UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

JEFF RIHN, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

ACADIA PHARMACEUTICALS INC., ULI HACKASELL and STEPHEN R. DAVIS,

Defendants.

STEVE A. WRIGHT AND VICKI G. WRIGHT, Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

v.

ACADIA PHARMACEUTICALS INC., ULI HACKSELL and STEPHEN R. DAVIS,

Defendants.

Case No.: 15cv00575 BTM(DHB)

ORDER DENYING MOTION TO DISMISS CONSOLIDATED CLASS ACTION COMPLAINT

Defendants Acadia Pharmaceuticals Inc. ("Acadia" or "Company"), Uli Hacksell, Stephen R. Davis, and Roger G. Mills have filed a motion to dismiss the Consolidated Class Action Complaint ("CCAC"). For the reasons discussed below,

Defendants' motion is **DENIED**.

I. FACTUAL BACKGROUND

The CCAC asserts claims for violations of (1) section 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5; and (2) section 20(a) of the Securities Exchange Act. The claims are premised on allegations that Defendants knowingly and recklessly made materially false and misleading statements regarding the timing and status of Acadia's New Drug Application ("NDA") of its lead product candidate, Nuplazid (pimavanserin). These false and misleading statements allegedly artificially inflated stock prices of Acadia between November 10, 2014 and March 11, 2015 (the "Class Period").

Acadia is a biopharmaceutical company focused on the development and commercialization of medicines to address unmet medical needs in neurological and related central nervous system disorders. (CCAC ¶ 2.) Acadia has a pipeline of product candidates led by Nuplazid, which is a treatment for Parkinson's Disease Psychosis. (Id.)

In April 2013, Acadia announced that the FDA agreed that the data from the Company's pivotal Phase III -020 study was sufficient to support the filing of an NDA for Nuplazid. (CCAC ¶ 3.) The Company announced that it was targeting an NDA submission near the end of 2014. (Id.) On a conference call held on April 11, 2013, Chief Medical Officer Roger Mills explained that before Acadia could file its NDA, the Company needed to complete drug-drug interaction studies and final aspects of CMC (chemistry, manufacturing, and controls) development, including stability testing of pimavanserin registration batches. (CCAC ¶ 69.)

On November 10, 2014, Acadia announced that it was delaying its submission of the NDA for Nuplazid to the first quarter of 2015—i.e., by March 31, 2015 (the "First Delay"). (CCAC ¶ 4.) The Company explained that the decision to move back the submission was "based on additional time required to complete

preparations needed to support the [FDA's] review of Nuplazid." (CCAC ¶ 71.) On a conference call, CEO Uli Hacksell explained that although the Company had "completed the drug-drug interaction program" and had the "stability as required in our registration program," the Company needed "some more time to complete the preparations." (Id.)

In the following months, Acadia made multiple assurances that it was "on track" to submit the NDA by March 31, 2015. On December 2, 2014, CFO Stephen Davis stated that with respect to the NDA "what we've guided is the first quarter of 2015, and we remain on track for that." (CCAC ¶ 74.) On January 13, 2015, Hacksell represented that Acadia was "comfortable" with its timeline for submitting the NDA by March 31, 2015. (CCAC ¶ 75.) On February 26, 2015, in a press release, Hacksell stated that Acadia "remain[s] on track to submit our New Drug Application to the FDA in the first quarter of 2015." (CCAC ¶ 76.) In a conference call that same day, Hacksell reiterated "we remain on track to submit our NDA this quarter." (CCAC ¶ 78.) In that same conference call, Mills stated, "As Uli mentioned at the beginning of the call, we are diligently completing preparations to support the FDA review of Nuplazid and remain on track to submit our NDA this quarter." (Id.)

However, less than a week after the February 26, 2015 press release and public statements, the Company cancelled its scheduled appearance at the Cowen and Company 35th Annual Health Care Conference on March 3, 2015, and then cancelled its scheduled appearance at the 27th Annual ROTH Conference on March 10, 2015. (CCAC ¶ 79.) These cancellations fueled rumors that Acadia was going to be acquired, causing Acadia's stock price to surge 18% to $45.88 per share on March 10, 2015. (CCAC ¶ 80.)

On March 11, 2015, Acadia announced that it was delaying its NDA submission again to the second half of 2015 ("Second Delay"). (CCAC ¶ 81.) It also announced that Hacksell was resigning as CEO and that CFO Davis was

being appointed Interim CEO. (Id.) As a result of the news, Acadia common stock dropped $9.94 per share to close at $34.82 per share on March 12, 2015, a one-day decline of 22% on the volume of 15 million shares. (CCAC ¶ 99.)

In the press release announcing the Second Delay, Acadia explained that the decision to delay the NDA submission was "based on additional time required to complete the preparation of systems to support commercial manufacturing and supply and, in turn, to support the U.S. Food and Drug Administration's (FDA) review of Nuplazid." (Id.) On a conference call that day, Davis further explained the reasons for the delay of the NDA submission:

> In preparation for submission of the NDA, we completed an assessment of our manufacturing, quality systems and procedures. This is a customary, but important step in preparing for an NDA review and the inspections that are part of that review. Based upon this assessment, we've determined that we need to do additional work to prepare our systems to support commercial-scale manufacturing and supply.
>
> I'm going to pause here and just take a second to provide some context around the system that I'm describing. Moving from a clinical-stage company to a commercial-stage company, as we are doing, requires building infrastructure to accommodate commercial-scale operations. These systems include things such as robust quality assurance systems, documentation and record-keeping systems, commercial-oriented Standard Operating Procedures or SOPs, systems to monitor activities of third-party suppliers, and simply the management of materials through the supply chain.
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> Many of these systems exist when you're a clinical-stage company, but have to be significantly expanded and much more robust for commercial-scale production. Establishing the infrastructure I've described requires close coordination between our internal manufacturing resources, external third-party suppliers and the quality assurance functions within each organization. Because these manufacturing and supply systems are subject to inspection as part of the NDA review process, it is an important that our systems be robust and ready for FDA review and of course for commercial launch.

To be ready for that review, the systems need to be established, they have to be tested and evaluated, and frequently, they need to be tested in connection with actual production runs completed by your third-party suppliers, in other words, it's not just a paper exercise. You sometimes need to test them in real production runs.

So, this requires coordination of our schedule with the schedules and availability of others and the logistics, quite frankly, can be challenging. With that context, the assessment we've recently concluded indicates that the network of systems needed to support commercial manufacturing and supply, and again importantly, the review of our NUPLAZID NDA, requires further implementation and additional testing, work that was not part of the company's original plan. As a result of information from this assessment, we've decided to move back the planned NDA submission of NUPLAZID to the second half of 2015.

* * *

[Analyst]: . . . So I guess just wondering, your 4Q call was two weeks ago and obviously you were confident in the 1Q timeline then. Can you just help us understand what has happened between then and now and how can we be at all confident in the new timeline you guys have given?

[Davis]: It is a fair question. I will just start by saying that preparing and filing an NDA is a huge amount of work across many functions of the Company and as we got closer to the final submission date and diverse functions of the Company became coordinated, the group of us sitting around this table became aware that we had more work to do to be prepared in the areas that I mentioned. . . . . Look, I'm going to be honest. Obviously mistakes were made. The Company should have been better prepared but we have taken decisive steps to address those missteps and I am very confident in the team here.

* * *

[Analyst]: And you mentioned just a breadth of things that are involved in these quality systems and procedures, things like standards, SOPs, raw material, supply chain. Is there one or two particular areas that are

> the focus of the ongoing activity? I can't imagine that every single one of these would need work.
>
> [Davis]: No, quite frankly as I mentioned, you do a lot of these things at a clinical stage level and when you go to commercial stage, they frankly need to be more robust, there are some things that you do that are new but most of the things just have to be done at a much more industrial scale. And again speaking quite frankly, the Company didn't start the process early enough to really get those things in place. We have made very good progress I think in the last few months but this recent assessment we had indicates that we've got more work to do.

(CCAC ¶ 82.)

An NDA must include, among other things, a CMC section. (CCAC ¶ 52.) The CMC section must include analytical test methods for the drug product, specifications of the drug product and drug components, and a description of the product's manufacturing and control procedures. (CCAC ¶ 53.) As part of the NDA approval process, the Company was required to demonstrate that its manufacturing and quality assurance systems and those of its third-party contract manufacturers and suppliers complied with Current Good Manufacturing Practices ("CGMPs") set forth in 21 C.F.R. §§ 210, 211. (CCAC ¶ 54.) The FDA typically conducts a pre-approval inspection to determine whether an applicant's manufacturing facilities comply with CGMPs. (CCAC ¶¶ 59-60, Ex. C.) If manufacturing facilities are not ready for inspection, the FDA may refuse to file the application. (CCAC ¶ 63.)

According to Acadia, the manufacturing quality assurance protocols/ documentation were not ready and would not be for months. (CCAC ¶ 100.) On April 14, 2015, Davis made the following comments regarding the delay:

> We gave a fairly broad range of the second half of the year. That was conscious and intentional, and the reason for that is the work that we need to do really revolves around making certain that we are ready for preapproval inspections. In order to get to that state of readiness, there's a certain amount of work that needs to be done in collaboration

with our third-party suppliers, and because we are relying on other people's schedules, it's important -- I felt like it was important to make certain that we had factored in a certain degree of uncertainty regarding just what their schedules will entail.

Just to give the broader context, to get a drug approved you need to do three things, right? One is the NDA is the primary focus of the drug approval. Our NDA is ready to go, so we can check that box. We could push the button tomorrow and submit the NDA. It's about 700,000 pages, so as you can see it's a very substantial document. That's not atypical, by the way. The other two buckets that are required to get a drug approved are passing what's referred to as preapproval inspections, and they come in two forms. One is on the clinical side and we've done what most companies do. We did an extensive amount of preparation, getting ourselves ready for those inspections, and we did again what most companies do. We hired former FDA inspectors, had them come in and do a mock inspection and do the same kind of inspection that we expect FDA to do. The results of that were that we are ready to go on the clinical side.

We did the same thing on the third bucket and that is on your preapproval inspections associated with manufacturing. We determined then that we have more work to do and so that's the subject of the work that we're doing now. I have said many times, I am not aware of any company that has failed to get their drug approved because they couldn't get a quality assurance system in place that passes a preapproval inspection.

So we will do that. It's a process that we need to get in place. I'm highly confident that we will get that in place. I think we've got the right team. We've got the right plan. It's an extensive plan and a very robust team working on this, and based on everything I know today, I'm confident that we will submit the NDA in the second half.

* * *

The remaining bucket that we need to address is getting the quality assurance system in place on the GMP side of the equation. Once we have that in place, which again every company does -- I'm highly confident we will -- the commercial group is ready to go.

(CCAC ¶ 102.)

On September 29, 2015, Davis stated: "the company just didn't start soon enough in building out the Quality Assurance system or making that transition to a commercial-grade QA system on the GMP front. We recognized that in March of this year or February this year, and began the process of building that out." (CCAC ¶ 103.)

Acadia submitted its NDA for Nuplazid on September 3, 2015, five months after March 31, 2015. (CCAC ¶ 103.) That day, the Company announced the appointment of Davis as CEO. (Id.)

II. DISCUSSION

Defendants contend that Plaintiff's claims must be dismissed because Plaintiff fails to plead falsity with particularity, fails to raise a strong inference of scienter, and fails to plead loss causation. The Court finds that Plaintiff has alleged sufficient facts that satisfy the pleading standards of Fed. R. Civ. P. 12(b)(6), Fed. R. Civ. P. 9(b), and the Private Securities Litigation Reform Act ("PSLRA").

A. Pleading Standard

Under section 10(b) of the Securities Exchange Act of 1934, it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered . . . any manipulative or deceptive device or contrivance . . . ." 15 U.S.C. § 78j(b). Rule 10b–5, which implements section 10(b), makes it unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5(b).

To state a securities fraud claim, plaintiff must plead: "(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." Halliburton Co. v. Erica P. John Fund, Inc., __ U.S. __, 134 S.Ct. 2398, 2407 (2014) (internal citation and quotation omitted).

At the pleading stage, claims under section 10(b) and Rule 10b-5 must satisfy both the heightened pleading standard of Rule 9(b) as well as the pleading requirements of the PSLRA. Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc., 759 F.3d 1051, 1058 (9th Cir. 2014). Under Rule 9(b), the complaint must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). The PSLRA imposes "more exacting pleading requirements," which require that the complaint plead with particularity both falsity and scienter. Reese v. Malone, 747 F.3d 557, 568 (9th Cir. 2014).

The PSLRA requires that the complaint "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u–4(b)(1)(B). If an allegation regarding the statement or omission is made on information and belief, the complaint must "state with particularity all facts on which that belief is formed." Id. To plead scienter, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A).

B. Materially False and Misleading Misrepresentations or Omissions

1. Defendants Made Materially Misleading Statements of Fact

The crux of the CCAC consists of allegations that during the Class Period, Defendants repeatedly stated that they were "on track" to submit the NDA by the March 31, 2015 deadline and were "comfortable" with the announced timeline even though Acadia had not performed a mock inspection of its manufacturing and

quality assurance systems and lacked critical information regarding these important systems.[1]

"To be actionable under the securities laws, an omission must be misleading; in other words it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." Brody v. Transitional Hospitals Corp., 280 F.3d 997, 1006 (9th Cir. 2002). As recognized by the Supreme Court, "[W]hether an omission makes an expression of opinion misleading always depends on context." Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, __U.S.__, 135 S.Ct. 1318, 1329 (2015).

To satisfy the materiality requirement, the complaint must allege sufficient facts to support the inference that there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231–32 (1976) (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)). "Although determining materiality in securities fraud cases should ordinarily be left to the trier of fact, conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim." Reese, 747 F.3d at 568 (quoting In re Cutera Sec. Litig., 610 F.3d 1103, 1108 (9th Cir. 2014)).

The CCAC sufficiently alleges that Defendants made materially misleading misrepresentations when they made statements during the Class Period that Acadia was "on track" to submit the NDA by March 31, 2015, as planned, and that they were "comfortable" with the timeline. According to the CCAC, as part of the NDA approval process, Acadia needed to be prepared for a pre-approval

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[1] Defendants contend that the CCAC violates the PSLRA because it relies on "puzzle-pleading." Although the CCAC includes multiple block quotes, it is clear from the italicized portions of the quotes and the other allegations of the complaint what statements Plaintiff alleges are misleading and why Plaintiff believes they are misleading.

inspection by the FDA of its manufacturing facilities. (CCAC ¶¶ 59-60.) Acadia needed to be ready to demonstrate that its manufacturing and quality assurance systems and those of its third-party contract manufacturers and suppliers complied with CGMPs. (CCAC ¶ 54.) As explained by Davis, moving from a clinical-stage company to a commercial-stage company requires building infrastructure to accommodate commercial-scale operations, including robust quality assurance systems, documentation and record-keeping systems, commercial-oriented Standard Operating Procedures, systems to monitor activities of third-party suppliers, and systems for the management of materials through the supply chain. (CCAC ¶ 82.)

It appears that Acadia did not complete an assessment of its manufacturing and quality assurance systems until February or March of 2015. This assessment alerted Acadia that its network of systems needed to support commercial manufacturing and supply required further implementation and testing. (CCAC ¶ 82.) Davis admitted that the Company did not start the process early enough to transition to a commercial-grade Quality Assurance system by March 31, 2015, and should have been better prepared. (CCAC ¶¶ 82, 103.) In fact, after the Second Delay was announced, it took another five months for the manufacturing and quality assurance issues to be addressed and for the NDA to be submitted.

Based on the allegations of the CCAC, the implementation of adequate manufacturing and quality assurance systems was a significant undertaking and was a critical component of the NDA approval process. However, Acadia did not perform a mock inspection of these systems until shortly before the Second Delay was announced. Accordingly, when Defendants represented that the NDA was "on track" to be submitted by March 31, 2015, without mentioning that no meaningful assessment of the manufacturing and quality assurance systems had been conducted, Defendants created an impression of a state of affairs that differed in a material way from the one that actually existed. Defendants led the

public to believe that all appropriate steps had been taken to make sure that the NDA was ready for review by the deadline and that barring unforeseen circumstances, the NDA would be submitted by that date. In actuality, Defendants lacked information regarding whether the necessary infrastructure for commercial-scale operations was in place. Thus, Defendants' assurances that the NDA remained "on track" for submission by March 31, 2015 were materially misleading.

2. The Statements Are Not Forward-Looking

Defendants contend that the challenged statements are forward-looking and are inactionable as a matter of law. The Court disagrees.

Under the PSLRA's "safe harbor," a defendant may not be held liable for a statement that (1) is, and is identified as, a "forward-looking statement"; and (2) is accompanied by "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A). A "forward-looking statement" is defined as any statement regarding (1) financial projection, (2) plans and objectives of management for future operations, (3) future economic performance, or (4) the assumptions underlying or related to any of the aforementioned statements. 15 U.S.C. § 78u-5(i)(1)(A)-(D).

Although statements that Acadia "planned" on submitting the NDA by March 31, 2015, viewed in isolation, may qualify as "forward-looking," Defendants' statements that Acadia remained "on track" to submit the NDA by the deadline do not. In the context of this case, Defendants' "on track" assurances were representations about the *current* state of affairs with respect to the NDA process, which were within Defendants' knowledge and control.

In Mulligan v. Impax Lab., Inc., 36 F. Supp. 3d 942, 951 (N.D. Cal. 2014), the court rejected the defendants' argument that the following statement by the CFO regarding the company's response to a Warning Letter from the FDA was

forward-looking: "Where we are now is on track, and, therefore, I think investors can be comfortable that we're where we need to be." The court explained that this statement "is fundamentally a representation of present fact regarding the status of Impax's response to the FDA Warning Letter." Id. at 964. See also In re MGM Mirage Sec. Litig., 2013 WL 5435832, at * 7 (D. Nev. Sept. 26, 2013) (holding that statements that a construction project is "on-track" or "on-schedule" are not forward-looking "but statements relating to *current* conditions.")

Although in some instances, a statement regarding a company being "on track" might be forward-looking,[2] under the facts of this case, the statements were a representation of present conditions pertaining to the NDA process. Therefore, the PSLRA's safe harbor does not apply.

3. The Statements Are Not Non-actionable Puffery/ Corporate Optimism

Defendants claim that the challenged statements are non-actionable statements of corporate optimism. For similar reasons as discussed in the prior section, the Court disagrees.

"[V]ague, generalized assertions of corporate optimism or statements of 'mere puffing' are not actionable material misrepresentations under federal securities laws." In re Impac Mortg. Holdings, Inc. Sec. Litig., 554 F. Supp. 2d 1083, 1096 (C.D. Cal. 2008). Non-actionable "puffing" statements are "not capable of objective verification and lack a standard against which a reasonable investor could expect them to be pegged." Id. (internal citation and quotation omitted). As explained by the Ninth Circuit:

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[2] In Police Retirement Sys. of St. Louis v. Intuitive Surgical, Inc., 2012 WL 1868874, at * 11 (N.D. Cal. May 22, 2012), the statement that revenue "is on track to grow 55% this year" was explicitly introduced as a financial forecast. In City of Marysville General Employees Ret. Sys. v. Nighthawk Radiology Holdings, 2011 WL 4584778, at * 20 (D. Idaho Sept. 12 2011), the court held that NightHawk's statements that it was "on track" and "positioned" to capitalize on opportunities," when read in context, were tied to future projections based on hopes of eventually expanding business services,

> When valuing corporations . . . investors do not rely on vague statements of optimism like "good," "well-regarded," or other feel good monikers. This mildly optimistic, subjective assessment hardly amounts to a securities violation. Indeed, professional investors, and most amateur investors as well, know how to devalue the optimism of corporate executives.

Cutera, 610 F.3d at 1111 (internal citation and quotation omitted).

In determining whether statements amount to nothing more than non-actionable puffery, "the court must analyze the context in which the statements were made." In re Bridgepoint Educ., Inc. Sec. Litig., 2013 WL 5206216, at * 17 (S.D. Cal. Sept. 13, 2013). "What might be innocuous 'puffery' or mere statement of opinion standing alone may be actionable as an integral part of a representation of material fact when used to emphasize and induce reliance upon such a representation." Casella v. Webb, 883 F.2d 805, 808 (9th Cir. 1989).

As discussed above, the statements regarding Acadia remaining "on track" to submit the NDA by the deadline were representations about current conditions regarding the NDA process. They were not vague statements of optimism, but, rather, statements premised on facts. In Mulligan, the court rejected the defendants' arguments that the statements at issue were mere puffery: "[T]he vast majority of the statements identified in the FAC contain factual representations at their core—that Defendants had responded to the FDA Warning Letter by instituting various changes to the manufacturing and/or quality control procedures or processes." Mulligan, 36 F. Supp. 3d at 967. Similarly, here, Defendants' statements were factual representations regarding Acadia's preparedness for the NDA submission and were material. See Silverman v. Motorola, Inc., 2008 U.S. Dist. Lexis 76799, at *27 (N.D. Ill. Sept. 23, 2008) ("Among the puffery lies certain specific statements of present fact that could be considered material. The fact that the 'competitive' products are 'on track,' 'quite on track,' or 'keyed up,' would be

material if in fact defendants knew that those products were not on track.")[3]

C. Scienter

Defendants argue that the CCAC fails to plead scienter with particularity, as required by the PSLRA, and impermissibly relies on speculation and conjecture. Considering all of the allegations of the CCAC collectively, the Court concludes that Plaintiff has pled sufficient facts giving rise to a strong inference of scienter.

Under the PSLRA, plaintiffs must plead "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). A strong inference of scienter "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007). "The inference must be that the defendant made false or misleading statements either intentionally or with deliberate recklessness." Reese v. Malone, 747 F.3d 557, 569 (9th Cir. 2014) (internal citation and quotation omitted). "[A]n actor is [deliberately] reckless if he had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort." In re Oracle Corp. Sec. Litig., 627 F.3d 376, 390 (9th Cir. 2010) (quoting Howard v. Everex Sys., Inc., 228 F.3d 1057, 1064

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[3] Allison v. Brooktree Corp., 999 F. Supp. 1342 (S.D. Cal. 1998), cited by Defendants, is distinguishable because in that case the defendants represented, "I think we're on the right track" in the early design stage of the BtV chipset: "In bringing any high-tech product to market, problems encountered in the early developmental stages are the norm, not the exception. Notably absent are allegations that Brooktree had encountered any insurmountable problems, or the problems were of such magnitude that Defendants knew the projected release dates to be unrealistic, or any other fact that would undermine the tentative and vague nature of these statements." Id. at 1348. The other cases upon which Defendants rely are also distinguishable. See In re Wet Seal, Inc. Sec. Litig., 518 F. Supp. 2d 1148, 1167-68 (C.D. Cal. 2007) (statement that Wet Seal was "on track to deliver improved financial performance in the fall, in line with our turnaround plan" was puffery because it projected vague optimistic results); In re DOT Hill Sys. Corp. Sec. Litig., 594 F. Supp. 2d 1150, 1158 (S.D. Cal. 2008) (statement that integration of technology into Dot Hill's products was "on schedule and continuing smoothly" was mere puffery—"Plaintiffs simply disagreed with defendants about how quickly the integration should have been accomplished.")

(9th Cir. 2000)).

The Supreme Court explains that courts "must review all the allegations holistically" when determining whether scienter has been adequately pled. Tellabs, 551 U.S. at 326. The relevant inquiry is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Id.

Allegations regarding management's role in a company may help satisfy the PSLRA scienter requirement in three circumstances:

> First, the allegations may be viewed holistically, along with other allegations in the complaint, to raise a strong inference of scienter under the Tellabs standard. Id. at 785–86. Second, the allegations "may independently satisfy the PSLRA where they are particular and suggest that defendants had actual access to the disputed information," as in Daou, 411 F.3d at 1023, and Oracle, 380 F.3d at 1234. S. Ferry, 542 F.3d at 786. Third, in rare circumstances, such allegations may be sufficient, without accompanying particularized allegations, where the nature of the relevant fact is of such prominence that it would be "absurd" to suggest that management was without knowledge of the matter. Id. (citing Berson, 527 F.3d at 988).

Reese, 747 F.3d at 575-76.

A combination of all three circumstances exist in this case. First, given the facts of this case, it would be incredible to conclude that the CEO, CFO, and Chief Medical Officer of Acadia were not aware of the information at issue that made their "on track" representations misleading. In Mulligan, the court held that it would be absurd to think that the CEO and CFO of Impax, a pharmaceutical company, would be unaware of the alleged substandard conditions pervading the company's manufacturing and control divisions: "[G]iven the importance of manufacturing and quality control to the success of Impax and the fact that both areas of operation had been flagged by the FDA, it is a logical, and strong, inference that the defendants were aware of the alleged severe and pervasive problems in Impax's Hayward facility." Mulligan, 36 F. Supp. 3d at 970. See also Flynn v. Sientra, Inc.,

2016 WL 3360676 (C.D. Cal. June 9, 2016) (finding that there was a strong inference that the CEO and CFO of medical aesthetics company were aware of quality control issues plaguing the company's sole manufacturer of silicone breast implants in light of the importance of manufacturing and quality control to the success of Sientra).

Nuplazid, Acadia's most advanced product candidate, was critical to the success of the company. (CCAC ¶ 112.) Furthermore, the implementation of manufacturing and quality assurance systems was an important component of the NDA process. In addition, Acadia was a relatively small company—97 employees as of December 31, 2014 (CCAC ¶ 112). It would be absurd to suggest that the CEO, CFO, and Chief Medical Officer did not know that there had been no mock inspection of its manufacturing facilities and that there had been no reliable assessment of the company's manufacturing and quality assurance systems at the time they made their statements.

The CCAC also contains allegations suggesting that Hacksell, Mills, and Davis had access to the information at issue. On March 11, 2015, the day Davis was appointed interim CEO, he stated that he was "the ultimate report for manufacturing and CMC." (CCAC ¶ 98.) It can reasonably be inferred that when Hacksell was CEO, he too was the "ultimate report" for manufacturing and CMC. Statements made by Defendants also indicate that they had knowledge regarding CMC issues pertaining to Nuplazid. Hacksell and Mills made statements regarding preparations Acadia needed to complete to support the NDA, including CMC development, and all three Defendants commented on the NDA remaining "on track." (CCAC ¶¶ 69, 71, 74, 76, 78.)

Finally, the allegations of Defendants' roles in the Company when viewed together with other allegations in the CCAC raise a strong inference of scienter. On February 26, 2015, Hacksell and Mills reiterated that Acadia remained "on track" to submit the NDA by March 31, 2015. However, less than a week later,

Acadia cancelled its scheduled appearance at a conference. Then on March 11, 2015, Acadia announced the Second Delay. Later, Davis said that Acadia recognized in February or March that the quality assurance system was not ready. (CCAC ¶ 103.) The issues with the manufacturing and quality assurance systems were of such significance that it took an additional five months for the NDA to be submitted.

The closeness in time of the February 26, 2015 representations and the March 11, 2015 disclosure supports an inference that Hacksell and Mills were deliberately reckless in claiming that the NDA remained "on track" for submission by the end of the next month. "Temporal proximity of an allegedly fraudulent statement or omission and a later disclosure can be circumstantial evidence of scienter." Reese, 747 F.3d at 574. See also Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 988 n. 5 (9th Cir. 2008) (explaining that temporal proximity of misleading statement and disclosure of stop-work order just two weeks later bolstered the inference that the defendants knew about the order when they made the statement).

The scope and significance of the events underlying a disclosure can also support an inference of scienter. See, e.g., Berson, 527 F.3d at 988 n. 5 ("The size of the contract and the prominence of the client raise a strong inference that defendants would be aware of this order."); Plumbers & Pipefitters Nat. Pension Fund v. Orthofix Intern. N.V., 89 F. Supp. 3d 602, 619 (S.D.N.Y. 2015) (explaining that "the size of the purported fraud may also contribute to an inference of scienter."). In light of the importance of the implementation of the manufacturing and quality control systems to the NDA process, the significant amount of work that actually remained to be done on those fronts, and the fact that no mock inspection occurred until February or March of 2015, it was highly likely that Defendants were aware that their "on track" assurances lacked a factual basis.

Viewing the allegations of the CCAC holistically, the Court concludes that

scienter has been adequately pled.[4]

D. Loss Causation

Defendants argue that Plaintiff has failed to plead loss causation because, according to Plaintiff's own allegations, the decline in Acadia's stock price upon announcement of the Second Delay was caused by the Company dispelling speculation that it was in the process of being acquired.

Loss causation is "a causal connection between the material misrepresentation and the loss." Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 342 (2005). "A plaintiff is not required to show that a misrepresentation was the sole reason for the investment's decline in value in order to establish loss causation. As long as the misrepresentation is one substantial cause of the investment's decline in value, other contributing forces will not bar recovery under the loss causation requirement but will play a role in determining recoverable damages." Nuveen Mun. High Income Opportunity Fund v. City of Alameda, 730 F.3d 1111, 1119 (9th Cir. 2013) (internal citation and quotation omitted).

As pointed out by Plaintiff, the merger speculation resulted in a $6.95 per share increase on March 10, 2015, whereas the announcement of the Second Delay resulted in a $9.94 per share decrease. (CCAC ¶¶ 13, 80, 99.) These facts arguably establish that the price of Acadia stock was artificially inflated in part for reasons separate from the merger rumors—i.e., Defendants' misleading statements regarding the NDA being on track for submission by March 31, 2015.

The Court finds that Plaintiff has adequately alleged loss causation and denies the motion to dismiss on this ground.

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[4] Plaintiff makes additional arguments in support of his position that the CCAC adequately pleads scienter, including arguments pertaining to Defendants' financial gains from stock sales and incentive compensation, and the timing of Hacksell's resignation as CEO. The Court does not find it necessary to reach these arguments and overrules as moot Plaintiff's objection to Defendants' request for judicial notice of alleged hearsay concerning Defendants' trading plans in SEC filings.

E. Section 20(a) Claim

To state a claim under section 20(a), a plaintiff must establish (1) a primary violation of federal securities law, and (2) that the defendant exercised actual power or control over the primary violator. See Howard v. Everex Sys., 228 F.3d 1057, 1065 (9th Cir. 2000). Defendants argue that Plaintiff has failed to state a claim under section 20(a) because Plaintiff has failed to plead a primary violation of section 10(b). However, because the Court has found that Plaintiff has sufficiently pled a claim for violation of section 10(b), Plaintiff's section 20(a) claim survives dismissal as well.

III. CONCLUSION

For the reasons discussed above, Defendants' motion to dismiss the CCAC is **DENIED**. Defendants shall file an answer to the CCAC within 20 days of the entry of this Order.

IT IS SO ORDERED.

Dated: September 19, 2016

Barry Ted Moskowitz, Chief Judge
United States District Court