UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE ACADIA PHARMACEUTICALS INC. SECURITIES LITIGATION

Case No.: 18-cv-01647-AJB-BGS

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS THE THIRD AMENDED COMPLAINT WITHOUT LEAVE TO AMEND

(Doc. No. 107)

Before the Court is Defendants' motion to dismiss Plaintiff's Third Amended Complaint ("TAC") in this securities-fraud action. (Doc. No. 107.) Plaintiff filed an opposition, to which Defendants replied. (Doc. Nos. 108, 109.) For the reasons set forth below, the Court **GRANTS** Defendants' motion to dismiss.

I. BACKGROUND

A. Factual Background

This case is a putative class action, involving a class of individuals who acquired ACADIA securities between April 29, 2016, and July 9, 2018, and are suing Defendants—Acadia Pharmaceuticals Inc. ("Acadia"), and individuals Stephen R. Davis ("Davis"), Todd S. Young ("Young"), Srdjan Stankovic ("Stankovic"), Terrance Moore ("Moore"), and Michael Yang ("Yang") (collectively, "Individual Defendants")—for violations of the

Securities Exchange Act of 1934 ("Exchange Act"). (Doc. No. 102, TAC at ¶ 1.) Acadia is a biopharmaceutical company that develops and commercializes medicines for central nervous disorders. (*Id.* at ¶ 2.) Acadia's first drug is NUPLAZID (pimavanserin), which treats hallucinations and delusions associated with Parkinson's disease psychosis ("PDP"). (*Id.*)

1. "Breakthrough Therapy Designation" and FDA Approval

The clinical research program for NUPLAZID consisted of four randomized, controlled trials for safety and efficacy, three of which failed to show a statistically significant improvement in psychosis symptoms. (*Id.* at ¶ 40.) Acadia thereafter met with the Federal Drug and Food Administration ("FDA") in April 2010 to discuss their clinical program and modifications to the design for a subsequent fourth trial. (*Id.*) The resulting fourth trial ("020") was statistically positive. (*Id.*) In August 2014, Acadia received a "Breakthrough Therapy Designation," which would speed up the FDA's drug approval process because it targets an "unmet medical need." (Doc. No. 102 at ¶ 42.)

On September 1, 2015, Acadia submitted a new drug application to the FDA. (*Id.* at ¶ 44.) On March 29, 2016, an Advisory Committee convened to evaluate NUPLAZID and make a recommendation to the FDA regarding approval. (*Id.* at ¶ 47.) Despite Dr. Andreason's (the primary reviewer) recommendation that the drug should not be approved "due to an unacceptably increased, drug related, safety risk of mortality and serious morbidity," (*id.* at ¶ 45), the Advisory Committee voted 12-2 in favor of approval primarily because of the drug's ability to treat an "unmet medical need" and the "lack of approved products to treat PDP" (*id.* at ¶ 48).

On April 29, 2016, Acadia received FDA approval for NUPLAZID, the only drug approved specifically for the treatment of PDP. (Doc. No. 102 at ¶ 2.) NUPLAZID contains a black box warning indicating that there is an increased risk of death in elderly patients with dementia-related psychosis treated with antipsychotic drugs. (*Id.* at ¶ 50.)

2. Commercialization Efforts

Upon receiving FDA approval for its drug, Acadia issued a press release entitled "FDA Approves Acadia Pharmaceuticals' NUPLAZID™ (pimavanserin) – The First Drug Approved for the Treatment of Hallucinations and Delusions Associated with Parkinson's Disease Psychosis." (*Id.* at ¶ 75.) The press release stated, among other things, that 020 was the largest research and development program in PDP to date; that NUPLAZID significantly reduced the "frequency and severity of psychotic symptoms compared to placebo"; that the "benefit was achieved without impairing motor function"; and that the most common adverse reactions were peripheral edema and confusional state. (*Id.*) The press release also announced Acadia's plans to make NUPLAZID commercially available, including a comprehensive program to provide financial assistance to patients, their caregivers, and physicians. (*Id.*).

A few days later, on a May 2, 2016 analyst conference call to discuss the FDA's approval of NUPLAZID, Defendants Davis and Stankovic remarked on NUPLAZID's unique pharmacology compared to other antipsychotics, and explained that due to the drug's novel mechanism of action, it reduces hallucinations and delusions in patients with PDP and does so without impairing motor function. (Doc. No. 102 at ¶ 77.) Defendant Stankovic also commented on the drug's safety information, describing the box warning and most common adverse events. (*Id.*) Defendant Moore then described Acadia's "well-designed plan" to commercialize NUPLAZID and convince physicians to prescribe the drug to their patients, as well as certain obstacles to successful commercialization. (*Id.* at ¶ 78.) The plan he described included market education, increasing awareness of NUPLAZID among 11,000 physicians identified as PDP treating physicians, onboarding 132 neuroscience sales specialists, and "direct educational efforts with a variety of multi-channel education activities." (*Id.*) Lastly, Defendant Davis described that the key components of Acadia's gross to net adjustments will include fees paid to specialty pharmacies and distributors. (*Id.* at ¶ 80.)

The next day, on May 3, 2016, Acadia filed a Form 8-K with the SEC announcing that two members of its Board of Directors were not running for reelection and another resigned. (*Id*. at ¶ 81.) A couple of days later, Acadia hosted another analyst call, during which Defendant Davis repeated his prior remarks about NUPLAZID's favorable safety profile and that the company's commercialization strategy included educating healthcare providers on the advantages of NUPLAZID. (*Id.* at ¶¶ 82–83.) On May 31, 2016, Acadia commercially launched NUPLAZID and issued a press release, which included statements that again highlighted the drug's safety profile and unique pharmacology, as well as the 020 study results showing significant reductions in severity and frequency of hallucinations and delusions in PDP patients without impairing motor function. (*Id.* at ¶¶ 51, 84.)

On August 4, 2016,[1] Acadia issued another press release, which reported on the company's commercialization efforts and detailed that Acadia is "expanding awareness of NUPLAZID among healthcare professionals through a number of initiatives including speaker programs, media and digital campaigns, and symposia at major medical meetings and . . . working with payors to make NUPLAZID available to eligible patients." (*Id.* at ¶ 86.) Acadia also filed a Form 10-Q quarterly report with the SEC signed by Defendant Davis. (*Id.* at ¶ 88.) The report included statements that Acadia's commercial strategy includes employing internal specialty sales force to market NUPLAZID and distributing the drug solely through a limited network of third-party specialty distributors and pharmacies. (*Id.*) In an analyst call that same day, Defendant Davis detailed the expenses that Acadia incurred and discussed that the company is executing its marketing initiatives, which include speaker programs, a strong presence at major medical events, hosting a NUPLAZID webinar featuring PDP experts. (*Id.* at ¶ 89.) Defendants Davis and Moore also emphasized the company's focus on broadening awareness of NUPLAZID among physicians to ensure patient access. (*Id.*)

[1] The TAC provides a different date for this press release, but Defendants assert that the correct date for it is August 4, 2016, and Plaintiff does not contend otherwise. (Doc. No. 107-2 at 4 n.4.)

On November 7, 2016, Acadia issued a press release wherein Defendant Davis touted solid month-to-month prescription growth for NUPLAZID and reiterated the company's continued efforts to expand awareness of NUPLAZID among movement disorder specialists, neurologists, and psychiatrists. (*Id.* at ¶ 92.) On an analyst call that same day, Defendant Davis detailed that the company's sales specialists have made excellent inroads in deepening awareness of NUPLAZID among physicians; that the company has received strong positive feedback from prescribing physicians; and that the drug's safety and tolerability was consistent with that observed in the clinical studies. (*Id.* at ¶ 95.) Defendant Moore also commented on the steady adoption of NUPLAZID by physicians, and Defendant Young restated the company's previously noted gross to net adjustments. (*Id.* at ¶¶ 95, 97.)

During an analyst call on February 28, 2017, Defendant Davis detailed that Acadia observed a growing number of patients starting therapy and a growing number of prescribers. (*Id.* at ¶ 101.) He also stated that the company has received favorable feedback from physicians regarding NUPLAZID's clinical profile, including its efficacy and safety profile. (*Id.*) Defendant Young discussed the company's expenses, and Defendant Moore remarked on NUPLAZID's strong introduction into the marketplace and the regular adoption of the drug among movement disorder specialists, which was expected given the high number of PDP patients they treat. (*Id.*) Defendant Moore also specified that educating key prescribers on the benefits of NUPLAZID is crucial to Acadia's commercialization strategy. (*Id.*)

On May 9, 2017, Acadia issued a press release wherein Defendant Davis described that use of NUPLAZID continues to expand as brand awareness among healthcare providers grows. (*Id.* at ¶ 103.) On a conference call that same day, he stated that NUPLAZID has performed almost exactly the same in terms of efficacy, side effect, and tolerability in the marketplace as expected based upon the drug's clinical profile. (*Id.* at ¶ 106.) Defendant Davis stated that a majority of physicians are satisfied by the drug's safety and efficacy, and Defendant Moore detailed that 88% of physicians surveyed who

are aware of NUPLAZID intend to increase their use of the drug for treatment of PDP. (*Id.* at ¶ 107.)

On an August 8, 2017 conference call, Defendant Young described Acadia's expenses, and Defendant Davis described the drug's progress stating, "So overall, patients are having a positive experience with NUPLAZID. They like the way the drug works. They are tolerating the medication very well." (*Id.* at ¶ 110.) Defendant Yang then discussed the company's efforts to generate additional NUPLAZID prescriptions, detailing that Acadia continues to focus on working with physicians to identify appropriate new patients. (*Id.* at ¶ 112.)

On November 7, 2017, Acadia issued a press release and held a conference call positively reporting on NUPLAZID's commercialization and growth. (*Id.* at ¶¶ 113, 115.) On February 27, 2018, Acadia hosted a conference call, in which Defendant Young described Acadia's expenses and Defendant Davis touted NUPLAZID's successful commercialization, attributing it to continued "growth in the number of physicians prescribing NUPLAZID" and "market research results that consistently continue to demonstrate very high levels of physician and patient satisfaction with NUPLAZID." *(Id.* at ¶ 118.) Defendant Stankovic also indicated that NUPLAZID has a more favorable tolerability profile compared to other antipsychotic drugs. (*Id.* at ¶ 120.)

3. Post-Commercialization Safety Issues

On April 9, 2018, CNN reported that physicians, medical researchers, and other experts were worried that NUPLAZID "had been approved too quickly, based on too little evidence that it was safe or effective." (*Id.* at ¶ 121.) These individuals stated that because NUPLAZID's adverse event data reflects "mounting reports of deaths," more needs to be done to assess the drug's true risks. (*Id.*) According to Plaintiff, the CNN article provided the first revelation of NUPLAZID's post-commercialization safety issues because the average investor cannot easily decipher the raw data regarding adverse events and deaths submitted to the FDA. (*Id.* at ¶ 122.) On this news, Acadia's stock price fell $5.03 per share to close at $16.50 per share. (*Id.*) The next day, Acadia issued a press release, stating that

it continually "analyze[s] new data to ensure the safety of NUPLAZID and the ongoing evaluation has revealed no change in the benefit/risk profile described in the NUPLAZID Prescribing Information." (*Id.* at ¶ 123.)

Then, on April 25, 2018, CNN reported that the FDA was reexamining the safety of NUPLAZID. (*Id.* at ¶ 125.) The article also stated that the FDA was not suggesting physicians to stop prescribing NUPLAZID or take patients off the drug during its safety evaluation, and that the death reports citing NUPLAZID "have typically involved elderly patients with advanced-stage Parkinson's disease who suffered from numerous medical conditions and often take other medications that can increase the risk of death." (*Id.*) Plaintiff claims that due to Acadia's earlier press release providing assurances regarding NUPLAZID's safety profile, investors were shocked by the news of the FDA's reexamination of NUPLAZID's safety. (*Id.* at ¶ 126.) Acadia's stock price fell $4.27 per share to close at $15.20 per share. (*Id.*)

Two days later, Acadia published a statement explaining that "as a manufacturer of a newly launched drug, [it is] routinely in contact with the FDA regarding requests for additional information on NUPLAZID, including post marketing safety surveillance information as part of the FDA's ongoing safety monitoring." (*Id.* at ¶ 127.) The company also stated that it collects and analyzes these post marketing events as part of its ongoing commitment to monitor NUPLAZID's safety profile, and that these events are submitted to the FDA and incorporated into the FDA's Adverse Event Reporting System ("FAERS"). (*Id.*) Acadia further explained that because NUPLAZID is distributed through a specialty distribution channel, the company has frequent contact with patients and caregivers, which naturally results in dramatically higher adverse event collection and reporting compared to products without such distribution method. (*Id.*)

On May 4, 2018, Acadia issued a press release, wherein Defendant Davis attributed the company's positive financial results to the fact that healthcare providers and patients continue to experience NUPLAZID's benefits. (*Id.* at ¶ 129.) On a conference call that same day, Defendants Davis and Young discussed Acadia's expenses, and Defendant

Stankovic reiterated previous statements concerning NUPLAZID's safety. (*Id.*) Defendant Stankovic also explained that since the drug's approval and launch in 2016, Acadia has monitored its safety, and based on ongoing evaluations and the totality of available information, NUPLAZID's benefit-risk profile remains unchanged and is appropriately described in the product labeling. (*Id.* at ¶ 131.) Later, in September 2018, the FDA indicated that it found no new or unexpected safety risks associated with NUPLAZID. (*Id.* at ¶ 137.)

4. Alleged Improper Payments to Physicians

On July 9, 2018, Southern Investigative Reporting Foundation ("SIRF") published a report stating that "evidence is mounting that something is horribly wrong with Acadia's sole drug, NUPLAZID" and that "Acadia has accomplished its growth in ways that have attracted intense regulatory scrutiny for other drug companies" including "dispensing wads of cash to doctors to incentive prescription writing and downplaying mounting reports of patient deaths." (*Id*. at ¶ 133.) On this news, the stock price fell $1.21 per share to close at $16.63 per share. (*Id.* at ¶ 135.)

According to the SIRF report, "[o]ver the six months that NUPLAZID was commercially available in 2016, Acadia spent $609,556 on consulting, speaking and travel and lodging payments to 1,578 doctors." (*Id*. at ¶ 134.) It then detailed that in 2017, "Acadia paid more than $8.6 million to 7,051 physicians, with 62 doctors receiving more than $50,000 apiece, and 26 receiving at least $100,000 each." (*Id.*) Reviewing the Centers for Medicare and Medicaid Services Open Payments data for 2016 and 2017 and Medicare Part D data to observe prescriber behavior, the SIRF report surmised there to be "a good deal of overlap between those who received Acadia consulting fee payments in 2016 and 2017 and the individuals who prescribed Nuplazid with some frequency in 2016." (*Id.*) The report also noted that one physician was a leading prescriber of NUPLAZID "but did not receive any consulting fees from Acadia in 2016 and 2017." (*Id.*)

Plaintiff alleges that Confidential Witness 1 ("CW1"), a sales specialist for Acadia from April 2016 to April 2020 indicated that Acadia's speaker program was important in

its commercialization efforts. (*Id.* at ¶ 74.) CW1 explained that "physicians who participated in the speaker program received compensation per program plus an honorarium and travel reimbursement, with the average speaking engagement payment over $3,000." (*Id.*) CW1 also concluded that "the speaker engagements influenced the physicians' prescribing practices." (*Id.*)

On November 28, 2018, Acadia filed a prospectus supplement with the SEC, which informed that two months prior, the company received a civil investigative demand from the U.S. Department of Justice ("DOJ") requesting certain documents and information related to Acadia's sales and marketing of NUPLAZID. (*Id.* at ¶ 136.) The investigation ended in October 2020. (*Id.* at ¶ 138.) DOJ informed the company that it would not be taking any further action related to the civil investigative demand at this time. (*Id.*)

B. Procedural History

Relevant here, on March 29, 2021, the Court granted Defendants' motion to dismiss Plaintiff's Second Amended Complaint but afforded Plaintiff a third opportunity to amend his complaint. (Doc. No. 101.) On April 16, 2021, Plaintiff filed his TAC. (Doc. No. 102.) The TAC alleges two causes of action: (1) a violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder; and (2) a violation of Section 20(a) of the Exchange Act. (*Id.*) Defendants have filed a motion to dismiss the TAC for failure to state a claim for securities fraud, and the parties have submitted briefs in support of their respective positions. (Doc. Nos. 107, 108, 109.) This Order follows.

II. LEGAL STANDARD

A. Federal Rule of Civil Procedure 12(b)(6) Standard of Review

A Rule 12(b)(6) motion tests the legal sufficiency of the claims made in the complaint.[2] Dismissal under Rule 12(b)(6) is proper where the complaint fails to set forth a "cognizable legal theory," or where there is "an absence of sufficient facts alleged to support a cognizable legal theory." *Navarro v. Block,* 250 F.3d 729, 732 (9th Cir. 2001).

[2] "Rule" refers to the Federal Rules of Civil Procedure.

Although a complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief" under Rule 8(a)(2), "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 544, 555 (2007) (internal quotations, alterations, and citations omitted); *accord Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In reviewing a Rule 12(b)(6) motion, "[a]ll allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party." *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337–38 (9th Cir. 1996).

B. Heightened Pleading Standard

Pertinent here, a complaint alleging fraud must comply with Rule 9(b). Pursuant to Rule 9(b), a party must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "In other words, the complaint must set forth what is false or misleading about a statement, and why it is false." *Rubke v. Capitol Bancorp Ltd.,* 551 F.3d 1156, 1161 (9th Cir. 2009) (internal quotation marks omitted). Additionally, claims brought under the Exchange Act are subject to the requirements of the Private Securities Litigation Reform Act ("PSLRA"). The PSLRA "requires that a complaint alleging misleading statements or omissions '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, . . . all facts on which that belief is formed.'" *Reese v. BP Exploration (Alaska) Inc.,* 643 F.3d 681, 690 (9th Cir. 2011) (quoting 15 U.S.C. § 78u-4(b)(1)). Although Rule 9(b) allows for "[m]alice, intent, knowledge, and other conditions of a person's mind" to be alleged generally, fraud claims made pursuant to the Exchange Act must "plead with particularity both falsity and scienter." *Zucco Partners, LLC v. Digimarc Corp.,* 552 F.3d 981, 990 (9th Cir. 2009), *as amended* (Feb. 10, 2009). "Thus, the misrepresentation claims pled must satisfy the 'particularity' requirement of Rule 9(b) of the Federal Rules of Civil Procedure, the

'plausibility' requirement of *Iqbal*, and the scienter requirement of the PSLRA." *Reese*, 643 F.3d at 690–91.

III. DISCUSSION

Defendants again move to dismiss both of Plaintiff's causes of actions in the TAC. As for the Section 10(b) cause of action, Defendants argue that Plaintiff fails to adequately plead a materially false or misleading statement, scienter, and loss causation. As for the Section 20(a) claim, Defendants argue that because this claim is contingent on a primary violation of Section 10(b), which Plaintiff fails to plead, the Section 20(a) claim necessarily fails.

A. Request for Judicial Notice and Incorporation-by-Reference

To begin, Defendants filed with their motion to dismiss a request for judicial notice and consideration of documents incorporated by reference. (Doc. No. 107-2.) "Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6)." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018). There are, however, "two exceptions to this rule: the incorporation-by-reference doctrine, and judicial notice under Federal Rule of Evidence 201." (*Id.*) Judicial notice "permits a court to notice an adjudicative fact if it is 'not subject to reasonable dispute.'" *Id.* at 999 (quoting Fed. R. Evid. 201(b)). "A fact is 'not subject to reasonable dispute' if it is 'generally known' or 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.'" *Id.* (quoting Fed. R. Evid. 201(b)(1)–(2)). In contrast, "incorporation-by-reference is a judicially created doctrine that treats certain documents as though they are part of the complaint itself." *Id.* at 1002. Through this doctrine, "[a] defendant may seek to incorporate a document into the complaint 'if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim.'" *Id.* (quoting *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003).

Here, Defendants attached 48 exhibits to their motion and contend that all are appropriate for the Court's consideration because they are subject to either judicial notice

or the incorporation-by-reference doctrine. (Doc. No. 107-2.) In support, Defendants presented arguments, as well as a chart that identifies what each exhibit is, whether it is subject to judicial notice or incorporation-by-reference, and if the latter, which paragraph in the TAC references it. (*Id.* at 3–6.) Plaintiff does not dispute Defendants' characterizations of the documents or otherwise oppose their request. Accordingly, and as more fully analyzed below, the Court **GRANTS** Defendants' request as to those documents specifically mentioned in this Order.[3]

B. Securities Fraud

Section 10(b) of the Exchange Act forbids: (1) the use or employment of any deceptive device, (2) in connection with the purchase or sale of any security, and (3) in contravention of Securities and Exchange Commission rules and regulations. 15 U.S.C. § 78j(b); *see Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 341 (2005). Additionally, Rule 10b-5, promulgated by the SEC under Section 10(b), forbids the making of any "untrue statement of a material fact" or the omission of any material fact "necessary in order to make the statements made not misleading." 17 C.F.R § 240.10b-5; *see Dura,* 544 U.S. at 341. The basic elements of a Section 10(b) claim are: (1) a material misrepresentation or omission; (2) made with scienter; (3) in connection with the purchase or sale of a security; (4) reliance by plaintiffs; (5) economic loss; and (6) a causal nexus between the misrepresentation or omission and the loss. *Dura*, 544 U.S. at 341–42.

In this case, Defendants argue that Plaintiff has failed to adequately plead a material misrepresentation or omission (also referred to as falsity), scienter, and loss causation. (Doc. No. 107-1 at 14.)

1. Material Misrepresentation or Omission

To allege an actionable false or misleading statement, a plaintiff must show that Defendants made statements that were "misleading as to a material fact." *Basic Incorporated, et al. v. Levinson,* 485 U.S. 224, 238 (1988). A material statement is one

[3] As for the documents not specifically cited in this Order and on which the Court does not rely to reach its conclusions, the Court **DENIES** Defendants' request as **MOOT**.

where there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Id.* at 231–32. Moreover, according to the Ninth Circuit:

> [n]o matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not. To be actionable under the securities laws, an 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 Hospitals Corp., 280 F.3d 997, 1006 (9th. Cir. 2002).

Here, Plaintiff's allegations regarding falsity fall into two categories: (i) a failure to disclose adverse event reports related to NUPLAZID and (ii) a failure to disclose that Acadia's commercialization strategy included kickbacks. (Doc. No. 108 at 18, 19.) The Court discusses each in turn.

ii. Adverse Event Reports

Plaintiff alleges throughout his TAC that Defendants failed to disclose "mounting reports of adverse events, serious adverse events, and deaths in patients using NUPLAZID post-commercialization." (Doc. No. 102 at ¶ 14.) In the prior Order dismissing Plaintiff's SAC, the Court found that Defendants' nondisclosure of FAERS data was not misleading because the data was publicly available and the existence of adverse events, standing alone, does not necessarily mean that the drug caused that event. (Doc. No. 101 at 15–17.) Plaintiff's new allegation that the average investor cannot easily decipher the reports of adverse events and deaths submitted to the FAERS database does not change the Court's earlier conclusion. (Doc. No. 102 at ¶ 15.) The additional allegation is inconsequential because an investor's inability to decipher publicly available data with ease does not necessarily establish that Defendants' nondisclosure of adverse event reports was misleading. Plaintiff cites no case law to persuade the Court to find otherwise. *Cf. Rubke v. Capitol Bancorp Ltd*, 551 F.3d 1156, 1163 (9th Cir. 2009) ("[I]t is pointless and costly to compel firms to reprint information already in the public domain.").

As previously noted, to satisfy the heightened pleading standards of the PSLRA, Plaintiff "must specify the reason or reasons why the statements made by [Defendants] were misleading or untrue." *Brody,* 280 F.3d at 1006. According to Plaintiff, Defendants' nondisclosure of reports concerning adverse events and deaths in patients taking NUPLAZID were misleading in light of Acadia's representations in press releases, SEC filings, and conference calls that NUPLAZID has a favorable safety profile. However, apart from implying that the adverse event reports necessarily reveal that NUPLAZID does not have a favorable safety profile, Plaintiff provides no explanation as to why the nondisclosure is misleading. Notably, the Supreme Court has stated that there is no requirement "that pharmaceutical manufacturers must disclose all reports of adverse events" and "[t]he fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43, 44 (2011). As such, to show that the nondisclosure was misleading in this case, Plaintiff must plead more than "the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events." *Id.* Plaintiff has not done so.

The TAC does not contain facts showing that the nondisclosure of all adverse events rendered Acadia's statements about NUPLAZID's safety profile misleading. *See Brody*, 280 F.3d at 1006 ("Often, a statement will not mislead even if it is incomplete or does not include all relevant facts."). Again, for an omission to be misleading "it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Id.* Plaintiff, however, has not shown that the nondisclosure of adverse events created an impression that NUPLAZID has a favorable safety profile, when in fact, it does not. There is also no indication that the number and type of adverse events reported were of unanticipated severity or frequency. Indeed, the TAC provides a couple of obvious alternate explanations for the high number of adverse event reports, which have no bearing on NUPLAZID's safety. *Eclectic Properties E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 996 (9th Cir. 2014) ("When considering plausibility, courts must also consider an

'obvious alternative explanation' for defendant's behavior." (quoting *Iqbal,* 556 U.S. at 682)).

First, the TAC includes allegations explaining that "NUPLAZID is distributed through a specialty distribution channel" which entails "frequent (in most cases monthly) contact with patients and caregivers," and that "this increased interaction naturally results in dramatically higher adverse event collection and reporting compared to products without such a distribution method." (Doc. No. 102 at ¶127.) Second, the TAC also acknowledges that "[t]he FDA has noted that the death reports citing Nuplazid have typically involved elderly patients with advanced-stage Parkinson's disease who suffered from numerous medical conditions and often take other medications that can increase the risk of death." (*Id.* at ¶ 125.) Further undercutting a finding that Defendants' nondisclosure of adverse event reports misled investors about NUPLAZID's safety profile, the TAC acknowledges that the FDA's reevaluation of the drug's safety "found no new or unexpected safety risks associated with NUPLAID (pimavanserin)." (*Id.* at ¶ 137.) The Court noted these same reasons in its prior Order, but Plaintiff still failed to offer facts to show how the nondisclosure of adverse event reports rendered Defendants' statements about NUPLAZID's safety misleading. Without more, the Court declines to find that Plaintiff has shown that nondisclosure of the adverse event reports "created an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody,* 280 F.3d at 1006.

For the foregoing reasons, the Court finds that Plaintiff has failed to plead facts establishing the Defendants' nondisclosure of publicly available adverse event reports were misleading. As such, there was no duty to disclose these events. Accordingly, the nondisclosure of adverse events does not amount to an actionable omission in this case.

Lastly, although Plaintiff alleges that Defendants failed to warn investors about the risk of regulatory scrutiny related to the adverse events, Acadia's quarterly SEC filings—of which the Court takes judicial notice—show that they did. (*See, e.g.*, Doc. Nos. 107-6 at 14–15; 107-8 at 75–78.) *See also Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540

F.3d 1049, 1064 n.7 (9th Cir. 2008) (finding that taking judicial notice of SEC filings was proper); *Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006) (same). Specifically, the Court takes judicial notice of Acadia's express statements in its SEC filings that although the FDA has granted approval of NUPLAZID, the drug "is still subject to substantial, ongoing regulatory requirements." (Doc. Nos. 107-6 at 14; 107-8 at 75.) The Court also takes judicial notice of Acadia's statements that the "adverse event reporting . . . for NUPLAZID will also continue to be subject to extensive and ongoing regulatory requirements" and that "[d]iscovery of any issues post-approval, including any safety concerns, such as . . . adverse events of unanticipated severity or frequency" may result in a variety of agency action, including restrictions on NUPLAZID and withdrawal of the drug from the market. (Doc. Nos. 107-6 at 14; 107-8 at 76.) In light of these statements, the Court finds Plaintiff's allegation that Defendants failed to warn of the risk of regulatory scrutiny related to adverse event reports unavailing.

iii. Alleged Kickbacks

Next, Plaintiff alleges that Defendants failed to disclose that their commercialization plan included paying doctors to prescribe NUPLAZID, which would raise the risk of regulatory and industry scrutiny, and that they failed to list the payouts to physicians in the company's gross-to-net revenue adjustments. (*E.g.*, Doc. No. 102 at ¶¶ 79, 80, 97, 132.) In the previous Order dismissing Plaintiff's SAC, the Court found—based on the record before it—that Plaintiff adequately pled "facts suggesting Defendants paid doctors to induce prescription writing of NUPLAZID, which constitutes a material fact that would have made it substantially likely that a reasonable investor would have viewed this information as having significantly altered the total mix of information made available." (Doc. No. 101 at 18.) In reaching this conclusion, the Court explained that "[t]he strongest fact evidencing kickbacks in this case is the DOJ investigation into the matter." (*Id.* at 17.)

Critically, however, the fact of an ongoing DOJ investigation is no longer pled. The TAC establishes that the investigation is no longer active, and DOJ informed Acadia that it "would not be taking any further action" at this time. (Doc. No. 102 at ¶ 138.) Plaintiff

insists that the cessation of the investigation is inconsequential because DOJ never expressly concluded that Defendants did not pay kickbacks. (Doc. No. 108 at 16.) The argument is unavailing because the Court cannot ignore common sense. *See Iqbal*, 556 U.S. at 664 (Motions to dismiss requires "the reviewing court to draw on its experience and common sense.") Based on its judicial experience and common sense, the Court finds that the reasonable inference drawn from the investigation's termination is that DOJ did not uncover evidence of kickbacks to proceed with charges against Defendants. Consequently, DOJ's termination of its investigation significantly undermines Plaintiff's kickback allegations.

To the extent Plaintiff argues that the "law of the case" precludes the Court from reconsidering its prior ruling that Plaintiff adequately pled falsity concerning kickbacks, he is mistaken. "Under the law of the case doctrine, a court is generally precluded from reconsidering an issue that has already been decided by the same court, or a higher court in the identical case." *United States v. Alexander*, 106 F.3d 874, 876 (9th Cir. 1997) (internal quotations and citation omitted). However, a court has "discretion to depart from the law of the case" where substantially different evidence or other changed circumstances exists. *Id. See, e.g.*, *Hampton v. Steen*, No. 2:12-CV-00470-AA, 2017 WL 11573592, at *2 (D. Or. Nov. 13, 2017) ("If plaintiffs were granted leave to amend and were successful in raising new factual allegations or sufficiently changed circumstances, I would be bound by neither my prior dismissal of claims nor the Ninth Circuit's affirmance of that dismissal.").

Here, the Court is not bound by its prior decision because that decision was tied to the existence of an ongoing DOJ investigation, and that allegation is no longer in the operative complaint. As the Court emphasized, the active DOJ investigation was the "strongest fact evidencing kickbacks." (Doc. No. 101 at 17.) As this fact no longer exists, there is substantially different evidence and changed circumstances before the Court, warranting a new adjudication. *See Alexander*, 106 F.3d at 876. Accordingly, the law of the case doctrine does not apply.

Turning again to the sufficiency of Plaintiff's kickback allegations, the Court reiterates that the fact it found to be the strongest evidence of kickbacks no longer exists. DOJ terminated its investigation without further action or prosecution. This fact and the reasonable inferences drawn therefrom do not support Plaintiff's claim that Defendants' marketing strategy included a kickback scheme. The Court acknowledges that in the prior Order, it noted that CW1's statements regarding the influence of speaker engagements on physicians and the exit of three directors from the company after the drug's approval provided additional support for its finding. Standing by themselves, however, these allegations are inadequate to substantiate Plaintiff's contention that Defendants paid kickbacks to increase NUPLAZID sales.

According to the TAC, "CW1 confirmed that the speaker engagements influenced the physicians' prescribing practices." (Doc. No. 102 at ¶ 74.) The TAC, however, does not contain facts sufficient to establish CW1's personal knowledge or reliability with respect to the conclusion CW1 reached. Plaintiff does allege that CW1 was an Acadia sales representative tasked with recruiting physicians "to participate in a speaker program to promote NUPLAZID." (*Id.*) However, it is not evident from CW1's position how CW1 would have personal knowledge of the physicians' prescribing practices or any kickback scheme. *See generally Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 996 (9th Cir. 2009) (noting with approval a case "validating a confidential statement when they 'are not conclusory allegations of fraud, but specific descriptions of the precise means through which it occurred, provided by persons said to have personal knowledge of them'") (quoting *In re Cabletron Sys., Inc.*, 311 F.3d 11, 30 (1st Cir. 2002)). Considering the lack of personal knowledge and reliability for CW1's statement, the Court finds it akin to a conclusory assertion, and therefore declines to accord it the presumption of truth. *See Iqbal*, 556 U.S. at 678 ("conclusory statements[] do not suffice"). Additionally, the Court notes that the TAC alleges that one of the leading prescribers of NUPLAZID received no consulting fees from Acadia, thereby undermining Plaintiff's claim that Defendants bribed physicians to prescribe NUPLAZID. (Doc. No. 102 at ¶ 134.)

As to the three company directors' resignations, Plaintiff does not allege any facts explaining the reasons for their departures or connecting them to the purported kickback scheme. The Court declines to assume, based merely on the timing of the resignations, that their departures were due to their awareness and disapproval of the alleged kickbacks strategy. Defendants maintain that the directors' resignations were part of Acadia's decision to downsize its board of directors. As Plaintiff's allegations are equally consistent with this alternative explanation, "[s]omething more is needed, such as facts tending to exclude the possibility that the alternative explanation is true." *Eclectic*, 751 F.3d at 996–97. Plaintiff presented no such facts. Consequently, Plaintiff has failed to raise his claim that the directors' resignations were related to kickbacks from possible to plausible. *See id.*

Furthermore, the Court finds Plaintiff's allegation that Defendants failed to disclose that the payments to physicians may subject Acadia to regulatory scrutiny unavailing. Acadia's SEC filings, of which the Court takes judicial notice, state that its marketing plan included educating healthcare providers about NUPLAZID, and that it paid external providers to support Acadia's commercial activities. (*See, e.g.*, Doc. No. 107-6 at 11–12.) The SEC filings go on warn that government authorities may conclude that its commercial practices do not comply with certain laws and regulations and could adversely affect Acadia's growth and reputation. (*See, e.g.*, *id.* at 17–18.)

Similarly, Plaintiff's contention that Defendants misleadingly did not include payments to physicians in Acadia's list of gross to net adjustments is unpersuasive. (Doc. No. 102 at ¶¶ 80, 97.) As the SEC filings show, Acadia accounted for payments to doctors in its "Selling, General and Administrative Expenses," explaining that those expenses included "fees paid to external service providers to support [its] commercial activities associated with NUPLAZID." (*See, e.g.*, Doc. No. 107-6 at 12.) As alleged in the TAC, Acadia was "expanding awareness of NUPLAZID among healthcare professionals through a number of initiatives including speaker programs, media and digital campaigns, and symposia at major medical meetings." (Doc. No. 102 ¶ 86). Plaintiff does not plead facts

tending to exclude the possibility that the fees were legitimate payments for services. *See Eclectic*, 751 F.3d at 996–97.

There being no particular facts in the TAC sufficient to substantiate Plaintiff's claims that Defendants engaged in a kickback scheme, the Court finds that Plaintiff has failed to plead an actionable omission relating to kickbacks. *See Brody*, 280 F.3d at 1006 (An omission "must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists."). For the foregoing reasons, the Court finds that Plaintiff failed to adequately plead falsity. Accordingly, the Court **GRANTS** Defendants' motion to dismiss Plaintiff's cause of action pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

2. Scienter and Loss Causation

Because the Court found that Plaintiff failed to plead falsity, the Court need not reach Defendants' additional challenges concerning the elements of scienter and loss causation.

C. Control-Person Liability Section 20(a) Claim

Turning to Plaintiff's control-person liability claim against all Individual Defendants, "under Section 20(a), plaintiff must prove: (1) a primary violation of federal securities laws[]; and (2) that the defendant exercised actual power or control over the primary violator." *Howard v. Everex Systems, Inc.*, 228 F.3d 1057, 1065 (9th Cir. 2000). Considering the Court's above finding that Plaintiff has failed to adequately state a claim for a violation of Section 10(b) and Rule 10b-5 of the Exchange Act, Plaintiff has not satisfied the first prong of a Section 20(a) claim. Accordingly, the Court **GRANTS** Defendants' motion to dismiss Plaintiff's cause of action pursuant to Section 20(a) of the Exchange Act.

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IV. CONCLUSION

For the reason stated herein, the Court **GRANTS** Defendants' motion to dismiss. (Doc. No. 107.) Moreover, because Plaintiff's complaint remains deficient despite ample time and opportunity to amend, the Court **DISMISSES** the TAC **WITHOUT LEAVE TO AMEND**. *See Ascon Properties, Inc. v. Mobil Oil Co.*, 866 F.2d 1149, 1160 (9th Cir. 1989) ("The district court's discretion to deny leave to amend is particularly broad where plaintiff has previously amended the complaint."). The Clerk of Court is directed to close this case.

IT IS SO ORDERED.

Dated: January 3, 2022

Hon. Anthony J. Battaglia
United States District Judge