UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

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

Plaintiffs,

v.

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

Defendants.

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

ORDER

HAYES, Judge:

The matter before the Court is the Motion for Class Certification and Appointment of Class Representatives and Class Counsel filed by Plaintiffs City of Birmingham Relief and Retirement System and Ohio Carpenters' Pension Fund. (ECF No. 108.)

I. PROCEDURAL BACKGROUND

On April 19, 2021, Denise Marechal initiated this action by filing a Class Action Complaint. (ECF No. 1.) On September 29, 2021, the Court issued an Order appointing City of Birmingham Relief and Retirement System ("Birmingham") as Lead Plaintiff. (ECF No. 38.)

On December 10, 2021, Birmingham and additional Plaintiff Ohio Carpenters' Pension Fund (collectively "Plaintiffs") filed an Amended Class Action Complaint (the "FAC"). (ECF No. 45.) The FAC alleges that Defendants Acadia Pharmaceuticals, Inc. ("Acadia"), Stephen R. Davis, and Srdjan (Serge) R. Stankovic (collectively "Defendants") violated federal securities laws by deceiving investors regarding the likelihood of Food and Drug Administration ("FDA") approval of a drug, which Acadia developed, to artificially inflate the market price of Acadia securities.

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

On October 25, 2022, Defendants filed the Motion for Reconsideration, requesting reconsideration of the September 27, 2022 Order. (ECF No. 75.) On February 2, 2023, the Court issued an Order denying the Motion for Reconsideration. (ECF No. 82.)

On August 21, 2023, Plaintiffs filed the Motion for Class Certification and Appointment of Class Representatives and Class Counsel. (ECF No. 108.) On October 10, 2023, Defendants filed a Response in opposition to the Motion for Class Certification. (ECF No. 117.) On December 12, 2023, Plaintiffs filed a Reply. (ECF No. 122.) On January 12, 2024, Defendants filed a Sur-reply. (ECF No. 126.)

On February 28, 2024, the Court heard oral argument on the Motion for Class Certification and Appointment of Class Representatives and Class Counsel.

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II. FACTUAL BACKGROUND

Acadia is a "biopharmaceutical company that focuses on the development and commercialization of small molecule drugs that address unmet medical needs in central nervous system [] disorders." (ECF No. 45 ¶ 27.) Defendant Stephen R. Davis "has served as Acadia's Chief Executive Officer and a member of [Acadia's] Board of Directors since September 2015." *Id.* ¶ 23. Defendant Srdjan (Serge) R. Stankovic served as "Acadia's Executive Vice President, Head of Research and Development, from November 2015 through November 2018" and "has served as Acadia's President and Head of Research and Development since November 2018." *Id.* ¶ 24.

In July 2011, Acadia initiated a Phase III medical study (the "-020 Study") to "evaluate[] the efficacy, tolerability and safety" of a drug called pimavanserin in patients with Parkinson's disease psychosis ("PDP"), a condition "associated with Parkinson's disease dementia." *Id.* ¶¶ 2, 45. In April 2016, the FDA "approved pimavanserin for the treatment of hallucinations and delusions associated with [PDP]." *Id.* ¶ 31.

In November 2013, Acadia initiated a Phase II medical study (the "-019 Study") to "evaluate the efficacy and safety of pimavanserin as a treatment for patients with Alzheimer's disease psychosis ('ADP')." *Id.* ¶ 48. "In December 2016, [Acadia] announced positive top-line results from the -019 [S]tudy," including that pimavanserin met its primary endpoint at week six but did not meet its secondary endpoint at week twelve. *Id.* ¶ 49.

"Following the -019 Study on ADP, in mid-2017, Acadia had an [e]nd-of-Phase II meeting with the FDA," at which Acadia "proposed a plan for a single Phase III study that would support approval not for an indication of pimavanserin for ADP, but for a broader indication of pimavanserin for [dementia-related psychosis ('DRP')]." *Id.* ¶ 50. DRP "occurs in patients with a *variety* of different types of dementia" including "Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia, and frontotemporal dementia spectrum

disorders." *Id.* ¶¶ 2, 70.

According to minutes from the end-of-Phase II meeting, which were not available to the public, the FDA "agree[d] that treatment of [DRP] is a potentially approvable indication [for pimavanserin]," and that "dementias need not be etiologically related for the common symptoms of psychosis to respond to pimavanserin." (Plaintiffs' Ex. 4, ECF No. 122-7 at 3.) When asked if the FDA "agree[d] with the proposed overall study design," the FDA replied that it had "concerns in basing a regulatory decision on a single, randomized withdrawal study," and proposed that Acadia conduct "an acute [placebo-controlled] trial followed by the proposed randomized withdrawal study." (Defendants' Ex. 18, ECF No. 117-4 at 63–64.) Notwithstanding the FDA's concerns, the FDA "agree[d] with the proposed study population as long as subjects are stratified by their current clinical diagnosis (as proposed)," and that "[l]abeling will reflect the actual composition and response of patients enrolled in the study." *Id.* at 63. The FDA also stated that "[if] you wish to rely on a single well-controlled study for your [Supplemental New Drug Application ('sNDA')] filing, the findings must be very persuasive." *Id.* at 65.

On October 4, 2017, Acadia announced that it had initiated the Harmony Study, a "Phase III, randomized, double-blind, placebo-controlled study," with aims "to evaluate the ability of pimavanserin to prevent relapse of psychotic symptoms in a broad population of patients with the most common subtypes of dementia," analyzed as a single group. (Defendants' Ex. 22, ECF No. 117-5 at 15.) Acadia also stated that the "Phase III development plan is supported by data" from the -019 and -020 Studies. *Id.*

On September 9, 2019, Acadia issued a press release in which Defendants "announced positive results for the Harmony Study." (ECF No. 45 ¶ 4.) The press release stated that the Harmony Study "met its primary endpoint, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis." *Id.* ¶ 107. Acadia also

announced that it was "planning to meet with the FDA regarding a[n] [sNDA] submission in 2020," *id.*, and that the FDA confirmed that the sNDA could "rely on a single, well-controlled study whose results were both statistically and clinically very persuasive," *id.* ¶ 5.

"In response to these positive reports, the price of Acadia's common stock shot up more than 63%, closing at $38.85 on September 9, 2019." *Id.* ¶ 6.

"On December 4, 2019, Acadia presented the Harmony Study's top-line results" to medical professionals and "released the full data set of the Harmony Study" in connection with the presentation. *Id.* ¶ 62.

"On June 3, 2020, Acadia submitted its sNDA for pimavanserin [to the FDA] for the treatment of hallucinations and delusions associated with DRP." *Id.* ¶ 43. The sNDA was "principally" based on the Harmony Study, "with further support from the Phase III '-020 Study,' and the Phase II '-019 Study.'" *Id.* ¶ 44.

On March 8, 2021, Acadia "issued a press release … that provided an update on its pimavanserin sNDA." *Id.* ¶ 9. The press release stated that Acadia was notified by the FDA that "as part of its ongoing review of the [sNDA], the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." *Id.* On April 5, 2021, Acadia "issued a press release announcing that [Acadia] had received a Complete Response Letter ('CRL') from the FDA which indicated that the sNDA could ***not*** be approved." *Id.* ¶ 10. The press release stated, in the relevant part:

> [T]he [FDA], in the CRL, cited a lack of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with certain less common dementia subtypes as lack of substantial evidence of effectiveness to support approval….
>
> The [FDA] also stated in the CRL that it considers the Phase 2 Alzheimer's disease psychosis study -019, a supportive study in the sNDA filing, to not be adequate and well controlled, citing that it was single center study with no type I error control of secondary endpoints in which certain protocol deviations occurred.

Id. ¶ 145. In response to the two announcements, Acadia's common stock price fell $20.76 per share (45.35%) on March 9, 2021, and an additional $4.41 (17.23%) on April 5, 2021.

Plaintiffs allege that between September 9, 2019 (the day Acadia announced positive results from the Harmony Study) and April 4, 2021 (the day before FDA approval was denied), Defendants misled investors by stating that the FDA agreed to base its review of the sNDA on the Harmony Study's overall results across all DRP patients, instead of analyzing the efficacy data for each dementia subgroup. *See id.* ¶¶ 125, 126, 132, 133, 135, 136. For example, Defendant Davis stated at a January 12, 2021, conference: "[W]e're seeking the treatment of [DRP]. So we're not looking at individual subtypes .... So we're seeking that broad indication. That's supported by a[n] … alignment we established with the FDA." *Id.* ¶ 135. Plaintiffs allege these representations were "materially false and misleading" because "even if there was a general agreement that [Acadia] could do a single adequate and well-controlled study, that agreement was obviously contingent on the data being supportive of the subgroups that Acadia sought to treat with pimavanserin …." *Id.* ¶ 103.

Plaintiffs further allege that Defendants misled investors by omitting adverse information about the Harmony and -019 Studies. Plaintiffs allege that "[a]s Defendants knew or recklessly disregarded even before launching the Harmony Study, [the] Harmony [S]tudy … was not reasonably designed to contain a sufficient number of patients … to conclude … that pimavanserin was an effective treatment for patients in [DRP] subgroups." *Id.* ¶ 8. "Instead, the Harmony Study was largely populated by patients suffering from dementia associated with Parkinson's disease – the condition for which pimavanserin was already FDA-approved." *Id.* Plaintiffs further allege that the "-019 Study's poorly analyzed data and poor design … rendered [that] dataset far from 'supportive.'" *Id.* ¶ 90.

Plaintiffs seek to certify the following proposed Class:

All persons and entities who purchased or otherwise acquired shares of

> Acadia common stock during the period from September 9, 2019 through April 4, 2021 (inclusive), and were damaged thereby. Excluded from the Class are (i) Defendants; (ii) the past and current officers and directors of Acadia; (iii) the immediate family members, legal representatives, heirs, parents, subsidiaries, predecessors, successors, and assigns of any excluded person or entity; and (iv) any entity in which any excluded person(s) have or had a majority ownership interest, or that is or was controlled by any excluded person or entity.

(ECF No. 108-1 at 11.) Plaintiffs additionally state: "The proposed class representatives are Birmingham and additional plaintiff Ohio Carpenters. Both purchased Acadia common shares during the Class Period at artificially inflated prices and suffered losses as the truth was revealed." *Id.*

III. LEGAL STANDARD

Federal Rule of Civil Procedure 23 governs the maintenance of class actions in federal court. Parties seeking class certification must satisfy each of the four requirements of Rule 23(a) and at least one of the requirements of Rule 23(b). *See Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 663 (9th Cir. 2022). The requirements of Rule 23(a) are as follows:

> (1) the class is so numerous that joinder of all members is impracticable;
> (2) there are questions of law or fact common to the class;
> (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
> (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). These Rule 23(a) requirements are known as numerosity, commonality, typicality, and adequacy. Plaintiffs seek certification pursuant to Rule 23(b)(3), which requires that "questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Plaintiffs, as the party seeking class

certification, bear the burden of demonstrating that the Rule 23(a) and Rule 23(b) requirements have been met. *See Olean Wholesale Grocery Coop.*, 31 F.4th at 663.

"The decision to grant or deny class certification is within the trial court's discretion." *Bateman v. Am. Multi-Cinema, Inc.*, 623 F.3d 708, 712 (9th Cir. 2010). "Before it can certify a class, a district court must be 'satisfied, after a rigorous analysis, that the prerequisites' of both Rule 23(a) and 23(b)(3) have been satisfied." *Olean Wholesale Grocery Coop.*, 31 F.4th at 664 (quoting *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 161 (1982)). This may "entail some overlap with the merits of the plaintiff's underlying claim," *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 351 (2011), but "Rule 23 grants courts no license to engage in free-ranging merits inquiries at the certification stage," *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 466 (2013). "[P]laintiffs must prove the facts necessary to carry the burden of establishing that the prerequisites of Rule 23 are satisfied by a preponderance of the evidence." *Olean Wholesale Grocery Coop.*, 31 F.4th at 665.

IV. CONTENTIONS

Plaintiffs contend that each of the Rule 23(a) requirements are satisfied. Plaintiffs contend the numerosity requirement is satisfied because, during the relevant time period, "over 632 million outstanding shares of Acadia common stock were traded on the NASDAQ, a national stock exchange." (ECF No. 108-1 at 12.) Plaintiffs contend the commonality requirement is satisfied because there are five common questions that will be proven by common evidence. Plaintiffs contend the typicality requirement is satisfied because "they allege that the same actionable misstatements and omissions caused all Class members to be injured in the same way." *Id.* at 7. Plaintiffs contend the adequacy requirement is satisfied because Plaintiffs do not have any conflicts with other Class members and have "already shown they are willing and able to prosecute this Action vigorously on behalf of the Class." *Id.* at 15. Plaintiffs contend the predominance requirement of Rule 23(b)(3) is satisfied because the element of reliance may be presumed under the fraud-on-the-

market theory, and damages can be determined on a class-wide basis. Plaintiffs contend that class treatment is superior to other forms of adjudication.

Defendants contend that Plaintiffs cannot establish the predominance requirement with respect to reliance and damages. Defendants contend that the presumption of reliance can be rebutted because the alleged misrepresentations did not have a "price impact." (ECF No. 117 at 13.) Defendants contend that there was no price impact because "the market already knew of the allegedly corrective information," and therefore Acadia's stock price "could not have been inflated through the omission of that information." *Id.* at 13. Defendants further contend that there was no price impact because "there is a mismatch in content between the alleged misrepresentations and what was revealed when the risk ultimately materialized." *Id.* at 25. Defendants contend that Plaintiffs' proposed damages model cannot support class certification because "it is incompatible with Plaintiffs' materialization-of-the-risk theory of liability," and "it cannot measure materialization-of-the risk damages on a class-wide basis." *Id.* at 29.

V. DISCUSSION

A. Rule 23(a)

1. Numerosity

Under Rule 23(a)(1), a certifiable class must be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). "The numerosity requirement requires examination of the specific facts of each case and imposes no absolute limitations." *Gen. Tel. Co. of the Nw., Inc. v. Equal Emp. Opportunity Comm'n*, 446 U.S. 318, 330 (1980). A proposed class of fifteen has been held to be too small, but a proposed class of more than sixty has been held to be of adequate numerosity. *See Harik v. Cal. Teachers Ass'n*, 326 F.3d 1042, 1051–52 (9th Cir. 2003).

Here, Plaintiffs contend that from September 9, 2019, through April 4, 2021, "over 632 million outstanding shares of Acadia common stock were traded on the NASDAQ, a national stock exchange." (ECF No. 108-1 at 12 (citing Report of

Professor Steven P. Feinstein, Ph.D., CFA ("Feinstein Report"), ECF No. 108-3 at 28).) Defendants do not contest that Plaintiffs' proposed Class satisfies the numerosity requirement. The Court concludes that the numerosity requirement under Rule 23(a)(1) is satisfied in this case.

2. Commonality

Under Rule 23(a)(2), there must be "questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). This requires that the class's claims "depend upon a common contention" that is "capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." *Dukes*, 564 U.S. at 350. "By contrast, an individual question is one where members of a proposed class will need to present evidence that varies from member to member." *Olean Wholesale Grocery Coop.*, 31 F.4th at 663 (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016)). "What matters to class certification ... is not the raising of common 'questions'—even in droves—but rather, the capacity of a class-wide proceeding to generate common *answers* apt to drive the resolution of the litigation." *Dukes*, 564 U.S. at 350 (quotation omitted). However, "[e]ven a single common question of law or fact that resolves a central issue will be sufficient to satisfy this mandatory requirement for all class actions." *Castillo v. Bank of Am., NA*, 980 F.3d 723, 728 (9th Cir. 2020) (citing *Dukes*, 564 U.S. at 359).

In the present case, Plaintiffs contend that "the claims of Class members depend on numerous common issues that can be resolved on a class-wide basis," including:

1. Whether Defendants' statements or omissions (as detailed at ¶¶ 107–42 of the [FAC]) violated federal securities laws;
2. Whether Defendants' statements or omissions were materially false or misleading;
3. Whether Defendants acted with the requisite scienter;

4. Whether the price of Acadia common stock was artificially inflated as a result of Defendants' misrepresentations or omissions; and

5. Whether disclosures of Defendants' wrongdoing caused Class members to suffer damages, and if so what is the proper measure of damages.

(ECF No. 108-1 at 13.) These questions depend on "common contention[s]" that are "capable of classwide resolution." *Dukes*, 564 U.S. at 350; *see In re Bridgepoint Educ., Inc. Sec. Litig.*, No. 12-cv-1737 JM (JLB), 2015 WL 224631, at *5 (S.D. Cal. Jan. 15, 2015) (commonality requirement met where common questions included "whether [the defendant] made false statements, whether those statements were material, whether they were intentionally false, and whether they caused class members' losses"). Defendants do not contest that Plaintiffs' proposed Class claims satisfy the commonality requirement. The Court concludes that the commonality requirement under Rule 23(a)(2) is satisfied in this case.

3. Typicality

Under Rule 23(a)(3), the claims or defenses of the named plaintiffs must be "typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). "Typicality refers to the nature of the claim or defense of the class representative, and not to the specific facts from which it arose or the relief sought." *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 508 (9th Cir. 1992) (quotations omitted). "The test of typicality is whether other members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the same course of conduct." *Id.* (quotation omitted). "Under the rule's permissive standards, representative claims are 'typical' if they are reasonably co-extensive with those of absent class members; they need not be substantially identical." *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1020 (9th Cir. 1998), *overruled on other grounds by Dukes*, 564 U.S. 338. However, "a named plaintiff's motion for class certification should not be granted if there is a danger that

absent class members will suffer if their representative is preoccupied with defenses unique to it." *Hanon*, 976 F.2d at 508.

Here, Plaintiffs' alleged injuries are based on the same course of conduct as those of the absent Class members: Defendants' statements and omissions that are alleged to be materially misleading. The alleged injury—purchasing Acadia shares at artificially inflated prices—is also not unique to Plaintiffs and is allegedly caused by the same course of conduct. Based upon the current record, Plaintiffs have shown that this "action is based on conduct which is not unique to the named [P]laintiffs," and there is not a substantial danger that absent class members will suffer because Plaintiffs are "preoccupied with defenses unique" to them. *Hanon*, 976 F.2d at 508. Defendants do not contest that the proposed Class claims satisfy the typicality requirement. The Court concludes that typicality under Rule 23(a)(3) is satisfied.

4. Adequacy

Under Rule 23(a)(4), the named plaintiffs must "fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). "Resolution of two questions determines legal adequacy: (1) do the named plaintiffs and their counsel have any conflicts of interest with other class members and (2) will the named plaintiffs and their counsel prosecute the action vigorously on behalf of the class?" *Hanlon*, 150 F.3d at 1020.

As to the first question, there does not appear to be any conflicts between Plaintiffs and their counsel and the proposed Class members. Rather, the interests of Plaintiffs align with the interests of the proposed Class because all allegedly suffered injuries from the same conduct. As to the second question, Plaintiffs put forth evidence that they are represented by competent and qualified counsel who have vigorously litigated this action, including by litigating dispositive motions and engaging in extensive discovery. (*See* Turner Decl., ECF No. 108-4 ¶¶ 4–6; Linville Decl., ECF No. 108-5 ¶¶ 5–7.) Based upon the current record, Plaintiffs have shown that they will "fairly and adequately protect the interests of the class." Fed. R. Civ.

P. 23(a)(4). Defendants do not contest that Plaintiffs satisfy the adequacy requirement. The Court concludes that adequacy is satisfied in this case.

B. Rule 23(b)(3)

Under Rule 23(b)(3), a court must find "that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3).

1. Predominance

"The predominance inquiry asks whether the common, aggregation-enabling, issues in the case are more prevalent or important than the non-common, aggregation-defeating, individual issues." *Tyson Foods*, 577 U.S. at 453 (quotation omitted). For purposes of this analysis, "[a]n individual question is one 'where members of a proposed class will need to present evidence that varies from member to member,' while a common question is one where 'the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof.'" *Torres v. Mercer Canyons Inc.*, 835 F.3d 1125, 1134 (9th Cir. 2016) (quoting *Tyson Foods*, 577 U.S. at 453).

Considering whether common questions are more prevalent than individual ones "begins, of course, with the elements of the underlying cause of action." *Erica P. John Fund, Inc. v. Halliburton Co.* ("*Halliburton I*"), 563 U.S. 804, 809 (2011). To establish a violation of § 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b–5, a plaintiff must show: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Amgen*, 568 U.S. at 460–61 (citation omitted). Defendants contend that Plaintiffs cannot establish predominance with respect to the elements of reliance and damages.

a. Reliance

"Whether common questions of law or fact predominate in a securities fraud action often turns on the element of reliance." *Halliburton I*, 563 U.S. at 910. Reliance "ensures that there is a proper 'connection between a defendant's misrepresentation and a plaintiff's injury,'" and is traditionally demonstrated by showing that plaintiff was "aware of a company's statement" and purchased the company's stock "based on that specific misrepresentation." *Id.* (quoting *Basic Inc. v. Levison*, 485 U.S. 224, 243 (1988)). In *Basic*, the Supreme Court "held that a plaintiff may also invoke a rebuttable presumption of reliance based on the fraud-on-the-market theory." *Goldman Sachs Group, Inc. v. Arkansas Teacher Retirement Sys.*, 141 S.Ct. 1951, 1959 (2021). The "fundamental premise" of the fraud-on-the-market theory is that "the market price of shares traded on well-developed markets reflects all publicly available information, and, hence, any material misrepresentations." *Basic*, 485 U.S. at 246. "Because the market 'transmits information to the investor in the processed form of a market price,'" courts can assume "that an investor relies on public misstatements whenever he 'buys or sells stock at the price set by the market.'" *Halliburton I*, 563 U.S. at 811 (quoting *Basic*, 485 U.S. at 244, 247); *Conn. Retirement Plans & Tr. Funds v. Amgen Inc.*, 660 F.3d 1170, 1173 (9th Cir. 2011) ("Anyone who buys stock at the prevailing market price is presumed to have relied on that price—and, by extension, each piece of publicly available information it reflects—as a measure of the stock's value, even if the investor never saw that information.").

To demonstrate the presumption of reliance, a plaintiff must show: "(1) that the alleged misrepresentations were publicly known, (2) that they were material, (3) that the stock traded in an efficient market, and (4) that the plaintiff traded the stock between the time the misrepresentations were made and when the truth was revealed." *Halliburton Co. v. Erica P. John Fund, Inc.* ("*Halliburton II*"), 573 U.S. 258, 268 (2014) (citations omitted). Here, rather than disputing whether Plaintiffs

made the requisite showing to establish the fraud-on-the-market presumption of reliance, Defendants attempt to rebut the presumption.

"Any showing that severs the link between the alleged misrepresentation and either the price received (or paid) by the plaintiff, or his decision to trade at a fair market price, will be sufficient to rebut the presumption of reliance." *Basic*, 485 U.S. at 248. *Basic* "affords defendants an opportunity to rebut the presumption by showing, among other things, that the particular misrepresentation at issue did not affect the stock's market price"—"that is, that the misrepresentation had no 'price impact.'" *Halliburton II*, 573 U.S. at 263–64, 278. For example, there may be a lack of price impact if "the market was already aware of the truth behind the defendant's supposed falsehoods … (the so-called 'truth-on-the-market' defense)." *Amgen*, 660 F.3d at 1174 (citing *Basic*, 485 U.S. at 248–49). "If a misrepresentation had no price impact, then *Basic*'s fundamental premise 'completely collapses, rendering class certification inappropriate.'" *Goldman Sachs*, 141 S.Ct. at 1958 (quoting *Halliburton II*, 573 U.S. at 283).

"[T]he defendant bears the burden of persuasion to prove a lack of price impact" by a "preponderance of the evidence." *Goldman Sachs*, 141 S.Ct. at 1960, 1963. In assessing whether price impact occurred, courts must consider "all probative evidence on that question—qualitative as well as quantitative—aided by a good dose of common sense." *Id.* at 1960. "The district court's task is simply to assess all the evidence of price impact—direct and indirect—and determine whether it is more likely than not that the alleged misrepresentations had a price impact." *Id.* at 1963.

In this case, Plaintiffs allege that Defendants misled the public as to the likelihood that the pimavanserin sNDA would be approved by misrepresenting Acadia's purported agreement with the FDA and omitting adverse information with respect to the Harmony and -019 Studies. Plaintiffs have produced evidence to show that these alleged misrepresentations and omissions affected the price of Acadia's stock. In particular, Plaintiffs submit an expert report by Professor Steven P.

Feinstein, which concludes that there was a statistically significant price increase when Acadia released the positive results of the Harmony Study on September 9, 2021, and statistically significant price decreases on March 9, 2021, when Acadia announced it had received the Deficiency Letter from the FDA, and on April 5, 2021, when Acadia announced that the sNDA was ultimately denied. (Feinstein Report, ECF No. 108-3 at 153, 161.)

Defendants do not dispute that the front-end increase or back-end price drops of Acadia's stock are statistically significant. Instead, Defendants attempt to rebut the presumption by asserting that "the market already knew of the allegedly corrective information, in which case the stock price could not have been inflated through the omission of that information." (ECF No. 117 at 13.) Defendants' expert, René M. Stulz, Ph.D., opines that information regarding the results and design of the Harmony and -019 Studies was "already publicly known prior to the March Deficiency Letter, and in an efficient market, could not have caused Acadia's stock price to decline following the March Deficiency Letter and April CRL." (Report of René M. Stulz, Ph.D. ("Stulz Report"), ECF No. 117-3 at 8–9.) Dr. Stulz further opines that "because the alleged misrepresentations regarding the agreement with the FDA for the HARMONY Study design were publicly known as early as 2017, prior to the beginning of the Proposed Class Period," the alleged misrepresentations "could not have caused Acadia's stock price to increase on the first day of the Proposed Class Period." *Id.* at 9.

As an initial matter, Plaintiffs contend that Defendants' price impact arguments amount to a "truth-on-the-market" defense, which, pursuant to *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455 (2013), cannot be considered at class certification. (ECF No. 122 at 19–20.) In *Amgen*, the defendant attempted to rebut the *Basic* presumption by presenting evidence that "news of the [truth] credibly entered the market and dissipated the effects of [prior] misstatements," i.e. the "truth-on-the-market" defense. *Amgen*, 568 U.S. at 481–82. The Supreme Court held that

because the truth-on-the-market defense "is a method of refuting an alleged misrepresentation's materiality," the district court did not err "by disregarding [the defendant's] rebuttal evidence in deciding whether [the] proposed class satisfied Rule 23(b)(3)'s predominance requirement." *Id.* at 481.

However, more recently, the Supreme Court stated that district courts "must take into account all record evidence of price impact, regardless [of] whether that evidence overlaps with materiality or any other merits issue." *Goldman Sachs*, 141 S.Ct. at 1961 n.2 ("We recognize that materiality and price impact are overlapping concepts and that the evidence relevant to one will almost always be relevant to the other. But 'a district court may not use the overlap to refuse to consider the evidence.'"); *In re Allstate Corp. Sec. Litig.*, 966 F.3d 595, 608 (7th Cir. 2020) ("A district court deciding whether the *Basic* presumption applies must consciously avoid deciding materiality and loss causation…. At the same time, a district court must be willing to consider evidence offered by the defense to show that the alleged misrepresentations did not actually affect the price of the securities…. And yes, the same evidence is likely to have obvious implications for the off-limits merits issues of materiality and loss causation."). To the extent *Goldman Sachs* permits the Court to consider Defendants' price impact arguments at this stage in the proceedings, the Court does so below.

i. Statements Concerning an Agreement with the FDA

Defendants contend that the alleged misstatements concerning Acadia's agreement with the FDA cannot support inflation of Acadia's stock price on September 9, 2019, because, beginning in 2017, Acadia "repeatedly" disclosed "its agreement with the FDA about pursuing an indication in DRP and relying on the [Harmony] Study to serve as the basis for submission of an sNDA." (ECF No. 117 at 24–25.)

Plaintiffs contend that although Defendants "point to general statements concerning 'an agreement' with the FDA," "such statements do not come close to

disclosing the key 'omitted term' about the 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." (ECF No. 122 at 19 (emphasis omitted).)

In support of their position, Defendants file several press releases, investor conference calls, and SEC filings to show that Acadia disclosed its agreement with the FDA prior to the proposed Class period. (*See* Defendants Exs. 19–24, 26–29, 32–33, 38–39, 43, 45–50, 52–61.) However, these filings indicate that Acadia did not fully disclose the terms of that agreement. The end-of-Phase II meeting minutes—which were not publicly disclosed—show the FDA agreed to the Harmony Study design on the conditions that (1) "subjects are stratified by their current clinical diagnosis (as proposed)," and (2) "labeling[1] will reflect the actual composition and response of patients enrolled in the study." (Defendants' Ex. 18, ECF No. 117-4 at 63.) Taken together, these conditions indicate that the FDA would base its decision to expand "labeling" of pimavanserin on the "actual composition and response of patients" in each dementia subtype. *Id.* In the CRL, the FDA stated that "[a]lthough [the Harmony Study] was not powered to demonstrate an effect in the subgroups of dementia included, we had advised you during development that labeling would reflect the actual composition and response of the subjects enrolled in the trial." (ECF No. 122-14 at 2.) Defendants have not provided evidence that investors were aware of this information before or during the Class period. Although Acadia generally informed the public that it had reached an agreement with the FDA regarding the Harmony Study design, this omitted term provides key information with respect to the significance of the subgroup data.

[1] Under FDA regulations, all prescription drug "labeling" must include the "[i]ndications and usage" of the drug. 21 C.F.R. § 201.57. In the present case, Acadia sought expanded "labeling" of pimavanserin to include a new "[i]ndication[] and usage," i.e. approval to treat DRP. *Id.*; *see* Defendants' Ex. 22, ECF No. 117-5 at 13.

On Sur-reply, Defendants contend that Plaintiffs have "rewrite[en] [their] entire theory of fraud" because the FAC "contains no allegations that Defendants misled investors about what the label might reflect if pimavanserin were approved for DRP." (ECF No. 126 at 9–10.) Defendants contend that "[o]n the pleadings, this was a dispute about the existence of an agreement with the FDA," but "has now morphed into a dispute about whether Defendants misled investors by failing to disclose a single sentence about labeling from the FDA's 15-page End of Phase 2 meeting minutes." *Id.* Defendants contend that "deciding class certification on Plaintiffs' unpled theory of fraud is both unworkable and prejudicial," and that "[i]f Plaintiffs intend to pursue a new theory of liability," "the proper course is to seek leave to amend the [FAC]." *Id.* at 10–11.

The FAC, however, not only contains allegations that Defendants misrepresented the existence of an agreement with the FDA, but alternatively alleges that Defendants mispresented the terms of an agreement with the FDA. For example, Plaintiffs allege: "[E]ven if there was a general agreement that [Acadia] could do a single adequate and well-controlled study, that agreement was obviously contingent on the data being supportive of the subgroups that Acadia sought to treat with pimavanserin, and that was most certainly not the case." (ECF No. 45 ¶ 103.) Elsewhere in the FAC, Plaintiffs allege that Defendants "failed to disclose that, due to a very small sample size of patients in each subgroup, the Harmony Study could not effectively determine whether pimavanserin was an effective treatment for the different subgroups. Therefore, undisclosed by Defendants, FDA approval was extremely unlikely unless the results from the Harmony Study were very strong. In fact, the data was disappointing, particularly as to the non-Parkinson's patients, indicating that the likelihood of approval was very low." *Id.* ¶ 109. The FAC also repeatedly alleges that "the assertion that the FDA had blessed Acadia's approach to the sNDA was false because no such agreement was reached." *Id.* ¶¶ 108, 110. The FAC adequately alleges that Defendants misrepresented any agreement with the FDA

by omitting that the FDA would focus on subgroup data when deciding to expand the "labeling" of pimavanserin. The FAC also adequately alleges that Defendants misrepresented any agreement with the FDA by implying that the FDA had prospectively agreed that the design of the study—including "a very small sample size of patients in each subgroup"—would readily support FDA approval for pimavanserin to treat all DRP patients.

Moreover, Plaintiffs have been clear in their papers about the theory of liability they intend to pursue. In Plaintiffs' Opposition to Defendants' Motion to Dismiss, Plaintiffs contended: "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 [to] allow the 'overall' results, in a mixed population of DRP patients, from a 'single, well-controlled study' such as HARMONY, to support approval." (ECF No. 56 at 5 (emphasis omitted).) Similarly, in Plaintiffs' Opposition to Defendants' Motion for Reconsideration, Plaintiffs contended: "[A]s the Court correctly found, Plaintiffs allege that Defendants [] misrepresented a purported agreement with the FDA about the design of their Harmony trial." (ECF No. 78 at 9.) And the Court has understood this theory in its Orders. (*See* Order Denying Defendants' Motion to Dismiss, ECF No. 65 at 9 ("[A] plausible inference may be drawn at the pleading stage that Defendants misrepresented the existence or terms of the agreement."); Order Denying Defendants' Motion for Reconsideration, ECF No. 82 at 2–3 ("[F]alse or misleading statements alleged in the FAC" include "allegations that Defendants affirmatively misrepresented the existence or terms of an agreement with the FDA concerning the approval of pimavanserin to treat [DRP].").) Accordingly, the FAC adequately alleged Plaintiffs' current theory of liability such that Defendants were put on notice.

Finally, even if this precise theory of liability had not been adequately alleged, Defendants had an opportunity to file a Sur-reply and submit a lengthy expert report responding to the theory discussed in Plaintiffs' Reply. (*See generally* ECF No. 126; Reply Expert Report of René M. Stulz, Ph.D., ECF No. 126-2.) The Court considers all materials submitted by the parties, including those submitted on sur-reply. Therefore, even if Plaintiffs had raised a new theory of fraud in Reply, Defendants would not have been prejudiced.

On Sur-reply, Defendants also contend that they had no obligation to disclose the end-of-Phase II meeting minutes to the public. Defendants contend that because "Acadia's policy is not to comment on the specific back-and-forth with the FDA," they were not obligated to divulge statements made by the FDA during the end-of-Phase II meeting. (ECF No. 126 at 10.) However, while a company has "no legal obligation to loop the public into each detail of every communication with the FDA," *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017), a company must disclose concerns raised by the FDA that would render its statements materially misleading. *See Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1008–09 (9th Cir. 2018) ("Even if a statement is not false, it may be materially misleading if it omits material information."); *In re Amylin Pharm., Inc. Sec. Litig.*, No. 01CV1455 BTM (NLS), 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003) ("A company seeking FDA approval of a new drug clearly is not under any obligation to disclose every single issue raised by the FDA throughout the process. However, if the FDA expresses significant concerns regarding the sufficiency of the trials, the company cannot make affirmative representations regarding the completeness or sufficiency of the trials without full disclosure."); *cf. In re Dybavax Sec. Litig.*, No. 4:16-cv-06690-YGR, 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018) ("In the absence of any factual allegations to suggest that the dialogue with the FDA was … so contradictory to [the defendant's] statements about [a drug's] approval prospects,

[the defendant's] failure to disclose the subject of an ongoing dialogue with the FDA does not constitute a material omission.").

Next, Defendants contend that the alleged misrepresentations concerning the FDA agreement had no price impact because "there is a mismatch in content between the alleged misrepresentations and what was revealed when the risk ultimately materialized." (ECF No. 117 at 25.) Specifically, Defendants contend that while the alleged misrepresentation concerned the FDA's discretion to deny the sNDA, the risk that materialized concerned the results of the Harmony Study.

Plaintiffs contend that "there is no mismatch" between Defendants' alleged misstatements about the FDA agreement and the corrective disclosures because the "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." (ECF No. 122 at 27 (quoting *In re Qualcomm Inc. Sec. Litig.*, No. 17cv121-JO-MSB, 2023 WL 2583306, at *14 (S.D. Cal. Mar. 20, 2023)).)

Another way to establish a lack of price impact is to show "a mismatch between the contents of the misrepresentation and the corrective disclosure." *Goldman Sachs*, 141 S.Ct. at 1961. This "may occur when 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')." *Id.* "Under those circumstances, it is less likely that the specific disclosure actually corrected the generic misrepresentation, which means that there is less reason to infer front-end price inflation—that is price impact—from the back-end price drop." *Id.*

Here, Plaintiffs allege that Defendants misrepresented any agreement with the FDA by suggesting that the design of the Harmony Study would not represent a barrier to approval and that the FDA would not base its decision on the data for individual subgroups in the Harmony Study. (*See* ECF No. 45 ¶ 5, ¶ 125 ("[W]e also

just asked FDA[:] … we just want to make certain that you are on board with approving a drug to treat [DRP] …. We want to make certain that you are on board with the concept of doing this if we followed the plan that we've agreed to. And they say, absolutely, we wouldn't agree to your Phase III plan if we weren't … of that mind."), ¶ 132 ("[W]e're seeking the treatment of [DRP]. So we're not looking at individual subtypes .... So we're seeking that broad indication. That's supported by a[n] … alignment we established with the FDA.").) Plaintiffs allege that Defendants corrected this misunderstanding on April 5, 2021, when Acadia announced that the FDA denied the sNDA due to "a lack of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with certain less common dementia subtypes as lack of substantial evidence of effectiveness to support approval." *Id.* ¶ 145. As alleged by Plaintiffs, this statement contradicts Acadia's earlier representations that the FDA considered the Harmony Study to be adequately designed and that it would not base its decision on individual subgroup data. Therefore, there is no "mismatch" between the contents of the alleged misrepresentations and the corrective disclosure. *Goldman Sachs*, 141 S.Ct. at 1961; *see In re Qualcomm*, 2023 WL 2583306, at *14 (concluding that defendants did not rebut the presumption of price impact where the alleged misrepresentations "directly contradict[ed]" later corrective disclosures). At this stage in the proceedings, Defendants have failed to show by a preponderance of the evidence a lack of price impact as to the statements concerning the FDA agreement.

ii. Statements Concerning the Harmony Study

Defendants contend that the alleged misstatements or omissions regarding the Harmony Study did not impact Acadia's stock price. Defendants contend that because the corrective disclosures repeated already public information concerning the Harmony Study's results and design, "[a]ny stock drop following the March Deficiency Letter or April [CRL] cannot support front-end inflation at the time of the alleged misrepresentations." (ECF No. 117 at 22.)

Plaintiffs contend that "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.'" (ECF No. 122 at 20 (citation and emphasis omitted).) Plaintiffs contend that although Defendants assert that they disclosed subgroup results, Defendants "improperly separated the disclosure of raw data from its fundamentally important context." *Id.* at 24.

According to Acadia's October 4, 2017, press release, Acadia announced that it had initiated the Harmony Study, a "Phase III, randomized, double-blind placebo-controlled study" with aims "to evaluate the ability of pimavanserin to prevent release of psychotic symptoms in a broad population of patients with the most common subtypes of dementia." (Defendants' Ex. 22, ECF No. 117-5 at 15.)

On September 9, 2019, Acadia announced that the Harmony Study "met its primary endpoint, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis." (Defendants' Ex. 62, ECF No. 117-9 at 10.) During an investor conference call held on the same day, Defendant Stankovic stated:

> The distribution of different dementia subtypes in our open-label stage as well as in the randomized population are similar and match roughly the epidemiology of the disease. Approximately 2/3 of patients were Alzheimer patients, about 15% of patients were with Parkinson's dementia, approximately 10% were with vascular dementia, and somewhat less than 10% patients with Lewy body dementia and with dementia with Lewy bodies, and the rest was frontotemporal dementia.

(Defendants' Ex. 63, ECF No. 117-9 at 26.)

On December 4, 2019, Acadia presented the Harmony Study's top-line results to medical professionals and released the full data set of the Harmony Study in connection with the presentation. (*See* Defendants' Ex. 66, ECF No. 117-9 at 60; Defendants' Ex. 71, ECF No. 117-10 at 2.) During an investor conference call on the same day, Acadia stated that some of the dementia subtypes in the study contained

"just an extremely small number of patients. So just a word of caution on overinterpretation." (Defendants' Ex. 67, ECF No. 117-9 at 74.) Following this announcement, multiple analysts reported on the design and results of the Harmony Study, including the sample sizes and results within each dementia subtype. (*See* Defendants' Exs. 24–33, 35–37, 41, 60.)

From these disclosures, it is apparent that Acadia released the top-line results of the Harmony Study and the number of patients and results within each dementia subgroup. However, as explained above, Acadia never disclosed the FDA's condition that expanding pimavanserin's label would turn on "the actual composition and response of patients enrolled" in the study, which rendered the data for individual subgroups more relevant than Acadia had previously disclosed. (Defendants' Ex. 18, ECF No. 117-4 at 63; *see* Order Denying the Motion for Reconsideration, ECF No. 82 at 9 ("[T]he allegations concerning the omission of adverse information must be considered in conjunction with the allegations that Defendants misrepresented an agreement with the FDA concerning the exact same information.").) Indeed, the significance of the subgroup data was not revealed until the corrective disclosure on April 5, 2021, when Acadia announced that the FDA denied the sNDA due to "a lack of statistical significance in some of the subgroups of dementia" as well as "insufficient numbers of patients with certain less common dementia subtypes." (Plaintiffs' Ex. 10, 122-13 at 4.) Therefore, the April 5, 2021, corrective disclosure contains information regarding the FDA's focus on the Harmony Study's subtype data that was not previously disclosed. Defendants have failed to show by a preponderance of the evidence a lack of price impact as to the alleged misrepresentations and omissions concerning the Harmony Study.

iii. Statements Concerning the -019 Study

Defendants contend that the alleged misstatements or omissions regarding the -019 Study did not impact Acadia's stock price because Acadia disclosed the results and design of the -019 Study "well before the March Deficiency Letter and April

CRL." (ECF No. 117 at 21.) Plaintiffs contend that Defendants have failed to rebut price impact because the April 5, 2021, corrective disclosure contained adverse information about the -019 Study that was not previously disclosed. (*See* ECF No. 122 at 25.)

In a November 7, 2016, investor conference call, Acadia stated:

> [The -019 Study] is being conducted through a single site with a large network of nursing homes in the London, England, area. This is an exploratory, Phase II, 12-week, randomized, double-blind, placebo-controlled study designed to examine the efficacy and safety of 34-milligram dose of pimavanserin compared to placebo in patients with AD psychosis. We enrolled 181 patients in this study.

(Defendants' Ex. 7, ECF No. 117-3 at 196.) In a December 20, 2016, press release, Acadia announced the top-line results of the study. The press release stated, in part:

> Pimavanserin demonstrated efficacy on the primary endpoint of the -019 Study with a 3.76 point improvement in psychosis at week 6 compared to a 1.93 point improvement for placebo, representing a statistically significant treatment improvement in the NPI-NH Psychosis score (p=0.0451) ….
>
> On the secondary endpoint of mean change in NPI-NH Psychosis score at week 12, pimavanserin maintained the improvement on psychosis observed at the week 6 primary endpoint, but did not statistically separate from placebo.

(Defendants' Ex. 8, ECF No. 117-3 at 214.)

On April 5, 2021, Acadia issued a press release stating that it had received a CRL from the FDA rejecting the pimavanserin sNDA. The press release stated, in part:

> The Division also stated in the CRL that it considers the Phase 2 Alzheimer's disease psychosis study -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.

(ECF No. 45 ¶ 145; *see* Plaintiffs' Ex. 10, ECF No. 122-13 at 14.) The same day, during an investor conference call, Acadia disclosed that the "protocol deviations"

cited by the FDA in the CRL included the "use of prohibited medications" and "certain deviations in terms of the administration of informed consent." (Plaintiffs' Ex. 10, ECF No. 122-13 at 14.)

The November 7, 2016 and December 20, 2016 disclosures demonstrate that Acadia informed the public about certain limitations of the -019 Study before the start of the Class period, including that it was a "single site" study and that it did not meet its "secondary endpoint" at week twelve. But Defendants point to no evidence that Acadia previously disclosed that certain "protocol deviations" occurred regarding the "use of prohibited medications" and "administration of informed consent." *Id.* Defendants' own expert concedes that the April 5, 2021, corrective disclosures revealed "potentially new" information regarding "protocol deviations." (Stulz Report, ECF No. 117-3 at 66.)

Defendants have failed to show by a preponderance of the evidence a lack of price impact.

b. Damages

The predominance requirement under Rule 23(b)(3) "takes into account questions of damages," and plaintiffs "must be able to show that their damages stemmed from the defendant's actions that created the legal liability." *Just Film, Inc. v. Buono*, 847 F.3d 1108, 1120 (9th Cir. 2017) (quotations and citations omitted). "To satisfy this requirement, plaintiffs must show that 'damages are capable of measurement on a classwide basis,' in the sense that the whole class suffered damages traceable to the same injurious course of conduct underlying the plaintiffs' legal theory." *Id.* (quoting *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013)). "[U]ncertainty regarding class members' damages does not prevent certification of a class as long as a valid method has been proposed for determining those damages." *Nguyen v. Nissa N. Am., Inc.*, 932 F.3d 811, 817 (9th Cir. 2017) (citation omitted).

Here, Plaintiffs' expert, Professor Steven P. Feinstein, opines that the "out-of-pocket damages methodology" is "consistent with Lead Plaintiff's theory of liability

and can be applied commonly for all Class members." (Feinstein Report, ECF No. 108-3 at 63.) The out-of-pocket damages model uses an "event study" to calculate the artificial inflation stemming from the alleged misrepresentations and omissions, where an "inflation ribbon" is constructed to represent "how much artificial inflation caused by the alleged misrepresentations and omissions was in the price of Acadia stock on each day during the Class Period, if any." *Id.* at 66. Under this method, damages "are measured as the difference between the amount of stock price inflation at purchase and the amount of inflation in the stock price at sale or, if held, at the end of the Class Period." *Id.* at 64. Dr. Feinstein opines that the calculation of each Class member's per-share damages "would be a mechanical arithmetic exercise for all Class members who bought Acadia stock during the Class Period, conducted the same way for all Class members, and applying the results of the same Class-wide analyses … to each Class member's stock trading data." *Id.*

Defendants contend that Plaintiffs' proposed damages model runs afoul of *Comcast Corp. v. Behrend*, 569 U.S. 27 (2013) because the out-of-pocket damages model is "incompatible with Plaintiffs' materialization-of-the-risk theory of liability." (ECF No. 117 at 29.) Defendants contend that Plaintiffs' expert "makes no attempt to attribute damages to materialization-of-the-risk theory," but simply "presume[s] that an out-of-pocket damages model is essentially a one-size-fits-all for securities fraud class actions." *Id.* at 30–31 (emphasis omitted).

Plaintiffs contend that "materialization of the risk articulates a loss-causation theory" and "[w]hether the loss-causation portion of Plaintiffs' claims are deemed to rely on 'materialization of the risk' or 'corrective disclosure' [theory] is irrelevant at this stage." (ECF No. 122 at 32 (emphasis and citations omitted).) Plaintiffs contend that their proposed damages model is consistent with *Comcast* because "the out-of-pocket method can reasonably isolate damages attributable only to the alleged misstatements here." *Id.* at 31.

In *Comcast*, plaintiff sought to certify a class of cable subscribers based on

four theories of liability, but the district court determined that only one of the four theories could proceed on a class-wide basis. *See Comcast*, 569 U.S. at 30–31. Nevertheless, plaintiff's proposed damages model "assumed the validity of all four theories" of liability. *Id.* at 36. The Supreme Court concluded that the proposed damages model did not satisfy the predominance requirement because it failed to "isolate" damages resulting from "the only theory of injury remaining in the case." *Id.* at 32. The Court emphasized that "a model purporting to serve as evidence of damages … must measure only those damages attributable to that theory." *Id.* at 35. Although "[c]alculations need not be exact," the proposed damages model "must be consistent with [plaintiff's] liability case." *Id.*

Here, unlike in *Comcast*, Plaintiffs have a single theory of liability: Defendants' material misrepresentations and omissions caused Class members to purchase Acadia shares at an artificially inflated price which subsequently declined after the truth emerged. Dr. Feinstein opines that "[t]he out-of-pocket damages methodology measures the losses caused by the introduction and subsequent dissipation of artificial inflation." (Rebuttal Report of Professor Steven P. Feinstein Ph.D., CFA, ("Feinstein Rebuttal Report"), ECF No. 122-4 at 43.) Dr. Feinstein further opines that he would use "the standard array of valuation tools" to "measure what the price of Acadia's stock would have been but-for the alleged misrepresentations and omissions concerning the design and results of the Harmony Study and the risks of obtaining the FDA approval of pimavanserin for DRP." (Feinstein Report, ECF No. 108-3 at 64–65.) The proposed damages model is therefore "consistent" with Plaintiffs' theory of liability and is able to "isolate" damages attributable to the alleged misrepresentations. *Comcast*, 569 U.S. at 45; *see also City of Sunrise Firefighters' Pension Fund v. Oracle Corp.*, No. 18-cv-04844-BLF, 2022 WL 1459567, at *8 (N.D. Cal. May 9, 2022) (concluding that plaintiff's damages model satisfies *Comcast* because plaintiff's expert "tied his damages disclosures" to plaintiff's single theory of liability); *In re Qualcomm*, 2023 WL

2583306, at *16 ("The Court finds that Plaintiffs' proposed damages methodology is sufficient under *Comcast* because the methodology can isolate different categories of misrepresentations and measure the damages stemming from each."); *In re Bofl Holding, Inc. Sec. Litig.*, No.: 3:15-cv-02324-GPC-KSC, 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 liability under Section 10(b) of the Securities and Exchange Act.") (citations omitted)). To the extent Plaintiffs rely on a materialization-of-the-risk theory, that does not preclude class certification under *Comcast*. *See Levya v. Medline Indus. Inc.*, 716 F.3d 510, 514 (9th Cir. 2013) (reading *Comcast* to require plaintiffs only "be able to show that their damages stemmed from the defendant's actions that created the legal liability"); *Junge v. Geron Corp.*, No. C 20-00547-WHA, 2022 WL 1002446, at *8 (N.D. Cal. Apr. 2, 2022) ("The possible existence of [a materialization-of-the-risk] theory does not contravene *Comcast* or defeat predominance.").

Defendants further contend that Plaintiffs' proposed model cannot measure damages on a class-wide basis because it "lumps together two classes of plaintiffs: (i) those who would have bought Acadia stock at the heightened risk for a lower price; and (ii) those who would not have bought the stock at all." (ECF No. 117 at 31.) In support of this position, Defendants cite *Ludlow v. BP, P.L.C.*, 800 F.3d 674 (5th Cir. 2015). In that case, plaintiffs sought to certify a class of investors who bought BP shares before the Deepwater Horizon disaster based on BP's alleged misstatements concerning the efficacy of its safety procedures. *See id.* at 680. Because the alleged misstatements took away the opportunity "to decide to divest BP stock in light of the heightened risk," plaintiffs sought consequential damages for "*entire* fall in stock price" following the Deepwater Horizon spill. *Id.* at 680, 690. The court concluded that plaintiffs' damages model "cannot be applied uniformly across the class," because their damages theory "hinges on a determination that each plaintiff would not have bought BP stock at all were it not for the alleged

misrepresentations," which is a determination "requiring individualized inquiry." *Id.* at 690–91.

Here, by contrast, Plaintiffs' proposed damages model does not seek to calculate consequential damages, but rather out-of-pocket damages for the difference between the artificially inflated stock price and the stock price but-for the alleged misrepresentations and omissions. Plaintiffs' damages theory therefore does not involve the individualized inquiry of whether a Class member would or would not have bought stock absent the alleged misrepresentations and omissions.[2] *See Junge*, 2022 WL 1002446, at *9 ("Unlike [*Ludlow*], plaintiffs do not seek consequential damages or argue that investors would have refused to purchase Geron stock had they known the truth about TSS and CR/PR data. They contend that Geron concealed information from the market, thus artificially inflating price. This order perceives no similar need for individualized inquiry.").

Finally, Defendants contend that Plaintiffs' proposed damages model is insufficient to calculate class-wide damages because it "fails to differentiate" between losses caused by the "disclosed" and "understated" portion of the risk and "fails to address how it would account for changes in the magnitude of the allegedly understated risk over time." (ECF No. 117 at 33 (citing Stulz Report, ECF No. 117-

[2] Defendants also rely on *Ludlow* to contend that Plaintiffs' materialization-of-the-risk theory is "fundamentally inconsistent with their request for the *Basic* presumption" because Plaintiffs "relied on something other than price: risk." (ECF No. 117 at 34 (citing *Ludlow*, 800 F.3d at 691).) *Ludlow* reasoned: "By claiming that class members may have divested themselves of BP stock if they had known about the true risk of an accident in the Gulf—as distinguished from the risk's impact on BP's stock *price*—the plaintiffs are arguing that their investment decisions were based substantially upon factors other than price." *Ludlow*, 800 F.3d at 691. Here, by contrast, Plaintiffs' damages theory is not premised on whether Class members would have divested themselves of Acadia's stock had they known the true risk of sNDA rejection. Rather, Plaintiffs' damages theory involves the impact of Defendants' alleged misstatements and omissions on Acadia's stock price. *See Cosby v. KPMG, LLP*, No. 3:16-CV-121-TAV-DCP, 2020 WL 3548379, at *28 (E.D. Tenn. June 29, 2020) (rejecting the argument that plaintiffs' materialization-of-the-risk theory is not entitled to the *Basic* presumption because "[p]laintiffs are not seeking consequential damages" and "[p]laintiffs' theory stems from [d]efendants' misstatements and omissions that affected the [stock] price"); *Rougier v. Applied Optoelectronics, Inc.*, No. 4:17-cv-02399, 2019 WL 6111303, at *17 (S.D. Tex. Nov. 13, 2019) (same). Plaintiffs' damages theory therefore does not "presume[] substantial reliance on factors other than price." *Ludlow*, 800 F.3d at 691.

3 at 79, 90–92).) However, Dr. Feinstein opines that he will account for these complexities and other confounding information by using the "standard tools of valuation," which will "accurately measure and accommodate any potential adjustments to inflation that are necessary." (Feinstein Rebuttal Report, ECF No. 122-4 at 44, 47, 50–61) (detailing how the damages model could account for "any difference between the disclosed and concealed likelihoods of a risk realization" and "time-varying inflation").) Dr. Feinstein states that the "selection of specific tools that could be brought to bear on such issues would be directly informed by the evidence" and chosen at the close of discovery. *Id.* at 47–48; *see In re Bofl Holding*, 2021 WL 3742924, at *9 (stating that plaintiff's expert need not "precisely identif[y] what approach he will use to control for every variable in [the] case").

Further, to the extent Defendants challenge Plaintiffs' ability to show "that a misrepresentation that affected the integrity of the market price also caused a subsequent economic loss," this is a merits-based inquiry. *See Halliburton I*, 563 U.S. at 813 ("The Court of Appeals erred by requiring [plaintiff] to show loss causation as a condition of obtaining class certification."); *Malriat v. QuantumScape Corp.*, No. 3:21-cv-00058-WHO, 2022 WL 17974629, at *15 (N.D. Cal. Dec. 19, 2022) (concluding that the defendants' argument that the proposed damages model "fails to distinguish between stock price changes caused by their alleged misrepresentations and stock price changes caused by other market factors" is essentially an "economic loss" argument and plaintiffs "[were] not required to prove that the misrepresentations, or subsequent corrective disclosures, caused the plaintiffs' loss at [the class certification] stage"); *Sheet Metal Workers Nat'l Pension Fund v. Bayer Aktiengesellschaft*, No. 20-cv-04737-RS, 2023 WL 3569981, at *8 (N.D. Cal. May 19, 2023) (concluding that defendants' argument that plaintiffs' damages method is unreliable because plaintiffs "have not offered a way to model the degree to which [d]efendants understated the risk" is "premature" at the class certification stage and "better left for a later stage of litigation"); *Hatamian v. Advanced Micro Devices,*

Inc., No. 14-cv-00226 YGR, 2016 WL 104502, at *9 (N.D. Cal. Mar. 16, 2016) ("Defendants' argument that Professor Coffman's methodology would not be able to 'disaggregate the price inflation' attributable to particular theories of liability … is appropriately understood as a loss causation analysis."). At this stage in the proceedings, Plaintiffs need only show that "damages could feasibly and efficiently be calculated once the common liability questions are adjudicated." *Levya*, 716 F.3d at 514. Plaintiffs' proposed damages model meets this burden.

For these reasons, the Court finds that the predominance requirement under Rule 23(b)(3) is satisfied.

2. Superiority

Rule 23(b)(3) requires plaintiffs to demonstrate "that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Rule 23(b)(3) states that the matters pertinent to this inquiry include:

> (A) the class members' interests in individually controlling the prosecution or defense of separate actions;
> (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;
> (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
> (D) the likely difficulties in managing a class action.

Id. "Where classwide litigation of common issues will reduce litigation costs and promote greater efficiency, a class action may be superior to other methods of litigation," and it is superior "if no realistic alternative exists." *Valentino v. Carter–Wallace, Inc.*, 97 F.3d 1227, 1234–35 (9th Cir. 1996). "This determination necessarily involves a comparative evaluation of alternative mechanisms of dispute resolution." *Hanlon*, 150 F.3d at 1023. "[W]hen the complexities of class action treatment outweigh the benefits of considering common issues in one trial, class action treatment is not the 'superior' method of adjudication." *Zinser*, 253 F.3d at 1192.

In the present case, the expenses associated with bringing individual cases compared to the potential recovery renders it unlikely that individual litigation would be undertaken. *See Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1190 (9th Cir. 2001) ("Where damages suffered by each putative class member are not large, this factor weighs in favor of certifying a class action."). Concentrating this litigation in the Southern District of California is also desirable because Acadia maintains its headquarters in this District. *See Hatamian v. Advanced Micro Devices, Inc.*, No. 14-cv-00226 YGR, 2016 WL 1042502, at *10 (N.D. Cal. Mar. 16, 2016) ("[C]oncentrating the litigation in this Court is adequately justified because [the defendant] maintains its headquarters in this District."). Finally, Plaintiffs have adequately shown that it is unlikely that there will be difficulties in managing this litigation. Under the facts of this case, a class action is superior to other methods of adjudicating the alleged claims. Defendants do not contest that the superiority requirement is satisfied. The Court finds that superiority is satisfied in this case.

The Court concludes that the requirements under Rule 23(a) and 23(b)(3) for class certification are satisfied.

C. Appointment of Class Counsel

Plaintiffs request that the Court appoint Scott+Scott as Class counsel. (*See* ECF No. 117 at 29–30.) Rule 23(g)(1) requires courts to appoint class counsel that will "fairly and adequately represent the interests of the class." Fed. R. Civ. P. 23(g)(1)(B), (4). In appointing class counsel, courts consider:

> (i) the work counsel has done in identifying or investigating potential claims in the action;
> (ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action;
> (iii) counsel's knowledge of the applicable law; and
> (iv) the resources that counsel will commit to representing the class.

Fed. R. Civ. P. 23(g)(1)(A).

Here, Scott+Scott has devoted substantial time and resources to litigating the

claims at issue, including conducting a pre-filing investigation, litigating dispositive motions, and engaging in extensive discovery. (*See* Fredericks Decl., ECF No. 108-2 ¶ 2.) The firm also has experience in the area of securities litigation and class actions. (*See* Turner Decl., ECF No. 108-4 ¶¶ 6–7.) Defendants do not dispute appointing Scott+Scott as Class counsel. The Court approves Plaintiffs' choice of counsel and appoints Scott+Scott as Class counsel.

VI. CONCLUSION

IT IS HEREBY ORDERED that the Motion for Class Certification and Appointment of Class Representatives and Class Counsel (ECF No. 108) is granted. The Court certifies the Class. The Court appoints Plaintiffs to serve as Class representatives and Scott+Scott to serve as Class counsel in this action.

IT IS FURTHER ORDERED that, pursuant to the March 17, 2023 Order (ECF No. 95), counsel for the parties shall place a joint call to Judge Berg's chambers to schedule a Case Management Conference within five days of the date of this Order, at which further discovery and pretrial deadlines will be set.

Dated: March 11, 2024

Hon. William Q. Hayes
United States District Court