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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,

vs.

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

Defendants.

No. 3:21-cv-00762-WQH-NLS

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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

Oral Argument Requested

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Lead Plaintiff City of Birmingham Relief and Retirement System and additional Plaintiff Ohio Carpenters' Pension Fund (together, "Plaintiffs") submit this Opposition to Defendants' Motion to Dismiss (Dkt. No. 53 (the "Motion")) and Defendants' accompanying brief in support thereof (Dkt. No. 53-1 ("Def.Br.")).

PRELIMINARY STATEMENT

This securities class action involves both outright false statements and misleadingly selective disclosures by Defendants, consisting of Acadia Pharmaceuticals, Inc. ("Acadia" or the "Company"), its CEO, Stephen Davis ("Davis"), and its President and Head of Research & Development, Srdjan Stankovic ("Stankovic"). Between September 9, 2019 and April 4, 2021, Defendants repeatedly told investors that Acadia had an agreement with the FDA regarding the nature of the scientific study work and supporting data needed to expand the treatment indication[1] for Acadia's marquee drug, pimavanserin—which (then as now) was limited to treating dementia-related psychosis ("DRP") only in patients with Parkinson's disease—to include the treatment of patients with ***any*** type of DRP. However, Acadia had no such agreement with the FDA, and the studies Defendants touted as supporting its supplemental new drug application ("sNDA") for pimavanserin suffered from such significant design and data inadequacies that, absent such an agreement, the chances of FDA approval were slim at best. Indeed, the FDA did reject the sNDA, citing these inadequacies as the basis for its decision.

Defendants' arguments for dismissal lack merit. For example, they assert that their descriptions of an agreement with the FDA to support an sNDA that could rely on the results of "single, well-controlled study" ("HARMONY") were true. However, their position requires this Court to assume that the FDA entered into an agreement that the FDA then reneged on. Defendants' position is inherently implausible, and fails to defeat Plaintiffs' well-pled allegations of false and

[1] An "indication" refers to FDA approval of a drug's use to treat a specific condition. Using a drug to treat something outside of its indication is considered "off-label."

misleading statements. Indeed, in circumstances where, as here, defendants' dismissal arguments depend on accepting as true assertions that the FDA double-crossed them, the inference that ***defendants*** acted with *scienter* is at least as strong as any contrary benign inference. *See, e.g.*, *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 809-10 (C.D. Cal. 2011). And Plaintiffs' already strong ***scienter*** inferences here are further strengthened by allegations that the scheme allowed Davis and Stankovic to sell over $44 million of their Acadia shares (and allowed Acadia to conduct a $287 million secondary offering) at artificially inflated prices during the Class Period. *See, e.g.*, *In re BioMarin Pharma Inc. Sec. Litig.*, 2022 WL 164299, at *13 (N.D. Cal. Jan. 6, 2022).

In sum, this is a classic case where Defendants are liable for falsely touting the purported likelihood of FDA approval while knowingly or recklessly disregarding that the clinical data supporting the sNDA was so insufficient as to likely doom its chances for FDA approval. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1011 (9th Cir. 2018); *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016). And loss causation is well-pled, as Plaintiffs allege how Acadia shares plummeted 45% on March 9, 2021 (when Defendants revealed that the FDA had rejected the sNDA for unspecified "deficiencies") and 17% more on April 5 (when it disclosed further details regarding the bases for the FDA's decision). The motion to dismiss should therefore be denied in its entirety.

STATEMENT OF FACTS

Acadia develops and manufactures drugs to treat central nervous system disorders. ¶¶2, 27.[2] The FDA approved Acadia's marquee product, pimavanserin, to treat Parkinson's disease psychosis in 2016—one of several types of DRP (along with dementia associated with, *e.g.*, Alzheimer's disease, Lewy bodies, vascular conditions, and "frontotemporal" conditions.) ¶¶2, 27, 31, 39, 70. Each type of

[2] Citations to "¶__" are to paragraphs of the Amended Class Action Complaint ("AC") (Dkt. No. 45); unless otherwise stated, all emphases in quoted materials are added, and all internal quotation marks and citations are omitted.

dementia is different, and patients with these different underlying conditions have different DRP symptoms, respond to different treatments, and face different health and safety issues. ¶70. For example, patients with Alzheimer's or Lewy bodies are more likely to have hallucinations than those with frontotemporal dementia (who are more likely to suffer from delusions, such as paranoia or erotomania)—and patients with the same underlying diagnosis can suffer different DRP symptoms. *Id.*

There is no FDA-approved drug to treat ***all*** the myriad forms of DRP. ¶41. Around 2.4 million Americans diagnosed with dementia suffer from DRP—but only 400,000 have Parkinson's DRP. ¶¶66, 69. Expanding pimavanserin's "indication" beyond Parkinson's to include ***all*** forms of DRP would thus dramatically increase the drug's commercial value. ¶69. Accordingly, in October 2017, Acadia launched HARMONY, a Phase III placebo-controlled relapse prevention study, to test pimavanserin as a treatment for DRP more broadly and (hopefully) support expanding its "indications" to ***non***-Parkinson's DRP patients.[3] ¶¶44, 52-53.

A. The Flawed HARMONY Study and Acadia's sNDA

HARMONY's design was dubious from the start because it was not sufficiently powered to separately address the different sub-groups of patients who suffer from DRP, and instead was populated by a mix of patients with the five most common forms of DRP to test pimavanserin's "overall" effectiveness. ¶¶73-74.

HARMONY enrolled 392 patients. ¶74. The distribution of diagnoses within the study population was: 66.3% Alzheimer's; 15.1% Parkinson's dementia; 9.7% vascular dementia; 7.1% Lewy bodies dementia; and 1.8% frontotemporal dementia. ¶75. This distribution was problematic. *First*, because the second largest cohort consisted of Parkinson's patients, the test population was skewed by including many patients who had the type of DRP for which pimavanserin had ***already*** been shown to be effective. ¶76. *Second*, HARMONY included only 73 patients suffering from

[3] HARMONY followed patients until a "relapse", defined as (a) hospitalization as a result of DRP, (b) deterioration of dementia symptoms, (c) withdrawal from the study due to lack of efficacy, or (d) use of another antipsychotic medication. ¶53.

vascular dementia, frontotemporal dementia, or dementia with Lewy bodies. ¶77. HARMONY thus lacked sufficient patients (*i.e.*, was "underpowered") to demonstrate pimavanserin's efficacy in treating DRP associated with any of these three forms of dementia—and because it had only about 260 Alzheimer's patients, it was also unlikely to have a sufficiently large population to show efficacy in Alzheimer's patients absent remarkably positive results. ¶¶77-83.

On September 9, 2019 (the first day of the Class Period), Acadia issued a press release declaring that HARMONY had met its primary endpoint by demonstrating a "statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo." ¶107. ***However,*** as Defendants also knew but did not disclose, HARMONY's data also showed that pimavanserin had failed to produce any meaningful benefit for ***non-Parkinson's*** patients. In short, although HARMONY showed a statistically significant ***15.7%*** improvement among *all* patients, ***a material portion of that benefit was attributable to Parkinson's patients, 43.3%*** of whom improved relative to placebo (a result consistent with prior studies in Parkinson's patients). ¶82. Excluding the Parkinson's patients, HARMONY showed a far smaller and statistically ***insignificant*** benefit of only 9%. *Id.*

Indeed, despite small sub-population sizes, HARMONY actually indicated pimavanserin was no better than—and in some cases even worse than placebo—in treating patients with ***non***-Parkinson's DRP. ¶83. For example, 17% of vascular dementia patients relapsed irrespective of whether they received pimavanserin or placebo. The results were even worse for frontotemporal dementia patients, where ***100%*** treated with pimavanserin relapsed vs. ***0%*** who got placebo. HARMONY also failed to show statistically significant benefit to Alzheimer's patients. However, Defendants' selective disclosure of only HARMONY's favorable "top line" results concealed how they depended on Parkinson's patient data, and how HARMONY had actually ***failed*** to show that pimavanserin had any meaningful benefit on patients suffering from other, ***non***-Parkinson's types of dementia. *Id.*

Given HARMONY's combination of structural deficiencies and lackluster results for non-Parkinson's patients, Defendants would soon try to cobble together additional clinical data to support Acadia's sNDA for expanding pimavanserin's indication by turning to two prior clinical trials, consisting of: (i) a July 2011 study ("020") that evaluated pimavanserin's efficacy, tolerability and safety to treat Parkinson's DRP (and which had provided the primary basis for the FDA's 2016 approval of pimavanserin to treat Parkinson's DRP); and (ii) an exploratory trial ("019") that designed to evaluate pimavanserin's efficacy and safety for Alzheimer's DRP, whose topline results had been previously announced in December 2016. ¶¶45-49. However, of these two studies, only 019 involved non-Parkinson's patients, and 019 suffered from its own problems. ¶84-90. For example, 019 had control deficiencies, as it allowed enrolled patients to also receive "prohibited medications" (thereby raising issues as to whether observed benefits were due to the drug or the meditations). ¶86. And, as for its results, 019 indicated that after six weeks of treatment pimavanserin had a beneficial impact *only* on visual hallucinations in Alzheimer's patients—but not on other (non-hallucinatory) types of Alzheimer's psychoses (¶85)—and even that benefit was doubtful because after 12 weeks (rather than 6) pimavanserin had no observable impact. ¶¶87-88. 019 also failed to show efficacy in six of seven subgroup analyses even in the shorter six-week period, and also failed to show efficacy for 17 of 18 secondary outcomes. ¶89.

HARMONY's design and results, either standing alone or together with 019 and 020, could thus not be reasonably expected (by Defendants or investors) to support FDA approval for an sNDA to expand pimavanserin's indication to include all DRP patients—*unless* there was an ***agreement*** with the FDA allow the "overall" results, in a *mixed* population of DRP patients, from a "single, well-controlled study" such as HARMONY, to support approval. ¶¶84, 90 ,92, 109-10.

B. Defendants' False and Misleading Statements

On September 9, 2019, the first day of the Class Period, Defendants

announced HARMONY's purportedly successful results, and advised that Acadia would soon be meeting with the FDA to discuss moving forward with its sNDA. ¶107. On an analyst call later that day, Stankovic again touted HARMONY's "positive" results—and also represented that the FDA had "confirmed" in prior conversations "that for our [sNDA] ... we could rely on a single, well-controlled study whose results were both statistically and clinically very persuasive." ¶109. In response, Acadia's shares skyrocketed, closing up 63%. ¶6.

However, these statements were materially false and misleading because they failed to disclose that HARMONY's "successful" and "positive" results were effectively due only to favorable (but expected) results in Parkinson's DRP patients, and thus were woefully insufficient to support expanding pimavanserin's existing FDA-approved indication beyond Parkinson's DSP. ¶¶108, 110. Moreover, Defendants' assertions that the FDA had "agreed" that Acadia could support an sNDA to expand pimavanserin's indication based on a "single, well-controlled study whose results were both statistically and clinically very persuasive" was materially false and misleading, because the FDA had ***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. ¶¶109-10.

Thereafter, as set forth at ¶¶107-42, Defendants repeated some version of these false and misleading statements on 17 more occasions after September 9, 2019, where they similarly claimed that the Company's data showed that pimavanserin (a) was an effective treatment for non-Parkinson's forms of DRP and/or (b) was sufficient to support FDA approval of its sNDA to expand the drug's existing treatment indications beyond Parkinson's DRP. These public statements included:

- May 7, 2020 statements that "sNDA preparation remains firmly on track" (¶115);
- June 15, 2020 statements that HARMONY "showed a meaningful reduction of the symptoms and stabilization of psychosis" (¶119);

- August 6, 2020 statements that HARMONY "demonstrat[ed] that pimavanserin significantly reduced the risk of relapse of psychosis" (¶127);
- September 14, 2020 statements that Defendants were "very confident . . . in our data," and had a "strong package" for FDA approval (¶128);
- November 17, 2020 statements that "we remain highly confident in [] the efficacy… data supporting our [sNDA]" and citing "the robust and meaningful results from HARMONY and additional supporting [efficacy] data." (¶132); and
- January 12, 2021 statements citing "strong and robust efficacy data" (¶134).

Defendants also continued to fraudulently embellish on their original September 9, 2019 assurances of having reached "agreements" with the FDA regarding the sufficiency of HARMONY's design and Acadia's plan for the sNDA. ¶¶109, 111, 117, 125, 128, 132, 135. For example, when asked on an October 30, 2019 analyst call whether Acadia would seek FDA approval to treat all forms of DRP, Defendant Stankovic stated:

> [A]ll discussions that we had with the FDA and our initial intention were related to us pursuing indication of treatment of hallucinations and delusions in dementia-related psychosis. ***So yes,... and that is what we had discussed with the FDA***.

¶111. Subsequently, at a May 12, 2020 healthcare conference, Defendant Davis reiterated that the FDA had precleared HARMONY's design:

> [W]e had our pre-sNDA meeting in the first quarter. The feedback 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 . . . .

¶117. On August 19, 2020, Davis reiterated that Acadia had "***got a clear agreement from ... the FDA***" to seek an indication to treat DRP more broadly, and that Acadia "executed the plan that we agreed to with them." ¶125. Similarly, when asked about HARMONY's trial design, he added that Acadia had "***agreed with the FDA on that approach at our end of Phase II meeting and agreed on the plan for [HARMONY] and then we've executed that plan***." *Id; see also* ¶128 (9/14/2020 statement citing agreement with FDA to pursue a broad indication for DRP). And on November 17, 2020, Davis claimed that the FDA had "agreed" to three things:

> "[O]ne, that we stud[y] DRP generally.... Two that we run a relapse-prevention study now to demonstrate...not only that we can stabilize patient symptoms, but that we get a durable effect over time. And then three... that ***a single relapse prevention study serve as the basis of approval***, together with the other supporting acute studies we've done.

¶132; *see also* ¶¶135-36.

Unfortunately for investors, however, such statements about a purported "agreement" with the FDA were materially false and misleading, because the FDA had ***never*** agreed (a) that a single study that was able to report positive "aggregate" results in DRP patients would support an expanded sNDA (to include a broadened treatment indication beyond just Parkinson's DRP patients) where, as in HARMONY, the data ***failed*** to also demonstrate positive results in the non-Parkinson's patients or any sub-group thereof; or that (b) any of Acadia's other existing "acute studies" (*e.g.* 019) could support FDA approval given HARMONY's problematic design and woeful results in non-Parkinson's DRP patients. *E.g.*, ¶92.

C. Defendants' Suspicious Insider Sales and Secondary Offering

As a result of Defendants' fraud, Acadia's stock price was artificially inflated throughout the Class Period—and Defendants took full advantage. For example, just 8 days after their misleading September 9 statements touting HARMONY's purported "success" (which caused Acadia shares to soar ***63%***), Defendants conducted a secondary offering on September 17, 2019—selling nearly ***7.2 million*** Acadia shares to Class members at the grossly inflated price of $40 per share for total net proceeds to the Company of ***over $270 million***. ¶104. Moreover, both Individual Defendants reaped millions from their own separate insider sales at inflated prices during the Class Period, with Davis' reaping nearly ***$25 million*** and Stankovic reaping nearly ***$19 million.*** ¶¶105-06. Such sales were unusual as to both their timing and size, as neither Davis nor Stankovic had previously sold ***any*** Acadia shares. *Id*. And although Davis and Stankovic's sales were made pursuant to so-called "Rule 10b5-1 trading plans", those plans raise no exculpatory inferences here as they were adopted either just before or *during* the Class Period. *Id.*

D. The Truth Begins to Emerge

After markets closed on March 8, 2021, Acadia issued a release stating that the FDA had advised that "as part of its ongoing review of [Acadia's pimavanserin sNDA], the FDA ha[d] identified [unspecified] deficiencies that preclude discussion of labeling and post-marketing requirements/commitments." This news stunned the market, causing Acadia shares to promptly plummet ***over 45%.*** ¶¶143-44.

On April 5, Defendants disclosed that they had received a Complete Response Letter ("CRL") from the FDA rejecting the sNDA. ¶145. Defendants have yet to release the CRL itself (¶12), but the April 5 release asserted as follows:

> ***Despite prior agreements with [the FDA] regarding the pivotal Phase 3 HARMONY study design targeting a broad DRP patient population analyzed as a single group, the [FDA], in the CRL, cited a lack of statistical significance in some [dementia] subgroups … and insufficient numbers of patients with certain less common dementia subtypes as lack of substantial evidence of effectiveness to support approval.***
>
> Statistical separation by dementia subgroups and certain minimum numbers of patients with specific subtypes were not among the ***prespecified requirements***. [CEO Davis stated that] "Acadia stands behind the robustly positive results from the … HARMONY study and the prospectively agreed trial design and criteria for establishing efficacy in DRP. Over the entire course of the review, the [FDA] did not raise any concerns regarding the agreed upon study design, including the issues raised in the CRL"….
>
> Th [FDA] also stated in the CRL that it considers the Phase 2 Alzheimer's disease psychosis stody 019, a supportive study in the sNDA filing, to not be adequate and well controlled, citing that it was a single center study with no type I error control of secondary endpoints in which certain protocol deviations occurred. The Company believes these observations impact neither the positive results on the study's primary endpoint, nor the study's overall conclusions of efficacy.

¶145. On these further disclosures, Acadia's stock price fell another 17%. ¶146.

ARGUMENT

I. RELEVANT PLEADING STANDARDS

"Dismissal is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support [one]." *Khoja*, 899 F.3d at 1008. In making this determination, courts accept as true all well-pled factual allegations and construe them in the light most favorable to plaintiffs. *In re Atossa Genetics Inc Sec. Litig.*,

868 F.3d 784, 793 (9th Cir. 2017); *In re Alphabet, Inc. Sec. Litig.*, 1 F.4th 687, 698 (9th Cir. 2021). Under Rule 9(b) and the PSLRA, Plaintiffs must also allege the "who, what, when, where and how" of the alleged misstatements. *Kendall v. Odonate Therapeutics, Inc.*, 2021 WL 3406271 at *3 (S.D. Cal. Aug. 4, 2021); *In re Obalon Therapeutics, Inc.*, 2019 WL 4729461, at *3 (S.D. Cal. Sept. 25, 2019).

Under the PSLRA, Plaintiffs must also allege facts supporting a "strong inference" of defendants' scienter (intentional or reckless misconduct). Such an inference "need not be irrefutable, *i.e.*, of the 'smoking gun' genre, or even the most plausible of competing inferences" but need only be "as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rts. Ltd.*, 551 U.S. 308, 324 (2007). In making this determination, courts must draw all reasonable inferences in plaintiffs' favor, *ESG Cap. Partners, LP v. Stratos*, 828 F.3d 1023, 1035 (9th Cir. 2016), and consider all of plaintiffs' allegations "holistically." *In re Alphabet*, 1 F.4th at 701 (quoting *Tellabs*, 551 U.S. at 326).

II. PLAINTIFFS ADEQUATELY ALLEGE THAT DEFENDANTS MADE MATERIALLY FALSE AND MISLEADING STATEMENTS

At the outset, Defendants argue that the AC fails to adequately identify "each statement alleged to have been false or misleading" or to explain why it was false or misleading when made. Def.Br. at 10-11. However, the AC identifies each challenged statement (and its surrounding context), and succinctly explains why it was false or misleading. ¶¶107-142.[4] Instead, Defendants' gripe is really that the AC purportedly fails to allege sufficient facts and circumstances from which one can plausibly infer that their statements were false or misleading. Defendants are wrong.

A. The AC Adequately Alleges that Defendants' Statements About an "Agreement" with the FDA Were False

Courts routinely hold that when a pharmaceutical company misstates "the

[4] Defendants incorrectly imply that there are heightened rules for pleading securities fraud with particularity "[i]n the context of clinical trials." Br. at 17. But their only supporting case did not involve clinical trials. *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 999-1000 (9th Cir. 2002) (hospital corporation and its officers allegedly misled plaintiffs as to progress toward a merger").

basic facts regarding the company's ongoing involvement with the FDA, and thus the likelihood of [] approval" of a drug, liability under the federal securities laws will follow. *MannKind*, 835 F. Supp. 2d at 809-10 (statements that "described the FDA's 'vetting' of, 'blessing' of, 'approval' of, and 'agreement' with" design of Defendant's studies were plausibly false, "[b]ased on the FDA's subsequent order of further studies" which indicated "that no 'agreement' or 'blessing' had ever been secured."); *see also, e.g.*, *BioMarin*, 2022 WL 164299, at *12 ("statements about [company's] relationship with the FDA" are actionable); *Skiadas v. Acer Therapeutics, Inc.*, 2020 WL 3268495, at *8 (S.D.N.Y. June 16, 2020) (plaintiff "plausibly alleged that Defendants' statements about what the FDA 'agreed to' were false or misleading"). The same holds true here.

The AC alleges that Defendants repeatedly assured investors that they had reached a prior agreement with the FDA regarding HARMONY's design and the data needed to support the sNDA. ¶¶109, 111, 113, 117, 125, 128, 132, 135. And the AC further alleges that these assurances were ***false*** because no such agreement existed. ¶¶110, 112, 118, 126, 129, 133, 136, 144-46. Plaintiffs further allege that Defendants made these false statements because they knew that HARMONY was underpowered, that 019 was not adequately controlled, that the non-Parkinson's DRP results from both studies were underwhelming at best, and that the chances of FDA approval of the sNDA were therefore slim at best. *Id*. In short, Defendants' statements whitewashed the threadbare science undergirding the sNDA by causing investors to believe that the FDA, despite these problems, had nonetheless already agreed that HARMONY and 019 were sufficient to support the sNDA—and thereby materially misled investors as to the sNDA's approvability.

Defendants respond by asserting that the AC's allegations are "conclusory and unsupported," and that Acadia ***had*** "obtained the FDA's consent regarding HARMONY's trial design and the Company's plan" for the sNDA. Def.Br. at 18-19. However, at the pleadings, the falsity of Acadia's claims to having an

"agreement" with the FDA can be readily inferred from the FDA's rejection of the sNDA on grounds inconsistent with the terms of the purported "agreement." For example, in *MannKind*, defendants assured investors that (i) their bioequivalency "study's design … was vetted with the FDA in advance"; (ii) they had "got [FDA's] blessing on the design"; and (iii) that they had an "agreement … with the FDA" about what data was necessary to support FDA approval of defendants' [NDA]"). *MannKind*, 835 F. Supp. 2d at 807-08. There, as here, the FDA ultimately rejected that NDA ***based on*** design flaws in the company's bioequivalency study and asked for two new "clinical trials." *Id.* at 804. On these allegations, the court found "that the most plausible inference to draw is that … no 'agreement' or 'blessing' had ever been secured," because the contrary inference—that the FDA rejected an NDA on grounds that were contrary to a prior agreement—was doubtful at best. *Id*. at 810.

Similarly, in *Skiadas*, defendants averred that the FDA had "agreed" that "additional clinical development [was] not needed" for their NDA. 2020 WL 3268495 at *8. The FDA, however, later rejected that NDA on the grounds that additional clinical trial work ***was*** necessary for approval—and *Skiadas* went on to hold that such facts sufficed at the pleadings to plausibly allege that the defendants' statements about an "agreement" were false because the FDA's actions were plainly inconsistent with any such "agreement." *Id*. at 9. In short, as in *MannKind* and *Skiadas*, "in light of what happened ... it is quite implausible that a written or oral agreement existed between the FDA and Acadia" (¶103), and instead the "common sense inference" here is "that the FDA would ***not*** 'approve,' 'bless' or 'agree to' that which it would reject several months later." *MannKind*, 835 F. Supp. 2d at 809.

Defendants' argument (Def.Br. at 12) that it is somehow more plausible to infer there was an agreement—and that the FDA reneged on it—is unsupported by any cited authority, and at best raises a factual dispute about the (non)existence of that "agreement" which cannot be resolved on a motion to dismiss. *See, e.g., Khoja*, 899 F.3d at 1003. Similarly unavailing (and unsupported) are their assertions that

the AC requires additional factual averments, such as confidential witness statements, to plausibly allege that no FDA agreement existed. *See, e.g.*, *Skiadas*, 2020 WL 3268459, at *8-*9; *MannKind*, 835 F. Supp. 2d at 809-10 (no CW allegations needed to further support inference of no FDA agreement).

B. The AC Alleges That Defendants Made Materially Misleading and Incomplete Statements as to the sNDA's Supporting Data

The AC also plausibly alleges that Defendants materially misled investors by touting the sNDA's likely success by emphasizing cherry-picked positive results while omitting "known shortcomings in the studies submitted with the sNDA, including disappointing data, [which] posed major obstacles to FDA approval." *E.g.*, ¶¶107-110, 113-14, 115-116 119-20, 127-36, 138-39; *see also supra* pp.6-7.

In this circuit, courts regularly hold that when a pharmaceutical company touts purportedly positive results from a drug study, it must *also* disclose known material facts that undercut the company's boosterism to avoid misleading investors. *E.g.*, *Khoja*, 899 F.3d at 1010-11 ("once Orexigen chose to tout the apparently positive 25% interim results, [it] had the obligation also to disclose that they were likely unreliable"); *Schueneman*, 840 F.3d 698, 705 (9th Cir. 2016) ("once defendants chose to tout [lorcaserin's likely approval by referencing allegedly positive animal and preclinical studies], they were bound to do so in a manner that wouldn't mislead investors as to [potentially negative information within their possession]") (alterations in original); *In re Nuvelo, Inc. Sec. Litig.*, 668 F. Supp. 2d 1217, 1230 (N.D. Cal. 2009) (statements actionable where they "concealed or downplayed known *present* risks related to regulatory approval"); *In re Amylin Pharm. Sec. Litig.*, 2003 WL 21500525, at *5 (S.D. Cal. May 1, 2003) (defendants liable if they "mislead [p]laintiffs about [the] risk [of FDA approval] by making assurances regarding the completeness of the data and the likelihood of FDA approval"). Consistent with such cases, Plaintiffs have adequately alleged that Defendants are liable for repeatedly touting the "robustness" of their data and its likely adequacy to

support FDA approval, while failing to disclose material adverse facts about the design flaws in, and lackluster results of, HARMONY and 019.

Defendants' misstatements and omissions must by assessed in the full context of what investors were told "if there is a substantial likelihood that a reasonable investor would have acted differently if the misrepresentation had not been made or the truth had been disclosed." *Khoja*, 899 F.3d at 1009. Here, Defendants' statements touting how HARMONY's "robust and meaningful results" had showed "meaningful" reduction of the symptoms and stabilization of [DRP]" and "that pimavanserin significantly reduced…relapse [risk]" (and those statements' related omissions) must also be analyzed against the backdrop of Defendants' false claims the FDA had "agreed" that it could support an sNDA for expanded DRP indications. ¶¶117, 119, 127. Accordingly, even if their statements about HARMONY, 019 and the sNDA were somehow deemed to be not materially misleading standing alone, they were *plainly* misleading in the context of Defendants' statements about a purported "FDA agreement. *See MannKind*, 835 F. Supp. 2d at 811-12 ("natural effect of these statements would be to create the impression for investors that ... there was a minimal chance of failure because the bioequivalence studies had been specifically approved or agreed by the very agency that would be reviewing them").

Defendants do not contest that they knew the truth about the designs of, and data from, HARMONY and 019 or that this information would have been material to investors. *See* Def.Br. at 15-18. Instead, they argue that "the information Plaintiffs claim was concealed...was fully disclosed," and that none of their statements could have materially misled investors as to the true strength of the relevant study data or the true likelihood of FDA approval." *Id.* at 15. These arguments are unavailing.

First, Defendants' "full disclosure" argument is just a form of the "truth-on-the-market" defense. *See In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1036 (S.D. Cal. 2005) (under this doctrine, if "information the defendants are alleged

to have withheld from or misrepresented to the market has entered the market through other channels, the market will not have been misled"). However, at the motion to dismiss stage "defendants bear a heavy burden of proof" to "show that no rational jury could find that the market was misled." *Id*.; *see also Khoja*, 899 F.3d at 1014 ("Only if the adequacy of the disclosure . . . is so obvious that reasonable minds could not differ are these issues appropriately resolved as a matter of law.");

At best, Defendants cite to ¶61-62, which alleges that Harmony's "full data set" was later (and separately) released in connection with a presentation made to *medical professionals*. But this falls far short of establishing the defense. *See In re Apple Comp. Sec. Litig.*, 886 F.2d 1109, 1116 (9th Cir. 1989) ("any material information which insiders fail to disclose must be transmitted to the public with a degree of intensity … sufficient to effectively counter-balance any misleading impression created by the insiders' one-sided representations"); *In re Thoratec Corp. Sec. Litig.*, 2006 WL 1305226 at *10 (N.D. Cal. May 11, 2006) (defense unavailable at pleadings as it is intensely fact-specific, and refusing to consider articles not included in complaint); *Provenz v. Miller*, 102 F.3d 1478, 1492-93 (9th Cir. 1996) (refusing to consider 31 documents submitted by defendants to try to establish market's knowledge on motion to dismiss).

Moreover, Defendants also ignore that all of their statements to investors were made in the context of their having repeatedly assured investors that the FDA had *precleared* the submission of an sNDA based on HARMONY (a "single, well-controlled study"), plus data from019. In this context, even if investors who reviewed all the data might have otherwise had concerns about its adequacy, they would ***still*** have been materially misled into believing that, because of the purported "FDA agreement," such concerns would be unlikely to adversely impact the chances of FDA approval. *MannKind*, 835 F. Supp. 2d at 811-12

Second, Defendants' "wall of precedent" where courts dismissed "critiques of a drug trial's design or methodology so long as the company did not affirmatively

misrepresent that design or methodology" (Def.Br. at 17), does not cite any Ninth Circuit cases. This is because courts in this circuit routinely hold companies accountable for touting the prospects of FDA approval for a drug where, as here, Defendants know that the underlying studies and data were likely *in*sufficient to obtain approval. *See, e.g.*, *Khoja*, 899 F.3d at 1011; *Schueneman*, 840 F.3d at 705; *Nuvelo*, 668 F. Supp. 2d at 1230; *Amylin Pharm.*, 2003 WL 21500525, at *5.

Moreover, even if Defendants were right—and they are ***not***—that some "affirmative misrepresentation" about study "design or methodology" (as opposed to a misleadingly positive statement that omits material adverse information) is required to plead a claim, the AC alleges that Defendants ***did*** affirmatively misrepresent HARMONY's design by falsely claiming that (i) the FDA had prospectively agreed on that trial's design (*e.g.* ¶¶109-117, 125, 132), and (ii) *inter alia*, HARMONY "demonstrate[d] that pimavanserin significantly reduced the risk of relapse of psychosis" sufficient to justify expanded indications to DRP patients generally (¶119), and (iii) HARMONY and 019 constituted a "strong package" of "robust efficacy data" that could support the sNDA (¶¶ 128, 134) despite their design flaws and lackluster data. Defendants' assertion that they did not mislead as to the "design or data" because they "never characterized … any particular dementia subgroups in HARMONY[]" is also nonsense. The very point of HARMONY was to support, in a single study, an sNDA for authorizing pimavanserin to treat DRP writ large. Their statements that HARMONY was sufficient for that purpose, given its design and data deficiencies, were thus material misrepresentations.

C. Defendants' Miscellaneous Arguments as to Why Their Misstatements Are "Not Actionable" All Fail

To avoid liability, Defendants (Br. at 12) also argue that "all" of the statements at issue are inactionable as a matter of law because they were either (i) true; (ii) immaterial puffery, (iii) inactionable opinion, or (iv) "forward-looking" statements immunized from liability by "meaningful cautionary language." Not so.

"True" Statements. Defendants construct a straw man by first creating an eight-page Appendix A—listing statement "fragments" that are obviously not at issue (*e.g.* App'x A at entry 3, citing "Breakthrough Therapy" designation)—and then arguing that ***all*** of the statements in Appendix A are also true, and hence inactionable. However, App'x A contains numerous examples of statements that (a) cited Acadia's purported "agreement" with the FDA (*e.g.* ¶¶109, 111, 113, 117, 125, 128, 132, 135), and which are adequately alleged to be ***false***), or (b) selectively and misleading touting the sNDA's data (and thus likely FDA approval) to investors while omitting known shortcomings in the studies submitted with the sNDA, including disappointing data that indicated that "the likelihood of FDA approval was very low." ¶¶107-110, 113-14; 115-116; 119-20; 127-36; 138-39. *See also Kendall*, 2021 WL 3406271, at *6 (statements that are literally true can be misleading and thus actionable where material adverse facts are omitted).

Puffery. Defendants (Br. at 12) assert that "many" challenged statements are mere "puffery," citing their App'x B. However, Defendants' statements—*e.g.*, characterizing HARMONY's results as representing a "step closer" to FDA approval (¶107, 119), that its efficacy data was "strong" (¶128) or "very strong" (¶135), merited "confidence" (¶¶130, 132), and was "robust and meaningful" (¶132) and that "every cut of data" continues to support approval (¶132) and "look very positive" (¶135)—were made in the context of describing *scientific results* and their fitness for supporting an sNDA, and not in the context of touting the inherently subjective qualities of, say, a new car model which no reasonable investor would consider material. *Compare, e.g.*, *In re Quality Sys., Inc. Sec. Lit.*, 865 F.3d 1130, 1143 (9th Cir. 2017) (even "general statements of optimism, ***when taken in context***, may form a basis for a securities fraud claim when those statements address specific aspects of a company's operation that the speaker knows to be performing poorly"); *Alphabet*, 1 F.4th at 700 (statements actionable where they "affirmatively create a plausibly misleading impression of a state of affairs that differed in a material way

[from] what actually existed"). Similarly, this court previously held that Acadia's statements that it was "on track" to submit the original NDA for pimavanserin (*cf.* similar statements at ¶¶115, 132, 138) were ***not*** puffery, but actionable "statements premised on facts" where the NDA was actually not "on track." *Rihn v. Acadia Pharms., Inc.*, 2016 WL 5076147, at *7 (S.D. Cal. Sept. 19, 2016). Being "premised on facts," as well as having been plainly used to "create a plausibly misleading impression of a state of affairs that differed in a material way [from] what actually existed," Defendants' puffery arguments should be rejected. *See also Mulligan v. Impax Labs, Inc.*, 36 F. Supp. 3d 942, 963-65 (N.D. Cal. 2014) (dismissal on puffery grounds requires a finding that a given statement is immaterial as a matter of law, and typically entails fact-intensive, context-based assessments that are more properly left to a jury) (citations omitted).

Opinions. Defendants next wrongly assert that "[o]pinion statements ... are actionable *only* 'if they are not honestly believed *and* lack a reasonable basis in fact." Def.Br. at 13 (citing *Smith v. Antares Pharma., Inc.*, 2020 WL 2041752 at *5 (D.N.J. Apr. 28, 2020). In fact, an opinion can be "misleading by omissions" where the statement "omit[s] material facts about the [defendants'] inquiry into or knowledge concerning a statement of opinion" and if those facts "conflict with what a reasonable investor would take from the statement itself." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 189 (2015); *Kendall*, 2021 WL 3406271, at *6 (same). Under the correct standard, the two types of "protected opinions" Defendants identify—namely those positively characterizing "clinical study results" and "pimavanserin's potential and the market need it could fill" (Def.Br. at 13)—are actionable for at least two reasons. *First*, such statements failed to disclose ***known adverse material facts*** that HARMONY and 019 were poorly designed and produced lackluster data in non-Parkinson's DRP patients that was highly *unlikely* to support FDA approval of the sNDA. *Cf. Kendall*, 2021 WL 3406271, at *6. *Second*, any opinions must be viewed in the context of

Defendants' false statements about Acadia's "agreements" with the FDA. *Acadia Pharms.*, 2016 WL 5076147, at *5 ("whether an omission makes an expression of opinion misleading always depends on context"); *accord Omnicare,* 575 U.S. 194. These statements, even if construed as "opinions", were clearly intended to, and did, reinforce for investors the sufficiency of HARMONY's and 019's design and data and the likelihood of FDA approval. *See MannKind,* 835 F. Supp. 2d at 811 ("natural effect" of "statements concerning 'approval' and 'blessing' by the FDA" is "the impression for investors that ... 'it was in the bag'"). A reasonable investor hearing Defendants' statements about the HARMONY and 019 "clinical study results" and "pimavanserin's potential" would have believed (wrongly) that there were no design flaws or data issues that materially threatened its approval, because Defendants had averred that the FDA had already "confirmed that the studies can support an sNDA." ¶117. The out-of-circuit authority Defendants cite[5] are inapposite for the same reason: ***none*** address a situation where a company falsely misrepresented an agreement with the FDA.

Forward-Looking Statements. Defendants (Def.Br. at 14 & App'x D) also aver that ***portions*** of 11 statements are protected by the PSLRA's "safe harbor," 15 U.S.C. §78u-5, because they were both "forward-looking" and accompanied by "meaningful cautionary language." However, the "forward-looking" statements Defendants identify all concern the sNDA, the FDA's review of that sNDA, and "the potential for [pimavanserin] becoming the first and only approved treatment" for DRP. Def.Br. at 14 & App'x D. The purpose of these statements was, at least in part, to assure investors that the FDA approval process was still "on track" and such "assurances were representations about the *current* state of affairs with respect to the [s]NDA process," and thus not protected by the PSLRA safe harbor. *Acadia*

[5] *See Tongue v. Sanofi*, 816 F.3d 199, 203-07 (2d Cir. 2016); *Antres Pharma, Inc.*, 2020 WL 2041752 at *1-*3; *Nguyen v. New Link Genetics Corp.*, 297 F. Supp. 3d 472, 478-82 (S.D.N.Y. 2018); *Biondolillo v. Roche Holding, AG*, 2018 WL 4562464, at *1-*3 (D.N.J. Sept. 24, 2018); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 517-25 (S.D.N.Y. 2015).

Pharms., 2016 WL 5076147 at *6-*7; *accord Mulligan*, 36 F. Supp. 3d at 963-65.

Moreover, 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. *Quality Sys.*, 865 F.3d at 1142 ("safe harbor is not designed to protect companies and their officials when they … [misrepresent] current or past facts, and combine [it] with a forward-looking statement").

In addition, Defendants' so-called "cautionary language" (Def.Br. at 14) "spoke entirely of as-yet-unrealized risks and contingencies" – but were patently inadequate as they "failed to alert the investors that some of these risks may have already come to fruition." *Khoja*, 899 F.3d at 1010; *Quality Sys.*, 865 F.3d at 1143-44 (statement that company "anticipates" a positive is actionable for omitting present facts that have already occurred). Here, none of defendants' recitations of their boilerplate "Risk Disclosures"—*e.g.* that the Company's statements were "only predictions" and that "[a]ctual events or results may differ materially"—come close to disclosing the then-existing design weaknesses in HARMONY or 019 or those studies' lackluster data with respect to non-Parkinson's DRP–or corrected their prior false assertions about an FDA "agreement." Nor did the boilerplate "risk warnings" address the very specific design and data issues that the FDA, predictably, focused on in rejecting the NDA. *See*, *e.g.*, *Biomarin*, 2022 WL 164299, at *7 (warnings "must precise[ly] and directly address the alleged misrepresentation").[6]

III. PLAINTIFFS ALLEGE A STRONG INFERENCE OF SCIENTER

A. Defendants' Knowledge Of and Access To Contrary Facts

"[F]alsity and scienter in … securities fraud cases are generally inferred from the same set of facts," such that both requirements are often considered as part of a "unitary inquiry." *Id.* at *13 n.6 (quoting *In re Daou Sys., Inc.*, 411 F.3d 1006, 1015 (9th Cir. 2005)). This is a paradigm case for such analysis.

[6] Nor does the AC plead "fraud by hindsight" (Def.Br. at 18); *compare MannKind*, 835 F. Supp. 2d at 809 ("Fraud is almost always detected after the fact.")

For example, after finding that plaintiff had adequately alleged the falsity of defendants' class period statements that they had an agreement with the FDA on the adequacy of the company's trial design and methodology for establishing "bioequivalency"—based on the "common sense" inference that the FDA would not renege on a prior agreement had one actually existed—*MannKind* found that the same facts supported a strong *scienter* inference. 835 F. Supp. 2d at 812 ("***taken alone***, Defendants' statements concerning 'approval' by or an 'agreement' with the FDA are sufficient to demonstrate a strong inference of scienter"); *see also Skiadas*, 2020 WL 3268495, at *10 (same). And, as in *Mannkind*, 835 F. Supp. 2d at 814, and *Skiadas*, 2020 WL 3268495, at *11, it can be readily inferred that the Individual Defendants had either actual knowledge that the FDA had not agreed to what Acadia claimed, or recklessly ignored material information that they had access to which contradicted their public statements regarding the FDA's positions.

Defendants' failure to disclose known design deficiencies in HARMONY and 019 and those studies' poor results with respect to *non*-Parkinson's DRP further buttresses the requisite strong inference of scienter. Indeed, it is well settled that a "failure to inform the market about the risk of non-approval or delayed approval [by the FDA]" can be "an extreme departure from the standards of ordinary care" that gives rise to an inference of scienter when a company knows its studies and data likely do not support FDA approval. *Schueneman*, 840 F.3d at 708; *see also Mannkind*, 835 F. Supp. 2d at 811 (even if defendants' misleading statements regarding the merits of their bioequivalency studies "do not alone" demonstrate scienter, they further supported the requisite strong inference). Nor do Defendants' actions in disclosing HARMONY's underlying data set (once) to *medical* professionals months after its initial September 9 statements (*see* ¶¶61-62) show "good faith." To the contrary, as in *In re Iso Ray, Inc. Sec. Litig.*, one may reasonably infer that Defendants repeatedly issued misleadingly incomplete statements about its "successful" studies precisely because they believed that investors would rely on

those statements without ever reviewing the underlying study data—particularly where that data may have been "too complex for a reasonable investor to understand"). 189 F. Supp. 3d 1057, 1073-74 n.11 (E.D. Wash. 2016).

Neither of Defendants' two cited cases are to the contrary. In both, plaintiffs "fail[ed] to establish that Defendant in fact had knowledge either of the allegedly omitted clinical data ... [or] that these data created any increased regulatory risk." *Carr v. Zosano Pharma Corp.*, 2021 WL 3913509, at *11 (N.D. Cal. Sept. 1, 2021); *see also Colyer v. AcelRx Pharms., Inc.*, 2015 WL 7566809, at *11-*12 (N.D. Cal. Nov. 25, 2015). Here, in contrast, Defendants do ***not*** dispute that they knew about HARMONY's and 019's design, 019's control deficiencies, or about those studies' lackluster data with respect to showing any meaningful benefit in non-Parkinson's DRP—yet Defendants repeatedly (and falsely) touted the purported likelihood of FDA approval of the sNDA.

B. Defendants' Motives to Commit Fraud

Although motive allegations are not even required, a defendant's "personal financial gain may weigh heavily in favor of a scienter inference." *Tellabs*, 551 U.S. at 325. Here, defendant Davis sold 541,205 Acadia shares during the Class Period for roughly ***$24.77 million*** (¶105)—equal to ***roughly 80%*** of his vested equity interests in Acadia shares as of his last reported insider sales on 2/4/2021 (*see* Def. Ex. EE at 166, showing he retained only 28,900 shares and 105,000 vested options as of that date). Similarly, Stankovic sold 368,993 shares during the same period for roughly ***$18.93 million*** (¶106)—equal to ***roughly 82%*** of Stankovic's vested beneficial interests in Acadia shares as of 2/4/2021 (*see* Def. Ex. FF at 193, showing he retained only 31,049 shares and 49,375 vested options as of that date). Tellingly, these sales were ***all*** "dramatically out of line with [defendants'] prior trading practices," *Ronconi v. Larkin*, 253 F.3d 423, 435 (9th Cir. 2001), as neither had sold ***any*** Acadia shares prior to the Class Period (and their insider selling shriveled once the Class Period ended). ¶¶105-06; *cf. BioMarin*, 2022 WL 164299 at *14 (scienter

inferred where defendant sold no shares in six months prior to Class Period, and then sold 64% of his stock for $23 million). And all sales here occurred after Defendants' September 9, 2019, statements caused Acadia shares to soar 63%, but before the March 2021 disclosures caused them to plummet 45%—allowing Defendants to sell at consistently high prices. *Compare* ¶14 *with* Def. Exs. EE & FF.

Defendants argue that because "many" of these sales were made pursuant to Rule 10b5-1 trading plans," any supporting scienter inferences are negated. However, Stankovic did not adopt any plan until ***after*** the Class Period had already started (*see* ¶106; Def. Ex. FF at 178)—while Davis sold (i) roughly 100,000 shares pursuant to an August 2019 plan adopted just *two weeks* before the Class Period started, and (ii) *all* of his remaining 441,000 shares ***after*** he adopted a new plan during the Class Period in December 2019. ¶105; Def. Ex. FF at 161. Given these facts, Defendants' trading plans offer no defense to an inference of scienter. *BioMarin*, 2022 WL 164299, at *14; *see also* 17 C.F.R. § 240.10b5-1(c)(1)(i) (trading plan provides affirmative defense to insider trading *only* if insider adopted it "[b]efore becoming aware of the [material nonpublic] information").[7]

Defendants (Br. at 21) also argue that "*routine* corporate objectives such as the desire to obtain good financing" cannot "by themselves" raise an inference of *scienter*. However, the timing of Acadia's $287 million September 2019 offering—which was consummated just *8 days* after Defendants' misleading statements of September 9 caused Acadia shares to jump 63%—was patently suspicious and anything but routine. ¶104; *In re Genworth Fin. Inc. Sec. Litig.*, 103 F. Supp. 3d 759, 786 (E.D. Va. 2015) (temporal proximity between issuance of misleading statements and subsequent public offering supported scienter); *see also Tellabs*, 551 U.S. at 326 (court must review "all [scienter] allegations holistically").

Defendants ultimately fall back to arguing that the "only cogent and

[7] Defendants' further assertion that "some" sales were made "to cover taxes" (Br. at 23) is not a judicially noticeable "fact," *Khoja*, 899 F.3d at 999, and in any event does not diminish the massive scale of their lucrative and well-timed insider sales.

compelling inference" is that they "honestly believed that [their product] would receive FDA approval." Def.Br. at 24. But this ignores that Defendants' falsely told investors the Company had "a clear agreement" with the FDA about the adequacy of HARMONY's design and that the "FDA [had] confirmed that the [Company's] studies [could] support an sNDA." ¶¶117, 125. Thus, as discussed above, accepting Defendants' "innocent inference" counter-narrative necessarily requires this Court to accept that the FDA either (i) affirmatively misled Acadia about its requirements for the sNDA, or (ii) reneged on a prior agreement. Accordingly, here the inference that Defendants made up or misrepresented an agreement with the FDA to mislead investors as to the (un)likelihood that Acadia's sNDA would be approved "is at least as compelling as" any opposing inference that it was the FDA that misled the Company. *See MannKind*, 835 F. Supp. 2d at 810-11; *Skiadas,* 2020 WL 3268495 at *11-12. And the inference of *scienter* is even stronger here than in *Mannkind*, given the additional compelling motive allegations against all Defendants.

IV. PLAINTIFFS ADEQUATELY ALLEGE LOSS CAUSATION

Pleading loss causation requires allegations of "a causal connection between the material [misstatements or omissions] and the loss." *Dura Pharms., Inc., v. Broudo*, 544 U.S. 336, 342 (2005), which "requires no more than the familiar test for proximate cause." *Mineworkers Pens. Scheme v. First Solar Inc.*, 881 F.3d 750, 753 (9th Cir. 2018) (citing *Dura*, 544 U.S. at 346). Plaintiffs need only allege that "revelation of fraudulent activity, rather than changing market conditions or other ***unrelated factors***, proximately caused the decline in defendant's stock price"—which is typically done by "plausibly" alleging corrective disclosures by which "defendant's fraud was revealed to the market and caused the resulting losses." *Grigsby v. BofI Holding, Inc.*, 979 F.3d 1198, 1205 (9th Cir. 2020). Plaintiff may also plead "materialization of the risk," alleging that corrective discloses revealed the true extent of relevant risks—*e.g.* the likelihood of adverse FDA action—that were obscured by Defendants' fraudulent statements. *See In re WageWorks, Inc.*

Sec. Lit., 2020 WL 2896547, at *8 (N.D. Cal. June 1, 2020). Loss causation allegations suffice "so long as they give defendant notice of plaintiffs' … theory and provide … some assurance that the theory has a basis in fact." *In re BofI Holding, Inc. Sec. Litig.*, 977 F.3d 781, 794 (9th Cir. 2020).

Plaintiffs easily meet this standard, having alleged that Acadia's share price fell ***sharply*** on March 8, 2021 (when Acadia announced that the FDA had identified unspecified "deficiencies" in the sNDA), and again on April 5 (when it announced that it had received a CRL citing deficiencies in HARMONY's design and lack of statistical significance in various dementia subgroups, and additional inadequacies in the "supportive" 019 study). ¶¶8-11, 143-46. Defendants counter by arguing that these disclosures "revealed, at most, disappointing news" and "prospective uncertainty" about FDA approval—but without any "disclosure of fraud or the correction of any prior misstatement." Def.Br. at 25. But the March and April disclosures were plainly construed by shocked investors as evidence that (i) Defendants' prior assurances that the FDA had prospectively agreed on HARMONY's trial design were likely false, (ii) their repeated characterizations of the sNDA's supporting efficacy data as "robust and meaningful" were at best materially misleading, and (iii) Defendants had, accordingly, similarly misled investors as to the true magnitude of the risk that the sNDA would be rejected. *See Mannkind*, 835 F. Supp. 2d at 815 (FDA rejection revealed both falsity of prior statements and materialization of risk).

V. PLAINTIFFS ADEQUATELY ALLEGE §20 CONTROL CLAIMS

Defendants attack the AC's §20(a) claims for failing to plead any underlying §10(b) claim. Because the §10(b) claims are well-pled, the §20(a) claims also stand.

CONCLUSION

Defendants' motion to dismiss should be denied in its entirety.[8]

[8] Should the Court find that the AC is inadequately pled in any respect, Plaintiffs request leave to replead. *BioMarin*, 2022 WL 164299 at *6 (citations omitted).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 18, 2022, I caused the foregoing document to be filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List.

Executed on April 18, 2022, at New York, NY.

s/ William C. Fredericks
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(*pro hac vice*)