SCOTT+SCOTT
ATTORNEYS AT LAW LLP
John T. Jasnoch (SBN 281605)
600 W. Broadway, Suite 3300
San Diego, CA 92101
Telephone: (619) 233-4565
Facsimile: (619) 233-0508
jjasnoch@scott-scott.com

Counsel for Lead Plaintiff City of Birmingham Retirement and Relief System

[*Additional Counsel on Signature Page*]

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.

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

PLAINTIFFS' REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN FURTHER SUPPORT OF MOTION FOR CLASS CERTIFICATION AND APPOINTMENT OF CLASS REPRESENTATIVES AND CLASS COUNSEL

Hon. William Q. Hayes
Courtroom 14B

TABLE OF CONTENTS

TABLE OF DEFINED TERMS

Term	Definition
"¶__"	Refers to specific paragraphs in the Complaint.
"019" or "019 Study"	Study ACP-103-019, a phase 2 clinical trial conducted by or for Acadia to evaluate the use of pimavanserin as a treatment for patients with Alzheimer's disease psychosis
"Acadia"	Defendant Acadia Pharmaceuticals, Inc.
"Complaint"	Plaintiffs' Amended Class Action Complaint for Violations of the Federal Securities Laws (Dkt. No. 45).
"CRL"	The April 2, 2021 Complete Response Letter (PX 11)
"Defendants"	Refers collectively to Acadia, Stephen R. Davis and Srdjan (Serge) R. Stankovic, the defendants in this action.
"DRP"	Dementia Related Psychosis
"DX __"	Exhibits attached to the October 20, 2023 Declaration of Peter M. Adams in Support of Defendants' Opposition to Plaintiffs' Motion for Class Certification and Appointment of Class Representatives and Class Counsel (Dkt. No. 117-1).
"FDA"	The United States Food and Drug Administration
"Feinstein Rebuttal" or "Feinstein Rbtl."	Rebuttal Report of Professor Steven P. Feinstein, Ph.D., CFA, dated December 12, 2023 (PX 1)
"Feinstein Report" or "Feinstein Rpt."	Professor Steven P. Feinstein's Report on Market Efficiency and Damages Methodology (Dkt. No. 108-3).

Term	Definition
"Harmony" or "Harmony Study"	Study ACP-103-045, a Phase 3 clinical trial conducted by or for Acadia to evaluate the use of pimavanserin as a treatment for hallucinations and delusions associated with DRP
"MTD Order"	The Court's September 27, 2022 Order denying Defendants' Motion to Dismiss (Dkt. No. 65).
"Opposition" or "Opp."	Defendants' Opposition to Plaintiffs' Motion for Class Certification and Appointment of Class Representatives and Class Counsel (Dkt. No. 117)
"Pltfs' Mem."	Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Class Certification and Appointment of Class Representatives and Class Counsel (Dkt. No. 108-1)
"PX __"	Exhibits attached to the December 12, 2023 Declaration of William C. Fredericks in Further Support of Plaintiffs' Motion for Class Certification and Appointment of Class Representatives and Class Counsel, filed concurrently herewith.
"Reconsideration Order" or "Recon. Order"	The Court's February 2, 2023 Order denying Defendants Motion for Reconsideration of the MTD Order (Dkt. No. 82).
"sNDA"	Acadia's supplemental new drug application to expand the approved indication for pimavanserin (¶4).
"Stulz Report" or "Stulz Rpt."	Report Defendants' Expert of Rene M. Stulz (DX 1).

Unless otherwise noted, in quoted language herein, citations are omitted and emphasis is added.

TABLE OF AUTHORITIES

Page(s)

Cases

Regulation

Lead Plaintiff City of Birmingham Retirement and Relief System and additional plaintiff Ohio Carpenters' Pension Fund submit this Reply Memorandum in further support of their Motion for Class Certification (Dkt. No. 108).

PRELIMINARY STATEMENT

Defendants concede that all class certification requirements are met except for predominance. On this issue, however, Defendants misread the allegations, ignore the Court's prior MTD and Reconsideration Orders, and seek to deflect from the discovery to date that has only confirmed that Defendants misled investors about the "FDA agreement" (thereby falsely reassuring investors as to the "strength" of the data underlying Acadia's sNDA and likelihood of FDA approval of that sNDA). With the evidence mounting up against them, Defendants now seek to short circuit this case in two ways: (1) by dressing up their twice-rejected "truth-on-the-market" defense—that all "the allegedly omitted information was publicly disclosed well before the two alleged stock drops"—to assert that their repeated misstatements had no "price impact" because investors somehow already knew the full truth; and (2) by asserting that Plaintiffs have not shown that they have a viable method for proving damages on a common, class-wide basis. Opp. at 2. Both arguments are meritless.

BACKGROUND

A. Plaintiffs' Core Allegations

Plaintiffs' falsity theory is that "Defendants affirmatively misrepresented the existence ***or terms of*** an agreement with the FDA concerning the approval of pimavanserin to treat [DRP]." Recon. Order at 2-3; *accord* MTD Order at 15 (same); ¶103 ("even if [FDA agreed] that [Defendants] could do a single adequate and well-controlled study, that agreement was obviously contingent on the data being supportive of the [non-PDP] subgroups that Acadia sought to treat with pimavanserin"). The misrepresented "term" here was that FDA had agreed to base its efficacy review of the sNDA on the Harmony Study's top-line results across all DRP patients (including PDP patients), without ***also*** weighing the efficacy data for

the non-PDP subgroups. *See* MTD Order at 15; *id*. at 17 (Defendants' statements "suggest that the FDA would base its decision on [Harmony's] overall results ... rather than on the data for individual subgroups"); Recon. Order at 3 (Defendants suggested that the FDA agreement "contained terms ... that the FDA would not 'base its decision on ... the data for [Harmony's] subgroups'"); *see also* ¶¶125, 132, 135.

Defendants' misrepresentations that FDA would base its decision on Harmony's results in DRP patients generally (*i.e.*, on the "top-line results") also tainted their statements touting Harmony's purported "success." *See, e.g.*, ¶¶107, 119, 127, 132, 135. Such statements misled as they failed to disclose that Harmony had actually relied on a high-risk trial design and produced poor subgroup data (¶8)—which, absent any FDA agreement to look past such problems, plainly "posed major obstacles to FDA approval." MTD Order at 18. In sum, "the allegations concerning the omission of adverse information [about Harmony's subgroup results and risky design] must be considered ***in conjunction with*** the allegations that Defendants misrepresented an agreement with the FDA concerning the exact same information." Recon. Order at 9; *accord* MTD Order at 19 (Defendants' misrepresentations as to FDA agreement also support inference that they knew that Harmony's shortcomings would "materially increase the risk" of FDA rejection).[1]

B. The Truth About Acadia's Agreement with FDA

Acadia and FDA apparently reached several "agreements" on May 15, 2017. *See* Opp. 3-4; DX 18. These agreements were documented in FDA's meeting minutes (DX 18)—***but those minutes (aside from a few cherry-picked lines) were never publicly disclosed until after the Class Period*** (PX 2 at 6-7). That

[1] Indeed, Harmony's results—showing very strong efficacy in PDP patients but no similar results in any non-PDP subgroup—***undercut*** one of Acadia's key rationales to FDA for doing just a single pivotal study (Harmony) that would contain a mix of different dementia subgroups. This is because Harmony's actual results showed that pimavanserin did ***not*** produce substantially similar results across subgroups—but instead performed ***far worse*** in non-PDP patients. *See also* DX 18 at 6 (Acadia telling FDA in 2017 that, because there was "a substantial overlap between clinical presentation and pathology associated with the various subtypes of dementia," it expected the drug to perform similarly across all DRP subgroups).

Defendants' expert nonetheless cites those minutes at length, even though he was unaware that they had never been made public (PX 3 at 176:2-17), is telling.

First, as per the May 2017 minutes, when Acadia asked if FDA "agree[d] with [Harmony's] proposed overall study design," FDA replied that it "***ha[d] concerns*** with the proposal to use a randomized withdrawal trial to establish efficacy" for all types of DRP. DX 18 at 7. Instead, FDA suggested an "alternative" study design, largely because it worried that Acadia's design would result in an "inflated response rate," given that the study's first phase would ***not*** be placebo controlled. *Id*. at 7-8. Acadia, however, rejected FDA's proposed alternative design for Harmony. *Id*. at 8-9. FDA ultimately agreed that notwithstanding the agency's concerns (which Acadia also concealed from the public) it would ***allow*** Acadia to proceed with its risky bet that Harmony's design would produce acceptable results. *See* DX 18 at 9.

Second, and even more important, the May 2017 minutes show that FDA had "agree[d] with [Harmony's] proposed study population" (*i.e.*, enrolling a mix of patients with the five most subtypes of DRP)—***provided, however***, that (1) "subjects are stratified by their current clinical diagnosis" (*i.e.*, by dementia subgroup), and that (2) ***"[l]abeling will reflect the actual composition and response of patients enrolled in the study***." *Id*. at 7-8.

"Labeling" in this context includes any treatment "indications and usage" for which a drug is approved. *See* 21 C.F.R. §201.57. In lay terms, what Acadia sought in the sNDA—and what FDA was being asked to approve—was expanded "labeling" for pimavanserin to include a new "indication[] and usage," namely approval to treat all types of DRP generally (and not just PDP). In sum, FDA told Acadia in May 2017 ***both*** that Harmony's study population had to be "stratified" so that responses of patients by DRP subgroup could be analyzed separately, ***and that any approval of new "labeling" for pimavanserin "will reflect the actual composition and response" of the subgroups***. Acadia's comments on the FDA minutes also confirm that Acadia "agree[d]" with these FDA conditions. PX 4 at -

424. That any new "labeling"—including approval of any new indications—would "reflect" (*i.e.*, consider) analysis of subgroup data is the key part of the "FDA agreement" that Acadia misrepresented and omitted when they discussed Harmony's results and/or the FDA agreement. *See, e.g.*, ¶103 (any "agreement was obviously contingent on the data being supportive of the [non-PDP] subgroups").

Instead, in describing the "FDA agreement," Defendants continue to rely on cherry-picked aspects of the May 2017 minutes, while ignoring FDA's warning that "labeling" would "reflect" subgroup results. *E.g.*, Opp. 4. But Acadia's statements that FDA had agreed, *e.g.*, that "hallucinations and delusions in [DRP generally] is a potentially approvable indication," and that Acadia would be allowed to base its sNDA on a "single well-controlled study" (Harmony) (DX 18 at 7-9), patently failed to disclose another key term: namely, FDA's insistence on ***also*** seeing ***non-PDP subgroup data*** that would justify approving an expanded pimavanserin label.

C. Defendants' Misleading Statements Caused Investors to Materially Overestimate the Likelihood of FDA Approval of the sNDA

On September 9, 2019, Acadia announced Harmony's "positive results" and that it had met its primary endpoint of showing a "highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis." ¶¶4, 107. Later that day, Defendant Stankovic also "remind[ed]" analysts that at Acadia's May 2017 meeting with FDA "we ***confirmed that for our [sNDA] DRP, we could rely on a single, well-controlled study whose results were both statistically and clinically very persuasive***." ¶109. In response, Acadia stock soared 49%. ¶6. Defendants, however, ***never*** disclosed—in September 2019 or at any other point in the Class Period—that FDA had warned that approval for expanding the drug's label beyond PDP would ***also*** depend on the "actual composition and response" of Harmony's non-PDP subgroups. DX 18 at 7.

Instead, while concealing the truth about the full scope of the FDA agreement, throughout the Class Period Defendants made "statements characterizing the results of the ... studies supporting the sNDA as 'positive' and 'strong,' expressing

'confiden[ce]' in the studies' data and in the potential for FDA approval." MTD Order at 7. The two-fold message was clear: (i) FDA had bought into Acadia's "plan" to rely on Harmony as an adequate "single study" on which to seek approval of pimavanserin to treat DRP generally; and (ii) Acadia had successfully "executed" this agreed plan by getting "highly statistically significant" top-line results from Harmony. *See, e.g.*, ¶125 (Aug. 19, 2020 statement by Davis that "***we agreed with the FDA on [the] approach***" ***and "agreed on the plan for [Harmony], and then we've executed that plan***"); ¶132 (Nov. 17, 2020 statement by Davis) (same).

Discovery has also identified further examples of Defendants' efforts to mislead investors. For example, on November 11, 2019 Stankovic told investors:

> The primary endpoint analysis, ***that we agreed with FDA on,*** is based on the ***robust statistical significance of the overall study population*** ... ***across all of the subtypes*** that present in the [Harmony] study ... [and] ***there is no requirement, nor expectation, nor power of analysis, of specific subtypes***.

PX 5 at -577. And Acadia reiterated this false message as late as early 2021, when Davis, in citing Harmony's "very strong" data, added: "we're ***not*** looking at individual [DRP] subtypes" ***and "[t]hat's supported by ... alignment we established with the FDA***." ¶135. And, although the reporting of Harmony's top-line data (and of certain subgroup data at a later CTAD meeting) was accurate, Defendants blatantly misled investors as to the significance of subgroup data in the context of their misleading statements about the FDA agreement.

Recent discovery has also shown that Defendants misrepresented what FDA told Acadia after the sNDA was submitted. On July 20, 2020, Acadia announced that FDA had accepted the sNDA for filing (though not for expedited "priority review") ***and that FDA had "not identified any potential review issues at this point.***" ¶¶121, 127; PX 6 at -205. But the full story is that, when Acadia had asked FDA a few days earlier why the sNDA had not been granted "priority review," FDA had responded by email on July 17 as follows:

> [Your sNDA would only be] eligible for priority review ***if supported by clinical data*** … demonstrating the potential to be a *significant*

> *improvement* in safety or effectiveness (e.g., evidence of safety and effectiveness in a new subpopulation)…. ***Based on a preliminary review of [the sNDA], it is unclear if the clinical data demonstrate this potential***.

PX 8 at -440. FDA also reiterated its unfavorable preliminary assessment on July 28. *Id*. Given that FDA never disclosed the FDA's July 2020 comments, Acadia's July 20 release—as well as its later statements touting the prospects of sNDA approval, *e.g.*, its August 6, 2020, statement that "FDA advised us that it has ***not*** identified any potential review issues at this point in their evaluation" (¶127; *see also* ¶¶123, 125, 128-41)—were also materially misleading.[2]

D. FDA Rejects the sNDA, and Acadia's Share Price Collapses

After the close of trading on March 8, 2021, Acadia announced that FDA had advised it on March 3 that the agency had "identified deficiencies [in the sNDA] that preclude discussion of labeling … at this time." ¶143. Acadia then held an analyst call, at which Davis said he was "extremely surprised and disappointed" because (he claimed) "[u]p until this notification, we've received confirmation from the FDA that they had not identified any review issues." PX 9 at -764. Davis then assured investors that Acadia planned "to work with the FDA to learn the nature of the deficiencies and seek to resolve whatever [sNDA] issues remain … so that we can bring this meaningful new therapeutic option to patients … as quickly as possible." *Id*. Stankovic similarly added that "we remain highly confident as we have since day 1 … that we have a complete and robust data package to support the approval of pimavanserin for the treatment of DRP." *Id.* In sum, during the March 8, 2021 call, Defendants assured investors that the sNDA was not necessarily dead in the

[2] FDA's July 10 letter did literally state that it had "not identified any potential review issues" (PX 7 at -084), but also (1) immediately qualified this comment as "not indicative of deficiencies that may be identified during our review," (*id.*) and (2) made clear that that comment's purpose was simply to advise that the sNDA was "sufficiently complete to permit a substantive review," *id*. at -083. But "[e]ven if a statement is not false, it may be misleading if it omits material information." MTD Order at 13. Here, Defendants' July 20 release misleadingly conveyed to investors that FDA had no substantive concerns—when in fact FDA's later July 17 (and July 28) emails plainly showed that even its preliminary review ***did*** raise such concerns.

water. For example, when one analyst asked "Is there any way to avoid a CRL at this point?", Davis responded that there were "precedent situations where other companies have received [similar] letters [and then a CRL]," but added "[w]e're still in the middle of a pandemic" and "I'm not sure that precedents earlier are necessarily the best guide now." *Id*. at -766.

On March 9, 2021, Acadia's stock fell ***over 60%***. ¶144.

On April 5, 2021, before markets opened, Acadia announced it had received the CRL denying the sNDA. ¶145. Defendants also claimed that the sNDA had been improperly rejected "[d]espite prior agreements with [FDA] regarding pivotal Phase 3 HARMONY study design targeting a broad DRP patient population analyzed as a single group." *Id*. In blaming FDA, Acadia also reiterated that Harmony "met its prespecified primary and secondary endpoints with robust and persuasive clinical and statistical superiority of pimavanserin over placebo, which was a prospectively agreed prerequisite for the DRP indication," but that FDA had moved the goal posts as to the "prespecified requirements" for approval. *Id*. In sum, Defendants claimed that FDA had reneged on its "agreement" on Harmony's "trial design and criteria for establishing efficacy in DRP." *Id*. Defendants then held a call with analysts and doubled-down on blaming FDA for the sNDA's failure. *See, e.g.*, PX 10 at -167 (claiming that in issuing CRL the FDA applied "new criteria" in finding that subtypes showed a "differential response," which Harmony's study design and the prior agreed criteria for showing efficacy in DRP were "never designed to prove"); *id*. at -173 (claiming FDA had breached its agreement that the question to be answered to obtain "approval for treatment of [DRP]" was "whether pimavanserin is efficacious … in this group of patients ***analyzed as a single group***").

In response to the news of April 5, 2021, Acadia's stock price fell over 18%.

Tellingly, despite blaming FDA for breaching its "agreement," Defendants have never publicly disclosed a copy of CRL. *See* PX 2 at 27-28. However, the actual CRL—obtained here, like the May 2017 minutes, only through discovery—

simply confirms that FDA's position has been consistent since May 2017. As FDA's CRL letter stated: "Although [Harmony] was not powered to [show] an effect in the subgroups of dementia included, ***we had advised you during development that labeling would reflect the actual composition and response of the subjects enrolled in the trial***." PX 11 at -088. The CRL then gave four reasons—all "[b]ased on an examination of dementia subgroups"—why FDA had concluded that the sNDA lacked "substantial evidence of effectiveness" to support expanding pimavanserin's label to treat DRP generally. *Id.*[3]

E. Procedural Posture

The evidence summarized above is part of a story that continues to unfold through ongoing discovery. To date, Defendants have produced over 180,000 documents since document discovery began in earnest this summer, of which roughly 96% were produced after August 3, 2023 (and 76% were produced after this Motion was filed on August 21). Fredericks Decl. ¶2. Thus, while the record to date strongly supports Plaintiffs' claims, Plaintiffs believe that additional documents from Defendants' still-ongoing productions, as well as from yet-to-be-commenced fact depositions and incomplete third-party discovery, will only further strengthen Plaintiffs' claims. The current fact discovery cut-off is March 15, 2024.

ARGUMENT

Defendants attack class certification on only two grounds, arguing that: (1) they have rebutted *Basic*'s presumption of reliance by proving lack of "price impact"; and (2) Plaintiffs have failed to offer a viable method to calculate damages on a common, class-wide basis under *Comcast.* Both arguments are meritless.

I. DEFENDANTS FAIL TO CARRY THEIR BURDEN OF PROVING THEIR MISSTATEMENTS HAD NO PRICE IMPACT.

All agree that to succeed on their "price impact" argument, Defendants must

[3] In rejecting the sNDA, the CRL also identified problems with Acadia's "supporting" 019 Study (which involved only "ADP" subgroup patients, *i.e.*, Alzheimer's patients with DRP). *See* PX 11 at -089. Plaintiffs also allege that those problems were not adequately disclosed to investors. ¶¶86-90.

present evidence that completely "severs the link between the alleged misrepresentation and either the price received (or paid) by the plaintiff." Opp. 8 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 248 (1988)); *see also Goldman Sachs Grp., Inc. v. Ark. Tchrs. Ret. Sys.*, 141 S. Ct. 1951, 1962-63 (2021) ("defendant must in fact sever the link between a misrepresentation and the price paid by the plaintiff—and a defendant's mere production of some evidence relevant to price impact would rarely accomplish that feat." (cleaned up)); *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 263-64 (2014) (defendant must "show[] that the alleged misrepresentation did not actually affect the stock price—that is, that it had no 'price impact'"). Where the price impact link is not cut ***completely***, *Basic*'s presumption of reliance holds (provided only that, as is undisputed here, the other requirements for invoking that presumption are met).[4]

There is also no dispute that Defendants "bear the burden of persuasion to prove a lack price impact by a preponderance of the evidence." Opp. 10 (quoting *Goldman Sachs*, 141 S. Ct. at 1958). And "plaintiffs need not directly prove price impact in order to invoke the *Basic* presumption." 141 S. Ct. at 1962-63. Instead, courts must look at all evidence presented, "aided by a good dose of common sense," to determine if defendants have carried their burden. *Id*. at 1960. Indeed, challenges to price impact at class certification "should impose no heavy toll on securities-fraud plaintiffs with tenable claims." *Halliburton*, 573 U.S. at 284 (Ginsberg, J.).

As detailed in §I.A below, both common sense and case law show that all of the hallmarks of "front-end"—as well as "back-end"—price impact are both present and obvious here, suggesting that only resorting to sophistry or sleight-of-hand might offer Defendants a path to carrying ***their*** burden of proving ***no*** price impact.

[4] *See also Bos. Ret. Sys. v. Alexion Pharms., Inc.*, 2023 WL 2932485, at *12 (D. Conn. Apr. 13, 2023) ("defendants have not met their burden to rebut the *Basic* presumption" where they have not shown "a complete lack of price impact"); *In re CenturyLink Sales Pracs. & Sec. Litig.*, 337 F.R.D. 193, 210 (D. Minn. 2020) ("the inquiry is whether Defendants have proven a complete lack of price impact during the Class Period") (collecting cases).

And as shown in §I.B-C, that is exactly what Defendants and their expert offer: first by improperly analyzing the elements of each alleged misstatement in isolation, rather than in context (*cf.* Recon. Order at 9); then by frivolously asserting that there could have been no price-impacting misrepresentations or omissions because all relevant facts were somehow "publicly known" throughout the Class Period; and finally by asserting that there is a fatal "mismatch" between their failure to disclose key terms of the FDA agreement and the news disclosed on March 8 and April 5, 2021. These arguments come nowhere close to carrying Defendants' burden on price impact here.

A. In Light of the Evidence Obtained to Date, Defendants Face a Near Impossible Task in Trying to Disprove Price Impact.

It is well settled that price impact can be "observed on the 'front-end' (*i.e.*, misstatements causing or maintaining inflation) or on the 'back-end' (*i.e.*, a decline in price caused by the corrective disclosures)." *In re Apple Inc. Sec. Litig.*, 2022 WL 354785, at *7 (N.D. Cal. Feb. 4, 2022). And here, there is no dispute that both the "front-end" increase in Acadia's share price on September 9, 2019, and the back-end declines in price on March 9, 2021, and April 5, 2021, were "highly statistically significant" beyond the 99% confidence level. Feinstein Rpt. Ex. 13 at 157, 165; Stulz Rpt. Ex. 2 at 129; PX 3 at 93:17-94:15. This means that the increases and decreases in Acadia's share price on those days were almost certainly caused by new news about Acadia. Feinstein Rpt. ¶144. In other words, Acadia's stock price (1) increased a "highly statistically significant" amount on the Class Period's first day when the first alleged misstatements were made, and (2) declined to a statistically significant degree on both days when Plaintiffs allege there were corrective disclosures. Feinstein Rbtl. ¶¶29-45.

Thus, right out of the gate, Defendants' arguments run into a buzzsaw, as ***all*** hallmarks of price impact are present here in spades: a statistically significant price increase of over 49% when the first misstatements were made, and statistically significant declines, of over 60% and 18% respectively, on the two corrective

disclosure dates. *Karinski v. Stamps.com, Inc.*, 2020 WL 6572660, at *6 (C.D. Cal. Nov. 9, 2020) (ample evidence of price impact where experts "conducted a robust event study and [found] statistically significant share price declines following the alleged corrective disclosures"); *In re Mattel, Inc. Sec. Litig.*, 2021 WL 4704578, at *5 (C.D. Cal. Oct. 6, 2021) ("statistically significant price adjustment following a corrective disclosure is evidence that the original misrepresentation did, in fact, affect the stock price"); *CenturyLink*, 337 F.R.D. at 210 ("Defendants' expert admits that there were statistically significant price drops following two of the three disclosure dates. This is sufficient to prevent Defendants from severing the link between the alleged misrepresentations and any impact on the stock price." (cleaned up)); *see also* Feinstein Rbtl. ¶¶ 29-58.

Indeed, ***by his own admission***, Defendants' expert ***did not even try to dispute*** that Plaintiffs' misstatement claims concerning the FDA agreement had back-end price impact, so Defendants have ***necessarily*** failed to completely "sever the link" between the alleged misstatements and Acadia's share price here. *See* Stulz Rpt. ¶13(c) (reflecting that his opinion, insofar as it related to the "price impact of the alleged misrepresentations regarding the FDA agreement," is limited only to "[t]he stock price increase at the start of the Proposed Class Period"); PX 3 at 141:6-16 (confirming that expert's price impact conclusions are limited to those stated in his report). Yes, Plaintiffs plainly allege that the sharp share price drops on March 9 and April 5, 2021 were caused at least in part by revelations of the truth regarding Defendants' misrepresentations about the terms of the FDA agreement and related materialization of the risk those misrepresentations concealed. *See* ¶¶143-47; Feinstein Rbtl. ¶¶35-45. Similarly, Defendants' expert offers no opinion on what front-end price impact the alleged misstatements about Harmony's top-line results had when first made on September 9, 2019. Stulz Rpt. ¶13(a). Plaintiffs allege these misstatements caused, in part, Acadia's stock price to increase a statistically significant amount on September 9. Feinstein Rbtl. ¶¶29-58. That Defendants' own

expert has not contested the "links" between these alleged misstatements and Acadia's share price is fatal to their "no price impact" argument.[5] *See, e.g.*, *In re Acadia Healthcare Co., Inc.*, 2023 WL 3620955, at *3 (6th Cir. May 23, 2023) (affirming class certification where defendants "conceded the statistically significant price reaction" and so "failed to show a lack of price impact"). The Court need read no further.

B. Defendants Actual Price Impact "Arguments" Are Baseless.

At their core, even the aspects of Defendants' "price impact" arguments that they actually ***try*** to support ultimately rely on (1) fundamentally distorting Plaintiffs' allegations (and the Court's prior rulings); and then (2) trying to regurgitate their already twice-rejected "truth-on-the-market" defense (MTD Order at 20-21; Recon. Order at 9-12) by arguing that (through their distorted lens) there simply were no misstatements that could have had price impact "because the allegedly omitted information was publicly disclosed before the two alleged stock drops." Opp. 2.

This argument is legally unsustained (and unsustainable) here. In sum, because there is no dispute that ***something*** Acadia-specific was impacting Acadia's share price on September 9, 2019 and March 9 and April 5, 2021 (*see* Feinstein Rbtl. ¶¶46-58), the only disputed issue is what ***caused*** the price impact on those days. Plaintiffs contend it was the alleged misstatements, and Defendants assert it must have been something else because (they claim) the full truth was known before the stock drops. *E.g.*, Opp. 2. Defendants are therefore actually disputing ***loss causation***, not ***price impact***, as they are arguing that the losses could not have been caused by fraud because there was no fraud (*i.e.*, a "truth-on-the-market" defense). But it is well-settled that neither loss causation (an element on which Plaintiffs bear the burden of proof on the merits) nor "truth-on-the-market" (an affirmative merits

[5] Defendants do claim that the back-end price impact "cannot be used to infer artificial inflation" from misstatements about the FDA agreement because there is a "mismatch in the content between the alleged misrepresentations and what was revealed when the risk ultimately materialized." Opp. 21. As show below (*see infra* §I.C) this argument is nonsense.

defense) can be resolved at class certification. *See, e.g.*, *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 481-82 n.11 (2013) ("whether news of the truth credibly entered the market and dissipated the effects of prior misstatements ... is a matter for trial" so district court properly disregarded "rebuttal evidence as an attempt to present a truth-on-the-market defense" (cleaned up)); *Junge v. Geron Corp.*, 2022 WL 1002446, at *6 (N.D. Cal. Apr. 2, 2022) (rejecting argument that "boil[ed] down" to loss causation because "plaintiffs need not show [loss causation] at this stage"); *Stamps.com*, 2020 WL 6572660, at *7 (whether "statements did not convey new information" is "a truth-on-the-market defense and is not properly considered at the class certification stage").[6] But even if Defendants' arguments were appropriate at class certification (and they are not), they are also meritless.

1. Defendants Wrongly Assume Their Misstatements Should Be Analyzed in Isolation.

Defendants' argument ultimately depends on their faulty assumption that their alleged misstatements should be viewed as falling into three isolated and completely ***separate*** categories: (1) the FDA agreement, (2) Harmony, and (3) 019. Opp. 10-24; Stulz Rpt. at 32-78. But—at least with respect to what Defendants categorize as separate FDA agreement and Harmony-related claims—the Complaint does ***not*** allege such a compartmentalized theory of fraud, nor has the Court ever viewed the Complaint's allegations as so constrained. *See supra* pp. 1-2. Instead, as the Court has already twice held, the misstatements and omissions relating to Harmony's design and results must be "considered ***in conjunction with*** the allegations that Defendants misrepresented an agreement with the FDA concerning the exact same information." Recon. Order at 9; *accord* MTD Order at 19. In other words, it was (i) Defendants' failure to disclose that a key term of the FDA agreement was that an expanded label for pimavanserin would turn on "the actual composition and

[6] One court in this district recently broke with this precedent to apparently consider a "truth-on-the-market" defense in the context of class certification. *In re Qualcomm Inc. Sec. Litig.*, 2023 WL 2583306 (S.D. Cal. Mar. 20, 2023). As discussed below, however (*see infra* pp. 18-20), *Qualcomm*'s facts are readily distinguishable.

response of patients enrolled" in Harmony (DX 18 at 7); in conjunction with (ii) their repeated touting of an "agreement" with FDA that would allegedly allow them to obtain approval of the sNDA based upon Harmony's overall results in just the general (unsegregated) DRP pool (*see supra* pp. 4-6); that (iii) misled investors into believing that Harmony's non-PDP subgroup data would be immaterial to FDA's decision on the sNDA. Defendants nowhere grapple with Plaintiffs' ***actual*** falsity theory or this Court's prior orders affirming them. *See Apple*, 2022 WL 354785, at *9 (rejecting price impact arguments that "fundamentally misconstrue plaintiff's theory").

Moreover, as Prof. Feinstein explains, viewing the alleged misstatements about the FDA agreement and Harmony in isolation also makes no economic sense. Feinstein Rbtl. ¶¶59-69. Indeed, as Prof. Feinstein's initial report notes, investors were most focused on "the potential future commercialization of [Acadia's] pipeline products, which was a function of the probability that [it] would be able to obtain FDA approval for new drugs and for the expanded use of pimavanserin," such that "[w]hether pimavanserin would receive approval for treatment of DRP was … critically important throughout the Class Period." Feinstein Rpt. ¶116. And here, the likelihood of FDA approval of the sNDA obviously depended on ***both*** Harmony's results ***and*** what the terms of the FDA agreement were as to what data it would review.[7] Consequently, the value and price impact of the Harmony data and the FDA agreement were necessarily interrelated. Feinstein Rbtl. ¶¶59-69.

Consistent with Prof. Feinstein's conclusion (and common sense), analysts who covered Acadia often discussed both Harmony's design and results in the context of the FDA "agreement." Feinstein Rbtl. ¶67. For example, on September 9, 2019, after Acadia announced Harmony's "positive" top-line results, analysts

[7] Defendants' argument that the agreement with FDA covered just "submission of an sNDA [] but not necessarily final approval" (*e.g.*, Opp. 5), is belied by their statements to investors, most clearly when Davis and Stankovic complained on April 5, 2021 that FDA had reneged on an agreement about what was necessary "to receive approval for treatment of [DRP]." *See supra* p. 7.

remarked upon the value of those results ***in the context*** of Defendants' statements about the FDA agreement:

- On September 9, 2019, Cowen issued a report that stated that the newly announced data from "HARMONY and other supportive Ph2/post-hoc analysis is enough to drive FDA approval," of the sNDA—and that Harmony's "data should address any FDA questions, especially given agency-conferred breakthrough status ***and written agreement that HARMONY would generate sufficient pivotal data to support sNDA review***." PX 12 at -022.

- Similarly, on September 9, Needham issued a report citing Harmony's "positive" results, which, after describing its top-line results, noted that "FDA reportedly informed mgmt. that a single well-controlled trial ***will be sufficient for approval in this indication***," *i.e.*, for DRP generally. PX 13 at -287.

Similarly, when more Harmony results (including subgroup data) were released on December 4, 2019, analysts noted that they were assessing that data and the odds of FDA approval in the context of the purported FDA agreement:

- On December 5, 2019, Cowen issued a report reiterating its prior view that Harmony's "data should address any FDA questions, ***especially given agency gave written agreement that HARMONY would generate sufficient pivotal data to support sNDA review,***" and adding, based largely on the foregoing, that Cowen "strongly expect[s] approval." DX 72 at 2, 6.

- A Goldman Sachs analyst report of December 5, 2019, after reviewing the Harmony data disclosed at CTAD, also cited Acadia's statements that "at the end of Ph2 meeting with the FDA" (*i.e.*, the May 2017 meeting), the FDA had agreed "that a single well-controlled study with statistically and clinically relevant data could serve as the basis for the [s]NDA." DX 74 at 4.

- On December 5, 2019, Stifel similarly wrote that Acadia "sees HARMONY as ***firmly meeting the bar set by the FDA*** at the end-of-ph2 meeting for 'clinically and statistically meaningful results.'" DX 79 at 2.

- On December 6, 2019, Oppenheimer wrote that ***Acadia "believes previous discussions [with FDA]*** indicate robust Ph3 HARMONY results along with Ph2 DRP and previous PDP data are supportive of [sNDA]." DX 80 at 2.

See also, e.g., PXs 15-18; Appendix A.

The record, unsurprisingly, also reflects that, due to Defendants' repeated misstatements/omissions about the "FDA agreement," the market was misled as to the true risk that FDA would not approve the sNDA in light of Harmony's poor subgroup results. For example, on March 5, 2020, Citibank issued a report stating:

> ***Based on the results of HARMONY by subgroup***, lack of prior regulatory precedent for approval in 'dementia' broadly rather than a specific subtype, and the class black box warning that pimavanserin carries in a modified form, a focus for investors is whether or not the

> drug will get a broad, clean label for use in DRP.
>
> Currently there are four NCEs approved to treat the symptoms of dementia . . . . ***The fact that these drugs have labels specific to one or more type of dementia could suggest that FDA may be inclined to approve new drugs for only the specific dementia subtypes where a stat sig benefit is shown. However, the HARMONY study was not powered to show an effect on a specific subtype based on discussions the company has had with FDA.*** Given that [and] that Acadia has Breakthrough Therapy Designation for pimavanserin in DRP enabling more frequent and open dialog with FDA, we find it unlikely that FDA will choose now to discriminate in the label based on dementia subtype barring any significant differences in safety between dementia subgroups. (PX 14 at -019.)

There is thus no basis in the Complaint, the Court's prior orders or the record to view the misstatements and omissions about (a) Harmony, and (b) the FDA agreement, in isolation—rather than in context and in conjunction with each other.

2. Defendants' Assertions That Investors Were Somehow Aware of the Full Truth Are Unsupported by the Record.

Defendants' price impact argument then proceeds to make an even bigger leap, by asserting that investors were somehow told the "whole truth" about the FDA agreement and Harmony. *See* Opp. 10, 19. Even assuming that such arguments are proper at the class certification stage (*cf. supra* pp. 12-13), this argument is nonsense.

To start, Defendants offer ***no evidence*** that they disclosed the FDA agreement's key terms (or FDA's concerns about Harmony's design) as described in the May 2017 minutes, or that investors had ever heard that "[l]abeling will reflect the actual composition and response of patients enrolled in the study." DX 18 at 7. At most, they point to general statements concerning "an agreement" with FDA on the "clinical development plan and the design of the Phase III study" or on an "alignment [with FDA] on the overall clinical development plan." Opp. 20. But such statements do not come close to disclosing the key "omitted term" about FDA's insistence on stratified subgroup data and statement that any approval of expanded "labeling" to include all DRP patients would turn at least in part on the non-PDP subgroup efficacy data. And analyst reports of "an [] agreement … to pursue a DRP indication," or that FDA had "agree[d] that robust results can serve as the basis for

a s[NDA]" (Opp. 21), do not remotely show that investors knew the full truth.

Defendants' factual assertions that they adequately disclosed all relevant information about Harmony's design and results fare no better. In particular, Defendants argue that the full truth concerning the non-PDP subgroup results was disclosed at CTAD on December 4, 2019. Opp. 13-14. But this argument improperly separates the disclosure of raw data from its fundamentally important context. The key omission here was of FDA's condition that expanding the labeling for pimavanserin would turn on "the actual composition and response of patients enrolled in [Harmony]," and that Harmony's non-PDP subgroup results would likely be highly relevant, if not dispositive. DX 18 at 7. Thus, although they shared some of Harmony's subgroup data at CTAD, Defendants ***never*** disclosed the truth about its significance to FDA at CTAD—or at any other point during the Class Period. Instead, Defendants tried to ***downplay the subgroup data on December 4***. For example, the data was presented on slides 27 and 28 of a 33-slide presentation (DX 68 at 28-29) was described as being part of mere "Exploratory Analyses by Most Likely Clinical Diagnosis" (*id.* at 27), and was expressly downplayed by the presenter with "a word of caution on overinterpretation" because it was "a bit hard to interpret these results given the small number[]," and given that Harmony was "not powered to look at this in any meaningful statistical way" (DX 67 at 8).

Defendants next point to post-CTAD analyst reports as purported proof that the full truth about Harmony was "publicly known." Opp. 17. Not so. For example, none of those analyst reports identified Harmony's non-PDP subgroup results as a problem; to the contrary, as shown above, many of those same reports cited Acadia's comforting "FDA agreement" about Harmony as part of what continued to be a positive overall market response to the December 4, 2019 data disclosures at CTAD.

Defendants also try to argue that repeating "old news" supposedly can never have price impact. But, as Prof. Feinstein explains, the value of information depends in part upon its full context, such that repeating that, *e.g.*, Acadia had an agreement

with FDA on Harmony's design and top-line results can have price impact at different times even if not technically new, because old news (as here) will often be seen in a materially new light when viewed in the context of ***other*** developments that ***are*** new, *e.g.*, news of Harmony's results. Feinstein Rbtl. ¶¶70-75.

Defendants' arguments about the 019 Study are no less flawed. Indeed, even Defendants' own expert conceded that at least some adverse information concerning "certain protocol deviations" in 019—"including the administration of 'prohibited medications' to patients enrolled in [019]," which was cited by FDA in the CRL—was "potentially new [*i.e.*, not previously disclosed] on April 5, 2021." Stulz Rpt. ¶116. Thus, Defendants cannot sever the link between this misstatement about 019 and the price drop on April 5, 2021.

3. Judge Ohta's Recent *Qualcomm* Decision

For all the additional reasons set forth in the Feinstein Rebuttal Report at ¶¶21-75, Defendants fall far short of carrying their burden of proving no price impact (and as noted above their expert does not even ***try*** to deny back-end price impact as to any FDA agreement-related statements or omissions).

Moreover—and even assuming *arguendo* that the Court declines to follow the holdings of *Junge* and *Stamps.com* that Defendants' truth-on-the-market arguments are not properly raised at class certification—Judge Ohta's recent *Qualcomm* decision would also be dispositive. There, plaintiffs alleged that defendants "deceived the public about Qualcomm's business model" by: (1) touting that Qualcomm "'broadly licensed' its technology throughout the industry when, in fact, Qualcomm did not license at the chip level and refused to license to competing chipmakers"; and (2) "stating that it kept its licensing and chip-supply businesses separate when, in fact, Qualcomm regularly bundled the two in negotiations and agreements." *Qualcomm*, 2023 WL 2583306, at *2. As here, the *Qualcomm* defendants tried to defeat certification by arguing their alleged misstatements had no price impact because the information that they had allegedly concealed had been

disclosed prior to the alleged corrective disclosure dates. *Id*. at *11-15.

As to the first category of misstatements, Judge Ohta found that "generic statements assigning the adjectives 'broad,' 'fair,' 'reasonable,' and 'non-discriminatory' to Qualcomm's overall licensing model" would not have been interpreted "to mean that Qualcomm licensed chips to chipmakers." *Id*. at *12. The court then concluded that "Qualcomm's device-level licensing policy was made public multiple times" prior to the corrective disclosures, including through publications that discussed regulators' investigations into Qualcomm's device-level licensing policy, and through Qualcomm's own public disclosures of its device-level licensing policy in congressional testimony, court filings, and submissions to certain standard-setting organizations. *Id.* at *13. Given this apparently undisputed evidence, *Qualcomm* held that the market was "privy to" the fact that "Defendants licensed only at the device level and refused to license chips to chipmakers" prior to the corrective disclosures, which demonstrated a lack of price impact. *Id*.

In contrast, *Qualcomm* rejected defendants' price impact argument—***and certified a class***—with respect to the alleged "bundling" misstatements. *Id*. at *14-15. In sum, the court held that Defendants' evidence that they had disclosed enough to allow investors to piece together the full truth concerning their allegedly improper bundling was insufficient, stating:

> Defendants have not pointed to evidence that [any of the four] precise [categories of allegedly withheld bundling] information was publicly available prior to the corrective disclosures. Although Defendants submit evidence that Qualcomm's practice of only selling chips to licensees was public, the corrective disclosures allegedly revealed far more than just this one practice. Further, although bundling and royalty rebate accusations had been levied against Qualcomm prior to the corrective disclosures, those prior allegations do not mirror the corrective disclosures quoted above. The latter disclosed far more detail regarding the alleged bundling, including the way it occurred, the customers involved, and Qualcomm's alleged abuse of market power. Accordingly, Defendants' evidence … does not sever the link between Defendants' alleged misrepresentations and their impact on the stock price.

Id. at *15. *Qualcomm* thus stands for the proposition that where defendants can show that the "precise information" that was allegedly concealed had in fact been

fully disclosed prior to the first corrective disclosure, price impact may be severed—but as with the detailed "bundling"-related misstatements and omissions in *Qualcomm*, Defendants here come nowhere near to making such a showing.

Like the "bundling" misstatements in *Qualcomm*, Defendants misleadingly touted Harmony's top-line results in conjunction with misleadingly "reminding" investors that FDA had agreed the sNDA could be approved based solely on such results. When, in this context, news of Harmony's top-line results was first announced, Acadia's stock shot up over 49%. Then on March 9 and April 5, 2021, Acadia's stock declined significantly on news that "FDA has identified deficiencies" in the sNDA, and did so again on news the sNDA had been denied. These developments in 2021 showed, contrary to Defendants' repeated misstatements, (1) FDA had ***not*** agreed to consider only Harmony's top-line efficacy data in deciding whether to approve the sNDA, and (2) Harmony's actual results did ***not*** support approval. As common sense and Plaintiffs' expert show, these facts establish price impact. *E.g.*, Feinstein Rbtl ¶¶46-75.

C. There Is No "Mismatch" Between Defendants' Misstatements About the FDA Agreement and the Corrective Disclosures.

Defendants next argue the back-end price drop cannot act as a proxy for front-end impact as there is a "mismatch in content" between the alleged misstatements and what was revealed when the risk ultimately materialized. Opp. 21.

An impact-severing "mismatch" may occur "[if] the earlier misrepresentation is generic (*e.g.*, 'we have faith in our business model') and the later corrective disclosure is specific (*e.g.*, 'our fourth quarter earnings did not meet expectations')." *Goldman Sachs*, 141 S. Ct. at 1961. However, there is no mismatch where "alleged misstatements are ***not*** at such a high level of generality that one cannot discern the inherent contradiction between those statements and the information in the corrective disclosures when viewed side by side." *Qualcomm*, 2023 WL 2583306, at *14. Moreover, there is no requirement whatever that a corrective disclosure must "be a 'mirror image disclosure'" or "a direct admission that a previous statement is

untrue." *Mattel*, 2021 WL 4704578, at *5-6; *Apple*, 2022 WL 354785, at *8-9.

Tellingly, Defendants argue neither that their alleged misstatements were "generic" nor that their later disclosures were "specific"—which should put an end to any "mismatch" argument. Instead, they try to frame the question as: "If Acadia had spoken truthfully at the outset regarding the FDA's discretion to deny the sNDA despite an agreement on [Harmony's] design, would the stock price have been lower?" Opp. 22. This misses the point. Indeed, as Defendants concede, Acadia's stock price declined (at least in part) following the alleged corrective disclosures ***because*** "FDA did not find the ***results*** of the HARMONY and -019 Studies to be sufficiently meaningful and persuasive to support approval of the sNDA for DRP." *Id*. Thus, even though it is likely true that the market always understood that there was ***some*** irreducible risk that FDA would deny the sNDA for ***some*** reason, Defendants' repeated misstatements and omissions misled the market as to true magnitude of the actual FDA rejection risk by telling investors both (a) that Acadia and FDA had prospectively agreed on what studies and data were needed to win FDA approval ("the plan"), and (b) that Acadia, in the sNDA, had provided FDA with what they agreed would be sufficient (*i.e.*, that Acadia had "executed the plan").

In sum, there is plainly no "mismatch" between what Plaintiffs allege to have been specifically misrepresented or omitted (and the market's resulting inflated perception of the odds of FDA approval), and what was disclosed on March 4 and April 8, 2021 (which revealed that the sNDA had been rejected). Indeed, not only did Defendants' alleged corrective disclosures state that the sNDA had been rejected (at least in part) due to previously undisclosed FDA concerns about the non-PDP subgroup results, but the evidence to date also amply confirms that the risk concealed by Defendants' misstatements—that "[l]abeling will reflect the actual composition and response of patients enrolled in the study" (DX 18 at 7)—is ***precisely*** the risk that materialized (*i.e.*, issuance of a CRL in which the FDA ***specifically*** told Acadia that it had denied the sNDA because "[as] we had advised you during development

… labeling ***would reflect*** the actual composition and response of the subjects enrolled in the trail" (PX 11 at -088)). Thus, although the law does not require "mirror image disclosure," the evidence here shows such a "match."

Defendants' final argument—that the failure of any analysts to interpret the March or April 2021 corrective disclosures as an indication that "Acadia lied or misled the public about [the FDA] agreement" somehow defeats price impact (Opp. 23)—is also unsupported and baseless. Defendants have never told the full truth about the FDA agreement, and until last week (after Plaintiffs notified them of our intent to submit them as exhibits) they had never allowed the CRL to be made public. Instead, since the spring of 2021, Defendants have repeatedly blamed FDA for reneging on "the agreement" and changing its position, when in the fact the ***evidence*** to date confirms that the FDA's position has been constant (and that it is Defendants that have lied and misled). *See supra* pp. 7-8. That Defendants have continued to lie, and the unsurprising failure of some analysts to "smell a rat" in such circumstances, is no defense to price impact.[8]

In sum, Defendants' price impact arguments and "evidence" are tissue thin, and come nowhere close to meeting their burden of completely severing the causal link between the alleged misrepresentations and Acadia's share price.

II. PLAINTIFFS' PROPOSED DAMAGES METHODOLOGY MEETS THE PREDOMINANCE REQUIREMENT.

To satisfy "predominance" with respect to damages, Plaintiffs need only show "that damages are ***capable*** of measurement on a classwide basis." *SEB Inv. Mgmt. AB v. Symantec Corp.*, 335 F.R.D. 276, 288 (N.D. Cal. 2020). This requires no more than showing that the damages that stemmed from the defendant's actions which created the legal liability "can 'feasibly and efficiently be calculated once the common liability questions are adjudicated.'" *Id*. Here, as further explained by Prof.

[8] *See, e.g.*, *Mattel*, 2021 WL 4704578, at *6 ("it would functionally defang *Basic* if a defendant-company could always rebut it by waiting to announce corrective information until it had offsetting good news").

Feinstein, he is confident that Plaintiffs will be able to use the out-of-pocket methodology to calculate class-wide damages, which courts routinely apply as an appropriately "common" damages methodology in securities class actions. *See, e.g.*, *In re BofI Holding, Inc. Sec. Litig.*, 2021 WL 3742924, at *7 (S.D. Cal. Aug. 24, 2021) ("Courts regularly reaffirm that the out-of-pocket, or event study, method matches plaintiffs' theory of [§10(b)] liability ... making it ***the standard method*** for calculating damages in virtually every [§10(b)] class action."); *City of Miami Gen. Emps.' & San. Emps.' Ret. Tr. v. RH, Inc.*, 2018 WL 4931543, at *3 (N.D. Cal. Oct. 11, 2018) (same); Pltfs' Mem. 22-23. Specifically, as Prof. Feinstein shows, the out-of-pocket methodology's use of an inflation ribbon will be able to isolate the difference between (a) the share price based on the market's perception of the risk of FDA rejecting the sNDA, and (b) the "but-for" price that would have reflected the true extent of the risk but for Defendants' misleading statements (Feinstein Rbtl. ¶101), and thereby isolate damages attributable only to Defendants' misstatements on a class-wide basis, consistent with *Comcast Corp. v. Behrend*, 569 U.S. 27, 36 (2013).

A. The Out-of-Pocket Methodology, as Plaintiffs' Expert Confirms, Is Plainly Capable of Calculating Damages on a Class-Wide Basis.

"[A]rticulating a workable class-wide damages model in relation to the predominance requirement" is not "a significant obstacle to class certification in securities litigation." *BofI Holding*, 2021 WL 3742924, at *7. "The Ninth Circuit reads *Comcast* to demand only that plaintiffs 'be able to show that their damages stemmed from the defendant's actions that created the legal liability.'" *Hatamian v. Advanced Micro Devices, Inc.*, 2016 WL 1042502, at *8 (N.D. Cal. Mar. 16, 2016). That is a straightforward exercise here because Plaintiffs have "a single theory of liability—that particular material misrepresentations [or omissions] caused putative class members to purchase [shares] at an artificially inflated price," which subsequently declined, causing damages. *BofI Holding*, 2021 WL 3742924, at *7. Plaintiffs' liability theory here is that Defendants' misstatements and omissions

concerning the FDA agreement and Harmony's "positive" results (and failures to disclose certain deficiencies in the 019 Study)—artificially inflated Acadia's share price throughout the Class Period, which dissipated as the full truth emerged. *See supra* pp. 1-2. This type of liability and resulting out-of-pocket damages theory is absolutely routine in §10(b) cases, and invariably results in class certification. *See, e.g.*, *Junge*, 2022 WL 1002446, at *6 (defendants' "misleading statements ... artificially inflated [the defendant company's share] price," which "declined" when "true" (*i.e.*, misleading) nature of those statements "came to light").

Plaintiffs' damages model, in turn, will calculate class-wide damages consistent with their theory of liability using the out-of-pocket, or event-study, methodology. The out-of-pocket damages methodology "uses an event study to determine the price inflation attributable to the alleged fraud," where an "inflation ribbon" is derived to represent "the daily level of artificial inflation in the prices of [Acadia] common stock caused by the alleged misrepresentations and omissions." *SEB*, 335 F.R.D. at 288; *see also* Feinstein Rbtl. ¶¶80-81. Here, Prof. Feinstein has amply explained how he can calculate an inflation ribbon that measures the magnitude of "the difference between the [market's] perceived risk" of sNDA rejection and the "true risk" of sNDA rejection under "a but-for scenario with full and timely disclosure." Feinstein Rbtl. ¶¶100-01. Thus, because the out-of-pocket method can reasonably isolate damages attributable to only the alleged misstatements here, it "represents an 'accepted method for the evaluation of materiality damages to a class of stockholders in a defendant corporation,'" as courts routinely find in securities actions. *Junge*, 2022 WL 1002446, at *6; *see, e.g.*, *Luna v. Marvell Tech. Grp., Ltd.*, 2017 WL 4865559, at *6 (N.D. Cal. Oct. 27, 2017) ("proposed damages model" sufficient where it "relie[d] on [] one theory of liability—that [defendant's] misstatements related to pull-in transactions artificially inflated prices, resulting in price declines when the true nature of those transactions was revealed"). No more is required for class certification.

B. Defendants' *Comcast*-based Arguments All Fail.

1. Materialization of the Risk Is a Theory of Loss Causation, Not Liability.

Defendants' *Comcast* arguments suffer from a fatal, threshold defect, as they mischaracterize the concept of materialization of the risk as a "theory of liability" (Opp. 24), when in reality "[m]aterialization of the risk ***articulates a loss-causation theory***," *Junge*, 2022 WL 1002446, at *8. Here, there is one basic liability theory: that Defendants' misrepresentations and omissions "artificially inflated [Acadia's] stock price, and that the price declined when the true nature" of the subject of those misleading statements "came to light" (*i.e.*, when the truth emerged). *Id.* at *6.

Whether the loss-causation portion of Plaintiffs' claims are deemed to rely on "materialization of the risk" or "corrective disclosure" is irrelevant at this stage, as Plaintiffs have shown that under either rubric their methodology will be able to calculate damages on a common, class-wide basis here. As Judge Alsup recently explained in rejecting essentially the same argument that Defendants proffer here, any approach to loss causation is "plaintiffs' burden to prove at the ***merits*** stage," but "[t]he possible existence of such a [materialization-of-the-risk] theory does ***not*** contravene *Comcast* or defeat predominance." *Id.* at *8. Any legalistic debates as to whether only one or both loss causation theories apply are thus irrelevant here, as the-out-of-pocket method "bases the inflation estimates on the price reactions to disclosures ***either related to or revealing*** the alleged misstatements and omissions." *SEB*, 335 F.R.D. at 288.[9]

[9] Even assuming the label of Plaintiffs' loss-causation theory is relevant now—which it is not—Plaintiffs do not concede that they are limited to proceeding under only a materialization-of-the-risk theory. When the Court sustained Plaintiffs' loss-causation allegations, it did not foreclose construing them under a corrective-disclosure theory. *See* MTD Order at 26 ("A reasonable investor could plausibly infer from Acadia's March and April 2021 press releases that they had previously been misled by Defendants' alleged misrepresentations and omissions. ***Further***, the FDA's denial of approval of the sNDA represented the materialization of the risk about which investors had allegedly been misled.").

2. Defendants' Remaining *Comcast* Quibbles Are Meritless.

Defendants' remaining arguments are facile, and even if they might have merit (which they do not) they would be premature at this class certification stage. Defendants do not seriously contend (nor could they) that the out-of-pocket methodology is inappropriate to use here, but simply posit that Prof. Feinstein has not provided in fine-enough detail how he will account for the potential complexities in this case when he sits down to calculate damages on the merits. *See* Opp. 25; Stulz Rpt. ¶143. Moreover, despite their misdirected attempts to style their merits-based damages arguments as related to predominance (Opp. 24-30), it is clear that "Defendants' objections to plaintiffs' damages approach boil down to loss causation, which plaintiffs need not show at this stage." *Junge*, 2022 WL 1002446, at *6.[10] Such attempts at legerdemain are routinely rejected. *See, e.g.*, *Luna*, 2017 WL 4865559, at *6 ("Defendants' argument that Professor Feinstein has not shown how he will disaggregate price inflation attributable to confounding events is not, as defendants would have it, an attack on his damages model, but is rather an inquiry into loss causation."); *see also, e.g.*, *Qualcomm*, 2023 WL 2583306, at *16 (rejecting similar predominance argument under *Comcast*).

The significant factual differences between *Comcast* and this case are patent, and render *Comcast* easily distinguishable. *Comcast* was an ***antitrust*** action in which the proposed damages model "assumed the validity of all four [liability] theories"—even though only one of those theories had survived dismissal. 569 U.S. at 36. Like numerous other courts, this court should find this distinction dispositive here as Plaintiffs (unlike in *Comcast*) advance only a single basic (and well-recognized) liability theory based on alleged false and misleading statements in violation of §10(b). *See Qualcomm*, 2023 WL 2583306, at *16 (rejecting *Comcast*-based predominance attacks); *In re Snap Inc. Sec. Litig.*, 334 F.R.D. 209, 217 (C.D.

[10] *See also Halliburton*, 563 U.S. at 807 ("The question presented [here] is whether securities fraud plaintiffs must also prove loss causation in order to obtain class certification. We hold that they need not.").

Cal. 2019); *Junge*, 2022 WL 1002446, at *5-6; *Hatamian*, 2016 WL 1042502, at *8; *City of Sunrise Firefighters' Pension Fund v. Oracle Corp.*, 2022 WL 1459567, at *9-10 (N.D. Cal. May 9, 2022); *BofI Holding*, 2021 WL 3742924, at *8; *SEB*, 335 F.R.D. at 288; *Luna*, 2017 WL 4865559, at *5-6.[11]

Indeed, with respect to Defendants' first *Comcast* argument, Defendants do not (and cannot) cite any authority for asserting that the out-of-pocket damages method is incompatible with a materialization-of-the-risk theory of loss causation. *See* Opp. 25-27.[12] Instead, they conclusorily assert that this methodology is "incompatible" with Plaintiffs' theory of liability because (they assert) the Feinstein Report provides insufficient details as to precisely ***how*** that methodology could be applied to measure (a) the true magnitude of the risk that the FDA would reject the sNDA versus (b) the market's (underestimated) assessment of that risk, such that (c) one could then calculate the resulting artificial inflation per share resulting from the differences between the two. *Id.*

However, as Prof. Feinstein stated in his opening report and further explains on rebuttal, he is confident that the out-of-pocket methodology can utilize event study analysis and other standard financial valuation tools to construct an "inflation ribbon" that will enable a financial economist to measure the difference between (a) actual historical share prices (which reflect what the market believed the risk to be),

---

[11] *See also Univ. of P.R. Ret. Sys. v. Lannett Co.*, 2023 WL 2985120, at *4 (3d Cir. Apr. 18, 2023); *Halman Aldubi Provident & Pension Funds Ltd. v. Teva Pharms. Indus. Ltd.*, 2023 WL 7285167, at *19-24 (E.D. Pa. Nov. 3, 2023); *Erickson v. Jernigan Cap., Inc.*, 2023 WL 5966785, at *3-5 (S.D.N.Y. Sept. 14, 2023); *In re NIO, Inc. Sec. Litig.*, 2023 WL 5048615, at *16 & n.18 (E.D.N.Y. Aug. 8, 2023); *Industriens Pens. A/S v. Becton, Dickinson & Co.*, 2023 WL 4981716, at *8 (D.N.J. Aug. 3, 2023); *Luna v. Carbonite, Inc.*, 2023 WL 4539855, at *10 (D. Mass. July 14, 2023); *Sheet Metal Workers Nat'l Pens. Fund v. Bayer AG*, 2023 WL 3569981, at *8 (N.D. Cal. May 19, 2023); *Alexion*, 2023 WL 2932485, at *13.

[12] Defendants' contention that "Plaintiffs and their expert presume that an out-of-pocket damages model is essentially a one-size-fits-all for securities fraud class actions" (Opp. 27) does not undermine the suitability of the out-of-pocket method here. As another court observed in rejecting defendants' identical challenge to Prof. Feinstein's opinions on the suitability of the out-of-pocket methodology: "[defendants'] assertion seems to reflect the fact that securities fraud cases fit Rule 23 'like a glove,' rather than suggest that class treatment is inappropriate." *RH, Inc.*, 2018 WL 4931543, at *3.

and (b) "but-for" prices. Feinstein Rbtl. ¶¶87-93 (listing array of financial valuation tools that can be used to account for potential complexities in implementing out-of-pocket methodology); *id.* ¶¶94-106 (rebutting argument that out-of-pocket method is somehow unable to account for materialization of relevant types of risk or other potentially confounding information); *id.* ¶¶107-08 (rebutting "missing key piece of information" argument of Defendants' expert, Dr. Stulz); *id.* ¶¶109-19 (rebutting Stulz's "time-varying inflation" concerns). Indeed, the discovery to date shows that financial analysts routinely calculated the odds of sNDA approval at various points during the Class Period, which changed in response to new Acadia-specific information. *See* Appendix B (illustrative examples of such analysis); *see also* Feinstein Rbtl. ¶90. Thus, Plaintiffs can—and at the appropriate time, will—account for each of the different types of potential "complexities" Defendants posit, including their "concerns" about properly accounting for various risk-related matters.[13]

Defendants' further argument that Plaintiffs' damages model improperly "lumps together two classes of plaintiffs" (Opp. 27) is also nonsense. In fact, the Complaint does ***not*** "acknowledge[]" two sets of Class members that are somehow differentiated based on whether they would have refrained from buying Acadia stock altogether or would have instead simply paid less than the artificially inflated prices they paid. *Id.* at 28. As both the Complaint and Plaintiffs' certification motion make

[13] Tellingly, the two cases Defendants cite to support their main "materialization of the risk" argument (Opp. 26) are readily distinguishable, and both actually certified a class as to at least some claims. To the extent *Mulderrig v. Amyris, Inc.* concerned materialization of the risk, the court "decline[d] to authorize class-action treatment as to [that] theory"—but only because neither plaintiffs nor their experts even "identifie[d] the materialized risk" allegedly at issue. 340 F.R.D. 575, 589-90 & n.7 (N.D. Cal. 2021). Here, by contrast, the parties and their experts have all identified the risk at play. And in any event, "many other district court[s] ... have disagreed with" *Mulderrig*'s "refram[ing]" of "materialization of the risk as a liability theory." *Junge*, 2022 WL 1002446, at *8. The only other case on which Defendants rely is an out-of-circuit case where plaintiff contended it was pursuing a materialization-of-the-risk liability theory as to only one of three sets of alleged misstatements at issue. *Ind. Pub. Ret. Sys. v. AAC Holdings, Inc.*, 2023 WL 2592134, at *24 (M.D. Tenn. Feb. 24, 2023). Here, by contrast, Plaintiffs are pursuing only one basic theory of liability with respect to all alleged misstatements or omissions.

clear, the Class consists simply of all those "who purchased or otherwise acquired Acadia common stock" during the Class Period "and were damaged thereby," without further distinctions. Pltf's Mem. 6; *see* ¶148.[14]

Defendants' remaining two points (Opp. 28–30), distill to a demand for more "details about [Plaintiffs'] damages theory," which "pertain to loss causation issues that courts generally do not consider at the class certification stage." *Oracle*, 2022 WL 1459567, at *9. First, Defendants claim Prof. Feinstein must "isolat[e] only th[e damages] attributable to" the alleged misstatements by detailing how he will "assess (i) the true risk [of FDA rejection of the sNDA] over time; and (ii) the degree to which the true risk was known to market participants." Opp. 29.[15] But this "is essentially an argument that the plaintiffs 'must demonstrate that the defendant's deceptive conduct caused their claimed economic loss'" at class certification. *Malriat v. QuantumScape Corp.*, 2022 WL 17974629, at *15 (N.D. Cal. Dec. 19, 2022). Prof. Feinstein need not "demonstrate" that at this stage, but only explain

[14] Defendants' only authority to support the false distinction they seek to draw—*Ludlow v. BP, P.L.C.*—is inapposite. That case involved two classes of investors—one of persons who bought BP shares before the Deepwater Horizon disaster and another of persons who bought after the spill—proceeding under different theories of liability, and seeking different measures of damages. *See* 800 F.3d 674, 679-80 (5th Cir. 2015) ("*BP*"). The pre-spill class (to which Defendants' reliance on *BP* is limited) sought consequential damages for their full economic loss following the Deepwater Horizon spill (*i.e.*, the full decline in stock price), rather than actual damages limited to the price decline attributable to the alleged misstatements related to the spill, but still proposed using the out-of-pocket methodology to calculate class-wide consequential damages. *Id.* at 687-89. Here, by contrast, there is only one theory of liability, and one proposed measure of damages common to the Class limited to only the actual (not consequential) damages resulting from the alleged misstatements or omissions. Given this key distinction, numerous courts have rejected similar predominance attacks that rely on *BP*, as should the Court here. *See BofI Holding*, 2021 WL 3742924, at *8; *Junge*, 2022 WL 1002446, at *9; *Hatamian*, 2016 WL 1042502, at *9; *Oracle*, 2022 WL 1459567, at *10.

[15] Defendants' reliance on *In re BP p.l.c. Sec. Litig.* to support this contention is misplaced. *See* 2014 WL 2112823, at *10 (S.D. Tex. May 20, 2014), *aff'd*, *BP*, 890 F.3d 674. Again, the portion of the opinion on which they rely pertained to the pre-spill class that sought consequential damages; that class "concede[d] that the pre-explosion damages methodology d[id] not calculate the amount of pre-explosion inflation in BP's stock price," and "expressly eschew[ed] that their recovery should be limited to the market price distortion." *Id.* at *10-11. Here, by contrast, Plaintiffs are seeking exactly what the pre-spill class eschewed—only the damages related to the artificial inflation in the stock price attributable to the alleged misstatements.

that he can, which he has done. *See*, *e.g.*, *Bayer AG*, 2023 WL 3569981, at *8 (proposed damages methodology met predominance where plaintiffs' expert showed that "investor uncertainty around the risk posed by the ongoing glyphosate litigation ***can be factored*** into the out-of-pocket damages model"); *see also Halman*, 2023 WL 7285167, at *19 ("In other words, Plaintiff must demonstrate that there is a reliable methodology for measuring damages with reasonable accuracy."); *see also* Feinstein Rbtl. ¶¶87-102.

Finally, Defendants demand that Prof. Feinstein's model "account for changes in the magnitude of the allegedly understated risk over time" at this stage. Opp. 29. Unsurprisingly, Defendants have no authority to back up this bold claim because no such burden exists where, as here, Prof. Feinstein has "generally explain[ed] the techniques used in an event study to adjust for confounding information's effect on [Acadia] share price," including "using financial analyses to differentiate price responses to different information," among other tools. *BofI Holding*, 2021 WL 3742924, at *9. He need not "precisely identif[y] what approach he will use to control for ***every variable in this case***," *id.*, as Defendants demand.[16]

Accordingly, Plaintiffs have shown they can use a common methodology to calculate damages on a class-wide basis in accord with Rule 23(b)(3).

CONCLUSION

For the reasons stated above and those in the Opening Brief, Plaintiffs respectfully request that the Motion be granted.

[16] Defendants' argument that Plaintiffs' theory "is fundamentally inconsistent with their request for the *Basic* presumption" proves too much. Opp. 30. If that were that case, the materialization-of-the-risk theory of loss causation would never be cognizable under §10(b). The *Basic* presumption has no bearing on loss causation, as even the *BP* case Defendants cite clarified. 800 F.3d at 691 ("The fraud-on-the-market theory does not provide any presumptions with regard to loss causation.").

DATED: December 12, 2023

Respectfully submitted,

SCOTT+SCOTT ATTORNEYS AT LAW LLP

/s/ William C. Fredericks
William C. Fredericks (*pro hac vice*)
Donald A. Broggi (*pro hac vice*)
Marc J. Greco (*pro hac vice*)
The Helmsley Building
230 Park Avenue, 17th Floor
New York, NY 10169
Telephone: (212) 223-6444
Facsimile: (212) 223-6334
wfredericks@scott-scott.com
dbroggi@scott-scott.com
mgreco@scott-scott.com

SCOTT+SCOTT ATTORNEYS AT LAW LLP
Jacob B. Lieberman (*pro hac vice*)
156 South Main Street
P.O. Box 192
Colchester, CT 06413
Telephone: (860) 537-5537
Facsimile: (860) 537-4432
jlieberman@scott-scott.com

SCOTT+SCOTT ATTORNEYS AT LAW LLP
John T. Jasnoch (SBN 281605)
600 W. Broadway, Suite 3300
San Diego, CA 92101
Telephone: (619) 233-4565
Facsimile: (619) 233-0508
jjasnoch@scott-scott.com

Counsel for Lead Plaintiff City of Birmingham Retirement and Relief System

LEVI & KORSINSKY, LLP
Shannon L. Hopkins (*pro hac vice*)
Gregory M. Potrepka (*pro hac vice*)
1111 Summer Street, Suite 403
Stamford, CT 06905
Telephone: (203) 992-4523
shopkins@zlk.com
gpotrepka@zlk.com

LEVI & KORSINSKY, LLP
Adam M. Apton (SBN 316506)
Adam C. McCall (SBN 302130)
75 Broadway, Suite 202
San Francisco, CA 94111
Telephone: (415) 273-1671
aapton@zlk.com
amccall@zlk.com

Attorneys for Additional Plaintiff Ohio Carpenters' Pension Fund