IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOHN ALBERICI, individually and on behalf of all others similarly situated **v.** **RECRO PHARMA, INC., GERALDINE A. HENWOOD, STEWART MCCALLUM**, and **JOHN HARLOW**	**CIVIL ACTION** **NO. 18-2279**

MEMORANDUM RE SECOND MOTION TO DISMISS AMENDED COMPLAINT

Baylson, J. **March 1, 2021**

I. Introduction

In the present case, Plaintiff alleges that Recro Pharma Inc. concealed concerns about a drug's efficacy and manufacturing quality control. As alleged, Recro's investors learned of these issues only after the FDA refused to approve the drug — intravenous meloxicam ("IV meloxicam") — causing the stock value of Recro to plummet. Plaintiff sued Recro and several of its executives, claiming that they perpetrated a fraud on a class of investors in violation of the Securities Exchange Act of 1934.

This Court has examined Plaintiff's claims once before: it granted Defendants'[1] motion to dismiss on the grounds that Plaintiff failed to sufficiently plead a culpable mental state for the alleged wrongdoing. ECF 47, Alberici v. Recro Pharma, Inc., No. 18-2279, 2020 WL 806719 (E.D. Pa. Feb. 14, 2020) (Baylson, J.) ("Alberici I"). Simultaneously, however, the Court held

[1] The term "Defendants" encompasses Recro and "Individual Defendants" — Geraldine Henwood, Stewart McCallum, and John Harlow.

that Plaintiff had satisfied its burdens in pleading the materiality of the misrepresentations and loss causation. The Court declined to rule on each statement's falsity or actionability.

Plaintiff filed its Second Amended Complaint, ECF 50 ("SAC"); it argues it has now met the Court's concerns. Additionally, since Alberici I and the filing of the SAC, the FDA has approved IV meloxicam. Defendants argue this update merits reconsideration of the Court's prior findings of materiality and loss causation.

The Court agrees with Plaintiff. The SAC satisfies the Court's prior concerns regarding insufficient allegations for scienter and the statements' falsity. While the FDA's subsequent approval of the drug may be relevant to loss causation, it does not fundamentally alter the Court's prior conclusions. The Court therefore DENIES Defendants' Second Motion to Dismiss.

II. Factual Allegations[2]

The Court takes the allegations in the SAC as true and draws all reasonable inferences in favor of Plaintiff, as is required at the motion to dismiss stage. Phillips v. Cty. of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008). Additionally, as the Court is "faced with a Rule 12(b)(6) motion to dismiss a § 10(b) action," it will consider information in "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007).[3]

Plaintiff's Second Amended Complaint contains many of the same factual allegations as this Court previously discussed in Alberici I. The Court therefore incorporates Alberici I's discussions regarding development of IV meloxicam and the FDA's initial review of the drug. See 2020 WL 806719, at * 1–3 (discussing "Factual Allegations"). Since Alberici I, Plaintiff has

[2] For ease of reference, this opinion will cite to filed documents using the page numbers printed on ECF (i.e. the PDF page number) where appropriate, even if they have internal pagination.
[3] See infra Section IV (discussing Judicial Notice).

revised its allegations relevant to scienter and list of allegedly actionable misstatements. The Court will discuss both. In addition, the Court takes judicial notice that the FDA approved IV meloxicam since the filing of the SAC. The FDA approved the drug for both hard- and soft-tissue uses on February 20, 2020. ECF 51 ("Defs.' Br.") at 186–91 (Def.'s Ex. L); see also infra Section IV (Judicial Notice).

a. Scienter: Defendants' Awareness of KOL Concerns

In preparing to launch IV meloxicam, Recro relied on 200–300 Key Opinion Leaders ("KOLs"), medical professionals and physicians who provide subject matter expertise, to shape its decision-making in marketing, research, and development. SAC at ¶¶ 32–34.

Plaintiff's confidential witness ("CW1") was employed in senior Medical Affairs roles throughout the class period; he and his team "frequently communicated" with KOLs and reported their feedback to Recro leadership. Id. at ¶¶ 35, 36. CW1 reported to Individual Defendants that KOLs did not intend to use for soft-tissue procedures and that they believed Recro's overseas manufacturing oversight of IV meloxicam was insufficient. Id. at ¶ 42.[4]

- Soft-Tissue Use: "[A]pproximately 75% of soft-tissue KOLs who had the ability to drive protocols in medical institutions . . . did not intend to use IV meloxicam in their procedures because of the trial data." Id. at ¶ 69. And "a significant majority" of all KOLs did not intend to use IV meloxicam in soft-tissue procedures based on the perceived weakness of the clinical trial data. Id. at ¶ 66. By contrast, 99.9% of KOLs "were convinced that IV meloxicam should be used in orthopedic (or hard tissue) procedures." Id.

[4] These conversations and reports took place between June 2017 to May 2018, as they allegedly occurred during CW1's employment at Recro during those months.

- Manufacturing Oversight: "[A]pproximately 30% of KOLs" were concerned about Recro's plan to manufacture IV meloxicam overseas in Ireland, including concerns about inadequate supervision. Id. at ¶¶ 59, 61. Recro had only one employee overseeing IV meloxicam's manufacturing and packaging; he lived in Pennsylvania and commuted to Ireland part-time for this role. Id. at ¶ 61.

i. Soft-Tissue Use Concerns

CW1 personally reported to McCallum and Harlow that KOLs "frequently" opined that "the trial data was not compelling enough for them to use the drug in soft-tissue procedures" and that "KOL reluctance was especially strong among colorectal surgeon KOLs, who were also concerned about bleeding risks." Id. at ¶ 72. CW1 and his team "frequently reported" this information to McCallum and Harlow and knew that it was "discussed by McCallum and Harlow" as well. Id. at ¶ 73.

Leadership Team Meetings: CW1 attended Recro's weekly Leadership Team meetings (in-person or remotely), held in a conference room at Recro's headquarters in Malvern, Pennsylvania, from June 2017 through May 2018. Id. at ¶¶ 35, 39. Individual Defendants were all members of the Leadership Team. Id. at ¶ 40. McCallum and Harlow "consistently attended" the meetings, and, while she "did not frequently attend," Henwood "always received reports of these meetings" from the other Individual Defendants. Id. At these meetings, CW1 and his Medical Affairs teams reported that KOLs had concerns for IV meloxicam, including about "oversight of manufacturing in Ireland, the lack of safety data on bleeding risks for IV meloxicam, and the fact that KOLs were not intending to use IV meloxicam in their soft-tissue procedures because the drug's efficacy clinical trial data was not compelling." Id. at ¶ 42.

Feedback Reports: CW1 compiled KOL feedback reports and submitted them to McCallum; McCallum then prepared summaries for Henwood based on his reading of those

reports and with CW1's input. Id. at ¶¶ 74, 75. McCallum presented these reports at monthly meetings in Malvern with Henwood (and with Harlow in attendance). Id. at ¶ 75. CW1 personally saw that these reports "included the information that KOLs did not want to use IV meloxicam for soft-tissue procedures." Id.

Advisory Board meetings: Recro hosted quarterly Advisory Board meetings, which featured a panel of approximately twelve orthopedic and colorectal KOLs (hard- and soft-tissue specialists, respectively) providing expert opinions on IV meloxicam. Id. at ¶ 76. CW1 personally attended four of these meetings in 2017 and 2018 (at least one of which took place in the Grand Hyatt at the Dallas-Fort Worth International Airport) that McCallum planned and both McCallum and Harlow attended. Id. At each of these Advisory Board meetings that CW1 attended, the colorectal KOLs "made their opinions clear to McCallum and Harlow . . . that the trial data did not convince the majority of them to start using IV meloxicam in their soft-tissue procedures" and it would "be a very hard sell" to include IV meloxicam in their institutions' treatment protocols for soft-tissue procedures. Id. at ¶¶ 76, 77. "[M]any of the KOLs on the Advisory Board question[ed] McCallum and Harlow as to why the Company was not seeking FDA approval for just the hard-tissue indication." Id. at ¶ 77. Following these meetings, CW1 helped McCallum prepare executive summaries for Henwood; these "reported that the majority of [colorectal] KOLs did not intend to use IV meloxicam in their procedures." Id. at ¶ 79.

Sales Strategies: Based on KOL feedback, Recro assumed the sales strategy of prioritizing IV meloxicam sales to orthopedic/hard-tissue uses and away from soft-tissue uses. Id. at ¶ 80. In designing sales representative training, Recro's sales leadership team advised "focusing the team on orthopedic procedures and staying away from recommending the product for soft-tissue

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.