United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JOE HUANG, et al.,

Plaintiffs,

v.

AVALANCHE BIOTECHNOLOGIES, INC., et al.,

Defendants.

Case No. 15-cv-03185-JD

ORDER RE: MOTION TO DISMISS

In this securities fraud class action, lead plaintiffs Arpan Bachhawat and Srikanth Koneru sue on behalf of purchasers of publicly traded Avalanche Biotechnologies, Inc. ("Avalanche") common stock between July 31, 2014 and June 15, 2015. Dkt. No. 71. Plaintiffs allege two sets of claims. Counts one and two allege that Avalanche, former CEO Thomas Chalberg ("Chalberg"), former CFO Linda Bain ("Bain"), board chairman Mark Blumenkranz ("Blumenkranz"), and board member Steve Schwartz ("Schwartz") made false and misleading public statements in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5. *Id.* ¶¶ 21-26, 194, 207. Counts three and four allege that Avalanche, Chalberg, Bain, Blumenkranz, Schwartz, board member John McLaughlin ("McLaughlin"), board member Paul Wachter ("Wachter"), and the IPO underwriters, Jefferies LLC ("Jefferies"), Cowen & Co., LLC ("Cowen"), Piper Jaffray & Co. ("Piper Jaffray") and William Blair & Co., LLC ("William Blair") made false and misleading statements relating to the IPO registration in violation of Sections 11 and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k,o. *Id.* ¶¶ 220-33, 253, 262. The Avalanche defendants move to dismiss the complaint for failure to state a claim under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4 and

Federal Rule of Civil Procedure 9(b), joined by the IPO underwriter defendants. Dkt. Nos. 74 and 98. The complaint is dismissed with leave to amend.

BACKGROUND

As alleged in the complaint, Avalanche is a clinical-stage biopharmaceutical company developing novel gene therapies to treat ocular diseases. Dkt. No. 71 ¶ 2. The drug at issue in this case is AVA-101, a gene therapy for wet Age-Related Macular Degeneration ("Wet AMD"). *Id.* Wet AMD is the leading cause of blindness in the developed world. *Id.* It develops when the membrane underlying the retina thickens and breaks. *Id.* ¶ 32. In response to the disruption of oxygen delivery, the eye grows new, abnormal blood vessels, an event called choroidal neovascularization ("CNV"). *Id.* The new vessels are very fragile and often leak, which floods the retina with fluids that damage photoreceptors and cause vision loss. *Id.*

Vascular endothelial growth factor ("VEGF") is a protein known to play a central role in the growth of the new blood vessels in the retina. *Id.* ¶¶ 33-34. It has been the target of several therapies because blocking it is likely to shrink the abnormal blood vessels and reduce the risk of fluid damage. *Id.* Current FDA-approved therapies targeting VEGF require intravitreal injections into the eye every 4-8 weeks, an unpleasant and sometimes risky procedure. *Id.* AVA-101 was conceived and designed to be a single-injection alternative by Professor Elizabeth Rakoczy at the Lions Eye Institute (LEI) in Perth, Australia. *Id.* ¶¶ 2-3. AVA-101 is comprised of the AAV2 vector, which contains a gene encoding sFLT-1, a naturally occurring anti-VEGF protein. *Id.* ¶ 35. Avalanche hypothesized that when administered in the eye and expressed by the host retinal cells, the sFLT-1 protein would inhibit the formation of new blood vessels and block VEGF activity. *Id.* In 2010, Avalanche entered into a license agreement with LEI to develop AVA-101 and they collaborated on the design of the first in-human trial. *Id.* ¶ 3.

The primary endpoint of the AVA-101 Trial was the "safety endpoint," measured by ensuring that there were no signs of unresolved ophthalmic complications, toxicity, or systemic complications one month post injection. *Id.* ¶ 47. Safety was determined by reviewing lab data and ocular examinations, and was monitored at each monthly visit. *Id.* Safety metrics included (a) ocular inflammation, (b) intraocular pressure, (c) best-corrected visual acuity, and (d) retinal

bleeding. *Id.* The secondary endpoint was the "efficacy endpoint" to determine the maintenance or improvement of vision without the need for doses of ranibizumab rescue (the currently approved treatment) by measuring (a) best-corrected visual acuity, (b) CNV fluid leakage, and (c) foveal (retinal) thickness. *Id.* ¶ 48. This endpoint evaluation was scheduled to take place at one month with extended follow up for three years. *Id.* Rescue treatments were given based upon pre-specified levels of (1) worsening visual acuity, (2) increases in retinal thickness, and (3) increases in CNV leakage. *Id.* ¶ 50. These three measures are the most commonly accepted measures used to determine whether a drug is inhibiting VEGF and causing an anti-VEGF response in the eye, which is why they are used to determine rescue injections in standard practice and the secondary endpoint of efficacy. *Id.* ¶ 54.

The AVA-Trial began in January 2012 at LEI. *Id.* ¶¶ 4, 44. Eight patients were enrolled by April 2012, and by the end of 2013, 38 patients had been successfully enrolled. *Id.* ¶¶ 56, 60. In June 2013, safety data for 17 patients was published in an abstract in the IOVS journal. *Id.* ¶ 80. In April 2014, Avalanche and LEI published an abstract with the one-year results of the "Phase 1" patients (referring to the first eight enrolled patients as "Phase 1" and the remaining patients as "Phase 2a" from this point on). *Id.* ¶ 63. Plaintiffs allege that defendants used the data from these first patients for an Initial Public Offering ("IPO") on May 30, 2014. *Id.* ¶ 73. In June 2014, Avalanche reviewed interim drug safety surveillance data from Phase 2a, the results of which were included in the July 2014 Registration Statement. *Id.* ¶¶ 70, 73. Plaintiffs allege that defendants "touted" this safety and efficacy data, and caused stock prices to rise inappropriately. *Id.* ¶¶ 76-77. A second offering was initiated on January 7, 2015, with the 2015 Registration Statement. *Id.* ¶ 78.

On June 15, 2015, Avalanche released the one-year results from the Phase 2a Trial. *Id.* ¶ 84. These results were unfavorable in that they did not show evidence of durable anti-VEGF response in the majority of subjects treated with AVA-101. *Id.* ¶ 86. Avalanche stock plummeted by 56% on June 16, 2015. *Id.* ¶ 88. Two months later, Avalanche announced that it would not be proceeding with Phase 2b of the trial. *Id.* ¶ 92.

Plaintiffs allege that before the final release of the unfavorable Phase 2a data, the Exchange Act defendants made "materially false and/or misleading" statements in press statements, scientific presentations, analyst reports, and SEC filings during the class period in violation of Section 10(b) of the Exchange Act and Rule 10b-5. *Id.* ¶ 195. Plaintiffs identify 24 actionable statements. *Id.* Exh. A. For the Securities Act claims, plaintiffs allege that the 2014 Registration Statement contained false or misleading statements concerning data from the AVA-101 Trial and the risks facing the company from efficacy. *Id.* ¶¶ 234, 239-241.

DISCUSSION

Well-established standards govern this motion to dismiss. To comply with the pleading requirements of Federal Rule of Civil Procedure 8(a)(2) and survive a Rule 12(b)(6) motion to dismiss, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly* at 556). In evaluating a motion to dismiss, the Court assumes that the plaintiff's allegations are true and draws all reasonable inferences in his or her favor. *Usher v. City of Los Angeles*, 828 F.2d 556, 561 (9th Cir. 1987). The Court need not, however, "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008). If the Court dismisses a complaint, it "should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000) (internal quotation marks and citation omitted).

I. JUDICIAL NOTICE

In resolving a motion to dismiss, the Court may consider facts on the face of the complaint, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). A court may take judicial notice of "a fact that is not subject to reasonable dispute because it: (1) is

generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201.

Defendants seek judicial notice of 55 documents. Dkt. No. 75. The first four are documents incorporated into the complaint and plaintiffs do not object. *Id.* at 1-2. As plaintiffs rely on these documents in the complaint and their authenticity is not questioned, the Court takes judicial notice of (1) a transcript of a conference call with investors, (2) the Lions Eye Institute's Annual Report, (3) the Form S-1 that Avalanche filed with the SEC on December 18, 2014, and (4) the Form DEF 14A proxy statement that Avalanche filed with the SEC on April 30, 2015.

Documents 5-55 are publicly available Form 4 filings. Public SEC filings are generally subject to judicial notice. *See Metzler Inv. GMBH v. Corinthian Coll., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008). But notice is limited to "what was in the public realm at the time, not whether the contents of those articles were in fact true." *Von Saher v. Norton Simon Museum of Art*, 592 F.3d 954, 960 (9th Cir. 2009) (internal quotation marks and citation omitted). Consequently, the Court takes judicial notice of the forms, but not the truth of their contents.

Plaintiffs object to judicial notice of Document 56, a demonstrative of stock holds during the class period, which was prepared by counsel. The Court does not take judicial notice because the conclusory statements asserted are neither generally known within the jurisdiction nor free from reasonable dispute.

II. EXCHANGE ACT CLAIMS

A. Pleading Standard

"At the pleading stage, a complaint stating claims under section 10(b) and Rule 10b-5 must satisfy the dual pleading requirements of Federal Rule of Civil Procedure 9(b) and the PSLRA." *Zucco*, 552 F.3d at 990. "To plead a claim under Section 10(b) and Rule 10b-5, the plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *Oregon Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 603 (9th Cir. 2014) (citing *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552

U.S. 148, 157 (2008)). Here, defendants do not contest elements (3) through (6), and so the Court focuses on whether plaintiffs have adequately pleaded the first two elements: falsity and scienter.

The circumstances constituting the alleged fraud must be stated with particularity under Federal Rule of Civil Procedure 9(b). *See Oregon Pub. Emps. Ret. Fund*, 774 F.3d at 604. The "[a]verments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003). Under the PSLRA, the complaint must "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)(1)(B). For each alleged misstatement or omission, the complaint must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2)(A).

B. Misrepresentations or Omissions

Plaintiffs must show that defendants made statements that were "*misleading* as to a material fact." *Matrixx Initiatives, Inc. v. Siracusano*, 564 U.S. 27, 38 (2011) (quoting *Basic Inc., et al. v. Levinson, et al.*, 485 U.S. 224, 238 (1988)) (emphasis in original). A statement is misleading "if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008) (internal quotation marks and citation omitted). A statement or omission is material when "there is 'a substantial likelihood that the disclosure of the [ ] fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Matrixx*, 563 U.S. at 38 (quoting *Basic*, 485 U.S. at 231-32). "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." *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1108 (9th Cir. 2010) (internal quotation marks and citations omitted).

Section 10(b) and Rule 10b-5(b) "do not create an affirmative duty to disclose any and all material information." *Matrixx*, 563 U.S. at 44. These rules prohibit only misleading and untrue

statements, not statements that are incomplete. *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 880 n.8 (9th Cir. 2012). Statements must be considered in the context of their total presentation. *See Hughes v. Dempsey-Tegeler & Co., Inc.*, 534 F.2d 156, 176 (9th Cir. 1976).

Plaintiffs identify 24 statements across the class period that are allegedly false and/or misleading. Despite the number, all of plaintiffs' allegations of falsity support the same contention: review of the June 2014 Interim Safety Surveillance Data would have "revealed AVA-101's Efficacy problems--or at the very least cast significant doubt on the drug's efficacy." Dkt. No. 99 at 2. Defendants say this theory of the June 2014 data is the "fundamental defect in Plaintiffs' claim." Dkt. No. 74 at 7. In their view, plaintiffs fail to identify a false statement or actionable omission because there is no identified "fact;" no fact of negative efficacy or additional safety data. *Id.* at 7-8. Defendants also argue that even if more robust data were collected, there is no duty to disclose all safety or efficacy information to prevent the statements from being misleading. Dkt. No. 105 at 3-4. Defendants do not ask to dismiss the statements on other grounds, such as forward-looking statements, assertions of corporate optimism or otherwise. Consequently, the Court focuses on the contested issue of known efficacy and safety information.

1. Statements Directly Mentioning Interim Drug Safety Surveillance Data

In the 2014 Registration Statement, 3Q 2014 Form 10-Q, 2015 Registration Statement, and 2015 Form 10-K, defendants reported that "Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated." Dkt. No. 71 ¶¶ 98, 113, 117, 127 (*for reference* Dkt. No. 117, Exh. A Nos. 1, 11, 14, 19). This is the complete statement, materially identical in each form:

> We are currently conducting a Phase 2a trial for AVA-101 at LEI with 32 additional wet AMD subjects. Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated. Most adverse events that have been observed to date are mild and not related to AVA-101 or the procedures used in the study. Adverse events related to study procedures include subconjunctival, vitreous and retinal hemorrhage, cataract progression and eye pain. Other infrequent adverse events may be related to study procedures, including retinal tears or holes and falls. A small number of adverse events may be possibly related to AVA-101, including inflammation and light chain analysis increase, but these were considered mild and transient and

> have not been associated with vision loss. We expect to receive top-line data from this ongoing Phase 2a trial in mid- 2015.
>
> * * *
>
> We are currently conducting a Phase 2a trial for AVA-101 in wet AMD. Interim drug safety surveillance data received in June 2014 from this ongoing study suggests that AVA-101 continues to be well tolerated. We expect to receive top-line data from this ongoing Phase 2a trial in mid-2015.

2. Disclaimer Statements

Defendants made disclaimer statements about the risks of clinical trials in the 2014 and 2015 registrations, 10-Q forms (2Q filed September 12, 2014, 3Q filed November 12, 2014, and 1Q filed May 13, 2015), and the 2015 10-K form filed with the SEC. *Id.* ¶¶ 99, 104, 114, 118, 128, 134 (Exh. A Nos. 2, 5, 13, 15, 21, 23). The relevant portions state:

> Our business currently depends substantially on the success of AVA-101, which is still under development. If we are unable to obtain regulatory approval for, or successfully commercialize, AVA-101, our business will be materially harmed.
>
> * * *
>
> Successful continued development and ultimate regulatory approval of AVA-101 is critical for our future business success. . . .
>
> The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:
>
> > we may not be able to provide evidence of efficacy and safety for AVA-101;
> >
> > the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory bodies for marketing approval.

3. Statements about Treatment Paradigm

In the above 2014 and 2015 10-Q forms, defendants also stated:

> We believe that this product candidate could transform the treatment paradigm and address the unmet need in the large wet AMD market, which is estimated to be over $6.0 billion worldwide. *Id.* ¶¶ 103,113, 234 (Exh. A Nos. 4, 11, 23).

4. Statements about Management Knowledge

As alleged in the complaint, Piper Jaffray published corrected statements on January 16, 2015 summarizing discussions with Avalanche management, stating "management

notes they do NOT know or see the data for the 1H15 P2a AVA-101 wet AMD data" and "Management notes they don't know the data: The company is insistent that there is nothing they know about the trial which would change their views or expectations for the study." *Id.* ¶ 122 (Exh. A No. 17).

On March 5, 2015, Cowen published a report following a lunch with Chalberg and Bain. *Id.* ¶ 125 (Exh. A No. 18). The report stated in relevant part:

> The trial included an interim safety analysis which was conducted in June of 2014, several months after dosing in most patients. Management noted that this safety analysis was successfully passed, with no serious or worrisome adverse events detected. As the study is ongoing, management said that it does not have knowledge of any adverse event or efficacy data other tha[n] the safety data from the June 2014 safety analysis. Nonetheless, management did say that the trial has a pharmacovigilance committee. Thus far the committee has not been notified of any serious adverse events in the trial. With nearly all patients at least nine months past their AVA-101 injection, we think this bodes well for AVA-101's safety profile in the Ph. IIa.

5. Statements at Scientific Presentations

Defendant Chalberg presented information about Avalanche and AVA-101 for the American Academy of Ophthalmology on October 16, 2014 and November 7, 2014. *Id.* ¶¶ 109, 111 (Exh. A Nos. 8, 9, 10). During his presentation and/or on his presentation slides, he stated in relevant part:

- "Potential for One-Time Transformative Treatment."
- "Promising Clinical Data."
- "Well tolerated with no drug-related adverse events."
- "Subjects gained/maintained vision with no or minimal need for additional treatment over one year."
- "Phase 2a trial fully enrolled in Australia; data expected mid-2015."
- "And so through this early trial data that we find very encouraging, we're looking forward to following up more patients . . ."

The remaining alleged statements indicate that the previously mentioned documents are misleading in their entirety or are false because they incorporate misleading statements by reference. *Id.* ¶¶ 101, 105, 107, 113, 120, 127, 132, 134 (Exh. A Nos. 3, 6, 7, 12, 16, 20, 22, 24).

C. Efficacy Data in Interim Safety Surveillance Data

Plaintiffs contend that the above statements are false or misleading because they "omitted that the data indicated that patients in Phase 2a were experiencing significant retinal thickening, requiring multiple rescue injections, and were not experiencing significant improvements in visual acuity. ('Efficacy Problems')." Dkt. No. 99 at 2. Plaintiffs assert that the June 2014 interim safety surveillance data was sufficient for defendants to observe these efficacy problems. *Id.* at 4-6. Plaintiffs admit they do not know what the "data" in June 2014 consisted of or showed, but say it can be inferred from "connecting the dots" in the study protocol to the final top-line data received in June 2015. *See* Dkt. No. 99 at 6; Dkt. No. 71 ¶ 74.

The dots are rather challenging to connect. To begin, plaintiffs allege that the interim surveillance safety data necessarily included all the safety endpoint measures. Plaintiffs argue based on FDA guidance that "safety surveillance data" is a "term of art used to describe the entirety of safety data collected during a clinical trial program to ensure that the drug is well tolerated." Dkt. No. 99 at 3. This collection of safety endpoint data would have included measures of ocular safety collected at monthly visits, including visual acuity, an efficacy measure. *Id.* at 3-5. It would also contain, based on the Australian Clinical Trial Handbook, a risk/benefit analysis considering patients' vision scores against adverse events. *Id.* at 5. Tracking patient enrollment, top-line data would have been known for 21 patients by June 2014. *Id.* at 5. Thus, when the June 2015 top-line results came out, plaintiffs claim that this data was already shown in the interim safety analysis.

The alleged connections between measures collected for primary safety endpoints and measures collected for efficacy endpoints are not trivial. There is no doubt that some measures were used for both endpoints, and that metrics to administer rescue injections overlapped with determining the efficacy of VEGF response. Dkt. No. 71 ¶¶ 47-55. The safety and efficacy endpoints may therefore be correlated based on the particulars of this study design. This could reasonably mean that doctors administering rescue injections would have a sense of whether a patient's vision was improving or worsening based on interim monthly safety visits. Or that a "cursory review of the efficacy data would indicate how many rescue injections were given to

each patient." *Id.* ¶ 54. Or that, *retrospectively*, patients' final efficacy results could have been the same from the "very beginning of the trial." Dkt. No. 99 at 5. But this possible correlation, combined with the other facts pleaded, does not lead to a plausible inference that the interim safety surveillance data in June 2014 contained efficacy data *and* showed materially negative efficacy under Rule 9(b).

Plaintiffs effectively invite the Court to speculate about what information besides adverse events was contained in the June 2014 interim data analysis, what the results were, and whether it was analyzed in a way to predict efficacy in the short or long term. The FDA sources plaintiffs cite certainly state that all study data must be monitored for safety events. They do not, however, stand for the proposition plaintiffs urge -- that all study data is "safety surveillance data" that would be presented to and analyzed by defendants. *Id.* at 3. In context, defendants' statements spoke only about the interim data as "safety data" and only as adverse event monitoring. Defendants were clear in public statements that they were receiving notice of serious adverse events from the safety committee, not all safety data. That defendants were experienced in drug trials and were aware the LEI investigators were testing visual acuity, retinal thickness, and leakage are not enough to plausibly allege with specificity that the interim safety surveillance data contained efficacy information. *See id.* ¶ 148.

In addition, as defendants and plaintiffs agree, the final study results showed positive safety end points and "mixed results" of efficacy. *Id.* ¶ 138; Dkt. No. 105 at 1 ("But that vague characterization of the alleged omission makes no sense because, as Plaintiffs' own source confirms, the top-line data that Avalanche disclosed in mid-2015 were 'somewhat positive' and, in fact, established that study participants treated with AVA-101 experienced statistically significant improvements in visual acuity. '42.9% of pts improved/maintained stable vision with =<2 Lucentis injections (vs. 9.1% control).'") Since the final data one year later showed a mix of positive results and a successfully passed safety analysis, plaintiffs must plead more than just these results to prove interim safety results put defendants on notice of efficacy problems.

Plaintiffs say that the Ninth Circuit has allowed "sufficient circumstantial evidence" to survive a motion to dismiss in securities fraud action. Dkt. No. 99 at 6 (citing *In re Finisar Corp.*

Sec. Litig., 646 Fed. Appx. 506 (9th Cir. 2016) (amended memorandum disposition)). But the key word is *sufficient*. In *In re Finisar*, the Ninth Circuit concluded that a complaint sufficiently pleaded falsity to survive a motion to dismiss because "it identifie[d] a specific statement in which Finisar's CEO denied having knowledge of an inventory build-up and down-played concerns of a looming inventory bubble. And it identifie[d] why that statement was misleading by alleging that inventory levels would have been disclosed to defendants during the annual contract negotiations." 646 Fed. Appx. at 507. The inferences do not lead to the same conclusion here.

D. Duty to Disclose Safety Information

Although not entirely clear in the papers, plaintiffs appear to also make a rather novel argument based on the omission of safety data. Plaintiffs do not contend that reporting the full set of interim data would call into question whether the drug was "well tolerated." Dkt. No. 71 ¶¶ 72, 74. They say instead that more safety data should have been reported because it could have shown that *efficacy* was negative. *Id.* ¶ 74 (stating that the failure to disclose all information "prevented the market from connecting the dots and realizing that the primary endpoints were actually measuring many of the same responses [as efficacy endpoints].")

Even assuming defendants "possessed some [safety] data which showed AVA-101's Efficacy Problems," the argument fails. Dkt. No. 99 at 4. To rely on this omissions-based theory of liability, plaintiffs must show that defendants possessed a duty to disclose the withheld information. *Basic*, 485 U.S. at 239 n. 17. Plaintiffs assert without much discussion that "Avalanche had an independent duty to disclose the Efficacy Problems before conducting offerings." Dkt. No. 99 at 2 (citing *WPP Lux. Gamma Three Sarl v. Spot Runner, Inc.*, 655 F.3d 1039, 1056 (9th Cir. 2011)). It is unclear what plaintiffs rely on for this legal conclusion. In *WPP*, the Ninth Circuit affirmed that there may be a duty to disclose insider participation in a secondary offering based on the parties' sale agreement. 655 F.3d at 1049. Although the panel declined to find a generalized duty to disclose based on the nature of the parties' relationship, it agreed that the ROFR/Co-Sale Agreement may have created such a duty. *Id.* at 1049-50. Plaintiffs do not cite a contractual or specific relationship here. To the extent plaintiffs are implying that there is a general duty to "disclose or refrain from trading," the portions plaintiffs

cite speak to disclosure standards for insider trading, not the statutory requirements for public offerings. Dkt. No. 99 at 2.

And plaintiffs overlook the test for disclosing safety information. "[A]s 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." *In Re Rigel*, 697 F.3d at 880 n. 8. Defendants never claimed that the safety data was all the safety results, current safety results, final safety results, or even promising results. *See id.* at 880-81. Though investors may have preferred to have more information (although it is speculative to guess what the data showed), Section 10(b)(5) and Rule 10b-5 do not require such disclosure as long as that which is disclosed does not misrepresent the remaining contents. *Jasin v. Vivus, Inc.*, No. 14-cv-03263-BLF, 2016 WL 1570164, at *14 (N.D. Cal. Apr. 19, 2016). Within the context of the adverse event disclosures, reasonable investors would not be misled to believe that defendants were making predictions as to the final safety or *efficacy* of the drug.

Plaintiffs references to *Reese v. Malone*, 747 F.3d 557, 573 (9th Cir. 2014) do not support a greater duty to disclose safety information. Dkt. No. 99 at 4 (arguing that defendants were required to disclose preliminary findings and adverse events known at the time). In *Reese*, BP's initial statements in response to the first Prudhoe Bay oil spill were misleading because it failed to "explicitly state or even imply that the findings are preliminary or somehow incomplete." *Id.* That is precisely the opposite here; defendants consistently said that the safety data was only interim and subject to revision based on top-line 2015 results.

To be clear, defendants said nothing about the efficacy of AVA-101. The risk of misleading investors is linked to the amount of information defendants chose to disclose. *See Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985-987 (9th Cir. 2008) ("Had defendants released no backlog reports, their failure to mention the stop-work orders might not have misled anyone. But once defendants chose to tout the company's backlog, they were bound to do so in a manner that wouldn't mislead investors as to what that backlog consisted of.") In context, it was not reasonable for an investor to assume the company was speaking as to the efficacy prospects of

the drug. Investors were told that the top-line results would be complete by mid-2015. This was true when spoken and true when the efficacy data was released as promised.

E. Scienter

Because plaintiffs have failed sufficiently to plead falsity, the Court consequently declines to address the parties' scienter arguments at this time. *See In re Mellanox Tech., Ltd.*, No. 13-cv-4909-JD, 2014 WL 7204864, at *5 (N.D. Cal. Dec. 17, 2014). The scienter analysis on the next round of 12(b)(6) motions will likely depend on whether plaintiffs can plead knowledge of as well as factual allegations related to efficacy in the amended complaint.

III. SECURITIES ACT CLAIMS

Plaintiffs also bring strict liability claims "separate and apart" from the Exchange Act under Section 11 and 15 of the Securities Act. Section 11 of the 1933 Securities Act creates a private remedy for any purchaser of a security if "any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading." *In re Daou Sys.*, 411 F.3d 1006, 1027 (9th Cir. 2005); 15 U.S.C. § 77k(a). There is no scienter requirement for liability under Section 11. *Id.* Plaintiffs' securities claims are based on the same statements and omissions made in the 2014 Registration Statement regarding interim data and the risks facing the company. Dkt. No. 71 ¶¶ 220-33, 253, 262.

The parties disagree on whether Rule 9(b) applies to the Section 11 claims. The heightened pleading requirements of the PSLRA do not generally apply to Section 11 claims, but when a complaint "sounds in fraud," plaintiffs are required to allege their claims with increased particularity under Federal Rule of Civil Procedure 9(b). *See Daou*, 411 F.3d at 1027. A complaint "sounds in fraud" when the complaint "allege[s] a unified course of fraudulent conduct and rel[ies] entirely on that course of conduct as the basis of a claim." *Vess*, 317 F.3d at 1103-04. A nominal disclaimer of fraud is unconvincing. *In re Stac Elec. Sec. Litig.*, 89 F.3d 1399, 1405 n. 2. If the Section 11 claims do not allege different misrepresentations or non-fraudulent course of conduct from the 10(b) claims, Rule 9(b) applies to the entirety of the complaint. *See In*

re Rigel, 697 F.3d at 886; *see also In re: Resonant Inc. Sec. Litig.*, No. CV 15–01970 SJO (PJWx), 2016 WL 1737959, at *5-6 (C.D. Cal. Feb. 8, 2016).

At oral argument, plaintiffs effectively conceded that the complaint sounds in fraud. Dkt. No. 114 at 39. In any event, the Court finds that it does. Plaintiffs tried to plead around this issue by disclaiming any allegation of fraud and not incorporating the alleged Section of 10(b) conduct in the Section 11 claim. They bring the Securities Act claims "separate and apart from the claims set forth above under the Exchange Act," Dkt. No. 71 ¶ 216, and allege that these defendants "negligently made untrue statements and omitted material facts," *Id.* ¶ 236. But these statements do not change or hide the fraudulent nature of the conduct alleged. Plaintiffs incorporate all of the factual allegations used for Exchange Act claims to prove that the statements of safety data and disclosed risks in the IPO registration were false and/or misleading. *Id.* ¶ 242. There are no new misstatements for the IPO filing. Plaintiffs assert the "same alleged misrepresentations" concerning the risks and disclosure of interim safety surveillance data. *See In re Rigel*, 697 F.3d at 886. Because the two alleged misrepresentations in the IPO were already dismissed under 10(b), the Section 11 claims are also dismissed without prejudice.

IV. SECTIONS 15 AND 20(a) CLAIMS

Sections 15 and 20(a) "control person" claims both require "underlying primary violations of the securities laws." *Id.* at 886 (citing 15 U.S.C. §§ 77o, 78t(a)). Since plaintiffs have not adequately alleged a violation of Section 10(b) or Section 11, plaintiffs' claims under Section 20(a) and Section 15 must also be dismissed. *See Oregon Pub. Emps. Ret. Fund*, 774 F.3d at 610.

CONCLUSION

The complaint is dismissed with leave to amend. Plaintiffs may file an amended complaint by **December 2, 2016**, consistent with the findings in this Order.

IT IS SO ORDERED.

Dated: November 3, 2016

JAMES DONATO
United States District Judge