UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CITY OF BIRMINGHAM RELIEF AND RETIREMENT SYSTEM; and OHIO CARPENTERS' PENSION FUND, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

v.

ACADIA PHARMACEUTICALS, INC.; STEPHEN R. DAVIS; and SRDJAN (SERGE) R. STANKOVIC,

Defendants.

Case No.: 3:21-cv-00762-WQH-MSB

ORDER

HAYES, Judge:

The matters before the Court are: (1) the Motion to Exclude the Expert Opinions and Testimony of Dr. Christopher Breder, Dr. Anton Porsteinsson, and Dr. Kenneth Lehn filed by Plaintiff City of Birmingham Relief and Retirement System (ECF No. 197); (2) the Motion to Exclude the Expert Opinions and Testimony of Dr. Carl C. Peck and Dr. Steven P. Feinstein filed by Defendant Acadia Pharmaceuticals, Inc. (ECF No. 198); and (3) the Motion for Summary Judgment filed by Defendant Acadia Pharmaceuticals, Inc. (ECF No. 199).

I. PROCEDURAL HISTORY

On April 19, 2021, Plaintiff Denise Marechal initiated this action by filing a Class Action Complaint asserting violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), (the "Exchange Act"), and Rule 10b-5 promulgated thereunder against Defendants Acadia Pharmaceuticals, Inc. ("Acadia"); Stephen R. Davis ("Davis"); and Elena H. Ridloff. (ECF No. 1.)

On September 29, 2021, the Court appointed City of Birmingham Relief and Retirement System ("City of Birmingham") as Lead Plaintiff. (ECF No. 38.)

On December 10, 2021, Plaintiff City of Birmingham and Plaintiff Ohio Carpenters' Pension Fund (together, "Plaintiffs") filed an Amended Class Action Complaint ("FAC") against Acadia, Davis, and Srdjan (Serge) R. Stankovic ("Stankovic") (collectively, "Defendants"). (ECF No. 45.)

On February 15, 2022, Defendants filed a Motion to Dismiss the FAC. (ECF No. 53.) On September 27, 2022, the Court issued an Order denying the Motion to Dismiss the FAC (the "Dismissal Order"). (ECF No. 65.)

On October 25, 2022, Defendants filed a Motion for Reconsideration of the Court's Dismissal Order. (ECF No. 75.) On February 2, 2023, the Court issued an Order denying the Motion for Reconsideration. (ECF No. 82.)

On August 21, 2023, Plaintiffs filed a Motion for Class Certification and Appointment of Class Representatives and Class Counsel. (ECF No. 108.) On March 11, 2024, the Court granted the Motion for Class Certification and Appointment of Class Representatives and Class Counsel. (ECF No. 140.)

On April 12, 2024, Acadia filed a Statement Noting Death of Defendant Srdjan (Serge) R. Stankovic. (ECF No. 146.) On October 9, 2024, the parties filed a Joint Motion to Substitute Party. (ECF No. 167.) On October 16, 2024, the Court issued an Order substituting Ana Stankovic for Srdjan (Serge) R. Stankovic. (ECF No. 168.)

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A. Designation of Expert Witnesses

On February 13, 2025, Plaintiffs designated the following expert witnesses and served their reports on Defendants: (1) Dr. Carl Peck, who offers testimony about the FDA's processes related to pharmaceutical drugs; (2) Dr. Lon Schneider, who offers testimony about dementia and clinical trials; (3) Dr. David Madigan, who offers testimony regarding biostatistical matters; and (4) Dr. Steven Feinstein, who offers testimony regarding loss causation, materiality, and damages. (ECF No. 197-1 at 11; ECF No. 197-2 at 2.)[1]

On March 27, 2025, Defendants designated five rebuttal expert witnesses and served the rebuttal reports on Plaintiffs. (ECF No. 197-2 at 2–3.) As relevant to the pending motions, Defendants designated the following rebuttal expert witnesses: (1) Dr. Christopher Breder, in rebuttal to Dr. Peck, offering testimony on issues related to the probability of FDA approval for pharmaceutical drugs; (2) Dr. Anton Porsteinsson, in rebuttal to Dr. Schneider, offering testimony on clinical trials; (3) and Dr. Kenneth Lehn, in rebuttal to Dr. Feinstein, offering testimony on loss causation, materiality, and damages. (ECF No. 207 at 9–10.) Defendants also designated Dr. Paul Andreason and Dr. Robert Gibbons as rebuttal expert witnesses. (ECF No. 197-2 at 3.)

B. Motions to Exclude Expert Testimony

On November 12, 2025, Plaintiffs filed the pending Motion to Exclude the Expert Opinions and Testimony of Dr. Christopher Breder, Dr. Anton Porsteinsson, and Dr. Kenneth Lehn ("Plaintiffs' Motion to Exclude Expert Testimony"). (ECF No. 197.)

On January 14, 2026, Defendants filed a Response in Opposition to Plaintiffs' Motion to Exclude Expert Testimony. (ECF No. 207.) On February 25, 2026, Plaintiffs filed a Reply in Support of their Motion to Exclude Expert Testimony. (ECF No. 209.)

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[1] Plaintiffs previously designated Dr. David Feigal as their expert witness regarding FDA and regulatory issues but moved to substitute Dr. Peck in his place on June 17, 2025. (ECF No. 179.) Magistrate Judge Michael S. Berg granted their motion on August 5, 2025. (ECF No. 187.)

On November 12, 2025, Defendants filed the pending Motion to Exclude the Opinions and Testimony of Plaintiffs' Expert Dr. Carl Peck and Dr. Steven Feinstein ("Defendants' Motion to Exclude Expert Testimony"). (ECF No. 198.)

On January 14, 2026, Plaintiffs filed a Response in Opposition to Defendants' Motion to Exclude Expert Testimony. (ECF No. 206.) On February 25, 2026, Defendants filed a Reply in Support of their Motion to Exclude Expert Testimony. (ECF No. 210.)

C. Defendants' Motion for Summary Judgment

On November 12, 2025, Defendants filed a Motion for Summary Judgment. (ECF No. 199.) On November 13, 2025, Defendants filed a Declaration in Support of the Motion for Summary Judgment. (ECF No. 200.) On November 13, 2025, Defendants also filed a Request for Judicial Notice in Support of the Motion for Summary Judgment. (ECF No. 201.)

On January 14, 2026, Plaintiffs filed a Response in Opposition to the Motion for Summary Judgment. (ECF No. 204.) On January 14, 2026, Plaintiffs also filed a Response to the Request for Judicial Notice in Support of the Motion for Summary Judgment. (ECF No. 205.)

On February 25, 2026, Defendants filed a Reply in Support of their Motion for Summary Judgment. (ECF No. 211.) On February 25, 2026, Defendants also filed a Reply in Support of their Request for Judicial Notice. (ECF No. 212.)

On April 6, 2026, Plaintiffs filed a Notice of Supplemental Authority in Support of the Opposition to the Motion for Summary Judgment. (ECF No. 215.)

On April 10, 2026, the Court held a Motion Hearing. (ECF Nos. 216, 217.)

On April 27, 2026, the Court granted the Defendants' Motion for Supplemental Briefing. (ECF No. 221.)

On May 1, 2026, Defendants filed a Supplemental Brief. (ECF No. 222; *see also* ECF No. 218 (submitting a related Notice of Supplemental Authority).)

On May 8, 2026, Plaintiffs filed a Supplemental Brief in Response. (ECF No. 223.)

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II. FACTUAL BACKGROUND[2]

Plaintiffs bring this federal securities class action seeking recovery under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 on behalf of all persons and entities that acquired Acadia common stock between September 9, 2019, and April 4, 2021. FAC at 2. Plaintiffs allege that Defendants misled investors while pursuing FDA approval of a drug application and, following the FDA's denial of its application, Acadia's stock price dropped and caused financial losses to those investors.

A. Development of Pimavanserin

Acadia is a biopharmaceutical company focused on developing and commercializing treatment for unmet medical needs in central nervous system disorders, including dementia. FAC ¶ 2. One of the drugs developed by Acadia is called pimavanserin. *Id.* ¶ 2.

In 2016, the FDA approved pimavanserin under the brand name NUPLAZID® for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis ("PDP"). *Id.* ¶¶ 29, 31. The FDA's approval of pimavanserin for PDP was based on the results from Acadia's Phase 3 trial in PDP patients (the "020 Study"), which met its primary and key secondary endpoints. *Id.* ¶¶ 46–47. In the context of trials like the 020 Study, primary endpoints are used to determine whether a drug has a clinically significant beneficial effect, whereas secondary endpoints are used to provide support to a primary endpoint or to demonstrate additional clinically beneficial effects. DUF ¶¶ 7–8.

In 2016, Acadia also completed a Phase 2 clinical trial of pimavanserin in patients suffering from hallucinations and delusions associated with Alzheimer's disease psychosis (the "019 Study"). FAC ¶ 48. The 019 Study met its primary endpoint. *Id.* ¶ 49.

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[2] Each party has filed a Separate Statement of Undisputed Facts. *See* Defendants' Separate Statement of Undisputed Facts, ECF No. 199-2 ("DUF"); Plaintiffs' Separate Statement of Undisputed Facts, ECF No. 204-1 at 144–320 ("PUF"). The facts in this section are drawn from each party's Separate Statement of Undisputed Facts, their responses to the opposing party's Separate Statement of Undisputed Facts, the exhibits filed in support, and the FAC (ECF No. 45). Facts that are immaterial for the purposes of adjudicating this motion are omitted from the Factual Background. All citations in this Order use the pagination generated by the CM/ECF filing system.

B. Acadia Seeks Broader Indication for Pimavanserin

In February 2017, Acadia requested an End-of-Phase-2 meeting ("EOP2 Meeting") with the FDA to discuss the development of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis ("DRP"). (ECF No. 200-3.) An FDA-approved indication for treatment of DRP would broaden the application of pimavanserin beyond its approval for treatment of symptoms related only to PDP. (ECF No. 199-1 at 11.)

To obtain FDA approval, Acadia would be required to satisfy various regulatory requirements, including the submission of a supplemental new drug application ("sNDA") for pimavanserin's application to patients with DRP. *Id.*

In April 2017, Acadia submitted a briefing package ("the EOP2 Briefing Package") to the FDA. (ECF No. 200-3 at 17–75 ("EOP2 Briefing Package Ex.").) The EOP2 Briefing Package posed questions to the FDA, including whether the federal agency agreed that Acadia's proposed Phase 3 trial was appropriately designed to potentially support approval for a DRP indication of pimavanserin. *See id.* The EOP2 Briefing Package also provided an overview of Acadia's proposed Phase 3 trial (the "045 Study" or "Harmony Study"). *Id.*

C. The Harmony Study

The Harmony Study was a randomized, double-blind, placebo-controlled, relapse prevention study with two phases. *Id.* In the "open-label" phase, all enrolled subjects would be administered pimavanserin. *Id.* In the following phase, subjects assessed as having responded to pimavanserin would be randomized 1:1 into placebo and treatment arms. *Id.*

Acadia proposed to the FDA that the Harmony Study would enroll patients with the five most common subtypes of dementia: Alzheimer's disease, dementia with Lewy bodies, vascular dementia, frontotemporal dementia, and Parkinson's disease dementia. *Id.*

D. EOP2 Meeting Between FDA and Acadia

On May 15, 2017, the FDA and Acadia convened for the EOP2 Meeting and, on May 24, 2017, the FDA issued official meeting minutes (the "EOP2 Minutes"). (ECF No.

200-3 at 163–82 ("EOP2 Minute Ex.").) The EOP2 Minutes reflect questions and answers exchanged between the FDA and Acadia, including the following:

> ***Question 1:*** Does the Agency agree that treatment of hallucinations and delusions in dementia-related psychosis is an approvable indication?
>
> ***FDA Response to Question 1***: We agree that treatment of hallucinations and delusions in dementia-related psychosis is a potentially approvable indication. We agree that dementias need not be etiologically related for the common symptom of psychosis to respond to pimavanserin.
>
> ***Question 2:*** The proposed [Harmony] study is a randomized, double-blind, placebo-controlled relapse prevention study to evaluate the efficacy and safety of pimavanserin in subjects with hallucinations and delusions in dementia-related psychosis associated with neurodegenerative disorders, and is intended to be the basis of an sNDA for the proposed indication.
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> a) Does the Agency agree with the proposed overall study design?
>
> b) Does the Agency agree with the proposed study population to be included in the study?
>
> c) Does the Agency agree with the timing and selection of study endpoints?
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> ***FDA Response to Question 2a***: We have concerns with the proposal to use a randomized withdrawal trial to establish efficacy. . . . After the above discussion [regarding the FDA's concerns about basing a regulatory decision on a single, randomized withdrawal study], the Division agreed that the randomized withdrawal trial as described in the [EOP2 Briefing Package] would be acceptable as a well-controlled trial for submission of a sNDA for the indication of hallucinations and delusions associated with dementia-related psychosis.
>
> ***FDA Response to Question 2b***: Yes, we agree with the proposed study population as long as subjects are stratified by their current clinical diagnosis (as proposed). Labeling will reflect the actual composition and response of patients enrolled in the study.
>
> ***FDA Response to Question 2c***: See our answer to Question 2a. In general, we agree with the timing and endpoints of the study. . .
>
> ***Question 3:*** It is ACADIA's position that in the context of the overall existing and planned safety database for pimavanserin that the single well-controlled Phase 3 study in the proposed patient population would be sufficient for a

> sNDA filing in the proposed indication. Additionally, the safety database would include the data contained in the approved NUPLAZID® NDA, safety exposures from the completed Phase 2 study in Alzheimer's disease psychosis, as well as additional ongoing and planned pimavanserin studies. Does the Agency agree?
>
> ***FDA Response to Question 3***: If you wish to rely on a single well-controlled study for your sNDA filing, the findings must be very persuasive. This means statistically significant with a very small probability of Type I error and a finding that is clinically meaningful. . . .

Id. at 170–72.

E. FDA Approval of the Harmony Study Protocol

In July 2017, Acadia submitted the Clinical Trial Protocol for the Harmony Study (the "Protocol") to the FDA. (ECF No. 200-3 at 184–281 ("Protocol Ex.").) The Protocol stated that the Harmony Study would enroll subjects with symptoms of psychosis who met clinical criteria for possible or probable Alzheimer's disease, dementia with Lewy bodies, vascular dementia, frontotemporal dementia, and Parkinson's disease dementia. *Id.*

The Protocol defined the primary endpoint of the Harmony Study as the time from randomization to relapse in the double-blind period for the entire randomized population and defined the secondary endpoint as time from randomization to discontinuation from the double-blind period for any reason. *Id.* The Protocol stated that the Harmony Study's "primary efficacy analysis will be based on the [Intent-to-treat ("ITT")] population, defined as all randomized subjects." *Id.* at 135. The Protocol stated that exploratory analyses would be performed based on variables including, but not limited to, "likely dementia subtype." *Id.* at 136.

On August 11, 2017, the FDA issued a "Study May Proceed" letter to Acadia, which confirmed that Acadia could commence the Harmony Study. (ECF No. 200-3 at 324–30.) On October 2, 2017, the FDA also granted Acadia's request to assign a Breakthrough Therapy Designation for pimavanserin. *Id.* at 332.

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F. Acadia's Statements Regarding the Harmony Study

On October 4, 2017, Acadia held a call with investors to announce the Harmony Study. (ECF No. 200-7 at 15–27.) On the call, Acadia disclosed that the Harmony Study population would be stratified by dementia subtype. *Id.* at 24. Investment analysts subsequently reported about the Harmony Study. (*See* DUF ¶ 47.)

On October 6, 2017, Acadia participated in the J.P. Morgan Biotechnology Conference Call Series. (ECF No. 200-7 at 28–59.)

G. Statistical Analysis Plan for the Harmony Study

In September 2018, Acadia submitted a draft of a Statistical Analysis Plan ("SAP") for the Harmony Study to the FDA. (DUF ¶ 49.) The SAP described a statistical framework for analyzing the results of the Harmony Study. *Id.* ¶ 50. The SAP identified primary and secondary endpoints based on the entire randomized study population. *Id.* ¶ 51. The SAP also described an "interim analysis" of data that, if certain thresholds were satisfied, would lead Acadia to terminate the Harmony Study earlier than expected. *Id.* ¶ 52.

In December 2018, the FDA provided comments on Acadia's draft SAP. (ECF No. 200-4 at 1–180.) On August 1, 2019, Acadia submitted its final SAP to the FDA. (ECF No. 200-4 at 187–269 ("SAP Ex.").) The SAP stated that "[t]reatment comparisons will be made with respect to the primary and key secondary efficacy variables using the Cox regression . . . for," among other variables, "[d]esignated dementia subtype." (SAP Ex. at 231.)

H. Termination of the Harmony Study

On September 9, 2019, Acadia announced that it had terminated the Harmony Study based on positive topline results from its pre-specified interim analysis. (FAC ¶ 107.)

On September 9, 2019, Acadia held a call with investors during which it disclosed that the Harmony Study met its primary endpoint. (ECF No. 200-7 at 60–71.) Acadia stated that it still needed to "conduct [the] full analysis of the study data" and was "not in a position to provide the detail on the response across subtypes." *Id*. at 70. Acadia also stated that "all [five] dementia subtypes were represented across both the enrolled population and

randomized population." *Id.* During the call, Stankovic stated: "I would also like to remind you that at the end of Phase II meeting with FDA, we confirmed that for our supplemental NDA submission in DRP, we could rely on a single, well-controlled study whose results were both statistically and clinically very persuasive." (FAC ¶ 109.) After the call, investment analysts discussed the positive top-line results and the anticipated release of more detailed information about results across dementia subtypes. (*See* DUF ¶ 64.)

On the same day, Acadia issued a press release, which stated that the "Harmony Study . . . met its primary endpoint, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis." (FAC ¶ 107.) The press release included a quote from Stankovic: "We are very excited that today's results bring us one step closer to the potential of offering patients with [DRP] a critically needed treatment option. . . . We look forward to speaking with the FDA about a supplemental new drug application to support pimavanserin for the treatment of dementia-related psychosis." *Id.*

On September 9, 2019, Acadia's stock price increased. (DUF ¶ 65 (identifying the increase as $22.43 per share on September 9, 2019); Plaintiffs' Response to DUF, ECF No. 204-1 ¶ 65 (identifying an increase of $15.05 per share from September 6, 2019, to September 9, 2019).) Acadia's stock price closed at $38.85 per share on September 9, 2019. (FAC ¶ 6.)

I. Public Statements in Late 2019 and Announcement of Results

On October 30, 2019, Acadia held its earnings call for the third quarter of 2019. (ECF No. 200-7 at 95–125). In response to a question, Stankovic stated that, at the upcoming 12th Clinical Trials of Alzheimer's Disease ("CTAD") Meeting on December 4, 2019, Acadia would "shar[e] all material top line results from the study, meaning efficacy data from the open-label portion of the trial, primary and key secondary endpoint details in the trial, particularly obviously, in the randomized withdrawal portion, as well as overall safety data. . . . [W]e will be presenting the data related to different subtypes of dementia as well." *Id.* at 85; FAC ¶ 111.

On November 21, 2019, Davis emailed Acadia's Board of Directors a summary of the top-line results from the Harmony Study. (ECF No. 200-10 at 409–11.) In his email, Davis communicated the expectation that the FDA would look at dementia subtype analyses and noted that, in his view, the results appeared "directionally aligned." *Id.*

On December 4, 2019, Acadia presented the results of Harmony Study at the CTAD Meeting and at an accompanying investor webcast on the same day ("the CTAD Investor Call"). (FAC ¶ 62; ECF No. 200-7 at 127–150 (CTAD Presentation); ECF No. 200-8 at 2–39 (CTAD Investor Call Presentation).) At each meeting, Acadia disclosed that the Harmony Study met its primary and secondary endpoints and had a favorable safety profile. (DUF ¶ 71.) At the CTAD Meeting, a slide in the presentation included information about the Harmony Study's dementia subtype sample sizes, response rates from the open-label phase, the number of patients on placebo versus drug, and relapse rates from the double-blind phase. (ECF No. 200-7 at 144; ECF No. 200-8 at 29.)

After these meetings, investment analysts produced reports regarding the Harmony Study, including reports indicating that the analysts understood the Harmony Study results to indicate positive results across dementia subtypes. (*See* DUF ¶¶ 74, 76; Plaintiffs' Response to DUF, ECF No. 204-1 ¶ 76.)

On December 5, 2019, Acadia's stock price increased from $44.28 per share and closed at $50.48 per share. (DUF ¶ 73.)

J. Acadia Seeks sNDA Approval

On February 13, 2020, Acadia submitted a briefing package to the FDA in anticipation of seeking sNDA approval of pimavanserin for DRP. (ECF No. 200-4 at 272–402.)

On February 26, 2020, Acadia held its earnings call for the fourth quarter of 2019. (FAC ¶ 113.) During the call, Stankovic stated: "The pivotal HARMONY study results will be the basis of the sNDA submission, which was previously agreed upon at the end of Phase II meeting." (ECF No. 200-8 at 48.)

On March 16, 2020, Acadia met with the FDA for a pre-sNDA meeting. (ECF No. 200-4 at 405.) On April 15, 2020, the FDA issued official meeting minutes for the pre-sNDA meeting. (ECF No. 200-4 at 403–28.)

On May 7, 2020, Acadia announced that the FDA had confirmed—at the pre-sNDA meeting—that the results from the 019 Study, 020 Study, and Harmony Study would support the submission of an sNDA. (FAC ¶ 115.) During an earnings call, Stankovic stated:

> As planned, we successfully completed a pre-sNDA meeting with the FDA and confirm that the pivotal data from our HARMONY study, together with the confirmatory and supportive results from our Alzheimer's disease psychosis Phase II study and our Parkinson's disease psychosis Phase III study will all support the submission of an sNDA for pimavanserin in dementia-related psychosis. In addition, we discussed the overall safety database and analysis plan. Our sNDA preparation remains firmly on track. As previously announced, we plan to submit the sNDA this summer. We expect a priority review with a potential approval for DRP around year-end.

(FAC ¶ 115; ECF No. 200-8 at 64.)

On May 12, 2020, Acadia attended the Bank of America Healthcare Conference. (FAC ¶ 117.) During the event, Davis stated:

> So as I mentioned, we had our pre-sNDA meeting in the first quarter. The feedback there was very consistent with what we heard with our end-of-Phase II meeting. The FDA confirmed that the studies conducted can support an sNDA submission with HARMONY as the pivotal study, and our Phase II Alzheimer's disease study and Phase III Parkinson's disease psychosis study as supportive efficacy studies.

(FAC ¶ 117; ECF No. 200-8 at 84.)

On June 15, 2020, Acadia announced in a press release that it had submitted its sNDA to the FDA. (FAC ¶ 119.) The press release included the following quote from Davis: "Our pivotal HARMONY study showed a meaningful reduction of the symptoms and stabilization of psychosis and a nearly three-fold reduction in the risk of relapse of psychosis for patients continuing treatment on pimavanserin compared to placebo. We look forward to working with the FDA as it reviews our submission." (ECF No. 200-6 at 82.)

K. FDA Considers the sNDA

Acadia's submission of the sNDA triggered the FDA's "review cycle," which begins with the FDA deciding whether to accept or "file" the sNDA. (DUF ¶ 87; ECF No. 200-5 at 73–107.)

On July 10, 2020, the FDA sent Acadia a Filing Letter indicating that it had accepted the sNDA for filing, classified the sNDA for a "standard" review, and had not identified any issues that—at this early stage of its review process—would serve as a basis to refuse to file the sNDA. (ECF No. 200-4 at 430.) Standard review, as compared to a "priority" review, was a less preferrable designation by the FDA at this stage of the approval process. (*See* PUF ¶¶ 207, 216, 219.) The Filing Letter advised that the FDA had no plans to convene an Advisory Committee ("AdCom") meeting. (*See* DUF ¶ 91.)

On July 20, 2020, Acadia announced that the FDA had accepted its sNDA for filing and held a conference call. (FAC ¶ 121.)

L. Additional Public Statements

On August 19, 2020, Acadia presented at the JMP Securities CNS Forum. (FAC ¶ 125; ECF No. 200-8 at 106–113.) During the event, Davis stated:

> [O]ne of the things we hear very consistently among KOLs, just physicians generally is the—and as we've said before, the "subtypes" of dementia are very difficult to diagnose. They overlap many times. And so it's a little bit of an artificial distinction to say someone has Alzheimers, dementia with Lewy bodies or vascular dementia, et cetera.
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> And so—and one of the advantages, of course, pursuing dementia-related psychosis broadly, which is just, as a reminder, we got a clear agreement from—with the FDA at our end of Phase II meeting, and we executed the plan that we agreed to with them.

(ECF No. 200-8 at 111.)

On September 14, 2020, Acadia presented at the Morgan Stanley Global Healthcare Conference. (FAC ¶ 128.) Stankovic stated that "[w]e continue to be very confident, as I said, in our data. It's very consistent with what we've been finding as we have been adding

the new information, both in terms of efficacy and safety. We have a strong package and are currently focusing on facilitating review toward approval." (ECF No. 200-8 at 121.)

On November 4, 2020, Acadia held its third quarter of 2020 earnings call. (ECF No. 200-8 at 125–45.) Davis stated: "We are confident in both the efficacy and safety data supporting our supplemental NDA and we will continue to work with the FDA to facilitate their review. . ." *Id.* at 129.

On November 17, 2020, Acadia presented at the Stifel Healthcare Conference. (FAC ¶ 132.) Davis stated:

> So let me just start by saying we remain highly confident in both the efficacy and safety data supporting our submission. And of course, at this point, we're focused on facilitating the FDA's review, which, as I mentioned, remains on track. And just as a brief reminder, our sNDA submission included an efficacy package, which was agreed upon with the FDA at the end of Phase II meetings before we conducted the pivotal HARMONY study. And based upon the robust and meaningful results from HARMONY and the additional supporting data from other efficacy studies in Alzheimer's and Parkinson's patients, and then just the overall safety profile of pimavanserin, we remain very confident in the potential approval for DRP. . . .
>
> One thing that I didn't mention is that in the Phase II meeting we had setting up our Phase III program that we then executed, is in addition to those 3 points, we also just asked FDA very specifically. We said we just want to make certain that you are on board with approving a drug to treat dementia-related psychosis. . . . We're following the same path that we did in the PDP review and that most companies do when they're in registration, that is, we're not going to comment on the specific back and forth that we're having with FDA.

(ECF No. 200-8 at 149.)

On January 12, 2021, Acadia presented at the J.P. Morgan Healthcare Conference. (FAC ¶ 134.) Davis stated that he was "pleased to report that our sNDA submission is progressing well and as we would expect at this point in the review cycle." (ECF No. 200-8 at 160.) Davis also stated:

> [W]e're not looking at individual subtypes as they are often referred to of dementia. The psychosis that we see is very similar between the—irrespective

> of the underlying etiology and it responds in a similar way. So we're seeking that broad indication. That's supported by a very both [*sic*] alignment we established with the FDA at our end of Phase II meeting and then again at their pre-sNDA meeting when we submitted our application.

Id. at 162.

M. Deficiency Letter from the FDA

On March 3, 2021, the FDA sent a letter (the "Deficiency Letter") to Acadia stating that the FDA had "identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time," but that the Deficiency Letter "does not reflect a final decision on the information under review." (ECF No 200-4 at 435–438.)

After receiving the Deficiency Letter, Acadia contacted the FDA to request information about the deficiencies the FDA had identified with its sNDA. (ECF No. 200-4 at 440–43.) The FDA did not explain the deficiencies it identified in the sNDA at that time. *Id.* at 441.

On March 8, 2021, Acadia announced its receipt of the Deficiency Letter. (FAC ¶ 143.) Investment analysts expressed surprise at the issuance of the Deficiency Letter. (*See* DUF ¶ 111.)

On March 9, 2021, Acadia's stock price fell $20.76 per share and closed at $25.02 per share. (FAC ¶ 144.)

N. Complete Response Letter from the FDA

On April 2, 2021, the FDA sent a complete response letter (the "CRL") to Acadia regarding its sNDA. (ECF No. 200-4 at 444–450 ("CRL Ex.").)

The CRL stated:

> We have concluded that [Acadia's] sNDA submission does not provide substantial evidence of effectiveness to support the approval of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis.
>
> Although [the Harmony Study] was not powered to demonstrate an effect in the subgroups of dementia included, we had advised you during development

> that labeling would reflect the actual composition and response of the subjects enrolled in the trial.

(CRL Ex. at 445.)

The CRL explained that the FDA chose to deny the sNDA because: (1) the dementia with Lewy bodies and frontotemporal dementia subgroups contained "too few subjects to be an adequate representation of the response to pimavanserin for either dementia subtype"; (2) the vascular dementia subgroup results did not reflect a "numeric difference on time-to-relapse between pimavanserin and placebo," in addition to having "a relatively small group of 24 subjects"; (3) the Alzheimer's disease subgroup results "were not nominally significant"; and (4) the Parkinson's disease dementia subgroup "was highly nominally statistically significant" and appeared to be "driving the overall study results." *Id.* at 445–46.

The CRL also stated that the FDA did not consider the 019 Study to be "adequate and well controlled," and thus could not "contribute to a finding of substantial evidence of effectiveness for pimavanserin in the treatment of hallucinations and delusions associated with AD psychosis." *Id.* at 446.

The CRL concluded: "In summary, the results of the three submitted studies do not support expanding the indicated population. The findings from [the Harmony Study] suggest a differential response to pimavanserin across dementia subtypes, which questions whether 'dementia-related psychosis' is a useful construct for a potential indication for pimavanserin." *Id.*

On April 5, 2021, Acadia announced its receipt of the CRL. (FAC ¶ 145.) Acadia's closing stock price declined from $25.59 on April 1, 2021 to $21.18 on April 5, 2021. *Id.* ¶ 146.

O. Defendants' Stock Sales

On August 22, 2019, Davis entered into a stock sale plan regarding his ownership of Acadia stock. (ECF No. 204-73.) On December 19, 2019, Davis entered into another stock sale plan. (ECF No. 204-78.) During the Class Period, Davis sold approximately 530,392

shares of Acadia common stock in the amount of approximately $24.6 million. (ECF No. 204-72.)

On November 8, 2019, Stankovic also entered into a stock sale plan regarding his ownership of Acadia stock. (ECF No. 204-75.) During the Class Period, Stankovic sold approximately 368,993 shares of Acadia common stock in the amount of approximately $18.9 million. (ECF No. 204-74; *see also* ECF No. 200-15 at 2462 (Stankovic testifying that he was "not sure that [he] had sold any stock in Acadia before this").)

III. LEGAL STANDARD

A. Exclusion of Expert Testimony

Federal Rule of Evidence 702 provides that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702.

A district court is tasked with acting as a gatekeeper to "ensur[e] that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 148 (1999) (applying this principle to "all experts, not just to 'scientific' ones"). "Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010), *as amended* (Apr. 27, 2010) (quoting *United States v. Sandoval-Mendoza*, 472 F.3d 645, 654 (9th Cir. 2006)). "To evaluate reliability, the district court 'must assess the expert's reasoning or methodology, using as appropriate criteria such as testability, publication in peer-reviewed literature, known or potential error rate, and

general acceptance.'" *Elosu v. Middlefork Ranch Inc.*, 26 F.4th 1017, 1024 (9th Cir. 2022) (quoting *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014)). "These factors are nonexclusive, and the trial court has discretion to decide how to test an expert's reliability based on the particular circumstances of the particular case." *Id.* (citations and quotations omitted).

The proponent of an expert bears the "burden of proving admissibility." *Lust ex rel. Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). An expert's use of peer-reviewed methodologies and the development of his opinion "outside the litigation" are typically "guarantees of reliability" and, in their absence, an expert must "must explain precisely how he went about reaching his conclusions and point to some objective source . . . to show that he has followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in his field." *Id.* at 597 (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318–19 (9th Cir. 1995) (*Daubert II*)).

The Ninth Circuit describes the district court's inquiry into the admissibility of expert testimony as a "flexible" one. *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013). "Basically, the judge is supposed to screen the jury from unreliable nonsense opinions, but not exclude opinions merely because they are impeachable. The district court is not tasked with deciding whether the expert is right or wrong, just whether his testimony has substance such that it would be helpful to a jury." *Id.* at 969–70. "Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." *Primiano*, 598 F.3d at 564. When "credible, qualified experts disagree," it is the "jury, not the judge" that decides whether a party has proved its case. *Sandoval-Mendoza*, 472 F.3d at 654.

B. Summary Judgment

"A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense—on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P.

56(a). "A material fact is one that is relevant to an element of a claim or defense, and whose existence might affect the outcome of the case." *See United States v. Grayson*, 879 F.2d 620, 622 (9th Cir. 1989) (citation omitted). The materiality of a fact is determined by the substantive law governing the claim or defense. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–24 (1986).

The moving party has the initial burden of demonstrating that summary judgment is proper. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 153 (1970). Where the party moving for summary judgment bears the burden of proof at trial, the moving party "must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial." *Houghton v. South*, 965 F.2d 1532, 1536 (9th Cir. 1992). Where the party moving for summary judgment does not bear the burden of proof at trial, "the burden on the moving party may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp.*, 477 U.S. at 325; *see also United Steelworkers of Am. v. Phelps Dodge Corp.*, 865 F.2d 1539, 1542–43 (9th Cir. 1989) ("[O]n an issue where the plaintiff has the burden of proof, the defendant may move for summary judgment by pointing to the absence of facts to support the plaintiff's claim. The defendant is not required to produce evidence showing the absence of a genuine issue of material fact with respect to an issue where the plaintiff has the burden of proof. Nor does Rule 56(c) require that the moving party support its motion with affidavits or other similar materials *negating* the nonmoving party's claim." (citations and quotations omitted)).

If the moving party meets the initial burden, the burden shifts to the opposing party to show that summary judgment is not appropriate. *Anderson*, 477 U.S. at 256; *Celotex Corp.*, 477 U.S. at 322, 324. The nonmoving party cannot defeat summary judgment merely by demonstrating "that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *see also Anderson*, 477 U.S. at 252 ("The mere existence of a scintilla of evidence in support of the [nonmoving party's] position will be insufficient[.]"). The nonmoving party must "go

beyond the pleadings and by [his] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Celotex Corp.*, 477 U.S. at 324 (quotations omitted). The nonmoving party's evidence "is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson*, 477 U.S. at 255. However, "'[w]here the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial,' and summary judgment is appropriate." *Zetwick v. County of Yolo*, 850 F.3d 436, 441 (9th Cir. 2017) (quoting *Ricci v. DeStefano*, 557 U.S. 557, 586 (2009)).

IV. MOTIONS TO EXCLUDE EXPERT TESTIMONY

At this stage of the proceedings, Plaintiffs' Motion to Exclude Expert Testimony (ECF No. 197) is denied without prejudice because the Court need not determine whether to exclude the testimony of Defendants' rebuttal experts Dr. Breder, Dr. Porsteinsson, and Dr. Lehn to adjudicate the pending Motion for Summary Judgment (ECF No. 199). Plaintiffs may raise contentions regarding the admissibility of Defendants' rebuttal expert witnesses at the motions in limine stage.

The Court considers only the Motion to Exclude Expert Testimony filed by Defendants (ECF No. 198) as it pertains to Defendants' Motion for Summary Judgment (ECF No. 199). In their motion, Defendants move to exclude the expert testimony of: (1) Dr. Carl Peck, a former FDA official retained by Plaintiffs to offer an opinion on the FDA's consideration and approval of drug applications and communications with pharmaceutical companies and (2) Dr. Steven Feinstein, an economist retained by Plaintiffs regarding the issues of loss causation, materiality, and damages. (ECF No. 198-1 at 8; ECF No. 206 at 12.)

A. Dr. Carl Peck

The Expert Report of Carl C. Peck, M.D. (the "Peck Report") states that Dr. Peck has been retained to "prepare a report setting forth whether, and to what extent, [he] could and would adopt the Expert Report of David W. Feigal Jr., M.D., MP.H." (Exhibit 3, Peter

M. Adams Decl. in Support of Defendants' Motion to Exclude Expert Testimony, ECF No. 198-5 at 8 (the "Peck Rpt.").)

Plaintiffs previously designated Dr. David Feigal as an expert on matters related to the FDA but, on June 7, 2025, filed an Ex Parte Motion to Substitute Expert because Dr. Feigal indicated that he would no longer be "available for anything further in this case." (ECF No. 179-1 at 3.) On August 5, 2025, Magistrate Judge Berg granted the Plaintiffs' motion after briefing and multiple teleconferences on the condition that "the substitute expert fully adopts the previous report and does not review any deposition transcripts or expert reports prior to joining the case." (ECF No. 187; *see also Park v. CAS Enters., Inc.*, No. CIV. 08CV385DMSNLS, 2009 WL 4057888, at *4 (S.D. Cal. Nov. 19, 2009) (permitting the substitution of an expert witness on the condition that the new expert "adopt the initial and rebuttal expert reports" of the previous expert "in their entirety").)

Dr. Peck offers testimony in which he "adopt[s] the Feigal Report (including the opinions set forth therein) in full." (Peck Rpt. at 9.) The Peck Report attaches the Expert Report of Dr. Feigal. *Id.* at 46–153. For the purposes of this Order, the Court considers the testimony in Dr. Feigal's Report to be part of Dr. Peck's Report and refers to the analysis and conclusions therein as Dr. Peck's own.

Dr. Peck served as the Director of the Center for Drug Evaluation and Research at the FDA and the Founding Director of the Center for Drug Development Science at Georgetown University. (Peck Rpt. ¶¶ 4–11.) Dr. Peck also founded a consulting company that provides "scientific and regulatory advice" to large pharmaceutical companies and government agencies. *Id.* The "Analysis" section of the Peck Report has three sections: (1) "The Meaning and Significance of Acadia's Communications with FDA," (2) "Acadia's Probability of Success for the sNDA," and (3) "What Senior Management of a Reasonable Drug Manufacturer Would Have Understood About the Company's Communications with FDA and the Probability of Success for the DRP sNDA." *Id.* at 85–100.

In the "Probability of Success" section of his Report, Dr. Peck testifies that he has often been asked to assess the "probability of successfully obtaining FDA approval of a

new indication" in his roles as a "pharmaceutical company executive and as a consultant." *Id.* at 95. Dr. Peck testifies that assessments about the probability of success require consideration of "industry-wide analysis of successful drug approvals combined with the specific facts of the indication being sought." *Id.* Dr. Peck testifies that the "probability of successfully obtaining FDA approval for a new DRP indication" of pimavanserin after the initiation of the Harmony Study—but prior to release of its results—was 50%. *Id.* at 97. Dr. Peck describes subsequent events, including the early termination of the Harmony Study and the release of "Harmony's subgroup efficacy results" in November 2019, and assigned a probability of success for Acadia's sNDA at various stages. *Id.* at 97–99.

In the "Reasonable Drug Manufacturer" section of his Report, Dr. Peck offers three paragraphs of testimony about how "a reasonable drug developer in the same situation as Acadia would have understood the relevant communications with FDA" and how "a reasonable drug developer would have assessed the probability of successfully obtaining FDA approval of the new DRP indication." *Id.* at 99–100.

Defendants contend that Dr. Peck's opinions regarding the probability of successful FDA approval of the sNDA and the state of mind of Acadia's senior management are "so methodologically flawed and unreliable that exclusion is the only adequate remedy." (ECF No. 198-1 at 9.) Defendants move to exclude Dr. Peck's report on the basis that (1) he fails to employ a "sound methodology" in his probability of success analysis; and (2) he offers "hopelessly arbitrary and speculative" opinions regarding the state of mind of pharmaceutical executives. *Id.* at 14.

1. Probability of Success

Defendants contend that Dr. Peck's opinions regarding the probability of success for Acadia's sNDA should be excluded because they are based on an "unreliable methodology" and "irrelevant source data." (ECF No. 198-1 at 15–23.) Defendants contend that the "aggregate success rates" that Dr. Peck uses as benchmarks in his analysis are unsupported by the documents that he claims to rely upon. *Id.* at 16–17. Defendants

contend that this failure renders Dr. Peck's "base-case" calculations "unreliable and irrelevant." *Id.* at 17–18.

Plaintiffs contend, in response, that Dr. Peck's analysis is "rooted in his deep experience, combined with relevant literature and case-specific facts." (ECF No. 206 at 18.) Plaintiffs contend that Dr. Peck relied on specific documents, including the "Tufts Center for the Study of Drug Development and summary level data published in the medical literature, including in the Kaitin & DiMasi articles." *Id.* at 17 n.6. Plaintiffs also contend that Defendants "misconstrue Dr. Peck's approach" by seeking a rigorous statistical methodology, whereas Dr. Peck's conclusions are based on his knowledge and expertise, which is a reliable and widely used approach to assessing the likelihood of success in pharmaceutical trials. *Id.* at 18–21. Plaintiffs also contend that Defendants' arguments go to the weight of Dr. Peck's testimony rather than its admissibility. *Id.* at 22–25.

The "*Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable to . . . testimony [] whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000) (citations omitted); *see Vanguard Logistics Servs. (USA) Inc. v. Groupage Servs. of New England, LLC*, No. CV180517DSFGJSX, 2022 WL 17369626, at *3 (C.D. Cal. Oct. 4, 2022) (holding that an expert on shipping logistics offered opinions that were "reliable based on his knowledge and experience, and he need not have used a particular methodology in arriving at his conclusions").

Dr. Peck states that his probability of success estimates are based on his experience at the FDA, his review of communications between Acadia and the FDA, and his assessment of the actual clinical data from Acadia's trials, in addition to published studies regarding the statistical likelihood of success during the regulatory process. (Peck Rpt. at 54–55.) Defendants' contention that Dr. Peck fails to employ a "generally accepted methodology" is unavailing because his analysis relies substantially on his experience in the relevant field. *See Holley v. Gilead Sciences, Inc.*, No. 18-CV-06972-JST, 2023 WL

2469632, at *2 (N.D. Cal. Feb. 27, 2023) (denying a motion to exclude the testimony of "an expert in FDA regulatory affairs" for failure to use a reliable methodology because his testimony was "reliable based on his knowledge and experience") (quoting *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1018 (9th Cir. 2004)); *see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503, 2018 WL 734655, at *6 (D. Mass. Feb. 6, 2018) (holding that an expert possessed the "requisite experience to offer an admissible opinion on probability of successfully developing" a prescription drug).

Dr. Peck adequately establishes that experts in the field rely on their experience and information from previous drug applications when determining the probability of success for new drug applications. (Peck Rpt. ¶ 149 ("I have been asked many times to assess the probability of successfully obtaining FDA approval of a new indication. Such assessments turn [*sic*] data from industry-wide analysis of successful drug approvals combined with the specific facts of the indication being sought, like the scientific data supporting the indication and the sponsor's interactions with FDA.").) Dr. Peck is qualified to offer an opinion regarding the likelihood of success regarding the FDA's approval of drug applications based on his experience as a Director for the Center of Drug Evaluation and Research at the FDA for twenty-six years, his related experiences in the private sector, and his discussion of "aggregate success rate[s]." *Id.* ¶¶ 4, 152–55.

An expert opinion may be deemed "unreliable where the opinion is based on data, a methodology, or studies that are inadequate to support the conclusions reached." *Hufnagel v. McGraw-Hill Cos., Inc.*, No. 2:12-CV-0579-SAB, 2014 WL 12527209, at *4 (E.D. Wash. July 24, 2014) (citation omitted); *see Klein v. Meta Platforms, Inc.*, 766 F. Supp. 3d 956, 961 (N.D. Cal. 2025) ("[T]rial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable.") (quotation omitted). Here, the purported discrepancies between Dr. Peck's estimates for the probability of success at various phases of the

regulatory approval process, *see, e.g.*, Peck Rpt. ¶ 96, and the literature cited in his Report, *see, e.g.*, ECF No. 198-1 at 17, are not so significant as to render his opinion unreliable.

Defendants' citation to *Pascal v. Nissan N. Am., Inc.*, in which the Central District of California excluded the testimony of an expert witness whose opinion "rel[ied] on and assume[d] the validity of" another expert's opinion that the district court held to be unreliable, is unavailing. No. 8:20-cv-00492-JLS-JDE, 2022 WL 19076763, at *17 (C.D. Cal. Dec. 21, 2022); *see id.* at *16 (explaining the "domino effect" that may occur when "a litigant proffers expert witnesses whose testimony is based on the conclusions of a single, foundational expert" that is excluded). Dr. Peck does not base his opinion on the excluded testimony of another expert witness, nor does he arrive at his conclusions without explanation or base his opinion on data inadequate to support his conclusions. Defendants' contentions regarding the fit between statistical analyses cited in the Peck Report and Dr. Peck's estimates go to the weight, rather than the admissibility, of his testimony. *See Aslan v. Ferrari N. Am., Inc.*, No. 2:16-CV-02574-AB-SS, 2018 WL 6321635, at *1 (C.D. Cal. Oct. 19, 2018) (stating that "certain weaknesses" in an expert's report "do not require exclusion; instead, they are proper topics for cross-examination").

The Court concludes that Plaintiffs have adequately shown the reliability of Dr. Peck's probability of success opinions such that they are admissible.

2. State of Mind

Defendants contend that Dr. Peck's analysis regarding pharmaceutical executives' states of mind, *see* Peck Rpt. § V.C, should be excluded because the testimony is unreliable and intrudes on the "jury's role as fact finder on the element of scienter." (ECF No. 198-1 at 23–26.) Plaintiffs respond that Dr. Peck's analysis reasonably relies on his extensive experience with "more than 500 new drug applications," and does not offer an conclusions on the ultimate issue of scienter. (ECF No. 206 at 26.)

Experts may not testify as to the "'intent, motives, or states of mind of corporations, regulatory agencies and others' because '[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony.'" *Holley*, 2023 WL 2469632, at *2.

(quoting *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004)). An expert may apply their knowledge to offer an opinion related to an ultimate issue; however, the expert may not usurp the role of the jury by reaching a legal conclusion such as, in this case, whether Defendants acted with scienter. *See* Fed. R. Evid. 704(a) ("An opinion is not objectionable just because it embraces an ultimate issue."); *Hangarter*, 373 F.3d at 1016–17 (holding that the district court did not abuse its discretion in admitting expert testimony that the defendants "deviated from industry standards," which "supported a finding that they acted in bad faith").

District courts have permitted expert witnesses to testify as to information that reasonable pharmaceutical executives would consider but have precluded experts from offering testimony regarding those executives' states of mind and, similarly, from offering an opinion that purports to decide an ultimate legal issue. In *Holley v. Gilead Sciences, Inc.*, for example, the court did not permit an expert in a failure-to-warn case to offer testimony that a "reasonable pharmaceutical company" would have acted differently than the defendant company because the expert's opinion was "equivalent to opining that [the defendant] did not act reasonably." 2023 WL 2469632, at *5. In *United Food and Commercial Workers Local 1776*, the court allowed an expert to testify as to the "factors [that] a reasonable pharmaceutical executive considers when deciding whether to launch a product 'at-risk,'" "why a reasonable pharmaceutical executive considers those factors," and how the applications of those factors to the facts of that case "would have made a reasonable pharmaceutical executive less likely" to launch the subject product. *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1180–81 (N.D. Cal. 2017); *see also Homyk v. ChemoCentryx, Inc.*, No. 21-CV-03343-JST, 2025 WL 1547625, at *11 (N.D. Cal. May 30, 2025) (allowing an expert to testify about the "meaning and significance of [] safety data" but not what the defendants actually knew because that testimony goes to "state of mind and invades upon the province of factual determinations that the jury can make").

To the extent that Plaintiffs offer Dr. Peck's testimony to show what Defendants thought at a particular time, including whether Defendants understood directional consistency across dementia subtypes in the Harmony Study to be a condition of FDA approval or whether they believed that the Harmony Study was adequate to support their sNDA, that testimony improperly invades the province of the jury and is not admissible. Cloaking such testimony as analysis of the thoughts and beliefs of a "reasonable drug developer" does not change this holding. However, Dr. Peck may properly offer testimony regarding the information considered by pharmaceutical executives during the clinical trial process for new drug indications, the information typically contained in communications with the FDA, and how a reasonable pharmaceutical executive might apply such information to make decisions.

Defendants' motion to exclude the expert testimony of Dr. Carl Peck is granted in part and denied in part as discussed above. This ruling is without prejudice as to any *Daubert* motion filed in advance of trial and as to objections to specific testimony offered by Dr. Peck at trial.

B. Dr. Steven Feinstein

The Report on Loss Causation and Damages of Professor Steven P. Feinstein, Ph.D., CFA (the "Feinstein Report") offers testimony regarding the economic effects of Defendants' alleged misstatements. (Exhibit 12 to Adam M. Peters Decl. in Support of Defendants' Motion to Exclude Expert Testimony, ECF No. 198-14 ("Feinstein Rpt.").)

Dr. Feinstein concludes, in relevant part:

> Based on the financial and econometric analysis presented in this report and in the Opening Feinstein Report, and based on the assumption that Plaintiffs will prove their factual allegations, I conclude that Defendants' alleged misrepresentations and omissions caused [the Class Members] to suffer losses on [their] purchases [of Acadia common stock], including damages that are recoverable under Section 10(b). Those Class [M]embers suffered losses that they would not have suffered had the Company not made the alleged misrepresentations and omissions. . . . I further conclude that for each Class member the damages caused by the alleged misrepresentations and omissions range up to $22.43 per share, depending on (a) the timing of when during the

> Class Period the respective Class [M]ember purchased Acadia shares, and (b) if and when that Class [M]ember subsequently sold those shares.

Id. ¶¶ 24–25.

Dr. Feinstein conducts his analysis by reviewing changes in the "market's average assessed" probability of success for the sNDA based on public materials, like investment analyst reports, and changes in Acadia's stock price following Defendants' public statements. *Id.* ¶ 30. Dr. Feinstein utilizes Dr. Peck's probability of success analysis to determine which portions of the increases in stock price are attributable to Defendants' alleged misstatements and/or omissions. *Id.* Dr. Feinstein uses "event studies," which "can determine if the subject security price rose when (and because) inflationary representations were made, and fell when (and because) corrective events occurred." *Id.* ¶ 199. In his Report, Dr. Feinstein also describes his qualifications, including a Ph.D. in economics from Yale University, a tenured position as an Associate Professor of Finance at Babson College, publications in the field of finance, and ownership of a financial consulting firm. *Id.* ¶¶ 9–20.

Defendants move to exclude Dr. Feinstein's testimony on the basis that "(1) his loss causation analysis is unreliable; (2) his calculation of artificial inflation on September 9, 2019 is unreliable, and (3) his calculation of artificial inflation on December 5, 2019 is unreliable." (ECF No. 198-1 at 9–10, 31.) After the Court held a Motion Hearing (ECF No. 216), Defendants filed Supplemental Briefing regarding a recent order from the Eastern District of New York, in which Dr. Feinstein's loss causation testimony was excluded. (*See* ECF No. 222 (citing *In re Vale S.A. Sec. Litig.*, 19-CV-526 (EK)(VMS), 2026 WL 1002335 (E.D.N.Y. Apr. 13, 2026).)

1. Loss Causation

Defendants contend that Dr. Feinstein's analysis "assumes the very element [of loss causation] that he was asked to prove" and fails to "disaggregate the losses, if any, caused by the disclosure of fraud-related and non-fraud related information." (ECF. No. 198-1 at 32–37.) Plaintiffs respond that Dr. Feinstein conducted an adequate analysis of loss

causation based on "basic financial principles, examination of Defendants' public statements, review of analyst commentary, and an empirical event study analysis." (ECF No. 206 at 31.)

Event studies are "routinely accepted by courts in securities fraud cases as a means by which to conduct loss causation analyses." *In re Twitter, Inc. Sec. Litig.*, No. 16-cv-05314-JST, 2020 WL 13863616, at *9 (N.D. Cal. Jan. 28, 2020) (citing *Mauss v. NuVasive, Inc.*, No. 13cv2005 JM (JLB), 2018 WL 656036, at *5 (S.D. Cal. 2018)); *see also In re Groupon, Inc. Sec. Litig.*, No. 12 C 2450, 2015 WL 1043321 (N.D. Ill. Mar. 5, 2015) (holding that Dr. Feinstein's event study analysis "met *Daubert*'s exacting standards"), *objections overruled,* 2015 WL 13628131 (N.D. Ill. May 12, 2015). Defendants' claim that Dr. Feinstein "simply assume[s]" causation is not supported by the record. The Feinstein Report describes the event studies, including *t*-tests conducted to determine whether the information released immediately prior to changes in Acadia's stock price had a statistically significant effect that could not be attributed to broader trends in the market or random volatility. Feinstein Rpt. ¶ 227; *see In re Twitter*, 2020 WL 13863616, at *9 (rejecting an argument that Dr. Feinstein "assume[d] the casual connections he purports to prove" because Dr. Feinstein "conducted event study analyses, *t*-Tests, F-Tests, and Ansari-Bradley tests before reaching his conclusion"). Defendants' citation to *In re Oracle Corp. Securities Litigation*, in which the district court excluded an expert's conclusion because he "assumes what he sets out to prove" is inapposite. *See In re Oracle Corp. Sec. Litig.*, No. C 01–00988 SI, 2009 WL 1709050, at *28 (N.D. Cal. June 19, 2009), *aff'd sub nom. In re Oracle Corp. Sec. Litig.*, 627 F.3d 376 (9th Cir. 2010). In this case, Dr. Feinstein's analysis was purportedly designed to answer the question of whether Defendants' alleged misstatements had a discernible impact on changes in Acadia's stock price. Dr. Feinstein's treatment of Plaintiffs' allegations as true for the purposes of his report does not erroneously assume a desired conclusion about loss causation.

A loss causation expert's analysis may be unreliable if that expert fails to consider factors other than a defendant's alleged misstatements that might have contributed to changes in the company's stock price. *See, e.g.*, *In re Twitter*, 2020 WL 13863616, at *9 (declining to exclude Dr. Feinstein's testimony on the basis that he ignored confounding variables because Dr. Feinstein "testified that he considered several of the potentially-confounding variables identified by [the defendants]"); *S.E.C. v. Leslie*, No. C 07-3444, 2010 WL 2991038, at *15 (N.D. Cal. July 29, 2010), *clarified on denial of reconsideration,* No. 5:07-CV-03444-JF, 2010 WL 3259375 (N.D. Cal. Aug. 18, 2010) (declining to exclude an expert on the basis that he "did not reliably filter out other confounding variables" that affected a company's stock price). Here, Dr. Feinstein states that his analysis considered "confounding information": public statements or news about Acadia that issued at or around the same time as Defendants' alleged misstatements and might have contributed to the decline in Acadia's stock price. (Feinstein Rpt. ¶¶ 235–36, 241–42.) Plaintiffs have adequately shown that Dr. Feinstein separated the allegedly misleading statements from other, unrelated news that affected Acadia's stock price during the same day.

Defendants' citation to *Struogo v. Tivity Health, Inc.* is unavailing. No. 3:20-CV-00165, 2025 WL 1415896 (M.D. Tenn. May 15, 2025). In that securities case concerning a defendant company's acquisition of another company, the district court excluded an expert's opinion regarding loss causation because the expert's event study "ma[de] no *attempt* to separate the varying purported causes of [the defendant company's] stock drop included in the [c]orrective [d]isclosure . . . to determine whether some, all, or none of that information was attributable to Defendants' fraud." *Id.* at *1, *5 (emphasis added). Here, by contrast, Dr. Feinstein's loss causation analysis expressly considers whether confounding information could have impacted Acadia's stock drop. The question of whether his analysis adequately assesses that information is an appropriate subject for cross-examination, but it is insufficient to exclude his opinion at the summary judgment stage.

2. Artificial Inflation on September 9, 2019

The Feinstein Report describes an event study analysis for September 9, 2019, which identifies a stock price increase of $15.40 per share related to Defendants' "announcement of the Harmony Study top-line results and accompanying statements." (Feinstein Rpt. ¶¶ 229–33.) Dr. Feinstein concludes that "32.56% of the $15.40 stock price increase" is attributable to Defendants' alleged misrepresentations and/or omissions. *Id.* ¶ 31.

Defendants contend that Dr. Feinstein's analysis regarding the events on September 9, 2019, is unreliable because he (1) unreasonably relies on probability of success opinions from the Peck Report and (2) fails to "measure and account for obvious error." (ECF No. 198-1 at 37–43.) Plaintiffs respond that Dr. Peck's probability of success estimates are reliable and that Dr. Feinstein's artificial inflation methodology is capable of accounting for "whatever [probability of success] figure that the jury ultimately finds is the best estimate of the true but-for [probability of success] number following the news" of September 9, 2019. (ECF No. 206 at 42–43.) In other words, Plaintiffs contend that a dispute regarding an input into Dr. Feinstein's analysis would not render his analysis unreliable. *Id.* at 44. Plaintiffs also contend that analysis of error rates is not customary "in the context of assessing" estimates from "Wall Street analysts." *Id.* at 46–47.

Expert witnesses may rely on each other's analyses if a court holds that each expert independently satisfies the requisite indicia of reliability. *See Pascal*, 2022 WL 19076763, at *16 ("[E]xperts may rely on one another, but they may only do so if the requisite standards for reliability are met each step of the way. If one expert's opinions are built upon a foundation laid by another, reliability of the latter requires reliability of the former.") (quoting *In re M/V MSC FLAMINIA*, No. 12-cv-8892 (KBF), 2017 WL 3208598, at *5 (S.D.N.Y. July 28, 2017)). Dr. Feinstein reviews and applies Dr. Peck's testimony regarding how the market would have assessed the probability of success for sNDA approval but for the publication of allegedly misleading information. By comparing the market's evident perception of the probability of success following publication of the allegedly misleading information to the change in "true [probability of success]" described

in the Peck Report, Dr. Feinstein reduces the corresponding change in Acadia's stock price on September 9, 2019, to account for only the increase that is "attributable to the alleged misrepresentations and omissions." (Feinstein Rpt. ¶ 31.) The Court has declined to exclude the Peck Report on the basis of reliability. Accordingly, there is no reason to find that Dr. Feinstein's artificial inflation methodology—which relies on Dr. Peck's testimony—is unreliable because it utilizes Dr. Peck's analysis.

Assessing the reliability of an expert's opinion may require consideration of "whether the known or potential rate of error is acceptable." *Daubert II*, 43 F.3d at 1316–17 (describing this factor and others as "illustrative rather than exhaustive") (citing *Daubert*, 509 U.S. at 591–95). Consideration of error rates is not "equally applicable (or applicable at all) in every case." *Id.* at 1317. Here, Dr. Feinstein's use of specific estimates, rather than intervals, for various probability of success calculations does not render his opinion unreliable. This case is distinguishable from Defendants' cited cases.[3] Dr. Feinstein substantiates his report with analysis that considers the statistical significance of alleged misstatements, the market's perception of the probability of success, and Acadia's stock price, in addition to a regression analysis. (Feinstein Rpt. ¶¶ 223–26; *see id.* at Exhibit 6.)

3. Artificial Inflation on December 5, 2019

The Feinstein Report also describes an event study analysis for December 5, 2019, that identifies a stock price increase of $7.03 per share related to Defendants' release of "more results from the Harmony Study, including some subgroup efficacy data," which

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[3] *See Grupo Televisa, S.A. v. Telemundo Commc'ns Grp., Inc.*, No. 04-20073-CIV, 2005 WL 5955701, at *3–*6 (S.D. Fla. Aug. 17, 2005) (excluding an expert that used "unreliable" information sourced from a "telenovea fan website" whose creators "disclaim[ed] any responsibility for the accuracy of the information"); *CCM Rochester, Inc. v. Federated Invs., Inc.*, No. 14-CV-3600 (VEC), 2016 WL 11617452, at *1–*5 (S.D.N.Y. Aug. 31, 2016) (excluding an expert that compared "net cash flow" between two types of investment funds because the opinion assumed that "investment advisers' efforts or lack thereof, and not any other variable, determined the relative allocation of new funds" but failed to employ a regression analysis to "demonstrate that there is any correlation" between those variables).

Plaintiffs contend misrepresented the FDA's communications regarding data that would be adequate to approve the sNDA. (Feinstein Rpt. ¶¶ 234–38.) Dr. Feinstein concludes that "[a]ll of this residual stock price increase was artificial inflation." *Id.* ¶ 34.

Defendants contend that Dr. Feinstein's analysis regarding December 5, 2019, is unreliable because (1) he "abandons his [probability of success] comparison methodology" and (2) he "fails to disentangle the fraud-related and non-fraud-related impacts on Acadia's stock price." (ECF No. 198-1 at 43–48.) Plaintiffs respond that Dr. Feinstein used the same methodologies as above to analyze the disclosures on December 5, 2019, and that the only relevant difference was that Dr. Feinstein included a disaggregation analysis in reviewing the events on September 9, 2019, because non-fraudulent news had also been disclosed. (ECF No. 206 at 50–51.) Plaintiffs also contend that Dr. Feinstein "found it unnecessary" to disentangle the information disclosed on December 5, 2019, because it was "all sNDA-related and relevant to the market's [probability of success] assessment." *Id.* at 53.

In their Supplemental Brief, Defendants contend that Dr. Feinstein incorrectly assumes that, if Acadia had made allegedly truthful disclosures regarding the FDA's requirements for dementia subtype results prior to December 5, 2019, "investors would have expected the absolute worst." (ECF No. 222 at 4.) Defendants contend that a worst-case-scenario assumption is unwarranted because of the "inherently subjective process of evaluating clinical trial data." *Id.* Plaintiffs respond that Dr. Feinstein does not assume that the public would have assumed the worst (i.e., that the sNDA would have been rejected) and, instead, based his analysis on the "implications" of Plaintiffs' allegations. (ECF No. 223 at 2–3.)

An expert witness's "failure to consistently apply his methodology" may call into question the reliability of the expert's opinions. *In re Ephedra Prods. Liab. Litig.*, 494 F. Supp. 2d 256, 258 (S.D.N.Y. 2007); *see also GPNE Corp. v. Apple, Inc.*, No. 12-CV-02885-LHK, 2014 WL 1494247, at *4 (N.D. Cal. Apr. 16, 2014) ("Experts must follow some discernable methodology . . ."). Here, there is no indication that Dr. Feinstein employed a different methodology in analyzing the events on December 5, 2019, as

compared to September 9, 2019. Dr. Feinstein states that, compared to the other event study, the entirety of the stock increase on December 5, 2019 was attributable to alleged misstatements because "[b]ut for the alleged misrepresentations . . . Defendants' statements and release of data on [the preceding evening] would have informed the market that no new optimism for FDA approval was warranted." (Feinstein Rpt. ¶ 34.) Plaintiffs have adequately shown that the difference in the event studies does not result from Dr. Feinstein applying his methodology inconsistently, but, instead, Dr. Feinstein making a different assumption about the public statements made on each date.

Defendants' contention that Dr. Feinstein failed to disaggregate fraud-related and non-fraud-related information in his review of the events on December 5, 2019 does not justify exclusion, for the same reason. The Feinstein Report states:

> While the additional Harmony Study results that were disclosed on [the evening of] 4 December 2019 (including certain subgroup efficacy data) may have been presented accurately, by themselves those results would not have warranted the dramatic stock price increase prompted by the Defendants' 4 December 2019 disclosures absent (a) the allegedly false and misleading aspects of those disclosures, which reiterated that Harmony's efficacy results met all the FDA's requirements, and (b) the allegedly false and misleading aspects of Defendants' pre-4 December 2019 disclosures, which had also touted Harmony's purportedly positive efficacy topline results without ever publicly disclosing the need to ***also*** obtain directionally consistent subgroup data.
>
> Had the market been apprised of the FDA's position that directionally consistent subgroup results were needed for approval of the contemplated sNDA, Acadia's stock price would not have risen at all—and instead would have fallen because the market would have known that the Harmony Study failed to produce results necessary for sNDA approval.

(Feinstein Rpt. ¶ 237–38). Dr. Feinstein reasons that, assuming Plaintiffs' allegations of the FDA's directional consistency requirement for Harmony Study results are true, the information disclosed on the evening of December 4, 2019, would not have caused an increase in Acadia's stock price the following day because the results across dementia subtypes did not satisfy that consistency requirement. Defendants may question the

strength of that reasoning, but those contentions go the weight, rather than the admissibility, of Dr. Feinstein's testimony. Dr. Feinstein adequately supports his assumption that the information disclosed on this date would not have resulted in an increase in Acadia's stock price, if the existence of the alleged consistency requirement had been disclosed to the investing public.

The district court's opinion in *In re Vale* does not persuade this Court to hold otherwise. 2026 WL 1002335. In that case, which concerns the collapse of multiple dams operated by a defendant company, Dr. Feinstein offered testimony that the full amount of stock price decline was attributable to "news about the dam collapse." *Id.* at *1–*3. Dr. Feinstein assumed that, if investors were aware of the earlier alleged misrepresentations about "dam stability," they would have expected that a collapse would certainly occur, and the price of the security would not have risen during the class period. *Id.* at *2. The Eastern District of New York wrote that Dr. Feinstein "provides no real basis for this assumption . . . . Ultimately, his assertion that investors would have fixed the probability of a collapse at 100% stands on nothing but his own *ipse dixit*." *Id.* at *5. The court also pointed out that the assumption "makes no sense: the fact that the dam collapse actually occurred does not mean it had a 100% probability of occurring." *Id.* In other words, the allegedly truthful information about dam stability may have increased the public's perception that another catastrophic event would occur but would not have rendered that outcome a certainty. The court in *In re Vale* held that Dr. Feinstein improperly assumed that the public would have expected a collapse with certainty.

In this case, Dr. Feinstein assumes that, without the alleged misrepresentations, the clinical results disclosed on the evening of December 4, 2019, would not have led the public to believe that the alleged requirement of directional consistency was satisfied. Dr. Feinstein reasons that the allegedly undisclosed consistency requirement would have precluded any increased optimism about the sNDA's likelihood of success based on the information released on that date. Unlike in *In re Vale*, Dr. Feinstein does not assume that

the ultimate event—here, the rejection of the sNDA as compared to the collapse of a dam—would have occurred with certainty.

Defendants' Motion to Exclude Expert Testimony (ECF No. 198) is granted in part and denied in part as discussed above. The Court declines to exclude entirely the testimony of Plaintiffs' experts Dr. Carl Peck and Dr. Steven Feinstein. This ruling is without prejudice as to any *Daubert* motion filed in advance of trial and as to objections to specific testimony offered by Plaintiffs' expert witnesses at trial.

V. MOTION FOR SUMMARY JUDGMENT

Plaintiffs bring two claims in this action: (1) violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all Defendants; and (2) violations of Section 20(a) of the Exchange Act against Defendants Davis and Stankovic. (FAC ¶¶ 157–172.)

Defendants move for summary judgment as to three elements of each claim: (1) falsity; (2) scienter; and (3) loss causation. (ECF No. 199-1 at 22.) In their Motion for Summary Judgment, Defendants identify two theories of liability purportedly advanced by Plaintiffs: the "directional consistency theory" and the "019 Study theory."[4] *Id.*

Plaintiffs describe their theory of liability as "challeng[ing] two categories of misstatements": (1) statements regarding whether "Defendants knew that the subgroup term of the FDA agreement required subgroup 'consistency' and 'directional alignment,'" and (2) statements regarding whether Defendants "were also concerned about Harmony's subgroup results and the results from [the] 019 [Study]." (ECF No. 204 at 9, 11–12.) Plaintiffs assert their claims on the theory that Defendants "knew that inconsistent subgroup efficacy data was a threat to FDA approval" for a broader indication of pimavanserin but failed to disclose that information to the investing public. *Id.* at 16.

[4] Directional consistency," as a general matter, describes the effect of pimavanserin across the five patient groups enrolled in the Harmony Study with different dementia subtypes. If each patient group reacted in the same manner to the drug, then the drug could be considered "directionally consistent" across all groups and their corresponding dementia subtypes.

A. Legal Standard

Section 10(b) of the Exchange Act provides that it is unlawful for any person "[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Rule 10b-5 promulgated thereunder provides that it is further unlawful for any person to: (a) "employ any device, scheme, or artifice to defraud," (b) "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made . . . not misleading," or (c) "engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5. Under Section 20(a) of the Exchange Act, a "controlling person" may be liable for violations of Section 10(b) and Rule 10b-5. 15 U.S.C. § 78t(a).

"To plead a claim under § 10(b) and Rule 10b-5, a plaintiff must allege '(1) a material misrepresentation or omission [i.e., falsity]; (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.'" *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 413 (9th Cir. 2020) (quoting *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 603 (9th Cir. 2014)).

B. Request for Judicial Notice

As a preliminary matter, the Court considers the Defendants' Request for Judicial Notice filed in support of their Motion for Summary Judgment. (ECF No. 201.) Defendants request that the Court take judicial notice, pursuant to Federal Rule of Evidence 201, of certain exhibits attached to the Declaration of Koji F. Fukumura in Support of their Motion

for Summary Judgment: (1) guidance documents authored and published by the FDA;[5] (2) press releases and call transcripts released by Acadia;[6] (3) SEC filings by Acadia;[7] and (4) an unpublished summary judgment order issued by the Northern District of California in *Homyk v. ChemoCentryx, Inc.*, Case No. 21-cv-03343-JST (N.D. Cal. Aug. 15, 2025).[8] (ECF No. 200 at 1–40.)

Plaintiffs oppose the Request for Judicial Notice (ECF No. 201) with respect to the first three groups of documents. (ECF No. 205.) Plaintiffs do not oppose Defendants' request for judicial notice of the unpublished summary judgment order. *Id.* at 2. The Request for Judicial Notice is therefore granted as unopposed with respect to the summary judgment order issued by the Northern District of California in *Homyk v. ChemoCentryx*.

"Judicial notice under [Federal Rule of Evidence] 201 permits a court to notice an adjudicative fact if it is 'not subject to reasonable dispute.'" *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018) (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)); *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001).

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[5] These documents are submitted as Exhibits 21–31 to the Fukumura Decl., ECF Nos. 200-5, 200-6 at 1–30.

[6] These documents are submitted as Exhibits 34 and 44–63 to the Fukumura Decl., ECF Nos. 200-6 at 59–64, 200-7 at 15–169, 200-8, 200-9 at 1–52.

[7] These documents are submitted as Exhibits 64–76 to the Fukumura Decl., ECF Nos. 200-9 at 53–401, 200-10 at 1–362.

[8] This document is submitted as Exhibit 155 to the Fukumura Decl., ECF No. 200-18 at 387–413. The order was also made available on Westlaw after Defendants filed their Request for Judicial Notice. *See Homyk v. ChemoCentryx, Inc.*, No. 21-CV-03343-JST, 2025 WL 4110430 (N.D. Cal. Aug. 15, 2025).

1. FDA Guidance Documents

Plaintiffs contend that judicial notice of the "factual assertions" in the FDA guidance documents is inappropriate because the contents of these documents are subject to reasonable dispute and because these documents "merely represent[ed] the current thinking" of the FDA. (ECF No. 205 at 5–6 (quotation omitted).) Defendants reply that courts have repeatedly permitted judicial notice of FDA guidance materials. (ECF No. 212 at 5–7.) Defendants also contend that Plaintiffs rely on, rather than dispute, the factual material in these documents and thereby waive their objection to the Request for Judicial Notice. *Id.*

"Courts routinely take judicial notice of similar FDA guidance documents, many of which also appear on the FDA's public website." *Wilson v. Frito-Lay N. Am., Inc.*, 260 F. Supp. 3d 1202, 1207 (N.D. Cal. 2017); *see also Strezsak v. Ardelyx Inc.*, No. 21-CV-05868-HSG, 2024 WL 1160900, at *4 (N.D. Cal. Mar. 18, 2024) (taking judicial notice of FDA guidance documents "that are publicly available on the FDA's website and not subject to reasonable dispute"). Judicial notice of FDA guidance documents "extends only to recognizing the[ir] *existence*[,] and not [the] truth of the conclusions contained within them." *Sneed v. Procter & Gamble Co.*, 779 F. Supp. 3d 1025, 1032 (N.D. Cal. 2025); *see also Constr. Laborers Pension Tr. of Greater St. Louis v. Neurocrine Biosciences, Inc.*, No. 07CV1111–IEG–RBB, 2008 WL 2053733, at *7 (S.D. Cal. May 13, 2008) (taking judicial notice of FDA guidance documents "insofar as they explain public understanding of the FDA approval process").

Here, Defendants seek judicial notice of the FDA guidance documents for "both (i) the fact that the FDA issued the document in question, and (ii) "the factual assertions contained within the document." (ECF No. 201 at 3.) The Court takes notice of the FDA guidance documents for the purpose of recognizing their existence and public availability but declines to assume the truth of the facts contained therein. *See Homyk*, 2025 WL 4110430, at *4 ("[T]he Court finds that it can take judicial notice of the existence of these documents without accepting the truth of any disputed content.").

For example, Defendants' contentions regarding the meaning of language in the FDA guidance documents, *see, e.g.*, ECF No. 199-1 at 22, which are reasonably disputed by Plaintiffs, do not fall within the scope of judicial notice. Plaintiffs' citation to the FDA guidance documents in their own pleadings does not require the Court to take judicial notice of all factual matter in the documents. *Cf. Thaut v. Hsieh*, No. 2:15-CV-0590-JAM-KJN, 2015 WL 4508779 (E.D. Cal. July 24, 2015), *report and recommendation adopted*, No. 215CV0590JAMKJNPS, 2015 WL 7430603, at *7 (E.D. Cal. Nov. 23, 2015) (taking judicial notice of public documents cited by both parties because "plaintiffs do not genuinely dispute the facts defendants seek to judicially notice").

2. Acadia's Press Releases, Call Transcripts, and SEC Filings

Plaintiffs contend that judicial notice of these documents is inappropriate because the parties dispute the meaning of the contents of Acadia's public statements and whether some of the statements are false or misleading. (ECF No. 205 at 3–4.) Plaintiffs also contend that the Court previously denied Defendants' Request for Judicial Notice of these documents at the motion to dismiss stage. *Id.* at 3 (citing ECF No. 65 at 3–4). Defendants reply that they seek judicial notice only for the purpose of demonstrating the information that had entered the public realm, rather than to show what investors knew at the time. (ECF No. 212 at 7–8.)

"SEC filings are a matter of public record and therefore are the proper subject of judicial notice." *Cullen v. RYVYL Inc.*, No. 3:23-CV-0185-GPC-SBC, 2024 WL 898206, at *4 (S.D. Cal. Mar. 1, 2024); *see also Lowe v. Tandem Diabetes Care Inc.*, No. 3:23-CV-01657-H-BLM, 2024 WL 1898473, at *5 (S.D. Cal. Apr. 30, 2024) (taking judicial notice of SEC filings and investment analyst reports); *Primo v. Pac. Biosciences of Cal., Inc.*, 940 F. Supp. 2d 1105, 1115 n.1 (N.D. Cal. 2013) (same). Judicial notice of publications is appropriate to "indicate what was in the public realm at the time, [but] not whether the contents of those articles were in fact true." *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010) (citations and quotation omitted); *see Huang v. Avalanche Biotechnologies, Inc.*, No. 15-CV-03185-JD, 2016 WL 6524401, at *3 (N.D.

Cal. Nov. 3, 2016) (taking judicial notice of SEC filings "but not the truth of their contents"); *Weston v. DocuSign*, 669 F. Supp. 3d 849, 872 (N.D. Cal. 2023) (taking judicial notice of earnings call transcripts and SEC filings only to "show what representations [the defendant] made to the market" but not "for the truth of any of the facts asserted").

Here, the parties do not dispute that judicial notice of Acadia's press releases, earnings calls, and SEC filings is appropriate for the fact that Acadia issued these statements and not for the truth of the facts asserted therein. (ECF No. 205 at 3; ECF No. 212 at 8).

Accordingly, the Request for Judicial Notice (ECF No. 201) is granted in part for these limited purposes.

C. Unpled Statements

Before considering Defendants' arguments related to the elements of Plaintiffs' claims, the Court reviews Defendants' contention that Plaintiffs improperly challenge statements that are not identified in their FAC. (ECF No. 199-1 at 41–43.) Defendants submit Appendix B to the Decl. of Koji F. Fukumura, which identifies statements made by Defendants that are cited in the Feinstein Report but not pled in the FAC. (ECF No. 200-2).

Defendants contend that Plaintiffs have been aware of these statements "as early as class certification more than two years ago" but failed to timely move to amend the FAC and are now precluded from challenging these statements at the summary judgment stage. (ECF No. 199-1 at 42.) Plaintiffs respond that Defendants "have been on notice for months that Plaintiffs intend to challenge" the unpled statements, which were identified in "answers to Defendants' contention interrogatories and expert reports." (ECF No. 204 at 43.) Plaintiffs contend that these statements may be introduced into evidence at trial and should be considered at the summary judgment stage. *Id.*

Federal Rule of Civil Procedure 9(b) requires a party to "state with particularity the circumstances constituting fraud . . . ." Fed. R. Civ. P. 9(b). The Private Securities Litigation Reform Act ("PSLRA") also requires that the complaint "specify each statement

alleged to have been misleading." 15 U.S.C. § 78u-4(b)(1)(B). A district court may decline to consider allegedly false or misleading statements in a securities action on the basis that the statements have not been fairly presented to the parties. *See Kaplan v. Rose*, 49 F.3d 1363, 1370 (9th Cir. 1994) (holding that a district court did not err by declining to consider four statements that were "were not present in any pleading before the district court," except the motion for summary judgment, and were not "fairly reflected in the complaint"), *overruled on other grounds by City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605 (9th Cir. 2017).

Upon review, the purportedly unpled statements are unnecessary to the Court's summary judgment analysis. The Court does not issue a ruling with respect to whether these statements are properly before the Court at this stage of the proceedings. The parties may raise contentions regarding the admissibility of these statements at the motions in limine stage.

D. Falsity

Falsity requires that "a plaintiff point[] to [a] defendant's statements that directly contradict what the defendant knew at that time." *Khoja*, 899 at 1008. "Even if a statement is not false, it may be misleading if it omits material information." *Id.* at 1008–09 (citation omitted). "[A] statement might be misleading because it affirmatively misstates information[,] [o]r a statement might be misleading because it is made outside the context of other material information." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1054 (9th Cir. 2014). "Once defendants choose to tout positive information to the market, they are bound to do so in a manner that wouldn't mislead investors, including disclosing adverse information that cuts against the positive information." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 706 (9th Cir. 2016) (cleaned up). A "[p]ure omission," however, is not actionable under the Exchange Act. *Macquarie Infrastructure Corp. v. Moab Partners, L. P.*, 601 U.S. 257, 263 (2024); *id.* ("A pure omission occurs when a speaker says nothing, in circumstances that do not give any particular meaning to that silence."). To assess falsity,

courts "look to the perspective of the reasonable investor." *Sneed v. Talphera, Inc.*, 147 F.4th 1123, 1133 (9th Cir. 2025).

"In setting forth the reasons why they contend that each challenged statement is misleading, securities plaintiffs may rely on either an affirmative misrepresentation theory or an omission theory." *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1188 (9th Cir. 2021) (citing 17 C.F.R. § 240.10b-5(b)). "Under Rule 10b-5, an affirmative misrepresentation is an untrue statement of a material fact, and a fraudulent omission is a failure 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." *Id.* (quotations omitted). "Even if a statement is not false, it may be misleading if it omits material information." *Khoja*, 899 F.3d at 1008–09.

1. Directional Consistency

Defendants contend that summary judgment is appropriate on the issue of falsity regarding Plaintiffs' theory that the FDA indicated that it would require the Harmony Study results to show directional consistency across dementia subtypes. Defendants raise three contentions: (i) the FDA did not expressly require that Harmony Study results be directionally consistent across dementia subtypes and no one interpreted the FDA's response to Question 2b at the EOP2 Meeting (the "Labeling Statement") as imposing that requirement; [9] (ii) the trial design, which described the "stratification of the Harmony Study by dementia subtype," was publicly available information; and (iii) Defendants' statements about the Harmony Study are inactionable opinions. (ECF No. 199-1 at 22–23, 30–31.)

i. **Existence of a Directional Consistency Requirement**

Defendants contend that there is no express mention of any requirement that subtype results be directionally consistent in the EOP2 Meeting Minutes, the Protocol, or the SAP,

[9] The Labeling Statement reads: "Yes, we agree with the proposed study population as long as subjects are stratified by their current clinical diagnosis (as proposed). Labeling will reflect the actual composition and response of patients enrolled in the study." (EOP2 Minutes Ex. at 170.)

and the "notion that the FDA communicated a requirement for approval by implication is inconsistent with FDA regulations and Guidance." (ECF No. 199-1 at 23 (emphasis and citations omitted).) In other words, Defendants contend that directional consistency was not a requirement of FDA approval and that the FDA never indicated that it was. Defendants identify the report of Dr. Andreason, who testifies that the FDA would clearly and expressly identify a directional consistency requirement for dementia subtypes during the early stages of its communications with Acadia regarding the Harmony Study. *Id.* at 24. Defendants also contend that "[e]very Acadia witness who was asked about the Labeling Statement" testified that it did not impose a directional consistency requirement; rather, it suggested only that "if the sNDA were approved, the label would disclose the dementia subtypes enrolled in the Harmony Study and how those subtypes responded." *Id.* at 26 (emphasis omitted).

Plaintiffs respond that a "battle of the experts" regarding the meaning of the FDA's statements—in particular, its responses to Acadia's questions as reflected in the EOP2 Meeting Minutes—precludes summary judgment on the question of whether directional consistency was a condition of approval for the sNDA. (ECF No. 204 at 27.) Plaintiffs contend that the "CRL makes clear that FDA believed there was a subgroup requirement for approval and nothing in the FDA guidance documents says otherwise." *Id.* at 28. Plaintiffs also contend that "[t]he key Acadia witnesses who were involving in overseeing . . . and [the] Harmony [Study] uniformly testified that consistency of the subgroup efficacy data was required by [the] FDA to obtain approval of the sNDA." *Id.* at 14.

District courts may deny a motion for summary judgment on the issue of falsity when there are "competing expert opinions" regarding the alleged misstatements. *In re REMEC Inc. Sec. Litig.*, 702 F. Supp. 2d 1202, 1228 (S.D. Cal. 2010) (denying summary judgment on falsity regarding whether the defendant's "valuation of goodwill violated GAAP" because competing experts disagreed); *see also Pearlstein v. Blackberry Ltd.*, No. 13 Civ. 7060 (CM) (KHP), 2022 WL 19792, at *9 (S.D.N.Y. Jan. 3, 2022) ("Summary judgment is inappropriate when there are dueling experts, both of whom have put forward opinions

in contradiction with each other, and when those opinions are important to resolution of a material factual dispute.") (quotation omitted).

Here, the parties' experts disagree about whether the FDA's communications with Acadia imposed a directional consistency requirement on the Harmony Study results. Dr. Peck testifies that the FDA's communications indicated to Acadia that "subgroup efficacy data would have to show directionally consistent benefit" across dementia subtypes. *See, e.g.*, Peck Rpt. ¶¶ 25a, 93, 135. Dr. Peck bases his opinion on the Labeling Statement and FDA Guidance regarding "[c]onsistency across study subsets," *id.* ¶¶ 92–93, and opines that the FDA rejected the sNDA because "the Harmony trial's results were not consistent (*i.e.*, were 'differential' across the subgroups)." *Id.* ¶ 117.[10] Dr. Andreason, in rebuttal, concludes that Dr. Peck's interpretation of the EOP2 Meeting Minutes is "mistaken[]" and that the FDA never communicated a directional consistency requirement for the Harmony Study. (ECF No. 198-3 ("Andreason Rpt.") ¶¶ 22, 26, 60–65.) Dr. Andreason testifies that the FDA's response in the EOP2 Meeting was an "unremarkable response by FDA to a straightforward question about the proposed study *population*—not the study's endpoints or any other efficacy-related approval requirements." *Id.* ¶ 59 (emphasis in original). The parties' experts diverge on the question of whether the FDA's communications indicated that directional consistency would be necessary to its approval of the sNDA.

Plaintiffs also identify testimony from Acadia witnesses indicating that Acadia understood that positive, directionally consistent results across dementia subtypes in the Harmony Study would be necessary for approval of the sNDA. *See* ECF No. 200-16 at 482 (Dr. Mark Knowles, who drafted the SAP for the Harmony Study, testifying that "[t]he expectation was that from an efficacy standpoint that the symptom and treatment would be

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[10] Plaintiffs' expert regarding the design of pharmaceutical trials, Dr. Schneider, also testifies that, "[p]ut simply, Acadia was positing that the different subtypes of dementia enrolled in the [Harmony Study] would react in a positive and directionally consistent manner to treatment with pimavanserin, such that the drug would result in across-the-board reductions in relapses regardless of the patient's underlying dementia type." (ECF No. 197-12 ¶ 56.)

consistent across the subtypes. . . That was our proposal that we presented to the FDA at the time of the end of Phase 2 meeting."); *id.* at 950–51 (Dr. Tom Laughren, who was hired by Acadia to assist in the development of the Harmony Study, testifying that "the expectation for when you're doing a stratified randomization to make sure that each subgroup is balanced for randomizations of drug and placebo, you would be looking, you know, across the subgroups to see if the effect is similar in different subgroups"); *id.* at 69 (Dr. Jim Youakim, VP of Acadia, testifying that the Harmony Study "would need to show consistency in the results across the subpopulations, which means that in the subpopulations, you would need to show that there's improvement consistent with the overall population"). Here, unlike cases cited by Defendants, the record provides adequate support to permit a reasonable factfinder to conclude that the FDA communicated a trial-specific condition regarding directionally consistent results to Acadia.[11]

At the summary judgment stage, Plaintiffs adequately raise a genuine question of material fact as to whether the FDA indicated that it would require the results of the Harmony Study to demonstrate directional consistency. The meaning of the EOP2 Meeting Minutes and the Labeling Statement are questions properly reserved for the jury.

ii. **Publicly Available Information**

Defendants also contend that Plaintiffs cannot establish falsity because the "concept of stratification" for the Harmony Study, in addition to generalized FDA Guidance stating that "stratification means subgroup analysis with the intention of evaluating across the subgroups where there is a consistent effect," was publicly available information. (ECF No. 199-1 at 27.) Defendants also contend that, even if there was a requirement of directionally consistent results for the Harmony Study, the omission of any reference to such a requirement in public statements does not render Defendants' comments misleading

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[11] *See Strezsak v. Ardelyx Inc.*, No. 21-cv-05868-HSG, 2024 WL 1160900 (N.D. Cal. Mar. 18, 2024); *Noble Assets Mgmt. v. Allos Therapeutics, Inc.*, No. CIVA–04CV–1030–RPM, 2005 WL 4161977 (D. Colo. Oct. 20, 2005); *In re Ocugen, Inc. Sec. Litig.*, 659 F. Supp. 3d 572 (E.D. Pa. 2020).

because their comments do "not even mention the agreements reached at the EOP2 Meeting or dementia subtypes." *Id.* at 28–30. In other words, Defendants contend that the information disclosed to the public was adequate for investors to understand the design and analysis of the Harmony Study.

Plaintiffs respond that Defendants failed to disclose a "critical term of the FDA agreement" and "this term was the very reason why FDA denied the sNDA." (ECF No. 204 at 23.) Plaintiffs contend that Defendants publicized the results of the Harmony Study but "never disclosed the EOP2 minutes" and "downplay[ed]" the "disappointing subgroup data by expunging references to subgroups from Acadia's press releases, misrepresenting the import of this data to FDA, and not fully disclosing the data at CTAD." *Id.* at 26, 30. Plaintiffs also respond that Defendants' position regarding the availability of information about the Harmony Study raises an affirmative truth-on-the-market defense, which requires that they establish the omitted information was transmitted to the public with "a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by insider's one-sided representations." *Id.* at 30 (quotation omitted).

In a securities action asserting a fraud-on-the-market theory of liability, an "omission is actionable under [S]ection 10(b) and Rule 10b–5 'only if the allegedly undisclosed information has not already entered the market.'" *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 975 (9th Cir. 1999) (citing *Morris v. Newman (In re Convergent Techs. Sec. Litig.)*, 948 F.2d 507, 513 (9th Cir. 1991)); *Macquarie Infrastructure Corp.*, 601 U.S. at 264 ("Rule 10b-5(b) does not proscribe pure omissions."). "If the market has become aware of the allegedly concealed information, the facts allegedly omitted by the defendant would already be reflected in the stock's prices and the market will not be misled." *Heliotrope General*, 189 F.3d at 975–76 (quotation omitted). The Ninth Circuit has stated that Section 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 880 n.8 (9th Cir. 2012). For an omission to be actionable, "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 Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002).

Here, Plaintiffs assert liability on the basis that Defendants disclosed information about the design of the Harmony Study and the FDA's conditions of approval without describing the existence of a directional consistency requirement that ultimately proved fatal for their sNDA. Plaintiffs identify the August 19, 2020 comment of Davis stating that Acadia "got a clear agreement [with] the FDA at the end of Phase II meeting, and we executed the plan that we agreed to with them." (FAC ¶ 125.) Plaintiffs also identify evidence suggesting that, after receiving the results of the Harmony Study, Acadia sought to minimize reference to dementia subtypes in public statements. (ECF No. 204-70 (Davis, in a suggested edit to a press release dated June 12, 2020, stating that he doesn't "think [Acadia] should be referring to subtypes" because "[w]e've tried very hard to get people to see our point of view that the subtypes are an artificial distinction"); ECF No. 204-32 (Acadia employee stating that she "understand[s] that we no longer want to mention the dementia subtypes" and deleting references to subtypes in a press release on June 14, 2020).) Defendants' descriptions of the Harmony Study and Acadia's agreement with the FDA about expected conditions of approval are adequate to create a genuine issue of material fact as to whether Defendants' public comments were misleading because they failed to discuss the importance of directional consistency and, upon learning the results of the Harmony Study, describe the actual strength of results across dementia subtypes. (*See* CRL at 446 (describing the Parkinson's disease dementia subtype results as "driving the overall study results").)

An omission by a defendant company is not misleading if the information is disclosed to the public by other means. *See Noble Assets Mgmt.*, 2005 WL 4161977, at *7 ("The fallacy in the plaintiff's argument is that the FDA's policies . . . are public. When a plaintiff complains that a defendant failed to disclose a material fact necessary to make its statement not misleading, the concealed information must be information known to the defendants that is not otherwise available to the investing public."); *In re AnaptysBio, Inc.*,

No. 20-CV-565 TWR (DEB), 2021 WL 4267413, at *5 (S.D. Cal. Sep. 20, 2021) (holding that the "alleged omission was disclosed" and, moreover, "appeared on the first page of [a] prospectus") (emphasis omitted). A theory of liability based on a defendant company's failure to describe publicly available FDA guidance is therefore inadequate to establish falsity. *Id.* ("Defendants did not have a duty to disclose the use of rescue therapy at every speaking engagement."). Here, however, Plaintiffs contend that the FDA's statements at the EOP2 Meeting established a specific condition, which was not otherwise available in public documents, and that Defendants failed to disclose this condition when making public statements about the Harmony Study. A reasonable jury could find that Defendants' statements merely characterizing the Harmony Study as stratified by dementia subtype do not clearly provide the necessary information for the public to avoid being misled about the FDA's conditions of approval.

Defendants' citations to cases in which courts held that challenged statements were not misleading by omission because the statements were insufficiently related to the omitted information are unavailing.[12] Here, the relationship between Defendants' affirmative statements and the purported omission is clearer. Plaintiffs identify statements describing Defendants' expectations about approval of their sNDA, including the November 17, 2020 comments by Davis after Acadia received the results of the Harmony Study and were assigned "standard" review by the FDA:

> And of course, at this point, we're focused on facilitating the FDA's review, which, as I mentioned, remains on track. And just as a brief reminder, our

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[12] *See Veal v. LendingClub Corporation*, 423 F. Supp. 3d 785, 794, 806–09 (N.D. Cal. Nov. 4, 2019) (finding that that "[m]any of the alleged misstatements" were not "relate[d] to the business practices at issue" in a pending FTC investigation); *River Canyon Total Return Bond Fund v. Credit Suisse Sec. USA LLC*, No. CV 24-3993-GW-EX, 2024 WL 4867562, at *6 (C.D. Cal. Sept. 17, 2024) ("Plaintiffs have failed to specifically tie the nine omissions noted in [the complaint] to affirmative statements in a way that clearly demonstrates how each omission makes a given affirmative statement misleading."); *Buhrke Fam. Revocable Tr. v. U.S. Bancorp*, 726 F. Supp. 3d 315, 340 (S.D.N.Y. Mar. 28, 2024) ("[T]he subject matter of the alleged statement must relate closely enough to the allegedly omitted information such that a reasonable investor might have drawn inferences about the omitted information because of the statement.").

> sNDA submission included an efficacy package, which was agreed upon with the FDA at the end of Phase II meetings before we conducted the pivotal HARMONY study. And based upon the robust and meaningful results from HARMONY and the additional supporting data from other efficacy studies in Alzheimer's and Parkinson's patients, and then just the overall safety profile of pimavanserin, we remain very confident in the potential approval for DRP. . . . So fast forward to today, **we then executed the exact plan that we laid out for them**. And again, that underlines the confidence we have in the potential for approval in DRP.

(FAC ¶ 132 (emphasis added).) A reasonable jury could find that the statements about the agreement between Acadia and the FDA, including expectations for FDA action based on the results of the Harmony Study, are directly related to the FDA's approval conditions.

iii. **Opinions about the Harmony Study**

Defendants also contend that their "assessment[] of whether the Harmony Study data achieved a certain result is an opinion" that cannot provide a basis for falsity. (ECF No. 199-1 at 30–31.) Plaintiffs respond that these statements may "nevertheless [be] actionable if the statements omit additional material information whose absence makes the fact or opinion misleading to a reasonable person reading the statement fairly and in context." (ECF No. 204 at 32 (quotation omitted).)

The Supreme Court holds that "a statement of opinion is not misleading just because external facts show the opinion to be incorrect." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 186 (2015). "[A] reasonable investor may, depending on the circumstances, understand an opinion statement to convey facts about how the speaker has formed the opinion—or, otherwise put, about the speaker's basis for holding that view. And if the real facts are otherwise, but not provided, the opinion statement will mislead its audience." *Id.*; *see also In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015) ("Courts have repeatedly held publicly stated interpretations of the results of various clinical studies to be opinions because reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.") (quotations omitted), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir.

2016). Statements that are "mere puffery" and "vague statements of optimism" are inadequate to establish falsity because a reasonable investor would not be misled. *River Canyon Total Return Bond Fund*, 2024 WL 4867562, at *6.

Here, Plaintiffs identify statements that describe with specificity the results of the Harmony Study and draw inferences related to the likelihood of approval for the sNDA. (FAC ¶ 119 ("The sNDA is supported by results from the pivotal Phase 3 HARMONY study, which met its primary endpoint, demonstrating that pimavanserin significantly reduced the risk of relapse of psychosis . . ."); *id.* ¶ 128 (stating that the Harmony Study results are "consistent with what we've been finding as we have been adding the new information, both in terms of efficacy and safety"); *id.* ¶ 132 ("[O]ur sNDA submission included an efficacy package, which was agreed upon with the FDA at the end of Phase II meetings before we conducted the pivotal HARMONY study. And based upon the robust and meaningful results from HARMONY and the additional supporting data from other efficacy studies in Alzheimer's and Parkinson's patients, and then just the overall safety profile of pimavanserin, we remain very confident in the potential approval for DRP.").) As to statements that do not merely express optimism about clinical results, but make specific claims about the Harmony Study results without discussing whether subgroup results satisfy a directional consistency requirement, Plaintiffs provide sufficient evidence for a reasonable jury to find those comments misleading because Defendants had information that belied their claims.

2. Statements Regarding the 019 Study

Defendants contend that their statements regarding the 019 Study were "inactionable opinions." (ECF No. 199-1 at 31 (emphasis omitted).) Defendants also contend that their interpretation of the data from the 019 Study was later accepted by the FDA, which demonstrates that the interpretations were reasonable at the time they were made. *Id.* at 31. As discussed above, viewing the evidence in the light most favorable to Plaintiffs, Defendants' public statements indicating that the 019 Study—like the Harmony Study—was adequate to support the sNDA without disclosure that the results failed to comply with

the FDA's requirements for approval may be actionable. (*See, e.g.*, FAC ¶ 113 ("The pivotal HARMONY study results will be the basis of the sNDA submission, which was previously agreed upon at the end of Phase II meeting. And in addition, we will have supportive efficacy results from our previous short-term studies, which provided evidence of acute efficacy of pimavanserin in Alzheimer's disease and in Parkinson's disease psychosis for patients—with patients with dementia.").)

Accordingly, Defendants' Motion for Summary Judgment is denied with respect to falsity.

E. Scienter

Scienter requires that a defendant possess "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 319 (2007) (citation and quotation omitted). "To allege the required scienter, a complaint must 'allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness.'" *Nguyen*, 962 F.3d at 414 (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009)). Deliberate recklessness is "an *extreme* departure from the standards of ordinary care . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so *obvious* that the actor must have been aware of it." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016) (quotation omitted). "The fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter." *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1022 (S.D. Cal. 2005) (quotation omitted). As a general matter, "scienter should not be resolved by summary judgment." *Provenz v. Miller*, 102 F.3d 1478, 1489 (9th Cir. 1996) (emphasis omitted).

1. Stock Sales

Defendants contend that "[s]tock sales, alone, are not enough to prove scienter." (ECF No. 199-1 at 32.) Plaintiffs contend, in response, that Defendants Davis and Stankovic "made massive stock sales" that were "out of line with their prior trading

because neither had sold any Acadia shares before the Class Period," which supports an inference of scienter. (ECF No. 204 at 36.)

A defendant's stock trading "in suspicious amounts or at suspicious times" may be probative of scienter, but "credible and wholly innocent explanations for the stock sales" are sufficient to "defeat any inference of bad faith." *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1117 (9th Cir. 1989). Courts consider: "(1) the amount and percentage of shares sold by insiders; (2) the timing of the sales; and (3) whether the sales were consistent with the insider's prior trading history." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009) (citation omitted).

Here, Plaintiffs identify the sale of "at least 530,392 Acadia shares" by Davis in the amount of "roughly $24.6 million" and the sale of "at least 368,993 shares" by Stankovic in the amount of "roughly $18.93 million." (ECF No. 204 at 36.) In its earlier Order on the Motion to Dismiss, the Court discussed the "substantial" amount of stock sales by Defendants Davis and Stankovic. (ECF No. 65 at 24.) The record suggests that these sales are inconsistent with prior trading activity by Davis and Stankovic and, although their stock sales are not independently sufficient to establish scienter, the sales support an inference of scienter.

2. Directional Consistency

Defendants contend that (i) there is no evidence that Defendants subjectively believed that there was a directional consistency requirement related to the results of the Harmony Study and (ii) "every witness who was asked testified that they believed the dementia subtypes results *were* directionally consistent." (ECF No. 199-1 at 33–35.) Plaintiffs contend that the record confirms that Defendants "Stankovic and Davis personally attended FDA meetings about the sNDA, contemporaneously received copies of the minutes of those meetings documenting FDA's position that the subgroup results mattered, and received and discussed the results of the studies," and indicated to Acadia's board that the FDA would consider directional consistency in its review of the sNDA. (ECF No. 204 at 33.)

On November 21, 2019, Davis privately stated to Acadia's board that the FDA "indicated they would look for directional alignment." (*See* ECF No. 204-24 (Davis, stating in an email: "As you may recall the FDA did not require that we achieve significance in individual dementia subgroups, but indicated they would look for directional alignment. In Harmony, subgroups are directionally aligned, however, the Parkinson's dementia and Lewy Body dementia subgroups outperformed others in the double-blind portion of the study.").) However, Davis later instructed Acadia employees that the company should not be "referring to subtypes" in its press release regarding the results of the Harmony Study. ECF No. 204-70.

On January 12, 2021, Davis made the following comment in response to an investor's question about what "a label would look like" for a broader indication of pimavanserin:

> [W]e're not looking at individual subtypes as they are often referred to of dementia. The psychosis that we see is very similar between the—irrespective of the underlying etiology and it responds in a similar way. So we're seeking that broad indication. That's supported by a very both [*sic*] alignment we established with the FDA at our end of Phase II meeting and then again at their pre-sNDA meeting when we submitted our application.

(FAC ¶ 135.)

At this stage of the proceedings, the question of whether Acadia employees were aware of the importance of subgroup consistency and whether public comments knowingly omitted that information is properly reserved for a jury's determination.

3. Statements Regarding the 019 Study

Defendants contend that Plaintiffs cannot prove scienter regarding the statements about the 019 Study because they were "later ratified by the FDA." (ECF No. 199-1 at 35.) In support, Defendants cite a Second Circuit Court of Appeal case in which the court affirmed the dismissal of a securities claim, in part, because the "interpretation of the data" from clinical trials discussed in the defendant company's statements was "eventually

accepted" by the FDA. *In re Philip Morris Int'l Inc. Sec. Litig.*, 89 F.4th 408, 422 (2d Cir. 2023).

In the Complete Response Letter provided to Acadia, the FDA stated:

> As conducted, we do not consider Study 019 to be an adequate and well-controlled study; therefore, it cannot contribute to a finding of substantial evidence of effectiveness for pimavanserin for the treatment of hallucinations and delusions associated with AD psychosis . . . In summary, the results of the three submitted studies do not support expanding the indicated population.

(ECF No. 200-4 at 446.) Viewing the evidence in the light most favorable to Plaintiffs, the evidence does not support a finding, as in *In re Philip Morris*, that Defendants' earlier statements about the 019 Study supporting a broader indication were "eventually accepted" by the FDA.

Accordingly, Defendants' Motion for Summary Judgment is denied with respect to scienter.

F. Loss Causation

Loss causation requires a plaintiff to "demonstrate that the defendant's deceptive conduct caused their claimed economic loss." *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 807 (2011). A plaintiff must "demonstrate that an economic loss was caused by the defendant's misrepresentations, rather than some intervening event." *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1209 (9th Cir. 2016) (citation omitted). "Typically, to satisfy the loss causation requirement, the plaintiff must show that the revelation of that misrepresentation or omission was a substantial factor in causing a decline in the security's price, thus creating an actual economic loss for the plaintiff." *Nuveen Mun. High Income Opportunity Fund v. City of Alameda, Cal.*, 730 F.3d 1111, 1119 (9th Cir. 2013) (quoting *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 425–26 (3d Cir. 2007)). "In the end, loss causation is simply a variant of proximate cause, and the ultimate issue is whether the defendant's misstatement, as opposed to some other fact, foreseeably caused the plaintiff's loss." *In re Genius Brands Int'l, Inc. Sec. Litig.*, 97 F.4th 1171, 1183 (9th Cir. 2024)

(quotation omitted). "[P]laintiffs often hire experts to opine on loss causation." *In re REMEC*, 702 F. Supp. 2d at 1266.

Defendants contend that Plaintiffs fail to establish loss causation for both their directional consistency theory and their theory regarding statements about the 019 Study.[13] (ECF No. 199-1 at 35–41.)

1. Directional Consistency

Defendants contend that Plaintiffs cannot prove loss causation regarding their directional consistency requirement theory because (i) the alleged corrective disclosures—the DL announced on March 8, 2021, and the CRL announced on April 5, 2021—did not identify any failure of directional consistency in the clinical trial results and (ii) the FDA's observations in these response letters only revealed information to the public that was already known, except for the fact of the FDA's ultimate determination. (ECF No. 199-1 at 36–40.) Defendants contend that the FDA's letters do not contain the phrase "directional consistency" nor suggest that the FDA had imposed that requirement and that "Acadia's stock dropped because the FDA unexpectedly did not approve [its] sNDA," which was a risk known to the market. *Id.* at 40. In other words, Defendants contend that it was merely the fact that the FDA denied the sNDA—rather than the revelation of any information related to Defendants' alleged misstatements—that caused Acadia's stock price to decline.

Plaintiffs respond that the omission of an explicit reference to "directional consistency" in the letter is irrelevant because a corrective disclosure is not required to use the precise language from an earlier, alleged misrepresentation. (ECF No. 204 at 39.) Plaintiffs contend that "news of the DL and CRL were corrective events that informed the market" that Defendants had "misrepresent[ed] the terms of the FDA agreement and the sufficiency of Harmony and 019 to support such approval." *Id.* at 40.

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[13] Defendants also contend that summary judgment on loss causation is appropriate because the Court should exclude Dr. Feinstein. The Court holds that Dr. Feinstein's expert opinion regarding loss causation is not excluded. *See supra* § VI.B.

"A corrective disclosure occurs when 'information correcting the misstatement or omission that is the basis for the action is disseminated to the market.'" *In re BofI Holding, Inc. Sec. Litig.*, 977 F.3d 781, 790 (9th Cir. 2020) (quoting 15 U.S.C. § 78u-4(e)(1)). The Ninth Circuit describes the "basic ground rules" that instruct a court's analysis as to whether a corrective disclosure has occurred: the corrective disclosure need not (1) "consist of an admission of fraud by the defendant or a formal finding of fraud by a government agency"; (2) "reveal the full scope of the defendant's fraud in one fell swoop"; or (3) "precisely mirror the earlier misrepresentation." *Id.* (citations and quotations omitted). The disclosure of negative information that is unrelated to an earlier misrepresentation, however, does not constitute a corrective disclosure. *See Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1063 (9th Cir. 2008) (holding that publication of a newspaper report about an investigation by the Department of Education did not disclose the defendant's alleged manipulation of student enrollment that plaintiff identified in its complaint); *see also In re Oracle*, 2009 WL 1709050, at *16 ("an earnings miss *alone* is not sufficient proof of loss causation").

The DL stated that, as part of the FDA's "ongoing review" of Acadia's sNDA, it had "identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." (ECF No. 200-4 at 437.) The CRL issued later advised Acadia that, although the Harmony Study "was not powered to demonstrate an effect in the subgroups of dementia included, we had advised you during development that labeling would reflect the actual composition and response of the subjects enrolled in the trial." (ECF No. 200-4 at 445). The FDA described its "examination of dementia subgroups" and concluded that the "findings from [the Harmony Study] suggest a differential response to pimavanserin across dementia subtypes, which questions whether 'dementia-related psychosis' is a useful construct for a potential indication for pimavanserin." *Id.* at 445–46.

Although the FDA's letters do not explicitly state that the sNDA was rejected for failure to comply with a requirement that the dementia subtype results be directionally

consistent, the CRL's description of the clinical trial results and reference to "labeling that would reflect the actual composition" of the trial population provides adequate evidence for a reasonable jury to find that the letter corrected a misapprehension in the marketplace regarding the FDA's primary considerations for approval of the sNDA. A reasonable jury could also find that the letters indicate, more generally, that Defendants' public comments about the Harmony Study were misaligned with the importance that the FDA placed on positive results across dementia subtypes. The record contains adequate evidence for a jury to find in favor of Plaintiffs on the element of loss causation.

2. Statements Regarding the 019 Study

Defendants contend that Plaintiffs cannot establish loss causation as to their 019 Study theory because Dr. Feinstein "concedes that the alleged misstatements about the 019 study did not cause any artificial inflation on either the September 9 or the December 4, 2019 dates analyzed in his report." (ECF No. 199-1 at 41 (citing ECF No. 200-17 at 526–27, 537–39).) Plaintiffs respond that Defendants "grossly mischaracterizes" the testimony offered by Dr. Feinstein at his deposition on June 2, 2025, and that Dr. Feinstein testified that all "material omissions at issue . . . 'have an inflationary effect.'" (ECF No. 204 at 42 (quoting ECF No. 200-17 at 528).) Plaintiffs also contend that "Dr. Feinstein's analysis does not seek to apportion artificial inflation in piecemeal fashion based on each 'category' of misstatements" identified by the parties. *Id.*

In the "Event Study Analysis" section of his report, Dr. Feinstein analyzed the effects of statements made by Defendants on, among other dates, September 9, 2019, and December 5, 2019. (ECF No. 198-14 at 152–155.) In his deposition, Dr. Feinstein testified—in response to a question regarding whether Defendants' failure to disclosure the consistency requirement would alone have been sufficient to cause the losses—that he didn't conduct his analysis "that way" by "breaking it down by the . . . partial elements of disclosure." (ECF No. 200-17 at 526–27.) Dr. Feinstein testified that he thought his "conclusion holds up, even if it's just the [consistency requirement] information that was concealed." *Id.* at 527. Read together, and viewed in the light most favorable to Plaintiffs,

these statements do not clearly suggest that Defendants' statements regarding the 019 Study issued on the same date and in the same documents as their statements about the consistency requirement were immaterial to Dr. Feinstein's analysis. The record does not support Defendants' contention that Dr. Feinstein's deposition testimony disclaims his position regarding artificial inflation. The potential contradiction described by Defendants between Dr. Feinstein's deposition testimony and his report does not establish that no reasonable juror could find that Dr. Feinstein's analysis supports a finding of loss causation regarding Defendants' statements about the 019 Study. The question of whether Dr. Feinstein's testimony adequately and independently considers statements regarding the 019 Study goes the weight of his analysis.

Defendants' Motion for Summary Judgment is denied with respect to loss causation.

VI. CONCLUSION

IT IS HEREBY ORDERED that Plaintiffs' Motion to Exclude Expert Testimony (ECF No. 197) is denied. Defendants' Motion to Exclude Expert Testimony (ECF No. 198) is granted in part and denied in part. Defendants' Motion for Summary Judgment (ECF No. 199) is denied.

IT IS FURTHER ORDERED that the Court sets the following deadlines: (1) counsel shall comply with the pre-trial disclosure requirements of Federal Rule of Civil Procedure 26(a)(3) by July 10, 2026; (2) counsel shall meet and take the action required by Civil Local Rule 16.1.f.4 by July 17, 2026; (3) Plaintiff's counsel shall provide opposing counsel with the proposed pretrial order by July 24, 2026; (4) the parties shall lodge the proposed pretrial order with the Court, including any objections to the other party's respective pretrial disclosures, by August 5, 2026; and (5) the final Pretrial Conference is scheduled on August 12, 2026 at 10:30 AM before the Honorable William Q. Hayes in Courtroom 15B.

Dated: June 8, 2026

Hon. William Q. Hayes
United States District Court