UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE BIOMARIN PHARMACEUTICAL INC. SECURITIES LITIGATION

Case No. 3:20-cv-06719-WHO

ORDER ON MOTION TO DISMISS

Re: Dkt. No. 59

The plaintiffs in this proposed securities class action allege that defendant BioMarin Pharmaceutical Inc. ("BioMarin") and several of its executives misled investors about the progress of a new hemophilia therapy it was developing. According to them, the defendants intentionally misrepresented their interactions with the Food and Drug Administration ("FDA") about the drug's approval process. They allege that BioMarin represented that it was working "closely" and "collaboratively" with the FDA to achieve accelerated approval when, in reality, it had "no dialogue" with the FDA for the period in question. And the plaintiffs assert that BioMarin misled investors by failing to disclose warning signs from the FDA—including cancelling an important inspection of BioMarin's manufacturing facility—that approval would be delayed or denied while claiming to still be "on track." When the FDA ultimately denied accelerated approval of the therapy, BioMarin's share price dropped substantially and, the plaintiffs allege, market participants and analysts were "shocked" due to the defendants' previous statements.

The defendants move to dismiss the case. The motion is denied. The plaintiffs have adequately pleaded that the alleged representations and omissions were false or misleading. They are not entitled to protection under the Private Securities Litigation Reform Act's ("PSLRA") safe harbor. And the defendants are plausibly alleged to have acted with scienter.

BACKGROUND

I. FACTUAL BACKGROUND

A. BioMarin and Valrox/Roctavian

BioMarin is a pharmaceutical company incorporated in Delaware and based in California. Amended Complaint ("Compl.") [Dkt. No. 54] ¶ 25. Defendant Jean-Jacques Bienaimé has been its CEO since 2005 and defendant Henry Fuchs was its "President of Worldwide Research and Development" during the Class Period of March 3 to August 18, 2020. *Id.* ¶¶ 26–27.

"Valrox" or "Roctavian" was a drug that BioMarin was developing to treat hemophilia A, a disorder that prevents blood from clotting properly. *Id.* ¶¶ 32–33. Valrox is a "gene therapy." *Id.* The disease is currently "treated by intravenously administering a clotting factor concentrate, called 'replacement therapy,' to patients as many as two or three times a week." *Id.* ¶ 38. That is "cumbersome" for patients and can cost "upwards of $400,000 annually." *Id.* But because valrox is a gene therapy, it would require "only a single, one-time infusion." *Id.* ¶ 39. Larger companies like Pfizer and Roche were also developing similar hemophilia A gene therapies. *Id.* ¶ 40. At least some analyses projected that valrox would double BioMarin's revenue and create $1.5 billion in sales each year. *Id.* ¶ 41. Gene therapies, however, typically cannot be given multiple times. *Id.* ¶ 44. Accordingly, valrox would have to "provide[] a durable and long-lasting reduction in bleeding events." *Id.*

According to the plaintiffs, it is "costly and difficult to manufacture" gene therapies and specialized physical facilities are required to do so. *Id.* ¶ 35. Beginning in 2016, BioMarin began developing its own manufacturing facility for valrox in Novato, California (the "Novato Facility").

B. Trial Data

In 2015, BioMarin began Phase I and II trials for valrox. *Id.* ¶ 47. Phase I trials are among a small group and Phase II are among a larger one. *Id.* Those trials "received formulations of valrox manufactured in small batches by a third-party laboratory specifically for use in the Phase I/II trial," not formulations manufactured by BioMarin itself. *Id.* Those trials "demonstrated encouraging efficacy." *Id.* ¶ 48.

In 2017, BioMarin began a Phase III trial with an even larger number of people. *Id.* ¶ 47.

This time, it used "valrox infusions manufactured by BioMarin at its new Novato Facility using the same manufacturing processes and controls that BioMarin would use to mass produce the valrox sold to patients if the treatment was approved." *Id.* Those results were less encouraging. The levels of the clotting agent in the blood had declined year over year in the first two phases. *Id.* But in Phase III—the phase with BioMarin's own drug—the clotting agent levels were "half" what they were in the Phase I and II. *Id.* ¶ 50. Nearly one in five Phase III patients also did not respond to the therapy. *Id.*

C. Investor Reaction

The Complaint alleges that "[i]nvestors were particularly enthusiastic about valrox because it would also give BioMarin the 'first-mover advantage' for gene therapy treatment for hemophilia." *Id.* ¶ 40. According to the plaintiffs, that meant that "accelerated approval" would be especially important. *Id.* ¶ 43. The results of the Phase III trial, however, created "concern[]" among investors. *Id.* ¶ 53.

D. Interactions with the FDA

BioMarin submitted a license application to the FDA to market valrox in December 2019. *Id.* ¶ 61. In February 2020, the FDA accepted it for review. *Id.* Under the Prescription Drug User Fee Act ("PDUFA"), the FDA has ten months to perform the review of a normal application and six months for accelerated applications like valrox. *Id.* The FDA set a deadline of August 21, 2020, to rule on the application—referred to as a "PDUFA date." *Id.* The Complaint alleges that PDUFA dates are "a focus of intense interest for analysts, investors, and any company that makes a submission to the FDA." *Id.* ¶ 62.

According to the plaintiffs, BioMarin repeatedly over-represented or misrepresented its interactions with the FDA to the public and investors. The complete statements appear below. As an example (of a quote not in the Class Period), in June 2019, at an investor conference, Fuchs said "we've had quite a lot of encounters with both the Food and Drug Administration here in the United States and the European Medicines Agency in Europe because in the United States, we have Breakthrough Therapy designation . . . . And under those interactions, we've had fairly clear dialogue with them about requirements for registration." *Id.* ¶ 66. The defendants also said they

were "working very closely" and "quite collaborative[ly]" with the FDA. *Id.* ¶ 78.

Despite the defendants' statements about their level of interaction with the FDA, the Complaint alleges that "Defendants have now admitted the Company had had 'no dialogue whatsoever' with the agency from mid-April 2020 to the end of the Class Period, apart from [a] deeply worrying June meeting." *Id.* In that June 2020 meeting, the FDA flagged the discrepancy in the trial data between Phases I and II and Phase III to BioMarin. *Id.* ¶ 78. The plaintiffs allege that, normally, the FDA has "numerous" communications with applicants during this period. *Id.* ¶ 84.

E. Facility Inspection

As noted, the physical facility at which the therapy was manufactured is especially important. The FDA has to carry out a "preapproval inspection" of the facility. *Id.* ¶ 74. The defendants allegedly told investors that the inspection of the Novato Facility would occur in the "second quarter of 2020." *Id.* ¶ 77. The FDA, however, allegedly told the defendants "at the start of the Class Period" that the inspection would be delayed past that date. *Id.* ¶ 79. According to the plaintiffs, this raised a serious risk of delay in the FDA approving the drug. *Id.* (This delay in the inspection is alleged to have occurred prior to "widespread" pandemic-related lockdowns. *Id.* ¶ 80.). The plaintiffs allege that a confidential witness—who is discussed in more detail below—reported that the inspection delays were "generat[ing] anxiety" inside of BioMarin and that he or she was surprised when the defendants told investors in August 2020 that valrox was on track. *Id.* ¶ 81.

F. PDUFA Deadline

The plaintiffs allege that analysts "eagerly awaited" news of the FDA's approval. *Id.* ¶ 112. On August 19, 2020, BioMarin announced that the FDA had sent a "Complete Response Letter" ("CRL") that declined to approve valrox. *Id.* ¶ 113. BioMarin faulted the difference in data between the Phase I/II and Phase III trials. *Id.* ¶ 114. BioMarin's stock price fell $35.28% on the news. *Id.* The plaintiffs assert that analysts were "shocked" and "surprised." *Id.* ¶ 115. Some even highlighted BioMarin' "positive commentary" about the FDA process. *Id.*

G. Allegedly Misleading Statements

The Complaint includes the following allegedly misleading statements (collectively, the "Challenged Statements") made by various defendants, a few of which were discussed above:[1]

- On March 3, 2020, Bienaimé said, "So this is pretty dramatic data, and this is why we believe the FDA gave us Accelerated Review and accepted the filing. So there it is—so we anticipate launching in the second half of this year." Compl. ¶ 118.

- On March 3, 2020, Bienaimé said, in response to an analyst's question about disagreements with the FDA, that "we've had a lot of interaction with the FDA over the past few years" and he was "not aware of any substantial discussion going on the CMC front. There are some discussions but we have been cooperating very closely with the FDA over the past few years. Actually, even when we designed the manufacturing facility, we interacted with them. We've been interacting with them very closely on the development of in-process assay, released assay. So we believe we have a very good relationship with them." *Id.* ¶ 119.

- On April 29, 2020, Fuchs said, in response to an analyst's question about regulatory delays, "The confidence from the FDA is that we're tracking to our milestones. And in some cases, they are accelerating their work. So, having been through a bunch of these [approvals] recently, all the signs are pointing favorably." *Id.* ¶ 122.

- On May 14, 2020, Bienaimé said, in response to an analyst's question about manufacturing and the inspection, "the inspection by the FDA is scheduled significantly before the PDUFA date. So, we are on track in this respect. I would say what makes us confident in—well the European approval is already a good one. I mean, manufacturing approval is already a good box to check. And second was, based on all our interactions we've had over the past three years or so, interact[ing] with the FDA as we were building the plant, budgeting the plant, makes us feel already confident that we're going to be in a good position with the FDA inspection." *Id.* ¶ 125.

- On May 19, 2020, Fuchs said "Our PDUFA action date of August 21 is holding firm. In spite of the pandemic, everything is going quite well, in review with the FDA." *Id.* ¶ 127.

- On May 31, 2020, BioMarin released a statement that said, "The inspection [of the Novato Facility] by FDA is expected to be completed during the second quarter, which would allow for potential licensure of the facility in the U.S. consistent with the August 21st PDUFA date." *Id.* ¶ 130.

[1] In some cases, BioMarin requests judicial notice of a more complete version of the statement and provides a supporting exhibit. Its request is GRANTED because the full statements are incorporated by reference into the Complaint. *See Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005). The quotations from the Complaint are supplemented with full quotations from Dkt. No. 59-2 and its supporting exhibits.

- On June 4, 2020, Fuchs said, in response to an analyst's question about the inspection and whether a date had been set, "Yeah. We have a schedule and, in fact, the agency has been quite collaborative. Inspections are part document review and part inspection onsite. So they accommodated a suggestion that we made, which was to start the document review already and so we shipped them a whole bunch of documents and they have begun their reviews. And I think that will make their onsite inspection just that much more efficient. Now, we have to pay attention to travel and stuff like that, and our working belief and [the] agency has signaled strongly that they intend to maintain their PDUFA action date." *Id.* ¶ 132.

- On June 9, 2020, Fuchs said, in response to an analyst's question about the PDUFA date, "Well, we're in the middle of a mesh with the FDA any given day it's like back and forth. What I would say is that in regards to major metrics, the agency is actually ahead of their PDUFA mandated regulatory metrics in terms of timeline. So, really what remains are inspections and completion of reviews. They have all the information on file that they need to complete their reviews. And so, we're working very closely with them to keep things on track. Obviously, they're very busy on their end. It's not like they didn't have anything to do before this all happened. So, we continue the collaborations." *Id.* ¶ 135.

- On June 24, 2020, Fuchs said, in response to an analyst question about whether BioMarin expected to have an inspection "in the first half of this year," that "Yeah, that's a good question to illuminate the thing that I said at the beginning, which is now that we're under two months away from PDUFA, I think our answer to these types of questions is going to be we're on track for our PDUFA [date of] 8/21/20. You know, at any given day during a regulatory review. There's a lot of stuff that goes on and it could be really difficult to interpret and that gets magnified as you get closer to the finish line. So I think the next big announcement from BioMarin is going to be about the action date." *Id.* ¶ 137.

- On June 24, 2020, Fuchs said, "We're so pleased with the clinical benefit demonstrated with Roctavian that it continues to be durable at the four years and counting. And on our call last week, our study investigator shared stories that gave insights into how dramatically their patients' lives have changed since being treated with Roctavian with many feeling like they no longer have hemophilia. And in fact it's quite transforming for the clinicians who are now better appreciating the burden of hemophilia because of the contrast between a fully-treated hemophilia patient and a post-gene transfer hemophilia patient. It's truly inspirational and a big reason why we're so passionate about the work that we're doing. So we continue to anticipate approval of Roctavian in the second half of this year based on the August 21 PDUFA action date." *Id.* ¶ 138.

- On June 24, 2020, Fuchs said, "I think the hemostatic efficacy even at low factor level statement under—and some level doesn't do enough justice to the profundity of the clinical benefit that that patient—those patients who are even in that range still experiencing profound benefits many years later. And those are our lowest patients. And so I think that's a pretty comforting thing is to think about the fact that the

expectations for a clinical benefit really can be fairly large." *Id.* ¶ 139.

- On August 4, 2020, Bienaimé said, "With the outcome of the Priority Review of our [approval process] anticipated August 21, 2020, our commercial team is preparing to launch what we believe is the most innovative product yet for people with bleeding disorders." *Id.* ¶ 142.

- On August 13, 2020, Fuchs said, in response to an analyst's question about gene therapy products, "I think Roctavian is generation 1 gene therapy. So Spark and Sangamo are generation 0.6 and 0.3, maybe even higher degree of discount just because they're so far behind." *Id.* ¶ 144.

II. PROCEDURAL BACKGROUND

This suit was filed in September 2020. Dkt. No. 1. I appointed Arbejdsmarkedets Tillaegspension ("ATP") lead plaintiff under the Private Securities Litigation Reform Act ("PSLRA") in December 2020. Dkt. No. 40. BioMarin moved to dismiss the amended complaint in April 2021 and the parties stipulated to extending the briefing schedule. Dkt. No. 67. I held a hearing on the motion on December 3, 2021.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a district court must dismiss a complaint if it fails to state a claim upon which relief can be granted. To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must allege "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). A claim is facially plausible when the plaintiff pleads facts that "allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). There must be "more than a sheer possibility that a defendant has acted unlawfully." *Id.* While courts do not require "heightened fact pleading of specifics," a plaintiff must allege facts sufficient to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555, 570.

In deciding whether the plaintiff has stated a claim upon which relief can be granted, the court accepts the plaintiff's allegations as true and draws all reasonable inferences in favor of the plaintiff. *Usher v. City of Los Angeles*, 828 F.2d 556, 561 (9th Cir. 1987). However, the court is not required to accept as true "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir.

2008).

Under the PSLRA, securities fraud claims must "plead with particularity both falsity and scienter." *Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001). This is the same standard under Federal Rule of Civil Procedure 9(b). With respect to falsity, "the complaint must specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u–4(b)(1)(B). With respect to scienter, "the complaint shall, with respect to each act or omission alleged ... 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). "[F]alsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, and the two requirements may be combined into a unitary inquiry under the PSLRA." *In re Daou Sys., Inc.*, 411 F.3d 1006, 1015 (9th Cir. 2005) (citation and internal quotation marks omitted).

"To adequately demonstrate that the defendant acted with the required state of mind, a complaint must allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009) (quotation marks and citation omitted). "Facts showing mere recklessness or a motive to commit fraud and opportunity to do so provide some reasonable inference of intent, but are not sufficient to establish a strong inference of deliberate recklessness." *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012) (citation omitted). Accordingly, "a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). "[A]n 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." *Id.* at 314. "The inference that the defendant acted with scienter need not be irrefutable, i.e., of the 'smoking-gun' genre, or even the 'most plausible of competing inferences. *Id.* at 324. "The inquiry . . . is 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." *Id.* at 322–23.

If the court dismisses the complaint, it "should grant leave to amend even if no request to

amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000). In making this determination, the court should consider factors such as "the presence or absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party and futility of the proposed amendment." *Moore v. Kayport Package Express*, 885 F.2d 531, 538 (9th Cir. 1989).

DISCUSSION

To plead a violation of the securities laws, a plaintiff must adequately allege: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1206 (9th Cir. 2016) (quoting *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804 (2011)). The plaintiffs allege that the defendants misrepresented the truth by insisting they were in close communication with the FDA when there was no communication, not revealing the FDA's concerns about the Phase III data, and not revealing that the Novato Facility inspection might be delayed. They bring their claims under Sections 10(b) and 20 of the Securities Exchange Act and the former's implementing Rule 10b-5.

BioMarin has three broad arguments for dismissal: (1) the Challenged Statements are protected by the PSLRA's safe harbor; (2) the Challenged Statements are not actionable misrepresentations; and (3) the plaintiffs have not adequately alleged that the defendants acted with scienter. I will discuss each in turn.

I. SAFE HARBOR

First, BioMarin argues that eleven of the statements at issue are protected under the PSLRA's safe harbor. *See* Motion to Dismiss ("Mot.") [Dkt. No. 59] 9–11. They are not.

The PSLRA's safe-harbor provision exempts certain "forward-looking" statements from liability. *See* 15 U.S.C. § 78u-5(c). "The PSLRA's safe harbor is designed to protect companies and their officials from suit when optimistic projections of growth in revenues and earnings are not borne out by events." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1142 (9th Cir. 2017).

To qualify for protection, the statements must be either: (1) "forward-looking statements that are identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement" or (2) forward-looking statements that were not "made with actual knowledge . . . that the statement was false or misleading." *Id.* §§ 78u-5(c)(1)(A)(i), (c)(1)(B).[2] I refer to the first statutory category as the cautionary-language prong and the second as the actual-knowledge prong. A forward-looking statement is:

> **(A)** a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
> **(B)** a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
> **(C)** a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;
> **(D)** any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C);
> **(E)** any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or
> **(F)** a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the [Securities and Exchange] Commission.

Id. § 78u-5(i)(1).

A. Cautionary Language

The Challenged Statements do not qualify under the cautionary-language prong. To determine whether "cautionary language" is adequate, courts ask whether the cautionary statements "precise[ly]" and "directly address" the alleged misrepresentations. *Provenz v. Miller*, 102 F.3d 1478, 1493 (9th Cir. 1996) (internal quotation marks and citation omitted). "Blanket warnings that securities involve a high degree of risk [are] insufficient to ward against a federal securities fraud claim." *Id.* (internal quotation marks and citation omitted). In other words, courts must examine the "mixture" of allegedly misleading and allegedly cautionary statements and

[2] The statute differentiates between statements made by "natural persons" and statements made by "executive officers" of business entities, but the actual-knowledge standard for both is the same. *See* 15 U.S.C. § 78u-5(C)(1)(A). Additionally, "immaterial" forward-looking statements are immunized under the statute, *see id*., but BioMarin does not rely on that provision here.

determine whether the cautionary language "discredit[s] the [allegedly misleading statement] so obviously that the risk of real deception drops to nil." *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1097 (1991).[3] Cautionary language is only adequate when it "identif[ies] important factors that could cause actual results to differ materially from those in the forward-looking statement." *Quality Sys.*, 865 F.3d at 1148 (quoting 15 U.S.C. § 78u-5(c)(1)(A)(i)).

The only cautionary language that BioMarin points to is in two forms that it filed with the SEC. *See* Mot. 10–11; Dkt. No. 59-9 (Form 10-K); Dkt. No. 59-20 (Form 10-Q).[4] Those forms were filed in February and August 2020. BioMarin relies on the following statements:

- That gene therapy is "a novel technology" that "presents additional development and treatment risks in relation to other, more traditional drug development programs"
- The FDA "has only approved a very small number of vector-based gene therapy products thus far"
- "[N]ew requirements and guidelines [the FDA] promulgate[s] may lengthen the regulatory review process, require us to perform additional or larger studies . . . [or] delay or prevent approval and commercialization"
- "COVID-19 could postpone necessary interactions with regulators" and "delay review or approval"

Mot. 10–11 (collecting citations).

None of these statements, nor all of them together, qualify as "meaningful cautionary language" for the specific allegedly misleading statements at issue. The Challenged Statements are focused on the past and future of the FDA approval process (in particular, on the good progress and good relationship between BioMarin and the FDA that its officers projected), on the inspection and on the trial data. *See supra* Background I.G. The warnings in the SEC forms,

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[3] *Provenz* addressed the "bespeaks caution" doctrine. As the Ninth Circuit has explained, the cautionary-language prong of the PSLRA's safe harbor "created a statutory version of this doctrine." *Emps. Teamsters Loc. Nos. 175 & 505 Pension Tr. Fund v. Clorox Co.*, 353 F.3d 1125, 1132 (9th Cir. 2004). And though *Virginia Bankshares* addressed reliance on and materiality of statements, the Ninth Circuit has explained that the bespeaks caution doctrine "is not new but a reformulation of two fundamental concepts in securities fraud law: reliance and materiality." *Provenz*, 102 F.3d at 1493.

[4] BioMarin's request for judicial notice of the SEC forms is GRANTED.

however, are not targeted or tailored to cautioning investors that *those* statements were qualified, incomplete, untrue, or otherwise misleading. Instead, they are geared toward more general concerns: the problems associated with novel gene therapies, new FDA rules, and COVID-19. They do not "precise[ly]" and "directly address" the alleged misrepresentations. *Provenz*, 102 F.3d at 1493. The statements about problems associated with new gene therapies are highly generalized. The statements about new FDA rules and COVID-19 are about specific risks that differ from the alleged misrepresentations in the Challenged Statements. None "discredit the [Challenged Statements] so obviously that the risk of real deception drops to nil." *Virginia Bankshares*, 501 U.S. at 1097.

B. Actual Knowledge

The statements also cannot qualify under the actual-knowledge prong; the Complaint adequately alleges that they were made with actual knowledge of their falsity. What happened between the FDA and BioMarin is, of course, within BioMarin's knowledge. The Complaint alleges that even though the FDA was uncommunicative and signaled problems, BioMarin's executives nonetheless made statements to the market the cut directly against this. For example, they talked about how they were "on track," had been "quite collaborative" with the FDA, were in a "mesh" with them, and they anticipated the inspection to occur on the date previously set. *See supra* Background I.G. And because it is plausible the defendants knew the truth was allegedly otherwise, the statements are adequately alleged to be knowingly false. *Cf. Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 708 (9th Cir. 2016) ("Arena's failure to inform the market about the risk of non-approval or delayed approval based on the FDA's 'concerns'" is sufficient to plausibly allege scienter.).[5]

[5] Because the statements do not qualify for safe harbor under either prong of the statute, there is no need to address the parties' debate over whether the statements are forward-looking. BioMarin's heavy reliance on the Ninth Circuit's recent decision in *Wochos v. Tesla, Inc.*, 985 F.3d 1180 (9th Cir. 2021), goes entirely to that issue. *Wochos* did not address the actual-knowledge prong. And its brief discussion of the cautionary-language prong is of no help to BioMarin because, there, "Plaintiffs did not directly challenge the adequacy of Tesla's cautionary statements below, and the same is true of Plaintiffs' briefs in this court." *Id.* at 1193.

II. ADEQUACY OF ALLEGED MISREPRESENTATIONS AND OMISSIONS

BioMarin argues that, for various reasons, none of the Challenged Statements include an adequate misrepresentation and that there is no actionable omission. *See* Mot. 11–20. I disagree.

When it comes to affirmative representations, "to properly allege falsity, a securities fraud complaint must now specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, state with particularity all facts on which that belief is formed." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 877 (9th Cir. 2012) (internal quotation marks, citation, and alteration omitted). When it comes to omissions, the "omission must be misleading; in other words it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). The securities laws "do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (internal quotation marks, citation, and alteration omitted). And "only if the adequacy of the disclosure or the materiality of the statement is so obvious that reasonable minds could not differ are these issues appropriately resolved as a matter of law." *Fecht v. Price Co.*, 70 F.3d 1078, 1081 (9th Cir. 1995) (internal quotation marks, citations, and alteration omitted).

Several cases address the context of FDA approval specifically. I begin with some that found statements about a defendant's interactions with the FDA actionable at the pleadings stage. In *Warshaw v. Xoma Corporation*, the defendant pharmaceutical company was developing a monoclonal antibody; the plaintiffs alleged that prompt FDA approval would have allowed it to capture the relevant market. 74 F.3d 955, 957 (9th Cir. 1996). An analyst had stated there was "no hope" for approving the antibody and, later, the FDA did in fact reject the Phase III study. *Id.* The plaintiffs alleged that the defendants then engaged in a campaign of misleading statements to combat this image. *Id.* They said, about FDA approval, that "everything is going fine," the market "misunderstood" the FDA's announcement, the Phase III rejection did not "in any way

imply a delay or setback in the agency's review," the FDA's rejection actually showed "positive forward progress," and that approval of the antibody was "imminent." *Id.* at 957–58. The FDA ultimately denied approval based on the disappointing Phase III data. *Id.* at 958. The plaintiffs claimed that, contrary to the defendants' representations, the defendants knew that there was "no chance" of expedited FDA approval. *Id.* The Ninth Circuit held that the defendants' statements were plausibly actionable under the securities laws. *Id.* at 959.

Likewise, in *Arena*, the pharmaceutical company was developing a drug, moved to Phase III human studies, and also began a study on rats to see if they developed cancer. 840 F.3d at 701–03. The rat study did indeed show tumor formation, but the FDA decided not to halt the human studies; instead, it "requested follow-up testing and bi-monthly updates" on the rat study. *Id.* at 701. The Ninth Circuit explained that the plaintiff "alleged that Defendants knew that the FDA's request for bi-monthly reports and follow-up studies was 'highly unusual' and 'out-of-process.'" *Id.* at 707. Based on this (and other allegations about the substance of the studies), the court found that the defendant's "failure to inform the market about the risk of non-approval or delayed approval based on the FDA's concerns about the Rat Study was an extreme departure from the standards of ordinary care that presented a danger of misleading buyers or sellers that was either known to [the defendant] or so obvious that [it] must have been aware of it." *Id.* at 708 (internal quotation marks, alterations, and citation omitted).[6]

In re MannKind Securities Actions involved a diabetes therapy whose success allegedly turned on whether the inhaler used to deliver it was easy to use. 835 F. Supp. 2d 797, 800 (C.D. Cal. 2011). In brief, the defendants needed to convince the FDA that a commercially desirable inhaler they were testing was "bioequivalent" to a previous version of the inhaler to get approval. *Id.* at 800–02. Among other types of statements, the defendants represented that a study they were performing had been "blessed" and "vetted" by the FDA even though it had not, that it was

[6] The issue before the court was whether scienter was adequately alleged. But its holding and rationale is relevant to the present analysis, largely because the court expressly analyzed the question under the rubric of whether the statements were misleading and the omissions triggered a duty to disclose and also because "falsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts." *In re Daou Sys., Inc.*, 411 F.3d 1006, 1015 (9th Cir. 2005).

designed based on FDA recommendations even though it was not, and that the FDA accepted all of the bioequivalence studies even though it had not. *Id.* at 802–03. The FDA refused to approve the therapy, including because of deficiencies in the study. *Id.* at 804. The court found statements like this actionable, explaining that "these representations are best read as a misstatement of the basic facts regarding the company's ongoing involvement with the FDA, and thus the likelihood of [the therapy's] approval." *Id.* at 809.

Conversely, some statements about defendants' interactions with the FDA have been found not to be actionable under the securities laws. *Tongue v. Sanofi* concerned the defendant's development of a multiple sclerosis treatment. 816 F.3d 199, 203 (2d Cir. 2016). The FDA repeatedly expressed concern to the defendant about its use of single-blind studies, rather than double-blind ones and told the defendant that those studies would not likely support approval. *Id.* But it later told the defendant that the study "may be adequate if the effect is large." *Id.* The defendant told investors that there was a 90% probability the drug would be approved by a certain date, it "anticipate[d] approval," it was "on track" to submit it, and that the studies were showing that the drug was safe and effective. *Id.* at 203–06. The FDA rejected the initial application. *Id.* at 206. (It ultimately approved a resubmission later than the deadlines the defendant had previously represented to investors. *Id.* at 207.)

The Second Circuit held that the statements about the timing of FDA approval were not misleading because "[t]here is no plausible allegation that the FDA's interim feedback conflicted with any reasonable interpretation of Defendants' statements about FDA approval." *Id.* at 211. In particular, "[t]hough the FDA had expressed concern about Defendants' testing methodology, it had also stated that any deficiency could be overcome if the results showed an 'extremely large effect.' The record reflects, and the parties do not dispute, that [the drug's] treatment effect was, in fact, large." *Id.* The court also held that because the plaintiffs were "sophisticated investors" they would be aware that there might be "tension" between the "ultimate projection" and its "underlying facts." *Id.* And they would expect the company to be engaged in a "dialogue" with the FDA in which the parties had "differing views." *Id.* This aside, the court found that the statements were accompanied by "numerous caveats to the reliability of the projections," though it

did not analyze them with more specificity. *Id.* Finally, the court held that the company did not need to disclose the FDA's feedback "merely because it tended to cut against their projections." *Id.* at 212.

I turn to each category of Challenged Statements here.

A. Deadline Statements

First, BioMarin challenges the statements about the PDUFA date and Novato Facility inspection date. It contends that the Challenged Statements that said the FDA was on track to meet the PDUFA date are accurate because, at the time, BioMarin believed the FDA was going to meet the deadline. Mot. 12. And it asserts that the statements about the timing of the inspection of the Novato Facility were accurate because BioMarin only learned of its delay after it made them. *Id.* 13–14.

Just like the statements about milestones in the cases cited above, these statements survive at this stage. The plaintiffs' position is not that the statements about the PDUFA date were misleading because the date would absolutely not be met, it is that they are misleading because BioMarin was allegedly aware of concrete risks that approval would be denied even as it projected that it would be granted. Statements to that effect are plausibly misleading. *Cf. Arena,* 840 F.3d at 708 (holding similar misrepresentations sufficient).

On the Novato Facility in particular, the Complaint includes allegations that come from a confidential witness inside the company and contradict BioMarin's argument. According to this confidential witness, the FDA warned BioMarin of that exact danger at the start of the Class Period. Compl. ¶¶ 79–81. Taking those allegations as true, BioMarin's statements to the contrary could be found to be misleading.[7]

To resist this, BioMarin argues that the confidential witness should not be relied on. In a PSLRA case in this Circuit, when (as here) a confidential witness's allegations are not supported by some independent evidence, "confidential witness statements may only be relied upon where

[7] At the hearing, BioMarin leaned heavily on the argument that COVID-19 caused the FDA's delay in the inspection, so prior statements about the inspection were not false when made. The impact of the pandemic is a highly fact-dependent matter that will be revealed during discovery. The pleadings are adequate today.

the confidential witnesses are described with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Zucco*, 552 F.3d at 995 (internal quotation marks and citations omitted). To test this, the court must look to "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.* (internal quotation marks and citation omitted).

This standard is satisfied. The Complaint describes the confidential witness's job with as much specificity as appropriate. It alleges that the witness is a former "senior business development executive." Compl. ¶ 80. It also alleges exactly who told the witness about the FDA's statements: BioMarin's vice president of corporate and business development. *Id.* And it alleges that other colleagues had increasing concern as the date approached. *Id.* The allegations are also sufficiently plausible. Though this witness is only a single source, he or she named the person from whom the information came, allowing the parties to conduct discovery. The allegations from this witness also cohere with other allegations in the Complaint that do not depend on his or her say-so. The allegations about the lack of FDA communication, for example, are in line not only with the other allegations in the Complaint but with what BioMarin executives publicly admitted after approval failed. *See* Compl. ¶ 148 (Fuchs admitting that there was no dialogue with the FDA). And all this aligns with the allegations that analysts and investors were "shocked" at the news, especially in light of the positive image that BioMarin had previously portrayed. *Id.* ¶ 115. Reliance on this confidential witness is appropriate at this stage. *Cf. Inchen Huang v. Higgins*, 443 F. Supp. 3d 1031, 1052 (N.D. Cal. 2020) (finding that a confidential witness "sufficiently established personal knowledge by identifying a particular meeting he attended, the time of day the meeting occurred, the identity of at least one additional participant, and the contents of a statement by that participant").[8]

[8] BioMarin replies that these statements are "at best, triple hearsay." Mot. 14. But while the test for plausibility of confidential witness allegations is more demanding than general pleading standards, that does not mean it requires a mini-trial on the admissibility of the evidence. The only reason "hearsay" even comes up in this context is that statements that are inherently "vague"

B. Approval and Launch Statements

BioMarin contends that the statements about valrox's approval and launch are not alleged to be false "when made." Mot. 14–15. I disagree. The plaintiffs' core theory is that the FDA had raised concerns about the drug's approval, that BioMarin had reason to know there was a heightened risk of denying approval, and that the FDA and BioMarin stopped communicating during the Class Period. This information might be material to a reasonable investor who has been assured that approval and launch are on track because the "total mix" of information would tilt much more against approval than without the information. *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988); *cf. Arena*, 840 F.3d at 708 (holding sufficient "Arena's failure to inform the market about the risk of non-approval or delayed approval based on the FDA's 'concerns'").

BioMarin argues that the plaintiffs cannot rely on the FDA's concern about the discrepancy between the Phase I/II and the Phase III data. Mot. 15–16. It argues that they cannot rely on statements about the delay or cancellation of the inspection. *Id.* 16–17. And it argues that they cannot rely on the alleged silence from the FDA. *Id.* ¶ 17–18. According to it, none of these was a sufficient indicator that approval would ultimately be *denied* (as opposed to made riskier). Though BioMarin attempts to separate the allegations, the correct analysis focuses on all allegations together. Under that lens, the argument fails. The plaintiffs do not assert that BioMarin was sure approval would be denied, nor do they need to. At the pleadings stage, it is plausible that the concerns about the Phase III data combined with a delay in the important inspection combined with an unusual period of silence from the FDA would raise "*serious doubts* about . . . prompt FDA approval," which is sufficient. *Warshaw*, 74 F.3d at 957 (emphasis added).

C. FDA Relationship Statements

BioMarin argues that the statements about BioMarin's relationship with the FDA are not actionable. Mot. 18–20. According to it, the statements that the relationship was positive were

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or "unreliable" hearsay may not be enough under the Ninth Circuit's test. *Zucco*, 552 F.3d at 997. Whether a statement will ultimately be admissible under the Federal Rules of Evidence is not the question here. In any event, the evidence seems likely to be reducible to an admissible form at trial, including at least by the testimony of the named vice president from whom it is said to have come.

simply opinions by their speakers or "corporate optimism." *Id.* 19. Again, I disagree. The Ninth Circuit has held statements like this actionable. *See, e.g., Warshaw*, 74 F.3d at 959. The statements were not empty opinions similar to puffery, they were undergirded by factual assertions such as timelines for approval and inspections. And the statements were not presented only as beliefs, they were presented as the truth of the situation. Nor are they just empty optimism: If it is true that BioMarin had reason to doubt the timeline and had not communicated with the FDA, they are simply untrue. *See, e.g., id.*; *Arena*, 840 F.3d at 708; *MannKind*, 835 F. Supp. 2d at 809.

III. SCIENTER

BioMarin's last broad argument is that the plaintiffs have failed to adequately allege scienter. Mot. 20–25. The plaintiffs' scienter allegations are adequate.

Under the PSLRA, plaintiffs must plead facts that create a "strong inference" of the defendant's scienter. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 323 (2007). Scienter is a mental state that covers "intent to deceive, manipulate, or defraud," and "deliberate recklessness." *Arena*, 840 F.3d at 705 (internal quotation marks and citations omitted). "Deliberate recklessness," in turn, means "more than *mere* recklessness or a motive to commit fraud"; it is instead "an *extreme* departure from the standards of ordinary care[,] which presents a danger of misleading buyers or sellers that is either known to the defendant or is so *obvious* that the actor must have been aware of it." *Id.* (internal quotation marks and citations omitted).

Again, several cases deal specifically with FDA statements and scienter. *Arena*—the facts of which are related above—held that the statements there were sufficiently indicative of scienter. As the court explained, "Arena was free to express confidence in FDA approval. It might have represented that Arena was working through some requests from the FDA and was confident the data would vindicate [the drug]. But what it could not do was express confidence by claiming that all of the data was running in [the drug's] favor [when it] was not. *Id.* at 708. Again, there, the FDA requested "highly unusual" bi-monthly updates on the rat study, so statements touting confidence in approval were indicative of scienter. *Id.*

In contrast, in *Nguyen v. Endologix, Inc.*, the defendant company made a device to seal ruptures caused by aneurysms. 962 F.3d 405, 408 (9th Cir. 2020). It first sought approval for the

device in Europe, where reports showed that the device was "slipping" and "migrating"—and therefore unsafe. *Id.* at 409–10. The plaintiffs alleged that, despite these reports, the defendant "assured investors that the FDA would likely approve" the device in the U.S. *Id.* at 410. It gave specific projections about the timeline for approval. *Id.*at 410–11. The company later released results from a U.S. clinical trial that met the FDA's safety guidance. *Id.* at 411. It revealed that the FDA had "questions" about migration but said the situation was "very easy" to remedy. *Id.* at 412. Ultimately, it turned out that the FDA would not approve the device on the timeline the defendant represented, causing a share price drop. *Id.*

The Ninth Circuit held that there was not an adequately strong inference of scienter to be drawn. The plaintiffs argued that the "defendants made false and misleading statements about whether the FDA was likely to approve [the device] because defendants knew, based on their experience in Europe, that [the device] would encounter migration issues." *Id.* at 415. But, the court explained, that theory was implausible: "why would defendants promise the market that the FDA would approve [the device] if defendants knew the FDA would eventually figure out that [the device] could not be approved due to 'intractable' and 'unresolvable' device migration problems?" *Id.* The court explained that if the theory was the defendants were trying to increase the stock price and sell at that high before the inevitable revelation of the information, it might hold up, but they did not. *Id.* And the court found that the U.S. data was both more promising than the European data and measured by a more company-friendly standard, so it did not support the inference of scienter. *Id.* at 416.

Taken together, the allegations in the Complaint create a sufficiently strong inference of scienter. *Tellabs*, 551 U.S. at 323 (holding that the inquiry must focus on all of the facts together). "[F]alsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, and the two requirements may be combined into a unitary inquiry." *In re Daou Sys., Inc.*, 411 F.3d 1006, 1015 (9th Cir. 2005). For the reasons explained above, falsity was adequately alleged. Those allegations also support a strong inference of scienter.

Put simply, the defendants allegedly told the market things that were allegedly not true and that it must have known were not true by their nature. Just as the defendant in *Arena* failed to tell

investors about risks while confidently touting its relationship with the FDA, the defendants here repeatedly told the market that they had high confidence in approval on the set timeline and had a good relationship with the FDA when in fact there were allegedly concrete warning signs otherwise and silence from the FDA. Still more, the defendants made statements later that, at least as alleged, contradict the statements they made during the Class Period. After the Class Period, Fuchs admitted that BioMarin had "no dialogue" with the FDA. Compl. ¶ 148. The defendants admitted that the FDA had concerns about Phase III data. *Id.* ¶ 147. And, as explained above, a confidential witness stated that the company was aware that approval was riskier than they let on publicly. *Id.* ¶ 79–81. All of this contributes to an inference of scienter. *See, e.g.*, *MannKind*, 835 F. Supp. 2d at 809 (finding later contradictory statements about FDA process help imply scienter). BioMarin takes issue with that interpretation of Fuchs's statement, arguing that a lack of contact with the FDA is not necessarily a problem. *See, e.g.*, Mot. 22. That may be so, but it is a problem when a company represents the opposite to the market as a positive sign. *Arena*, 840 F.3d at 708.

Several other sets of allegations reinforce this conclusion. It is notable that valrox was going to be a significant and lucrative product and that two drugs that made up about one-third of BioMarin's revenue were about to end their exclusivity periods. Compl. ¶ 31; *see also id.* ¶ 39 (alleging that BioMarin planned to charge $2 million for a single infusion of valrox); *cf. Hatamian v. Advanced Micro Devices, Inc.*, 87 F. Supp. 3d 1149, 1163 (N.D. Cal. 2015) (finding that a product was "critical" to the defendant's "financial success" contributed to an inference of scienter).

Further, the defendants' sale of stocks helps contribute to an inference of scienter. As the Supreme Court has explained, "motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference." *Tellabs*, 551 U.S. at 325. During the six months that preceded the Class Period, Fuchs did not sell any BioMarin stock. Compl. ¶ 111. During the Class Period, he sold 64% of his stock, worth $23 million. *Id.* During the six months before the Class Period, Bienaimé sold 13% of his shares; during the class period, he sold 23%. *Id.* Fuchs's sales pattern, in particular, appears "dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside

information." *Ronconi v. Larkin*, 253 F.3d 423, 435 (9th Cir. 2001). At the least, it contributes to the inference that the defendants knew that they were withholding material information. BioMarin replies that the trades were nondiscretionary and pre-planned, which would lessen the implication that they were improper. But concealing the negative information before the sale and setting the sale to occur prior to the PDUFA date *were* discretionary choices, so it is sufficient at the pleadings stage to contribute to the plausibility of the scienter allegations.

Finally, BioMarin argues that the most plausible inference from all this is an innocent one. Mot. 25. While it is true that courts should consider competing inferences that can be drawn when assessing scienter pleading, the inference need not be "the 'smoking-gun' . . . or even the most plausible of competing inferences." *Tellabs*, 551 U.S. at 324 (internal quotation marks and citations omitted). BioMarin's argument attacks a straw man, contending that it makes no sense to spend so much investment on a product they knew was doomed. Mot. 25. In some circumstances that is true, as *Endologix* explained. *See* 962 F.3d at 415. But, here, the allegations are not that the defendants were *convinced* the FDA would deny approval, it is that they withheld important *warning signs* from the market. *See Skiadas v. Acer Therapeutics Inc.*, No. 1:19-CV-6137-GHW, 2020 WL 4208442, at *8 (S.D.N.Y. July 21, 2020) (distinguishing *Endologix* on this basis). The plaintiffs have alleged a "cogent and powerful" inference of scienter.

IV. ALLEGEDLY ABANDONED STATEMENTS

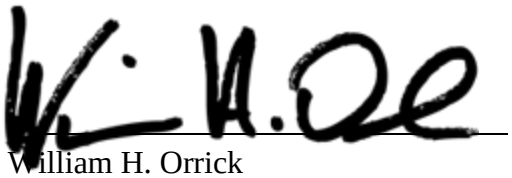
BioMarin points out that the plaintiffs' Opposition failed to defend a few discrete statements, even though the Motion sought dismissal. In some circumstances, the plaintiffs' silence would constitute abandonment. But here, the particular statements are essentially duplicative in substance of those that the Opposition does defend. They were not subject to any particularized argument for dismissal and are adequate for the reasons described in this Order.

CONCLUSION

The motion to dismiss is DENIED. Defendants shall answer the Amended Class Action Complaint within 20 days.

IT IS SO ORDERED.

Dated: January 6, 2022



William H. Orrick
United States District Judge