UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PETER LEUNG, individually and on behalf of all others similarly situated,	
Plaintiff,	
v.	**Case No. 21-cv-10335-DJC**
BLUEBIRD BIO, INC., NICK LESCHLY, and CHIP BAIRD,	
Defendants.	

MEMORANDUM AND ORDER

CASPER, J. **April 21, 2022**

I. Introduction

Lead plaintiff Jerry Hannah ("Plaintiff")[1] has filed this class action lawsuit against bluebird bio, Inc. ("bluebird" or the "Company"), Nick Leschly ("Leschly") and Chip Baird ("Baird"), bluebird's chief executive officer and chief financial officer, respectively, (collectively, "Defendants") alleging securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Securities and Exchange Commission Rule 10b-5 ("Rule 10b-5") between May 11, 2020 and November 4, 2020 (the "Class Period"). D. 26. Defendants have moved to dismiss the amended complaint. D. 30. For the reasons stated below, the Court ALLOWS the motion.

[1] This action was originally filed by Peter Leung, individually and on behalf of all others similarly situated. D. 1. The Court, upon motion, subsequently appointed Jerry Hannah as lead plaintiff. D. 22. !

II. Standard of Review

For allegations of securities fraud under Sections 10(b) and 20(a) of the Exchange Act, a plaintiff "must plead the circumstances of the fraud with particularity, pursuant to Rule 9(b)," Hill v. Gozani, 638 F.3d 40, 55 (1st Cir. 2011), and, pursuant to the Private Securities Litigation Reform Act ("PSLRA"), must also "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading," id. (alteration in original) (citation and internal quotation marks omitted).

As part of the inquiry under Tellabs v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322–23 (2007), courts engage in a particularized scrutiny of private securities complaints. See, e.g., Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 996 (9th Cir. 2009). Nevertheless, the PSLRA's pleading standard is not an insurmountable bar. As required by Tellabs, the Court considers the allegations collectively to determine whether they give rise to a strong inference of scienter. Id. at 991–92 (citing Tellabs, 551 U.S. at 323).

As with any Rule 12(b)(6) motion, the Court must "accept 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).

III. Factual Background

A. Materials Outside the Pleadings

As a preliminary matter, Plaintiff argues that the Court may not consider, or may consider only in a limited capacity, eighteen exhibits marked A through R submitted by Defendants in connection with their motion to dismiss. D. 34 at 17–22; see D. 32. According to Plaintiff, the Court may consider Exhibits B, G, H, I, J, N, P and Q, which reference documents cited or quoted in the amended complaint, only for the purpose of assessing "the existence of warning language for purported forward-looking statements." D. 34 at 20–21. Further, Plaintiff contends that the

Court may not consider Exhibits C through F, K through M, or O through R since they are neither referenced in the amended complaint nor submitted for any allowable purpose. Id. at 21–22.

At the motion to dismiss stage, the Court ordinarily "may not consider any documents that are outside of the complaint, or not expressly incorporated therein, unless the motion is converted into one for summary judgment." Alt. Energy, Inc. v. St. Paul Fire & Marine Ins. Co., 267 F.3d 30, 33 (1st Cir. 2001). "There is, however, a narrow exception 'for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; or for documents sufficiently referred to in the complaint.'" Id. (quoting Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993)).

Exhibits B, G, H, I, J, N, P and Q—Securities and Exchange Commission ("SEC") filings, analyst conference call transcripts and a Food and Drug Administration ("FDA") guidance document—constitute documents "sufficiently referred to in the complaint" for consideration at the motion to dismiss stage. See Alt. Energy, 267 F.3d at 33; D. 32. Plaintiff argues that, while the Court may note these exhibits' existence, it may not consider them for the truth of any matter asserted therein. D. 34 at 19, 21. These exhibits, however, are "relevant not for the truth of anything asserted in [them]." See Torrens v. Lockheed Martin Servs. Grp., Inc., 396 F.3d 468, 473 (1st Cir. 2005). Rather, they address bluebird's representations to its investors and what, if any, FDA guidance was available to bluebird when it made those representations. Cf. id. (considering document "relevant . . . simply as a legally significant event, like a treaty or a will"); Kader v. Sarepta Therapeutics, Inc., No. 1:14-CV-14318-ADB, 2016 WL 1337256, at *11 (D. Mass. Apr. 5, 2016) (considering FDA statements relevant to, among other things, "the total mix of information available to the market during the Class Period"). Accordingly, the Court may consider these exhibits without the restriction argued by Plaintiff.

The Court also may consider Exhibits C, D, E, F, G, K and R as official public records. See D. 32. While not referenced in the amended complaint, these exhibits contain excerpts from SEC filings and FDA documents proper for consideration at the motion to dismiss stage. See Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 59–60 (2d Cir. 2016) (considering FDA guidance at motion to dismiss stage because it "is publicly available and its accuracy cannot reasonably be questioned"); Leavitt v. Alnylam Pharms., Inc., 525 F. Supp. 3d 259, 266 n.1 (D. Mass. 2021) (stating that the court "may, in its discretion, take judicial notice of FDA documents"); In re Vertex Pharms. Inc., Sec. Litig., 357 F. Supp. 2d 343, 352 n.4 (D. Mass. 2005) (taking judicial notice of FDA policy "as a matter of public record"); In re Stone & Webster, Inc., Sec. Litig., 253 F. Supp. 2d 102, 128 n.11 (D. Mass. 2003) (explaining that a district court may "consider documents required to be filed, and actually filed, with the SEC on a motion to dismiss").

By contrast, Exhibits L, M and O do not fall within any of the exceptions for consideration at this stage. Exhibit L purports to be an academic journal article. D. 32-12. Exhibits M and O purport to be conference presentation transcripts neither referenced in the amended complaint nor included in any public SEC filing. D. 32-13; D. 32-15. These documents "are not properly before the Court, nor are they essential to evaluating the sufficiency of the [c]omplaint." See Kader, 2016 WL 1337256, at *10 (granting motion to strike exhibits attached to declaration in support of defendants' motion to dismiss). Accordingly, the Court has not considered these three exhibits in the resolution of the motion to dismiss.

B. Factual Allegations

The following facts are drawn from Plaintiff's amended complaint, D. 26, and from the exhibits Defendants filed in support of their motion, except Exhibits L, M and O, as discussed above, see D. 32.

1. Bluebird plans to apply for FDA approval of LentiGlobin

Bluebird is a biotechnology company that develops gene therapies for severe genetic diseases and cancer. D. 26 ¶ 6. The Company uses lentiviral vectors to introduce a functional copy of a gene to a patient's own stem cells *ex vivo* (i.e., outside the patient) and then the modified stem cells with the functional gene are reinserted into the patient. Id. ¶¶ 29, 32. Bluebird's gene therapy programs in development include LentiGlobin for the treatment of sickle cell disease ("LentiGlobin"). Id. ¶¶ 6, 30. Sickle cell disease ("SCD") is a hereditary blood disorder with significant negative health effects caused by a mutation in the beta-globin gene that results in polymerized hemoglobin and abnormal red blood cell function. Id. ¶ 30. Currently, treatments for the disease are limited to chronic blood transfusions and hydroxyurea, a generic drug. Id. ¶ 31. LentiGlobin is designed to be a one-time treatment that would use bluebird's lentiviral vector platform to replace damaged cells' mutated beta-globin genes, enabling SCD patients to form normally functioning hemoglobin and normal red blood cells. Id. ¶¶ 32–33.

Bluebird announced plans to apply for FDA approval to market LentiGlobin. See id. ¶¶ 7, 53. If approved, LentiGlobin could be a "blockbuster therapy" for bluebird, with analysts projecting peak global sales at $2.1 billion, nearly as much as all of bluebird's other four products in development combined. Id. ¶ 34.

The process for obtaining FDA approval to market a biological product generally involves: (1) completion of nonclinical laboratory tests and animal studies; (2) submission of an application for an investigational new drug; (3) performance of adequate and well-controlled human clinical studies to establish the safety and efficacy of the product for its intended use; (4) submission of a Biologics License Application ("BLA") for marketing approval that includes evidence of safety, purity and potency from results of nonclinical testing and clinical studies; (5) inspections of the

manufacturing facilities; (6) potential audit of nonclinical and clinical study sites; and (7) FDA review and approval of the BLA. Id. ¶ 50.

To submit a viable BLA, an applicant must demonstrate both adequate clinical results and the adequacy of its chemistry, manufacturing and controls ("CMC") for production to the FDA. Id. ¶ 9. Clinical studies of biological products are typically conducted in three sequential phases, which may overlap or be combined. Id. ¶ 48. In Phase 1, the product is introduced into healthy subjects and tested for safety. Id. In Phase 2, the product is evaluated in a limited patient population preliminarily to evaluate the product's efficacy and optimal dosage. Id. In Phase 3, the product is evaluated in an expanded patient population at geographically dispersed clinical study sites to establish the product's overall risk-benefit ratio and provide an adequate basis for product labeling. Id.

The FDA has published guidance regarding the development and submission of gene therapy protocols, including on CMC-related issues. Id. ¶ 51. For example, in January 2020, the FDA issued a final guidance document "to inform sponsors how to provide sufficient CMC information required to assure product safety, identity, quality, purity, and strength (including potency) of the investigational product." Id. ¶ 52; see D. 32-7 at 4. The document includes guidance on how gene therapy developers should account for changes in manufacturing processes during product development, stating: "[i]f you make significant manufacturing changes, then comparability studies may be necessary to determine the impact of these changes on the identity, purity, potency, and safety of the product." D. 26 ¶ 52; see D. 32-7 at 6. As with other FDA guidance documents, this guidance "do[es] not establish legally enforceable responsibilities" but instead "describe[s] the FDA's current thinking on a topic and should be viewed only as [providing] recommendations." D. 32-7 at 5.

Bluebird has conducted multiple clinical studies for LentiGlobin, including a Phase 3 study involving the treatment of patients with SCD that was ongoing in 2020. D. 26 ¶¶ 35–36. These clinical studies used lentiviral vectors manufactured using an "adherent" process. Id. ¶ 37. In May 2020, bluebird announced that, for commercial purposes, it would shift to a "suspension-based" manufacturing process. Id. ¶ 40. Baird explained that this process would enable the Company to produce LentiGlobin more efficiently and at greater scale, which was "critical from both a cost of goods perspective and a capacity perspective" and a "key component" to "financial sustainability." Id. ¶¶ 41–42; see D. 32-9 at 8, 20. Around that time, numerous competitors were also seeking to develop gene treatment therapies and other alternative treatments for SCD. See D. 26 ¶¶ 39–40.

2. Bluebird announces accelerated approval timeline

On May 11, 2020, bluebird announced that it had reached "general agreement with FDA that the clinical data package required to support a BLA submission for [LentiGlobin] will be based on data from a portion of patients in the [Phase 1/2 clinical study] that have already been treated." Id. ¶ 54. Accordingly, the Company stated that it planned "to seek an accelerated approval and expect[ed] to submit the [BLA] for sickle cell disease in the second half of 2021." Id. ¶ 55. Defendants repeated similar statements that day in SEC filings and an analyst conference call. See, e.g., id. ¶¶ 59, 61, 63; D. 32-8 at 5; D. 32-9 at 6. When asked during the conference call how the newly announced suspension manufacturing process would impact the BLA submission, Leschly stated that "we don't anticipate that standing in the way." D. 26 ¶ 61; D. 32-9 at 20.

Bluebird simultaneously advised investors that it "anticipate[d] additional guidance from FDA regarding the commercial manufacturing process, including suspension lentiviral vector." D. 26 ¶ 55; see D. 32-8 at 5. During the May 11, 2020 conference call, one bluebird representative stated that "[t]he only other nuance . . . is to address alignment on CMC as well, and we have

planned engagements coming up to ensure that we're aligned on that." D. 32-9 at 10. Bluebird's quarterly SEC filing for the first quarter of 2020 noted that, because the Company was "transitioning . . . to a scalable suspension process," in seeking regulatory approval it "may need to conduct additional studies to demonstrate comparability of the modified versions to earlier versions." D. 26 ¶ 65; D. 32-14 at 7. The filing further explained: "[w]e are engaged with regulatory agencies on the data that we will be required to collect to demonstrate comparability." D. 32-14 at 7. Moreover, the filing cautioned that bluebird's "ability to submit and obtain approval of a BLA is ultimately an FDA review decision" and, "[d]epending on the outcome of these ongoing clinical studies, the FDA may require that we conduct additional or larger pivotal trials before we can submit or obtain approval for a BLA." Id. at 8.

3. Bluebird announces public offering

The day after bluebird announced its "general agreement with FDA," D. 26 ¶ 54, the Company's share price increased $0.95 on unusually high trading volume, id. ¶ 69. On May 18, 2020, one week after the announcement, bluebird commenced a public offering. Id. ¶ 73. In connection with the offering, the Company filed a prospectus supplement, id. ¶ 74, which confirmed that bluebird was "planning to seek an accelerated approval [for LentiGlobin] and expect[ed] to submit the BLA for sickle cell disease in the second half of 2021," id. ¶ 77. Bluebird's share price rose $0.48 on May 18, 2020 and another $7.27 on May 20, 2020 to close at $65.17. Id. ¶ 74. Through the public offering, bluebird sold 10.5 million shares of common stock at $55.00 per share, raising aggregate net proceeds of $541.5 million. Id. ¶ 75.

Bluebird previously reported in an SEC filing that it "has incurred losses since inception and to date has financed its operations primarily through the sale of shares of the Company's stock." Id. ¶ 71. It further stated that "[t]he Company expects to continue to generate operating

losses and negative operating cash flows for the next few years and will need additional funding to support its planned operating activities through profitability." Id.

4. Bluebird announces delayed submission of licensing application

On August 5, 2020, bluebird announced that it was transitioning to the new suspension manufacturing process for LentiGlobin. See D. 32-10 at 8. Bluebird maintained its stance regarding the LentiGlobin BLA submission timeline, announcing that it still intended to file its application for regulatory approval in the second half of 2021. D. 26 ¶¶ 80, 84. The Company again noted in a press release "the risk that our plans for submitting a BLA for LentiGlobin for SCD may be delayed if the FDA does not accept our comparability plans for the use of the suspension manufacturing process." Id. ¶ 82. Similarly, the Company's quarterly SEC filing stated: "[d]epending on the outcome of our ongoing and planned studies, the FDA may require that we conduct additional or larger clinical trials before our LentiGlobin product candidate is eligible for approval for the treatment of patients with SCD." D. 32-10 at 7. The filing further cautioned that "[t]he FDA may not agree with our plans for demonstrating comparability of the adherent manufacturing process to the suspension manufacturing for lentiviral vector, which may result in delays in our ability to submit a BLA for regulatory approval of LentiGlobin." D. 26 ¶ 88; D. 32-10 at 7–8 (noting the possibility that FDA "may require us to conduct additional studies, collect additional data, develop additional assays, or modify release specifications, which may delay our ability to submit a BLA . . . for regulatory approval").

On November 4, 2020, bluebird issued a press release stating that it no longer planned to submit its BLA for LentiGlobin in the second half of 2021. D. 26 ¶ 103. Bluebird explained that, with respect to the LentiGlobin comparability analysis, "FDA requested the use of drug product manufactured from sickle cell disease (SCD) patient cells in addition to healthy donors as well as

commercial lentiviral vector to demonstrate drug product comparability." Id. The Company stated that this would push the BLA submission to late 2022. Id. On an analyst conference call that day, Leschly said that, "[w]hile this interaction with the FDA confirmed the robustness of our clinical data package and overall CMC confidence, the requirements to demonstrate comparability are . . . different than the plan we proposed and expected." Id. ¶ 104. Leschly further explained that this change, along with COVID-19-related operational delays, caused the Company to "adjust[] the timing of the BLA submission back to the more conservative initial target timing of late 2022." Id. When asked for more detail regarding the FDA's rationale for requesting more comparability data, bluebird's chief medical officer, David Davidson, responded: "[i]n the past, we have used healthy donor cells in terms of demonstrating comparability. . . . [O]ur hope had been that normal volunteer cells would be acceptable given the robustness of the clinical data we're seeing, so far." Id. ¶ 105. The Company's chief technology and manufacturing officer, Derek Adams, further stated: "[t]he presumption, I guess, would be that the healthy donor cells . . . clearly don't allow us to be able to check the actual resulting potency of the drug product. . . . I want to presume that they are concerned about . . . checking the potency of the results . . . ." Id.

Following this announcement, bluebird's stock price fell $9.72 per share, or 16.6%, to close at $48.83 per share on November 5, 2020. Id. ¶¶ 5, 112.

IV. Procedural History

This class action was initiated on February 12, 2021 in the Eastern District of New York, D. 1, and later transferred to this Court, D. 11. Plaintiff filed an amended complaint on July 6, 2021. D. 26. Defendants now have moved to dismiss. D. 30. The Court heard the parties on the pending motion and took the matter under advisement. D. 38.

V. Discussion

A. Section 10(b) and Rule 10b-5 Claim (Count I)

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must adequately plead (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. Amgen Inc. v. Conn. Ret. Plans & Tr. Funds, 568 U.S. 455, 460–61 (2013). Defendants challenge the adequacy of the amended complaint's allegations regarding scienter, actionable misrepresentations or omissions and loss causation. D. 31 at 9–10.

1. Scienter

Defendants argue that Plaintiff has failed to allege facts supporting a strong inference of scienter. Id. at 19–29. "Scienter is defined as either the 'intentional or willful conduct designed to deceive or defraud investors' or 'a high degree of recklessness.'" Metzler Asset Mgmt. GmbH v. Kingsley, 928 F.3d 151, 158 (1st Cir. 2019) (quoting In re Biogen Inc. Sec. Litig., 857 F.3d 34, 41 (1st Cir. 2017)). Recklessness in this context refers to "a highly unreasonable omission" involving "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." Brennan v. Zafgen, Inc., 853 F.3d 606, 613 (1st Cir. 2017) (citation and internal quotation marks omitted). This "definition of recklessness does not encompass ordinary negligence and is closer to a lesser form of intent." Greebel v. FTP Software, Inc., 194 F.3d 185, 199 (1st Cir. 1999). Defendants must have had the requisite scienter at the time of the allegedly fraudulent statements. In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d 744, 751–52 (1st Cir. 2016).

The PSLRA's requirement to plead facts giving rise to a "strong inference" of scienter

means that "[a] complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. Thus, in evaluating securities class action complaints, courts "must take into account plausible opposing inferences." Id. at 323–24 (instructing courts to "consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff"). This is necessarily a fact-specific inquiry, Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002), which may rely upon indirect evidence of scienter, Greebel, 194 F.3d at 195, 202. Courts conducting such an inquiry must determine "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Tellabs, 551 U.S. at 322–23 (emphasis omitted).

a) Intentional or Reckless Disregard of Plan's Deficiency

Plaintiff claims that Defendants intentionally or recklessly disregarded that the comparability plan could not show the comparable potency of LentiGlobin when manufactured using the suspension process because the plan did not involve using SCD patient cells. D. 34 at 24. For support, Plaintiff primarily relies upon alleged statements made by Derek Adams, bluebird's chief technology and manufacturing officer, on a November 4, 2020 analyst conference call, D. 34 at 25; see D. 26 ¶ 105, and FDA guidance regarding the potential need for comparability studies upon significant changes to manufacturing methods, D. 34 at 26; see D. 26 ¶ 52.

As Defendants argue, however, such allegations do not support that Defendants intentionally or recklessly disregarded the comparability plan's deficiency. See D. 31 at 22; D. 37 at 10–11. Derek Adams made his statements regarding the comparability plan's ability to assess potency after the FDA had already provided feedback on the plan. See D. 26 ¶ 105. In context,

Derek Adams's statements attempted to explain the FDA's position; they did not constitute an admission of bluebird's prior knowledge of the plan's deficiency. See id. (stating that "[t]he presumption, I guess, would be that the healthy donor cells . . . clearly don't allow us to be able to check the actual resulting potency of the drug product" and "I want to presume that they [i.e., FDA] are concerned about the potency"). Moreover, immediately prior to Derek Adams's statements, David Davidson, bluebird's chief medical officer, explained: "[i]n the past, we have used healthy donor cells in terms of demonstrating comparability. . . . [O]ur hope had been that normal volunteer cells would be acceptable given the robustness of the clinical data we're seeing, so far." Id. Taken together, these statements do not suggest that bluebird intentionally or recklessly disregarded that the FDA would require use of SCD patient cells in its comparability study. Instead, they indicate that bluebird believed prior to receiving the FDA's feedback that using healthy donor cells could demonstrate comparability.

Further, the non-binding FDA guidance cited by Plaintiff, id. ¶ 52; D. 34 at 26, also does not support a strong inference of scienter. Such guidance noted that "[i]f you make significant manufacturing changes, then comparability studies may be necessary to determine the impact of these changes on the identity, purity, potency, and safety of the product." D. 26 ¶ 52. Such does not require manufacturers to conduct comparability studies, prescribe a way in which comparability studies must be conducted or state that potency must always be tested in comparability studies. See id. The guidance, therefore, does not support an inference that Defendants intentionally or recklessly disregarded that not using SCD patient cells in the comparability study would materially increase the risk of delay to the Company's projected FDA approval timeline.

As Defendants observe, D. 31 at 21; D. 37 at 8, the amended complaint does not otherwise

identify any admission, internal record, witnessed discussion or communication to suggest that bluebird knew or was warned that its proposed comparability plan would be insufficient to support a BLA, see generally D. 26. Without facts to support Plaintiff's assertion that the FDA was "highly likely to reject bluebird's plan" because it "could not show comparable potency at all," D. 34 at 26, such amounts to Plaintiff's own scientific opinion, which is insufficient support a claim of securities fraud. See Harrington v. Tetraphase, No. CV 16-10133-LTS, 2017 WL 1946305, at *5 (D. Mass. May 9, 2017) (stating that "scientific opinions are just that: opinions"); In re Sepracor, Inc. Sec. Litig., 308 F. Supp. 2d 20, 35–36 (D. Mass. 2004) (rejecting scienter allegations based upon "subjective scientific disagreements"); In re Medimmune, Inc. Sec. Litig., 873 F. Supp. 953, 966–67 (D. Md. 1995) (rejecting scienter allegations because "[m]edical researchers may well differ over the adequacy of given testing procedures" and plaintiffs "pleaded no specific facts to show why [d]efendants knew or should have known [their use of blinding in a study] to be a problem").

Plaintiff's allegations, therefore, constitute a claim of "fraud by hindsight"—that is, "'contrast[ing] a defendant's past optimism with less favorable actual results' in support of a claim of securities fraud." ACA Fin., 512 F.3d at 62 (quoting Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1223 (1st Cir. 1996)); see Corban v. Sarepta Therapeutics, Inc., 868 F.3d 31, 39 (1st Cir. 2017) (rejecting that "overly optimistic" announcement regarding likelihood of new drug application being accepted constituted securities fraud in absence of prior knowledge); Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 457 (1st Cir. 2017) (affirming dismissal where plaintiff did not "point to any FDA requirement" supporting contention that company should have known its projected timeline for submission of data was "impossible to achieve" and explaining that defendant did not commit securities fraud by failing to have "greater clairvoyance" (citation

omitted)). In, for one example, Corban, the First Circuit affirmed the dismissal of a securities fraud class action complaint for lack of a strong inference of scienter despite the FDA expressing "serious concerns" to the company regarding the drug's potential approval several months before the relevant stock drop. Corban, 868 F.3d at 35, 38 (noting that the defendant's "mix of optimism and caution" "convey[ed] opinion more than fact" and "came replete with caveats").

Here, Defendants received no such warning from the FDA but did similarly caution investors. For one example, in announcing its plan to seek accelerated approval for LentiGlobin, bluebird noted its "general agreement with FDA" regarding the sufficiency of its "clinical data package" but also stated that it "anticipate[d] additional guidance from FDA regarding the commercial manufacturing process, including suspension lentiviral vector." D. 26 ¶¶ 54–55; see D. 32-9 at 10; D. 32-14 at 8. The Company, therefore, informed investors that its alignment with FDA was limited to the clinical data package. Bluebird also promptly disclosed the feedback it received from the FDA regarding its comparability plan, informing investors on November 4, 2020 that "FDA requested the use of drug product manufactured from [SCD] patient cells in addition to healthy donors as well as commercial lentiviral vector to demonstrate drug product comparability," pushing the BLA submission timeline to late 2022. D. 26 ¶ 103. Such "full and prompt disclosure . . . further undercut[s] any inference of fraudulent intent." In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 42 (1st Cir. 2014); see Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 243 (1st Cir. 2015) (stating that company's prompt disclosure of FDA warning letter did not represent "the actions of a company bent on deceiving investors as to their future earnings prospects").

Cases upon which Plaintiff relies do not support the allegations of scienter. See D. 34 at 25 (citing In re Illumina, Inc. Sec. Litig., No. 3:16-CV-3044-L-KSC, 2018 WL 500990, at *5

(S.D. Cal. Jan. 22, 2018); Todd v. STAAR Surgical Co., No. CV-14-05263-MWF-RZ, 2016 WL 6699284, at *14 (C.D. Cal. Apr. 12, 2016)). For example, Illumina concluded that the plaintiffs adequately alleged scienter for false earnings guidance where the defendants forecasted a rise in sales when they knew sales were in decline, despite that it remained "possible" that the defendants believed the company could achieve its earnings guidance. Illumina, 2018 WL 500990, at *5. There, the complaint alleged statements by the defendants indicating knowledge of declining sales. Id. Here, by contrast, Plaintiff has alleged no such statements.

Further, Todd concluded that allegations that the defendants knew facts "produc[ing] a sufficiently great possibility of a future [w]arning [l]etter" supported an inference of scienter. Todd, 2016 WL 6699284, at *14. That case involved allegations indicating that the defendants knew about adverse observations during FDA inspections and so could have anticipated receiving a violation form and warning letter from the agency. Id. at *12. In concluding that the plaintiff adequately pleaded scienter, the court noted alleged conversations between company management and the FDA inspector explicitly referencing the violations, as well as the defendants' familiarity with FDA procedures given the company's many past violations. Id. at *12–13. The case also involved undisclosed, repeated negative feedback from confidential witnesses who reported to management the substantial defects that ultimately formed the warning letter's basis. Id. at *3–4. Contrastingly, while the amended complaint here does cite Defendants' "ample experience in the field" and previous "manufacturing issues," D. 26 ¶¶ 94–95, such is unlike the notice of warnings from the regulator and substantial defects giving rise to same in Todd and fails to support a claim of fraud. Cf. Whitehead v. Inotek Pharm. Corp., No. 17-CV-10025-LTS, 2018 WL 4732774, at *4–5 (D. Mass. June 27, 2018) (rejecting argument that scienter could be inferred from defendants' knowledge of "certain negative outcomes in earlier trials" because it was "certainly plausible" that

optimism regarding future of drug remained defendants' "sincere view" and the plaintiff "alleged no evidence that [made] the opposite inference as or more compelling").

For all these reasons, Plaintiff's argument that Defendants possessed the requisite scienter based upon their intentional or reckless disregard for the comparability plan's deficiency fails.

b) Motive and Opportunity

A "plaintiff may combine various facts and circumstances indicating fraudulent intent to show a strong inference of scienter," including allegations "that the defendants had the motive ('concrete benefits that could be realized by . . . the false statements and wrongful nondisclosures') and opportunity ('the means and likely prospect of achieving concrete benefits by the means alleged') to commit the fraud." Aldridge, 284 F.3d at 82 (alteration in original) (quoting Novak v. Kasaks, 216 F.3d 300, 307 (2d Cir. 2000)) (further citation omitted). "[E]vidence of motive and opportunity may establish a strong inference of scienter" but requires "additional factual support." See id.

According to Plaintiff, Defendants misled investors "to raise sorely needed capital" by selling the Company's stock at artificially inflated prices. D. 34 at 28. Bluebird previously reported that it "has incurred losses since inception and to date has financed its operations primarily through the sale of shares of the Company's stock" and "expects to continue to generate operating losses and negative operating cash flows for the next few years and will need additional funding to support its planned operating activities through profitability." D. 26 ¶ 71. Plaintiff, therefore, argues that bluebird's May 2020 public offering, which raised aggregate net proceeds of $541.5 million, was "critical for the Company" and provided a motive to commit fraud. D. 34 at 28; see D. 26 ¶¶ 73–75.

Even assuming Plaintiff adequately pleads motive, Plaintiff still has not alleged sufficient

facts to establish a strong inference of scienter. Plaintiff cites Meyer v. Biopure Corp., 221 F. Supp. 2d 195, 209 (D. Mass. 2002) for the proposition that specific allegations as to a defendant company's need to raise capital may establish motive. See D. 34 at 28. Meyer, however, also noted that "evidence of motive and opportunity is not enough to create a blanket presumption that any omissions were made with intent to defraud; there must be some other indication of knowledge or a high degree of recklessness with respect to each act or omission," which the plaintiff there failed to allege. Meyer, 221 F. Supp. 2d at 209 (citing Aldridge, 284 F.3d 72, 82; Geffon v. Micrion Corp., 249 F.3d 29, 36 (1st Cir. 2001) (asserting that "a plaintiff must allege some additional misconduct from which a jury can draw a reasonable inference of intentional deception")); see Lenartz v. Am. Superconductor Corp., 879 F. Supp. 2d 167, 185–86 (D. Mass. 2012) (noting that the "mere statement" that a company obtained funding tied to an allegedly inflated stock price is "insufficient to create a strong inference either of an intent to deceive or of recklessness" (citation omitted)).

As concluded above, Plaintiff fails to allege facts indicating that Defendants intentionally or recklessly disregarded the comparability plan's deficiency in announcing the accelerated approval timeline. The amended complaint, moreover, contains no allegations of insider trading, a divergence between internal reports and public statements, bribery by top company officials, significant GAAP violations or any other "factors that the First Circuit has found to support an inference of scienter." See Angelos v. Tokai Pharm., Inc., 494 F. Supp. 3d 39, 57 (D. Mass. 2020). Accordingly, Plaintiff's allegations of Defendants' motive and opportunity fail to establish a strong inference scienter absent additional allegations of intentional or reckless misconduct.

c) Core Operations Theory

Plaintiff further contends that a "core operations" theory supports a strong inference of

scienter. D. 34 at 32–33. Under such a theory, "facts critical to a business's core operations . . . are so apparent that their knowledge may be attributed to the company and its officers." Crowell v. Ionics, Inc., 343 F. Supp. 2d 1, 19 (D. Mass. 2004) (alteration and citation omitted). Courts, however, "have been hesitant to apply significant weight to 'core operations' allegations without other significant evidence of a defendant's intent or recklessness, or a 'plus factor.'" In re Biogen Inc. Sec. Litig., 193 F. Supp. 3d 5, 51 (D. Mass. 2016), aff'd, 857 F.3d 34 (1st Cir. 2017) (quoting In re A123 Sys., Inc. Sec. Litig., 930 F. Supp. 2d 278, 285 (D. Mass. 2013)). "As a general matter, corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter—at least absent some additional allegation of specific information conveyed to management and related to the fraud or other allegations supporting scienter." Metzler Asset Mgmt., 928 F.3d at 165 (quoting S. Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 784–85 (9th Cir. 2008)) (internal quotation marks and further citation omitted).

Plaintiff argues that the fact that "LentiGlobin stood to be by far bluebird's most lucrative development, and its most attractive offering for shareholders," supports "a strong inference that Leschly and Baird were directly involved in, or at least knowledgeable of," the comparability plan. D. 34 at 33; see D. 26 ¶ 34 (alleging that LentiGlobin could be a "blockbuster therapy" for bluebird), ¶¶ 41–42 (alleging statements by Baird describing the suspension-based manufacturing process as "critical"), ¶ 44 (alleging statements by Leschly describing same).

Even assuming Leschly and Baird's knowledge of the suspension process as being critical to LentiGlobin's value proposition, such is insufficient to support that any one aspect of the comparability analysis plan was so "apparent" that knowledge of such aspect "may be attributed to the company and its officers." See Crowell, 343 F. Supp. 2d at 19; see also Venkataraman v. Kandi Techs. Grp., Inc., No. 20 CIV. 8082 (LGS), 2021 WL 4952260, at *4 (S.D.N.Y. Oct. 25,

2021) (stating that management "would not necessarily have known (as part of core operations of the business) the test for what constitutes a related party under the applicable accounting rules"). The Court cannot impute to Leschly and Baird knowledge of the comparability plan's specific deficiency "absent some additional allegation of specific information conveyed to management and related to the fraud or other allegations supporting scienter." See Metzler Asset Mgmt., 928 F.3d at 165 (citation and internal quotation marks omitted). Plaintiff has failed to allege particularized facts as to such plus factor supporting that Leschly or Baird knew or should have known that the FDA would request further comparability analysis, delaying LentiGlobin's approval timeline. Thus, Plaintiff's core operations theory fails to support a strong inference of scienter.[2]

d) Weighing Opposing Inferences

Considering the complaint as a whole, including "plausible opposing inferences," Tellabs, 551 U.S. at 323, the strongest inferences favor Defendants. Plaintiff's theory of scienter relies upon the unsupported claim that the FDA was "highly likely to reject bluebird's plan" because it

[2] Following the motion hearing, Plaintiff filed a notice of supplemental authority arguing that Construction Industry & Laborers Joint Pension Trust v. Carbonite, Inc., 22 F. 4th 1 (1st Cir. 2021), supports a strong inference of scienter here. D. 39. That decision, however, compels no different outcome. Construction Industry concluded that the company's view of the product at issue as "important"—evidenced by "two specific plugs from top management"—supported a strong inference of scienter. Id. at 9. But such inference of scienter was bolstered by other factors, including that "it does not require a PhD to know that a product cannot be 'super strong' if it has never once done what it is supposed to do" and internal reports stating that the product was not ready for market. Id. at 9-10 (noting that "it is not enough to say that senior management would have paid some attention to the product that they were raving about; the complaint must allege particular facts strongly suggesting that that attention exposed them to information that either rendered their public statements false or necessarily invited further investigation"). Here, Plaintiff alleges no such "red flag[s]." See id. at 10.

The Court ALLOWS *nunc pro tunc* Defendants' motion for leave to file a response to Plaintiff's notice of supplemental authority, D. 41, and also has considered that response, D. 41-1, in resolving the motion to dismiss.

"could not show comparable potency at all." D. 34 at 26. As concluded above, however, the amended complaint fails to allege sufficient facts to support the claim that Defendants knew or recklessly did not know that the plan would be rejected by the FDA for this deficiency. The competing, nonculpable inference from the facts alleged—that bluebird designed a comparability study it thought would be sufficient given that the FDA has not prescribed a specific method for showing comparability and that bluebird used healthy donor cells to demonstrate comparability in the past—is more compelling than Plaintiff's proposed inference. Further, this nonculpable inference is particularly strong given Defendants' repeated disclaimers about the possibility that the FDA would require additional studies or data collection, see Corban, 868 F.3d at 38–39, as well as bluebird's prompt disclosure of the agency's feedback regarding the need for further comparability analysis, see Fire & Police Pension Ass'n of Colo., 778 F.3d at 243; Genzyme, 754 F.3d at 42. Accordingly, Plaintiff fails to allege facts supporting a strong inference of scienter.

2. Actionable Misstatement or Omission

Defendants also argue that the amended complaint fails to allege an actionable misstatement or omission on two grounds: (1) Plaintiff has not shown that Defendants made a materially false or misleading statement or omission, D. 31 at 29–31, and (2) most of the alleged misstatements are further immunized by the PSLRA's "safe harbor" provisions, id. at 31–34.

a) Materially False or Misleading

"To establish a material misrepresentation or omission, [a plaintiff] must show 'that defendants made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading.'" Ganem, 845 F.3d at 454 (quoting Geffon, 249 F.3d at 34). "Information is material if a reasonable investor would have viewed it as having significantly altered the total mix of information made available." Miss. Pub. Emps. Ret. Sys. v.

Boston Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008) (citations and internal quotation marks omitted). The allegations in the complaint also must meet the standard under Fed. R. Civ. P. 9(b) and the "heightened pleading requirements" imposed by the PSLRA. Id. Although "[i]n most circumstances, disputes over the materiality of allegedly false or misleading statements must be reserved for the trier of fact," Shaw, 82 F.3d at 1217, dismissal is appropriate where "[t]he Court finds that, even taking all facts alleged as true, most of the challenged statements were not material misrepresentations or omissions," Wasson v. LogMeIn, Inc., No. 18-cv-12330-ADB, 2020 WL 5946813, at *17 (D. Mass. Oct. 7, 2020). The Court also must dismiss a securities fraud complaint "predicated on the concealment of information if that information was, in fact, disclosed." In re First Marblehead Corp. Sec. Litig., 639 F. Supp. 2d 145, 155 (D. Mass. 2009) (citations omitted).

None of Defendants' alleged statements was materially false or misleading. Plaintiff argues that Defendants misled investors by omitting that their comparability analysis plan entailed using only healthy cells and could not demonstrate comparable potency. D. 34 at 34. As Defendants contend, D. 31 at 29, however, and this Court concludes above, Plaintiff's argument amounts to a claim of "fraud by hindsight." ACA Fin., 512 F.3d at 62. Plaintiff alleges no contemporaneous facts demonstrating that bluebird knew or should have known that the FDA would require further comparability analysis based upon the Company's use of healthy patient cells. Further, bluebird's press releases, periodic reports and other statements cautioned that the timing of its BLA submission might be delayed if the FDA required additional analysis. See, e.g., D. 26 ¶¶ 55, 65, 82; D. 32-10 at 7; D. 32-14 at 7. Because the facts alleged indicate that Defendants disclosed to investors the relevant risk as understood at the time of disclosure, Plaintiff cannot establish that Defendants' statements were materially false or misleading. See First Marblehead Corp., 639 F. Supp. 2d at 155.

b) Safe Harbor

The PSLRA's "safe harbor" provisions further immunize Defendants' statements. These provisions "sharply limit liability of companies and their management for certain 'forward-looking statements,' . . . when such statements are accompanied by appropriate cautionary language." In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d 68, 71 n.3 (1st Cir. 2012) (citing 15 U.S.C. § 78u-5). Forward-looking statements include statements "of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer." Meyer, 221 F. Supp. 2d at 203 (quoting 15 U.S.C. § 78u-5(i)(1)(B)). "[T]o be meaningful, cautionary statements must be 'substantive and tailored to the specific future projections, estimates or opinions . . . which plaintiffs challenge.'" Isham v. Perini Corp., 665 F. Supp. 2d 28, 39 (D. Mass. 2009) (quoting Smith & Wesson, 604 F. Supp. 2d at 340). Further, "if a forward-looking statement is accompanied by meaningful cautionary language the defendant's state of mind is wholly irrelevant." Leavitt v. Alnylam Pharms., Inc., 451 F. Supp. 3d 176, 186 (D. Mass. 2020) (citing In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 212 (1st Cir. 2005)).

Here, Defendants' alleged statements discussing potential FDA approval constituted forward-looking statements. See, e.g., D. 26 ¶ 55 (stating that bluebird was "planning to seek an accelerated approval" and "expect[ed] to submit" its BLA in late 2021); Leavitt, 451 F. Supp. 3d at 186 (referring to challenged statements, "which discussed potential FDA approval," as "typical forward-looking statements" because they "anticipated a hoped-for future event, FDA approval" and, therefore, "fit squarely within the [PSLRA's] safe harbor"); In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 535 (S.D.N.Y. 2015), aff'd sub nom. Tongue v. Sanofi, 816 F.3d 199 (2d Cir. 2016) (noting that statements about FDA approval "are classically forward-looking—they address

what defendants expected to occur in the future"). Moreover, these statements were accompanied by meaningful cautionary language. See, e.g., D. 32-14 at 7–8; Harrington, 2017 WL 1946305, at *9 (concluding that "statements identify[ing] specific risk factors including . . . the possibility of the FDA not approving the drug . . . is precisely what the law requires").

Plaintiff argues that, "[w]hile Defendants accurately disclosed the nature of the risk—that the FDA may not accept its plan, which may delay the LentiGlobin BLA submission"—Defendants failed meaningfully to "disclose the high probability of the risk materializing because they misleadingly omitted that bluebird's comparability analysis plan could not show comparable potency." D. 34 at 37. Plaintiff cites Hill, in which the First Circuit stated that "[t]he omission of a known risk, its probability of materialization, and its anticipated magnitude, are usually material to any disclosure discussing the prospective result from a future course of action." Hill, 638 F.3d at 57 (quoting Lormand v. US Unwired, Inc., 565 F.3d 228, 248 (5th Cir. 2009)). Hill, however, also noted that, "[t]o the extent that the plaintiff's complaint is that the precise degree of risk was not stated, that failure is not sufficient to have rendered the statements misleading." Id. at 60 (stating that "where the level of risk is unknown and the existence of a risk is disclosed, we shall hesitate to conclude that disclosure is misleading merely because it did not state that the risk was 'serious'").

Here, Defendants disclosed to investors the risk known at the time of the relevant SEC filings, press releases and analyst conference calls. Plaintiff has not alleged sufficient facts to support that a more precise degree of risk was, or should have been, known to Defendants prior to the Company receiving the FDA's feedback on its comparability analysis plan. Cf. Hill, 638 F.3d at 60. Accordingly, Defendants' forward-looking statements, accompanied by meaningful cautionary language, fall within the PSLRA's safe harbor.

For all these reasons, the amended complaint also fails to allege an actionable misstatement or omission.

3. Loss Causation

The PSLRA provides that "the plaintiff shall have the burden of proving that the act or omission of the defendant . . . caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4). Plaintiffs may establish loss causation by showing that a corrective disclosure was "a 'substantial' cause of their losses." See Mass. Ret. Sys. v. CVS Caremark Corp., 716 F.3d 229, 237–39 (1st Cir. 2013) (quoting FindWhat Inv. Grp. v. FindWhat.com, 658 F.3d 1282, 1309 (11th Cir. 2011)). A "corrective disclosure" occurs when a company "release[s] . . . information that reveals to the market the pertinent truth that was previously concealed or obscured by the company's fraud." Id. at 237 (quoting FindWhat Inv. Grp., 658 F.3d at 1311–12); see Coyne v. Metabolix, Inc., 943 F. Supp. 2d 259, 273 (D. Mass. 2013) (explaining that "the announcement must connect the current, present, negative information to the earlier false or misleading statement" (emphasis omitted)).

Plaintiff cannot show loss causation because he has not alleged any corrective disclosure. Even assuming Plaintiff can connect bluebird's November 4, 2020 announcement that the Company planned to delay its BLA submission to the following day's stock drop, D. 26 ¶¶ 103, 112, Plaintiff has not adequately alleged that Defendants "reveal[ed] to the market [a] pertinent truth that was previously concealed or obscured by the company's fraud." See Mass. Ret. Sys, 716 F.3d at 237; In re Wayfair, Inc. Sec. Litig., 471 F. Supp. 3d 332, 350 (D. Mass. 2020) (concluding that a press release "was not a 'corrective disclosure' because [p]laintiffs have not adequately pleaded scienter, so there is no adequate allegation that the defendants 'concealed' or 'obscured' any information from the public"). The Company's announcement that it had

"adjust[ed] the timing of the BLA submission back to the more conservative initial target timing of late 2022," D. 26 ¶ 104, did not correct some untruth about the previously projected timeline but rather updated the Company's projection based upon new information.

Plaintiff's "zone of risk" theory, D. 34 at 38, fails for similar reasons. Under this theory, Plaintiff contends that his losses were caused by the materialization of a concealed risk—that is, the high probability of the risk that the FDA would require that bluebird conduct further comparability analysis to show comparable potency under the suspension process. Id. at 38–39; see Lentell v. Merrill Lynch & Co., 396 F.3d 161, 173 (2d Cir. 2005) (stating that "a misstatement or omission is the 'proximate cause' of an investment loss if the risk that caused the loss was within the zone of risk concealed by the misrepresentations and omissions alleged"). As noted above, however, Defendants did not conceal the risk that the FDA could require additional comparability analysis but disclosed that risk several times throughout the Class Period.

Accordingly, Plaintiff also fails to allege sufficient facts supporting loss causation.

B. Section 20(a) Claim (Count II)

Plaintiff claims that Leschly and Baird are individually liable under Section 20(a) of the Exchange Act based upon their positions of control and authority within the Company. D. 26 ¶¶ 135–40; D. 34 at 41–42. Section 20(a) imposes joint and several liability on "[e]very person who, directly or indirectly, controls any person liable" for a securities fraud violation. 15 U.S.C. § 78t(a). Thus, to state a claim under Section 20(a), a plaintiff must allege a primary violation of the Exchange Act. ACA Fin., 512 F.3d at 67 (stating that "[t]he plain terms of [S]ection 20(a) indicate that it only creates liability derivative of an underlying securities violation"). Because Plaintiff fails to plead a primary securities law violation, Plaintiff's claim under Section 20(a) against Leschly and Baird also fails.

C. Leave to Amend

Plaintiff requests that, if this Court determines that the amended complaint fails adequately to state a claim for relief, Plaintiff be granted leave further to amend the complaint. D. 34 at 42. Plaintiff observes that "the PSLRA does not alter the liberal amendment policy" of Rule 15(a). Id. (quoting ACA Fin., 512 F.3d at 57). Such, however, does not justify granting Plaintiff's request for at least one reason, namely futility. See ACA Fin., 512 F.3d at 56 (noting that grounds for denial of motion to amend include "futility of amendment"); Hatch v. Dep't for Child., Youth & Their Fams., 274 F.3d 12, 19 (1st Cir. 2001) (stating that "[w]here an amendment would be futile or would serve no legitimate purpose, the district court should not needlessly prolong matters" (quoting Correa-Martinez v. Arrillaga-Belendez, 903 F.2d 49, 59 (1st Cir. 1990)). Because Plaintiff does not suggest "that new information has been discovered such that amendment would not be futile," see Sousa v. Sonus Networks, Inc., 261 F. Supp. 3d 112, 121 (D. Mass. 2017), the request to amend is denied.

VI. Conclusion

For the foregoing reasons, the Court ALLOWS Defendants' motion to dismiss, D. 30.

So Ordered.

/s/ Denise J. Casper
United States District Judge