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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

REPLY 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

The Opposition makes one thing clear: Plaintiffs' theory of securities fraud in this case hinges entirely on two conclusory claims—*i.e.*, (1) that Defendants touted a fictitious agreement between Acadia and the FDA, and (2) that they knew all along that Acadia's Supplemental New Drug Application ("sNDA") was doomed to failure. To concoct this imagined theory, Plaintiffs work backward from the FDA's denial of Acadia's sNDA and, in lieu of particularized facts, fill in the gaps with their own speculation and guesswork. This is a classic example of pleading "fraud by hindsight"—which is not permitted under the law. Indeed, as the Ninth Circuit recently explained,

> [p]harmaceutical companies often suffer setbacks in their clinical trials after earlier testing offered highly promising results. That is ***the nature of the industry***, and—without more—it ***does not necessarily mean that a pharmaceutical company committed securities fraud***.

In re Nektar Therapeutics Sec. Litig., 2022 WL 1573821, at *7 (9th Cir. May 19, 2022) (emphasis added).

Plaintiffs' first argument is their most egregious attempt to plead fraud by hindsight. They conclude that Acadia never had an agreement with the FDA regarding the studies and data necessary to support ***submission*** of the sNDA because the FDA ultimately rejected it. (Opp. at 11–12 (declaring that the absence of any agreement "can be readily ***inferred*** from the FDA's rejection of the sNDA").) But the existence of an agreement with the FDA regarding HARMONY and the FDA's ultimate denial of Acadia's sNDA are not mutually exclusive. And there is nothing in the Amended Class Action Complaint ("CAC") that allows for such an inference.

Plaintiffs' second argument—that the FDA's denial of Acadia's sNDA was a *fait accompli*—is equally faulty. They plead no facts indicating that ***anyone*** believed Acadia's clinical trial design and data were insufficient to support the sNDA, including the ***medical professionals*** to whom Acadia presented the full HARMONY data set. There are no internal documents, no confidential witnesses, not even a

skeptical analyst report predating the FDA's denial of the sNDA. There is only the FDA's decision and Plaintiffs speculating ***afterward*** that Defendants must have known the bad news was coming.

The securities laws do not permit fraud claims to be reverse engineered from bad news and a stock drop. That is all the CAC offers, so it should be dismissed.

II. ARGUMENT

A. Plaintiffs Still Fail to Plead Falsity With Particularity.

As set forth in Defendants' Motion, the CAC fails to plead with particularity that any challenged statement was materially false or misleading ***when made***. (Mot. at 15–18.) The Opposition does nothing to remedy this fatal flaw. Instead, Plaintiffs double down on their imagined omissions—*i.e.*, that (1) no agreement between Acadia and the FDA ever existed (Opp. at 10–13); and (2) the studies and data supporting the sNDA were so obviously deficient that it was certain to fail (*id.* at 13–16).[1] But there are no well-pled facts to support Plaintiffs' conjecture.

1. There are no facts supporting Plaintiffs' conjecture about Acadia's "non-agreement" with the FDA.

According to Plaintiffs, Defendants' arguments "require[] this Court to assume that the FDA entered into an agreement that the FDA then reneged on" and that "the FDA double-crossed them." (Opp. at 1, 2.) This is a strawman; Defendants' Motion requires no such assumptions. Plaintiffs cite no facts (because there are none) to support their manufactured theory that Acadia never had an agreement with the FDA. Rather, they admit their conclusion is based solely on "the FDA's rejection of the sNDA." (Opp. at 11–12.) That is pure hindsight, and it pervades all of Plaintiffs' falsity arguments.[2]

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[1] Plaintiffs repeat these claims as support for scienter. (*See* Section II.B, *infra*.)

[2] (*See* Opp. at 14 (Defendants' statements regarding HARMONY's results "must also be analyzed against the backdrop of Defendants' false claims the FDA 'agreed' that it could support an sNDA for expanded DRP indications"); *id.* (if statements were "not materially misleading standing alone, they were plainly misleading in the context of Defendants' statements about a purported FDA agreement").)

First, Plaintiffs mischaracterize Acadia's agreement with the FDA. They surmise that the FDA "*never* agreed that a single study that was able to report positive 'aggregate' results in DRP patients would support an expanded sNDA if (as in HARMONY) the data failed to also demonstrate positive results in the non-Parkinson's patients or any sub-group thereof." (Opp. at 6.) But Defendants never claimed that HARMONY would suffice to gain ***approval*** of its sNDA regardless of the study's results. Defendants stated only that the FDA had agreed that HARMONY could support ***submission*** of the sNDA ***if*** its results "were both statistically and clinically very persuasive." (Mot. at 19.)[3]

Second, Plaintiffs insist that Defendants must have been lying because the FDA would not "reneg[]" on its agreement or "double-cross[]" Acadia by rejecting its application. (Opp. at 2, 12.) But, again, Defendants ***never*** claimed the FDA was obligated to ***approve*** the sNDA because it had an agreement with the Company regarding HARMONY's protocol. Indeed, such a claim would be counter to explicit guidance, reserving the FDA's right to approve or reject ***any*** NDA. (*See* Mot. at 20.) In short, Plaintiffs' argument is just another example of pleading fraud by hindsight. *See In re Nektar*, 2022 WL 1573821, at *1 ("Experimental drug candidates do not always live up to their potential, . . . [but] that does not mean that a pharmaceutical company has defrauded the investing public.").

Third, the Opposition relies on authorities that are easily distinguished from the facts in this case. (Opp. at 11–12 (citing *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797 (C.D. Cal. 2011); and *Skiadas v. Acer Therapeutics, Inc.*, 2020 WL 3268495 (S.D.N.Y. June 16, 2020)).) In *MannKind*, the company met with the FDA

[3] Plaintiffs also fail to plead why a failure to demonstrate efficacy against any specific subtypes of dementia would have been ***material*** to investors. *Retail Wholesale & Dep't Store Union Loc. 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1274 (9th Cir. 2017). Which dementia subtypes did investors care most (or at all) about? What showing of efficacy, with respect to which subtypes, did investors hope to see? "We cannot answer any of these questions because the complaint has failed to plead sufficient facts to provide context that would allow us to assess the alleged falsity" of Defendants' statements. *Nektar*, 2022 WL 1573821, at *6.

after starting its one-and-only clinical trial of a new insulin delivery system. 835 F. Supp. at 801. The defendants stated, contrary to certain well-pled facts, that their study had been verbally "blessed" and "vetted" by the FDA; that their study was designed based on FDA recommendations; and that the FDA had accepted previous studies as supportive, which had used a wholly different delivery system. *Id*. at 802–03. In *Skiadas*, a company sought FDA approval of a drug by shopping for a ***retrospective*** clinical trial—a practice the FDA regards as a "red flag"—rather than conducting its ***own*** clinical trials. 2020 WL 3268495 at *3–4. And the company's statements about what the FDA had verbally agreed to conspicuously ***changed*** during the class period. *Id*. at *4. On those very different facts, the *MannKind* and *Skiadas* courts found that plaintiffs had plausibly alleged that no ***verbal*** agreement with the FDA ever existed.

No such facts are alleged in this case, where (1) Acadia met with the FDA regarding HARMONY and their planned sNDA ***before*** the trial began (CAC ¶¶ 113, 125, 128, 132, 135); (2) Defendants' statements about Acadia's discussions with the FDA reflected a process ***specifically recommended by federal law*** (Mot. at 19–20)[4]; and (3) Defendants stated that the FDA's agreement was documented ***in writing*** in the minutes of its End-of-Phase II meeting (*id*.). Plaintiffs offer nothing, other than their own conjecture, to the contrary. Put simply, they have not met their burden to plead "particularized" facts in alleging falsity, and for this reason alone the CAC should be dismissed. *Curry v. Yelp Inc.*, 875 F.3d 1219, 1225 (9th Cir. 2017).

2. No well-pled facts support Plaintiffs' conjecture about "known design deficiencies" and certain failure of the sNDA.

Plaintiffs argue that Defendants misled investors by "claim[ing] that the Company's data showed that pimavanserin . . . was sufficient to support FDA approval of its sNDA to expand the drug's existing treatment indications beyond

[4] Plaintiffs abandon their misguided argument that the FDA would have had to rescind a Special Protocol Assessment to deny the sNDA. (¶¶ 99–103; Mot. at 20.)

Parkinson's DRP" (Opp. at 6), while allegedly concealing "known design deficiencies" and "insufficient" clinical trial data that "doom[ed] its chances for FDA approval" (*id.* at 2, 21). This argument fails for several reasons.

First, Plaintiffs again mischaracterize the facts. They ignore the distinction between studies or data sufficient to support (a) Acadia's ***submission*** of the sNDA versus (b) the FDA's ultimate ***approval*** of the sNDA. To be sure, Defendants touted what they regarded as pimavanserin's "significant ***potential***" to help a broad population of patients and expressed "confiden[ce] . . . in [the drug's] ***potential*** for [FDA] approval." (Mot. at 13.) But Defendants never promised investors that Acadia's studies would be enough for the FDA to ***approve*** the Company's sNDA—or even that approval was likely. On the contrary, Acadia consistently warned investors that FDA approval was far from assured. (*Id.* at 5.)

Second, nothing about Acadia's clinical trial designs or resultant data was concealed. Investors had access to HARMONY's entire dataset ***because Acadia publicly released that data***. Plaintiffs do not contest that these disclosures included the design and results of the 019 and HARMONY studies, including itemized data broken down by the five "most common clinically diagnosed subtypes of dementia" evaluated in those studies. (*See* CAC ¶¶ 62, 74–77, 82–83, 87.[5]) Instead, they conclude (without supporting facts) that these disclosures were insufficient to "counter-balance" Defendants' other supposed "one-sided representations." (Opp. at 15; *see also* Section II.A., *supra*.) They do not, however, say ***how or why*** the Company's disclosures were insufficient; again, defaulting to their own supposition (that no agreement with the FDA ever existed) as support. Incredibly, Plaintiffs accuse Defendants of attempting to ***conceal*** HARMONY's design and results from investors, while at the same time ***disclosing*** the same information to ***medical***

[5] Plaintiffs wrongly characterize Defendants' argument as "just a form of the 'truth-on-the-market" defense. (Opp. at 14.) Not so. Defendants rely on, and take as true, the allegations in the CAC, in which ***Plaintiffs*** claim that Acadia released HARMONY's full data set. (CAC ¶¶ 61–62.)

professionals (Opp. at 15), who are best positioned to identify any flaws or deficiencies in the study's design and data. This is plainly not enough. *See In re Sona Nanotech, Inc. Sec. Litig.*, 2021 WL 5504758, at *7 (C.D. Cal. Oct. 28, 2021) ("A plaintiff is hard-pressed to build a fraud case from publicly disclosed information.").

Third, the Opposition does not fix the CAC's failure to allege with particularity that Acadia's clinical studies and data were plainly insufficient[6] to support the sNDA or that Defendants must have known their statements regarding HARMONY's data were false. (Opp. at 3–5, 13–16.) The facts show precisely the opposite. Acadia announced on September 9, 2019, that HARMONY met its primary endpoint and, as Plaintiffs admit, pimavanserin increased the time to relapse for all except two dementia subtypes. (Opp. at 4.) After Acadia presented the full HARMONY dataset on December 4, 2019 (CAC ¶ 61–62), analysts characterized the results as "a clear win" for the Company, stating that the data "looked great on all key metrics." (Ex. KK at 213.) Analysts also stated that HARMONY "showed strong initial response as well as relapse prevention with pima treatment across the subtypes." (Ex. LL at 215.) They further expressed that HARMONY's demonstrated reduction in risk of relapse of 65% "beat our expectations . . . by quite a margin," ***even after specifically addressing the relative underperformance of pimavanserin in treating some dementia subtypes***, and believed the study "demonstrate[ed] strong, clinically meaningful efficacy that should drive approval and commercial adoption." (*Id*. at 215, 217–18.) Here again, there are no facts alleged showing that ***anyone*** regarded HARMONY's design or its data as flawed before the FDA rejected Acadia's sNDA. The only plausible inference is that Defendants reasonably believed the clinical data was supportive of the sNDA.

Fourth, the Opposition relies on inapposite caselaw. (*See* Opp. at 13.) For

[6] Plaintiffs cite ***no authority*** for their conclusory claim that Acadia's studies and data were "threadbare science," "statistically insignificant," and insufficient to support an sNDA. (Opp. at 11.) "[C]onclusory adjectives do not meet the PSLRA's heightened pleading requirements." *Nektar*, 2022 WL 1573821 at *4–5.

example, in *Khoja v. Orexigen Therapeutics, Inc.*, the FDA specifically warned the defendant company that its early clinical trial results were unreliable and likely to change. 899 F.3d 988, 996 (9th Cir. 2018). As the trial continued, the results did in fact change for the worse. *Id.* at 1015. And, in *Schueneman v. Arena Pharmaceuticals, Inc.*, the company expressed confidence that its drug would be approved by the FDA, citing the company's animal studies, without disclosing that one of those studies indicated the company's drug caused cancer in rats. 840 F.3d 698, 707 (2016). These cases held that defendants' failure to disclose information they ***knew*** cast serious and obvious doubt on what they said publicly was sufficient to allege falsity. No such particularized factual allegations can be found in the CAC.

Fifth, it is undisputed that Defendants "never characterized . . . any particular dementia subgroups in HARMONY[]" because "[t]he very point of HARMONY was to support . . . an sNDA for authorizing pimavanserin to treat DRP writ large." (Mot. at 17–18; Opp. at 16.) Plaintiffs cannot identify any challenged statement to the contrary because Defendants never made one. Rather, Defendants made clear to investors that HARMONY was ***not*** designed to target specific subgroups within DRP, and that the impact of the drug within subgroups was not a primary or secondary endpoint of the clinical trial. (Mot. at 16–18.)

Sixth, and finally, Plaintiffs cannot wish away application of the PSLRA safe harbor. They contend that, "even if some portions of the cited statements arguably had a forward-looking element, they are still actionable where they contain an actionable element of present or historical fact," and Acadia's accompanying risk disclosures were supposedly "boilerplate." (Opp. at 20.) But Plaintiffs do not identify a single statement containing an "actionable element of present or historical fact." And they do not even address the host of risk disclosures ***specifically*** warning investors about HARMONY, the Company's engagement with the FDA, and FDA approval of pimavanserin for treatment of DRP. (Mot. at 14.)

At best, Plaintiffs allege a differing opinion as to the sufficiency of

HARMONY's design and results—not the falsity of any statement by Defendants.

B. Plaintiffs Still Fail to Plead a Strong Inference of Scienter.

To adequately plead scienter, Plaintiffs must allege, "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). The CAC does not come close to clearing this high bar (*see* Mot. at 21), and nothing in Plaintiffs' Opposition alters this result. Plaintiffs argue that Defendants (1) were motivated to defraud investors because of Acadia's public offering and certain stock sales; and (2) knowingly lied about an FDA agreement and the supposed flawed trial design and data. (Opp. at 20–24.) Neither allegation is well pled.

1. Acadia's public offering and Defendants' stock sales do not support a strong inference of scienter.

To start, Acadia's September 2019 public offering is insufficient as a matter of law to establish scienter in the Ninth Circuit. (*See* Mot. at 21–22.) Plaintiffs characterize the timing of the offering as "patently suspicious," presumably because it followed an uptick in Acadia's stock price following the September 9, 2019, announcement that HARMONY had met its primary endpoint. But, as explained above, Defendants never concealed anything about HARMONY, and there are no facts alleged as to any individual Defendant's state of mind, much less suggesting that he intended to defraud investors via the stock offering.[7]

Mr. Davis's and Mr. Stankovic's individual stock sales are likewise insufficient to support a strong inference of scienter. (Mot. at 22–23.) Plaintiffs still fail to link any ***particular*** sale to any ***specific*** challenged statement. Moreover, Plaintiffs argue that Mr. Stankovic "did not adopt any [10b5-1] plan until after the

[7] Notably, when Acadia disclosed HARMONY's full dataset on December 5, 2019, its stock price ***increased*** to $50.48, a 14% rise from the day prior. (Ex. MM at 221.) This belies Plaintiffs' argument that Acadia's presentation of the full data set at a medical conference was insufficient to counter-balance Defendants' other statements about its clinical trials. (*See* Opp. at 15.)

Class Period had already started," that "Davis sold . . . shares pursuant to an August 2019 plan adopted just two weeks before the Class Period started," and that Mr. Davis sold all of his remaining shares after he adopted a new 10b5-1 plan in December 2019. (Opp. at 22–23.) But Plaintiffs make no allegation that the information disclosed by Acadia in September 2019 was available when Mr. Davis entered into his August 2019 10b5-1 plan, and his second 10b5-1 plan was entered into on December 19, 2019—***after*** Acadia publicly released HARMONY's full data set. (Ex. EE at 161.) Plaintiffs likewise make no attempt to link any of Mr. Stankovic's sales to any challenged statement.[8] Plaintiffs have simply failed to sufficiently allege that any of these stock sales were suspicious. (Mot. at 22.)

2. Acadia had no motive to lie about an FDA agreement or to knowingly mischaracterize its clinical trial data.

Unable to plausibly allege a motive for fraud, Plaintiffs default to their conclusory (and erroneous) allegations regarding the FDA agreement and the HARMONY clinical trial. But these arguments fail for the same reasons as presented above. (*See* Section II.A, *supra*.) Further, they make no sense. Plaintiffs do not explain ***why*** Defendants would lie about the FDA agreement and the Company's clinical data, knowing they would eventually be found out when they submitted pimavanserin for approval. Plaintiffs ask this Court to believe that Defendants would pursue an outcome they ***knew*** to be impossible—one that would surely and severely damage Acadia—and that the Company would waste years of time and millions of dollars in the process. That theory "does not make a whole lot of sense" and "the PSLRA neither allows nor requires [courts] to check [their] disbelief at the door." *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 408, 415 (9th Cir. 2020).

[8] Mr. Stankovic's only sales prior to Acadia's presentation of the full HARMONY data set in December 2019 were made to pay taxes on vested stock units. (Ex. FF.) These sales did not indicate scienter. *N. Collier Fire Control & Rescue Dist. Firefighter Pension Plan & Plymouth Cty. Ret. Ass'n v. MDC Partners, Inc.*, 2016 WL 5794774, at *20 (S.D.N.Y. Sept. 30, 2016) ("[T]he disposition of shares to pay taxes do[es] not demonstrate a defendant's motive to defraud[.]").

C. Plaintiffs Still Fail to Adequately Plead Loss Causation.

Plaintiffs admit that, to adequately plead loss causation, they must allege "corrective disclosures by which 'defendant's fraud was revealed to the market and caused the resulting losses.'" (Opp. at 24 (quoting *Grigsby v. BofI Holding, Inc.*, 979 F.3d 1198, 1205 (9th Cir. 2020).) But no such revelation of fraud ever occurred, which Plaintiffs also admit. (*See* Opp. at 2 (describing March 8 as the date on which "Defendants revealed that the FDA had rejected the sNDA for unspecified 'deficiencies,'" and describing April 5 as "when [Acadia] disclosed further details regarding the bases for the FDA's decision").) So, what prior misstatement or untruth was corrected by these disclosures? Plaintiffs do not (and cannot) say. *See Or. Pub. Emps. Ret. Fund v. Apollo Grp.*, 774 F.3d 598, 608 (9th Cir. 2014) (plaintiffs failed to plead loss causation because "[i]t is unclear what claims made by the Defendants were invalidated" by alleged corrective disclosure).

Instead, Plaintiffs declare that the March and April 2019 disclosures "were plainly construed by shocked investors as evidence" (i) that no FDA agreement had ever existed, (ii) that Defendants' statements about the sNDA's supporting data were "at best materially misleading," and (iii) that Defendants had "misled investors as to the true magnitude of the risk that the sNDA would be rejected." (Opp. at 25.) However, this is self-serving and made up; Plaintiffs provide ***no*** factual support for these conclusions. Accordingly, they cannot meet their pleading burden by baldly asserting that, ***at the time*** of the alleged corrective disclosures, investors "plainly construed" Acadia's announcements as Plaintiffs do now. *See Nektar Therapeutics*, 2022 WL 1573821, at *7 ("[Plaintiffs'] factual allegations most plausibly suggest that relatively disappointing test results, not any revelation of earlier falsehoods, caused [the company]'s share price to plunge.").

III. CONCLUSION

For these reasons, as explained above and in Defendants' Motion, the Court should dismiss the CAC.

Dated: June 2, 2022

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