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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-NLS

CLASS ACTION

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Date: June 9, 2022
Courtroom: 14B
Judge: Hon. William Q. Hayes

Oral Argument Requested

Demand for Jury Trial

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I. INTRODUCTION

Publicly traded life-sciences companies are frequent targets of shareholder plaintiffs for a simple reason: announcements of clinical-trial results and the U.S. Food and Drug Administration's ("FDA") approval or rejection of drug applications often have dramatic and binary impacts on a company's stock price. These risks and stock-price fluctuations, endemic to the entire pharmaceutical sector and well known to investors, are perfectly illustrated in this case. The Class Period alleged by Plaintiffs begins in September 2019, when Acadia Pharmaceuticals, Inc. ("Acadia" or "the Company") announced positive clinical-trial results and saw its stock price climb by more than 60%. The Class Period ends in April 2021, when Acadia announced that the FDA had rejected the Company's pending drug application, and saw its stock price decline by more than 60%. This lawsuit followed soon after.

Plaintiffs accuse Defendants of violating the federal securities laws. But the law requires much more than bad news and a stock drop—which is all that Plaintiffs offer. Their Amended Class Action Complaint for Violations of the Federal Securities Laws ("CAC")[1] is lengthy, with extended digressions into the complexities of disease diagnosis and treatment, clinical trial design, statistical significance, and the nuances of the FDA regulatory landscape. But as securities fraud cases go, this one is simple. Every fact that Defendants allegedly concealed was fully disclosed to investors; every statement that Plaintiffs allege to be false or misleading was either demonstrably true or not actionable as a matter of law; and there is no allegation in the CAC that even suggests any Defendant intended to deceive investors or acted with reckless disregard of the truth. This case should be dismissed.

Acadia's primary drug product is pimavanserin, the first and only FDA-approved therapy for hallucinations and delusions associated with dementia caused by Parkinson's disease (known as Parkinson's disease psychoses, or "PDP"). After

[1] Citations to "¶ _" are to the CAC. (Dkt. 45.) Citations to "Ex. _" and "Appendix _" are to the Declaration of Peter M. Adams, filed concurrently herewith. Citations and quotations are omitted, and emphasis added, unless otherwise noted.

pimavanserin received FDA approval for the treatment of PDP in 2016, Acadia sought to expand pimavanserin's authorized uses to cover a broader range of psychosis-causing diseases. To meet this objective, the Company met with the FDA to discuss the potential uses of pimavanserin beyond PDP, reached agreement with the FDA on the design and objectives of a large "Phase 3" clinical trial, conducted that trial, and submitted the results, with supporting data from two prior clinical trials, in support of a supplemental New Drug Application ("sNDA").

At every step in this process, before and during the Class Period, Acadia kept its investors informed of the facts and aware of the risks. The Company fully disclosed the design, objectives, results, and complete data set for each of the clinical trials it submitted in support of its sNDA. It explained the purpose and substance of its communications with the FDA, including its agreement with the FDA that Acadia's studies were sufficient to support submission (but not necessarily approval) of its sNDA. And, most importantly, Acadia prudently and repeatedly cautioned investors that gaining FDA approval for the sNDA was fraught with risk and far from assured.

When the FDA rejected the sNDA in April 2021, Acadia and its executives were surprised and disappointed, to put it mildly. Investors were too; hence the sell-off and resulting stock drop. But the sudden realization of a fully disclosed risk is not securities fraud. Nor is it sufficient to allege, after the fact, that a company and its executives knew or should have known that bad news was coming. In other words, a shareholder plaintiff cannot plead "fraud by hindsight." No phrase better describes Plaintiffs' theory in this case, as well as each of the CAC's core allegations.

First, Plaintiffs allege that Defendants knew of, and concealed from investors, design flaws in Acadia's clinical trials, as well as disappointing results from those trials, which rendered the FDA's rejection of the sNDA a foregone conclusion. But every detail that Plaintiffs recite about the trial designs and results were publicly disclosed long before Acadia submitted its sNDA. So, Plaintiffs just crib the

deficiencies cited by the FDA in its rejection notice and hypothesize that Defendants wasted years and millions of dollars in quixotic pursuit of a drug approval they knew was doomed from the start. The CAC contains no well-plead facts to substantiate this nonsensical theory.

Second, the CAC alleges that Acadia's agreement with the FDA regarding the studies it conducted in support of its sNDA was entirely fictitious. In other words, accordingly to Plaintiffs, Acadia publicly disclosed that it had reached an agreement with a federal agency, described the agreement's terms and its documentation (exactly as prescribed by FDA regulations), and informed investors that the agreement was of critical importance to its sNDA—but all the while, no such agreement ever existed. Publicly available evidence of such a brazen scheme would surely be plentiful, *e.g.*, a rebuke or denial from the FDA, or statements from a whistleblower or confidential witness. The CAC offers none, and for good reason; it is Plaintiffs' guesswork, not Acadia's agreement with the FDA, that is cut from whole cloth.

Third, Plaintiffs allege that Defendant intentionally lied to investors because they sold Acadia stock during the Class Period. However, the CAC's scant allegations fall short of showing that Acadia's public stock offering or the individual defendants' personal stock sales were unusual or suspicious in any way (they were not). At most, the stock sales suggest only motive and opportunity, which under binding Ninth Circuit law cannot establish a cogent and compelling inference of intent to deceive.

The CAC fails to satisfy the particularized pleading requirements of Rule 9(b) and the Private Securities Litigation Reform Act. Plaintiffs have not met their burden to plead three essential elements of their Section 10(b) claim: falsity, scienter, and loss causation. For these reasons, Rule 12(b)(6) requires that the CAC be dismissed.

II. STATEMENT OF FACTS

A. Defendants

Acadia developed pimavanserin, the first and still-only FDA-approved therapy for Parkinson's disease psychoses ("PDP"). (Ex. A at 2.) Pimavanserin (marketed as NUPLAZID), has also shown promise in treating hallucinations and delusions associated with dementia caused by other diseases, collectively known as dementia-related psychoses ("DRP"). (Ex. B at 7.) Davis is Acadia's CEO and Stankovic is President and Head of Research and Development. (¶¶23–24.)

B. Pimavanserin: FDA Approval and Potential Expanded Indications

Investors in pharmaceutical companies such as Acadia understand, as the CAC correctly notes, that "[g]aining FDA approval is no small feat." (¶65.) Before a new drug can be sold commercially, the FDA typically requires—as it did for pimavanserin—that the drug undergo clinical studies involving three successive phases (Phases 1, 2, and 3) of human testing involving increasingly larger patient populations. Drug testing is inherently uncertain and only a small percentage of drugs ultimately gain FDA approval. (Ex. C at 10.) With pimavanserin, Acadia successfully navigated a 10-year development process and received FDA approval for the treatment of PDP in April 2016. (Ex. A at 2.)

Although pimavanserin is FDA-approved treatment for PDP, there is no approved treatment for a broader range of dementia caused by other disorders, including DRP. (¶ 119; Ex. D at 12.) Roughly eight million people in the U.S. suffer from dementia caused by various disorders, about 30% of whom live with DRP. (¶ 127; Ex. E at 17.) DRP carries a poor prognosis and is associated with earlier placement into nursing homes. (Ex. F at 25.) The underlying causes of DRP are often difficult to diagnose—the cause often is not known until an autopsy—and the symptoms and response to treatment are often similar regardless of the underlying disorder. (¶¶128, 135; Ex. G at 30; Ex. H at 36.) Doctors thus often focus on treating a patient's DRP symptoms rather than on pinpointing the underlying cause. (¶125; Ex. I at 41.)

Against this backdrop, Acadia understood that gaining FDA approval of

pimavanserin for a broader range of indications would fill a significant unmet need. (¶119; Ex. D at 12.) Indeed, while developing pimavanserin to treat PDP, Acadia also explored the drug's use in treating DRP in general—including psychosis caused by Parkinson's and Alzheimer's, among other dementia-causing conditions—through Phase 2 and Phase 3 clinical studies. (¶2; Ex. B at 7.)

Gaining FDA approval for pimavanserin for the treatment of broader indications was, as Acadia consistently warned its investors, far from assured:

> While pimavanserin has been approved in the U.S. by the FDA for the treatment of hallucinations and delusions associated with PDP, it has not been approved by the FDA for any other indications . . . . In order to market pimavanserin for other indications . . . we must obtain regulatory approval for each of those indications . . . , and ***we may never be able to obtain such approval***. . . . (Ex. J at 46).

Acadia disclosed this risk to investors because, under the FDA Modernization Act of 1997, the Company would need to submit data from a single well-controlled clinical investigation and confirmatory evidence demonstrating pimavanserin's efficacy for the expanded indications to support a supplemental New Drug Application ("sNDA"). 21 U.S.C. §355(d). Even then, as the Company repeatedly cautioned investors, the studies and data that Acadia would use to support its *submission* of an sNDA might be insufficient to obtain FDA *approval*. 21 C.F.R. 314.10(a); 21 C.F.R. 314.10(f). For example, Acadia warned investors that previous studies had tested pimavanserin "in a limited number of patients and in limited populations," and the Company did not know whether studies with a "larger number of patients and broader populations w[ould] be consistent with the results from [previous] clinical studies." (Ex. K at 55.) In other words, even if the Company successfully completed the requisite clinical trials and submitted an sNDA, there was still no guarantee that the FDA would approve pimavanserin for the treatment of DRP or any "indications other than [] PDP." (*Id.*)

C. The Clinical Studies Supporting Acadia's sNDA

To support pimavanserin's safety and efficacy in connection with its sNDA,

Acadia relied on three clinical studies conducted over nearly a decade.

The 020 Study: In July 2011, the Company initiated a Phase 3 study to evaluate the efficacy, tolerability, and safety of pimavanserin in patients with PDP (the "020 Study"). (¶45.) This study was the basis for the FDA's approval of pimavanserin for the treatment of PDP in April 2016. (Ex. A at 3.)

The 019 Study: In November 2013, Acadia initiated a Phase 2 study (the "019 Study") to evaluate the efficacy and safety of pimavanserin as a treatment for patients with ADP. (¶48.) Three years later, Acadia announced that pimavanserin demonstrated efficacy on its primary endpoint, showing a statistically significant treatment improvement at week six compared to placebo. (¶49; Ex. F at 25.) Pimavanserin also did not impair cognition and had a favorable tolerability profile compared to known adverse effects of current antipsychotics. (Ex. F at 25.)

The HARMONY Study: In October 2017, building on the promising results from the 019 Study, Acadia announced the start of its Phase 3 HARMONY study. (¶35.) The objective of the HARMONY study was to evaluate the ability of pimavanserin to prevent relapse of psychotic symptoms in a broad range of patients with the most common subtypes of dementia under the umbrella of DRP: dementia caused Alzheimer's disease and Parkinson's disease, as well as dementia with Lewy bodies, vascular dementia, and frontotemporal dementia. (Ex. B at 7.) The Company also announced that the FDA had expressed confidence in pimavanserin's potential to treat DRP by granting the drug "Breakthrough Therapy Designation" for that indication. (Ex. B at 6.)[2]

In September 2019, Acadia announced that HARMONY met its primary and secondary endpoints, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to a placebo. The study's

[2] Breakthrough Therapy Designation is reserved for "drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)." (Ex. L at 58.)

independent data monitoring committee recommended that the study be stopped early because it met pre-specified stopping criteria based on positive efficacy. (¶¶57, 58, 107; Ex. M at 61.)

Acadia publicly disclosed not only the interim and final results of these three pivotal studies, but also detailed information regarding the studies' designs, dosages, locations, durations, and the various dementia-causing disorders (PDP, Alzheimer's, etc.) amongst the patient populations. (¶¶44–58; Ex. N; Ex. F; Ex. O.)

D. The Supplemental New Drug Application

When the Company announced HARMONY's positive results, it stated that it intended to speak to the FDA about filing an sNDA in 2020. (Ex. M at 61.) But that was not the first time Acadia discussed an sNDA or the supporting studies with the FDA. Two years prior, at an End-of-Phase 2 Meeting in mid-2017, the Company and the FDA prospectively agreed on HARMONY's trial design targeting a broad DRP population and analyzing that population as a single group; Acadia informed its investors that this agreement was documented in the FDA's meeting minutes. (Ex. P at 96.) This agreement with the FDA was not, however, any guarantee that HARMONY or any broader set of studies and data would suffice to gain final FDA approval. Indeed, Acadia further disclosed that, per its agreement with the FDA, HARMONY would have to meet its prespecified primary and secondary endpoints with persuasive clinical and statistical superiority of pimavanserin over a placebo as a criteria for establishing efficacy in treating DRP. (Ex. Q at 102; ¶109.)

Acadia's meetings with the FDA prior to its submission of the sNDA were not unusual. Federal law recites that meetings between the FDA and a drug's sponsor are "useful in resolving questions and issues raised during the course of a clinical investigation," and specifically states that End-of-Phase-2 meetings are "of considerable assistance in planning later studies." 21 C.F.R. § 312.47(a)–(b).

On May 7, 2020, the Company further informed investors that, during a pre-sNDA meeting, it had confirmed with the FDA that the results from HARMONY,

020, and 019 would support the *submission* of an sNDA—but not necessarily final *approval*. (Ex. R at 107.) Consistent with its prior risk disclosures, the Company cautioned investors that its submission of the sNDA did not assure final approval: "the sNDA will be subject to FDA review to determine whether [it] is adequate to support approval of pimavanserin for [DRP]. ***Even if a sNDA submission is accepted for filing by the FDA***, the FDA retains complete discretion in deciding whether or not to approve a sNDA and ***there is no guarantee that pimavanserin will be approved*** for the treatment of [DRP]." (Ex. S at 111.)

Acadia filed its sNDA on June 15, 2020. (Ex. D at 12.) The FDA accepted the sNDA on July 20, 2020 (Ex. T at 115), and advised the Company that the FDA had not identified any potential review issues and was not planning to hold an Advisory Committee meeting (*id.*; ¶ 127.)

E. The FDA's Notification of Deficiencies and CRL

Following the FDA's acceptance of the sNDA, Acadia and its executives expressed optimism about FDA approval, but continued to warn investors that the studies and data supporting the sNDA may not prove sufficient. (Ex. J at 46.) As the market awaited the FDA's response, analysts also expressed cautious optimism. Several analysts noted the FDA's decision to conduct a standard review for the sNDA, rather than the expected priority review. (Ex. U at 118, Ex. V at 120.) And one analyst stated that "investors may consider trading strategies to hedge against the potential near-term downside risk" of a possible 50% share price decline in the event the FDA rejected Acadia's sNDA. (Ex. V at 120.)

Acadia announced on March 8, 2021, that "the FDA [had] identified deficiencies that preclude[d] discussion of labeling and post-marketing requirements/commitments at this time." The FDA's notification did not specify the nature of the deficiencies. (Ex. W at 123; ¶143.)

One month later, on April 5, 2021, the Company announced that it had received a Complete Response Letter ("CRL") from the FDA. The CRL cited a "lack

of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with certain less common dementia subtypes" as insufficient evidence of efficacy supporting approval. The FDA also considered the 019 Study to not be "adequate and well controlled" because it was a "single center study with no type I error control of secondary endpoints in which certain protocol deviations occurred." (Ex. X at 126; ¶145.)

Acadia expressed complete surprise at receiving the CRL, citing the positive results of HARMONY, the fact that the FDA had agreed to HARMONY's trial design—and the lack of any previously expressed concerns from the FDA about HARMONY, the 020 Study, or the 019 Study. (*Id.*) Analysts were surprised as well. One analyst maintained, "we still think DRP can work" while declaring that the magnitude of Acadia's share price decline "makes no sense to us." (Ex. Y at 129.)

Acadia's stock price fell following the Company's March 8 and April 5, 2021, announcements. (¶¶144, 146.)

F. This Litigation

On the heels of this bad news, shareholder plaintiffs raced to the courthouse to capitalize on the Company's stock drops. The initial complaint in this case was filed on April 19, 2021, just two weeks after Acadia disclosed the CRL. (Dkt. 1.) On December 10, 2021, Plaintiffs filed their CAC accusing Defendants of violating Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), and Rule10b-5 promulgated thereunder.

III. LEGAL STANDARDS

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must plausibly allege: (1) a material misrepresentation or omission ("falsity"), (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance, (5) loss causation, and (6) economic loss. *Curry v. Yelp Inc.*, 875 F.3d 1219, 1224 (9th Cir. 2017). These elements are subject to three significant hurdles at the pleading phase.

First, Plaintiff must meet the Rule 8(a) pleading standard, under which the Court need not accept unsupported or conclusory allegations, allegations based on unwarranted deductions or unreasonable inferences, or allegations that contradict matters properly subject to judicial notice. *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). The Court may consider, however, materials incorporated by reference in the complaint and other matters subject to judicial notice. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009).

Second, because fraud allegations harm livelihoods and reputations, *see Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009), Plaintiffs must also satisfy Rule 9(b)'s heightened pleading requirements, which compel them to "state with particularity the circumstances constituting fraud [or mistake]." Thus, Plaintiffs must allege the "who, what, when, where, and how" of the alleged fraudulent conduct, and "set forth what is false or misleading about a statement, and why it is false." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003).

Third, the Complaint must satisfy the Private Securities Litigation Reform Act ("PSLRA"), which imposed "formidable" pleading hurdles for securities fraud claims. *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1054–55 (9th Cir. 2008). Congress enacted the PSLRA because securities class actions "can extort a great deal of undeserved settlement money if the courts do not filter out the unfounded ones early enough to avoid huge litigation expenses." *Ronconi v. Larkin*, 253 F.3d 423, 428 (9th Cir. 2001).

Returning to the elements of Plaintiffs' Section 10(b) claim, three are pertinent here—each of which must be alleged with "particularity." *Oregon Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 605 (9th Cir. 2014).

Falsity: The PSLRA requires Plaintiffs to identify *specifically* each statement alleged to have been false or misleading, and to provide the *reasons why* the statement was false or misleading *when made*. *In re Rigel Pharms, Inc.*, 697 F.3d 869, 876–77 (9th Cir. 2012).

Scienter: Plaintiffs must also allege facts that give rise to a "*strong* inference" that Defendants acted with the intent to deceive shareholders or in reckless disregard of the truth. *Ronconi*, 253 F.3d at 429. A complaint will survive a motion to dismiss "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing [nonculpable] inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 324 (2007). The Court "must consider plausible, nonculpable explanations" for Defendants' conduct, *id*. at 324–26, as well as the economic plausibility of Plaintiffs' claims, *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 415–16 (9th Cir. 2020).

Loss Causation: Finally, Plaintiffs must allege that the Company's share price declined because of the Company's misstatements, and not due to "other intervening causes, changed investor expectations . . . or other events." *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 812–13 (2011).

IV. PLAINTIFF'S SECTION 10(b) CLAIM FAILS

Plaintiff's Section 10(b) claim should be dismissed for three separate and independent reasons: (A) Plaintiffs fail to plead falsity with particularity, (B) Plaintiffs fail to plead a strong inference of scienter, and (C) Plaintiffs fail to adequately plead loss causation.

A. Plaintiffs Fail to Plead Falsity With Particularity

Plaintiffs' theory of fraud rests primarily on Defendants' alleged knowledge of and failure to disclose certain "facts"—*i.e.*, supposed design flaws in the 019 Study and HARMONY, as well as the clinical results from those studies—that rendered FDA approval of the sNDA unlikely. (*See* ¶¶73–78, 90.) According to Plaintiffs, these omissions rendered false or misleading virtually every statement Defendants made during the Class Period. Plaintiffs are wrong. The CAC does not adequately plead that any challenged statement was materially false or misleading when made—and most are not actionable at all.

1. The Challenged Statements Are Not Actionable

The volume of lengthy block quotes in the CAC makes it difficult to discern which specific statements Plaintiffs are actually challenging. Even so, all of the statements Plaintiffs appear to challenge are inactionable as a matter of law because they are: (a) demonstrably true, (b) corporate optimism (or puffery), (c) opinions, or (d) forward-looking statements accompanied by meaningful cautionary language.

***Demonstrably True Statements*:** A fraud claim cannot arise from statements that were unquestionably true when made. *See In re Tesla Motors, Inc. Sec. Litig.*, 671 F. App'x 670, 670 (9th Cir. 2016). For example, Defendants made many general statements about DRP, the market for a drug to treat DRP, and quantitative data from clinical studies. (*See, e.g.*, ¶134 ("The psychosis that we see [in DRP patients] is very similar . . . irrespective of the underlying etiology and it responds in a similar way."); ¶119 ("2.4 million people in the U.S. . . . suffer from dementia-related hallucinations and delusions, representing a large unmet need with currently no approved treatment options."); ¶127 ("the pivotal Phase 3 HARMONY study . . . met its primary endpoint . . . ."); *see also* **Appendix A**.) These statements are demonstrably true, and Plaintiffs plead no facts to the contrary. Thus, they cannot support a Section 10(b) claim.

***Statements of Corporate Optimism*:** Many of the challenged statements are not actionable because they are corporate puffery. *See Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1060 (9th Cir. 2014) (holding that "mere corporate puffery, [such as] vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers, are not actionable"). For example, Defendants made optimistic descriptions of Acadia's performance and pimavanserin's prospects as a treatment for DRP. (*See, e.g.*, ¶130 ("[w]e are confident in both the efficacy and safety data supporting our supplemental NDA"); ¶132 ("[w]e remain just as confident as we've ever been in the *potential* for approval"); ¶138 ("[w]e're on the cusp of *potential* approval in DRP"); *see also* **Appendix B**.) But puffing statements, such as these, are inactionable as a matter of

law because reasonable investors do not rely them. *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010).

***Expressions of Opinion*:** Many of the challenged statements are opinions, which are "generally not actionable" because they (like puffery) are not statements on which a reasonable investor would rely. *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1196 (9th Cir. 2021); *see also Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 184 (2015) ("[T]he words 'I believe' themselves admit[] [the] possibility" that the opinion "could later prove . . . erroneous.").

For example, Plaintiffs challenge certain opinions regarding pimavanserin's *potential* and the market need it could fill ***if*** the drug gained FDA approval. (*See, e.g.*, ¶132 ("[w]e remain just as confident as we've ever been in the *potential* for approval"); ¶138 ("[t]he significant *potential* of pimavanserin . . ."); *see also* **Appendix C**). These statements are inactionable as a matter of law. *See Nguyen v. New Link Genetics Corp.*, 297 F. Supp. 3d 472, 488 (S.D.N.Y. 2018) (phrases like "suggests potential," and "we felt," are opinions).)

Plaintiffs also challenge Defendants' statements about Acadia's clinical study results, but "[c]ourts have repeatedly held publicly stated interpretations of [clinical study results] to be opinions because reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015). This precludes Plaintiffs' from relying on statements such as "positive HARMONY results" (¶107), clinical data "demonstrating a highly statistically significant longer time to relapse" (*id.*), and a "positive [ADP] study . . . which showed statistically significant reduction in psychotic symptoms" (¶109; *see also* **Appendix C**).

Opinion statements like these are actionable *only* "if they are not honestly believed *and* lack a reasonable basis" in fact. *Smith v. Antares Pharma, Inc.*, 2020 WL 2041752, at *5 (D.N.J. Apr. 28, 2020). But the CAC offers nothing—no confidential witness accounts, documents, or any other information—even

suggesting that Defendants did not honestly believe their opinions, or that any of their opinions lacked a factual basis. Simply put, Plaintiffs' disagreement with Defendants' stated opinions regarding the design and results of the 019 and HARMONY studies does not render those statements actionable. *See Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) ("Plaintiffs' allegations regarding Defendants' stated opinion about the [ ] trial results are little more than a dispute about the proper interpretation of data, a dispute this Court rejected as a basis for liability"); *see also Biondolillo v. Roche Holding AG*, 2018 WL 4562464, at *5 (D.N.J. Sept. 24, 2018) ("The press release called the [study] results 'positive,' but such interpretations of trial data are matters of opinion.").

***Forward-Looking Statements*:** Many of the remaining challenged statements are facially forward-looking and subject to the PSLRA's "safe harbor." 15 U.S.C. § 78u-5; *Intuitive Surgical, Inc.*, 759 F.3d at 1059 (forward-looking statements relate to "future expectations and performance"). Plaintiffs challenge statements such as "[w]e look forward to speaking with the FDA about a supplemental new drug application" (¶107); "[w]e look forward to *potentially* bringing this important treatment advancement to patients, caregivers and physicians" (¶121); and "we look forward to the *potential* [of] NUPLAZID becoming the first and only approved treatment for this indication" (¶138; *see also* **Appendix D**). These statements were accompanied by meaningful cautionary language. (*See, e.g.*, Ex. M at 63 (warning that forward-looking statements about HARMONY, the Company's engagement with the FDA, and planned timelines regarding the development of pimavanserin for the treatment of DRP were "only predictions" and that "[a]ctual events or results may differ materially" from those predictions.).) Further, Acadia's SEC filings repeatedly cautioned investors about the risks regarding pimavanserin's potential to treat DRP and the uncertainty of FDA approval. (*See* **Appendix E**.) Finally, the CAC contains no allegations to show that any forward-looking statement was made with "actual

knowledge" that it was "false or misleading" (*see* Section IV.A.2., *supra*). *See Intuitive Surgical, Inc.*, 759 F.3d at 1058; *Cutera*, 610 F.3d at 1111–13.

2. Plaintiffs Fail to Plead That Any Challenged Statement Was False or Misleading When Made

To the extent any of the challenged statements are actionable, Plaintiffs have not pled with the requisite particularity that any were materially false or misleading ***when made***. In other words, Plaintiffs have not pled "*contemporaneous* statements or conditions" that are "inconsistent" with any challenged statement. *Rubke v. Capitol Bancorp, Ltd.*, 551 F.3d 1156, 1161 (9th Cir. 2009).

a. Defendants concealed nothing about their clinical studies' designs, results, or complete data sets

The CAC rests primarily on allegations that Defendants knew but failed to disclose information that "posed major obstacles to FDA approval" and rendered FDA approval "extremely unlikely"—specifically, that the designs of the 019 Study and HARMONY were flawed and the results of both studies were very weak.[3] These allegations cannot overcome two fatal flaws: (1) the information Plaintiffs claim was concealed was, in fact, *fully disclosed* to investors; and (2) the statements Defendants made about their studies and data were not misleading in any way.

First, Defendants fully disclosed the trial designs and results of every study it cited in support of its sNDA: 020, 019, and HARMONY. Indeed, Plaintiffs do not allege that any information regarding the 020 study was concealed (¶¶45–47), and their Complaint admits that the Company's disclosures regarding 019 (¶¶48–49) and HARMONY (¶¶52–58, 61–62) were equally extensive. For example, Acadia

[3] *E.g.*, Defendants "knew that [HARMONY] did not effectively take into account the disparate nature of the individuals that Acadia was seeking approval to treat" (¶73); HARMONY did not contain enough patients in each of the various subgroups of conditions that cause DRP (¶108); Defendants failed to disclose "known shortcomings" in the 019 Study, which was "predicated on a single center study with no type 1 error control of secondary endpoints in which certain protocol deviations occurred" (¶¶86, 145–46).

disclosed that it was "not looking at individual subtypes" in HARMONY (Ex. G at 30; ¶135), but instead focused on DRP as a whole because "subtypes of dementia are very difficult to diagnose [and] overlap many times," and "[s]ubtype diagnosis is very subjective." (Ex. H at 36; Ex. I at 40; ¶¶125, 128). Accordingly, in designing HARMONY, the Company included patients from several subgroups, including PDP patients, because they sought an indication for the treatment of ***all*** DRP patients. For the same reason, HARMONY's primary and secondary endpoints were "prevent[ing] relapse of psychotic symptoms in a *broad population* of patients" (Ex. B at 7) and reducing the risk of discontinuation for any reason (Ex. O at 73). The impact among subgroups was *not* a primary or secondary endpoint—and investors always knew that.

More broadly, ***every fact*** that Plaintiffs allege was concealed from investors (¶¶65–71), *i.e.*, the design and results of the HARMONY study, including data related to the five "most common clinically diagnosed subtypes of dementia" evaluated in the study (¶¶74–77, 82–83), *and* the design and results of the 019 study (¶¶86–89) had been ***fully disclosed*** to investors long before Acadia submitted the sNDA in June 2020. (Ex. F at 25; Ex. Z at 133–34; Ex. AA at 136; ¶87 (019 study data set "was presented in full in the *Journal of Prevention on Alzheimer's Disease* in August 2018"); ¶62 ("On December 4, 2019, Acadia presented the Harmony Study's top-line results" and "released the full data set of the Harmony Study").) In short, nothing was concealed from investors and analysts. They were fully aware of 019's and HARMONY's trial design, top-line results, and clinical data regarding subgroups, and could interpret that information as they saw fit.

Second, Plaintiffs fail to plead with particularity that any of the statements Defendants made about these studies were materially false or misleading. To be clear, Section 10(b) does not "create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44–45 (2011). Rather, disclosure is required "only when necessary to make . . . statements made, in

the light of the circumstances under which they were made, not misleading." *Id.* In the context of clinical trials, the Ninth Circuit holds that Rule 10b-5 prohibits "*only* misleading and untrue statements, not statements that are incomplete." *Brody v. Transitional Hosps. Corp.,* 280 F.3d 997, 1006 (9th Cir. 2002).

Against this backdrop, Plaintiffs' challenges to Defendants' statements regarding HARMONY's design and the data necessary to support a successful sNDA are insufficient to plead falsity. Notwithstanding Defendants' full disclosure of their study designs and data, Plaintiffs allege that Defendants *concealed* that the sNDA—supported by those same studies and data—was effectively dead on arrival. (*E.g.*, ¶91 ("[B]y any measure, Defendants knew, despite their repeated claims suggesting otherwise, that the sNDA was doomed.").) There are no facts plead to support Plaintiffs' conjecture. And, regardless, this theory runs headlong into a wall of precedent: courts have repeatedly dismissed securities-fraud claims premised on critiques of a drug trial's design or methodology so long as the company did not affirmatively misrepresent that design or methodology. *See, e.g.*, *Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013) (allegation that clinical trial "deviated from the established protocol" was insufficient to allege falsity); *Vallabhaneni v. Endocyte, Inc.*, 2016 WL 51260, at *12, *21 (S.D. Ind. Jan. 4, 2016) (a "pharmaceutical company does not have a duty to reveal potential flaws to study design or data analysis methodology"); *In re Keryx Biopharmaceuticals, Inc., Sec. Litig.,* 2014 WL 585658, at *1 (S.D.N.Y. Feb. 14, 2014) (securities laws are not a "tool to second guess how clinical trials are designed and managed"); *Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869, at *15 (S.D.N.Y. May 29, 2013) (allegation that "defendants did not engage in best practices in the design and conduct of the Phase 2 study" was "insufficient to allege material misstatements or omissions").

Defendants made no misrepresentations regarding clinical study design or data. In particular, Defendants never characterized the sufficiency of any particular

dementia subgroups in HARMONY's design, nor did they specifically discuss the sufficiency of clinical data regarding subgroups. Instead, Defendants made clear to investors that the Company was focused on evaluating pimavanserin as a treatment for DRP *generally* and would *not* focus on subgroups. (Ex. H at 36; ¶128.)

The CAC also presents a quintessential example of pleading "fraud by hindsight." Most glaringly, Plaintiffs borrow the deficiencies referenced by the FDA in the *April 2021* CRL, and then claim that Defendants must have known of these shortocmings all along. But Plaintiffs plead no contemporaneous facts—*i.e.*, no confidential witness statements or documents or admissions or any other form of particularized evidence—to show that any challenged statement was materially false or misleading *when made*. To the contrary, Defendants had good reason to believe, and did believe, that HARMONY's design was sufficient, and that the data from all of their clinical studies would support approval of their sNDA. The Company had received assurances from the FDA, at a pre-sNDA meeting, that Acadia's studies could "support an sNDA *submission* with HARMONY as the pivotal study, and [020 and 019] as supportive efficacy studies." (Ex. BB at 142; ¶117.) After accepting the sNDA in June 2020, the FDA expressed no concerns regarding the sNDA's supportive data until issuing its CRL in April 2021. (Ex. E at 17; Ex. X at 126; ¶¶127, 145.)

Put simply, if the CRL alone was enough to allege securities fraud, then the prohibition on pleading fraud by hindsight would be meaningless. "It is easy for Plaintiffs to see what went wrong in hindsight; but that does not make Defendants' failure to see that problem prior to [its occurrence] fraudulent." *See Anderson v. Peregrine Pharms., Inc.*, 654 F. App'x 281, 282 (9th Cir. 2016).

b. Plaintiffs cannot engineer falsity by alleging that Acadia's agreement with the FDA did not exist

The CAC's allegation that Defendants "fabricate[d] the existence of an agreement with the FDA" (¶¶92, 99–102), is entirely conclusory and unsupported by

any well-plead facts. Much more is required to allege falsity under the federal securities laws.

As Plaintiffs concede, the FDA may consider data from a single well-controlled clinical investigation to support the submission of an sNDA. (¶¶96–97.) And federal law recommends meetings between a drug's sponsor and the FDA. Indeed, the Code of Federal Regulations expressly encourages an End-of-Phase-2 Meeting, which "should be directed primarily at establishing agreement between FDA and the sponsor of the overall plan for Phase 3 and objectives and design of particular studies." 21 C.F.R. § 312.47(v). That is precisely what happened here.

In accordance with this common process, Acadia obtained the FDA's consent regarding HARMONY's trial design and the Company's plan to use this single, well-controlled study (along with supportive data from its other studies) to support its sNDA. (Ex. P at 96; ¶132.) And throughout the Class Period, Defendants repeatedly and publicly referenced this agreement with the FDA: "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" (Ex. CC at 146); "[A]t 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" (Ex. Q at 102); "The FDA agreed to the HARMONY design—"[t]hat's documented in our minutes" (Ex. P at 96; *see also, e.g.*, Exs. G, H, I; ¶113, ¶125, ¶128, ¶132, ¶135.)

Plaintiffs plead no facts to the contrary. Instead, they baldly allege that Defendants lied about the FDA's consent because there is no *public, written copy* of an agreement with the FDA. (¶92.) It is Plaintiffs' burden to adequately plead falsity, not Defendants' burden to disprove their supposition and speculation. Plaintiffs do not identify a single confidential witness, or any other source, discrediting Acadia's agreement with the FDA. And although Defendants cannot introduce evidence at the pleadings stage—and have no burden to do so—FDA regulations expressly provide

that agreements regarding trial design and objectives may be recorded in the minutes of an End-of-Phase 2 meeting, and that those minutes may serve as a permanent record of the agreement. *See* 21 C.F.R. § 312.47(b)(1)(v). That is exactly what Defendants publicly disclosed. (Ex. P at 96; ¶132.)

Plaintiffs' only other allegation, regarding the Special Protocol Assessment ("SPA") provisions (¶¶99–103), is a red herring. Defendants never claimed that their agreement with the FDA was a formal SPA. Regardless, the FDA itself has made clear that "[t]he existence of an SPA agreement does not guarantee the FDA will [accept an NDA] . . . or that the trial results will be adequate to support approval." (Ex. DD at 150.) In other words, the FDA need not rescind an SPA in order to deny an NDA—so it is meaningless for Plaintiffs to allege that "it is highly unlikely that the FDA *sua sponte* rescinded or changed its course" (¶102).

Finally, it defies common sense to allege that Defendants would fabricate the existence of an agreement and then repeatedly tell the public about it—heedless of the risk that the FDA would, at a minimum, publicly disclaim any such agreement. Without confidential witness statements or any other evidence even suggesting that the agreement was a myth, there is only one plausible conclusion: there *was* an agreement between the FDA and Acadia, and Defendants honestly and reasonably believed their clinical studies' designs and resultant data would support their sNDA. *Cf. Jun Shi v. Ampio Pharmas., Inc.*, 2020 WL 5092910, at *5 (N.D. Cal. June 19, 2020) ("[Plaintiffs alleged] that Defendants knew or were deliberately recklessly to the fact that the [clinical] trial was poorly designed and would not be approved by the FDA. But the idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly carry on a defective trial—so that any defects were not remedied—virtually defies reason."). The fact that the FDA ultimately disagreed (and denied the sNDA) does not render Defendants' prior statements false or misleading when made.

B. Plaintiffs Fail to Plead a Strong Inference of Scienter

In addition to Plaintiffs' failure to adequately plead falsity, the CAC should be dismissed because it does not plead a "strong inference" of scienter. To do so, a plaintiff "must plead, in *great detail*, *facts* that constitute *strong* circumstantial evidence of *deliberately reckless* or *conscious* misconduct." *In re Silicon Graphics, Inc.*, 183 F.3d 970, 974 (9th Cir. 1999). A complaint will survive dismissal "only if a reasonable person would deem the inference of scienter *cogent and at least as compelling* as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. Thus, courts "must consider *all* reasonable inferences to be drawn from the allegations, including inferences unfavorable to the plaintiffs." *Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002).

Of the CAC's 172 paragraphs, only three are dedicated to scienter (¶¶104–106). Nowhere in those three paragraphs—or anywhere else—is there a single allegation suggesting that any Defendant intended to deceive investors. Nor is there anything to indicate that any Defendant knew or believed any fact that contradicted any statement they made during the Class Period. Also absent are nearly all the usual hallmarks of scienter—confidential witnesses, admissions, documents inconsistent with public statements, or other "red flags." Instead, Plaintiffs' scienter allegations consist entirely of (1) Acadia's follow-on offering of common stock, (2) the Individual Defendants' stock sales, and (3) Defendants' alleged omissions regarding the designs and results of their clinical studies. But none of these allegations, individually or collectively, create the required "strong inference" of scienter. And courts routinely reject far more robust and detailed allegations than those pled here. *See, e.g.*, *Intuitive Surgical, Inc.*, 759 F.3d at 1062–64; *Zucco*, 552 F.3d at 992–1001.

Acadia's Follow-On Offering. Plaintiffs first allege that Acadia "monetized [its] fraud" in a follow-on public offering by selling 7,187,500 shares of common stock raising approximately $217.5 million on or about September 17, 2019. (¶104.) But allegations of "routine corporate objectives such as the desire to obtain good financing" cannot, by themselves, raise an inference of scienter. *In re Arrowhead*

Pharms., Inc. Sec. Litig., 782 F. App'x 572, 575 (9th Cir. 2019); *Lipton v. Pathogenesis Corp.,* 284 F.3d 1027, 1038 (9th Cir. 2002) ("alleged desire[] to obtain favorable financing" held inadequate motivation for fraud). Plaintiffs must allege *particularized* facts "indicat[ing] that Defendants' motivations were anything other than routine business objectives." *In re Regulus Therapeutics Inc. Sec. Litig.*, 406 F. Supp. 3d 845, 862 (S.D. Cal. 2019). Otherwise, the PSLRA's scienter bar would mean nothing: *all* companies have an incentive to raise money, and it is commonly more efficient to do so in the wake of good news. There was nothing suspicious about Acadia's follow-on offering, and Plaintiffs do not plead any facts suggesting the contrary—much less that it supports a strong inference of scienter.

Individual Defendants' Stock Sales. Plaintiffs also make generalized allegations that Defendants Davis and Stankovic sold stock during the Class Period (¶¶105–106), but they fail to "plead *how* the timing of any specific sale by any specific defendant is *linked* to intentional misrepresentations or omissions or gives rise to an inference of scienter as to *specific* misstatements or omissions." *In re LeapFrog Enterprises, Inc. Sec. Litig.*, 527 F. Supp. 2d 1033, 1052 (N.D. Cal. 2007).

To start, Plaintiffs allege in conclusory fashion that these sales were "highly unusual in terms of both their size and timing" (¶13) without even attempting to plead with particularity *why* they were "highly unusual." It is not enough to allege that the Individual Defendants sold no stock prior to the Class Period and have sold a relatively small amount since. (¶¶105–106.) Tellingly, Plaintiffs do not identify the date or amount of any of the allegedly suspicious stock sales—much less explain how the size or timing of any *specific* sale was linked to any *particular* alleged misrepresentation or omission. At best, Plaintiffs allege "a motive to commit fraud and [the] opportunity to do so," which is insufficient to show the requisite strong inference of scienter. *Zucco*, 552 F.3d at 990–91.

Further, as Plaintiffs concede, many of the sales made here were made pursuant to Rule 10b5-1 plans. (Exs. EE and FF; ¶¶105–106). "[A]utomatic sales

made pursuant to Rule 10b5-1 plans do not support a strong inference of scienter," *Rodriguez v. Gigamon Inc.*, 325 F. Supp. 3d 1041, 1056 (N.D. Cal. 2018), especially when Plaintiffs offer no particularized allegations suggesting that the timing of these plans was suspicious or unusual. The remaining sales were made solely to cover taxes incurred upon the vesting of restricted stock units. (Exs. EE and FF.)

Acadia's Clinical Studies. As explained above, Defendants did not omit any material information about the designs of its clinical studies or about the data from those studies. Even so, Plaintiffs' reliance on alleged omissions to establish scienter requires them to clear a very high bar at the pleadings stage: they "must plead a *highly unreasonable* omission, involving not merely simple, or even inexcusable negligence, but an *extreme departure* from the standards of ordinary care, and 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." *Zucco*, 552 F.3d at 991. The CAC does not come close to meeting this standard.

Here, Plaintiffs allege that, in virtually every public statement Defendants made regarding pimavanserin's potential as a treatment for DRP, they "failed to disclose that known shortcomings in the studies submitted with the sNDA, including disappointing data, posed major obstacles to FDA approval." (*See, e.g.*, ¶ 112.) This begs the question how "*known* shortcomings" in publicly disclosed study data can be concealed from investors—and in fact, Defendants concealed nothing. Acadia was fully transparent about each study's design and publicly released quantitative data from all of its studies, including data about dementia subgroups. (*See, e.g.*, Ex. F; Ex. B; Ex. M; Ex. AA; ¶¶45–46, 48–49, 57, 61–62, 107, 111.) Courts have found substantially similar allegations to be inconsistent with common sense and plainly insufficient to establish scienter. *See, e.g.*, *Carr v. Zosano Pharma Corp.*, 2021 WL 3913509, at *8 (N.D. Cal. Sept. 1, 2021) (rejecting allegations that "Defendants omitted important clinical data—namely those concerning the very problems that the FDA later identified in rejecting the [ ] NDA—when touting the results of Zosano's

various clinical studies."); *Colyer v. AcelRx Pharms., Inc.*, 2015 WL 7566809, at *12 (N.D. Cal. Nov. 25, 2015) (no inference of scienter arose from allegations that "Defendants knew about, but actively tried to hide, evidence of [medical device]'s optical system errors, and that Defendants therefore made materially misleading statements about [device]'s likelihood of approval either with intent or with deliberate recklessness").

Holistic Review. Finally, in conducting a "holistic" review of scienter allegations, "a court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Zucco*, 552 F.3d at 991. Here, the malicious inference Plaintiffs ask the Court to draw is not compelling at all, and far less so than the "innocent inferences cognizable from the facts pled." *See id.*; *Tellabs*, 551 U.S. at 324. Defendants fully disclosed the design and results of the studies supporting their sNDA, and consistently warned investors that FDA approval of pimavanserin for treating DRP was uncertain. (*See* Section IV.A.2., *supra*.) It was not until the FDA issued its CRL in April 2021 that Defendants were informed of the FDA's misgivings about the studies and their data. (*See id.*) The only cogent and compelling inference here is that "Defendants honestly believed that [their product] would receive FDA approval but—like all drugs submitted to the FDA—understood that such approval was not guaranteed." *Colyer*, 2015 WL 7566809, at *14; *see also Carr*, 2021 WL 3913509, at *12 ("[T]he complaint alleges little more than that the FDA ultimately found the [data] material, coupled with Plaintiffs' conclusory allegation that Defendants must have seen it coming.").

C. Plaintiffs Fail to Adequately Plead Loss Causation

Finally, Plaintiffs' allegations do not show that any misrepresentation "caused the loss" for which they seek to recover damages. 15 U.S.C. § 78u-4(b)(4). The loss-causation requirement ensures that the securities laws do not "becom[e] a system of

investor insurance that reimburses investors for any decline in the value of their investments." *Meyer v. Greene*, 710 F.3d 1189, 1196 (11th Cir. 2013). To satisfy this element, Plaintiffs must allege with particularity that the "misstatement, as opposed to some other fact, foreseeably caused [their] loss." *Mineworkers' Pension Scheme v. First Solar Inc.*, 881 F.3d 750, 753 (9th Cir. 2018).

The CAC asserts a causation theory based on market revelation of the fraud (¶¶143–47, 164–66), which requires Plaintiffs to have pleaded the facts relevant to that theory. *See Curry v. Yelp Inc.*, 875 F.3d 1219, 1225 (9th Cir. 2017). There are no such facts here. Acadia's press releases of March 8, 2021, and April 5, 2021, revealed, at most, disappointing news. For example, the March 8, 2021, press release disclosed only that the "FDA has identified [unspecified] deficiencies that preclude discussion of labeling and post marketing requirements/commitments *at this time*." (Ex. W at 123; ¶¶143–144.) There was no *corrective* disclosure by the Company to which the market could have reacted—only the prospective uncertainty that the FDA might not approve the sNDA. Likewise, when Acadia announced the receipt of the CRL on April 5, 2021, there was no disclosure of fraud or the correction of any prior misstatement—only the market's predictable reaction to the FDA's rejection of the sNDA. Such allegations do not establish that a misstatement (as opposed to some other factor) caused Plaintiffs' losses. *See, e.g.*, *Fort Worth Employers' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 229 (S.D.N.Y. 2009) ("all-but-inevitable" decline in stock price was caused by FDA's "failure to approve the drug—not by any 'corrective' disclosure of some prior untruth").

V. PLAINTIFF'S SECTION 20(a) CLAIM FAILS

Because Plaintiffs fail to plead a primary violation of Section 10(b), their Section 20(a) claim also fails. *See Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 n.15 (9th Cir. 2002).

VI. CONCLUSION

For the foregoing reasons, the CAC should be dismissed.

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