UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ADAM PAXTON, Individually and On Behalf of All Others Similarly Situated, Plaintiffs, v. PROVENTION BIO, INC., ASHLEIGH PALMER, and ANDREW DRECHSLER, Defendants.	Civil Action No. 3:21-cv-11613

OPINION

Plaintiffs George L. Jordan, Jr. and Adam Paxton, individually and on behalf of all others similarly situated, filed an amended class action complaint ("CAC") against Provention Bio, Inc. (the "Company"), its founder and Chief Executive Officer Ashleigh Palmer, and its Chief Financial Officer Andrew Drechsler (collectively, "Defendants"), alleging securities fraud in connection with statements and omissions concerning teplizumab, the Company's candidate drug for delaying Type One Diabetes ("T1D"). ECF No. 32 (CAC) ¶¶ 1-2, 25, 26. Before the Court is Defendants' motion to dismiss the CAC pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), and the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b). ECF No. 44. For the reasons below, Defendants' motion will be granted.

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Teplizumab is a drug intended to delay or prevent the progression of T1D. CAC ¶ 58. T1D is an autoimmune disease that generally progresses in three stages—Stage 1,

[1] Plaintiffs object to the Court considering "nearly two-thirds" of the Exhibits Defendants submitted in connection with their motion to dismiss. Pl. Br. at 22 (citing Exs. 1-11, 13-17, 29-30, 32-37). Many of those documents (Exs. 1-3, 5-6, 9, 11, 13-15, 30, 32-34), however, are ones Defendants were required to file with the SEC, see, e.g., Form 8-K, S.E.C., https://www.sec.gov/fast-answers/answersform8k, and to which the public has "unqualified access," Pension Ben. Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1197 (3d Cir. 1993). Accordingly, the SEC-filed documents are "matters of public record of which the court can take judicial notice," and the Court does so here. Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014); see also In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1331 (3d Cir. 2002) (affirming a District Court's noticing "documents filed with the SEC, but not relied upon in the Complaint").

In addition, one of the exhibits was created by the FDA and the other was produced by the FDA during the review process, and both are publicly available on the FDA's website. See Exs. 29, 37. Courts regularly take notice of such documents. See, e.g., Kos Pharms., Inc. v. Andrx Corp., 369 F.3d 700, 705 n.5 (3d Cir. 2004); In re Egalet Corp. Sec. Litig., 340 F. Supp. 3d 479, 496-97 (E.D. Pa. 2018), aff'd sub nom. Spizzirri v. Zyla Life Scis., 802 F. App'x 738 (3d Cir. 2020); see also, e.g., Sierra Club v. United States Env't Prot. Agency, 964 F.3d 882, 893 n.9 (10th Cir. 2020); United States v. Garcia, 855 F.3d 615, 621-22 (4th Cir. 2017); Wildman v. Medtronic, Inc., 874 F.3d 862, 866 n.2 (5th Cir. 2017); Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011); United States ex rel. Dan Abrams Co. v. Medtronic, Inc., No. 15-CV-01212, 2018 WL 5266863, at *2 n.3 (C.D. Cal. June 7, 2018); In re Zyprexa Prod. Liab. Litig., 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008). The Court therefore takes notice of these documents as well.

As for the objected-to non-SEC-filed press releases and earnings call transcript (Exs. 4, 7-8, 10, 16-17, 35), the Court concludes, contrary to Plaintiffs' contention, Pl. Br. at 21-22, that they are integral to the CAC, see Schmidt, 770 F.3d at 249; see also CAC Intro. (stating the allegations are "based upon . . . a review of Defendants' public documents, conference calls, and announcements . . ."). They are also from the same sources and of the same type as other documents to which Plaintiff do not object, and Plaintiffs also do not question their authenticity. Although the Court may consider them, see Pension Ben. Guar. Corp., 998 F.2d at 1196-97, it will not because they are

Stage 2, and Stage 3—corresponding to decreasing cell function. CAC ¶¶ 50-52. After the University of Chicago developed teplizumab, MacroGenics, Inc. acquired it in 2005 and partnered with Eli Lilly to manufacture the drug in Ireland and conduct clinical trials testing whether teplizumab could delay the progression of T1D in newly diagnosed Stage 3 T1D patients (the "Stage 3 clinical trial"). CAC ¶ 56. In 2010, the Stage 3 clinical trial concluded that teplizumab failed to delay the progression of T1D in Stage 3 T1D patients, and MacroGenics halted development of the drug. CAC ¶ 56.

The following year, the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDKD") and TrialNet spearheaded another clinical trial to test whether teplizumab could delay the progression of T1D in at-risk Stage 2 T1D patients and prevent progression to Stage 3 T1D (the "Stage 2 clinical trial"). CAC ¶¶ 57-60. In June 2019, the Stage 2 clinical trial announced positive results, concluding that "a single 14-day course of teplizumab in patients with Stage 2 T1D significantly delayed the median onset of clinical Stage 3 T1D by a minimum of two years compared to the placebo" and "more patients who took teplizumab remained free of clinical Stage 3 T1D beyond five years compared to patients who took the placebo." CAC ¶¶ 60-61. TrialNet published the results of the Stage 2 clinical trial, which ultimately involved seventy-six participants

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unnecessary to the resolution of the motion. The Court does not take notice of the presentation Defendants filed, Ex. 36, as they have provided no information regarding the document's origins, and it does not appear to be integral to the CAC.

The Court also takes notice of the documents on which "Plaintiffs take no position." Pl. Br. at 21 (citing Exs. 12, 18-28, and 31). First, many of the documents (Exs. 19, 21-22, 24-26, 28) are "public records" or publicly available FDA-created documents of which the Court may take notice. Second, these documents are "integral to or explicitly relied upon in the complaint." Schmidt, 770 F.3d at 249.

(forty-four of whom were treated with teplizumab and thirty-two of whom were given a placebo), in the New England Journal of Medicine on August 15, 2019. See CAC ¶ 84; Kevan C. Herold, et al., An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes, 381 New Eng. J. Med. 603-13 (August 15, 2019), https://www.nejm.org/doi/pdf/10.1056/NEJMoa1902226?articleTools=true.[2]

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In May 2018, while the Stage 2 clinical trial was ongoing, the Company acquired teplizumab from MacroGenics. CAC ¶¶ 2-3, 49. A few months later, the Company contracted with AGC Biologics to manufacture the drug in Seattle, Washington. CAC ¶ 49. After release of the positive results of the Stage 2 clinic trial, the Company applied for a Breakthrough Therapy Designation for teplizumab, which the U.S. Food and Drug Administration ("FDA") granted in August 2019. CAC ¶¶ 4, 64. A Breakthrough Therapy Designation expedites the FDA's review of a drug "and is only given to potential drugs that are intended to treat a serious condition and [where] preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint[]." CAC ¶ 64. The designation also allows a developer to submit a Biologics License Application ("BLA") on a rolling basis

[2] The Court takes judicial notice of this publicly available scientific publication that is referenced in, and relevant to, the CAC, see CAC ¶ 84, but only for "the publication of such information," not for "the truth of the matter asserted" therein, see Abdin v. CBS Broad. Inc., 971 F.3d 57, 60 n.2 (2d Cir. 2020) ("The district court properly took judicial notice of the [scientific] publications discussed herein . . . not necessarily for the truth of the matter asserted, but for the publication of such information[.]").

and obtain priority review. CAC ¶ 4. If granted, a BLA permits the developer to introduce the drug into interstate commerce. CAC ¶ 33. Generally, a BLA requires the developer to show that its drug is safe to use and safely manufactured. CAC ¶ 36 (citing 42 U.S.C. § 262(a)(2)(C)).

On April 16, 2020, the Company announced the start of its rolling submission of a BLA for teplizumab. CAC ¶ 65. Because the Company's BLA relied on the Phase 2 clinical trial that used teplizumab manufactured in Ireland, and the Company would be manufacturing its teplizumab in Seattle, the Company had to demonstrate that the two drugs were "biocomparable." CAC ¶¶ 37, 66. To accomplish this, the Company conducted a bridging study to show that the Ireland-manufactured drug and its Seattle-manufactured drug "ha[d] a similar lasting impact on a patient's body in both time and effect" (the "Bridging Study"). CAC ¶¶ 67-69. The Bridging Study analyzed pharmacokinetic ("PK") and pharmacodynamic ("PD") data. CAC ¶ 67. PK refers to the "activity of drugs in the body over a period of time, including the process by which drugs are absorbed, distributed in the body, localized in the tissues, and excreted" (i.e., time data), CAC ¶ 67, and PD refers to "how the body reacts to a drug" (i.e., effect data), CAC ¶ 67. The "traditional" measure of PK is called "area-under-the-curve" ("AUC"). CAC ¶¶ 37, 68. In this context, AUC refers to the area underneath a curved line on a graph of data where the y axis is concentration of the drug in the body and the x axis is time—meaning AUC "reflects the actual body exposure to a drug after the administration of a dose" with a higher AUC corresponding to increased concentration of the drug in the body at that particular point in time along the x axis. CAC ¶¶ 37, 68. The Bridging

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