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United States District Court, D. Massachusetts.

IN RE SAREPTA THERAPEUTICS SECURITIES LITIGATION

Civil Action No. 25-13530-BEM
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MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS

Brian E. Murphy Judge, United States District Court

***1** In this class action complaint, plaintiff investors allege Defendant Sarepta Therapeutics, Inc. ("Sarepta") and its executives, Douglas Ingram, Louise Rodino-Klapac, and Ian Estepan (collectively, "Individual Defendants," together with Sarepta, "Defendants"), misled investors about Sarepta's novel treatment for a rare genetic condition. According to Plaintiffs, Sarepta executives' alleged misstatements constitute violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Securities Exchange Commission Rule 10b-5. Defendants move to dismiss for failure to state a claim, arguing that the statements were not misleading and that Plaintiffs have failed to establish a strong inference of scienter or loss causation. For the foregoing reasons, the Court will grant Defendants' motion to dismiss.

I. Background

A. Factual Background

The Court draws the following facts from Plaintiffs' amended complaint, Dkt. 133, ("Complaint" or "Compl."), and accepts them as true for the purposes of the instant motion.

Plaintiffs are investors who purchased or acquired shares of Sarepta stock between June 22, 2023, and November 3, 2025 (the "Class Period"). *Id.* ¶ 310. Sarepta is a publicly traded biopharmaceutical company incorporated in Delaware and headquartered in Cambridge, Massachusetts. *Id.* ¶ 28. Its primary area of focus is developing and marketing treatments for neuromuscular diseases such as muscular dystrophy. *Id.* ¶ 33. Ingram is Sarepta's Chief Executive Officer, having served in that role since June 2017. [1] *Id.* ¶ 29. Rodino-Klapac has been Sarepta's Executive Vice President, Chief Scientific Officer, and Head of Research & Development since December 2020. *Id.* ¶ 30. Estepan has been Sarepta's President and Chief Operating Officer since July 2025. *Id.* ¶ 31. Prior to his current role, Estepan was the Chief Financial Officer and Executive Vice President of Sarepta beginning in December 2018. *Id.* ¶ 31.

1 Ingram was also President of Sarepta during the Class Period, but left that position in July 2025. Compl. ¶ 29.

During the Class Period, Sarepta's business revolved around two broad product categories: (1) gene therapies and (2) RNA, or "exon-skipping," therapies. *Id.* ¶ 33. Gene therapies treat genetic diseases like muscular dystrophy by "introducing a normal copy of the affected genetic material into the body's cells in order to repair or replace the patient's malfunctioning genes."

Id. ¶ 34. Companies like Sarepta develop proprietary "vectors" to deliver those genetic materials to patients. *Id.* ¶¶ 34–37. Though potentially revolutionary for patients, vectors carry inherent risks, most notably the possibility of a significant, and sometimes fatal, immune response in organs such as the liver and heart. *Id.* ¶¶ 35–36. During the Class Period, Sarepta's vector, rAAVrh74 ("rh74"), was the base for many of its gene therapy products and differed from the "non-proprietary adeno-associated virus, or 'AAV,' vectors," which were "widely used" in the industry. *Id.* ¶¶ 37–38. Sarepta's other class of products, exon-skipping therapies, "use synthetic molecules to skip faulty sections of messenger RNA," thus ensuring that cells produce essential proteins. *Id.* ¶ 54.

***2** Plaintiffs allege that Defendants made material misstatements about products in both categories.[2] *Id.* ¶ 1. The eventual "disclosure of the truth concealed by" these misstatements "erased more than 80% of Sarepta's stock price and wiped out billions of dollars in shareholder value." *Id.* ¶ 21. Where allegations overlap, the Court categorizes these statements by product, beginning with statements related to the safety of Elevidys, Sarepta's gene therapy treatment for Duchenne Muscular Dystrophy ("DMD").

2 Throughout the opinion, the Court will utilize the same statement numbering system as found in the parties' appendices. *See generally* Dkts. 146-1, 153-1.

1. Elevidys

According to the Food and Drug Administration ("FDA"), DMD is a rare and devastating genetic condition which weakens patients' muscles over time. Dkt. 147-1 at 2. DMD chiefly afflicts young boys, with symptom onset often beginning "between 3 to 6 years of age." *Id.* As the disease progresses, patients develop increasingly serious symptoms, including "trouble walking and running, falling frequently, fatigue, learning disabilities/difficulties, heart issues as a result of impact on heart muscle functioning, and breathing problems." *Id.* Patients often "succumb to the disease in their 20s or 30s because of heart and/or respiratory failure." *Id.*

Elevidys, Sarepta's latest entry in a line of products that treat DMD, utilized the rh74 vector. *See* Compl. ¶ 2; *see also Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 34 (1st Cir. 2017) (describing eteplirsen, a prior Sarepta product candidate); *see also Kader v. Sarepta Therapeutics, Inc.*, 887 F.3d 48, 52–53 (1st Cir. 2018) (same). Prior to the Class Period, Sarepta established a non-human preclinical testing program for Elevidys. Compl. ¶¶ 68–70. Plaintiffs, citing to statements by a former employee referred to in the Complaint as FE 1, allege that "regulatory failures pervade[d] Sarepta's preclinical program."[3] *Id.* ¶¶ 70, 71–74. Plaintiffs also claim that preclinical data revealed "deeply troubling signals of rh74's unusual and significant liver toxicity." *Id.* ¶ 79; *see also id.* ¶ 83. In response to these concerns, in the fall of 2021, "Sarepta privately convened a panel of outside experts" to review rh74's safety. *Id.* ¶ 84. Rodino-Klapac attended several meetings personally and FE 3 stated that "others" kept minutes and slide decks from the meeting which "would've gone up the chain" to Rodino-Klapac and Ingram. *Id.* ¶ 86.

3 The Court adopts Plaintiffs' monikers for their confidential witnesses and will refer to former employees as FE 1, FE 2, etc.

On June 22, 2023, the FDA, having reviewed the preclinical data, granted accelerated approval to Elevidys "for the treatment of pediatric patients 4 through 5 years of age with [DMD]."[4] Dkt. 147-1 at 2. But the FDA was not unanimous in its decision. In fact, some "FDA staff reviewing Sarepta's application for Elevidys' approval later expressed concerns" about Elevidys's safety. Compl. ¶ 87. While the FDA Advisory Committee voted to recommend Elevidys for accelerated approval by an 8-6 vote, Dkt. 147-4 at 13–14, a later FDA review team concluded that the data was "insufficient" to support Elevidys's safety and recommended against approval, Dkt. 147-3 at 2. Ultimately, however, the head of the FDA's Center for Biologics Evaluation and Research, Dr. Peter Marks, "overruled the Agency scientists' concerns" and granted accelerated approval to Elevidys. Compl. ¶ 75; *see also* Dkt. 147-3 at 2. In making its decision, the FDA weighed the "potential risks associated with the drug" alongside the "life-threatening and debilitating nature of the disease for these children, and the urgent medical need." Dkt. 147-1 at 3.

[4] In its press release, the FDA noted that "accelerated approval of Elevidys was based on data from the randomized clinical trial" and that data submitted by Sarepta indicated it was "reasonably likely to predict clinical benefit" in the approved population. Dkt. 147-1 at 3.

***3** The FDA's approval was conditioned upon Sarepta confirming that Elevidys "was not only effective, but also, critically ... safe." Compl. ¶ 12. In order to retain FDA approval and expand to other groups of DMD patients, the FDA told Sarepta, "it would need to test its therapy in a substantially larger and more diverse cohort of DMD patients." *Id.* ¶ 94. Sarepta organized two clinical trials, EMBARK and ENDEAVOR, to meet these FDA conditions. *Id.* Notably, Sarepta began enrolling a population of non-ambulatory patients (that is, patients who had lost the ability to walk), in its ENDEAVOR trial. *Id.*

Plaintiffs allege that by October 2023, shortly after commercial distribution of Elevidys began, "Sarepta's safety data ... showed that Elevidys posed a far greater risk of liver injury than any other approved gene therapy in mainstream use."[5] *Id.* ¶ 97. Around the same time, Sarepta also learned of a number of non-fatal adverse events related to the rh74 vector. *Id.* ¶ 102. This conceivably contrasted with public statements made in the ensuing months by Defendants indicating that Elevidys's safety profile was "laudable ... given its potential benefit," *id.* ¶ 216 (Stmt. 4), "favorable," *id.* ¶ 218 (Stmt. 6), "manageable," *id.* ¶ 219 (Stmt. 7), "stable," *id.* ¶¶ 224, 233 (Stmts. 11, 18), and "consistent," *id.* ¶ 237 (Stmt. 22).

[5] Plaintiffs base this conclusion in part on two charts showing what is purportedly Sarepta's safety data. Compl. ¶¶ 97–98, 101–02.

On June 20, 2024, roughly one year after initial approval, the FDA, again reviewing Sarepta's clinical trial data, expanded Elevidys's approval to include all ambulatory patients over four years of age as well as non-ambulatory patients. *Id.* ¶ 49, *see also* Dkt. 147-14 at 2. In a press release, the FDA noted that clinical trial data showed "substantial evidence of effectiveness to support accelerated approval" in the non-ambulatory population. Dkt. 147-14 at 4. Defendants, in statements to investors, reemphasized the strength of Elevidys's safety profile both for ambulatory patients and non-ambulatory patients. Compl. ¶¶ 229, 233–34. At the time of expanded approval, Plaintiffs allege that internal Sarepta data indicated that the risk of liver toxicity was 56% or greater to non-ambulatory patients compared to ambulatory patients. *Id.* ¶ 104. By the end of 2024, that same data showed "at least ... a 22% increase in liver risk" for non-ambulatory patients compared to ambulatory patients. *Id.* ¶ 105. The confirmatory clinical trials continued into 2025 and by January 27, 2025, over 600 patients had been dosed with Elevidys—including ambulatory and non-ambulatory patients. *Id.* ¶ 241.

On March 18, 2025, Sarepta disclosed that a 16-year-old non-ambulatory patient being treated with Elevidys had died. *Id.* ¶ 135. Following this disclosure, Sarepta stock "declined by more than 27%." *Id.* ¶ 139. A few weeks later, on April 4, 2025, Sarepta confirmed that "in light of the safety concerns raised by the death of the 16-year-old DMD patient," the European Medicines Agency froze clinical trial enrollment in Elevidys dosing in the European Union. *Id.* ¶ 142. Following this announcement, Sarepta's stock again dropped, this time by "nearly 13%." *Id.* ¶ 144. Finally, on May 6, 2025, Sarepta downwardly adjusted its earnings guidance on news that "doctors and patients canceled scheduled treatments" with Elevidys following the disclosure of the first patient death on March 18, 2025. *Id.* ¶¶ 147–48. The stock dropped another 21% over the next two days. *Id.* ¶ 149. In the aftermath of these stock drops, Defendants stressed that the safety profile of Elevidys remained strong, especially in comparison to other gene therapies, and that this serious adverse event was unique. *Id.* ¶¶ 140–41, 150–52. In addition, Ingram told investors that despite the adverse outcome for one non-ambulatory patient, there was "no reason to believe" that "something about being ambulatory versus non-ambulatory plays a role" and also that there was "no difference between ambulatory and non-ambulatory ... risk of elevated liver enzymes or liver injury." *Id.* ¶¶ 250–51 (Stmts. 31–32).

***4** On June 15, 2025, Sarepta disclosed that another non-ambulatory patient had died from liver failure while undergoing treatment with Elevidys. *Id.* ¶ 153. In conjunction with that disclosure, Sarepta announced that "it was suspending shipment of Elevidys" for non-ambulatory patients and "was discussing with the FDA the inclusion of additional warnings, restrictions, and commitments in the Elevidys label." *Id.* After this news, the stock price fell another 42%. *Id.* ¶ 158. Defendants continued to

assure investors that despite the second patient death, Elevidys was still comparable to "other full-body gene therapy infusions that are commercially available today" and that patient deaths remain "very rare." *Id.* ¶¶ 259–60 (Stmts. 36–37).

On July 16, 2025, Sarepta announced that, pursuant to FDA instruction, it would add a "black box" warning for acute liver injury and acute liver failure to Elevidys's label.[6] *Id.* ¶ 163; *see also* Dkt. 147-20 at 2. On July 18, 2025, Sarepta disclosed a third patient death that had occurred in "the previous month." *Id.* ¶ 164. There were key differences between this patient death and the prior two patient deaths. First, the patient was in treatment for Limb-Girdle Muscular Dystrophy ("LGMD")—a related, but distinct class of muscular dystrophies with "a market almost as large as DMD's." *Id.* ¶ 12; *see also id.* ¶ 164. Second, the patient was not taking Elevidys, but was undergoing a different treatment with a "higher dose of Sarepta's rh74 vector."[7] *Id.* ¶ 164. That same day, the FDA revoked Sarepta's rh74 platform designation, which made it "more difficult for Sarepta to obtain approval for any future gene therapies" based on that vector. *Id.* ¶ 165. The FDA also asked Sarepta to withdraw Elevidys from the market, which the company did "within days." *Id.* ¶ 165 n.46. Following the news of the black box warning, the third patient death, and Elevidys's withdrawal from the market, Sarepta's stock fell once more, this time by "another 36%." *Id.* ¶ 169. All told, Sarepta's stock fell from $101.35 per share on March 17, 2025, to $14.07 per share on July 18, 2025. *Id.* ¶¶ 139, 169.

6 "Black box" warnings are "the FDA's most serious warning reserved for the most dangerous side effects." *Id.* ¶ 85. The inclusion of a "black box" warning did not mean risk of acute liver injury was disclosed on the label for the first time. Prior labels disclosed the risk of acute liver injury. *See* Dkt. 147-6 at 2 (Elevidys's label and prescribing information as of June 20, 2023). The black box warning *did* mark the first instance of a warning of acute liver *failure*, which is fatal.

7 Plaintiffs do not allege this LGMD patient was part of the company's "LGMD program," discussed in Section I.A.2.

2. LGMD Program

Simultaneous with its Elevidys efforts, Sarepta was also working on a gene therapy for patients in the LGMD population. The LGMD disease includes five different subtypes, Type 2A through 2E, with 2A and 2B being the "most common." *Id.* ¶ 111. Sarepta's LGMD program attempted to treat all five subtypes and used the same "core rh74 platform" also utilized in Elevidys. *Id.* ¶ 42; *see also id.* ¶¶ 111–12.

Plaintiffs allege that, throughout the Class Period, Defendants overstated the progress of the LGMD program. *Id.* ¶¶ 107–119. Plaintiffs allege that, according to multiple former employees, the LGMD program "had significantly stalled by the start of the class period," the program's "key assets were plagued by intractable development issues," and Sarepta was "diverting resources away from the program." *Id.* ¶ 110. FEs 2, 3, and 6 all identified "severe manufacturing difficulties" at the start of the Class Period with Type 2A, 2B, and 2C treatments. *Id.* ¶¶ 112–13. Even still, shortly after the start of the Class Period, Sarepta had three LGMD studies ongoing: (1) a "fully enrolled" study of Types 2C, 2D, and 2E patients, (2) another early-stage study for a Type 2E treatment, and (3) a study for a gene treatment for Type 2B. Dkt. 147-28 at 8.

***5** By mid-2024, Sarepta was, according to FE 6, "pulling back on existing clinical trial commitments," "dropping study sites," and "freezing grant funding" for some LGMD programs. Compl. ¶ 116. Despite these setbacks, Defendants told the market that the LGMD program was making "continue[d] ... progress," *id.* ¶ 269 (Stmt. 41); was "obviously making good progress," *id.* ¶ 273 (Stmt. 44); "rapidly progressing," *id.* ¶ 276 (Stmt. 46); "moving in the fastest speed possible," *id.* ¶ 277 (Stmt. 47); and "mov[ing] rapidly," *id.* ¶ 279 (Stmt. 48). Defendants also told investors that they were "committed to driving" the LGMD program, *id.* ¶ 283 (Stmt. 51); "very, very excited" about the program, *id.* ¶ 281 (Stmt. 50); and "pleased" with the program, *id.* ¶¶ 273, 275, 280 (Stmts. 44–45, 49). FE 7 called some of these statements "deceitful" and "bullshit," given the aforementioned setbacks. *Id.* ¶¶ 117–18.

On July 16, 2025, Sarepta announced that it would reduce its workforce by 36% and that, "as a result of its reprioritization," "most" of the LGMD program would be reduced. Dkt. 147-20 at 3. Sarepta confirmed that it would continue its efforts to treat Type 2E patients. [8] *Id.* That same day, Sarepta's stock increased by 22%. *See* Dkt. 148-5 at 8.

[8] This news came in the very same press release that announced Sarepta would suspend shipment of Elevidys to non-ambulatory DMD patients. Dkt. 147-20 at 2.

3. ESSENCE Trial

As noted above, Sarepta's business also included developing exon-skipping therapies. Compl. ¶¶ 33, 54, 120. This was a lucrative business for Sarepta, accounting for "more than 90% of the Company's total revenue," at the start of the Class Period. *Id.* ¶ 55. In the years before the Class Period, Sarepta had commercially released three exon-skipping therapies, also designed to treat certain DMD patients. *Id.* ¶ 54. The FDA had conditioned its approval of these exon-skipping therapies on Sarepta's commitment to "conduct a larger study" of the treatments' actual outcomes on patient mobility. *Id.* ¶ 58. Sarepta began enrolling patients in a blinded clinical trial called the ESSENCE trial in 2016 to test actual outcomes. *Id.*

The ESSENCE trial continued for many years, including into the COVID-19 pandemic beginning in 2020. *Id.* ¶ 126. The rate of missed doses during the pandemic was "unusually high." *Id.* ¶ 125. These disruptions to the ESSENCE trial ultimately prevented researchers from "collect[ing] enough patient data" to achieve statistically significant results. *Id.* During the pandemic and after, Sarepta disclosed in SEC filings that COVID-19 had disrupted its clinical trials. *See e.g.* Dkt. 148-24 at 8 ("The COVID-19 pandemic has resulted and may continue to result in disruptions to our commercialization, clinical trials, manufacturing and other business operations, which could have a material adverse effect on our business."); *see also* Dkt. 148-25 at 8 (same).

After multiple delays, Sarepta released the ESSENCE trial results on November 3, 2025. Compl. ¶¶ 127–28, 178. On an investor call that same day, Defendants told investors that the study had failed to achieve statistical significance due to " 'operational' problems in collecting adequate patient data during the COVID-19 pandemic." *Id.* ¶ 179. The next day, Sarepta's stock declined by "nearly 34%." *Id.* ¶ 182.

B. Procedural Background

Plaintiffs filed their first complaint against Defendants on June 26, 2025 in the United States District Court for the Southern District of New York. *See generally* Dkt. 1. On October 17, 2025, the court appointed Anthony Defilippis, Nicholas Barrass, William Wrede, and Robert Feldstein as lead plaintiffs. Dkt. 84. Shortly thereafter, on October 24, 2025, Plaintiffs moved change venue pursuant to 28 U.S.C. § 1404(a). Dkt. 91. The case was transferred to the United States District Court for the District of Massachusetts on November 6, 2025, Dkt. 95, and was assigned to this Court on November 24, 2025, Dkt. 97. Plaintiffs filed an amended complaint on January 22, 2026. *See generally* Compl. Plaintiffs raise two claims against Defendants: violations of Section 10(b) of the Exchange Act and Rule 10b-5 (Count I), *id.* ¶¶ 320–27, and violations of Section 20(a) of the Exchange Act (Count II), *id.* ¶¶ 328–33.

***6** Defendants moved to dismiss both claims on March 9, 2026. Dkts. 145–46. In addition, Defendants filed a request for judicial notice and incorporation by reference of 59 exhibits attached to the motion to dismiss. Dkt. 149. The Court heard argument on August 4, 2026, and took the motion to dismiss and request for judicial notice under advisement.

II. Legal Standard

Courts analyzing claims under Federal Rule of Civil Procedure 12(b)(6) ("Rule 12(b)(6)") must determine whether a plaintiff's factual allegations—disregarding all "conclusory" statements—"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)). In making its determination, a court must "accept the truth of all well-pleaded facts and draw all reasonable inferences therefrom in the pleader's favor."

Grajales v. P.R. Ports Auth., 682 F.3d 40, 44 (1st Cir. 2012). At the pleading stage, a plaintiff need not demonstrate that he is likely to prevail, but the "claim must suggest 'more than a sheer possibility that a defendant has acted unlawfully.' " *García-Catalán v. United States*, 734 F.3d 100, 102–03 (1st Cir. 2013) (quoting *Iqbal*, 556 U.S. at 678). "The inquiry is usually limited to the facts alleged in the complaint, incorporated into the complaint, or susceptible to judicial notice," *Whelden v. U.S. Bank Nat'l Ass'n*, 494 F. Supp. 3d 68, 73 (D. Mass. 2020) (citing *In re Colonial Mortg. Bankers Corp.*, 324 F.3d 12, 15 (1st Cir. 2003)), "but the court may also consider other documents the authenticity of which is not disputed by the parties, documents central to the plaintiff's claim, and documents sufficiently referred to in the complaint," *id.* (citing *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993)).

III. Discussion

A. Request for Judicial Notice and Incorporation by Reference

Before addressing the merits of Plaintiffs' claims, the Court briefly turns to Defendants' request for incorporation by reference and judicial notice. Dkt. 149. Defendants attach 59 exhibits to their motion to dismiss, all of which, they argue are "subject to judicial notice." [9] *Id.* at 1. Plaintiffs oppose the Court's consideration of 20 of those 59 documents. [10] *See generally* Dkt. 154.

9 At the outset, the Court will take judicial notice of the 39 documents that Plaintiffs do not challenge because they are sufficiently referenced in the Complaint. Many of these exhibits include the very statements at issue in this case.

10 Specifically, Plaintiffs oppose consideration of Defendants' Exhibits 1–2, 4–5, 11, 14–15, 20–24, 26, 29–30, 32–33, and 36–38.

On a motion to dismiss, a court cannot ordinarily consider "materials outside the pleadings without converting the motion into one for summary judgment." *Olsen v. Agenus Inc.*, 2026 WL 810814, at *4 (D. Mass. Mar. 24, 2026) (citing *Giragosian v. Ryan*, 547 F.3d 59, 65 (1st Cir. 2008)). However, as mentioned above, *see supra* Section II, courts have established narrow exceptions for certain types of documents: official public records, documents central to plaintiff's claim, and documents incorporated by reference in the Complaint. *See Giragosian*, 547 F.3d at 65; *see also Trans-Spec Truck Serv., Inc. v. Caterpillar Inc.*, 524 F.3d 315, 321 (1st Cir. 2008).

Exhibits 1, 4, 14–15, and 24 include press releases, transcripts, and a memorandum, all issued by the FDA. Dkts. 147-1, 147-4, 147-14, 147-15, 147-24. The Court will take judicial notice of these official public records. *See Leavitt v. Alnylam Pharms., Inc.*, 525 F. Supp. 3d 259, 266 n.1 (D. Mass. 2021) (noting the Court "may, in its discretion, take judicial notice of FDA documents"); *see also In re Vertex Pharms. Inc., Sec. Litig.*, 357 F. Supp. 2d 343, 352 n.4 (D. Mass. 2005) ("The Court may take judicial notice of [FDA] policy, as a matter of public record."). Furthermore, the FDA documents are relevant insofar as they "address [Sarepta's] representations to its investors and what, if any, FDA guidance was available to [Sarepta] when it made those representations." *Leung v. bluebird bio, Inc.*, 599 F. Supp. 3d 49, 57 (D. Mass. 2022). Importantly, the Court does not consider these documents for the truth of the FDA's statements, only for the fact the statements were made. *See Kader v. Sarepta Therapeutics, Inc.*, 2016 WL 1337256, at *11 (D. Mass. Apr. 5, 2016) ("Although the Court is not considering the FDA's statements for the truth of the matter asserted, the mere existence of such statements may be relevant to the allegedly misleading nature of Defendants' representations and omissions; whether Defendants acted with the requisite scienter; and the total mix of information available to the market during the Class Period."), *aff'd*, 887 F.3d 48 (1st Cir. 2018).

***7** Exhibits 5 and 20, Dkts. 147-5, 147-20, are press releases from Sarepta, both of which were referenced in the Complaint itself, Compl. ¶¶ 162–63, 212–13. Plaintiffs challenge the Court's consideration of these two documents because they are "duplicative of the Complaint's allegations." Dkt. 154 at 8. But the sole case that Plaintiffs cite expressing doubt that "duplicative" exhibits can be considered notes that a "document 'whose contents are alleged in the complaint' " *are* relevant for the Court's consideration. *McLeod v. Fessenden School*, 624 F. Supp. 3d 36, 41 n.2 (D. Mass. 2022); *see also* Dkt. 154 at 8. Plaintiffs do not dispute that the press releases, even if containing material duplicative of certain allegations, are documents the contents of which are referenced in the Complaint. Dkt. 154 at 8. Accordingly, the Court will consider them.

Exhibits 37 and 38 are public SEC filings, albeit filings submitted before the Class Period. Dkts. 148-7, 148-8. Like FDA documents, the Court may consider documents filed with the SEC as official public records. *See In re Stone & Webster, Inc. Sec. Litig.*, 253 F. Supp. 2d 102, 128 n.11 (D. Mass. 2003) (determining a district court may "consider documents required to be filed, and actually filed, with the SEC on a motion to dismiss"). While "the age of the materials may affect the weight investors could reasonably attribute to them," the mere fact that the SEC filings "predate the Class Period does not preclude judicial notice." *Olsen*, 2026 WL 810814, at *5. Therefore, in its discretion, the Court will consider these documents publicly filed with the SEC.

The Court will not, however, consider three of Defendants' own documents which fall outside the Class Period: Exhibit 26, a Sarepta press release predating the Class Period; Exhibit 29, an investor presentation postdating the Class Period; and Exhibit 36, an investor call transcript predating the Class Period. Dkts. 147-26, 147-29, 148-6. Defendants do not claim that these documents are referenced anywhere in the Complaint. Instead, they ask the Court to consider the exhibits merely "to show 'what the market knew' at relevant times." Dkt. 160 at 3 (quoting *In re Karyopharm Therapeutics Inc., Sec. Litig.*, 552 F. Supp. 3d 77, 91 n.1 (D. Mass. 2021), *aff'd sub nom., Thant v. Karyopharm Therapeutics Inc.*, 43 F.4th 214 (1st Cir. 2022)). But what 'the market knew' outside of the Class Period is hardly relevant to the Court's inquiry at this stage. *See Shash v. Biogen*, 627 F. Supp. 3d 84, 99 (D. Mass. 2022) (finding "no basis to consider," among other documents, a company press release that fell "outside the presumptive class period"), *aff'd in relevant part*, 84 F.4th 1 (1st Cir. 2023); *see also Pizzuto v. Homology Meds. Inc.*, 2024 WL 1436025, at *2 (D. Mass. Mar. 31, 2024) ("Post-Class Period materials are not properly before the Court at the motion to dismiss stage.").

Defendants also ask the Court to consider a variety of press releases, investor transcripts, and other documents which are not referenced in the Complaint but are offered "to show what was publicly disclosed or otherwise in the public realm at a given time" or "for the fact that the [press] releases were issued on the dates set forth therein, and that the released information was publicly available." Dkt. 149 at 10. This tranche of documents includes Exhibits 2, 11, 21, 30, and 32–33. Dkts. 147-2, 147-11, 147-21, 147-30, 148-2, 148-3. But most of these documents are, by Defendants' own admission, only tangentially connected to Plaintiffs' allegations in the Complaint. For example, Defendants ask the Court to consider Exhibits 30, 32, and 33 because they purport to show that "Defendants publicly announced specific LGMD program milestones that Plaintiffs have *not* alleged were inaccurate." Dkt. 160 at 3 (emphasis in original). By Defendants' own admission, those exhibits are related to facts not alleged in Plaintiffs' Complaint. Plaintiffs' allegations are not "expressly linked to—[or] admittedly dependent upon"—these documents. *Beddall v. State Street Bank & Tr. Co.*, 137 F.3d 12, 17 (1st Cir. 1998). Accordingly, the Court will not consider them in its analysis.

***8** Finally, the Court will not consider Exhibits 22 and 23, two Wall Street Journal editorials regarding Elevidys. Dkts. 147-22, 147-23. These editorials were published after the patient deaths, are not referenced in the Complaint, and do not provide any insight into what Defendants knew about Elevidys's safety. Dkt. 154 at 14–15. Therefore, judicial notice of these documents is inappropriate.

Accordingly, in addition to the unchallenged documents, the Court will take judicial notice of Defendants' Exhibits 1, 4–5, 14–15, 20, 24, 37, and 38. The Court will disregard Defendants' Exhibits 2, 11, 21–23, 26, 29, 30, 32–33, and 36.

B. Puzzle Pleading

Defendants first argue that the Court should dismiss the case before even reaching the merits of the motion to dismiss for failure to state a claim because the Complaint constitutes impermissible "puzzle pleading."[11] Dkt. 146 at 22. But Defendants do not point to a single case in this Circuit where a securities litigation case was dismissed solely based upon the burdensome complexity of the complaint. In the two in-Circuit cases Defendants do cite, the courts continued to analyze the claims despite substantial flaws in the pleadings, including unparticularized facts and no statement-by-statement analysis. *See Wilson v. MicroFinancial, Inc.*, 2006 WL 1650971, at * 3 (D. Mass. June 13, 2006) (lamenting the "cobbled together" nature of the complaint, which provided no "factual analysis or dissection," but nevertheless refusing to dismiss based upon "puzzle

pleading"); *In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 154 (D. Mass. 2009) (addressing the merits even though plaintiffs could "have identified with greater particularity the reasons why each statement was allegedly false or misleading"). The Complaint at issue in this case possesses none of those issues.

11 "A puzzle-style complaint may fail to satisfy the federal pleading standards due to its 'evasive, non-committal style,' which 'significantly increases the burdens to both the defendants and the court in evaluating a complaint's satisfaction of the PSLRA pleading requirements.' " *In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 154 (D. Mass. 2009) (quoting *In re Cornerstone Propane Partners, L.P.*, 355 F. Supp. 2d 1069, 1081 (N.D. Cal. 2005)). Hallmarks of puzzle pleading include Complaints where plaintiffs "provide[ ] no clear sense of the time line of defendants' alleged knowledge, nor particularized allegations as to the reasons for any given statement's alleged falsity." *Cornerstone*, 355 F. Supp. 2d at 1081.

Here, Plaintiffs' Complaint, though lengthy, is not an especially perplexing puzzle. Plaintiffs identify specific statements throughout the Complaint, categorized by time period and product type, and explain why each statement is allegedly misleading. Though the Complaint is dense, "[t]he [C]ourt has nonetheless made its best effort to cull those statements that might be actionable from those that appear to have been incorporated in the [Complaint] simply because they were made." *Wilson*, 2006 WL 1650971, at * 3. The Court is able to parse out Plaintiffs' claims—and based upon their appended chart, Defendants were able to do the same. *See generally* Dkt. 146-1. Accordingly, Defendants' "puzzle pleading" argument fails, and the Court will address the merits of Defendants' motion to dismiss for failure to state a claim.

C. Count I: Violation of Section 10(b) of the Exchange Act and Rule 10b-5

1. Heightened Pleading Standards

***9** To survive a motion to dismiss on a claim of securities fraud, Plaintiffs must meet a more demanding standard. Claims for securities fraud under Section 10(b) and Rule 10b–5 must contain six elements: (1) "a material misrepresentation or omission"; (2) "scienter"; (3) "a connection with the purchase or sale of a security"; (4) "reliance"; (5) "economic loss"; and (6) "loss causation." *In re Apellis Pharms., Inc. Sec. Litig.*, --- F.4th ---, 2026 WL 2425924, at *3 (1st Cir. Aug. 19, 2026) (quoting *Premca Extra Income Fund LP v. Angle*, 178 F.4th 712, 723 (1st Cir. 2026)). Here, Defendants challenge Plaintiffs' claims under three of those six elements: material misrepresentation, scienter, and loss causation. *See* Dkt. 146 at 10–12.

Along with the typical plausibility requirements of Rule 12(b)(6), securities litigation claims under section 10(b) must also satisfy the stringent standards of Federal Rule of Civil Procedure 9(b) ("Rule 9(b)"). *State Tchrs. Ret. Sys. of Ohio v. Charles River Lab'ys Int'l, Inc.*, 152 F.4th 1, 9 (1st Cir. 2025). Rule 9(b) requires the plaintiff to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The particularity standard is "notably strict and rigorous ... in securities fraud actions." *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 193 (1st Cir. 1999).

As a final hurdle, securities law claims are subject to the "exacting" pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). *Tellabs, Inc. v. Makor Issues & Rts, Ltd.*, 551 U.S. 308, 313 (2007); *see also* 15 U.S.C. § 78u–4. The PSLRA "requires the complaint to 'specify each statement alleged to have been misleading' and 'the reason or reasons why the statement is misleading.' " *Premca*, 178 F.4th at 723 (quoting 15 U.S.C. § 78u–4(b)(1)(B)). For the scienter element, the PSLRA requires Plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A). "[P]laintiffs must 'show either that the defendants consciously intended to defraud, or that they acted with a high degree of recklessness.' " *Mehta v. Ocular Therapeutix, Inc.*, 955 F.3d 194, 206 (1st Cir. 2020) (quoting *Kader*, 887 F.3d at 57). The "inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314; *see also id.* at 323 ("The strength of an inference cannot be decided in a vacuum. The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts?"). Put simply, while " 'the PSLRA does not require plaintiffs to plead evidence' ... a significant amount of 'meat' is needed on the 'bones' of the complaint." *Hill v. Gozani*,

638 F.3d 40, 56 (1st Cir. 2011) (quoting *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 63 (1st Cir. 2008)). [12] With that heightened pleading standard in mind, the Court first addresses material misrepresentation, followed by scienter.

12 Congress passed the PSLRA "with 'twin goals: to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims.' " *Hill*, 638 F.3d at 54 (quoting *Tellabs*, 551 U.S. at 322); *see also Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81–82 (2006) (detailing the legislative history of the PSLRA).

2. Material Misrepresentation

To plausibly allege a material misrepresentation, Plaintiffs must show that "[D]efendants made a materially 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) (quoting *Geffon v. Micron Corp.*, 249 F.3d 29, 34 (1st Cir. 2001)). Plaintiffs must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." *ACA Fin. Guar. Corp.*, 512 F.3d at 58 (alteration in original) (quoting 15. U.S.C. § 78u–4(b)(1)(B)). "[W]hether a statement is misleading depends on the perspective of a reasonable investor." *Karth v. Keryx Biopharmaceuticals, Inc.*, 6 F.4th 123, 135 (1st Cir. 2021) (alteration in original) (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 186 (2015)). Courts must " 'consider the entirety of the relevant facts available at the time of the allegedly misleading statement,' focusing on the 'total mix of information' available to investors at the time." *State Tchrs. Ret. Sys. of Ohio*, 152 F.4th at 10 (quoting *Karth*, 6 F.4th at 135–36). False or misleading statements must be false or misleading "at the time they were made." *City of Mia. Fire Fighters' & Police Officers' Ret. Tr. v. CVS Health Corp.*, 46 F.4th 22, 35 (1st Cir. 2022) (quoting *Suna v. Bailey Corp.*, 107 F.3d 64, 69 (1st Cir. 1997)). "A plaintiff may not plead 'fraud by hindsight'; i.e., a complaint 'may not simply contrast a defendant's past optimism with less favorable actual results' in support of a claim of securities fraud." *ACA Fin. Guar. Corp.*, 512 F.3d at 62 (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1223 (1st Cir. 1996)).

***10** In total, Plaintiffs allege that 59 statements were materially. [13] *See* Dkts. 146-1, 153-1. To efficiently resolve the claims and "because many of the statements are largely duplicative, the Court will evaluate them categorically." *Homology*, 2024 WL 1436025, at *7 (citing *Urman v. Novelos Therapeutics, Inc.*, 796 F. Supp. 2d 277, 282 (D. Mass. 2011) (permitting categorical consideration of similar statements "without diminishing the individualized attention needed to be given to each")); *see also Leavitt v. Alnylam Pharms., Inc.*, 451 F. Supp. 3d 176, 183 (D. Mass. 2020) ("Because the challenged statements are numerous and verbose the Court will refer to them cumulatively or by general groupings."). [14]

13 The sheer volume of alleged misstatements is larger than all but one pharmaceutical case the Court could identify in this Circuit in recent years. *See e.g.*, *Homology*, 2024 WL 1436025, at *7 (25 alleged misstatements); *see also Leavitt v. Alnylam Pharms., Inc.*, 451 F. Supp. 3d 176, 183 (38 alleged misstatements); *cf. In re Bos. Sci. Corp. Sec. Litig.*, 646 F. Supp. 3d 249, 294 n. 42 (D. Mass. 2022) (75 alleged misstatements). As the Court will discuss in greater detail below, many of these statements are blatantly taken out of context—sometimes omitting a prior sentence which renders the statement obviously true. Plaintiffs would do well to avoid the "kitchen sink" approach and focus on fewer, stronger allegations of securities fraud.

14 For the avoidance of doubt, the Court has individually and thoroughly reviewed each of the 59 alleged material misstatements. Even still, if Plaintiffs believe a specific material misstatement is not explicitly addressed by the Court's analysis, the Court's findings on scienter further foreclose relief. *See infra* Section III.C.3.

a. Statements about Elevidys's Safety

Plaintiffs' largest category of alleged misleading statements is those regarding Elevidys's safety profile. [15] Plaintiffs allege that preclinical data showed that the rh74 vector posed an elevated risk of liver toxicity, especially in non-ambulatory patients,

which was confirmed by the clinical trial data. Compl. ¶¶ 101–106. They claim that Defendants' statements, in light of the actual safety data and on-the-ground adverse events, were materially misleading to investors, who were unaware of the true safety risks. *Id.* ¶¶ 212–68. Defendants argue that none of the alleged misstatements were false or misleading because they were objectively true, constituted non-actionable opinions interpreting clinical data, were made alongside frequent risk disclosures, or constituted mere optimistic puffery. Dkt. 146 at 23–28.

15 In total, Plaintiffs allege 40 material misstatements regarding Elevidys beginning on June 22, 2023, Compl. ¶ 212, and ending on June 16, 2025, *id.* ¶ 267.

"The situation involved here is paradigmatic of securities fraud cases against drug development companies where a promising drug or medical device is approved by the FDA and then later proves to have health risks which affect the market for the drug." *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 47 (1st Cir. 2008) (collecting cases). In this category of statements, a majority of the "challenged statements ... convey opinion more than fact." *Corban*, 868 F.3d at 38. Chief among these are statements based on the results of Elevidys's preclinical and clinical trials. Throughout the Class Period, Defendants emphasized the "wealth of data showing the safety and efficacy" of Elevidys. Compl. ¶ 241 (Stmt. 25). Defendants stated that based on the data available, Elevidys's safety profile was "laudable ... given its potential benefit," *id.* ¶ 216 (Stmt. 4); "favorable," *id.* ¶ 218 (Stmt. 6), "manageable," *id.* ¶ 219 (Stmt. 7), "stable," *id.* ¶¶ 224, 233 (Stmts. 11, 18), and "consistent," *id.* ¶ 237 (Stmt. 22); and most strongly, "one of the most impressive safety profiles in the context of AAV-mediated gene therapy that has ever existed," *id.* ¶ 252 (Stmt. 33). They emphasized the "enormous amount" of data supporting that conclusion. *Id.* ¶ 241 (Stmt. 25). In addition, Defendants, comparing the safety profile between ambulatory and non-ambulatory patients, noted that there was "no difference" in the "risk of elevated liver enzymes or liver injury," *id.* ¶ 250 (Stmt. 31), and that based on the clinical data, they had "not seen a difference in any safety metrics" across those two populations, *id.* ¶ 238 (Stmt. 23).

***11** The case law is clear that, so long as Defendants' characterizations of company data have a reasonable basis, they are "non-actionable opinions." *Homology*, 2024 WL 1436025, at *9 ("Courts have repeatedly held that interpretations of results of clinical studies are opinions." (collecting cases)); *see also Harrington v. Tetraphase Pharms. Inc.*, 2017 WL 1946305, at *5 (D. Mass. May 9, 2017) ("[S]cientific opinions are just that: opinions."). This is especially true here, where Defendants were reporting on preclinical data and clinical trial results *before* the end of the study. "Companies reporting on clinical trial data may lawfully disclaim and defend their use of partial data and 'cast [their] trial results in a positive light.' " *Homology*, 2024 WL 1436025, at *9 (quoting *Corban v. Sarepta Therapeutics, Inc.*, 2015 WL 1505693, at *6 (D. Mass. Mar. 31, 2025), *aff'd* 868 F.3d 31 (1st Cir. 2017)). Another session of this Court, in another securities case involving Sarepta, cogently distilled this point:

> Plaintiffs' claim, therefore boils down to their disagreement with [Sarepta's] interpretation of [the drug's] ... trial results.... [S]uch opinions are non-actionable unless Plaintiffs allege that Defendants did not subjectively believe them, that self-embedded facts within the opinion were untrue, or that material facts related to Defendants' inquiry into or knowledge concerning the opinion were omitted.

Corban, 2015 WL 1505693, at *11 (citing *Omnicare,* 575 U.S. at 188–190). The same rings true here.

Plaintiffs emphasize, however, that even if the Court does determine the alleged misstatements are merely opinions about clinical data, the *Omnicare* standard requires an inquiry into whether those opinions had a reasonable basis. Dkt. 153 at 24–25. Plaintiffs allege, given Sarepta's data, they did not. Compl. ¶¶ 88–106. But optimistic opinions about Elevidys's safety were not uniquely held by Sarepta's executives. The FDA too, was aware of, and publicly discussed, the results of the preclinical studies. *Id.* ¶ 87 ("FDA staff reviewing Sarepta's application for Elevidys' approval later expressed concerns about the impurity of Sarepta's commercial rh74 product."); *see also* Dkt. 147-1 at 3 ("In making this decision, the FDA considered the potential risks associated with the drug, the life-threatening and debilitating nature of the disease for these children, and the urgent unmet medical need."). After review, the FDA ultimately approved Elevidys for clinical trials in a subset of DMD patients. [16] Compl. ¶¶ 11, 43. A

few months later, based upon additional clinical trial data, the FDA expanded Elevidys's approval to encompass all ambulatory DMD patients and certain patients in the non-ambulatory population. *Id.* ¶ 46; *see also* Dkt. 147-14 at 4 ("Based on the totality of the evidence, the FDA determined the available evidence verifies the product's clinical benefit for its original indication.").

16 It is also for this reason that Sarepta's June 22, 2023 press release confirming that "[Elevidys] has met the full statutory standards for safety and effectiveness," is not misleading. Compl. ¶ 212 (Stmt. 1). The FDA, weighing the preclinical safety data in light of its statutory mandate, approved Elevidys for human trials and "[c]ontinued approval" would be contingent upon verification of a clinical benefit in confirmatory trials." Dkt. 147-5 at 4. That very same press release noted that "acute serious liver injury has been observed." *Id.* at 3.

Defendants contend that this FDA approval functions as an endorsement of the challenged statements. Dkt. 146 at 24–25. The Court agrees that FDA approval renders Defendants' statements about Elevidys's safety reasonable. Where, as here, "the FDA eventually accepts a defendant's interpretation of the data, that interpretation is per se reasonable as a matter of law." *In re Philip Morris Int'l Inc. Sec. Litig.*, 89 F.4th 408, 421 (2d Cir. 2023) (cleaned up). Plaintiffs dispute the applicability of *Philip Morris*, an out-of-Circuit case, in light of an earlier First Circuit holding in *Shash v. Biogen.* Dkt. 153 at 25 ("Defendants' 'per se' rule that later FDA action immunizes past securities fraud is inconsistent with First Circuit precedent." (citing 84 F.4th 1, 12–13 (1st Cir. 2023)). But the Court sees no daylight between the two cases. [17] In *Shash*, unlike here, the FDA had not yet weighed in on the drug's safety before the misleading statement was made. 84 F.4th at 12–13. Not only that, the alleged misstatement in *Shash* was particularly concerning because defendant executives erroneously affirmed that "all data" in a clinical trial supported their position. *Id.* The FDA's subsequent approval was dependent on the clinical data providing "some" support for a higher dose—not universal support. *Id.* Thus, in *Shash*, the FDA cannot be said to have accepted the "defendant's interpretation of the data" when it approved the drug. *Philip Morris*, 89 F.4th at 421.

17 As Defendants also note, courts in this District continue to cite to *Philip Morris*, particularly for its analysis of whether a defendant's "interpretation of data" is reasonable. *See e.g.*, *PS Lit Recovery, LLC v. Pegasystems Inc.*, 814 F. Supp. 3d 190, 201 (D. Mass. 2026) ("When it comes to opinions, 'an investor cannot state a claim by alleging only that an opinion was wrong; the complaint must as well call into question the issuer's basis for offering the opinion.' " (quoting *Omnicare*, 575 U.S. at 194)); *see also* Dkt. 155 at 8 (highlighting favorable citations to *Philip Morris* in this District).

***12** The situation is markedly different here. Plaintiffs do not allege that Defendants made a statement like the one in *Shash*, where it was claimed that "all data" pointed in a positive direction. [18] Defendants' broad statements about Elevidys's safety aligned with the FDA's approval of human studies in ambulatory patients and the FDA's subsequent approval of clinical trials in a limited number of non-ambulatory patients. *See, e.g.*, *Alnylam Pharms*, 451 F. Supp. 3d at 185 ("In light of the FDA's safety evaluation and findings, particularly the data analysis limitations inherent in a small sample size, defendants' challenged statements regarding safety were not material misrepresentations or misrepresentation by omission."). Given the FDA's own approval twice-over, the Court finds these opinions to be *per se* reasonable.

18 Nor could they, because Defendants repeatedly acknowledged the risk of elevated liver enzymes and acute liver injury throughout the Class Period.

The FDA's decision-making process, which considered safety risks suggested by Plaintiffs' submission to the Court, proves that reasonable minds could differ as to the interpretation of the preclinical data. Plaintiffs insert two charts purporting to represent "data available to Sarepta" on safety risks inherent to the rh74 vector. Compl. ¶¶ 97–98, 101–02. Plaintiffs do not describe how they obtained the dataset or whether these particular charts were presented to Ingram, Rodino-Klapac, or Estepan. To the extent these charts are Plaintiffs' own construal of the raw preclinical data, the Court finds that they only serve to emphasize the competing signals the FDA balanced when it approved Elevidys for human trials in both ambulatory, and later, non-ambulatory patients. After all, liver toxicity was just one of a number of safety concerns the FDA considered in its approval. Dkt. 147-14 at 5 ("Patients given Elevidys may also be at risk for severe immune-mediated myositis (muscle inflammation). Additionally, myocarditis (inflammation of heart muscle) and elevations of troponin-I (a heart protein found in the blood after heart muscle injury) have been observed following use of Elevidys in clinical trials."). Not only that, but the initial approval vote by the FDA

was also a hotly contested: with eight votes in favor of approval and six in opposition. Dkt. 147-4 at 13–14. The preclinical and clinical data were obviously subject to robust disagreement and conflicting interpretations.

In addition, Sarepta frequently disclosed the risks of liver toxicity "in the same [statements] in which it reported the positive [clinical trial] results. So it would seem most likely that [Sarepta] itself did not view the former as belying the latter, and neither apparently did the market." *Local No. 8 IBEW Retirement Plan & Tr. v. Vertex Pharms., Inc.*, 838 F.3d 76, 82 (1st Cir. 2016). On investor calls, Sarepta executives noted that they had seen "liver enzyme issues," Dkt. 148-20 at 24, and that "every AAV-mediated gene therapy comes with a risk of elevated liver enzymes," *id.* at 13. Public filings with the SEC affirmed treatment with Elevidys "may result in unforeseen adverse events." *See, e.g.*, 147-12 at 4. From the beginning, the FDA-approved label also identified "acute serious liver injury" as an observed harmful side effect, Dkt. 147-6 at 2, and the public summary of the FDA's decision to approve Elevidys included numerous pages on the potential risks, *see generally* Dkt. 147-3 (noting that while "[c]ertain members of the Review Committee recommend[ed] approval," multiple review teams "conclude[d] that the data" was "not adequate to meet the threshold for approval" in part because of "serious adverse events observed in the ELEVIDYS clinical studies"). The market was therefore well informed of both the benefits *and* the risks of Elevidys because Defendants "disclosed to investors the relevant risk[s] as understood at the time." *Leung*, 599 F. Supp. 3d at 68. Sarepta "was not required to disclose *all* the details of the risk involved when 'the overall risk [was] disclosed and the nature of the future risk remain[ed] uncertain.' " *Homology*, 2024 WL 1436025, at *12 (quoting *Hill*, 638 F.3d at 60 n.5); *see also Thant*, 43 F.4th at 225 ("Given this background information, it is difficult to imagine that any investor would read the defendants' statements that Karyopharm had a 'predictable,' 'manageable,' and 'consistent' tolerability profile to indicate that [the drug] was benign."). [19]

19 It is worth addressing here the type of risk investors took on when investing in Sarepta. "[T]he investing public is well aware that drug trials are exactly that: trials to determine the safety and efficacy of experimental drugs. And so trading in the shares of companies whose financial fortunes may turn on the outcome of such experimental drug trials inherently carries more risk than some other investments. This is true even when the FDA has given fast-track approval to a new drug." *Biogen IDEC*, 537 F.3d at 48.

***13** The Court next turns to a few miscellaneous statements about Elevidys's safety not related to interpretations of clinical data that are easily dispensed with for the simple fact that the statements were not false or misleading when made. As an example, Plaintiffs point to a May 16, 2025 press release, in which Sarepta said that "no new safety signals were observed in the EMBARK study over the two-year duration." Compl. ¶ 255 (Stmt. 35). Plaintiffs claim that statement was misleading because two non-ambulatory patients in *other* studies, a patient in "the companion ENDEAVOR study and an LGMD patient," were recently hospitalized. Compl. ¶ 256. But Plaintiffs cannot deny that it was an objective fact that no new safety signals were observed *in the EMBARK study.* This same analysis applies to other statements following the disclosure of patient deaths. On a June 16, 2025 investor call following the death of a second patient, Ingram told analysts that "[a]t the time of our first approval ... we had no signal of this serious [acute liver failure]," *id.* ¶ 262 (Stmt. 38). It is objectively true that no patients had experienced acute liver failure at the time of first approval or that acute liver failure occurred in the LGMD population prior to the first reported death.

In their most salacious allegation, Plaintiffs claim that Rodino-Klapac "flatly lied" on that same June 16, 2025 investor call. *Id.* ¶ 5; *see also id.* ¶¶ 64, 184, 263. (Stmt. 39). At the time, Plaintiffs allege Sarepta knew a third non-ambulatory patient, with LGMD and not taking Elevidys, had already died of liver failure. *Id.* ¶¶ 64, 170. Therefore, Plaintiffs argue, when Rodino-Klapac told investors Sarepta had, at that point, "not seen a signal of [acute liver failure] in [the LGMD] population," she lied. *Id.* ¶ 263. But Plaintiffs do not allege a death date for the LGMD patient. They merely assert that Rodino-Klapac's July 18, 2025 statement that the patient death "occurred about a month ago," *implies* that on June 16, 2025, Rodino-Klapac knew of the death and nevertheless lied to investors. *Id.* ¶ 170. This is pure speculation. Without more 'meat on the bones' to allege that the LGMD patient had died as of June 16, 2025 or that Rodino-Klapac knew of that death, this allegation does not meet the heightened pleading standards under Rule 9(b) or the PSLRA. *See Ganem*, 845 F.3d at 455 ("[A]lthough the PSLRA does not require plaintiffs to plead evidence, a significant amount of 'meat' is needed on the 'bones' of the complaint." (cleaned up)).

In addition, Plaintiffs point to a series of statements by Sarepta executives comparing Elevidys to competing treatments on the market. Most of these statements about competitors are rooted in the FDA-backed safety conclusions reflected in the Elevidys's label. By Plaintiffs' own admission, Elevidys's FDA-approved "label carried standard gene therapy warnings regarding the potential for liver-related adverse events" and "these warnings were no more severe or proscriptive than rh74's competing vectors, and indeed, even *more* benign than some." Compl. ¶ 50. It was therefore not misleading, at the time, for Defendants to say, for example, Elevidys had "a laudable safety profile not shared by other programs for Duchenne." *Id.* ¶ 220 (Stmt. 8). In addition, these statements were reasonable given the positive clinical outcomes at the time they were made. Plaintiffs note that other gene therapies had resulted in fatalities. *Id.* ¶ 36. It was therefore not misleading at the time to say Elevidys "has had a very good safety profile relative to other programs." *Id.* ¶ 234 (Stmt. 20).

Other statements are mere puffery, commonplace in the pharmaceutical industry.[20] *See Celano v. Fulcrum Therapeutics, Inc.*, 2025 WL 928783, at *13 (collecting cases). Ingram's claim, on an investor phone call, that "Elevidys has one of the most impressive safety profiles in the context of AAV-mediated gene therapy that has ever existed" is, in addition to an interpretation of clinical data, also optimistic puffery.[21] Compl. ¶ 252 (Stmt. 33); *see also Celano*, 2025 WL 928783, at *13 (finding statement that a product was a "potential best-in-class" was non-actionable puffery). Another clear instance of puffery includes Ingram's March 11, 2024 statement that he was "thrilled with the product quality" of Elevidys and was "very pleased that we chose rh74." Compl. ¶ 225 (Stmt. 12); *see also Shih v. Amylyx Pharms., Inc.*, 805 F. Supp. 3d 410, 415 (D. Mass. 2025) (noting that "[s]tatements regarding 'encouragement,' a 'strong start,' executives being 'thrilled,' etc.," are non-actionable puffery).

20 Some of the prior statements about Elevidys's safety profile are also clear puffery. *See e.g.*, *Thant*, 43 F.4th at 223 (noting that non-actionable puffery includes statements such as "compelling clinical data").

21 Ingram's very next sentence also reminded investors of the risks: "It is true that every AAV-mediated gene therapy comes with a risk of elevated liver enzymes. And in other cases, there have been significant consequences for that. They are rare. With respect to us, they are particularly rare." Dkt. 148-20 at 14.

***14** However, Defendants' statements about similar outcomes for ambulatory and non-ambulatory Elevidys patients require a more thorough analysis. Plaintiffs "may not plead fraud by hindsight," *Omnicare*, 575 U.S. at 187 (quoting *ACA Fin. Guar. Corp.*, 512 F.3d at 62), by "assert[ing] no more than that because something eventually went wrong, [D]efendants must have known about the problem earlier," *Miss. Pub. Emps. Ret. Sys.*, 523 F.3d at 90. While there were ultimately tragic differences in non-ambulatory patient outcomes, at the time of multiple alleged misstatements, the relative occurrence of adverse events was not discernably different between the two populations.[22] It was an objective fact, for example, when Ingram said at a March 12, 2024 conference that Sarepta had not "to date seen any difference in the [adverse event] rates." Compl. ¶ 226 (Stmt. 13). The FDA also agreed with this conclusion. *See* Dkt. 147-15 at 4 ("No clear difference in occurrence of adverse events was noted for the non-ambulatory patients, compared to the ambulatory patients.").

22 What is more, not all adverse events are "necessarily material." *Brennan v. Zafgen, Inc.*, 199 F. Supp. 3d 444, 470 (D. Mass. 2016), *aff'd* 853 F.3d 606 (1st Cir. 2017); *see also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43–44 (2011) ("Adverse event reports are daily events in the pharmaceutical industry.... The fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event. The question remains whether a *reasonable* investor would have viewed the nondisclosed information as having *significantly* altered the total mix of information made available.") (cleaned up; *see also Biogen IDEC Inc.*, 537 F.3d at 50 (noting an adverse event "does not in and of itself show a causal relationship between a drug and the illness" because "[s]ome adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill.").

But two of Ingram's statements went further. On a May 6, 2025 investor call, rather than attest to no differences in *observed* adverse events or the *overall* safety profile,[23] on a May 6, 2025 investor call, Ingram stated twice that there was no difference in the "risk of elevated liver enzymes or liver injury" between ambulatory and non-ambulatory patients.[24] Here, Ingram's statements, even if plausibly an opinion about clinical data, did not align with Sarepta's data. By June 2024, Elevidys's safety

data indicated non-ambulatory patients faced a "most likely" 56% greater risk of liver issues compared to ambulatory patients. Compl. ¶ 104. By May 2025, Sarepta's data showed non-ambulatory patients "faced at least a 34% increase in liver risk versus ambulatory patients." Compl. ¶ 105. Even the FDA, which up until now in the Court's analysis has coated Defendants' statements in a sheen of reasonability, did not go as far as Ingram. While the FDA *did* approve Elevidys for use in non-ambulatory patients, thus implying a degree of confidence about its *overall* safety, it did not conclude that the *risk* profile of the drug was identical between ambulatory and non-ambulatory patient populations. *See e.g.*, *Shash*, 84 F.4th at 12–13 (finding defendants' statement that "all data" indicated a clinical benefit where only "some" data showed such a benefit was a material misstatement). These two statements, Statements 31 and 32, were therefore misleading when made.

23 On a November 6, 2024 investor call, Ingram noted that "the safety profile" between ambulatory and non-ambulatory patients was "the same." Compl. ¶ 106 (Stmt. 23). At this point, there had been no fatalities in the non-ambulatory population and unlike the statements on the May 6, 2025 investor call, this interpretation of observed clinical data did not explicitly compare the *risk* of liver injury. As noted earlier, Defendants' statements about the overall safety profile of the drug were opinions based on the interpretation of clinical data and were "per se reasonable" based on FDA approval. *Philip Morris*, 89 F.4th at 421.

24 The full statements are as follows: "And one of the things I want to remind us about is that there is no difference in any of the markets, any of the elevated liver enzyme markers, any of the bilirubin marker, there is no difference between ambulatory and non-ambulatory and for instance, risk of elevated liver enzymes or liver injury. So there really should be no reason if we educate properly why there would be a significant difference in start forms." Compl. ¶ 250; Dkt. 148-20 at 18 (Stmt. 31); and "The second piece of information, I think, that's really important to families to contextualize is, do you see anything different here? Is there something about being ambulatory versus non-ambulatory that plays a role? And the answer to that is no. We've looked at all the signals, there is no reason to believe that at all. All of the liver enzyme issues are the same across ambulatory or non-ambulatory, [delivery room] is the same." Compl. ¶ 251; *see also* Dkt. 148-20 at 24 (Stmt. 32).

***15** All told, Plaintiffs fail to allege that the vast majority of statements related to Elevidys's safety were material misstatements. Most of Plaintiffs' alleged misstatements are opinions about clinical data, made reasonable by virtue of the FDA's initial and subsequent approvals of Elevidys, and couched in routine disclosures of liver toxicity risk. Other statements, including those about competitors, are mere puffery or similarly rooted in opinions about clinical data. For these reasons, almost all of Plaintiffs claims related to Elevidys fail to allege a material misstatement. Two statements, however, comparing the *risk* of liver injury between ambulatory and non-ambulatory patients, were materially misleading.

b. Statements about the LGMD Program

Plaintiffs' second category of materially false or misleading statements concerns the progress of Sarepta's LGMD program. [25] Compl. ¶¶ 269–87. Plaintiffs, relying heavily on accounts from confidential former employees, allege that, despite Defendants' chipper attitude in statements to investors, the LGMD program had actually "significantly stalled" and was "stuck at the starting gate." *Id.* ¶ 110. Defendants argue that Plaintiffs' challenged statements about the LGMD program are "a slew of non-actionable puffery," forward-looking statements protected by the PSLRA's safe harbor provision, or rooted in unreliable anonymous sources. Dkt. 146 at 30–32.

25 In total, Plaintiffs allege 13 material misstatements regarding the LGMD program between August 2, 2023, Compl. ¶ 269, to February 26, 2025, *id.* ¶ 286.

The bulk of Defendants' statements about the LGMD program are non-actionable puffery. As noted earlier, "[t]he corporate puffery rule applies to loose optimism about both a company's current state of affairs and its future prospects." *In re Bos. Sci. Corp. Sec. Litig.*, 2011 WL 4381889, at *11 (D. Mass. Sept. 19, 2011) (quoting *Fitzer v. Sec. Dynamics Techs.*, 119 F. Supp. 2d 12, 23 (D. Mass. 2000)). "[V]ague optimism about a product's future, even when touting 'successful' or 'compelling' clinical

support, cannot constitute a material misstatement for purposes of the pleading requirements set by the PSLRA." *Thant*, 43 F.4th at 223. But that is precisely the genre of statements Plaintiffs allege misled investors here. Defendants said that the LGMD program "continue[d] to make progress," Compl. ¶ 269 (Stmt. 41); was "obviously making good progress," *id.* ¶ 273 (Stmt. 44); "rapidly progressing," *id.* ¶ 276 (Stmt. 46); "moving in the fastest speed possible," *id.* ¶ 277 (Stmt. 47); and "mov[ing] rapidly," *id.* ¶ 279 (Stmt. 48). Defendants also told investors that they were "committed to driving" the LGMD program, *id.* ¶ 283 (Stmt. 51); "very, very excited" about the program, *id.* ¶ 281 (Stmt. 50); and "pleased" with the program, *id.* ¶¶ 273, 275, 280 (Stmts. 44–45, 49).

These statements are clear examples of puffery. *See e.g.*, *Celano*, 2025 WL 928783, at *13–14 (finding statements that a product trial was "on track," made "significant progress," and had "tremendous momentum" were non-actionable puffery); *see also Shih*, 805 F. Supp. 3d at 415 (D. Mass. 2025) (noting that "[s]tatements regarding 'encouragement,' a 'strong start,' executives being 'thrilled,' etc.," are non-actionable puffery). Nevertheless, Plaintiffs claim that these statements arere still actionable because Plaintiffs allege "progress ha[d] stalled." Dkt. 153 at 29. However, "[t]he securities laws do not make it unlawful for a company to publicize an aggressive timeline or estimate for a proposed action without disclosing every conceivable stumbling block to realizing those plans." *Ganem*, 845 F.3d at 457.

Beyond puffery, Defendants argue that Plaintiffs cannot plausibly allege a material misstatement because they rely on "flawed" and "conclusory assertions" from anonymous former employees. Dkt. 146 at 32. Of the seven former employees mentioned in the complaint, four were alleged to have had knowledge of the LGMD program: FE 2, FE 3, FE 6, and FE 7.[26] In considering allegations supported by confidential sources, courts must "look at all of the facts alleged to see if they 'provide an adequate basis for believing that the defendants' statements were false.' " *In re Cabletron Sys., Inc.*, 311 F.3d 11, 29 (1st Cir. 2002) (quoting *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000)). Courts must also evaluate "the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Id.* at 29–30.

26 In opposition, Plaintiffs also claim that FE 4's role at Sarepta "required knowledge of the [LGMD] program's safety and manufacturing challenges," Dkt. 153 at 30, but do not provide a job title as it "would likely compromise his anonymity," Compl. ¶ 84, n.23. Even assuming that his role *did* give FE 4 insight into the LGMD program, the Court finds just one fact related to LGMD provided by FE 4 along with FE 6: "some of those serious manufacturing problems stemmed from the fact that LGMD patients are typically older and heavier than DMD patients." *Id.* ¶ 112. This statement from FE 4 explains why there may have been manufacturing problems, but does not explicitly affirm that manufacturing problems had halted progress in the LGMD program.

***16** The former employees lack sufficient reliability to plausibly allege that Defendants' statements were false or misleading. First, though FE 2 and FE 3 "oversaw the LGMD program," Dkt. 153 at 30, they did not work for Sarepta during the Class Period, Compl. ¶¶ 83–84, and were therefore not in a position to know the status of the LGMD program at the time the statements were made. FE 6 was a "Patient Affairs Manager" who worked at Sarepta during the Class Period "until 2025." *Id.* ¶ 95. But Plaintiffs provide no further explanation of FE 6's role or whether they were actually in a position to know about the progress of the LGMD program. That leaves FE 7, a director "on the commercial side of Sarepta's business" who worked at Sarepta until mid-2024.[27] *Id.* ¶ 115. FE 7 was "responsible for collecting, synthesizing, and distributing competitive intelligence for Sarepta's therapeutics." *Id.* ¶ 115, n.36. But here, again, Plaintiffs do not explain how this commercial role gave FE 7 insight into the clinical progress of the LGMD program or how they would know Defendants' statements were "deceitful." *Id.* ¶ 117. Even still, Plaintiffs' allegations do not indicate that the LGMD program was "dead in the water." *Id.* ¶ 154. FE 6 noted that by 2023, Sarepta instructed personnel to "suspend patient outreach and related work" for some—but not all—LGMD programs. *Id.* ¶ 114. Plaintiffs too claim that "outside of the 2E program" Sarepta made little progress in its LGMD program. *Id.* ¶ 115. But during the Class Period studies continued in Types 2B–2E patients, Dkt. 147-28 at 8, and even after the July 16, 2025 staff reduction announcement, Sarepta told the market that its LGMD program would continue with respect to Type 2E patients, Dkt. 147-20 at 3. This is plainly not a program that was "abandoned." Compl. ¶¶ 4, 110, 162.

[27] Only four of the alleged misstatements related to the LGMD program were made prior to mid-2024. This did not stop Plaintiffs from quoting FE 7, who was no longer working at Sarepta at the time, for his punchy line that Rodino-Klapac's August 2024 claims of rapid progress were "bullshit." *Id.*¶ 118.

For these reasons, and the fact that Defendants' LGMD program statements were clear forms of non-actionable corporate puffery, Plaintiffs have failed to plead a false or misleading statement about the LGMD program.

c. ESSENCE Trial

Finally, Plaintiffs allege that Defendants made at least 6 material misstatements about the progress of the ESSENCE trial.[28] *Id.* ¶¶ 288–294. They claim that in investor calls, Rodino-Klapac told investors that the ESSENCE trial was "complete," "fully enrolled," and "on track." *Id.* ¶¶ 292–94 (Stmts. 56–59). Plaintiffs also allege that in SEC filings throughout the Class Period, Defendants understated the impacts of COVID-19 on its ESSENCE trial. *Id.* ¶¶ 288–91 (Stmts. 54–55). Defendants argue that they fully disclosed the disruption risks posed by the COVID-19 pandemic in public SEC filings, and that Plaintiffs fail to allege with particularity how Rodino-Klapac's statements were false. Dkt. 146 at 33–34.

[28] Plaintiffs allege at least six material misstatements. At least some of these statements were repeated in multiple public SEC filings. Compl. ¶ 288–89.

Defendants are correct and the Court need not belabor the point. Plaintiffs selectively pull quotes from multiple SEC filings to suggest that Defendants were not forthcoming about COVID-19's "present and materialized" impact on clinical trials like ESSENCE. *See e.g.* Compl. ¶ 288. They emphasize squishy language about the COVID-19's impact, including that missing data "*could* undermine data integrity," that the pandemic "*may* negatively impact enrollment" and that some clinical investigators "*may* be unable" to participate in the trial. *See e.g.*, *id.* ¶¶ 289–90 (emphasis added) (Stmts. 54–55). But Plaintiffs ignore Defendants' clear and repeated disclosures in the very same documents that the pandemic *had* caused disruptions. *See e.g.* Dkt. 148-24 at 8 ("The COVID-19 pandemic has resulted, and may continue to result in disruptions to our commercialization, clinical trials, manufacturing and other business operations, which could have a material adverse effect on our business."); *see also* Dkt. 148-25 at 8 (same). To the extent some later SEC filings, submitted years after the start of the pandemic, declined to include the same fulsome disclosures as earlier filings, Sarepta "was simply not under any duty to repeat information already known or readily accessible to investors." *Ponsa-Rabell v. Santander Secs. LLC*, 35 F.4th 26, 35 (1st Cir. 2022).

As for Rodino-Klapac's statements about enrollment, Plaintiffs do not plead any facts to plausibly suggest that the ESSENCE trial *was not* fully enrolled. Just because the data collection was ultimately unsuccessful, does not imply that the study lacked full enrollment at any time. To hold otherwise would permit impermissible "hindsight" pleading. *ACA Fin. Guar. Corp.*, 512 F.3d at 62. For these reasons, Plaintiffs fail to allege any material misstatements about the ESSENCE trial.

3. Scienter

***17** There is another independent reason for dismissal in this case. Plaintiffs fail to plead facts indicating a *strong* inference of scienter, as required by the PSLRA, for any of its alleged misstatements. *See supra* Section III.C.1. Rather than regurgitate similar conclusions for each category of statements, the Court addresses Plaintiffs' failure to meet the pleading standards for scienter writ-large. *ACA Fin. Guar. Corp.*, 512 F.3d at 59 ("[S]cienter should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations.").

Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *Id.* at 58 (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976)). Plaintiffs allege that Defendants either knowingly deceived the market or did so recklessly. Compl. ¶ 183. For the purposes of scienter, "recklessness requires more than 'simple, or even inexcusable, negligence'; rather,

recklessness is 'a highly unreasonable omission' amounting to 'an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers and sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.' " *Shash*, 84 F.4th at 13 (quoting *Mehta*, 955 F.3d at 206). And as noted earlier, the strong inference of scienter must be "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc.*, 551 U.S. at 314.

Plaintiffs argue that "the Complaint need not allege *any* motive to plead scienter." Dkt. 153 at 35. While it is true that motive is "not required to make out a claim under Section 10(b), courts often look to a defendant's *possible* motive ... in assessing allegations of scienter." *Sousa v. Sonus Networks, Inc.*, 261 F. Supp. 3d 112, 120 (D. Mass. 2017) (emphasis added). But here, Plaintiffs do not allege any of the "telltale" motives which usually form a basis for a strong inference of scienter. *Id.*; *see also In re iRobot Corp. Sec. Litig.*, 527 F. Supp. 3d 124, 143 (D. Mass. 2021) ("Although there is no checklist for such showing of scienter, little of the indicia usually relied upon to support such strong inference is alleged here."). There is no allegation of insider trading. *Brennan v. Zafgen, Inc.*, 199 F. Supp. 3d at 465 ("The 'presence of [contemporaneous] insider trading can be used, in combination with other evidence, to establish scienter.' " (alteration in original) (quoting *Biogen IDEC*, 537 F.3d at 55)). There is no allegation that Ingram, Rodino-Kaplan, or Estepan misled the market to save their jobs. *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 196 (1st Cir. 1999) (listing a litany of "different types of evidence as relevant to show scienter" including "the self-interested motivation of defendants in the form of saving their salaries or jobs"). Instead, Plaintiffs provide mostly indirect evidence: allegations of financial incentives and reports from anonymous former employees. But "where a complaint is devoid of any direct-evidence allegations, the indirect-evidence allegations in the complaint will need to do more work to carry the burden of raising a strong inference of scienter on their own." *Shash*, 84 F.4th at 16 (quotation marks omitted). Plaintiffs fail to meet that burden in this case.

To summarize Plaintiffs' scienter argument, Defendants allegedly knew about safety issues with Elevidys, the impending failure of the LGMD program, and complications with the ESSENCE trial because (1) they were financially incentivized to keep tabs on the clinical study data due to a "crushing debt load" and "unique and highly significant commercial pressures," Compl. ¶¶ 78, 205, and (2) former employees confirmed Defendants were informed of problems with Elevidys and the LGMD program by Sarepta employees before and during the Class Period, *id.* ¶¶ 188–89. With knowledge of these purported issues, Plaintiffs claim that Defendants "knowingly, or at least recklessly, misled investors." *Id.* ¶ 183. This theory does not lead to an inference of scienter stronger than any innocent inference.

***18** First, *all* corporate executives face pressure to deliver positive financial returns, especially in competitive industries. Such is the nature of leading a company beholden to shareholders. As such, " 'the usual concern by executives to improve financial results' does not support an inference of scienter." *Corban*, 868 F.3d at 41 (quoting *In re Cabletron Sys., Inc.*, 311 F.3d 11, 39 (1st Cir. 2002)); *see also Homology*, 2024 WL 1436025, at *18 ("Any corporation would be motivated to raise capital, make a profit, avoid bankruptcy, or finance the successful launch of a promising product.").

Second, the details provided by Plaintiffs' seven confidential former employees fail to demonstrate that any one of them had knowledge of Defendants' mental state or the information in their possession. FE 1, FE 2, FE 3, and FE 5 did not work at Sarepta during the Class Period "and thus cannot have 'firsthand knowledge of the state of mind of [Sarepta]'s management during [the class] period.' " *iRobot*, 527 F. Supp. 3d at 142 (quoting *Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 245 (1st Cir. 2015)). That leaves FE 4, FE 6, and FE 7. None of these former employees, the majority of whom had left Sarepta by the middle of the Class Period, are alleged to have had direct contact with Defendants around the time of their alleged misstatements or more broadly known about their mental states or the precise information they received. *See e.g.*, *Metzler Asset Mgmt. GmbH v. Kingsley*, 928 F.3d 151, 162 (1st Cir. 2019) ("[P]laintiffs do not allege that any of the confidential witnesses who made these statements spoke with [Defendant] before he made his statements ... and most of these confidential witnesses are, by the complaint's account, several levels removed from the company's executive team."); *see also Abiomed*, 778 F.3d at 245 ("[N]one of the witnesses were in senior management positions, and they appear to have had relatively little ongoing contact with senior management." (internal quotations removed)). Here, there is no concrete allegation that *any* of the anonymous former employees directly "conveyed any such skepticism to any defendant" during the Class Period—including

about any distinctions in the risk profile between ambulatory and non-ambulatory patients. *Vertex Pharms.*, 838 F.3d at 82. What is more, the former employees' "opinions about what management knew are insufficient to establish an intent to deceive." *Shih*, 805 F. Supp. 3d at 416. All told, the Court finds that the former employees do not tip the scales in generating a strong inference of knowing or reckless intent to deceive the market.

Even still, assuming that Defendants were aware of all clinical data and some employees' safety concerns, that still would not lead to a strong inference of scienter. "[A] defendant's close attention to clinical data 'is only helpful in establishing scienter if that close attention would have revealed an incongruity so glaring as to make the need for further inquiry obvious.' " *Shash*, 84 F.4th at 15 (quoting *Vertex Pharms.*, 838 F.3d at 82). Here, again, the FDA's approval of Elevidys's clinical trial twice-over looms large. As in *Shash* it is "difficult to say" the gap between alleged safety issues arising in the preclinical data and Sarepta's "conclusion as to [Elevidys's] efficacy was 'glaring' " where hundreds of patients in the clinical study had shown encouraging results and the FDA had approved human trials not once, but twice.[29] *Id.*; *see also* Compl. ¶¶ 11, 46, 105. Given the positive results for the vast majority of the clinical study's population,[30] and the FDA's own determination that the product was safe for clinical trials, the Court finds the innocent inference—that Sarepta's executives genuinely and reasonably believed their statements regarding Elevidys's safety across patient populations—is more likely. *See Shash*, 84 F.4th 1, at 16 (noting that "[t]he fact that the FDA ... agreed with Biogen's interpretation of the data ... support[ed] the inference that Biogen sincerely disbelieved" warnings from other parties); *see also id.* ("[T]he complaint lacks any allegation that the Defendants honestly believed [other] interpretation[s] of the data over their own." (citing *Vertex Pharms.*, 838 F.3d at 82)); *see also Yarborough v. Ardelyx*, 2025 WL 4483297, at *14 (D. Mass. Dec. 24, 2025) (finding no strong inference of scienter because the plaintiffs failed to plead facts suggesting that the defendants "harbored serious doubts" and "knowingly or recklessly concealed" those doubts from investors). This is also true with respect to the differences in risk between ambulatory and non-ambulatory patients. "[E]ven if Defendants were aware of the subgroup data, it is not evident or inferable from the complaint that Defendants knew or believed that said data undermined their statements." *Shash*, 84 F.4th at 15.

29 In *Shash*, the Court determined that certain statements *were* a material omission in part because "FDA approval of [the drug] had not yet occurred when the statement was made." *Shash*, 84 F.4th at 13. The opposite is true here.

30 Hundreds of patients were treated with Elevidys without acute liver failure. *Id.* ¶ 105 ("[B]y May of 2025 ... Sarepta had dosed a total of 800 patients.").

***19** Perhaps most importantly, Defendants frequently disclosed risks associated with Elevidys and the ESSENCE trial. In SEC filings, investor calls, conference presentations, press releases, and on the FDA label itself, Sarepta repeatedly disclosed the risks of acute liver injury when undergoing treatment with Elevidys. *See e.g.* Dkt. 147-7 at 4 ("Elevidys and our gene therapy product candidates ... may result in unforeseen adverse events."); *see also* Dkt. 146-1 (highlighting multiple disclosures of liver toxicity risk in the same documents as the alleged misstatements). As noted earlier, the same forthright disclosures occurred in relation to the ESSENCE trial as well. *See supra* Section III.C.2.c. These repeated "warnings to investors" work to "erode[ ] inferences of scienter." *Kader*, 887 F.3d at 58–59 (citing *Abiomed*, 778 F.3d at 244); *see also City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 760 (1st Cir. 2011) ("[A]ttempts to provide investors with warnings of risks generally weaken the inference of scienter." (alteration in original) (quoting *Ezra Charitable Tr. v. Tyco Int'l, Ltd.*, 466 F.3d 1, 8 (1st Cir. 2006))). Put simply, "[s]uch voluntary disclosures 'are not the actions of a company bent on deceiving investors.' " *In re Karyopharm*, 552 F. Supp. 3d at 91 (quoting *Abiomed*, 778 F.3d at 243–44). Again, the innocent inference, that Defendants genuinely believed their statements in spite of scientifically disputed red flags, is the stronger inference.

Without an admission of intent, insider stock sales, a credible financial incentive, or reliable former employees with actual knowledge of the Defendants' mental states during the Class Period, the Court is left with "at best, weak circumstantial evidence of scienter." *Brennan*, 199 F. Supp. 3d at 467. "The First Circuit has found complaints containing far stronger allegations insufficient under the PSLRA's robust scienter standard." *Id.* (collecting cases). As in another case involving Sarepta, "[t]his is simply a case in which the complaint focuses too much on nuance rather than false facts or material omission to support the necessary strong inference of scienter." *Corban*, 868 F.3d at 42. Given the repeated public disclosures of liver toxicity

risk, including in both the ambulatory and non-ambulatory populations, "the most cogent inferences from the record favor the defendants." *In re Biogen Inc. Sec. Litig.*, 857 F.3d 34, 41–42 (1st Cir. 2017). Accordingly, the Complaint's allegations concerning Defendants' knowledge of Elevidys's safety profile, the LGMD program's progress, and issues with the ESSENCE trial are insufficient to raise a strong inference that Defendants' statements were made with intent to defraud or recklessness. [31]

31 Because the Court finds that Plaintiffs fail to plead a material misrepresentation for all but two statements, *see supra* Section III.C.2, and that all statements, including the two material misrepresentations, lack a strong inference of scienter, *see supra* Section III.C.3, the Court does not address Defendants' arguments regarding loss causation.

D. Count II:

Plaintiffs' claim under Section 20(b) rises and falls with their securities fraud count. *See In re Vertex Pharms. Inc., Sec. Litig.*, 357 F. Supp. 2d at 355 ("Because the § 10(b) claim in this case is dismissed and 'there must be a primary violation for liability under section 20(a),' ... the § 20(a) claim must be dismissed as well." (quoting *Aldridge*, 284 F.3d at 84)). Plaintiffs fail to plead a valid claim under Section 10b. *See supra* Section III.C. Their claim under Section 20(b) is therefore dismissed as well.

E. Leave to Amend

In the event of dismissal, Plaintiffs "request leave to amend the Complaint, which should be 'freely given.' " Dkt. 153 at 37 (quoting Fed. R. Civ. P. 15(a)). But here, the Court finds any amendment would be futile. Plaintiffs have already amended their complaint once, more than five months after the original complaint was filed. *See Brennan*, 199 F. Supp. 3d at 473 (denying leave to amend where "plaintiffs had approximately four additional months between the filing of the initial complaint and the amended complaint to investigate their claims thoroughly"). And Plaintiffs have not identified any new facts that would appear in a second amended complaint. *See Apellis*, 2025 WL 8366491, at *11 ("[P]laintiffs fail to identify, however, any additional factual allegations that they would include in a potential second amended complaint. Nor do they explain why justice otherwise requires amendment."). Plaintiffs' "bare request for leave to amend" without more, is "sufficient reason for the denial of leave to amend." *Aponte-Torres v. Univ. of P.R.*, 445 F.3d 50, 58 (1st Cir. 2006). Plaintiffs' request for leave to amend is therefore denied.

IV. Conclusion

***20** For the foregoing reasons, Defendants' request for incorporation by reference and judicial notice is GRANTED in part and DENIED in part. Defendants' motion to dismiss is GRANTED. The amended complaint is DISMISSED with prejudice and without leave to amend.

So Ordered.

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