UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WILLIAM KADER, Individually and On Behalf of All Other Persons Similarly Situated,	*	
Plaintiff,	*	
v.	*	Civil Action No. 1:14-cv-14318-ADB
SAREPTA THERAPEUTICS, INC., CHRISTOPHER GARABEDIAN, and SANDESH MAHATME,	*	
Defendants.	*	

MEMORANDUM AND ORDER

In this securities fraud putative class action, Plaintiff William Kader, and Lead Plaintiffs Morad Ghodooshim, Roger Lam, and Laxmikant Chudasama (collectively, "Plaintiffs") seek to represent a class of all purchasers of securities issued by Sarepta Therapeutics, Inc. ("Sarepta" or "the Company") during the period from March 4, 2014 to October 27, 2014 (the "Class Period").[1] The named defendants are Sarepta, along with its former CEO, Christopher Garabedian ("Garabedian"), and the Company's Chief Medical Officer, Edward Kaye, M.D. ("Kaye") (collectively, "Defendants").[2]

Presently before the Court is Plaintiffs' Motion for Leave to Amend the Complaint [ECF No. 50]. Because Plaintiffs have unduly delayed in seeking leave to amend and because Plaintiffs' Proposed Second Amended Complaint ("PSAC") fails to address the shortcomings in

[1] Plaintiffs' Amended Complaint alleged a class period of April 21, 2014 through October 27, 2014.

[2] Plaintiffs have removed Sandesh Mahatme as a defendant in the Proposed Second Amended Complaint.

the Amended Complaint, such that granting leave to amend would be futile, Plaintiffs' Motion [ECF No. 50] is DENIED.

I. BACKGROUND

This action was commenced on December 3, 2014. Plaintiffs filed a two-count Amended Complaint on March 20, 2015 [ECF No. 17], which alleged that by making misrepresentations and material omissions in connection with the purchase or sale of Sarepta's securities, all Defendants violated Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 (Count I), and that the individual Defendants violated Section 20(a) of the Exchange Act (Count II).

On May 11, 2015, Defendants moved to dismiss [ECF No. 21], arguing that the Amended Complaint failed to state a claim for securities fraud because Plaintiffs failed to allege any actionable misstatements, and further failed to allege sufficient facts on the element of scienter. The Court held a hearing on Defendants' Motion to Dismiss on March 29, 2016, and on April 5, 2016, the Court granted Defendants' motion, dismissing Plaintiffs' Amended Complaint. [ECF No. 46].

Three days later, on April 8, 2016, Plaintiffs filed the instant Motion for Leave to Amend the Complaint, along with a supporting Memorandum and Proposed Second Amended Complaint. [ECF Nos. 50, 51]. Defendants filed an opposition to Plaintiffs' Motion for Leave to Amend [ECF No. 55], Plaintiffs replied [ECF No. 60], and Defendants filed a surreply [ECF No. 63].

The Court only briefly reviews the factual background of this case, which is set forth in greater detail in the Court's prior Memorandum and Order, and familiarity with which is assumed for purposes of this Memorandum and Order. See [ECF No. 46]. Sarepta is a

biopharmaceutical company focused on developing RNA-based therapeutics for the treatment of rare and infectious diseases. The Company has developed a drug candidate called "eteplirsen" to treat Duchenne muscular dystrophy ("DMD"). Plaintiffs contend that during the Class Period, Sarepta and its executives made materially misleading statements and omissions regarding the Company's ongoing efforts to file a New Drug Application ("NDA") for eteplirsen with the U.S. Food and Drug Administration ("FDA"). Specifically, Plaintiffs allege that the Defendants misstated guidance and omitted information that the FDA purportedly provided to the Company, which pertained to the sufficiency of Sarepta's clinical data on eteplirsen.

In granting the Defendants' Motion to Dismiss [ECF No. 21] on April 5, 2016, the Court held that Plaintiffs had failed to plausibly allege facts showing that Defendants made materially misleading statements or failed to disclose information that was necessary to make their statements not misleading. The Court also concluded that Plaintiffs' Amended Complaint failed to allege facts that gave rise to a sufficiently strong inference of scienter to survive a motion to dismiss.

As the instant litigation was ongoing, the NDA for eteplirsen was filed in May 2015, with a public hearing scheduled for January 2016. [ECF Nos. 51-1 at 12, 51-2 at ¶ 24]. Prior to the scheduled hearing, in January 2016, the FDA published a briefing document (the "FDA briefing document" or "January 2016 FDA briefing document") which, according to Plaintiffs, contained concerns communicated by the FDA to Defendants both prior to and during the Class Period, which were concealed from investors by Defendants. [ECF No. 51-2 at 79–152]. Many of the new allegations in the PSAC are allegedly based on information revealed by this briefing document. Plaintiffs state that the FDA briefing document is "highly negative to eteplirsen's prospects for approval." Id. at ¶ 24. On September 19, 2016, the FDA issued a press release

announcing the approval of eteplirsen use on DMD patients.[3] See United States Food & Drug Admin., FDA Grants Accelerated Approval to First Drug for Duchenne Muscular Dystrophy (Sept. 19, 2016), available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm521263.htm.

Plaintiffs now request leave to amend their complaint again, claiming that they have addressed the pleading deficiencies identified by the Court by adding substantial facts that were not available prior to the release of the FDA briefing document in January 2016. [ECF No. 51]. According to Plaintiffs, this FDA briefing document included the following: (1) FDA criticism of Sarepta's dystrophin analysis; (2) evidence of Defendants' improper breaking of the blinded nature of the dystrophin study and their "purposeful and unilateral" post hoc discarding of data that failed to yield positive results; and (3) documentation of Defendants' use of inconsistent and biased standards in their analysis of dystrophin biomarker data, all of which provide additional support for their claims. Plaintiffs also claim that Defendants were aware during the Class Period, but failed to publicly disclose, that the FDA, as early as July 2013, had advised Defendants to obtain an independent laboratory reassessment of the dystrophin data. Plaintiffs contend that this alleged awareness of the FDA's advice makes the statements that were made by Defendants during the Class Period false, misleading, and made with scienter. In support of their motion for leave to amend, Plaintiffs also argue that they have not unduly delayed in making this motion, are not acting in bad faith or in such a way as would unduly prejudice the Defendants, and that their motion would not be futile.

[3] The Court is well within its discretion in taking judicial notice of this government record. See Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 59–60 (2d Cir. 2016) (taking judicial notice of FDA document in deciding motion to dismiss); In re Vertex Pharm. Inc., Securities Litig., 357 F. Supp. 2d 343, 352 (D. Mass. 2005) (taking judicial notice of FDA policy as a matter of public record).

In response, Defendants argue that Plaintiffs' Motion for Leave to Amend should be denied as both belated and futile. Defendants criticize Plaintiffs for relying on the FDA briefing document from January 2016 but not filing their Motion for Leave to Amend until April 2016, three days after the Court issued its Memorandum and Order granting the motion to dismiss on the previous complaint. [ECF No. 55]. Defendants assert that the timing of Plaintiffs' filing of the PSAC constitutes undue delay and that, in any event, allowing Plaintiffs' PSAC would be futile as it fails to cure the pleading deficiencies identified by the Court in its earlier Memorandum and Order. Defendants further argue that criticism of study methodologies made in a 2016 FDA briefing document cannot give rise to a claim for fraud relating to statements made in 2014. Defendants also note that Defendants' public statements in 2014 repeatedly disclosed FDA concerns about the study methodology. Defendants dispute that descriptions of the study as "blinded" were misleading since the FDA briefing document itself states that the study was first carried out on a blinded baseline. Defendants also note that the Court previously addressed the question of the FDA's alleged request for an independent reassessment of the dystrophin data and concluded that this request was not necessarily inconsistent with Defendants' other statements. Finally, Defendants argue that Plaintiffs have done nothing to cure the deficiencies in the allegations of scienter that were fatal to the Amended Complaint.

Plaintiffs' Reply argues that leave to amend should be freely given and denies that they unduly delayed filing the PSAC. Plaintiffs also assert that the January 2016 FDA briefing document, as reflected in the PSAC, provides proof of falsity, materiality, and scienter on the part of Defendants during the Class Period. Specifically, Plaintiffs allege that Defendants had a duty to disclose:

> material adverse facts regarding dystrophin that they knew or recklessly disregarded, including: that the dystrophin data was

> materially flawed and unreliable due to Sarepta's biased selection and analysis of data; and, as a result of these methodological problems, the FDA specifically instructed Sarepta as early as July 2013, and again in July 2014, to obtain independent laboratory review of the dystrophin data prior to filing the NDA (which Defendants ignored).

[ECF No. 60 at 6–7]. Plaintiffs also add that "more recent developments destroy any notion that Defendants fairly and accurately represented the FDA review process during the Class Period" because during an FDA meeting on eteplirsen on April 25, 2016, the FDA "took pains to 'set the record straight' on what the agency told Sarepta *throughout* its eteplirsen trials, including about the many serious problems with Sarepta's dystrophin data." Id. at 7 (emphasis in original). In a footnote to their Reply brief, Plaintiffs indicate that the documents distributed prior to the April 25, 2016 FDA meeting contained additional supportive facts that Plaintiffs would include in a future amended complaint.

In their Surreply, Defendants argue that Plaintiffs' mention in a footnote to their Reply that they intend to file an additional amended complaint is improper and that such a proposed amendment should have been attached to their pending Motion for Leave. Defendants also argue that Plaintiffs relied on an impermissible theory of "fraud by hindsight" and reiterate that Plaintiffs have still failed to cure defects in their scienter allegations.

For the reasons set forth in this Memorandum and Order, Plaintiffs' Motion for Leave to Amend [ECF No. 50] is DENIED, and this case is DISMISSED WITH PREJUDICE.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 15(a)(2) provides that the Court should freely grant a party leave to amend when justice so requires. "[Rule 15] reflects a liberal amendment policy but even so, the district court enjoys significant latitude in deciding whether to grant leave to amend. We defer to the district court's decision 'if any adequate reason for the denial is apparent on the record.'" ACA Fin. Guaranty Corp. v. Advest, Inc., 512 F.3d 46, 55 (1st Cir. 2008) (quoting LaRocca v. Borden, Inc., 276 F.3d 22, 32 n.9 (1st Cir. 2002)) (other internal citation omitted). A Court may deny leave to amend for reasons including "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment." Foman v. Davis, 371 U.S. 178, 182 (1962). A request to amend a complaint "requires the court to examine the totality of the circumstances and to exercise its informed discretion in constructing a balance of pertinent considerations." Palmer v. Champion Mortg., 465 F.3d 24, 30–31 (1st Cir. 2006). If the proposed amendment would be futile because the amended complaint still fails to state a claim, a district court acts within its discretion in denying the motion for leave to amend. Abraham v. Woods Hole Oceanographic Inst., 553 F.3d 114, 117 (1st Cir. 2009).

In assessing whether a proposed amendment would be futile, the district court must apply the same standard it applies to motions to dismiss under Federal Rule of Civil Procedure 12(b)(6). Adorno v. Crowley Towing & Transp. Co., 443 F.3d 122, 126 (1st Cir. 2006). In assessing the complaint's sufficiency under Rule 12(b)(6), the Court must accept all "well-pleaded factual allegations in the Complaint as true and view all reasonable inferences in the plaintiffs' favor." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). To

survive a motion to dismiss, the complaint must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "To state a claim for securities fraud under Section 10(b), a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) in connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." Fire & Police Pension Ass'n of Colorado v. Abiomed, Inc., 778 F.3d 228, 240 (1st Cir. 2015) (internal quotations and citation omitted).[4]

Because this case involves claims of securities fraud, Plaintiffs' PSAC must also satisfy the Federal Rule of Civil Procedure 9(b) standard for alleging fraud with particularity, and comply with the heightened pleading requirements imposed by the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737. See Advest, Inc., 512 F.3d at 58. The PSLRA "requires plaintiffs' complaint to 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'" Id. (quoting 15 U.S.C. § 78u–4(b)(1)) (alteration in original). If plaintiffs' allegation regarding the statement or omission "is made on information and belief, the complaint must state with particularity all facts on which that belief is formed." Id. (quoting 15 U.S.C. § 78u–4(b)(1)).

The PSLRA also imposes a "rigorous pleading standard" for allegations of scienter, which is a "'mental state embracing intent to deceive, manipulate, or defraud.'" Id. (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)). A complaint must state "with

[4] "Claims brought under section 20(a) of the Securities Exchange Act, 15 U.S.C. § 78t(a), are derivative of 10b-5 claims." Hill v. Gozani, 638 F.3d 40, 53 (1st Cir. 2011). Section 20(a) provides that once a company has been found to have violated the Act's substantive provisions, "[e]very person who, directly or indirectly, controls" the company "shall also be liable jointly and severally with and to the same extent as [the company] . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a).

particularity facts giving rise to a 'strong inference' that defendants acted with a conscious intent 'to deceive or defraud investors by controlling or artificially affecting the price of securities' or 'acted with a high degree of recklessness.'" Abiomed, Inc., 778 F.3d at 240 (quoting City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011)). The facts alleged must make the inference of scienter "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007). "When there are equally strong inferences for and against scienter, the draw is awarded to the plaintiff." Waters Corp., 632 F.3d at 757.

While the PSLRA does not modify the liberal amendment policy of Rule 15(a), "[p]laintiffs may not, having the needed information, deliberately wait in the wings . . . with another amendment to a complaint should the court hold the first amended complaint was insufficient." Advest, Inc., 512 F.3d at 56-57.

III. ANALYSIS

a. Undue Delay

Plaintiffs contend that they did not unduly delay in filing their Motion for Leave to Amend because it was filed just three days after this Court issued its Memorandum and Order dismissing the Amended Complaint. While the Plaintiffs did file their Motion for Leave to Amend shortly after the Court issued its Memorandum and Order on April 5, 2016, the document that Plaintiffs claim added additional facts to their allegations was, at the latest, available in January 2016, well before the Court ruled on Defendants' Motion to Dismiss the Amended Complaint. Despite the availability of this document, Plaintiffs did not request leave to amend at the hearing held on the Motion to Dismiss on March 29, 2016 and instead argued against the

motion to dismiss, without citing the availability of other supporting information. Nor did they move for leave to amend before the Court entered its April 2016 order, which they should have done if the FDA briefing document cured deficiencies identified by Defendants in their Motion to Dismiss or at the argument on the motion. There was thus more than a three-month delay from the release of the new information Plaintiffs claim to have relied upon in their PSAC. The timing of the filing of the motion to amend suggests that rather than moving promptly for leave to file a new complaint based on new information discovered in January 2016, the Plaintiffs instead waited for the Court's ruling on the Motion to Dismiss before seeking leave to amend. Undue delay alone can be a sufficient reason for a Court to deny leave to amend. In re Lombardo, 755 F.3d 1, 3 (1st Cir. 2014). The Plaintiffs' actions qualify as undue delay.

Further, Plaintiffs' suggestion in a footnote of their Reply brief that there are additional FDA briefing documents from April 2016 that Plaintiffs may plan to incorporate into a future amended complaint also suggests improper delay. Plaintiffs state that "[t]hese documents contain additional supportive facts that Plaintiffs would intend to include in an operative amended complaint, should the instant motion be granted." [ECF No. 60 at 1, n.1]. To date, Plaintiffs have still not filed a Proposed Third Amended Complaint, and the Court is left only to speculate about what additional allegations Plaintiffs may plan to make based on those documents and the outcome of this motion. This "wait and see" approach to pleading, coupled with the successive filing of motions to amend, is an abuse of the rules that allow complaints to be freely amended and constitutes undue delay.

As the First Circuit has recognized, the "wait and see" approach to pleading falls squarely within the definition of "undue delay."

> The plaintiffs argue that in the end, they were entitled to wait and see if their amended complaint was rejected by the district court

> before being put to the costs of filing a second amended complaint. They claim this would promote efficiency in the judicial system. Plaintiffs have it exactly backwards—their methodology would lead to delays, inefficiencies, and wasted work. The plaintiffs do not get leisurely repeated bites at the apple, forcing a district judge to decide whether each successive complaint was adequate under the PSLRA. Plaintiffs may not, having the needed information, deliberately wait in the wings for a year and a half with another amendment to a complaint should the court hold the first amended complaint was insufficient.

Advest, Inc., 512 F.3d at 57; see also Abiomed, Inc., 778 F.3d at 247 (denying leave to amend based on Advest). Like the plaintiffs in Advest, Plaintiffs may not wait in the wings with yet another amended complaint to see if this Court determines that its prior pleading was insufficient. See United States ex rel. D'Agostino v. EV3, Inc., 153 F. Supp. 3d 519, 540–41 (D. Mass. 2015) (denying leave to amend based on plaintiff's wait and see approach to pleading); see also United States ex rel. Hagerty v. Cyberonics, Inc., 146 F. Supp. 3d 337, 343–44 (D. Mass. 2015) (noting that periods as short as three months can constitute undue delay and denying leave to file second amended complaint).

Because Plaintiffs have had ample opportunity to properly and promptly seek leave to amend, and have failed to do so, this Court concludes that Plaintiffs unduly delayed the filing of their Motion for Leave to Amend. Their "wait and see" approach is highlighted by the fact that they anticipate filing yet another such motion if this one fails. Accordingly, Plaintiffs' Motion for Leave to Amend is DENIED on the basis that Plaintiffs have unduly delayed in seeking leave to amend.

b. Futility of Amendment

In addition to concluding that Plaintiffs' Motion for Leave to Amend should be denied on the basis of Plaintiffs' undue delay, the Court finds that Plaintiffs' PSAC fails to state a claim. Therefore, the Court also denies Plaintiffs' Motion for Leave to Amend because allowing such an amendment would be futile.

Plaintiffs' PSAC seeks to add various allegations that are related to the sufficiency and integrity of the dystrophin data and the Company's failure to adequately communicate concerns about the data that were raised by the FDA. The PSAC, in some instances, recycles allegations that the Court has already rejected and, in total, fails to allege misrepresentations sufficient to state a claim. The PSAC also fails to satisfy the Court that Plaintiffs have established a strong inference of scienter. In this section, the Court summarizes the thrust of the new allegations, which come largely from the January 2016 FDA briefing document, and explains why these allegations—first, the alleged misrepresentations and, second, the allegations of scienter—are still insufficient under the pleading standards.

1. New Allegations

In their new allegations in the PSAC, based in significant part on the January 2016 FDA briefing document, Plaintiffs conclude that "Defendants misrepresented Sarepta's dystrophin data and ability to file an NDA by the end of 2014, in that they misrepresented that the dystrophin analysis was conducted in a properly blinded and controlled manner, and they misrepresented, omitted, and recklessly ignored the FDA's repeated guidance to seek independent laboratory verification of the dystrophin assessment results." Plaintiffs claim generally that the suggestion that the data was good enough for an NDA was false and misleading and that ignoring the FDA's concerns was so deliberately reckless "as to constitute a

fraud and deceit upon Plaintiffs and the class." Plaintiffs further aver that "[w]hile the FDA had expressed concerns regarding the reliability of Defendants' eteplirsen data, and therefore had requested that Defendants show reproducibility of the results vis-à-vis independent laboratory verification, Defendants repeatedly misrepresented that the FDA simply wanted to become more 'comfortable' with the manner in which the data was assessed by the laboratory, and repeatedly assured investors that the study was well-controlled and properly blinded." Plaintiffs claim that although Defendants "seemingly disclosed that the FDA expressed 'concerns' regarding Sarepta's dystrophin data during the Class Period, even those purported cautionary statements were themselves misleading, and made with actual knowledge of falsity" because they misrepresented "the nature and import of the FDA's concerns" about the data.

Plaintiffs further allege that that "FDA confirmed that on March 13, 2013, Defendants were informed that the FDA did not believe that Sarepta adequately characterized the quantity of dystrophin produced by eteplirsen treatment and that 'the immunofluorescence data you presented suggest that a much lower quantity of truncated dystrophin is produced by eteplirsen treatment than is present in BMD.'" The PSAC also adds allegations that the FDA had specifically advised Sarepta on a number of occasions as early as July 2013 to obtain independent laboratory reassessment of the dystrophin data prior to an NDA submission. Plaintiffs plead on information and belief that, as early as July 2013, the FDA advised Sarepta that "[w]e are open to considering an NDA based on these data for filing. However, we have a number of concerns [which] should be addressed prior to filing." [ECF No. 51-1 at ¶ 18 (emphasis omitted)]. Plaintiffs also allege that the 2013 FDA guidance stated that "[dystrophin] image interpretation is susceptible to bias and analyses of medical images require scrupulous attention to and documentation of blinded analysis." Id. (emphasis omitted). Plaintiffs assert that

the FDA advised Defendants to "confirm with an independent laboratory the immunohistochemical findings for dystrophin and associated proteins." Id. (emphasis omitted).

2. Misrepresentations As Alleged Are Insufficient.

Plaintiffs' amended allegations focus on two primary areas. First, Plaintiffs criticize the methods used in Defendants' clinical studies of eteplirsen and argue that Defendants misrepresented how the studies were carried out. Second, Plaintiffs rely on the FDA's subsequent statements that Sarepta was informed about the need to conduct further clinical testing in order to submit their NDA and misrepresented what the FDA required. On both issues, Plaintiffs' PSAC fails to sufficiently allege material misrepresentations sufficient to satisfy the pleading requirements.

Plaintiffs' arguments about alleged flaws in clinical testing methodology do not sufficiently state a claim for securities fraud. Disagreements with or criticism of drug study methodology is insufficient to state a claim for securities fraud, particularly where there is no showing of an intent to deceive or improper manipulation of results. See In re Adolor Corp. Securities Litig., 616 F. Supp. 2d 551, 567 (E.D. Pa. 2009) ("Defendants' statements that the Phase III trials were randomized and double-blinded amount to disagreements over the proper methodology and conduct of clinical studies. These allegations are not sufficient to establish falsity for purposes of a Rule 10b-5 claim."); In re Sanofi Securities Litig., 87 F. Supp. 3d 510, 544 (S.D.N.Y. 2015) (noting that, "[b]y far the most logical inference on the facts pled—indeed, the only plausible inference—is that defendants (1) sincerely held their optimistic views of the clinical trial results, and (2) were surprised and disappointed by the FDA's temporary—for the FDA eventually reversed course—rejection of these results as inadequate.").

Here, Defendants' course of conduct suggests that they believed the FDA would eventually become comfortable with the study results and the methodology employed. While the FDA communicated to Defendants that additional testing would eventually be necessary, the many cautionary statements by Defendants more than made clear to investors that there was an ongoing discussion underway with the FDA regarding the data that would be required to support an NDA. While Plaintiffs argue that the evidence shows that Defendants were on notice from the FDA about the need for additional clinical testing, it is unclear from Plaintiffs' allegations that Defendants were unequivocally told that further data would be required for submission of the NDA and made contrary representations to investors. Thus, the facts pled by Plaintiffs do not show that Defendants statements were knowingly or recklessly false when made. Like in Sanofi, "the most logical inference on the facts pled" by Plaintiffs is that the Defendants here held optimistic views of the clinical trial results and were surprised by the FDA's temporary rejection of the results as inadequate. See Sanofi, 87 F. Supp. 3d at 544. The fact that the NDA was ultimately approved in September 2016 supports the inference that the Defendants' initial statements that their testing data may have been sufficient for an NDA were accurate and undercuts any argument that Defendants disregarded FDA requirements while representing otherwise to the public. The eventual approval notwithstanding, Plaintiffs' reliance on the post hoc FDA briefing document showing that the FDA "consistently" expressed the need for additional testing is misplaced because the document does not sufficiently particularize what was said and when, or what sorts of conditions were communicated to the Defendants.

Plaintiffs' allegations that Sarepta misrepresented the nature of the clinical testing, particularly its "blinded" nature, are also deficient. Plaintiffs argue that Sarepta misrepresented that the clinical trial was carried out on a blinded baseline. But, as even the January 2016 FDA

briefing document cited by Plaintiffs acknowledged, "[t]he measurement of total dystrophin immunofluorescence by Bioquant was first carried out on *blinded baseline*, Week 12, and Week 24 images, captured at 20x magnification." [ECF No. 51-2 at 105 (emphasis added)]. The FDA document continued that "[t]he 20x immunofluorescence images on samples obtained through Week 24 were selected by an individual blinded to treatment group, but the microscopic fields to be photographed were selected manually by the operator." Id.[5] Plaintiffs cannot explain how Defendants misrepresented facts by describing their clinical testing as proceeding from a blinded baseline, when even the FDA acknowledged that this occurred. That certain results from the testing were not carried out on a blinded baseline, and that the FDA briefing document raised potential issues with some of the methods used in the study, without more, is insufficient to show a misrepresentation, particularly where such allegations are also largely based on apparent criticism of the study methodology. Plaintiffs have leveled no allegations that Defendants improperly interfered with the clinical study, manipulated results, or were otherwise improperly involved with the studies that would allow the Court to conclude that Defendants were deliberately engaging in efforts to deceive investors.

3. Allegations of Scienter Are Insufficient.

Plaintiffs' threadbare new allegations that Defendants acted with the requisite scienter likewise fail. The PSAC fails to allege additional facts "giving rise to a 'strong inference' that defendants acted with a conscious intent 'to deceive or defraud investors by controlling or artificially affecting the price of securities' or 'acted with a high degree of recklessness.'" Abiomed, Inc., 778 F.3d at 240 (quoting Waters Corp., 632 F.3d at 757). Plaintiffs' allegations

[5] Plaintiffs' additional allegations about statements made by Garabedian on March 4, 2014 also fail to sufficiently allege misrepresentations since these appear to be neither false nor misleading. [ECF No. 51-2 at ¶¶ 20–23].

that "[o]n information and belief . . . the FDA unequivocally informed Defendants at least as early as July 2013 that independent laboratory assessment of dystrophin—the data supporting eteplirsen's primary surrogate endpoint—needed to be addressed prior to filing" lack the requisite specificity to satisfy the heightened PSLRA and Rule 9(b) pleading standards. [ECF No. 51-2 at ¶ 122(b)]. These allegations fail to make the inference of scienter "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc., 551 U.S. at 314. While Plaintiffs continue to claim that Defendants ignored FDA feedback expressing concerns about the sufficiency of Sarepta's clinical trial data, Plaintiffs still have not alleged any facts that overcome the cautionary language employed by Defendants in their public statements, or show that Defendants knew or recklessly disregarded definitive FDA guidance about what was required for their NDA. Plaintiffs' PSAC fails to allege additional facts that would allow the Court to infer that the Defendants acted with the requisite scienter to survive a motion to dismiss, or to change the previous conclusion that Plaintiff's scienter allegations are deficient.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Leave to Amend [ECF No. 50] is DENIED, and all claims against the Defendants are hereby DISMISSED WITH PREJUDICE.[6]

SO ORDERED.

Dated: January 6, 2017

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE

[6] Because Plaintiffs fail to plead a viable claim for securities fraud under Section 10 and Rule 10b-5, all derivative claims against the individual Defendants necessarily fail as well. See Hill, 638 F.3d at 70.