United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

In re DYNAVAX SECURITIES LITIGATION	Case No. 4:16-cv-06690-YGR **ORDER GRANTING MOTION TO DISMISS CONSOLIDATED SECOND AMENDED COMPLAINT** Dkt. No. 68
This Document Relates To: ALL ACTIONS.	

Lead Plaintiff Kwok Pang, individually and on behalf of all other persons similarly situated, brings this consolidated class action against defendants Dynavax Technologies Corporation, Eddie Gray, Michael S. Ostrach, and Robert Janssen for violation of federal securities laws. Plaintiff alleges violation of Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5). The consolidated amended complaint on behalf of the putative class was filed March 17, 2017. (Dkt. No. 47.) Defendants moved to dismiss the consolidated amended complaint and the Court granted that motion with leave to amend. (Dkt. No. 61, "First MTD Order".) Plaintiff filed a Consolidated Second Amended Class Action Complaint ("CSAC") on October 3, 2017. (Dkt. No. 65.) Defendants have again moved to dismiss on the grounds that the CSAC does not allege the elements of the 10(b) claim with sufficient particularity as required by the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u-4(b), and that the claim for control person liability under section 20(a) fails for the same reason.

Having carefully considered the papers submitted, the pleadings in this action, the matters judicially noticeable,[1] and the parties' oral arguments, and for the reasons set forth below, the Court **GRANTS** the Motion to Dismiss **WITHOUT LEAVE TO AMEND**.

I SUMMARY OF FACTS ALLEGED

Defendant Dynavax is a clinical-stage biopharmaceutical company engaged in the development of products for the prevention of infectious disease, including hepatitis. (CSAC ¶ 23.) Defendant Eddie Gray is the CEO and a director of the company; defendant Michael S. Ostrach is a Senior Vice President, Chief Financial Officer, and Chief Business Officer; and defendant Robert Janssen is a Vice President of Clinical Development and Chief Medical Officer. (*Id.* ¶¶ 24-26.)

Dynavax submitted an initial Biologics License Application ("BLA") for its investigational hepatitis B vaccine, HEPLISAV-B, in April 2012, to the U.S. Food and Drug Administration ("FDA"). After the FDA rejected its initial BLA, Dynavax designed and implemented a Phase III clinical trial of the vaccine known as "HBV-23." (CSAC ¶¶ 1, 6.) In response to safety concerns raised by the FDA in its review of the initial BLA, particularly with respect to autoimmune complications, Dynavax designed the HBV-23 trial with the stated purpose to "evaluate the overall safety of HEPLISAV-B with respect to clinically significant adverse events." (*Id.*) The study specifically evaluated potential autoimmune disorders the FDA had indicated were "Adverse Events of Special Interest" or AESIs in addition, to overall data on safety and efficacy. (CSAC ¶¶ 57; RJN Exh. 24 at 19.)

In October 2015, Dynavax completed the HBV-23 trial, and compiled safety and efficacy data, based on the larger patient database therein. The HBV-23 data revealed what defendants would later refer to as "a numerical imbalance in a small number of cardiac events" not observed in the prior clinical trials for HEPLISAV-B. (*Id.* ¶¶ 42, 92.) In light of those results, defendants

[1] Defendants' Request for Judicial Notice (Dkt. No. 68-1, "RJN"), unopposed by plaintiff, is **GRANTED IN PART**. The Court takes judicial notice of Exhibits 1-17, 20-26. Judicial notice as to the remainder of the exhibits is **DENIED** as they concern matters outside the allegations in the pleadings and therefore are not relevant to the motion.

undertook "expanded work" on the cardiac event data, seeking "consultation from very highly regarded external experts" regarding the imbalance. (*Id.* ¶¶ 9, 55, 56, 99.)

On January 7, 2016, the alleged start of the class period here, Dynavax issued a press release and an SEC Form 8-K, announcing preliminary "top-line results" from HBV-23 and plans to submit a revised BLA for approval of HEPLISAV-B at the end of the first quarter of 2016. (*Id.* 57.) "All adverse events considered to represent potential autoimmune disorders (Adverse Events of Special Interest, or AESIs) were reviewed by an independent panel of experts from the Mayo Clinic." (*Id.*) Dynavax informed the market, during its January 7 market call regarding HBV-23, that "[t]he overall safety profile of HEPLISAV-B was similar to that of Engerix-B," and that "[a]dverse events were generally balanced between the vaccine groups." (*Id.* ¶ 60.)[2] Defendant Gray stated that Dynavax was on track to resubmit the HEPLISAV-B BLA to the FDA by March 31, 2016, based on the results of HBV-23. (*Id.*)

On March 8, 2016, the Company filed a Form 8-K with the SEC, attaching a press release the Company issued that day. (*Id.* ¶ 62.) In the press release, defendant Gray stated that "this third pivotal study [ ] met both co-primary endpoints. We plan to resubmit the HEPLISAV-B BLA . . . to the FDA by the end of this month . . . [and] if our application is approved we expect to launch this product in the fourth quarter of this year." (*Id.*) It also filed a Form 10-K reiterating that HBV-23 met the safety endpoints set for the clinical trial and that "rates of clinically significant adverse events were consistent with randomization." (*Id.* ¶ 64.)

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[2] During the January 7 market call, defendant Gray stated that he was "very pleased to report today that this study met all of our expectations . . . . HEPLISAV-B and HBV-23 met our expectations with respect to safety and immunogenicity. We are on track to submit our BLA at the end of this quarter." (RJN Exh. 3 at 3.) Defendant Janssen stated:

> regarding safety, in HBV-23, the overall safety profile of HEPLISAV-B was similar to that of Engerix-B. Adverse events were generally balanced between the vaccine groups and AESIs as predetermined by FDA were also balanced. Additionally, as with every study, especially of this size, we've noted some numerical imbalances, none of which are statistically significant.

(*Id.* at 5.) Analysts posed follow-up questions regarding what defendants meant by imbalances, to which Gray responded that "the key message here is that all of the numbers appear to be balanced. The only obvious imbalance in numbers appears to be Bell's palsy, and that's balanced out across the total database." (RJN Exh. 3 at 7-8.)

Shortly thereafter, on March 30, 2016, Dynavax issued another press release, followed by a Form 8-K, announcing that the FDA had accepted Dynavax's BLA for HEPLISAV-B for review, and that the BLA was based on "positive immunogenicity results from clinical trials" and "an equivalent safety profile compared to . . . Engerix-B." (*Id*. ¶ 67.) This announcement was followed by a string of positive press releases from Dynavax, proclaiming that HEPLISAV-B had a similar safety profile to the existing Engerix-B vaccine.[3] (*Id*. ¶¶ 69, 70, 72, 73, 75, 76.)

Then, on September 2, 2016, the FDA issued a notice cancelling the Vaccines and Related Biological Products Advisory Committee ("VRBPAC") meeting scheduled for November 16, 2016, which would have been the next step in the approval process.[4] (*Id.* ¶ 91.) In reaction, the stock price per share of Dynavax declined from $15.94 on September 1, 2016, to close at $10.91 on September 2, 2016. (*Id.* ¶ 91.) On September 4 and 6, respectively, Dynavax issued a press release and filed a Form 8-K announcing that the VRBPAC meeting had been cancelled by the FDA, and stating that "remaining questions will be addressed between Dynavax and the review team via the normal process" over the coming weeks. (*Id.* ¶ 79.) The September 4 Press Release stated:

> During recent conversations between Dynavax and the FDA, the Agency communicated decisions to enable compliance with the current Prescription Drug User Fee Act (PDUFA) date of December 15, 2016. . . . The FDA informed Dynavax that it plans to provide information requests related to remaining questions in the upcoming weeks. Dynavax is prepared to address these questions expeditiously in order to enable the FDA to complete its review as soon as possible.

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[3] On April 27, 2016, Dynavax issued a press release and a Form 8-K announcing that it had "receive[d] notification of [a] PDUFA [Prescription Drug User Fee Act, 21 U.S.C. § 355] extension [date] for HEPLISAV-B to December 15, 2016," and again reiterating that "HEPLISAV-B has a safety profile similar to that of existing vaccines." (*Id*. ¶¶ 69, 70.) Likewise, in a June 11, 2016 press release and Form 8-K, Dynavax announced that it had presented data on HEPLISAV-B at the 76th Annual Scientific Sessions of the American Diabetes Association and that the "rates of adverse events, serious adverse events and deaths were similar between the HEPLISAV-B and Engerix-B groups." (*Id*. ¶¶ 72, 73.)

[4] Previously, on August 5, 2016, Dynavax issued two press releases and a Form 8-K announcing the FDA's scheduling of a November 16, 2016 VRBPAC meeting as the next step in its review of HEPLISAV-B. (*Id.* ¶ 75.) One of the press releases also stated that, in the HBV-23 trial, HEPLISAV-B "demonstrated a similar safety profile to the existing vaccine." (*Id.* ¶ 76.)

(CSAC ¶ 79.)

On October 3, 2016, Dynavax filed a Form 8-K stating that it had received "anticipated requests for information from the [FDA] review team in connection with the pending [BLA] for HEPLISAV-B . . . . [and t]he review team's questions are in line with the company's expectations." (*Id.* ¶ 81.) It continued, stating that Dynavax was "working with the FDA to resolve remaining questions regarding the BLA in order to enable the FDA to complete its review by the scheduled Prescription Drug User Fee Act ('PDUFA') action date of December 15, 2016, which remains unchanged." (*Id.*) Later that same month, on October 26, 2016, Dynavax issued a press release and Form 8-K announcing "sub-group results" from the HBV-23 clinical trial which it stated showed "rates of adverse events, serious adverse events and deaths were similar between the HEPLISAV-B and Engerix-B groups." (*Id.* ¶¶ 83, 84.)

On November 7, 2016, Dynavax issued a press release and a Form 8-K announcing financial results for the third quarter and stating that:

> In late August, the U.S. Food and Drug Administration (FDA) cancelled its previously scheduled Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting to review the Biologics License Application (BLA) for HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)]. The FDA indicated that remaining questions on the BLA will be addressed between Dynavax and the FDA review team. The Company has since provided responses to information requests by the FDA related to remaining questions . . . . In the total Phase 3 trial population, the rates of adverse events, serious adverse events and deaths were similar between the HEPLISAV-B and Engerix-B groups. . . . Preparations for launch of HEPLISAV-B are continuing . . . .

(*Id.* ¶¶ 88, 89.)

On November 14, 2016, the FDA issued a complete response letter (CRL) to Dynavax regarding the March 2015 BLA submission. Dynavax's press release about the CRL indicated that the FDA sought:

> information regarding several topics, including clarification regarding specific adverse events of special interest (AESIs), a numerical imbalance in a small number of cardiac events in a single study (HBV-23), new analyses of the integrated safety data base across different time periods, and post-marketing commitments. In the CRL, the FDA acknowledged that it has not yet completed its review of responses received from Dynavax in early October, including those

> pertaining to AESIs and the numerical imbalance in cardiac events. The responses included an extensive analysis that included independent expert consultation supporting our view that the imbalance was driven by an unexpectedly low number of events in the comparator arm. It would appear the Agency could not fully assess the responses in the current review period. In the CRL, there is no request for additional clinical trials and there are no apparent concerns with rare serious autoimmune events.

(*Id.* ¶ 92.) The press release that day quoted defendant Gray as stating, "[t]he CRL is consistent with our opinion that HEPLISAV-B is approvable and we are seeking to meet with the FDA as soon as possible." (*Id.* ¶ 93.) On an earnings conference call that same day, when queried by an analyst about details of the cardiac events, Gray stated "we are not going to go into any more detail than we have given . . . . We have [an] imbalance in a single term which the agency referred to as cardiac events and so we have utilized their language in our communication of it." (*Id.* ¶ 96.) When pressed on "not having more transparency" in the call, Gray responded by stating that it "would not be normal practice to talk about numeric imbalances unless it reaches some degree of statistical significance or [if] perhaps you feel there is a good reason to believe that there might be a relationship. This situation meets neither of those criteria. And I think I will ask Rob [Janssen], as our Chief Medical Officer, who has [lived] with this data for the last year to give you his assurance of our confidence in this position." (*Id.* ¶ 98.) Janssen added,

> So I led the team that did all the analyses and wrote the BLA and responses to the information requests and actually did many of the analyses myself, wrote the response to the information requests. We did seek external consultation from very highly regarded external experts. And all of this expanded work I think just continued to convince me that there is no relationship between the cardiac events and the vaccine."

(*Id.* ¶ 99.)

The next business day, the price of Dynavax common stock dropped 64% -- from $11.60 per share on Friday, November 11, 2016, to close at $4.10 per share on Monday, November 14, 2016, the alleged end date of the class period. (*Id.* ¶¶ 5, 103.)

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II. APPLICABLE STANDARD

To state a claim under Section 10b, a plaintiff must "show that the defendant made a statement that was '*misleading* as to a *material* fact.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988) (emphasis in original)). Thus, a plaintiff must allege: "(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." *Id.* at 37-38 (quoting *Stoneridge Investment Partners, LLC v. Scientific–Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). Under the PSLRA, "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321 (2007); *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 877 (9th Cir. 2012) (quoting 15 U.S.C. § 78u-4(b)(1)). The PSLRA also requires particularity in pleading the required state of mind: "in any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, 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). Thus the PSLRA requires a plaintiff alleging securities fraud to "plead with particularity both falsity and scienter." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009) (internal quotation omitted); *see also Tellabs*, 551 U.S. at 313.

Under Section 20(a), "a defendant employee of a corporation who has violated the securities laws will be jointly and severally liable to the plaintiff, as long as the plaintiff demonstrates 'a primary violation of federal securities law' and that 'the defendant exercised actual power or control over the primary violator.'" *Zucco*, 552 F.3d at 990.

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III. DISCUSSION

Plaintiff alleges that defendants violated section 10(b) because they made a series of statements, from January 2016 to November 2016, in which they failed to disclose information regarding the imbalance in the cardiac events data for the HBV-23 trial. The allegations can be categorized into two groups. First, plaintiffs allege that in January, March, April, June, and August of 2016, Dynavax had a duty to disclose affirmatively an imbalance in cardiac events because it "opened the door" with certain other statements, namely that (i) the HBV-23 trial was to evaluate safety with respect to "clinically significant adverse events," (ii) the safety profile for HEPLISA-B and Engerix (the previously approved hepatitis B vaccine) were similar, and (iii) Dynavax anticipated FDA approval by the end of 2016. (CSAC ¶¶ 58, 61, 63, 65, 68, 71, 74, 77.) The second concerns statements made on and after September 2, 2016. Here, plaintiffs allege that Dynavax "concealed the enhanced risk that the FDA would delay approving HEPLISAV-B" and omitted the cardiac imbalance data. (CSAC ¶¶ 15, 80, 82, 85, 87, 90.) The alleged duty to disclose the "enhanced risk" and cardiac imbalance data arose because Dynavax continued to make statements about "comparable" safety data between the two groups, and disclosed only limited information about adverse events, even though the FDA had issued "information requests to Dynavax" and expressed its concerns about the safety data in the HBV-23 trial, including cardiac events. (CSAC ¶¶ 79, 80.)

A. Falsity and Materiality

"Under the PSLRA, to properly allege falsity, a securities fraud complaint must now 'specify each statement alleged to have been misleading'" and "'the reason or reasons why the statement [was] misleading'" when it was made. *In re Rigel*,697 F.3d at 877 (quoting 15 U.S.C. § 78u-4(b)(1)). When plaintiff alleges an omission, the omission is only material if "a *reasonable* investor would have viewed the non[-]disclosed information as having *significantly* altered the total mix of information made available." *Matrixx*, 563 U.S. at 44 (emphasis in original). Section 10(b) and Rule 10b-5(b) "do not create an affirmative duty to disclose any and all material information," but instead a duty to include all facts necessary to render a statement accurate and not misleading, once a company elects to disclose that material information. *Id.* at 44-45, 47; 17 C.F.R. § 240.10b–

5(b). Material information only needs to be disclosed if its omission would "affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). However, "once defendants cho[o]se to tout" positive information to the market, "they [are] bound to do so in a manner that wouldn't mislead investors," including disclosing adverse information that cuts against the positive information." *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 706 (9th Cir. 2016) (quoting *Berson v. Applied Signal Tech. Inc.*, 527 F.3d 982, 987 (9th Cir. 2008).)

Plaintiff specifically identifies more than twenty statements in Dynavax's SEC filings, press releases, and earnings call transcripts which he contends were misleading, beginning with its January 7[5] press release, Form 8-K, and earnings call, and continuing through its November 7 press release and Form 8-K. (CSAC ¶¶ 57–90.) Plaintiff's theory of section 10(b) liability is that defendants made a material omission in that they "omitted the numerical imbalance in the occurrence of the cardiac adverse events during HBV-23, misrepresenting the comparability of the safety profile of HEPLISAV-B to Engerix-B and leading the market to believe that no numerical imbalance in adverse events was material." (CSAC ¶ 12.)[6] Plaintiff further alleges that defendant's representation that "[t]he overall safety profile of HEPLISAV-B was similar to that of Engerix-B . . . [a]dverse events were generally balanced between vaccine groups," along with disclosure of some numerical imbalances in other events, was misleading because Dynavax omitted information about the imbalance in cardiac events. (*Id*. at ¶ 13.) By selectively disclosing "some numerical imbalances" and certain non-cardiac adverse events, but not the imbalance in cardiac adverse events, plaintiff contends that defendants misled investors into believing that no cardiac adverse events had occurred during HBV-23, and that no adverse events threatened to derail timely FDA approval of HEPLISAV-B. (*Id*. at ¶ 14.) Thus, "in the context of" defendants' statements

[5] All dates are in 2016 unless otherwise stated.

[6] The CSAC contains allegations that defendants falsely claimed both that HEPLISAV-B's safety profile was "similar" or "comparable" to that of Engerix and that numbers of adverse events were "generally balanced." (CSAC ¶ 14.) However, plaintiff disavows reliance on a theory of affirmatively false statements for his Section 10(b) claim; his theory is one of omissions only. (Oppo. at 5:4, n.1.)

regarding the timeline for FDA approval, defendants' failure to disclose cardiac events that they knew or should have known would delay or halt the approval process violated section 10(b). (CSAC ¶ 58.)

Under *Matrixx*, a court must conduct a holistic, "contextual inquiry" to assess materiality. *Matrixx*, 563 U.S. at 44. With respect to pharmaceutical and similar products, the "total mix" standard does not require manufacturers to disclose all reports of adverse events. *Id*. at 43-44. "Adverse event reports are daily events in the pharmaceutical industry . . . . [and the] fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event." *Id*. at 44. "[T]he mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy this standard[; s]omething more is needed . . . and can come from 'the source, content, and context of the reports.'" *Id.* Moreover, "[e]ven with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market." *Id.* at 45; *In re Rigel*, 697 F.3d at 880 ("as long as the omissions do not make the actual statements misleading, a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant"). Further, the PSLRA requires that a plaintiff allege specific facts indicating why each statement challenged in a securities fraud case was false *when made*, "because it forces plaintiffs to reveal whether they base their allegations on an inference of earlier knowledge drawn from later disclosures or from contemporaneous documents or other facts." *In re Vantive Corp. Sec. Litig.*, 110 F. Supp. 2d 1209, 1216 (N.D. Cal. 2000), *aff'd*, 283 F.3d 1079 (9th Cir. 2002), *abrogated on other grounds by Tellabs*, 551 U.S. at 324-25; *see also In re Rigel*, 697 F.3d at 881 (in the context of pharmaceutical approval process, "subsequent release of more extensive information . . . was not inconsistent with the results that originally were reported. Moreover, even if some investors might have wanted more extensive information related to [adverse effects] . . . that would not be sufficient to make the alleged original statements false or misleading.")

A comparison between *Matrixx* and the case at bar is instructive. In *Matrixx*, the company told the market that revenues were going to rise, but had information indicating a significant risk to its leading revenue-generating product. *Id*. More specifically, Matrixx had received information that "plausibly indicated a reliable causal link between" its product and a serious adverse effect, including information from three medical professionals and researchers, additional patient reports of the adverse effect, and previous studies that demonstrated a biological causal link between similar products and the adverse effect. *Id.* at 45–46. The company knew there was evidence of a causal link, and had not conducted any studies of its own to disprove that the product caused the adverse effect, or to counter that evidence. *Id*. The company nevertheless publicly stated that "the safety and efficacy of [the product] . . . [is] well established," discounting reported safety risks from its product as "completely unfounded and misleading," and withholding the information it had about the causal link to the adverse effect. *Id.* at 47. The Supreme Court held the alleged information regarding the adverse effects and the causal link to its product "were material facts 'necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.'" *Id*. (quoting 17 C.F.R. § 240.10b–5(b)).

Here, by contrast, the facts alleged by plaintiff do not establish that the omission of the cardiac events data rendered Dynavax's statements false or misleading, or that Dynavax's statements gave rise to a duty to disclose the cardiac events. The mere existence of an adverse event or a data imbalance is not sufficient to give rise to a duty to disclose unless its omission would "affirmatively create an impression of a state of affairs that differ[ed] in a material way from the one that actually exist[ed]." *Brody*, 280 F.3d at 1006; *see also Matrixx*, 563 U.S. at 44-45. Dynavax made statements that: it had reviewed all adverse events in the trial; had found 33 events on the list of AESIs provided by the FDA; the "overall safety profile" was similar to Engerix-B; and "adverse events were generally balanced." Indeed, Dynavax had stated in its January 7 call that "as with every study, especially of this size, we've noted some numerical imbalances, none of which are statistically significant." (CSAC ¶ 60.) Dynavax also stated that "we expect to launch the product in the fourth quarter of 2016." (CSAC ¶¶ 62, 64.) Omission of the cardiac imbalance data does not render these statements misleading. The statements cannot reasonably be said to have

misled investors into believing that no cardiac adverse events had occurred, nor did Dynavax state that there were no adverse events that could affect the FDA approval timeline.[7]

Similarly, the CSAC does not allege specific facts to indicate that, at the time of the alleged misleading statements, Dynavax had been informed by the FDA that the cardiac events data jeopardized approval.[8] Indeed, plaintiff does not allege any particular issues that the FDA raised with Dynavax at or before the time of any of the alleged misleading statements.

Instead, plaintiff attempts to establish materiality by speculation and improper inference. First, the CSAC alleges that cardiac events were a "known area of concern" for the FDA, because FDA officials had authored an article in the *Journal of the American Medical Association* two years prior (hereinafter "JAMA Article"), which stated that cardiac events were some of the most frequent safety concerns preventing approval of new drugs. (CSAC ¶ 43.) The CSAC offers no additional facts to support the assumptions that defendants knew about this article, or more generally "knew" the cardiac events data would delay approval, when they made the alleged statements.

Second, the CSAC relies on an inference that, because the FDA later issued a CRL halting the approval process, Dynavax must have known earlier that approval was in jeopardy, but failed to disclose it. However, the CSAC is bereft of allegations that the FDA had indicated that the cardiac events data would halt the approval timeline at some time before it issued its November 13 CRL. Instead, plaintiff alleges that, prior to the November 13 CRL, Dynavax's stated that the FDA issued

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[7] Plaintiff argues that Dynavax "conditioned the market" to expect transparency due to its disclosure of a "small imbalance" with respect to Bell's palsy, and a single case of a rare autoimmune condition (Takayasu's arteritis), thus requiring it to disclose even data about cardiac events even if they were small in number or statistically insignificant. However, Dynavax's disclosure of these minor events was consistent with the FDA's requirement going into the Phase III clinical trial that potential *autoimmune* disorders were "Adverse Events of Special Interest" or AESIs, of special concern to the FDA approval process. As plaintiff has previously conceded, the cardiac events here were not AESIs.

[8] Likewise, in contrast to *Schueneman*, at the time the company made the alleged misleading statements about the animal studies' findings being "favorable" and supportive of its confidence in FDA approval, "the company knew that the animal studies were *the* sticking point with the FDA." *Schueneman*, 840 F.3d at 708.

"information requests," had "remaining questions," was engaged in a "very open and productive" dialogue with Dynavax, and its questions were "in line with the company's expectations." (CSAC ¶¶ 11, 45, 79, 81.) In its November 14 press release, Dynavax stated that "[i]n the CRL, the FDA acknowledged that it has not yet completed its review of responses received from Dynavax in early October, including those pertaining to AESIs and the numerical imbalance in cardiac events." (CSAC ¶ 92.)

The FDA approval process necessarily involves a dialogue between the company and the agency and a company has "no legal obligation to loop the public into each detail of every communication with the FDA." *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017). Simply failing to "divulge the details of interim 'regulatory back-and-forth' with the FDA. . . alone cannot support an inference of scienter." *Kader v. Sarepta Therapeutics, Inc.*, 887 F.3d 48, 59 (1st Cir. 2018). Reasonable investors would expect that the company and the FDA would be engaged in a dialogue about the sufficiency of the clinical trials and that such dialogue inherently would include presentation of contrary views. *Tongue v. Sanofi*, 816 F.3d 199, 212 (2d Cir. 2016) (no plausible allegation that FDA interim feedback conflicted with company's opinion about FDA approval timeline or that failure to disclose it made opinion misleading); *see also Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1329 (2015) (statements of opinion must reasonably align with the information in the company's possession but are not misleading simply because the company knows some information that contradicts that opinion). In the absence of any factual allegations to suggest that the dialogue with the FDA was "highly unusual," outside the normal process, or so contradictory to Dynavax's statements about HEPLISAV-B's approval prospects, Dynavax's failure to disclose the subject of an ongoing dialogue with the FDA does not constitute a material omission. *Cf. In re Amylin Pharm., Inc. Sec. Litig.*, No. 01CV1455 BTM (NLS), 2003 WL 21500525, at *6 (S.D. Cal. May 1, 2003) (while company seeking FDA approval of a new drug is not obligated to disclose every issue raised by FDA, defendants were obligated to disclose significant concerns that rendered FDA approval seriously doubtful); *Schueneman*, 840 F.3d at 707 (FDA was engaged in "highly unusual"

review procedures and requirements, not merely a good faith disagreement about the meaning of an underlying study).[9]

In short, the CSAC does not allege that facts to establish that defendants had a duty to disclose the cardiac events data in order to prevent the affirmative statements they made about AESIs or the overall balance of adverse events and safety data from misleading investors. The facts alleged by plaintiff do not establish that the omission of the cardiac events data rendered Dynavax's statements misleading as to the true facts at the time they were made. While plaintiff contends that defendants "opened the door" by discussing the timeline and trajectory for FDA approval, the CSAC has not alleged any facts that, at the time the statements at issue were made, the FDA had indicated that approval was seriously doubtful.

B. Scienter

Even assuming the CSAC had alleged materially misleading statements due to defendants' omissions, the CSAC does not allege scienter sufficiently to state a PSLRA claim. Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319. To plead scienter, a complaint must identify specific contemporaneous facts establishing "a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading

[9] Dynavax argues that it cannot be liable because the alleged omissions all concern forward-looking statements subject to the PSLRA's safe harbor provision, 17 C.F.R. § 240.10b-5(b), *i.e.*, statements regarding projections, plans, future performance and the assumptions underlying them. *Costabile v. Natus Med. Inc.*, 293 F. Supp. 3d 994, 1013 (N.D. Cal. 2018). Under the safe harbor, even if forward-looking statements are material and are made with defendants' knowledge of their falsity, they are inactionable so long as they are accompanied by meaningful cautionary language. *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111–12 (9th Cir. 2010).

The alleged misleading statements do not appear to be purely forward-looking statements, but instead misleading statements of fact or, at the very least, mixed statements. The Court declines to reach the safe harbor question here, since it is not necessary to the disposition of the complaint. However, the Court notes that, contrary to defendant's argument, the Ninth Circuit recently joined several other circuits in holding that, "where defendants make mixed statements containing non-forward-looking statements as well as forward-looking statements, the non-forward-looking statements are *not* protected by the safe harbor of the PSLRA." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1141-42 (9th Cir. 2017) *petition for cert. filed* January 28, 2018 (internal citations omitted, emphasis supplied).

buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Zucco*, 552 F.3d at 991. The scienter analysis at the pleading stage "is inherently comparative" and must take into account plausible nonculpable explanations for a defendant's conduct as well as inferences favoring the plaintiff. *Tellabs*, 551 U.S. at 323. "A court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Zucco*, 552 F.3d at 991. "[O]missions and ambiguities [in the complaint] count against inferring scienter." *Tellabs*, 551 U.S. at 326.

Plaintiff contends that defendants knew their failure to disclose the cardiac events imbalance risked misleading investors about the prospects and timeline for FDA approval. Plaintiff alleges defendants knew: (1) the FDA had concerns about cardiac events data in the HBV-23 study; (2) cardiac events were a "known concern" based on the JAMA Article; (3) Dynavax retained an outside expert to look into the cardiac imbalance in the HBV-23 study; and (4) HEPLISAV-B was Dynavax's only potential revenue-generating product in the works at the time.

First, as stated above, the fact that Dynavax engaged in a dialogue with the FDA regarding cardiac events during the approval process, standing on its own, does not suggest that defendants knew that failure to disclose this information to investors would risk misleading them about prospects for approval. There are no plausible allegations that the FDA expressed concerns about the cardiac imbalance data in the HBV-23 study any earlier than September 2, 2016. Though the CSAC alleges that defendants later stated that the FDA's questions in September 2016 were "in line with the company's expectations" (CSAC ¶ 45), and that Dynavax submitted responses to the FDA's questions in October 2016 (CSAC ¶ 92), it does not allege that defendants knew, at the time of their statements, that the FDA had concerns about the data that were likely to halt or delay approval. There are no allegations of internal documents, confidential witness statements, or FDA correspondence to suggest anyone at Dynavax knew or should have known that the cardiac imbalance would be a significant issue with the FDA that might jeopardize the timing, or ultimate approval, of HEPLISAV-B. It is not enough for plaintiff to contend, looking back from the vantage

point of the CRL in November, to allege that defendants must have known that the FDA was going to issue the CRL when they made statements in September, October, and early November.

Second, the fact of cardiac events being a "known concern" for the FDA, based on the JAMA Article, is not sufficient to support a strong inference of scienter. There are no allegations that defendants were aware of the JAMA Article, much less that they believed that generalized concerns expressed in an article about drug approval confirmed that the HBV-23 cardiac events data would be of such concern that it was likely to hold up FDA approval. *See Brennan v. Zafgen, Inc.*, 853 F.3d 606, 614–15 (1st Cir. 2017) (articles regarding risks of similar drugs did not support allegation that defendants should have disclosed such risks to investors in the absence of factual allegations of warnings or expressions of concern by company insiders).

Third, Dynavax's retention of an outside consultant to aid in its review of the cardiac data does not, in itself, raise a strong inference of scienter. The CSAC alleges that a former Dynavax employee disclosed that the cardiac events data prompted the company to conduct detailed analysis and retain an outside consultant for additional perspective. There are no allegations that the outside consultant reached any particular conclusion about the data, or that such a consultation was anything but a normal part of the FDA approval process.

With respect to the allegation that HEPLISAV-B was the only revenue-generating product, and that the company had pinned all its hopes on approval, while this fact suggests a motive to deceive, it does not support actual deception. This fact alone is not sufficient to support a strong inference of scienter. Here, there are no allegations of insider trading or suspicious stock sales. *In re Pixar Sec. Litig.*, 450 F. Supp. 2d 1096, 1107 (N.D. Cal. 2006) ("[t]he absence of insider trading by a defendant is highly relevant and undermines any inference of scienter"); *see also Rigel*, 697 F.3d at 884. To the contrary, two individual defendants purchased stock during the time period (RJN Exh. 21-23), undermining an inference of scienter. *See In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1424-25 (9th Cir. 1994) (if defendants knew a company's stock price was overvalued, they ""probably would have bailed out" rather than incur the same "losses as . . . Plaintiffs"), *superseded by statute on other grounds*, 15 U.S.C. § 78u-4(b)(2).

Based upon the allegations in the CSAC, the Court cannot find the inference that defendants acted with deliberate recklessness or intent to mislead investors is "at least as compelling" as the inference that they did not. *Matrixx*, 563 U.S. at 50. Plaintiff therefore has failed to allege scienter sufficiently.

IV. CONCLUSION

Having failed to allege a material misleading statement or a strong inference of scienter, plaintiff's 10(b) claim must be dismissed. Moreover, Plaintiff's failure to plead a primary violation of Section 10(b) requires the dismissal of the Section 20(a) claim against the individual defendants. *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 623 (9th Cir. 2017).

Based upon the foregoing, and having provided plaintiffs with a prior opportunity to amend, the motion to dismiss the CSAC is **GRANTED WITHOUT LEAVE TO AMEND**. This action is **DISMISSED**.

This terminates Docket No. 68.

IT IS SO ORDERED.

Date: June 4, 2018

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT COURT JUDGE

United States District Court
Northern District of California