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9 UNITED STATES DISTRICT COURT
10 SOUTHERN DISTRICT OF CALIFORNIA

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

16 Plaintiffs,

17 v.

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

21 Defendants.

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

ORDER

22 HAYES, Judge:

23 The matter before the Court is the Motion to Dismiss the FAC filed by
24 Defendants Acadia Pharmaceuticals, Inc., Stephen R. Davis, and Srdjan (Serge) R.
25 Stankovic. (ECF No. 53.)

I. PROCEDURAL BACKGROUND

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

1 On December 10, 2021, Birmingham and additional Plaintiff Ohio Carpenters’
2 Pension Fund (collectively “Plaintiffs”) filed an Amended Class Action Complaint
3 (the “FAC”). (ECF No. 45.) The FAC alleges that Defendants violated federal
4 securities laws by deceiving investors regarding the likelihood of Food and Drug
5 Administration (“FDA”) approval of a drug, which Defendant Acadia
6 Pharmaceuticals, Inc. (“Acadia”) developed, to artificially inflate the market price of
7 Acadia securities.

8 On February 15, 2022, Defendants filed the Motion to Dismiss the FAC. (ECF
9 No. 53.) On April 18, 2022, Plaintiffs filed a Response in opposition to the motion.
10 (ECF No. 56.) On June 2, 2022, Defendants filed a Reply. (ECF No. 58.)

11 **II. JUDICIAL NOTICE AND INCORPORATION-BY-REFERENCE**

12 Defendants request that the Court take judicial notice and/or incorporate-by-
13 reference 36 documents attached as exhibits to Defendants’ Motion to Dismiss the
14 FAC.¹ (ECF No. 53-5.) The exhibits include Acadia press releases and presentation
15 transcripts, Defendants’ SEC filings, and articles and reports.

16 Plaintiffs “do not contest that ... documents which were extensively quoted in
17 the [FAC] are judicially noticeable and/or incorporated by reference into the [FAC].”
18 (ECF No. 57 at 2 n.1.) However, Plaintiffs contend that the following exhibits cannot
19 be considered by the Court at this stage in the proceedings: Exhibits A, B, C, F, K,
20 L, N, O, S, U, V, Y, AA, and DD (the “disputed exhibits”).

21 “Generally, district courts may not consider material outside the pleadings
22 when assessing the sufficiency of a complaint under Rule 12(b)(6) of the Federal
23 Rules of Civil Procedure.” *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998
24 (9th Cir. 2018). However, “[t]here are two exceptions to this rule: the incorporation-
25 by-reference doctrine, and judicial notice under Federal Rule of Evidence 201.” *Id.*
26

27 ¹ Defendants further request that the Court take judicial notice and/or incorporate-by-reference
28 three additional exhibits—two analyst reports and a record of Acadia’s daily stock price. *See* ECF
No. 58-2. This request is denied because it was raised for the first time in Defendants’ Reply and
Plaintiffs have not had an opportunity to respond to the request.

1 “[I]ncorporation-by-reference is a judicially created doctrine that treats certain
2 documents as though they are part of the complaint itself.” *Id.* at 1002. “The doctrine
3 prevents plaintiffs from selecting only portions of documents that support their
4 claims, while omitting portions of those very documents that weaken—or doom—
5 their claims.” *Id.*

6 None of the disputed exhibits are extensively referenced or quoted in the FAC.
7 *See id.* (stating that incorporation-by-reference is proper if the plaintiff refers
8 “extensively to the document”). The documents do not form the basis of Plaintiffs’
9 claims. *See id.* (stating that incorporation-by-reference is proper if the document
10 “forms the basis of the plaintiff’s claim”). The overlap between the FAC’s allegations
11 and the content of these documents is not sufficient to support incorporation-by-
12 reference. *See id.* at 1007 (denying a request for incorporation-by-reference because
13 “[t]he Complaint only alleges facts that the press release happens to report”).
14 Defendants’ request for incorporation-by-reference of the disputed exhibits is
15 denied.²

16 Judicial notice permits a court to notice an adjudicative fact if it is “not subject
17 to reasonable dispute”—i.e. if it is “generally known,” or “can be accurately and
18 readily determined from sources whose accuracy cannot reasonably be questioned.”
19 Fed. R. Evid. 201(b). A district court must clearly specify what fact or facts it
20 judicially notices. *See Khoja*, 899 F.3d at 999. “Just because the document itself is
21 susceptible to judicial notice does not mean that every assertion of fact within that
22 document is judicially noticeable for its truth.” *Id.*

23 Exhibit L is an article on breakthrough therapy designation published by the
24 FDA. The Court takes judicial notice of this article and the factual assertions
25 contained within it regarding when breakthrough therapy designation is granted by
26

27
28 ² The Court grants Defendants’ unopposed request for incorporation-by-reference of Exhibits D, E,
G, H, I, J, K, P, Q, R, T, W, X, Z, BB, CC, GG, HH, II, and JJ because these exhibits were
extensively referenced in the FAC.

1 the FDA. *See id.* at 1001 (stating that courts may take judicial notice of agency
2 reports).

3 The other disputed exhibits are Acadia press releases, an Acadia presentation,
4 SEC filings, and news articles and reports. The fact that Acadia issued these press
5 releases, presentations, and filings, and that the information contained in the
6 documents was available to the market is not subject to reasonable dispute. However,
7 Defendants also cite several of these documents to demonstrate the truth of assertions
8 of fact contained within the documents. *See, e.g.*, ECF No. 53-1 at 11 (citing Exhibit
9 A, a press release, for the proposition that “Acadia developed pimavanserin, the first
10 and still-only FDA-approved therapy for Parkinson’s disease psychoses”); *id.* (citing
11 Exhibit C, a news article, for the proposition that “[d]rug testing is inherently
12 uncertain and only a small percentage of drugs ultimately gain FDA approval”).
13 Judicial notice of the fact that Acadia issued these press releases, presentations, and
14 filings, and that the information contained in the documents was available to the
15 market is granted. *See Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 981
16 (9th Cir. 1999) (taking judicial notice of the fact “that the market was aware of the
17 information contained in news articles submitted by the defendants”). Judicial notice
18 of these documents is otherwise denied.

19 **III. ALLEGATIONS IN THE FAC**

20 Acadia is a Delaware biopharmaceutical company with common stock that
21 trades on the Nasdaq Global Selection Market under the ticker symbol “ACAD.”
22 (ECF No. 45 ¶ 22.) Defendant Davis “has served as Acadia’s Chief Executive Officer
23 and a member of [Acadia’s] Board of Directors since September 2015.” *Id.* ¶ 23.
24 Defendant Stankovic served as “Acadia’s Executive Vice President, Head of
25 Research and Development, from November 2015 through November 2018” and
26 “has served as Acadia’s President and Head of Research and Development since
27 November 2018.” *Id.* ¶ 24. Davis and Stankovic “possessed the power and authority
28 to control the contents of Acadia’s SEC filings, press releases, and other market

1 communications” and had “access to material information available to them but not
2 to the public.” *Id.* ¶ 26.

3 In July 2011, Acadia initiated a Phase III medical study (the “-020 Study”) to
4 “evaluate[] the efficacy, tolerability and safety” of a drug called pimavanserin in
5 patients with Parkinson’s disease psychosis (“PDP”), a condition “associated with
6 Parkinson’s disease dementia.” *Id.* ¶¶ 2, 45. “In November 2012, [Acadia] announced
7 positive top-line results for the -020 Study.” *Id.* ¶ 46. In April 2016, the FDA
8 “approved pimavanserin for the treatment of hallucinations and delusions associated
9 with [PDP].” *Id.* ¶ 31. The -020 Study was “the primary basis for the FDA’s 2016
10 approval.” *Id.* ¶ 47. Pimavanserin is Acadia’s “most valuable drug” and “only
11 commercial product to date.” *Id.* ¶¶ 2, 32.

12 In November 2013, Acadia initiated a Phase II medical study (the “-019
13 Study”) to “evaluate the efficacy and safety of pimavanserin as a treatment for
14 patients with Alzheimer’s disease psychosis (‘ADP’).” *Id.* ¶ 48. “In December 2016,
15 [Acadia] announced positive top-line results from the -019 [S]tudy.” *Id.* ¶ 49.

16 “Following the -019 Study on ADP, in mid-2017, Acadia had an [e]nd-of-
17 Phase II meeting with the FDA,” at which Acadia purportedly “proposed a plan for
18 a single Phase III study that would support approval not for an indication of
19 pimavanserin for ADP, but for a broader indication of pimavanserin for [dementia-
20 related psychosis (‘DRP’)].” *Id.* ¶ 50. DRP “occurs in patients with a *variety* of
21 different types of dementia” including “Alzheimer’s disease, dementia with Lewy
22 bodies, Parkinson’s disease dementia, vascular dementia, and frontotemporal
23 dementia spectrum disorders.” *Id.* ¶¶ 2, 70. Expanding pimavanserin’s label to
24 encompass treatment of DRP “would be of significant commercial value” to Acadia
25 because DRP is “about tenfold the size of PDP in terms of addressable population.”
26 *Id.* ¶¶ 36-37.

27 “In October 2017, [Acadia] initiated the Harmony Study, a pivotal Phase III
28 study, to assess pimavanserin as a treatment for DRP.” *Id.* ¶ 52. The Harmony Study

1 “enrolled 392 patients” divided into “subgroups” for each of “the five most common
2 forms of [DRP].” *Id.* ¶¶ 74-75. The same month, Acadia “announced that the FDA
3 had granted Breakthrough Therapy Designation to pimavanserin for the treatment of
4 DRP.” *Id.* ¶ 35. “The primary completion date of the Harmony Study ... was July 31,
5 2019,” and Defendants “possessed data from the Harmony Study starting in at least
6 early September 2019.” *Id.* ¶ 56.

7 On September 9, 2019, Acadia issued a press release in which Defendants
8 “announced positive results for the Harmony Study.” *Id.* ¶ 4. The press release stated:

9 Acadia ... today announced that its Phase 3 [Harmony Study] ... met its
10 primary endpoint, demonstrating a highly statistically significant longer
11 time to relapse of psychosis with pimavanserin compared to placebo in
a planned interim efficacy analysis.

12

13 [Acadia] is planning to meet with the FDA regarding a supplemental
[New Drug Application (“sNDA”)] submission in 2020....

14

15 “We are very excited that today’s results bring us one step closer to the
16 potential of offering patients with [DRP] a critically needed treatment
option,” said Serge Stankovic “We look forward to speaking with
17 the FDA about a [sNDA] to support pimavanserin for the treatment of
[DRP].”

18 *Id.* ¶ 107. During a conference call held on the same day, Defendant Stankovic stated:

19 I would also like to remind you that at the end of Phase II meeting with
20 [the] FDA, we confirmed that for our [sNDA] submission in DRP, we
21 could rely on a single, well-controlled study whose results were both
statistically and clinically very persuasive.

22 *Id.* ¶ 109 (emphasis omitted).

23 “In response to these positive reports, the price of Acadia’s common stock shot
24 up more than 63%, closing at \$38.85 on September 9, 2019.” *Id.* ¶ 6. “Eight days
25 later, on September 17, 2019, [Acadia] announced a proposed follow-on offering of
26 approximately \$250 million of common stock.” *Id.* ¶ 59. “On September 20, 2019,
27 the follow-on offering closed and Acadia sold 7,187,500 shares at a price of \$40 per
28

1 share, for gross proceeds totaling \$287.5 million.” *Id.* ¶ 60.

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

5 On February 26, 2020, Defendant Stankovic stated: “The pivotal [Harmony
6 Study] results will be the basis of the sNDA submission, which was previously agreed
7 upon at the end of Phase II meeting.” *Id.* ¶ 113. On May 7, 2020, Stankovich stated:

8 [W]e successfully completed a pre-sNDA meeting with the FDA and
9 confirm that the pivotal data from our [Harmony Study], together with
10 the confirmatory and supportive results from [the -020 Study and -019
11 Study] will all support the submission of an sNDA for pimavanserin in
12 [DRP] Our sNDA preparation remains firmly on track. As
13 previously announced, we plan to submit the sNDA this summer. We
expect a priority review with a potential approval for DRP around year-

14 *Id.* ¶ 115. On May 12, 2020, Defendant Davis stated: “[W]e had our pre-sNDA
15 meeting [with the FDA] in the first quarter. The feedback there was very consistent
16 with what we heard with our end-of-Phase II meeting. The FDA confirmed that the
17 studies conducted can support an sNDA submission.” *Id.* ¶ 117.

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

22 From June 15, 2020, to February 25, 2021, Defendants made a series of public
23 statements characterizing the results of the three studies supporting the sNDA as
24 “positive” and “strong,” expressing “confiden[ce]” in the studies’ data and in the
25 potential for FDA approval, asserting that FDA review was progressing, and
26 describing an agreement between Acadia and the FDA. *Id.* ¶¶ 119, 121, 123, 125,
27 127, 130, 132, 134-35, 137, 140-41.

28 Acadia “issued a press release ... that provided an update on its pimavanserin

1 sNDA” on March 8, 2021. *Id.* ¶ 9. The press release stated that Acadia was notified
2 by the FDA that “as part of its ongoing review of the [sNDA], the FDA has identified
3 deficiencies that preclude discussion of labelling and postmarketing
4 requirements/commitments at this time.” *Id.* On April 5, 2021, Acadia “issued a press
5 release announcing that [Acadia] had received a Complete Response Letter (‘CRL’)
6 from the FDA which indicated that the sNDA could **not** be approved.” *Id.* ¶ 10. The
7 press release stated:

8 Despite prior agreements with the [FDA] Division of Psychiatry
9 regarding the pivotal [Harmony Study] design targeting a broad DRP
10 patient population analyzed as a single group, the Division, in the CRL,
11 cited a lack of statistical significance in some of the subgroups of
12 dementia, and insufficient numbers of patients with certain less common
13 dementia subtypes as lack of substantial evidence of effectiveness to
14 support approval.

15 The DRP pivotal [Harmony Study] met its prespecified primary and
16 secondary endpoints with robust and persuasive clinical and statistical
17 superiority of pimavanserin over placebo, which was a prospectively
18 agreed prerequisite for the DRP indication. Statistical separation by
19 dementia subgroups and certain minimum numbers of patients with
20 specific subtypes were not among the prespecified requirements.
21 ‘Acadia stands behind the robustly positive results from the pivotal
22 [Harmony Study] and the prospectively agreed trial design and criteria
23 for establishing efficacy in DRP. Over the entire course of the review,
24 the Division did not raise any concerns regarding the agreed upon study
25 design, including the issues raised in the CRL,’ said Steve Davis, Chief
26 Executive Officer of Acadia....

27 The Division also stated in the CRL that it considers the Phase 2 [-019
28 Study], a supportive study in the sNDA filing, to not be adequate and
well controlled....

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.

In their public statements between September 9, 2019 (the day Acadia

1 announced positive results from the Harmony Study) and April 4, 2021 (the day
2 before FDA approval was denied), “Defendants represented that the FDA had already
3 blessed the adequacy of the study’s design for purposes of obtaining ... approval” of
4 pimavanserin for the treatment of DRP. *Id.* ¶ 5. These representations were
5 “materially false and misleading” because “[c]ontrary to Defendants’ claim that the
6 FDA and Acadia agreed to the pivotal Harmony Study’s design ..., no such
7 agreement actually existed.” *Id.* ¶¶ 7, 92. Acadia has not published “an agreement
8 between the FDA and Acadia that provides for approval based on results for the
9 overall DRP population enrolled in the Harmony Study” and “the FDA’s history of
10 issuing [Special Protocol Assessments (‘SPAs’)] ... supports a finding that it is
11 highly unlikely that the FDA *sua sponte* rescinded or changed its course.” *Id.* ¶¶ 100,
12 102. “[E]ven if there was a general agreement that [Acadia] could do a single
13 adequate and well-controlled study, that agreement was obviously contingent on the
14 data being supportive of the subgroups that Acadia sought to treat with pimavanserin
15” *Id.* ¶ 103.

16 Defendants’ public statements were further “false and misleading” because
17 Defendants “failed to disclose that in fact the Harmony Study’s design was so flawed
18 that ... [it] could not support FDA approval of pimavanserin for additional types of
19 DRP beyond [PDP].” *Id.* ¶ 7. “As Defendants knew or recklessly disregarded even
20 before launching the Harmony Study, [the] Harmony [S]tudy ... was not reasonably
21 designed to contain a sufficient number of patients ... to conclude ... that
22 pimavanserin was an effective treatment for patients in [DRP] subgroups.” *Id.* ¶ 8.
23 “Instead, the Harmony Study was largely populated by patients suffering from
24 dementia associated with Parkinson’s disease – the condition for which pimavanserin
25 was *already* FDA-approved.” *Id.* When the results of the Harmony Study became
26 available, “the limited data [Acadia] possessed on each [DRP] subgroup was poor
27 and demonstrated a lack of efficacy, dooming [Acadia’s] sNDA from the outset”
28 *Id.* ¶ 79. “[T]he Harmony Study’s data showed that, despite the small sample size,

1 the drug was actually ineffective or in some cases less effective [than the placebo] in
2 the subgroups Acadia was seeking new approval for.” *Id.* ¶ 83. The “-019 Study’s
3 poorly analyzed data and poor design ... rendered [that] dataset far from
4 ‘supportive.’” *Id.* ¶ 90.

5 Prior to the announcement of the Harmony Study’s results on September 9,
6 2019, neither Defendant Davis nor Defendant Stankovic had sold any Acadia stock.
7 Between September 9, 2019, and April 4, 2021, Davis sold 541,205 shares of Acadia
8 common stock for \$24,771,568 and Stankovic sold 368,993 shares for \$18,932,729.
9 Much of these sales were made pursuant to Rule 10b5-1 trading plans adopted by
10 Davis on August 22, 2019, and December 19, 2019, and by Stankovic on November
11 8, 2019, and December 3, 2020. Since April 4, 2021, Davis has sold an additional
12 10,813 shares of common stock and Stankovic has sold an additional 8,371 shares.

13 Plaintiffs are entities that purchased Acadia common stock “at artificially
14 inflated prices.” *Id.* ¶¶ 20-21. Plaintiffs seek to bring this action on behalf of a
15 putative class of all those who acquired Acadia stock between September 9, 2019
16 (the day Acadia announced positive results from the Harmony Study) and April 4,
17 2021 (the day before FDA approval was denied). “As a result of Defendants’
18 wrongful acts and omissions, and the precipitous decline in the market value of
19 [Acadia’s] securities, Plaintiff and other [putative class] members have suffered
20 significant losses and damages.” *Id.* ¶ 147. Plaintiffs bring two claims: (1) violation
21 of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against
22 all Defendants; and (2) violation of Section 20(a) of the Exchange Act against
23 Defendants Davis and Stankovic. Plaintiffs request damages, interest, fees, and costs.

24 **IV. CONTENTIONS**

25 Defendants contend that “Plaintiffs have not met their burden to plead three
26 essential elements of their Section 10(b) claims: falsity, scienter, and loss causation.”
27 (ECF No. 53-1 at 10.) Defendants contend that “every statement that Plaintiffs allege
28 to be false or misleading was either demonstrably true or not actionable as a matter

1 of law” and “[e]very fact that Defendants allegedly concealed was fully disclosed to
2 investors.” *Id.* at 8. Defendants contend that “there is no allegation in the [FAC] that
3 even suggests any Defendant intended to deceive investors or acted with reckless
4 disregard of the truth.” *Id.* Defendants contend that the FAC’s allegations “do not
5 establish that a misstatement (as opposed to some other factor) caused Plaintiffs’
6 losses.” *Id.* at 32. Defendants contend that “[b]ecause Plaintiffs fail to plead a primary
7 violation of Section 10(b), their Section 20(a) claim also fails.” *Id.*

8 Plaintiffs contend that at the pleading stage, “the falsity of Acadia’s claims to
9 having an ‘agreement’ with the FDA can be readily inferred from the FDA’s rejection
10 of the sNDA on grounds inconsistent with the terms of the purported ‘agreement.’”
11 (ECF No. 56 at 16-17.) Plaintiffs contend that the FAC “plausibly alleges that
12 Defendants materially misled investors ... by emphasizing cherry-picked positive
13 results while omitting known shortcomings in the studies submitted with the sNDA,
14 including disappointing data, which posed major obstacles to FDA approval.” *Id.* at
15 18 (quotation and alteration omitted). Plaintiffs contend that scienter can be inferred
16 from the same set of facts alleged to demonstrate falsity as well as Defendants’
17 alleged stock sales. Plaintiffs contend that causation is demonstrated by the decline
18 in Acadia’s share price following Acadia’s disclosures that the FDA identified
19 deficiencies in the sNDA and denied approval of the sNDA. Plaintiffs contend that
20 “[b]ecause the §10(b) claims are well-pled, the §20(a) claims also stand.” *Id.* at 30.

21 **V. LEGAL STANDARD**

22 Rule 12(b)(6) of the Federal Rules of Civil Procedure permits dismissal for
23 “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6).
24 In order to state a claim for relief, a pleading “must contain . . . a short and plain
25 statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P.
26 8(a)(2). Dismissal under Rule 12(b)(6) “is proper only where there is no cognizable
27 legal theory or an absence of sufficient facts alleged to support a cognizable legal
28 theory.” *Shroyer v. New Cingular Wireless Servs., Inc.*, 622 F.3d 1035, 1041 (9th

1 Cir. 2010).

2 “To survive a motion to dismiss, a complaint must contain sufficient factual
3 matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’”
4 *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550
5 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads
6 factual content that allows the court to draw the reasonable inference that the
7 defendant is liable for the misconduct alleged.” *Id.* However, “a plaintiff’s obligation
8 to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and
9 conclusions, and a formulaic recitation of the elements of a cause of action will not
10 do.” *Twombly*, 550 U.S. at 555 (alteration in original) (quoting Fed. R. Civ. P. 8(a)).
11 A court is not “required to accept as true allegations that are merely conclusory,
12 unwarranted deductions of fact, or unreasonable inferences.” *Sprewell v. Golden*
13 *State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). “In sum, for a complaint to survive
14 a motion to dismiss, the non-conclusory factual content, and reasonable inferences
15 from that content, must be plausibly suggestive of a claim entitling the plaintiff to
16 relief.” *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009).

17 “A securities fraud complaint under § 10(b) and Rule 10b–5 must [also] satisfy
18 the dual pleading requisites of Federal Rule of Civil Procedure 9(b) and the [Private
19 Securities Litigation Reform Act (“PSLRA”)].” *In re VeriFone Holdings, Inc. Sec.*
20 *Litig.*, 704 F.3d 694, 701 (9th Cir. 2012). Under Rule 9(b), a complaint “must state
21 with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P.
22 9(b). The pleader must “identify the who, what, when, where, and how of the
23 misconduct charged, as well as what is false misleading about the purportedly
24 fraudulent statement, and why it is false.” *Davidson v. Kimberly-Clark Corp.*, 873
25 F.3d 1103, 1110 (9th Cir. 2017), *as corrected* (Mar. 12, 2018) (quoting *Cafasso, U.S.*
26 *ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011)). “To
27 comply with Rule 9(b), allegations of fraud must be specific enough to give
28 defendants notice of the particular misconduct which is alleged to constitute the fraud

1 charged so that they can defend against the charge and not just deny that they have
2 done anything wrong.” *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001)
3 (citation omitted).

4 Under the PSLRA, a plaintiff must “state with particularity both the facts
5 constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the
6 defendant’s intention to deceive, manipulate, or defraud.” *Tellabs, Inc. v. Makor*
7 *Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). To adequately allege scienter, a
8 complaint’s allegations must give “rise to a strong inference that the defendant acted
9 with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A).

10 **VI. SECTION 10(b) CLAIM**

11 “To state a federal securities fraud claim, in violation of § 10(b), a plaintiff
12 must show: ‘(1) a material misrepresentation or omission by the defendant;
13 (2) scienter; (3) a connection between the misrepresentation or omission and the
14 purchase or sale of a security; (4) reliance upon the misrepresentation or omission;
15 (5) economic loss; and (6) loss causation.’” *ESG Cap. Partners, LP v. Stratos*, 828
16 F.3d 1023, 1032 (9th Cir. 2016) (quoting *Thompson v. Paul*, 547 F.3d 1055, 1061
17 (9th Cir. 2008)).

18 **A. Material Misrepresentation or Omission**

19 “To prevail on a § 10(b) claim, a plaintiff must show that the defendant made
20 a statement that was ‘*misleading* as to a *material* fact.’” *Matrixx Initiatives, Inc. v.*
21 *Siracusano*, 563 U.S. 27, 38 (2011) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224,
22 238 (1988)) (emphasis in original). “Falsity is alleged when a plaintiff points to
23 defendant’s statements that directly contradict what the defendant knew at that time.”
24 *Khoja*, 899 F.3d at 1008. “Even if a statement is not false, it may be misleading if it
25 omits material information.” *Id.* at 1008-09. “[A] misrepresentation or omission is
26 material if there is a substantial likelihood that a reasonable investor would have
27 acted differently if the misrepresentation had not been made or the truth had been
28 disclosed.” *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 946

1 (9th Cir. 2005).

2 Plaintiffs' allegations regarding falsity fall into two general categories. First,
3 Plaintiffs allege that Defendants' assurances "that the FDA had already blessed the
4 adequacy of the [Harmony Study's] design for purposes of obtaining ... approval" of
5 pimavanserin for the treatment of DRP were "materially false and misleading"
6 because "no such agreement actually existed." (ECF No. 45 ¶¶ 5, 7, 92.) Second,
7 Plaintiffs allege that Defendants' statements concerning the results of the Harmony
8 Study and approval process were "false and misleading" because Defendants "failed
9 to disclose that in fact the Harmony Study's design was so flawed that ... [it] could
10 not support FDA approval of pimavanserin for additional types of DRP beyond
11 [PDP]," and that "the limited data [Acadia] possessed on each [DRP] subgroup was
12 poor and demonstrated a lack of efficacy, dooming [Acadia's] sNDA from the
13 outset." *Id.* ¶¶ 7, 79.

14 **1. Statements Concerning an Agreement with the FDA**

15 Defendants contend that the allegation in the FAC "that Defendants fabricated
16 the existence of an agreement with the FDA is entirely conclusory and unsupported
17 by any well-plead[ed] facts." (ECF No. 53-1 at 25-26 (quotations, citation, and
18 alteration omitted).) Defendants contend that "Plaintiffs mischaracterize Acadia's
19 agreement with the FDA" by conflating an agreement regarding submission of the
20 sNDA with an agreement regarding approval. (ECF No. 58 at 7.) Defendants contend
21 that the absence of a public, written copy of an agreement does not support Plaintiffs'
22 allegations because "[i]t is Plaintiffs' burden to adequately plead falsity." (ECF No.
23 53-1 at 26.) Defendants contend that the allegation regarding the FDA's history of
24 issuing SPAs is inapposite because "Defendants never claimed that their agreement
25 with the FDA was a formal SPA." *Id.* at 27.

26 Plaintiffs contend that at the pleading stage, "the falsity of Acadia's claims to
27 having an 'agreement' with the FDA can be readily inferred from the FDA's rejection
28 of the sNDA on grounds inconsistent with the terms of the purported 'agreement.'"

1 (ECF No. 56 at 16-17.) Plaintiffs contend that “additional factual averments, such as
2 confidential witness statements,” are not necessary at the pleading stage. *Id.* at 18.

3 According to Acadia’s April 5, 2021, press release, the FDA denied approval
4 of Acadia’s sNDA based on concerns with the design and results of the Harmony and
5 -019 Studies. *See* ECF No. 45 ¶ 145 (stating that the FDA cited the Harmony Study’s
6 “lack of statistical significance in some of the subgroups of dementia, and insufficient
7 numbers of patients with certain less common dementia subtypes” as well as issues
8 with the -019 Study, as grounds for denying approval of the sNDA). The FAC alleges
9 that prior to the FDA’s denial of approval of the sNDA, Defendants repeatedly stated
10 that Acadia had an agreement with the FDA. To the extent that Defendants
11 represented that the agreement contained terms that are inconsistent with the FDA’s
12 basis for ultimately denying approval—namely, that the FDA had approved the
13 design of the Harmony and -019 Studies or would base its decision on the overall
14 results of the Harmony Study rather than on the data for individual subgroups—a
15 plausible inference may be drawn at the pleading stage that Defendants
16 misrepresented the existence or terms of the agreement.

17 On August 19, 2020, Defendant Davis stated:

18 [O]ne of the things we hear very consistently among ... physicians
19 generally is ... [that] the “subtypes” of dementia are very difficult to
20 diagnose. They overlap many times. And so it’s a little bit of an artificial
21 distinction to say someone has Alzheimers, dementia with Lewy bodies
or vascular dementia, et cetera.

22 [A]s a reminder, we got a clear agreement from ... the FDA at our
23 end of Phase II meeting [to “pursue DRP broadly”], and we executed
24 the plan that we agreed to with them.

25

26 [T]he sNDA that we’ve submitted includes the [relapse prevention
27 Harmony Study] ... but also includes ... acute data [from the -020 and
-019 Studies] So we have both in the submission

28 [W]e agreed with the FDA on that approach at the [end-of-Phase II]

1 meeting and agreed on the plan for Phase III, and then we've executed
2 that plan.

3 *Id.* ¶ 125. On November 17, 2020, Davis stated:

4 [O]ur sNDA submission included an efficacy package, which was
5 agreed upon with the FDA at the [end-of-Phase II meeting]

6 [A]t our [end-of-Phase II] meeting, we went to the FDA. We said ...
7 [w]e'd like you to agree to 3 things: one, that we studied DRP generally
8 Two, that we run a relapse-prevention study now to demonstrate ...
9 a durable effect over time. And then three, that ... a single relapse
10 prevention study serve as the basis of approval, together with the other
11 supporting acute studies we've done. And they've agreed to all 3 of
12 those So fast forward to today, we then executed the exact plan that
13 we laid out for them.

14

15 One thing that I didn't mention in that in the [end-of-Phase II]
16 meeting] we had setting up our Phase III program that we then executed
17 ... we also just asked FDA[:] ... we just want to make certain that you
18 are on board with approving a drug to treat [DRP] We want to make
19 certain that you are on board with the concept of doing this if we
20 followed the plan that we've agreed to.

21 And they say, absolutely, we wouldn't agree to your Phase III plan if we
22 weren't ... of that mind.

23 *Id.* ¶ 132. On January 12, 2021, Davis further stated: "[W]e're seeking the treatment
24 of [DRP]. So we're not looking at individual subtypes So we're seeking that broad
25 indication. That's supported by a[n] ... alignment we established with the FDA." *Id.*

26 ¶ 135.

27 The assertions that the FDA prospectively agreed on the "plan" for Phase III
28 (i.e. the Harmony Study), that Acadia subsequently "executed that plan," and that the
FDA was "on board" with the concept of "approving a drug to treat [DRP]" if Acadia
"followed the plan" plausibly connote to a reasonable investor that the Harmony
Study's design had been prospectively approved by the FDA and would not represent
a further barrier to approval. Likewise, considered in context, the assertions that the

1 FDA agreed that Acadia “studied DRP generally” and that “a single relapse
2 prevention study serve as the basis of approval,” and that the FDA supported
3 Acadia’s decision to not “look[] at individual subtypes” suggest that the FDA would
4 base its decision on the overall results of the Harmony Study rather than on the data
5 for individual subgroups.

6 Defendant Davis’ statements asserting an agreement with the FDA plausibly
7 contradicted what he is alleged to have known at the time the statements were made
8 and were material because they concerned the likelihood of approval of Acadia’s
9 “only commercial product to date.” (ECF No. 45 ¶ 32.) The Court concludes that the
10 FAC alleges sufficient facts to support a plausible inference that Defendant Davis’
11 statements concerning an agreement with the FDA were materially false or
12 misleading.

13 **2. Omissions of the Negative Harmony Study Results**

14 Defendants contend that Defendants’ other allegedly misleading statements
15 “are inactionable as a matter of law because they are: (a) demonstrably true,
16 (b) corporate optimism (or puffery), (c) opinions, or (d) forward-looking statements
17 accompanied by meaningful cautionary language.” (ECF No. 53-1 at 19.) Defendants
18 contend that Defendants “fully disclosed the trial designs and results of every study
19 ... cited in support of [the] sNDA.” *Id.* at 22. Defendants contend that Defendants
20 “made no misrepresentations regarding clinical study design or data” and that the
21 FAC “presents a quintessential example of pleading ‘fraud by hindsight.’” *Id.* at 24-
22 25.

23 Plaintiffs contend that the FAC “plausibly alleges that Defendants materially
24 misled investors ... by emphasizing cherry-picked positive results while omitting
25 known shortcomings in the studies submitted with the sNDA, including
26 disappointing data, which posed major obstacles to FDA approval.” (ECF No. 56 at
27 18 (quotation and alteration omitted).) Plaintiffs contend that “when a pharmaceutical
28 company touts purportedly positive results from a drug study, it must *also* disclose

1 known material facts that undercut the company’s boosterism to avoid misleading
2 investors.” *Id.* Plaintiffs contend that the disclosure of the Harmony Study’s dataset
3 was not sufficient to counterbalance the misleading impression created by
4 Defendants’ statements.

5 The FAC alleges that Defendants made a series of at least fifteen statements
6 during the class period that were misleading because they failed to disclose that the
7 Harmony Study was not properly designed and had disappointing data, and that these
8 known shortcomings posed major obstacles to FDA approval. These statements
9 included objective descriptions of the results of the Acadia studies, *see, e.g.*, ECF
10 No. 45 ¶¶ 107, 119 (the Harmony Study “met its primary endpoint,”
11 “demonstrate[ed] a highly statistically significant longer time to relapse of
12 psychosis,” and showed a “nearly three-fold reduction in the risk of relapse”), as well
13 as Defendants’ interpretations of the data and results of the studies, *see, e.g., id.* ¶¶
14 119, 127, 132, 135 (the data and results of the studies were “meaningful,” “positive,”
15 “pivotal,” “robust,” and “strong”).

16 The FAC alleges that in fact, “[the] Harmony [S]tudy ... was not reasonably
17 designed to contain a sufficient number of patients ... to conclude ... that
18 pimavanserin was an effective treatment for patients in [DRP] subgroups.” *Id.* ¶ 8.
19 “Instead, the Harmony Study was largely populated by patients suffering from
20 dementia associated with Parkinsons’ disease – the condition for which pimavanserin
21 was *already* FDA-approved.” *Id.* The FAC alleges that “the Harmony Study’s data
22 showed that, despite the small sample size, the drug was actually ineffective or in
23 some cases less effective [than the placebo] in the subgroups Acadia was seeking
24 new approval for.” *Id.* ¶ 83. The FAC alleges that “-019 Study’s poorly analyzed data
25 and poor design ... rendered [that] dataset far from ‘supportive.’” *Id.* ¶ 90. The FAC
26 alleges that “[t]herefore, undisclosed by Defendants, FDA approval was extremely
27 unlikely.” *Id.* ¶ 108.

28 There are no adequately alleged facts from which the Court can infer that

1 Defendants' objective descriptions of the Acadia studies were false. Further,
2 Defendant's interpretation of the data and results of the studies were plainly
3 expressions of opinion. However, statements that are demonstrably true or
4 expressions of opinion are nevertheless actionable if the statements omit additional
5 material information whose absence makes the fact or opinion misleading to a
6 reasonable person reading the statement fairly and in context. *See Khoja*, 899 F.3d at
7 1008-09 ("Even if a statement is not false, it may be misleading if it omits material
8 information."); *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align*
9 *Tech., Inc.*, 856 F.3d 605, 616 (9th Cir. 2017) (stating that a plaintiff can plead that
10 an opinion statement is misleading based "on a theory of omission" by "alleg[ing]
11 'facts going to the basis for the issuers opinion ... whose omission makes the opinion
12 statement at issue misleading to a reasonable person reading the statement fairly and
13 in context.'" (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus.*
14 *Pension Fund*, 575 U.S. 175, 194 (2015))).

15 The allegation that Defendants Davis and Stankovic were high-level corporate
16 officers with "access to material information available to them but not to the public,"
17 (ECF No. 45 ¶ 26), supports an inference at the pleading stage that Defendants were
18 aware of the shortcomings of the Harmony and -019 Studies. Despite allegedly
19 possessing information that the studies were not properly designed and that the
20 Harmony Study had disappointing subgroup data, Defendants touted the studies'
21 results. Defendants' alleged misrepresentations concerning the agreement with the
22 FDA support an inference that Defendants knew that the studies' shortcomings would
23 materially increase the risk that the sNDA would not be approved. At the pleading
24 stage, the allegations in the FAC are sufficient to show that a failure to disclose that
25 the studies were not properly designed and that the Harmony Study had disappointing
26 subgroup data rendered Defendants' positive statements regarding the results of the
27 studies materially misleading. *See Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698,
28 705-06 (9th Cir. 2016) ("[O]nce defendants cho[o]se to tout' positive information to

1 the market, ‘they [are] bound to do so in a manner that wouldn’t mislead investors,’
2 including disclosing adverse information that cuts against the positive information.”
3 (quoting *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008))
4 (alteration in original)).

5 The FDA’s subsequent citation of the shortcomings of the Harmony and -019
6 Studies in denying approval of the sNDA supports a plausible inference that this same
7 information would have been material to a reasonable investor at the time the
8 statements were made. *Cf. Matrixx Initiatives*, 563 U.S. at 43 (“Given that medical
9 professionals and regulators act on the basis of [certain evidence], it stands to reason
10 that in certain cases reasonable investors would as well.”).

11 Defendants assert that the allegedly negative information about the studies was
12 fully disclosed to investors because the FAC alleges that “[o]n December 4, 2019,
13 Acadia presented the Harmony Study’s top-line results” to medical professionals and
14 “released the full data set of the Harmony Study” in connection with the presentation.
15 (ECF No. 45 ¶ 62; *see also* ¶ 87 (stating that the -019 Study’s dataset was presented
16 in full in August 2018)). Under the “truth-on-the-market” doctrine, “[i]n a ‘fraud on
17 the market’ case ‘an omission is materially misleading only if the information has
18 not already entered the market.’” *Provenz v. Miller*, 102 F.3d 1478, 1492 (9th Cir.
19 1996) (quoting *In re Convergent Tech. Sec. Litig.*, 948 F.2d 507, 513 (9th Cir. 1991)).
20 “However, before the ‘truth-on-the-market’ doctrine can be applied, the defendants
21 must prove that the information that was withheld or misrepresented was ‘transmitted
22 to the public with a degree of intensity and credibility sufficient to effectively
23 counterbalance any misleading impression created by insider’s one-sided
24 representations.’” *Id.* at 1492-93 (quoting *Kaplan v. Rose*, 49 F.3d 1363, 1376 (9th
25 Cir. 1994)). The allegation that the data set of the Harmony Study was released in
26 connection with a presentation to medical professionals is not sufficient at the
27 pleading stage to establish that this disclosure was sufficient to counterbalance any
28 misleading impression generated by Defendants’ omissions. Further, the release of

1 the data set did not occur until December 4, 2019, almost three months after the first
2 allegedly misleading statement.

3 The Court concludes that the allegations contained in the FAC support a
4 plausible inference that Defendants' statements touting the results of the Harmony
5 Study and -019 Study, (ECF No. 45 ¶¶ 107, 109, 113, 115, 119, 127, 128, 132, 134,
6 135), misled investors by omitting the adverse information the FDA later cited in
7 denying approval of the sNDA.

8 **B. Scienter**

9 In a § 10(b) action, scienter refers to "a mental state that not only covers intent
10 to deceive, manipulate, or defraud, but also deliberate recklessness." *Schueneman*,
11 840 F.3d at 705. "[D]eliberate recklessness is 'an extreme departure from the
12 standards of ordinary care ... which presents a danger of misleading buyers or sellers
13 that is either known to the defendant or is so obvious that the actor must have been
14 aware of it.'" *Id.* (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981,
15 991 (9th Cir. 2009)).

16 Under the PSLRA, the allegations of a complaint must give "rise to a strong
17 inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-
18 4(b)(2)(A). This requires a weighing of competing inferences from the underlying
19 allegations—"a complaint will survive, ... only if a reasonable person would deem
20 the inference of scienter cogent and at least as compelling as any opposing inference
21 one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. With respect to
22 omissions, "the plaintiff must plead 'a highly unreasonable omission, involving not
23 merely simple, or even inexcusable negligence, but an extreme departure from the
24 standards of ordinary care, and which presents a danger of misleading buyers or
25 sellers that is either known to the defendant or is so obvious that the actor must have
26 been aware of it.'" *Zucco Partners*, 552 F.3d at 991. To determine if the scienter
27 requirement is satisfied, a "court's job is not to scrutinize each allegation in isolation
28 but to assess all the allegations holistically." *Id.* at 326.

1 Defendants contend that the FAC does not contain a single allegation
2 “suggesting that any Defendant intended to deceive investors” or “believed any fact
3 that contradicted any statement they made” during the class period. (ECF No. 53-1
4 at 28.) Defendants contend that Defendants’ alleged omissions do not create a strong
5 inference of scienter. Defendants contend that allegations concerning Defendants’
6 sales of stock are conclusory and do not support an inference of scienter because
7 “many of the sales ... were made pursuant to Rule 10b5-1 plans” or “to cover taxes.”
8 *Id.* at 29-30.

9 Plaintiffs contend that the same allegations supporting the element of falsity
10 also demonstrate scienter. Plaintiffs contend that Defendants’ sales of stock establish
11 a motive that “weigh[s] heavily” in favor of a scienter inference. (ECF No. 56 at 27
12 (quotation omitted).) Plaintiffs contend that the Rule 10b5-1 plans do not shield
13 Defendants from an inference of scienter because the plans were adopted during or
14 shortly before the class period.

15 Defendants Davis and Stankovic “possessed the power and authority to control
16 the contents of Acadia’s SEC filings, press releases, and other market
17 communications” and had “access to material information available to them but not
18 to the public.” *Id.* ¶ 26. Accordingly, Defendants plausibly would have been aware
19 of the terms of any agreement with the FDA and the alleged shortcomings with the
20 design and results of the Harmony and -019 Studies. The FAC’s allegations that
21 Defendants affirmatively misrepresented the terms of the purported agreement with
22 the FDA support an inference that Defendants acted with intent or deliberate
23 recklessness. Further, Acadia’s press release announcing that the FDA had denied
24 approval stated:

25 Despite prior agreements with the [FDA] Division of Psychiatry
26 regarding the pivotal [Harmony Study] design targeting a broad DRP
27 patient population analyzed as a single group, the Division, in the CRL,
28 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 DRP pivotal [Harmony Study] 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. Statistical separation by dementia subgroups and certain minimum numbers of patients with specific subtypes were not among the prespecified requirements. ‘Acadia stands behind the robustly positive results from the pivotal [Harmony Study] and the prospectively agreed trial design and criteria for establishing efficacy in DRP. Over the entire course of the review, the Division did not raise any concerns regarding the agreed upon study design, including the issues raised in the CRL,’ said Steve Davis, Chief Executive Officer of Acadia....

The Division also stated in the CRL that it considers the Phase 2 [-019 Study], a supportive study in the sNDA filing, to not be adequate and well controlled....

Id. ¶ 145. This press release asserts that the FDA agreed to the Harmony Study’s design, agreed to analyze DRP as a single group, and did not require statistical separation by subgroup, but that the FDA denied approval “despite” these prior agreements. These assertions support an inference that Defendants intended that their earlier statements be understood by investors as suggesting that Acadia and the FDA had reached agreements concerning test design and analysis that were ultimately not consistent with the FDA’s rationale for denying approval.

Unusual or suspicious stock sales by corporate insiders may also constitute circumstantial evidence of scienter. *See Zucco*, 552 F.3d at 1005. “Among [the] factors that must be considered to determine whether stock sales raise a strong inference of deliberate recklessness are: ‘(1) the amount and percentage of shares sold by insiders; (2) the timing of the sales; and (3) whether the sales were consistent with the insider’s prior trading history.’” *Id.* (quoting *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1990)).

The FAC alleges that prior to the announcement of results for the Harmony

1 study on September 9, 2019, neither Defendant Davis nor Defendant Stankovic had
2 sold any Acadia stock. The FAC alleges that during the class period, Davis sold
3 541,205 shares of Acadia common stock for \$24,771,568 and Stankovic sold 368,993
4 shares for \$18,932,729. The FAC alleges that many of these sales were made
5 pursuant to Rule 10b5-1 trading plans adopted by Davis on August 22, 2019, and
6 December 19, 2019, and by Stankovic on November 8, 2019, and December 3, 2020.
7 The FAC alleges that since April 4, 2021, Davis has sold an additional 10,813 shares
8 of common stock and Stankovic has sold an additional 8,371 shares.

9 The FAC does not allege the percentage of shares sold by the individual
10 Defendants or the timing of the sales within the nineteen-month period relative to
11 any of the allegedly misleading statements or omissions. However, the amount of
12 Acadia stock sold by the individual Defendants during the class period is substantial.
13 Although the FAC alleges that many of these sales were made pursuant to Rule 10b5-
14 1 trading plans, the trading plans in question were not adopted until after the motive
15 and opportunity to mislead investors allegedly arose. Further, the absence of any sales
16 of stock prior to the class period supports an inference that the individual Defendants'
17 sales were unusual or suspicious and weigh in favor of an inference of scienter.

18 The competing inference—that Defendants did not intentionally or recklessly
19 mislead investors—is supported in part by Defendants' release of the Harmony
20 Study's dataset in connection with a presentation to medical professionals. However,
21 this disclosure occurred almost three months after the initial actionable omission and
22 was followed by Defendants' assurances that Acadia had an agreement with the FDA.

23 Defendants further assert that it "defies common sense" for them to have
24 misrepresented the terms of an agreement with the FDA and the likelihood of
25 approval, knowing the whole time that approval would not be granted. (ECF No. 53-
26 1 at 27.) However, Defendants' actions plausibly demonstrate that that they misled
27 investors into overestimating the likelihood of approval, not that Defendants knew
28 from the start that the sNDA would not be approved. Further, Defendants' substantial

1 stock sales provide a motive for Defendants to temporarily prop up Acadia’s stock
2 price, despite the risk that the company’s stock price would fall when the truth was
3 uncovered. *See Nguyen v. Endologix, Inc.*, 962 F.3d 405 (9th Cir. 2020) (stating that
4 a theory that the defendants promised that a medical device would be approved by
5 the FDA despite knowing approval would not be granted “does not make a whole lot
6 of sense,” but acknowledging that “[i]f defendants had sought to profit from this
7 scheme in the interim, such as by selling off their stock or selling the company at a
8 premium, the theory might have more legs”). Weighing all of the allegations
9 holistically, the Court finds that a reasonable person would deem the inference of
10 scienter cogent and at least as compelling as any opposing inference one could draw.

11 **C. Loss Causation**

12 Loss causation is a plaintiff’s “burden of proving that the act or omission of
13 the defendant alleged to violate this chapter caused the loss for which the plaintiff
14 seeks to recover damages.” 15 U.S.C. § 78u-4(b)(4). “To prove loss causation,
15 plaintiffs need only show a ‘causal connection’ between the fraud and the loss, by
16 tracing the loss back to ‘the very facts about which the defendant lied.’ *Mineworkers’*
17 *Pension Scheme v. First Solar Inc.*, 881 F.3d 750, 753 (9th Cir. 2018) (quoting
18 *Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111,
19 1120 (9th Cir. 2013)). “Disclosure of the fraud is not a sine qua non of loss causation,
20 which may be shown even where the alleged fraud is not necessarily revealed prior
21 to the economic loss.” *Nuveen*, 730 F.3d at 1120.

22 Defendants contend that the FAC alleges a causation theory based on market
23 revelation of the fraud but fails to allege facts relevant to that theory. Defendants
24 contend that “there was no disclosure of fraud or correction of any prior
25 misstatement.” (ECF No. 53-1 at 32.)

26 Plaintiffs contend that Acadia’s disclosures in March and April of 2021 “were
27 plainly construed by shocked investors as evidence” that they had been misled as to
28 the purported agreement with the FDA, the strength of the sNDA supporting studies,

1 and the risk that the sNDA would be rejected. (ECF No. 56 at 30.)

2 The Court has determined that the FAC alleges sufficient facts to support an
3 inference that Defendants' statements concerning the agreement with the FDA and
4 omissions of adverse information about the Harmony and -019 Studies misled
5 investors into underestimating the risk that the FDA would deny Acadia's sNDA.
6 The FAC alleges that Acadia's April 5, 2021, press release disclosed that the FDA
7 cited issues with the designs of Acadia's studies and DRP subgroup results as the
8 basis for denying approval. The FAC alleges that Acadia's common stock price fell
9 \$20.76 per share (45.35%) on March 9, 2021, and an additional \$4.41 (17.23%) on
10 April 5, 2021. A reasonable investor could plausibly infer from Acadia's March and
11 April 2021 press releases that they had previously been misled by Defendants'
12 alleged misrepresentations and omissions. Further, the FDA's denial of approval of
13 the sNDA represented the materialization of the risk about which investors had
14 allegedly been misled. *See Nuveen*, 730 F.3d at 1120 ("[M]aterialization of the risk
15 recognizes that 'a misstatement or omission is the "proximate cause" of an
16 investment loss if the risk that caused the loss was within the zone of risk *concealed*
17 by the misrepresentations and omissions alleged by a disappointed investor.'" (quoting *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 173 (2d. Cir. 2005))).
18 The Court concludes that the FAC alleges sufficient facts to support an inference that
19 Plaintiffs' losses were caused by Defendants' alleged misrepresentations.
20


21 **VII. SECTION 20(a) CLAIM**

22 Defendants request dismissal of the § 20(a) claims on the basis that the
23 Plaintiffs fail to adequately plead an underlying § 10(b) violation. *See Lipton v.*
24 *Pathogenesis Corp.*, 284 F.3d 1027, 1035 n.15 (9th Cir. 2002) ("[T]o prevail on their
25 claims for violations of § 20(a) and § 20A, plaintiffs must first allege a violation of
26 § 10(b) or Rule 10b5."). The Court has determined that Plaintiffs adequately allege
27 facts in support of their § 10(b) claims against Defendants. Defendants' motion to
28 dismiss Plaintiffs' § 20(a) claims is denied.

1 **VIII. CONCLUSION**

2 IT IS HEREBY ORDERED that the Motion to Dismiss the FAC (ECF No. 53)
3 is denied.

4
5 Dated: September 27, 2022

6 
7 Hon. William Q. Hayes
8 United States District Court
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