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and on behalf of all other persons similarly situated, bring this action against Juno and the individual defendants Hans E. Bishop, Steven D. Harr, and Mark J. Gilbert.

Juno is a development stage biopharmaceutical company traded on the NASDAQ exchange under the symbol "Juno." Juno has an immunotherapy under development known as JCAR015, which focuses on the use of chimeric antigen receptor cells ("Car-T") to treat a type of blood cancer called Acute Lymphoblastic Leukemia ("ALL").

Plaintiffs allege that throughout the Class Period, Defendants repeatedly touted positive results from an incomplete preliminary Phase I trial for JCAR015, and recklessly failed to tell investors that patients were dying from the toxic side effects associated with JCAR015 in the Company's Phase II/ROCKET trial that the Company initiated in the third quarter of 2015.

At the same time, Novartis AG and Kite Pharmaceuticals, Juno's primary competitors in the development of Car-T therapies, were competing to be the first to market an FDA approved Car-T therapy. Because of this, Juno adopted a "fast to market strategy" for JCAR015 with an initial target to launch the therapy in 2017. To achieve this goal, Defendants allegedly repeatedly withheld material information from investors and recklessly misrepresented vital information about the safety and efficacy of JCAR015, including the fact that JCAR015 led to severe neurotoxicity that resulted in death.

In December 2015, Juno decided to introduce a combination of two chemotherapies, cyclophosphamide and fludarabine, to eradicate a patient's existing T-cells before the injection of JCAR015 into the patients enrolled in the Phase II/ROCKET trial. Juno claimed that the combination would increase the efficacy of the Phase II/ROCKET trial.

On July 7, 2016, Defendants disclosed that the FDA had instructed the Company to halt the trial after one patient had died in May of 2016 and two more patients died thereafter. On

this news, Juno's stock price fell by more than 30%. Juno then delayed the launch date of JCAR015 to 2018, impacting its ability to be the first to market a Car-T therapy for ALL.

Plaintiffs claim that Defendants withheld from the market additional facts associating JCAR015 with neurotoxicity and death. Although 15% of patients enrolled in the trial had died due to severe neurotoxicity associated with JCAR015 (three patients out of approximately twenty enrolled), Defendants claimed that it was the addition of fludarabine in combination with JCAR015 that resulted in cerebral edemas, which led to the death of two additional patients.

Plaintiffs allege that Defendants knew or recklessly disregarded that neurotoxicity and the resulting deaths were associated with JCAR015 itself rather than the addition of fludarabine. Defendants had already launched their own investigation, and industry experts knew that (a) reliable and valid scientific studies do not show any correlation between fludarabine and cerebral edema, (b) fludarabine/cyclophosphamide combinations are routinely used to treat chronic lymphocytic patients with no adverse incidence of cerebral edema, (c) most Car-T cell therapies from previous years of use did not result in cerebral edema and (d) severe neurotoxicity reported in the Phase II/ROCKET trial that was associated with JCAR015 led to the death of the patients.

On July 12, 2016, after telling the FDA that it was the fludarabine combined with JCAR015 that led to the deaths, Defendants convinced the FDA to lift the hold and enroll patients in the Phase II/ROCKET trial by utilizing only cyclophosphamide as a preconditioning regimen to attack a patient's existing T-cells. Upon the market learning that the hold had been lifted, the price of Juno common stock rose 9.4%, closing at \$30.42 on July 13, 2016 from its previous day closing price of \$27.79.

From July through November 2016, the Defendants allegedly misled investors to believe that it was the "intensity" of fludarabine, the chemotherapy used to destroy a patient's existing T-cells, combined with JCAR015, or the genetically modified T-cells engineered by Juno, that caused a rapid expansion of the genetically modified T-cells, which resulted in cerebral edemas, leading to the prior deaths of three patients enrolled in the Phase II/ROCKET trial.

At 8:00 a.m. on November 23, 2016, before the market opened, Juno disclosed that it was placing the Phase II/ROCKET trial on a voluntary hold because two additional patients died from cerebral edemas, leading to a total of five deaths of patients treated with JCAR015. The stock price declined \$7.32 per share, or approximately 25%, to close at \$22.56 on November 23, 2016. Since the November 23, 2016 disclosure of two additional deaths, Juno's stock price has continued to decline, and as of the filing of the Amended Complaint, Juno common stock trades under \$19 per share.

Plaintiffs allege that the Individual Defendants in this case "reaped over \$15 million from sales of Juno stock during the Class Period" and that these sales were dramatically out of line with their previous sale of Juno stock.

III. DISCUSSION

A. Legal Standard

In making a 12(b)(6) assessment, the court accepts all facts alleged in the complaint as true, and makes all inferences in the light most favorable to the non-moving party. *Baker v. Riverside County Office of Educ.*, 584 F.3d 821, 824 (9th Cir. 2009) (internal citations omitted). However, the court is not required to accept as true a "legal conclusion couched as a factual allegation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The complaint "must contain sufficient factual matter, accepted as

true, to state a claim to relief that is plausible on its face." *Id.* at 678. This requirement is met when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* The complaint need not include detailed allegations, but it must have "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Absent facial plausibility, a plaintiff's claims must be dismissed. *Id.* at 570.

Securities fraud claims are subject to heightened pleading standards under Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). To satisfy Rule 9(b), a claim of fraud must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Particularity under Rule 9(b) requires the plaintiff to plead the "who, what, when, where, and how" of the misconduct alleged. Kearns v. Ford Motor Co., 567 F.3d 1120 (9th Cir. 2009). Pursuant to the PSLRA, a complaint alleging private securities fraud must "plead with particularity both falsity and scienter." In re Daou Systems, Inc., 411 F.3d 1006, 1014 (9th Cir. 2005) (quoting Gompper v. VISX, 298 F.3d 893, 895 (9th Cir. 2002)). A securities fraud complaint must consequently "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 omissions is made on information or belief, the complaint shall state with particularity all facts on which that belief is formed." Id.; 15 U.S.C. § 78u-4(b)(1). When examining whether plaintiffs' allegations of scienter are sufficient to survive a motion to dismiss under the PSLRA, the Court "must consider all reasonable inferences to be drawn from the allegations, including inferences unfavorable to the plaintiffs." Gompper, 298 F.3d at 897.

B. Claims brought under Section 10(b) and Rule 10b-5

To adequately state a claim under Section 10(b) of the Exchange Act and Rule 10b-5, Plaintiffs must allege facts sufficient to show: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008). Defendants argue the CAC is deficient as to the first and second factors only.

1. Misrepresentations or Omissions

To meet the first element of a claim under Section 10(b) or Rule 10b-5, a complaint must "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). Plaintiffs must further show that Defendants made statements that were "misleading as to a material fact." Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1318, 563 U.S. 27, 179 L. Ed. 2d 398 (2011) (quoting Basic Incorporated, et al. v. Levison et al., 485 U.S. 224, 238, 108 S. Ct. 978, 99 L. Ed. 2d 194 (1988) (emphasis in original). A statement is material when 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, 485 U.S. at 231-32. A statement is misleading if it gives 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. 2007) (quoting Brody v. Transitional Hospitals Corp., 280 F.3d 997, 1006 (9th Cir. 2002)). "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 Pharms., Inc., 840 F.3d 698, 705-06 (9th Cir. 2016) (internal quotation marks and citations omitted). "Whether a statement is misleading and whether adverse facts are adequately disclosed are generally questions that should be left to the trier of fact." In re Immune Response Sec. Litig., 375 F. Supp. 2d 983, 1017 (S.D. Cal. 2005) (citing Fecht v. Price Co., 70 F.3d 1078, 1081 (9th Cir.1995)); In re Amgen Inc. Sec. Litig., 544 F. Supp. 2d 1009, 1018 (C.D. Cal. 2008) ("the truth-on-the-market defense is intensely fact-specific, so courts rarely dismiss a complaint on this basis.").

Plaintiffs set forth Defendants' materially false and misleading statements and omissions in paragraphs 49 through 81 of the CAC. Dkt. #47 at 11-21. Some specific examples include the following paragraphs:

- 50. On June 4, 2016, the start of the Class Period, and several weeks after the purported first patient's death in the Phase II/ROCKET trial, Defendants released a glowing press release about JCAR015, in which Gilbert boasted that:
- "[t]he ongoing efficacy and duration of response for a large percentage of patients, specifically those who do not go on to stem cell transplant, continues to be impressive . . . [t]hese findings provide us with further confidence about our development strategy and the ongoing Phase II Rocket pivotal trial."
- 51. The statement identified in paragraph 50 was materially false and misleading when made because Gilbert (a) cherry picked partial data from an incomplete Phase I study to tout JCAR015's safety and efficacy, and (b) recklessly failed to disclose to investors that a patient had died in the Phase II/ROCKET trial due to severe neurotoxicity associated with JCAR015.
- 58. On June 7, 2016, Harr attended the Jefferies Health Care Conference where he boasted that:

"We have across multiple different studies now, somewhere between 82% and 100% complete remission rates. And, in fact, with our *most advanced product candidates* and our current way we're treating patients, we've now treated 36 patients over the course of the last year in either adults or kids with ALL. And all 36 patients have not only a complete remission, but all 36 patients

have the tougher bar of a complete molecular remission. So, standard of care is kind of a 3% to 5% complete molecular remission rate. We're now at 100%.

... JCAR015 is our fast-to-market strategy. So, it's currently in a trial that, if positive, will serve as a registration study. You can see we have a complete remission rate of around 80% and a complete molecular remission rate of 65%.

(Emphasis added).

62. On June 9, 2016, Bishop attended the Goldman Sachs Global Health Care Conference where he made the following material misrepresentations about JCAR015:

"So, our most advanced program is with the product candidate called JCAR015. It's an adult ALL. It's currently enrolling a multicenter Phase II study which we plan to support approval, accelerated approval."

. . .

"So, we're very encouraged by that response rate in the 70% range. Percentage of patients when you look at all-comers getting to a durable response in the 40% range. JCAR015 by the way is pretty, for today, pretty conventional Car-T cell technology, in that we do know selection of incoming cells from the patient. We take what we start with and make the product."

Id. Plaintiffs also allege that Defendants made false and misleading statements about the cause of the two deaths that occurred in the ROCKET trial in June 2016. ¶¶ 70, 76, 78, 80. Plaintiffs claim that Defendants falsely "led the market to believe that flu[darabine] when combined with JCAR015 was the cause of cerebral edema." ¶ 70; see also ¶ 71 ("Defendants misled the FDA and the market to believe that a combination of flu/cy with JCAR015 was the cause of death").

Defendants argue in their Motion that Plaintiff's theory that Juno "cherry-picked" certain pieces of data "fails because Plaintiffs identify no facts about the MSK Phase I trial that were omitted from the reported interim results, let alone any material facts that would have rendered the reported results misleading." Dkt. #55 at 15-16. Defendants argue that Section

10(b) and Rule 10b-5 "prohibit only misleading and untrue statements, not statements that are incomplete," that Plaintiffs cannot simply allege that the reported MSK Phase I interim results were "partial," and that Plaintiffs must allege that the reported results "affirmatively create[d] an impression of a state of affairs that differ[ed] in a material way from the one that actually exist[ed]." Id. at 16 (citing Brody v. Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002)). Defendants argue that any alleged violation of Juno's Code of Business Conduct and Ethics is irrelevant because "a violation of an internal code of conduct does not equate to a violation of the federal securities laws" under Ninth Circuit law. Id. at 16-17 (citing Retail Wholesale & Dep't Store Union Local 338 Ret. Fund v. Hewlett-Packard Co., No. 14-16433, 2017 U.S. App. LEXIS 955 at *16 (9th Cir. Jan. 19, 2017). Defendants cite In re Rigel Pharms., Inc. Sec. Litig., 697 F.3d 869 (9th Cir. 2012) to support their argument that reporting results from the Phase I trial does not mean that excluding the death from the Phase II trial was a material misrepresentation. Id. at 17-18. Defendants argue that Plaintiffs fail to "allege that the May death would have altered the total mix of information available to investors about the safety profile of JCAR015" because "Juno had already told the market that severe neurotoxicity was one of the two most notable side effects of JCAR015 (Ex. 8 at 18) and that as of November 2015, approximately 28% of 46 adult r/r ALL patients treated with JCAR015 in the MSK Phase I trial had experienced severe neurotoxicity." *Id.* at 18.

Defendants argue that the allegations of false and misleading statements about the cause of the two deaths that occurred in the Phase II trial in June 2016 fail because "the challenged statements about the suspected causes of the deaths are all statements of opinion." Dkt. #55 at 19-20 (citing *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318 (2015)). If the challenged statements are statements of opinion, Plaintiffs must (a) allege

facts that show "the speaker did not hold the belief she professed[,]" or (b) allege specific, undisclosed facts that "call into question the [speaker's] basis for offering the opinion." *Omnicare*, 135 S. Ct. at 1327, 1332. Defendants also argue that Plaintiffs fail to allege that Defendants did not subjectively believe these opinions, fail to allege any omitted or concealed facts, or facts that otherwise preclude Defendants' opinion statements. Dkt. #55 at 22-25.

In Response, Plaintiffs argue that *Matrixx* supports their position that "Defendants had a duty to disclose the [first] death when they chose to tout JCAR015's partial and preliminary clinical trial results." Dkt. #56 at 18. Plaintiffs assert it is "inappropriate to determine whether an undisclosed death is material at the pleadings stage." *Id.* (citing *SEC v. Phan*, 500 F.3d 895, 908 (9th Cir. 2007). Plaintiffs argue that the CAC contains plausible allegations that the failure to disclose that a patient enrolled in the Phase II/ROCKET had died due to a cerebral edema in May 2016 was material to investors. *Id.* at 18-19. Further, that Defendants "were careful not to release information" about the death that occurred in May 2016, "their evident concern about the potential market reaction" and that "Juno's stock price declined by nearly 32% after it disclosed that all three patients died from the same cause," are all cited by Plaintiffs as evidence that materiality has been adequately pled. Dkt. #56 at 19-20 (citing, *inter alia*, *No.* 84 *Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920, 935 (9th Cir. 2003)).

Plaintiffs argue that the materially misleading statements "spoke in factual terms" and therefore "do not involve opinions." *Id.* at 23. Plaintiffs admit that Defendants qualified their misleading statements with words such as "we believe" and "we think," but argue that this does not transform them into statements of opinion under the law. *Id.* (citing *Omnicare*, 135 S. Ct. at 1331 ("the phrases 'we believe' or 'we think' . . . can preface nearly any conclusion, and the

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resulting statements . . . remain perfectly capable of misleading investors"). Purported statements of "opinion" that contain untrue "embedded facts" are not "opinions" shielded from liability under the securities laws. Id. (citing Omnicare, 135 S. Ct. at 1327). Plaintiffs argue that, "[e]ven if Defendants' misrepresentations had a subjective element, Omnicare supports liability here because the misrepresentations conflicted with facts in Defendants' possession and known to them." Id. at 25 (citing Omnicare, 135 S. Ct. at 1329). Plaintiffs argue that Defendants' "truth on the market" affirmative defense cannot be used to dismiss these claims at the pleading stage because it raises questions of fact for the jury. Id. at 26-27 (citing In re Immune, supra).

On Reply, Defendants reiterate prior arguments. Defendants argue that "Plaintiffs do not plead a single fact to suggest, much less show, that Defendants did not honestly hold the opinions they expressed about the deaths, or that any undisclosed facts precluded those opinions." Dkt. #62 at 5. Defendants argue that "Plaintiffs offer no direct evidence that any Defendant sought to mislead investors..." *Id*.

Plaintiffs do not need to prove their case to survive this Motion. The Court finds that Plaintiffs have more than adequately pled misrepresentations or omissions under the PSLRA and Rule 9.2 Plaintiffs have specified each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and when and how the statements were made. See Gompper, 298 F.3d at 895. Taking all facts pled as true, the Court agrees with Plaintiffs that Defendants may have had a duty to disclose the deaths at issue given the statements made in June and July of 2016. See Schueneman, 840 F.3d at 705-06 ("Once

² The Court is able to reach this conclusion without reliance on the numerous exhibits submitted outside of the pleadings by both parties. See Dkts. #55-1; #57-1; #58-#59; #63-#65. Defendants, and to a lesser extent Plaintiffs, are attempting to conduct a trial by paper. The Court does not appreciate being flooded with hundreds of pages of evidence, including medical journal articles and other documents not incorporated by reference into the CAC.

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."); *Matrixx*, 131 S.Ct. at 1321 (the duty to disclose is triggered either by a specific requirement under the relevant regulations or "when necessary to make statements made, in the light of the circumstances under which they were made, not misleading."). Whether Defendants' statements were materially misleading is an intensely fact-specific inquiry. Defendants have failed to show that the statements could *not* have been materially misleading. Even if the risk of death was known to investors, the disclosure of an actual death could easily be viewable by the reasonable investor as having significantly altered the 'total mix' of information, and it appears investors reacted negatively to the subsequent disclosure with a drop in Juno's stock price. Based on the undeveloped record currently before the Court, there are simply too many questions of fact to dismiss this case a matter of law.

2. Scienter

The PSLRA requires that the complaint "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). To satisfy this state of mind element, the "complaint must allege that the defendant made false or misleading statements either intentionally or with deliberate recklessness." *In re Verifone Holdings, Inc. Sec. Litig.*, 704 F.3d 694 (9th Cir. 2012) (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009) (internal alterations omitted)). While facts showing a motive and opportunity to commit fraud "provide some reasonable inference of intent," they are "not sufficient to establish a strong inference of deliberate recklessness." *In re Verifone*, 704 F.3d at 701. The Supreme Court has instructed that allegations are to be reviewed "holistically" in determining whether scienter has been adequately pled. *Id.* (quoting *Matrixx*,

131 S.Ct. at 1324). At the end of the day, "[a] complaint will survive... only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324, 127 S. Ct. 2499, 168 L. Ed. 2d 179 (2007).

Defendants argue "[t]here are no facts alleged about any Defendant's state of mind, knowledge, or access to information at any point during the Class Period that would have alerted Defendants that JCAR015 was per se unacceptably unsafe," and that "[t]he only plausible inference from the facts alleged is that the Defendants honestly believed their stated opinions regarding the suspected causes of the May and June deaths." Dkt. #55 at 29. Defendants argue that the allegations of insider trading are insufficient to show scienter, citing *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1999) for the proposition that "insider trading is suspicious only when it is 'dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." *Id*.

In response, Plaintiffs argue that the facts in this case are "almost identical" to those in *Schueneman*, where the Ninth Circuit reversed the district court's dismissal of plaintiff's complaint on the ground that "the complaint sufficiently alleged that the defendants withheld material information that undermined the prospect of FDA approval of their drug." Dkt. #56 at 30 (citing 840 F.3d at 709). Plaintiffs argue that scienter may be satisfied "by a scienter theory that infers that facts critical to a business's 'core operations' or an important transaction are known to a company's key officers." *Id.* at 30-31 (citing *S. Ferry LP No. 2 v. Killinger*, 542 F.3d 776, 783-84 (9th Cir. 2008)). Plaintiffs argue that "in addition to adequately alleging scienter based on deliberate recklessness and the core operations doctrine, the CAC also alleges

compelling motive allegations," referring to Defendants' motive to win the race to the market and the CAC's allegations of suspicious stock sales in the class period. *Id.* at 31-36.

On Reply, Defendants argue that "unlike the unequivocal statements in *Schueneman* that "all animal studies" supported approval, Plaintiffs cannot identify any statement that affirmatively misrepresented the clinical data in either the MSK Phase I or ROCKET trial." Dkt. #62 at 15. Defendants argue that they "accurately described the MSK Phase I data" and that "Plaintiffs fail to allege how the May death changed the safety profile or outlook for JCAR015 or contradicted any of Defendants' statements." *Id.* Defendants argue that Plaintiff's motive allegations do not establish scienter. *Id.* at 16-19.

The Court finds *Schueneman* instructive and on point. After reviewing the CAC holistically, the Court finds that Plaintiffs have pled scienter with sufficient particularity through allegations that show deliberate recklessness and point to compelling possible motivations for Defendants to make the alleged misleading statements and omissions. Again, despite Defendants' arguments to the contrary, Plaintiffs need not prove these claims to survive this Motion.

C. Claims brought under Section 20(a)

A Section 20(a) claim requires underlying primary violations of the securities laws. 15 U.S.C. §§ 78t(a); *In re Rigel Pharms., Inc. Secs. Litig.*, 697 F.3d 869, 886 (9th Cir. 2012). Because Plaintiffs have satisfactorily pled an underlying violation of the federal securities laws, this claim will not be dismissed.

IV. CONCLUSION

Having reviewed the relevant pleadings and the remainder of the record, the Court hereby finds and ORDERS that Defendants' Motion to Dismiss, Dkt. #55, is DENIED.

DATED this 14 day of June, 2017.

RICARDO S. MARTINEZ

CHIEF UNITED STATES DISTRICT JUDGE