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')").)

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