024, deadline for applying for TDAPA arrived, Ardelyx did not submit an application. Doc. No. 33-11 at 6.

On July 2, 2024, Ardelyx published a press release announcing that that the company had chosen not to file a TDAPA application for XPHOZAH by the deadline. Doc. No. 25 ¶ 104. In a call about the decision, Raab stated: "It is absolutely clear that, within the Bundle and beginning with TDAPA, the restrictions placed on XPHOZAH would effectively eliminate patient access." Doc. No. 33-11 at 6. Raab proceeded to mention various considerations that informed Ardelyx's decision to forego TDAPA. He noted other drugs' poor outcomes after the TDAPA process. Id. at 8. He explained that the bundling of oral drugs placed a "huge burden" on dialysis organizations, which would be required to set up new infrastructure to dispense oral drugs to patients. Id. at 10. He also stated that opting out of TDAPA "enables us to continue exploring all options to support patient access." Id. at 6. He conveyed that the "best option to preserve access" would be for Congress to pass legislation extending XPHOZAH's exclusion from the Bundle. Id. at 7. As for other options, Raab said: "We still have more analyses to conduct in the weeks and months ahead to determine the best strategy . . . . Once we have made final decisions, we will communicate that information." Id. He also expressed that Ardelyx was not foreclosing the option to apply to TDAPA in the future, noting that he believed "there would be opportunities to subsequently file for TDAPA." Id. at 10.

In addition to these considerations, Raab pointed to CMS's June 27 proposed rule as part of what "drove" Ardelyx to the decision not to apply for TDAPA. Doc. No. 25 ¶ 108. More specifically, Raab claimed that the rule changed Ardelyx's calculus regarding TDAPA because CMS's decision to separate XPHOZAH from phosphate binders meant that XPHOZAH faced less favorable prospects for TDAPA:

> So, if you follow what people have believed up until the draft guidance that was earlier this—couple of months ago, everyone was of the mind that we would be part of the TDAPA period similar- along with [phosphate] binders. Which then, it's been a unique process for binders, where there's a base rate increase similar to what occurred to Parsabiv. That is not how we're being treated. As you read the documents, you can see that it's explicit that we will not be included in the TDAPA period, the binders and the calculation of the binders are going to go through. We will be treated as new renal dialysis drugs, which is how Korsuva was treated.

Id. However, later during the call, Raab noted that he was "not sure" that Ardelyx would have decided to apply for TDAPA even if XPHOZAH "were treated like binders" under the CMS rule, because "that means that we still would be like the other innovative drugs that ultimately aren't utilized because of the inconsequential amount of binders that's ultimately distributed to the dialysis organizations." Doc. No. 33-11 at 14. After Raab's call, the price of Ardelyx's shares fell by 30.2% by the close of the day. Doc. No. 25 ¶ 137.

Plaintiffs allege that Raab's explanation attributing the decision to CMS's June 27 rule "was designed to give investors the impression that the change in Ardelyx's position resulted from changed circumstances." Id. ¶ 145. But this explanation was mere pretext, according to Plaintiffs. They argue that the June 27 rule did not change any of the circumstances surrounding XPHOZAH and the TDAPA process, because CMS had already revealed how XPHOZAH would be treated in the Bundle in its April 29 guidance and May 13 letter; therefore, Ardelyx had known in advance that XPHOZAH would be treated differently from phosphate binders. Doc. No. 36 at 29. Moreover, Plaintiffs dispute Defendants' argument that CMS's differential

treatment put XPHOZAH at a disadvantage with respect to Bundle reimbursements under TDAPA. Id. at 15, 20. Accordingly, they allege that Raab's explanation linking Ardelyx's decision not to apply for TDAPA to the June 27 rule constitutes a "false exculpatory statement." Doc. No. 25 ¶¶ 145-146.

Plaintiffs point to one more fact to support their allegation that Ardelyx's decision to opt out of TDAPA predated CMS's June 27 rule. On July 17, 2024, Ardelyx sued CMS to challenge its decision to add XPHOZAH to the Bundle. Id. ¶ 112. In that case, Ardelyx attached a declaration of Williams with its reply brief in support of a preliminary injunction, in which Williams delineated how Ardelyx arrived at its decision not to apply for TDAPA. Id. ¶ 118. In the sworn declaration, Williams explained that while "Ardelyx began with the assumption that it would apply to . . . the TDAPA program," id. ¶ 119, "[a]s Ardelyx further analyzed XPHOZAH's commercial opportunity in the first half of 2024, Ardelyx determined that even during the TDAPA period, the restrictions placed on XPHOZAH would be such that patient access to this novel therapy would be effectively eliminated for all patients." Id. ¶ 120. Williams further explained that "Ardelyx's decision . . . to change its previously assumed path and forego applying to include XPHOZAH in TDAPA was grounded in a well-studied assessment of market realities and the TDAPA program's structural shortcomings." Id. ¶ 125. Relying on these statements, Plaintiffs claim that Ardelyx "had known long before July 2, 2024" that TDAPA would be unsuccessful and yet concealed its decision not to apply for TDAPA from investors. Id. ¶ 126. However, elsewhere in the declaration, Williams described that Ardelyx's TDAPA application "continued to be drafted until late June 2024," Doc. No. 37-3 ¶ 8, up until "Ardelyx's June 2024 decision not to apply for TDAPA," id. ¶ 13.

Plaintiffs commenced this action on August 16, 2024, Doc. No. 1, and filed the amended complaint on January 13, 2025, Doc. No. 25. They currently advance four counts: (1) securities fraud violations of Section 10(b) of the Exchange Act and Rule 10b-5 against Ardelyx, Raab, and Rodriguez,[5] (2) insider trading violations of Section 10(b) of the Exchange Act against Grammer and Williams, (3) violations of Section 20A of the Exchange Act against Grammer and Williams, and (4) violations of Section 20(a) of the Exchange Act against Grammer, Williams, Raab, and Rodriguez. Defendants moved to dismiss all of Plaintiffs' claims for failure to state a claim. Doc. No. 32. The Court held a hearing on the motion to dismiss on December 4, 2025.

II. LEGAL STANDARD

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). The court must "take all factual allegations [in the complaint] as true and . . . draw all reasonable inferences in favor of the plaintiff." Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 96 (1st Cir. 2007). But "[t]he court need not accept a plaintiff's assertion that a factual allegation satisfies an element of a claim, . . . nor must a court infer from the assertion of a legal conclusion that factual allegations could be made that would justify drawing such a conclusion." Cordero-Hernandez v. Hernandez-Ballesteros, 449 F.3d 240, 244 n.3 (1st Cir. 2006). In addition, the court "may augment these facts and inferences with data points gleaned from documents incorporated by reference into the complaint, matters of public record, and facts susceptible to judicial notice." Haley v. City of Bos., 657 F.3d 39, 46 (1st Cir. 2011).

[5] Plaintiffs originally asserted Count I against all Defendants in their amended complaint. Doc. No. 25 ¶ 173. However, Plaintiffs have since agreed to dismiss their Section 10(b) claims set out in Count I against Grammer and Williams. Doc. No. 36 at 30 n.8.

III. DISCUSSION

A. Securities Fraud Claims (Count I)

The Court begins with Plaintiffs' securities fraud claims. "For a complaint to state a claim for securities fraud under section 10(b) and Rule 10b–5, it must plead six elements: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). Because Rule 9(b) applies to claims of securities fraud, Plaintiffs are "required to plead the circumstances of the securities fraud with particularity." Zhou v. Desktop Metal, Inc., 120 F.4th 278, 287 (1st Cir. 2024).

1. *False or Misleading Statements*

The Court first considers whether Plaintiffs have sufficiently alleged that Defendants made materially false or misleading statements during the Class Period. The Private Securities Litigation Reform Act ("PSLRA") requires Plaintiffs to "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u–4(b)(1). "To establish a material misrepresentation or omission, [plaintiffs] must show that defendants made a material false or misleading statement or omitted to state a material fact necessary to make a statement not misleading." Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 454 (1st Cir. 2017) (citation modified).

Plaintiffs offer four allegedly false statements made by Defendants between February 22, 2024, and May 2, 2024. The first is a 2023 Form 10-K that Ardelyx filed with the SEC on February 22, 2024. Doc. No. 25 ¶ 127; Doc. No. 33-1. The second involves statements by Rodriguez at a healthcare conference on March 5, 2024. Doc. No. 25 ¶ 129; Doc. No. 33-14. The third is a 10-Q filed by Ardelyx with the SEC on May 2, 2024. Doc. No. 25 ¶ 131; Doc. No.

33-5. And the fourth involves statements by Raab during an earnings call on May 2, 2024. Doc. No. 25 ¶ 133; Doc. No. 33-7.

With all reasonable inferences drawn in favor of Plaintiffs, each of the statements either directly expressed or indirectly implied Ardelyx's then-present intent to apply for TDAPA. The SEC disclosure statements implied Ardelyx would apply for TDAPA by explaining the risks of rejection from the TDAPA program and the potential downsides of participation in TDAPA without indicating any prospect of not applying. Doc. No. 25 ¶¶ 127, 131. The Raab statement expressly announced that "currently, . . . our intent is to enter TDAPA." Id. ¶ 133. The Rodriguez statement is more ambiguous. She acknowledged that XPHOZAH would move into a "transition period" in the event the Bundle was not delayed and noted that "TDAPA is really very hard to predict," while expressing a general commitment to do "everything we can to make sure that all patients who need XPHOXAH will have access." Id. ¶ 129. Nonetheless, given her detailed discussion of the mechanics of the TDAPA process, the Court reads her statement as also implying a present intent to participate in TDAPA.

Plaintiffs contend that Defendants had already decided not to apply for TDAPA before making each of the challenged statements, thus rendering each statement false and misleading. See id. ¶¶ 128, 132 ("Defendants' statements were misleading because . . . Ardelyx did not intend to apply for TDAPA because XPHOZAH would lose its market even during the TDAPA period, let alone thereafter."); id. ¶ 134 ("Defendants' statements were false because Ardelyx did not intend to apply for TDAPA as it was not a viable option."); Doc. No. 36 at 21 ("Defendants' statements misleadingly described their present intentions by concealing that Ardelyx did not intend to apply for TDAPA."); id. at 23 (arguing that at time of statements "Defendants knew TDAPA was not a viable option, such that Ardelyx did not intend to apply for TDAPA"). At the

motion hearing, however, Plaintiffs softened their stance to suggest that Defendants at least harbored serious doubts about applying to TDAPA at the time the statements were made, even if they had not yet finalized their decision to not apply. This theory was not advanced in the complaint nor argued by Plaintiffs in their opposition brief and is, therefore, waived. United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990) (citation modified) ("[A] litigant has an obligation to spell out its arguments squarely and distinctly, or else forever hold its peace."). Nonetheless, for completeness' sake, the Court addresses this additional theory below.

As a threshold matter, Plaintiffs offer no factual allegations contemporaneous with any of the challenged statements that directly show Defendants either had decided not to apply or harbored serious doubts about applying for TDAPA. That is, Plaintiffs point to no internal emails or documents, no statements or reports from confidential sources, nor anything else from the period of the challenged statements expressly stating that Defendants did not intend to apply to TDAPA or harbored serious doubts about applying. Plaintiffs advance no such direct or express allegations. Moreover, Plaintiffs do not identify a specific point in time when Defendants decided not to apply for TDAPA or began having serious doubts. Miami Fire Fighters' & Police Officers' Ret. Tr. v. CVS Health Corp., 46 F.4th 22, 31 (1st Cir. 2022) (finding that plaintiffs "fail to allege that defendants made statements of fact that were false . . . or misleadingly incomplete in light of contemporaneous circumstances" where plaintiffs did not allege "sufficiently specific facts" about state of business at time of statements). Nor do Plaintiffs allege a triggering event that prompted Defendants' decision not to apply or caused them to harbor serious doubts.

Instead, Plaintiffs construct a circumstantial case from the following building blocks. Before and throughout the Class Period, four other drugs—Korsuva, Sensipar, Parsabiv, and

Jesduvroq—went through the TDAPA process, and their sales significantly declined either during or after their TDAPA periods. Doc. No. 25 ¶¶ 72-81. Defendants knew about these other drugs' outcomes from TDAPA because they mentioned these drugs in their private communications to CMS in March of 2024. Id. ¶¶ 58-70. More specifically, during a March 11, 2024, presentation to CMS discussing the impact of the Bundle, Ardelyx characterized these four drugs as "Innovation Lost." Id. ¶¶ 65-66. In Plaintiffs' telling, Defendants necessarily and immediately knew, merely from knowing this information about other drugs, that they would not apply to TDAPA or harbored serious doubts about applying. Plaintiffs allege that Defendants understood this at the time of each challenged statement.

To augment these assertions, Plaintiffs cite two other communications by Ardelyx executives, which allegedly reveal that Defendants knew all along that TDAPA was not a viable option. First, Plaintiffs point to Raab's July 2 call announcing Ardelyx's decision not to apply for TDAPA. During that call, Raab stated that "[i]t is absolutely clear that within the Bundle and beginning with TDAPA, the restrictions . . . would effectively eliminate patient access" to XPHOZAH. Id. ¶ 106. Of course, Raab also mentioned CMS's June 27 rule as the factor that "drove" Ardelyx's decision. Id. ¶¶ 108-110. But Plaintiffs argue that the June 27 rule served as mere pretext for the decision to forego TDAPA; in reality, Ardelyx knew all along that it would not apply for TDAPA "based on the experience of Korsuva and Parsabiv." Id. ¶ 111. Similarly, Plaintiffs cite to Williams's October 16 declaration, in which she explained that Ardelyx decided not to apply for TDAPA based on "a well-studied assessment of market realities and the TDAPA program's structural shortcomings," which included "Korsuva's recent experience" on TDAPA. Id. ¶¶ 118-126. Based on the foregoing facts, Plaintiffs advance the following chain of inference: (1) Defendants knew about the negative experiences of other drugs on TDAPA before

the Class Period; (2) Defendants made the decision not to apply for TDAPA (or, at least, harbored serious doubts about applying for TDAPA) based on the experiences of those other drugs; therefore, (3) Defendants made the decision not to apply or at least harbored serious doubts about applying for TDAPA before the Class Period and, thus, before making the challenged statements.

The Court declines to make this inferential leap. On the record before the Court, the inference Plaintiffs wish the Court to draw—that Defendants had decided not to apply for TDAPA at the time of the challenged statements (as alleged in the complaint) or harbored serious doubts about applying (as argued at the hearing)—is neither a reasonable inference nor a plausible allegation of false or misleading statements pled with particularity. Five considerations dictate the Court's decision.

First, the performance of the four other drugs during and after TDAPA fails to support the inference the Plaintiffs urge. As Plaintiffs themselves note in the amended complaint, one of the four drugs, Parsabiv, experienced its "sales r[i]se" during its TDAPA period, generating sales of $156 million. Id. ¶ 77. That Parsabiv did well during its TDAPA period defeats the notion that Defendants necessarily decided not to apply for TDAPA based on the performance of these four drugs. This is especially so because Plaintiffs, as noted above, offer no direct factual allegations showing that Defendants had decided not to apply (or had serious doubts about applying) for TDAPA before making any of the challenged statements. Nor do they provide any factual allegations showing that at the time of the challenged statements, Defendants understood XPHOZAH as necessarily akin to the three drugs that did badly during TDAPA, rather than the one drug that did well. The foregoing suffices to show that Plaintiffs lack the factual allegations

required to support their assertions that the challenged statements were false and misleading. But, there is more.

Second, that TDAPA was an ineffective program for some other drugs is consistent, rather than inconsistent, with Defendants' challenged statements. While Defendants expressed their then-present intent to apply for TDAPA during the Class Period, they never presented TDAPA as a panacea for combatting the harms of the Bundle. Instead, they reiterated to investors before, during, and after the Class Period that staying out of the Bundle altogether presented the best-case scenario and characterized TDAPA as the intended fallback if XPHOZAH were placed in the Bundle. Id. ¶¶ 54, 129, 133; see also Doc. No. 33-2 at 11-12; Doc. No. 33-11 at 7. Defendants also disclosed on multiple occasions that TDAPA was not nearly as promising as staying out of the Bundle and that the consequences of TDAPA on XPHOZAH's market were unpredictable. The challenged SEC disclosures made these points; in those statements, Ardelyx cautioned that XPHOZAH's revenue "could be significantly less in the TDAPA period than it would be if XPHOZAH is not bundled," and that any increase in the Bundle base rate from TDAPA may not "be sufficient to adequately reimburse the dialysis facilities" "at a price that is profitable for us." Doc. No. 25 ¶¶ 127, 131. Rodriguez's March 5 statement echoed this ambivalent perspective, noting that "TDAPA is really very hard to predict." Id. ¶ 129. Raab's May 2 statement similarly referenced the unknowns of the TDAPA process. Id. ¶ 133 (noting that "the specifics" of XPHOZAH entering TDAPA would "play out over time"). Put simply, all the challenged statements cautioned investors about the risks and potential downsides of the TDAPA process. None of this supports the conclusion that Defendants had decided not to apply for TDAPA or harbored serious doubts about applying at the time of the statements.

Plaintiffs argue that such statements were still misleading because Defendants failed to disclose that it was "certain," not just "possible," that "XPHOZAH's use would decrease during the TDAPA period." Id. ¶ 128. They ask the Court to infer that Defendants knew TDAPA was "not viable" based on the poor performance of the four drugs that Ardelyx referenced in its March 11 presentation to CMS. Id. ¶¶ 72-81, 148. But nothing in the March 11 presentation supports the inference that Defendants knew "XPHOZAH's use would decrease during the TDAPA period" based on the prior experiences of other drugs. While most of the referenced drugs, especially Korsuva, performed poorly during TDAPA, id. ¶¶ 71-74, one of the drugs, Parsabiv, did reasonably well during the TDAPA period, as mentioned above, id. ¶ 77.[6] It was only after the conclusion of the two-year TDAPA period that use of Parsabiv dropped off substantially. Id.

That Parsabiv's "sales rose" during its two-year TDAPA period, id., precludes (absent other allegations, none of which are sufficient as discussed elsewhere) Plaintiffs' assertion that Defendant understood, solely based on the performance of other drugs, that TDAPA was "not viable," id. ¶ 148. Indeed, Ardelyx's executives publicly explained, and investors understood, that Ardelyx viewed TDAPA as a short-term measure to help XPHOZAH survive for two years should it be placed in the Bundle. See id. ¶ 54 (quoting Ardelyx executive's explanation that TDAPA "could give . . . two or more years of extended time for the government to figure out utilization); id. ¶ 57 (quoting market analyst's statement that TDAPA will "provid[e] a carve-out till 2027, thus providing insulation if in fact other orals go into the bundle"). Thus, even if

[6] The Court notes here that Parsabiv is a calcimimetic, a type of drug that CMS placed into TDAPA in a special, aggregated basis. This is the same TDAPA process that CMS later used for phosphate binders, but not for XPHOZAH, under the proposed rule issued on June 27, 2024. CMS's differential treatment between XPHOZAH and phosphate binders will be discussed in more detail below.

Defendants believed that XPHOZAH's market was likely to plummet after the two-year TDAPA period as Parsabiv's market had (a reasonable inference drawn in Plaintiffs' favor on this record), that does not support a further inference that they concluded TDAPA was not worth pursuing as a second-best, short-term option.

Third, the regulatory developments that occurred during the Class Period run counter to the inference Plaintiffs propose. Not until after all of the challenged statements did CMS provide a full picture of the following regulatory decisions: that it was not delaying the application of the Bundle to oral drugs, that it was placing XPHOZAH in the Bundle, and that it was not grouping XPHOZAH with phosphate binders.

On April 29, 2024, CMS issued a guidance announcing its plan to add oral-only drugs to the Bundle starting on January 1, 2025, shutting down Ardelyx's hopes of delaying the expansion of the Bundle. Doc. No. 37-1 at 2. In the same guidance, CMS also previewed how it would treat certain drugs in the Bundle, noting that "CMS will use the same process that it used for calcimimetics to incorporate phosphate binders" into the Bundle but would not use this process for "any other oral drugs or biological products." Id. Neither this statement nor anything else in the guidance specified whether XPHOZAH, an oral phosphate-lowering drug, would be classified with phosphate binders or with "other drugs or biological products."

On May 13, 2024, CMS sent a letter to Ardelyx confirming that XPHOZAH would be added to the Bundle, thereby ending the possibility of an exception and identifying XPHOZAH as a "renal dialysis service" "used as an add-on therapy in patients . . . who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy." Doc. No. 37-2. The letter urged Ardelyx to submit a TDAPA application as soon as possible to ensure eligibility, id. at 3, seeming to imply that XPHOZAH would not undergo the special

TDAPA process carved out for phosphate binders. But the letter left some uncertainty about XPHOZAH's treatment. Nowhere in the letter did CMS expressly state that it would treat XPHOZAH separately from phosphate binders. And, adding to the ambiguity, the letter noted that CMS's April 29 "operational guidance . . . in connection with the incorporation of phosphate binders" in the Bundle "may provide helpful information to Ardelyx." Id.[7]

Finally, on June 27, 2024, CMS issued a proposed rule. It publicly and explicitly confirmed that XPHOZAH would not be treated like phosphate binders during TDAPA or when placed in the Bundle.[8] While phosphate binders would enter TDAPA on an aggregated basis

[7] The Court draws all reasonable inferences in favor of Plaintiffs when reading the May 13 letter. But whether a particular inference Plaintiffs seek to draw from the letter is a reasonable one requires consideration of the entire letter. Furthermore, even if the Court were to infer that the May 13 letter revealed to Defendants that XPHOZAH would be treated separately from phosphate binders, this inference would not render any of the challenged statements false or misleading, as the letter was issued after all the statements.

[8] Plaintiffs argue Defendants knew about CMS's differential treatment as early as April 29, 2024, because, in their view, CMS's April 29 guidance made clear that phosphate binders would be treated differently than XPHOZAH. Doc. No. 36 at 20. There are several issues with this argument. First, Plaintiffs never mentioned the April 29 guidance in their amended complaint and raised it for the first time in their opposition brief. Id. Moreover, the April 29 guidance did not clearly communicate to Ardelyx, as Plaintiffs insist that it did, that XPHOZAH would be treated separately from phosphate binders. The April 29 guidance vaguely laid out that the TDAPA process for phosphate binders would not apply to "any other oral drugs or biological products." Doc. No. 37-1 at 2. Similarly, the May 13 letter described XPHOZAH as a "renal dialysis service" used as "an add-on therapy" to phosphate binders, but did not state that XPHOZAH would be grouped separately from phosphate binders under the upcoming rule and noted that the April 29 guidance about the incorporation of phosphate binders "may provide helpful information to Ardelyx." Doc. No. 37-2 at 2-3. It was not until the June 27 rule that CMS made explicit its decision to treat XPHOZAH differently from phosphate binders for the TDAPA process. Plaintiffs make much of the scientific difference between XPHOZAH and the binders, arguing that Ardelyx must have known on April 29 that XPHOZAH would not be considered a phosphate binder because its mechanism does not technically "bind" to phosphorus. Doc. No. 36 at 20. The scientific distinction is undisputed. But regulatory and insurance decisions regarding drug reimbursements are decisions of a different nature. The intertwined medical relationship between XPHOZAH and phosphate binders precludes, on this record, the conclusion Plaintiffs draw from the scientific differences. And, Plaintiffs point to nothing else to support their conclusion.

similar to calcimimetics (such as Parsabiv), the regular TDAPA process would govern XPHOZAH, along with all other oral drugs or biological products.

The parties dispute whether this differential treatment meant that XPHOZAH would be treated worse off under CMS's Bundle payment adjustment formula. Doc. No. 34 at 17; Doc. No. 36 at 20. Resolving that dispute is not only beyond the scope of the issues and briefing before the Court, but also immaterial to the disposition of the pending motion. The June 27 rule's plain language makes clear that CMS said it was treating XPHOZAH differently from phosphate binders in some manner; the rule states that "CMS will use the same process that it used for calcimimetics to incorporate phosphate binders," but "will not be following this process for any other oral drugs or biological products . . . such as XPHOZAH." Prospective Payment System Proposed Rule at 55795. And Raab repeatedly stated during his July 2 call that CMS's decision to treat XPHOZAH differently mattered to Ardelyx. Doc. No. 33-11 at 6, 12-13. Raab explained that CMS's differential treatment meant that XPHOZAH would be treated like Korsuva rather than Parsabiv, making it more likely that XPHOZAH's sales would mirror Korsuva's negative trajectory during its TDAPA period. Id. at 11-13. Thus, the evolving regulatory developments run directly counter to the inference Plaintiffs urge—that Defendants always knew how XPHOZAH would fail under TDAPA.

Fourth, Plaintiffs argue that Raab's July 2 statements attributing Ardelyx's decision not to apply for TDAPA to the June 27 rule "was not true" because "Ardelyx had decided not to enter TDAPA based on the experience of Korsuva and Parsabiv." Doc. No. 25 ¶ 111. Plaintiffs further contend that Raab's reliance on the June 27 rule was "designed to give investors the [false] impression that the change in Ardelyx's position resulted from changed circumstances, rather than the facts Ardelyx had known all along." Id. ¶ 145. But this argument is not

supported by Raab's actual statements during the July 2 call or by other facts alleged in the complaint.

For starters, Plaintiffs allege no facts to show that Raab's assessment of the June 27 rule—that the rule treated XPHOZAH similarly to Korsuva under the TDAPA process—was false or fabricated. Furthermore, Plaintiffs cherry-pick from Raab's July 2 call. Cf. In re Synchrony Fin. Sec. Litig., 988 F.3d 157, 171 (2d Cir. 2021) (noting that securities fraud plaintiff "may not cherry pick certain public statements for its complaint and divorce them from the universe of disclosed information to plausibly allege fraud"). Raab never expressed that Ardelyx's decision to forego TDAPA was based on one reason alone. Rather, he referenced various considerations and priorities that Ardelyx weighed before reaching its final decision. He mentioned infrastructural limitations of dialysis organizations in dispensing drugs to patients. Doc. No. 33-11 at 10. He referenced Ardelyx's continued efforts to avoid the Bundle altogether by pushing Congress to pass legislation delaying the inclusion of oral-only drugs. Id. at 7. He flagged that the decision not to apply for TDAPA was not a permanent one, articulating his belief that "there would be opportunities for us to subsequently file for TDAPA." Id. at 10. He also stated that Ardelyx's decision not to apply "provides the most optionality to explore alternatives to protect access for all patients." Id. at 7. Raab did not specify what these other alternatives entailed, noting that Ardelyx "still ha[d] more analyses to conduct in the weeks and months ahead to determine the best strategy." Id. But the allegations of the complaint disclose at least one other option Ardelyx pursued. Two weeks after Raab spoke, Ardelyx sued CMS, seeking an injunction barring CMS from putting XPHOZAH in the Bundle. Doc. No. 25 ¶ 112.

Raab also admitted during the July 2 call that the negative experiences of other drugs on TDAPA "drove a big part of our consideration for this decision." Doc. No. 33-11 at 8.

However, Raab's consideration of other drugs' poor outcomes under TDAPA do not support Plaintiffs' conclusory assertion that "Defendants' assessment on July 2, 2024 [that TDAPA would effectively eliminate access to XPHOZAH], is the same assessment they had on February 22, 2024, and it is the same assessment they presented to CMS on March 11, 2024." Doc. No. 36 at 21. Plaintiffs' own allegations and the record before the Court show that Defendants' assessment of XPHOZAH's prospects under TDAPA dimmed over time as the Bundle loomed closer (Doc. No. 37-3 ¶¶ 5-26), the regulatory landscape evolved (Doc. No. 37-1; Doc. No. 37-2; Prospective Payment System Proposed Rule), and Ardelyx grew its understanding of how XPHOZAH would fare under TDAPA (Doc. No. 37-3 ¶¶ 9-19).

Williams's October 16 declaration, which is incorporated by reference, is instructive on this matter. In that declaration, Williams stated, "[a]s Ardelyx further analyzed XPHOZAH's commercial opportunity in the first half of 2024, Ardelyx determined that even during the TDAPA period, the restrictions placed on XPHOZAH would be such that patient access to this novel therapy would be effectively eliminated for all patients." Doc. No. 37-3 ¶ 10. Plaintiffs rely on this statement to argue that Ardelyx abandoned its plan to apply for TDAPA before any of the challenged statements were made. Doc. No. 25 ¶¶ 118-126. But by contrast, Williams's declaration conveyed that Ardelyx stuck to its plan to apply for TDAPA until late June 2024. Doc. No. 37-3 ¶ 8. Williams further explained that Ardelyx "conducted extensive analysis to more fully understand the impact of TDAPA on XPHOZAH" "[i]n parallel with preparing its TDAPA application in the first half of 2024." Id. ¶ 9. As part of that "extensive analysis," Ardelyx "considered the real-world experience of Korsuva," and found that patients had minimal access to Korsuva during the drug's two-year TDAPA period. Id. ¶¶ 11-12. Korsuva's poor outcomes during its TDAPA period became more pertinent to Ardelyx in light of the

implications of CMS's June 27 rule, "which suggested that reimbursement for XPHOZAH was likely to be at the same level as Korsuva." Id. ¶ 14. Accordingly, Williams came to learn that, "as with Korsuva, providers would have been heavily disincentivized to prescribe XPHOZAH during the TDAPA period in order to avoid having to cease prescribing XPHOZAH at the end of that short period." Id. ¶ 16. These realizations contributed to Ardelyx's decision to abandon its TDAPA application in late June. Id. ¶ 19.

Williams's declaration highlights two points. First, the declaration does not describe or imply Plaintiffs' theory that Ardelyx cemented its decision to forego (or at least harbored serious doubts about) TDAPA promptly upon learning about other drugs' failures on TDAPA. Rather, the declaration states that it took time for Ardelyx to synthesize and interpret the existing market data and the shifting regulatory landscape. Second, the declaration suggests that Ardelyx did not fully appreciate the relevance of Korsuva's TDAPA experience until CMS's June 27 rule indicated that XPHOZAH would be treated in a similar manner to Korsuva. This conforms with Raab's July 2 statement that Ardelyx understood the June 27 rule as treating XPHOZAH "how Korsuva was treated." Doc. No. 33-11 at 12. Thus, while Plaintiffs portray Williams's declaration as proving "that the June 27 proposed rule had no impact on expected recovery during TDAPA," Doc. No. 36 at 18, the actual declaration states the opposite. Williams's declaration—which explains that Ardelyx gave up applying for TDAPA in late June 2024 after evolving its assessment based on changing regulatory circumstances—"contains commentary that tends to confirm, rather than correct, [Defendants'] representations to the market." Kader v. Sarepta Therapeutics, Inc., No. 1:14-cv-14318-ADB, 2016 WL 1337256, at *14 (D. Mass. Apr. 5, 2016). Accordingly, Raab's July 2 statements and Williams's October 16 declaration directly contradict the inference Plaintiffs urge.

Finally, Plaintiffs contend Defendants always knew XPHOZAH would not "thrive" under TDAPA simply based on their understanding of "the nature of the dialysis market." Doc. No. 25 ¶¶ 82-92. Plaintiffs explain that under TDAPA, bundled drugs are reimbursed under Medicare Part B, which means the drugs must be dispensed by the dialysis center directly rather than through a pharmacy. Id. ¶ 82. Dialysis providers are "reluctant to draft protocols that include drugs that are on TDAPA," because rewriting protocols "is complicated and takes extensive employee time," and because "dialysis providers know that after two years, drugs on TDAPA will . . . become a significant expense." Id. ¶ 89. With dialysis centers disincentivized to stock drugs on TDAPA, Plaintiffs conclude that switching to Medicaid Part B "significantly restricts access" to dialysis drugs, even when the drugs are separately reimbursed by the TDAPA program. Id. ¶ 91. Plaintiffs further claim that, "[t]hough these facts are obscure to investors, they were well known to Defendants" because they were experts in nephrology with large networks in the dialysis industry. Id. ¶ 92. Based on these facts, Plaintiffs argue that Ardelyx knew all along that TDAPA was not a viable path for XPHOZAH yet concealed this knowledge from the public during the Class Period.

This theory is unsupported by the record before the Court. For one, Plaintiffs' arguments reach too broadly. Their allegations about the industry-wide drawbacks of the TDAPA program have little to do with XPHOZAH's specific circumstances within the dialysis industry. Rather, their theory is just another way of saying TDAPA was not a viable option for any drug, and that anyone with sufficient industry experience, including Defendants, would have known so. Plaintiffs plead no non-conclusory facts—besides the noted industry-level observations about dialysis centers—to support such a sweeping theory. And while dialysis centers' burdensome protocols may disincentivize them from stocking drugs on TDAPA to some extent, that is quite

different from asserting that this infrastructural burden meant that all drugs on TDAPA were fated to fail.[9] Moreover, Plaintiffs' own factual allegations undermine this theory: As discussed above, several different drug manufacturers did apply for TDAPA, and one drug enjoyed substantial sales during the TDAPA period. Id. ¶¶ 72-81. Nor have Plaintiffs pled that no drug manufacturers applied for TDAPA at the July 1, 2024, deadline or any time since then.

In light of the foregoing, Plaintiffs have not sufficiently alleged that Defendants did not intend to apply to TDAPA or harbored serious doubts about applying at the time they made the challenged statements. Plaintiffs offer no direct factual allegations to support this account. Furthermore, Plaintiffs' circumstantial facts fail to support the inference they urge or plausibly allege the existence of any false or misleading statements. At this stage, the "relevant inquiry focuses on the reasonableness of the inference of liability that the plaintiff is asking the court to draw from the facts alleged in the complaint." Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 13 (1st Cir. 2011). Even if it is conceivable on Plaintiffs' facts that Defendants knew Ardelyx would not apply for TDAPA or harbored serious doubts about TDAPA at the time of some or all of the challenged statements, "the combined allegations, taken as true, must state a plausible, not a merely conceivable, case for relief." Id. (quoting Sepúlveda–Villarini v. Dep't of Educ. of P.R., 628 F.3d 25, 29 (1st Cir. 2010)). Plaintiffs' pleadings fail to meet this standard. Therefore, the Court concludes that Plaintiffs have not sufficiently pled the falsity of Defendants' challenged statements.

[9] Plaintiffs also have not advanced any particularized facts to show that these infrastructural shortcomings of dialysis centers posed a unique disadvantage for XPHOZAH. The only specific fact they allege is that XPHOZAH was priced at a "30% premium to the most expensive new branded phosphate binder." Doc. No. 25 ¶ 44. But XPHOZAH's relative costliness is not sufficient to support the conclusion Plaintiffs advance—that any rational actor in Ardelyx's shoes would have automatically and immediately decided against applying for TDAPA based on dialysis centers' burdensome protocols and XPHOZAH's cost.

2. *Scienter*

Since Plaintiffs have not sufficiently alleged the existence of any false statements, Plaintiffs' securities fraud claims cannot survive dismissal. Nonetheless, the Court addresses Plaintiffs' scienter allegations for the sake of thoroughness. They, too, are unavailing.

The PSLRA "imposes a rigorous pleading standard on allegations of scienter." ACA, 512 F.3d at 58. "In this circuit, a plaintiff may satisfy the scienter requirement with a showing of either conscious intent to defraud or 'a high degree of recklessness.'" Id. (quoting Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002)). Plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" for each false statement. 15 U.S.C. § 78u–4(b)(2)(A). "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 309.

Plaintiffs raise various allegations in support of scienter, but they fail to create a strong inference that Defendants acted with a conscious intent to defraud or a high degree of recklessness. For one, Plaintiffs stress that XPHOZAH's central importance to Ardelyx's business would have made the falsity of the statements obvious to Defendants. Doc. No. 36 at 33-34. XPHOZAH's success was a high priority for Defendants, given that it was one of only two products sold by Ardelyx. Id. at 33. Investors, too, were concerned with XPHOZAH's future performance and repeatedly brought up their interest in TDAPA. Doc. No. 25 ¶¶ 139-144. Furthermore, Defendants were experts in nephrology and were familiar with the workings of the renal therapeutics market. Id. ¶¶ 150-153. Based on these facts, Plaintiffs argue that Defendants would have learned that TDAPA was not a viable option before the Class Period because they would have been paying close attention to XPHOZAH and the prospect of entering it into TDAPA.

However, Plaintiffs do not explain how and when Defendants would have reached the conclusion that TDAPA was not viable merely by paying attention to XPHOZAH and the dialysis industry. Plaintiffs attempt to analogize this case to the First Circuit's decision in Carbonite, Doc. No. 36 at 34, but the facts there are meaningfully distinguishable. That case involved a company's statements touting a new product created to perform cloud-based backups. Constr. Indus. & Laborers Joint Pension Tr. v. Carbonite, Inc., 22 F.4th 1, 4 (1st Cir. 2021). However, the company's product had fumbled in every trial run, producing "not one successful backup." Id. The company's employees internally reported that the product was not ready for market, and yet a senior officer publicly proclaimed that it was "super strong." Id. at 7, 10. There, the First Circuit found a strong inference that the company's senior management acted with scienter because paying attention to the product would have revealed that it plainly did not work. Id. at 10.

This case is entirely different. Here, there are no facts to suggest that paying close attention to XPHOZAH during the time of the challenged statements would have revealed that its market would plummet under TDAPA. Unlike in Carbonite, Plaintiffs do not allege that Defendants had access to any internal reports or communications that would have made it clear that XPHOZAH would face disastrous outcomes under TDAPA. Cases where the First Circuit has found scienter "often contain[] clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012). Plaintiffs provide no such "clear allegations" of scienter. Indeed, Plaintiffs' own allegations demonstrate Defendants were paying attention and were neither overstating

XPHOZAH's chances of success nor downplaying the risks of TDAPA. Defendants repeatedly emphasized many of the problems that could arise if XPHOZAH were placed into TDAPA. The question posed by this case is not whether Defendants were paying attention, but whether Defendants lied (by stating they intended to apply for TDAPA when they did not so intend) or misled (by stating they intended to apply when they harbored serious doubts about doing so). For scienter, both theories require an inference that the experience of the other drugs virtually dictated the conclusions Plaintiffs reach—that Defendants must have decided not to apply or harbored serious doubts about applying and knowingly or recklessly concealed their decision or doubts from investors. But Plaintiffs fail to allege sufficient facts to support this inference.

Plaintiffs merely point to Ardelyx's March 2024 communications to CMS emphasizing the decline of four other drugs that had undergone the TDAPA process. Doc. No. 36 at 34. They insist that these communications with CMS were "inconsistent" with the statements that Defendants made to investors about their intent to apply for TDAPA. Doc. No. 25 ¶¶ 147-149. But as discussed in the preceding section, nothing in Ardelyx's March communications to CMS indicate that Defendants knew then that TDAPA was not a viable option for XPHOZAH. One drug mentioned in the March presentation enjoyed high sales during its TDAPA period, suggesting that TDAPA might well serve as a useful stop-gap program for some drugs. Id. ¶ 77. This precisely matches how Defendants had been describing TDAPA to investors: as a temporary remedy, rather than a long-term solution. And to the extent that Defendants knew about the risks and downsides of the TDAPA process, they shared these concerns with investors. See, e.g., id. ¶ 127 (warning that "revenue for sales of XPHOZAH could be significantly less in the TDAPA period" and that any post-TDAPA adjustment to the Bundle may not be "sufficient to adequately reimburse the dialysis facilities . . . at a price that is profitable for us"). Unlike

Carbonite, where the senior official publicly expressed unfettered optimism about a non-functional product, here, Defendants' statements to the public disclosed mixed feelings and uncertainties about the TDAPA process. Thus, Carbonite does not aid Plaintiffs' scienter allegations.

Additionally, Plaintiffs contend that Raab's July 2 statements blaming the June 27 rule amounted to "false exculpatory statements," thereby supporting a strong inference of scienter. Id. ¶¶ 145-146. But as explained above, Plaintiffs have not sufficiently alleged that Raab's explanation of the June 27 rule's impact on XPHOZAH was false or fabricated. Raab explained that the June 27 rule informed Ardelyx that XPHOZAH would be treated in a similar manner to Korsuva, a drug that performed poorly during its TDAPA period. Doc. No. 33-11 at 12. Raab also described several other considerations that contributed to Ardelyx's ultimate decision to forego TDAPA. Id. at 6-12. Williams's October 16 declaration similarly expressed that Ardelyx abandoned its TDAPA application in late June 2024 upon conducting a market evaluation and considering Korsuva's TDAPA experiences in light of the June 27 rule. Doc. No. 37-3 ¶¶ 9-26. In the face of these statements, that Defendants reevaluated their prior intent to apply for TDAPA based on evolving priorities and changing regulatory circumstances presents a far more

cogent inference than the opposing inference advanced by Plaintiffs—that Defendants had always known they would not apply.[10]

What remains of Plaintiffs' scienter arguments are allegations about Williams's and Grammer's stock sales during the Class Period. Doc. No. 25 ¶ 138. "Insider trading in suspicious amounts or at suspicious times may be probative of scienter." Miss. Pub. Emps'. Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 92 (1st Cir. 2008). "For stock sales by corporate officials to bolster an inference of scienter, the trading must be, '[a]t a minimum . . . unusual, well beyond the normal patterns of trading by those defendants.'" Angelos v. Tokai Pharms., Inc., 494 F. Supp. 3d 39, 58 (D. Mass. 2020) (quoting Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 761 (1st Cir. 2011)).

[10] In their opposition brief, Plaintiffs theorize that Raab presented his "false exculpatory statement" on July 2, 2024, to cover up Defendants' prior negligence. Doc. No. 36 at 34-35. They argue that before the Class Period, Defendants made several optimistic statements about entering TDAPA even though they had not yet investigated the viability of the TDAPA program. Id. at 31. Defendants quickly realized that TDAPA was not a viable option, but they did not want to publicly admit that they had made material statements to investors without justification. Id. Therefore, Defendants continued to advance false statements about applying for TDAPA to conceal their earlier negligence and later used the June 27 rule as pretext for their decision not to apply. Id. at 31-40.

Plaintiffs' theory is neither plausible nor a reasonable explanation of the events. Even if Defendants had done what Plaintiffs allege—lie about their intent to apply for TDAPA to cover up their prior negligence—they had every reason to continue their deception and apply for TDAPA by the July 1, 2024, deadline, rather than to "reveal" their lies. Nothing forced Defendants' hand at the deadline. Plaintiffs do not allege that submitting the TDAPA application would have been costly or infeasible for Defendants; in fact, according to Williams's declaration, Ardelyx had already begun drafting the TDAPA application. Doc. No. 37-3 ¶ 8 ("Ardelyx began preparing a TDAPA application for XPHOZAH, which application continued to be drafted until late June 2024."). And if XPHOZAH were accepted into TDAPA, Defendants could have blamed CMS when TDAPA ultimately proved unsuccessful, which Defendants' cautionary statements foreshadowed. Plaintiffs allege no reason why Raab was forced to resort to making a false exculpatory statement on July 2 instead of simply carrying on his longstanding lie. The more cogent inference to be drawn here is that Defendants arrived at their decision to forego TDAPA as circumstances changed and as they weighed other strategies, as Raab explained to investors during the July 2 call.

Plaintiffs allege that Grammer and Williams respectively sold 37.6% and 33.7% of all shares available to sell during the Class Period. Doc. No. 25 ¶ 101. Plaintiffs further state that neither executive "had ever engaged in similar sales" before the Class Period. Id. ¶ 98. While these allegations on their own may raise eyebrows, Plaintiffs' insider trading claims fall short in other respects. For starters, all stock sales besides the sales on May 6 and June 5 were made pursuant to Rule 10b-5 trading plans that Williams and Grammer adopted before the Class Period. Id. ¶ 97. "[T]he presence of a trading plan rebuts an inference of scienter and supports the reasonable inference that stock sales were pre-scheduled and not suspicious." Stiegele ex rel. Viisage Tech., Inc. v. Bailey, No. 05-cv-10677-MLW, 2007 WL 4197496, at *13 (D. Mass. Aug. 23, 2007). Furthermore, Plaintiffs allege that only two executives committed insider trading, neither of whom made any of the allegedly false statements. Plaintiffs make no claim that Raab and Rodriguez, who allegedly spread falsehoods about XPHOZAH's plans to apply for TDAPA, engaged in any suspicious trading during the Class Period. This is notable given that "'even unusual sales by one insider do not give rise to a strong inference of scienter' when other insiders had not engaged in suspicious trading during the class period." N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 56 (1st Cir. 2008) (quoting Abrams v. Baker Hughes Inc., 292 F.3d 424, 435 (5th Cir. 2002)).

In any case, the First Circuit has established that "[i]nsider trading cannot establish scienter on its own, but it can be used to do so in combination with other evidence." Miss. Pub. Emps'., 523 F.3d at 92. Plaintiffs' allegations taken together fail to establish a strong inference that Defendants made the challenged statements with a conscious intent to defraud or a high degree of recklessness. Plaintiffs offer no direct allegations of scienter, and their circumstantial case is neither cogent nor compelling. At bottom, their theory that Defendants

had decided long before July 2 not to apply for TDAPA or harbored serious doubts about making such an application is not as "cogent" or "strong" an inference as the alternative—that Defendants' evaluation of the risks and benefits of TDAPA shifted after the challenged statements in light of changing regulations and further evaluation. See Tellabs, 551 U.S. at 309. Therefore, Plaintiffs' amended complaint fails to state a Section 10(b) claim on falsity and scienter grounds.

In light of this finding, the Court need not address the remaining elements of securities fraud nor resolve Defendants' arguments that the challenged statements constitute inactionable forward-looking statements or opinions. Count I is DISMISSED.

B. Insider Trading Claims (Counts II, III)

Plaintiffs also bring insider trading claims against Williams and Grammer under Section 10(b) and Section 20A. Doc. No. 25 ¶¶ 182-194. To state a claim of insider trading, Plaintiffs must allege that "(1) a corporate insider traded; (2) plaintiff traded contemporaneously with the insider; and (3) the insider traded while in possession of material non-public information." In re Lernout & Hauspie Sec. Litig., 286 B.R. 33, 41 (D. Mass. 2002).

Only the third prong is at issue here. Plaintiffs allege that Williams and Grammer sold their shares of Ardelyx stock while possessing material non-public information—that is, the information that "Ardelyx would not apply for TDAPA" and that "the reason Ardelyx would not apply for TDAPA was that it had concluded that access to XPHOZAH would be 'effectively eliminated' during the TDAPA period." Doc. No. 25 ¶ 183.

However, Plaintiffs have not alleged with plausibility or particularity that Williams and Grammer possessed such information at the time of their stock sales. They again rely on Ardelyx's presentation to CMS in March 2024, arguing that "when selling their Ardelyx shares in May and June, Defendants Grammer and Williams were still in possession of the information

they presented to CMS in March." Doc. No. 36 at 38. But the information Grammer and Williams possessed and presented to CMS in March was simply that four other drugs that had gone through TDAPA experienced negative outcomes from the Bundle. Plaintiffs do not allege that any of the underlying information about these other drugs was "non-public." In any case, the information in the March 11 presentation to CMS in no way supports Plaintiffs' assertion that Williams and Grammer had concluded then that TDAPA was not a viable option for XPHOZAH. As addressed above, one of the four drugs mentioned in the presentation enjoyed rising sales during its TDAPA period. Doc. No. 25 ¶ 77. This directly undermines Plaintiffs' contention that Defendants "had concluded" at the time of the presentation "that access to XPHOZAH would be 'effectively eliminated' during the TDAPA period." Id. ¶ 183. In light of these facts, Plaintiffs have not sufficiently pled that Grammer and Williams traded with material non-public information based on their knowledge of other drugs' experiences on TDAPA.

There is another theory of insider trading before the Court. During the motion hearing, Plaintiffs' counsel pointed to CMS's May 13 letter as the material non-public information that Williams and Grammer possessed during their stock sales. Counsel argued that the May 13 letter informed Ardelyx that XPHOZAH would not be treated with phosphate binders under the upcoming rule. Thus, upon receiving the letter, Williams and Grammer would have understood how XPHOZAH would be treated under the TDAPA program and would have subsequently known that Ardelyx would not apply, according to Plaintiffs' counsel.

Plaintiffs did not raise this theory of insider trading in their complaint. Nor have they pled any facts to support this inference from the May 13 letter. Notably, the complaint's only mention of the May 13 letter is the following sentence: "CMS formally communicated to Ardelyx its decision to add XPHOZAH to the Bundle in a May 13, 2024, letter-decision

addressed to Williams." Doc. No. 25 ¶ 102. This passing reference to the May 13 letter fails to allege, with any level of detail, that Williams and Grammer gained material non-public information from the letter. Moreover, the plain language of the May 13 letter, which is subject to judicial notice, does not support Plaintiffs' theory. In the letter, CMS did not state whether it planned to treat XPHOZAH with phosphate binders and instead urged Ardelyx to review the April 29 guidance, available publicly on CMS's website. Doc. No. 37-2 at 2-3. On the record before the Court, the first time CMS expressly communicated that XPHOZAH would be treated differently from phosphate binders occurred on June 27, 2024, which postdates all the stock sales.

Overall, Plaintiffs' allegations fail to meet the heightened pleading standard required by Rule 9(b) and the PSLRA for Section 10(b) insider trading claims. See In re Silver Lake Grp., LLC Sec. Litig., 108 F.4th 1178, 1191 (9th Cir. 2024) (noting that Section 10(b) insider trading actions must be pled according to Rule 9(b) and PSLRA); Edward J. Goodman Life Income Tr. v. Jabil Cir., Inc., 594 F.3d 783, 793 (11th Cir. 2010) (noting that PSLRA's scienter standard applies to Section 10(b) insider trading claims). Because Plaintiffs have not sufficiently pled that Williams and Grammer possessed material non-public information at the time of their stock sales, the Court DISMISSES Plaintiffs' Section 10(b) insider trading claim (Count II).

Accordingly, Plaintiffs have not pled a predicate violation of the Exchange Act, and thus, cannot advance a Section 20A claim of insider trading. Carney v. Cambridge Tech. Partners, Inc., 135 F. Supp. 2d 235, 257 (D. Mass. 2001) ("To state a claim for insider trading [under Section 20A], the plaintiffs must have adequately alleged a violation of the Exchange Act."). Thus, the Court also DISMISSES Plaintiffs' insider trading claim under Section 20A (Count III).

C. Section 20(a) Claims (Count IV)

Section 20(a) of the Exchange Act "provides for derivative liability of persons who 'control' others found to be primarily liable under the Exchange Act." Greebel v. FTP Software, Inc., 194 F.3d 185, 207 (1st Cir. 1999). Where a plaintiff fails to sufficiently plead an underlying violation of the Exchange Act, a court must dismiss the plaintiff's derivative Section 20(a) claims. See Waters Corp., 632 F.3d at 762 ("The district court properly dismissed the plaintiff's Section 10(b) and Rule 10b–5 claims. Because the plaintiff's Section 20(a) claim was derivative of the Rule 10b–5 claim, it was properly dismissed as well."). Here, Plaintiffs have not adequately alleged a predicate violation of the Exchange Act that could give rise to Section 20(a) liability. Therefore, Plaintiffs' Section 20(a) claim cannot stand, and the Court DISMISSES Count IV.

IV. CONCLUSION

For the foregoing reasons, the motion to dismiss, Doc. No. 32, is ALLOWED. A separate judgment of dismissal will enter. Each side shall bear its own costs and fees.

SO ORDERED.

/s/ Leo T. Sorokin
United States District Judge