IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

DAVID F. BERLINGER,

Plaintiff,

v.

JEAN-JACQUES BIENAIME, et al.,

Defendants.

Case No. 21-cv-08254-MMC

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS; AFFORDING PLAINTIFFS LEAVE TO AMEND

Re: Dkt. No. 48

Before the Court is defendants BioMarin Pharmaceutical Inc. ("BioMarin" or the "Company"), Jean-Jacques Bienaimé ("Bienaimé"), Henry J. Fuchs ("Fuchs"), and Lon Cardon's ("Cardon") "Motion," filed May 25, 2022, "to Dismiss" the Amended Complaint ("AC"). Plaintiffs Local 282 Pension Trust Fund and Local 282 Annuity Trust Fund have filed opposition, to which defendants have replied. The Court, having read and considered the papers filed in support of and in opposition to the motion, rules as follows.[1]

BACKGROUND[2]

BioMarin is "a biotechnology company that develops and commercializes . . . therapies to address rare diseases and medical conditions." (See AC ¶ 3.) Bienaimé, Fuchs, and Cardon[3] are officers of BioMarin. (See AC ¶¶ 23-25.)

On November 7, 2018, at BioMarin's 2018 Research and Development Day ("R&D

[1] By order filed October 24, 2022, the Court took the matter under submission.

[2] The following facts are taking from the AC, the operative complaint.

[3] Plaintiffs allege Cardon left BioMarin by October 4, 2021. (See AC ¶ 25(c).)

Day") "for investors and analysts," the Company announced it was developing "a new investigational . . . gene therapy," BMN 307, for the treatment of phenylketonuria ("PKU"). (See AC ¶¶ 6, 51.)[4] In connection therewith, "Cardon presented pre-clinical data for BMN 307 and described some of the mouse models used to develop BMN 307." (See AC ¶ 6.)

The following year, on November 14, 2019, at BioMarin's 2019 R&D Day, Cardon stated that BioMarin's investigational new drug ("IND") submission[5] to the Food and Drug Administration ("FDA") for BMN 307 was "imminent." (See AC ¶ 62). Thereafter, on January 13, 2020, "BioMarin announced that BMN 307 had been approved for clinical trials" (see AC ¶ 69), and, on April 29, 2020, the Company confirmed it was in the "'Clinical Phase 1/2' stage"[6] of developing BMN 307 (see AC ¶ 75).

Plaintiffs allege that defendants, between November 14, 2019, and February 23, 2022 (the "Class Period"), made "materially false and misleading statements and omitted material facts concerning the status and development of" BMN 307. (See AC ¶ 138.) Specifically, plaintiffs allege, defendants did not disclose until September 5, 2021, that they "had observed liver tumors in a pre-clinical mouse study." (See AC ¶ 66(a).) Plaintiffs further allege that the FDA, as a result of those observations, placed a clinical hold on Phase 1/2 testing of BMN 307 (see AC ¶ 106), which hold, in turn, caused a drop in the price of BioMarin stock (see AC ¶ 107).

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[4] "PKU is a rare inherited disorder that causes an amino acid called phenylalanine (Phe) to build up in the body" due to "a defect in the gene that helps create the enzyme needed to break down [Phe]," without which enzyme "a dangerous buildup can develop when a person with PKU eats foods that contain protein," which "can eventually lead to serious health problems." (See AC ¶ 46.)

[5] According to plaintiffs, "the results of preclinical testing are submitted to the FDA as part of an IND," after which "researchers . . . decide whether the drug should be tested in people" in clinical trials. (See AC ¶¶ 31-32.)

[6] Plaintiffs allege that "[c]linical trials to support new drug applications are typically conducted in three sequential phases, although the phases may overlap." (See AC ¶ 32.) Plaintiffs further allege that "[d]uring Phase 1, clinical trials are conducted with a small number of human subjects," that "Phase 2 usually involves studies in a limited patient population," and that "[i]f a compound is found to be potentially effective and to have an acceptable safety profile in Phase 1 and 2 evaluations, Phase 3 trials are undertaken . . . in an expanded patient population." (See AC ¶ 33.)

Based on the above allegations, plaintiffs assert, on behalf of themselves and a putative class, two claims: (1) a claim alleging, as against all defendants, violations of § 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder (Count I), and (2) a claim alleging, as against all defendants, violations of § 20(a) of the Exchange Act (Count II).

LEGAL STANDARD

Dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure "can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." See Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1990). "To survive a motion to dismiss, a complaint must contain sufficient factual material, accepted as true, to 'state a claim to relief that is plausible on its face.'" See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)); see also Twombly, 550 U.S. at 555 (holding "[f]actual allegations must be enough to raise a right to relief above the speculative level"). In analyzing a motion to dismiss, a district court must accept as true all material allegations in the complaint and construe them in the light most favorable to the nonmoving party. See NL Indus., Inc. v. Kaplan, 792 F.2d 896, 898 (9th Cir. 1986). Courts, however, "are not bound to accept as true a legal conclusion couched as a factual allegation." See Iqbal, 556 U.S. at 678 (internal quotation and citation omitted).

DISCUSSION

Section 10(b) of the Exchange Act makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." See 15 U.S.C. § 78j(b). Rule 10b–5, promulgated pursuant to § 10(b), makes it unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." See 17 C.F.R. § 240.10b–5(b).

To plead a claim under § 10(b) and Rule 10b-5, a plaintiff must allege "(1) a material misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." See Oregon Pub. Emps. Ret. Fund v. Apollo Grp. Inc., 774 F.3d 598, 603 (9th Cir. 2014). Additionally, "a complaint stating claims under section 10(b) and Rule 10b–5 must satisfy the dual pleading requirements of Federal Rule of Civil Procedure 9(b) and the [Private Securities Litigation Reform Act of 1995 ('PSLRA')]." See Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 990 (9th Cir. 2009). Under Rule 9(b), a plaintiff "must state with particularity the circumstances constituting fraud . . . ." See Fed. R. Civ. P. 9(b). Under the PSLRA, a plaintiff must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading," see 15 U.S.C. § 78u-4(b)(1), as well as "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," see § 78u-4(b)(2).

Here, defendants argue, plaintiffs "fail to adequately identify the statements they challenge," "fail to adequately plead any false or misleading statement," and "fail to plead a strong inference of scienter." (See Defs.' Mot. to Dismiss ("Defs.' Mot."), at 11:4, 12:5 & 19:20, Dkt. No. 51.) As set forth below, the Court agrees.[7]

A. Identification of Statements

In response to defendants' argument, plaintiffs, first contend they have "identif[ied] each challenged statement in italics and bold." (See Lead Pls.' Opp'n to Defs.' Mot. to Dismiss Am. Compl. ("Pls.' Opp'n"), at 6:23, Dkt. No. 55.) The AC, however, includes no explanation as to the significance of the italics and boldface, which are scattered among numerous and relatively lengthy blocks of quoted text. Indeed, plaintiffs' use of such manner of emphasis appears to go considerably beyond whatever factual assertions

[7] In light of this finding, the Court does not address herein the remaining argument raised by defendants in support of dismissal. (See Defs.' Mot. at 1:25-26.)

plaintiffs may be challenging as false. (See, e.g., AC ¶ 63 (italicizing and bolding analyst's question "[C]an you just comment maybe a little bit more on durability considerations for PKU?"); ¶ 73(b) (italicizing and bolding "first goal [of the clinical trials] is to find the dose").) Moreover, adding to the lack of clarity is plaintiffs' inconsistent treatment of several statements, by quoting the statement without emphasis in one paragraph and italicizing and bolding it in another. (Compare AC ¶ 99 with ¶ 102.)

Under such circumstances, the AC fails to adequately "give fair notice of the grounds" on which plaintiffs' claims are based. See 3226701 Canada, Inc. v. Qualcomm, Inc., 2017 WL 971846, at *14 (S.D. Cal. Jan. 27, 2017) (dismissing complaint for failure to satisfy Rule 9(b) and PSLRA where complaint "place[d] emphasis—such as using bold or italic fonts—on portions of paragraphs of statements without explanation regarding the emphasis").[8]

Accordingly, the AC is subject to dismissal on that ground alone. Moreover, as discussed below, the AC fails for additional reasons.

B. Falsity of Statements

Whatever the allegedly false statements may be, plaintiffs allege only one reason as to why they were false, namely, defendants' "fail[ure] to disclose that, as admitted beginning on September 5, 2021, they had observed liver tumors at 52 weeks in a preclinical study in 85% of mice dosed at the 2e14 Vg/kg[9] level" (hereinafter, "Highest Dose Study"). (See AC ¶ 66(b) (internal citations omitted); see also AC ¶¶ 66(a), (c)-(e),

[8] Although plaintiffs, citing defendants' briefing as to other asserted deficiencies in the AC, contend defendants "have no trouble identifying the challenged statements or the reasons why such statements are alleged to be false in raising their remaining arguments" (see Pls.' Opp'n, at 7:11-13), "[d]efendants are not required to guess at the basis of [p]laintiffs' claims," see Primo v. Pac. Biosciences of California, Inc., 940 F. Supp. 2d 1105, 1112 (N.D. Cal. 2013) (noting defendants' "ab[ility] to argue that the pleading was inadequate does not establish that it provided them with sufficient notice of the claims against them").

[9] Plaintiffs allege "2e14 Vg/kg" is "the highest dose group." (See AC ¶ 12; see also Defs.' Mot. at 6:22-23 (noting dose is "measured by the number of vector genomes ('vg') per kilogram ('kg') of bodyweight ('vg/kg')").)

73(a)-(c), 77(a)-(c), 82(a)-(c), 89(a)-(e), 96(a)-(d), 103(a)-(b).)

"Falsity is alleged when a plaintiff points to defendant's statements that directly contradict what the defendant knew at that time." See Khoja v. Orexigen Therapeutics, Inc., 899 F.3d 988, 1008 (9th Cir. 2018). Here, as defendants argue, the AC contains no factual allegation as to when defendants obtained the knowledge attributed to them, or any factual allegations from which such a finding reasonably can be inferred, e.g., "when the study that prompted the clinical hold started, when dosing concluded, when BioMarin received data from the study, when BioMarin began analyzing the data, how long that analysis took, when and how BioMarin learned that mice in the highest dose arm developed liver tumors, and when and how that information was communicated to the individual defendants." (See Reply in Supp. of Mot. to Dismiss ("Defs.' Reply"), at 4:2-6, Dkt. No. 57.) Rather, plaintiffs point to statements made by defendants, which statements, plaintiffs essentially argue, constitute admissions as to the alleged knowledge. As discussed below, the Court disagrees.

In support of their claims, plaintiffs first note that Cardon, on November 7, 2018, stated, "[a]ll of our nonclinical studies will be done in the first half of next year," and that Bienaimé, on February 21, 2019, stated, "[w]e plan to complete preclinical studies in the first half of 2019." (See Pls.' Opp'n, at 7:17-18 n. 6 (citing AC ¶¶ 53, 57) (emphases omitted).) Such statements of optimism do not, however, suffice to plead the actuality, i.e., that defendants in fact completed all preclinical studies, much less the Highest Dose Study, in 2019.

Plaintiffs next point to their allegation that "on the first day of the Class Period, Cardon discussed the completion of pre-clinical trials." (See id. at 8:7-8 (citing AC ¶ 62).) As quoted in the AC, however, Cardon's statement does not make reference to all preclinical trials, but rather, "nonhuman primate studies" (see AC ¶ 62 (emphasis omitted)), and, as noted, the study on which plaintiffs rely involved mice, not primates (see AC ¶ 66(a)).

Likewise unavailing is plaintiffs' reliance on their allegation that Cardon, on

November 14, 2019, stated, "We finished our nonhuman primate and mass GLP[10] studies." (See AC ¶ 62.) Contrary to plaintiffs' assertion, such statement did not constitute a "confirm[ation] that BMN 307 had completed pre-clinical mouse and non-human primate studies in the first half of 2019" (see AC ¶ 123 (citing AC ¶ 62)), in that, as alleged in the AC, Bienaimé explained that the Highest Dose Study was a "non-GLP pharmacology study in . . . mice" (see AC ¶ 109).

Plaintiffs' argument based on BioMarin's Form 10Qs fares no better. (See Pls.' Opp'n, at 8:13-14 (citing AC ¶ 75).) In particular, plaintiffs cite to "BioMarin's Form 10Q for 3Q 2019," which lists the "Stage" of development for "BMN 307" as "Preclinical," and "BioMarin's Form 10Q for 1Q 2020," which lists the "Stage" of development as "Clinical Phase 1/2" (see AC ¶ 75 n.10), to support their argument that the Highest Dose Study was completed prior to 2020. As defendants point out, however, BioMarin, before and during the Class Period, "repeatedly told investors that preclinical testing may continue after its 2019 IND submission." (See Defs.' Mot. at 5:18-19; see also Decl. of Joshua Walden in Supp. of Defs.' Mot. to Dismiss ("Walden Decl."), Ex. 10, at 14, Dkt. No. 51-1 (BioMarin's Form 10-K for 2018, filed with SEC on February 27, 2019, stating "[l]ong term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND . . . is submitted"); see also Walden Decl. Ex. 13, at 13 (BioMarin's Form 10-K for 2019, filed with the SEC on February 27, 2020, stating same); Ex. 15, at 16 (BioMarin's Form 10-K for 2020, filed with the SEC on February 26, 2021, stating same).[11]

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[10] According to plaintiffs, GLP refers to the "good laboratory practice" regulations of the FDA, and "[r]esearchers typically use GLP . . . for preclinical laboratory studies," although "[i]n some cases, researchers use non-GLP studies that do not require the rigor of GLP studies." (See AC ¶ 31.)

[11] The Court hereby GRANTS defendants' request for judicial notice as to the above-referenced three exhibits to the extent they establish that the statements therein were made. See Mir v. Little Co. of Mary Hosp., 844 F.2d 646, 649 (9th Cir. 1988) (noting "it is proper for the district court to take judicial notice of matters of public record outside the pleadings and consider them for purposes of [a] motion to dismiss") (internal quotation and citation omitted); see also Dreiling v. Am. Exp. Co., 458 F.3d 942, 946 n.2 (9th Cir. 2006) (noting courts "may consider . . . any matter subject to judicial notice, such

Without allegations sufficient to plead the requisite chronology, plaintiffs fail to plead that any challenged statement "was untrue or misleading *when made*." See Fecht v. Price Co., 70 F.3d 1078, 1082 (9th Cir. 1995) (emphasis in original) (internal quotation and citation omitted).

Accordingly, plaintiffs' claims are subject to dismissal on this additional ground as well.[12]

CONCLUSION

For the reasons set forth above, defendants' motion to dismiss the AC is hereby GRANTED, and the AC is hereby DISMISSED with leave to amend.

Any Second Amended Complaint shall be filed no later than February 21, 2023.

IT IS SO ORDERED.

Dated: January 19, 2023

MAXINE M. CHESNEY
United States District Judge

as SEC filings"); In re Veritas Software Corp. Sec. Litig., 2004 WL 7338912, at *4 (N.D. Cal. May 19, 2004) (taking judicial notice of SEC filings "to determine the statements that were made therein").

[12] As plaintiffs have failed to state a claim under § 10(b) and Rule 10b-5, their § 20(a) claim likewise is subject to dismissal. See Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1035 n.15 (9th Cir. 2002) (noting "to prevail on . . . claims for violations of § 20(a) . . . , plaintiffs must first allege a violation of § 10(b) or Rule 10b-5").