UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE REGULUS THERAPEUTICS INC. SECURITIES LITIGATION

Case No.: 3:17-cv-0182-BTM-RBB

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS AND GRANTING PLAINTIFFS LEAVE TO AMEND

[ECF No. 22]

This is a putative securities class action filed on behalf of all purchasers of common shares of Regulus Therapeutics, Inc. ("Regulus") between February 17, 2016 and June 12, 2017, inclusive (the "Class Period"). Plaintiffs allege that Defendants Regulus, Joseph P. Hagan, Paul C. Grint, M.D., and Michael Huang, M.D.[1] made misleading statements regarding a pharmaceutical product being

[1] Defendant Grint was Regulus's Chief Executive Officer ("CEO") from June 1, 2015 through his resignation on May 4, 2017. (ECF No. 19, ¶ 17.) Defendant Hagan was Regulus' Chief Operating Officer from January 4, 2016 through his

developed by Regulus that artificially inflated its common stock prices during the Class Period. Based thereon, Plaintiffs assert claims for violation of Section 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), Rule 10b-5, 17 C.F.R. § 240.10b-5, and Section 20(a) of the Securities Exchange Act, 15 U.S.C. § 78t(a). (ECF No. 19.) Defendants move to dismiss Plaintiffs' Consolidated Complaint under Federal Rule of Civil Procedure 12(b)(6). (ECF No. 22.)

I. BACKGROUND

Regulus is a biopharmaceutical company that was developing a drug ("RG-101") to treat the hepatitis C virus ("HCV"). (ECF No. 19, ¶¶ 2, 27-28.) As part of the process of seeking approval from the United States Food and Drug Administration ("FDA") to market and sell RG-101 to the public, Regulus was required to submit an investigational new drug application ("IND") to obtain approval to test RG-101 on human subjects (*i.e.*, to engage in "clinical" studies). *See* 21 C.F.R. §§ 312.20, 312.40. Generally, an IND must contain, inter alia, "[a] summary of the pharmacological and toxicological effects of the drug in animals, and to the extent known, in humans."[2] 21 C.F.R. § 312.23(a)(5)(ii).

In late 2015 and early 2016, Regulus initiated its first clinical trials. (ECF No. 19, ¶¶ 3-4.) On February 17, 2016, Regulus issued a press release in which it announced interim results from one of the clinical trials. (*Id*. ¶ 56.) Notably, the

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appointment as CEO on May 4, 2017. (*Id*. ¶ 18.) Defendant Huang was Regulus's Vice President of Clinical Development during the Class Period. (*Id*. ¶ 19.)

[2] The pharmacological and toxicological effects of the drug under investigation are often gleaned from initial non-human studies conducted in laboratories and/or utilizing animals, referred to as "preclinical" or "nonclinical" studies. (*See* ECF No. 22-1, at 10; ECF No. 23, at 9.)

press release included a statement that "[t]o date, RG-101 has been generally well tolerated with the majority of adverse events considered mild or moderate, and with no study discontinuations."[3] (*Id*. ¶¶ 56-57; *see also id*. ¶ 64.) In a conference call discussing the interim results held that same day, however, Defendants disclosed two serious adverse events (each, an "SAE") experienced during the study and that an independent investigator had determined that one of the SAEs was "possibly" related to RG-101.[4] (*Id*. ¶¶ 58, 61; ECF No. 22-4, at 7, 11.) Nevertheless, Defendant Huang downplayed the importance of these SAEs during the call, noting that they "occurred several weeks after dosing" and in a patient population suffering from "chronic hepatitis C [and] other medical issues." Defendant Grint did the same, stating that the SAEs were "not concerning" to Defendants because the test subjects had HCV and thus "[t]here's multiple other comorbidities as you follow a set of patients like this over a prolonged period of time, [such that] you are going to get serious adverse events reported by definition." (ECF No. 19, ¶ 61; ECF No. 22-4, at 11, 14.) Defendant Grint repeated

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[3] Regulus reiterated similar statements in subsequent press releases and regulatory filings. (*See* ECF No. 19, ¶ 57 (February 17, 2016 Form 8-K filing), ¶ 64 "February 22, 2016 press release and Form 8-K filing), ¶ 70 (February 23, 2016 Form 10-K filing), ¶ 74 (April 15, 2016 press release), ¶ 77 (April 15, 2016 conference call), ¶ 81 (May 2, 2016 press release), ¶ 84 (May 2, 2016 earnings call), ¶ 88 (May 2, 2016 Form 10-Q filing), § 112 (November 1, 2016 Form 10-Q filing), ¶ 128 (March 2, 2017 Form 10-K filing).

[4] An adverse event is "serious" if "it results in . . . [d]eath, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition." 21 C.F.R. § 312.32.

similar messaging in an earnings call held on February 22, 2016. (ECF No. 19, ¶ 67 ("[W]e're certainly not worried about the safety profile of RG-101 or in fact the reports SAEs. . . . Just to remind you, these are patients that have chronic hepatitis C, they have multiple other co-morbid conditions, and we're following them for very prolonged periods of time, and we'd expect to see other things reported over a follow-up period.").)

On April 15, 2016, Regulus hosted a conference call to present additional interim results from the clinical trials, including further discussion of the two SAEs identified during the February 16 conference call. (*Id*. ¶ 77; *see also* ECF No. 22-5 (April 15, 2016 conference call edited transcript).) During that call, Defendant Grint stated that while "[i]nvestigators . . . determined that" the first SAE, a "transient episode of dyspnea,"[5] was "not related to" RG-101, further investigation was ongoing to determine the cause of the second SAE, "an event of jaundice."[6] (ECF No. 19, ¶ 77-78; *see also* Doc. 22-6, at 16 (Regulus slide presentation accompanying conference call stated "Jaundice (Daklinza arm) – Possibly related to Study Drug[.] 56-year old male presented with jaundice, fatigue, abdominal pain, and nausea 21 days after completion of therapy. Clinical chemistry showed significantly elevated total and direct bilirubin with minimal changes in transaminases. Ultrasound indicated potential sludge/debris in biliary tract and

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[5] *i.e.*, difficult or labored breathing.

[6] "Jaundice occurs when there is too much bilirubin (a yellow pigment) in the blood – a condition called hyperbilirubinemia." (ECF No. 19, ¶ 43.) "Bilirubin is formed when hemoglobin (the part of red blood cells that carries oxygen) is broken down as part of the normal process of recycling old or damaged red blood cells. Bilirubin is carried in the bloodstream to the liver, where it binds with bile. Bilirubin is then moved through the bile ducts into the digestive tract, so that it can be eliminated from the body. Most bilirubin is eliminated in stool, but a small amount is eliminated in urine. If bilirubin cannot be moved through the liver and bile ducts quickly enough, it builds up in the blood and is deposited in the skin. The result is jaundice." (*Id*. ¶ 44.)

gallbladder wall thickening. Additional medical history included diabetes (not well-controlled) and alcohol use. Work-up ongoing to determine etiology. Patient currently recovering and remains active in study with favorable virologic response.").) Nevertheless, Defendant Hagan stated during the call that "treatment with RG-101 has shown an encouraging and consistent safety profile in clinical studies to date." (ECF No. 19, ¶ 77.)

On June 27, 2016, Regulus issued a press release announcing that the FDA had verbally issued a "clinical hold" on RG-101 after Regulus reported a second jaundice SAE in another clinical trial.[7] (*Id*. ¶ 91.) In a conference call held that same day, Defendant Grint again downplayed the importance of the SAEs, stating that both patients had comorbidities and attendant treatment that could potentially explain their jaundice. (*Id*. ¶¶ 95-96; ECF No. 22-7, at 4, 8 ("In addition to chronic hepatitis C, the [first jaundice SAE] patient had poorly controlled diabetes, requiring insulin therapy, and a history of alcohol abuse. . . . This second serious adverse event of jaundice occurred 117 days after receiving a single dose of RG-101 in our Phase 1 US IND study in an HCV patient who also had end-stage renal disease requiring dialysis. In addition to his renal insufficiency and HCV infection, this patient also had poorly controlled type II diabetes requiring insulin therapy, coronary artery disease with prior open-heart surgery, high cholesterol, high blood pressure, and recent herpes zoster infection requiring the oral antiviral, Acyclovir. The patient is on over a dozen concomitant medications, including blood pressure

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[7] "A clinical hold is an order issued by FDA to the sponsor of an IND application to delay a proposed clinical investigation or to suspend an ongoing investigation." (ECF No. 19, ¶ 38.) "The FDA may issue a clinical hold in several circumstances, including when human subjects are or would be exposed to an unreasonable and significant risk of illness or injury; or the IND application does not contain sufficient information needed to assess the risks to subjects of the proposed studies." (*Id*. ¶ 39.)

medications, statin therapy, and insulin. . . . [W]e only have two cases, but if one looks for common themes both these patients had long-standing type II diabetes. They were both poorly-controlled diabetics, on insulin, with a number of other underlying medical conditions.").) In response to an analyst's inquiry whether the FDA would require Regulus to identify the cause of the jaundice SAEs prior to the FDA lifting the clinical hold, Defendant Grint stated that, despite having an "extensive nonclinical program on RG-101, including dosing in nonhuman primates," they had not observed "any hint of bilirubin elevation" in any of the nonclinical studies, the results of which were included in the original IND submission that led to the initiation of the clinical studies. In response to the analyst's follow-up inquiry whether any of the preclinical studies "uncovered anything of bilirubin or liver toxicity source," Defendant Grint stated "no[,] Bilirubin is not something that we've seen. . . . we haven't seen any bilirubin increases in our chronic tox studies." (ECF No. 19, ¶ 96; ECF No. 22-7, at 9-10.) Regulus's common stock share price declined from $5.01 on June 27, 2016 to $2.54 on June 28, 2016. (ECF No, 19, ¶ 93.)

On July 27, 2016, Regulus issued a press release announcing that it had "received written communication from the [FDA] outlining information required to resolve the clinical hold[,]" including, *inter alia*, "detailed safety data analysis from preclinical and clinical studies; exploration of potential mechanisms for hepatoxicity in non-clinical models; [and] review and input from independent hepatoxicity experts[.]" (ECF No. 19, ¶ 100.) Regulus's common stock share price declined from $4.10 on July 27, 2016 to $3.57 on July 28, 2016. (*Id*. ¶ 102.)

On August 2, 2016, Regulus held an earnings call to discuss its 2016 second quarter results. (*Id*. ¶ 103; ECF No. 22-8 (August 2, 2016 earnings call edited transcript).) During that call, Defendant Grint addressed the FDA's request for documentation, stating that "[m]uch of what is being asked of us is information we have or can obtain over the next couple of months." In response to analysts' follow-

up questions regarding how many additional studies would be needed to satisfy the FDA, Defendant Grint stated that Regulus had already "conducted a significant formal toxicology program" with regards to RG-101, that Defendants had "not seen increases in bilirubin in a number of different animal species or studies that [they had] conducted[,]" that there were "a limited set of [additional] studies [they were] contemplating," and that, while "there [was] no obvious mechanism that would associate" RG-101 with the increases in bilirubin that caused the jaundice SAEs, they "ha[d] some ideas . . . [they would] continue to pursue." (ECF No. 19, ¶ 103; ECF No. 22-8, at 4, 6-9.)

On December 6, 2016, Regulus held another conference call wherein it discussed RG-101's progress with corporate analysts. (ECF No. 19, ¶ 115; ECF No. 22-10 (December 6, 2016 conference call edited transcript).) During that call, Grint outlined efforts taken by Regulus in response to the FDA's request for information and stated that "[w]e've undertaken a lot of additional work that we believe that we have a good idea of how [RG-]101 maybe [sic] associated with some of the impacts we see in patients and we believe that we have a good part forward and that's basically what we're going to be submitting to the FDA." Asked to elaborate on "how [RG-]101 maybe [sic] associated with some of the side effects," Grint stated that while Regulus had "done a lot of pre-clinical work" and had not "seen any changes in bilirubin" therein, continued investigation had revealed some "interesting biology" that would be included in Regulus's response to the FDA. (ECF No. 19, ¶ 115; ECF No. 22-10, at 31, 33.)

On January 27, 2017, Regulus issued a press release announcing that, despite having submitted a "complete response to the FDA's initial request for information, which included identification of a potential mechanism of hyperbilirubinemia . . . [and] a proposal to mitigate this risk[,]" the FDA had decided to maintain its clinical hold on RG-101 until it received "a final preclinical study safety report", final results from certain clinical trials, and additional expert

feedback and that Regulus anticipated providing its complete response to the FDA in the "fourth quarter of 2017." (ECF No. 19, ¶ 118; ECF No. 22-11 (press release).) Regulus's common stock share price declined from $2.25 on January 27, 2017 to $1.30 on January 30, 2017. (ECF No, 19, ¶ 120.)

On March 2, 2017, Regulus issued a press release and held a conference call in which it announced that four additional SAEs involving elevated bilirubin (but not necessarily jaundice) had been reported in the RG-101 clinical trials.[8] (ECF No. 19, ¶¶ 121, 123.) On May 4, 2017, Regulus issued a press release that announced the resignation of Grint as well as the severance compensation he would receive from Regulus. (*Id*. ¶ 131; ECF No. 22-12 (press release).) In an earnings call held that same day, Grint stated that his resignation was part of a larger "corporate restructuring to streamline [Regulus's] operations" and "extend [its] cash runway through potential significant milestones in 2018." (ECF No. 19, ¶ 132.) Regulus's common stock share price declined from $1.70 on May 4, 2017 to $1.20 on May 5, 2017. (*Id*. ¶ 134.)

On June 12, 2017, Regulus issued a press release announcing that "[c]omprehesive pre-clinical investigation and thorough evaluation of the clinical data from RG-101 . . . led to the identification of a bilirubin transport mechanism as the likely cause for the cases of hyperbilirubinemia" observed in the clinical studies, Regulus was discontinuing the development of RG-101. (ECF No. 19, ¶ 135.) Regulus's common stock share price declined from $1.40 on June 9, 2017 to $1.10 on June 12, 2017. (ECF No, 19, ¶ 137.)

II. STANDARD

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) should be granted only where a plaintiff's complaint lacks a "cognizable legal theory" or

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[8] Thus, there was a total of six reported SAEs involving elevated bilirubin levels and/or jaundice in all clinical studies involving RG-101.

sufficient facts to support a legal claim. *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1988). When reviewing a motion to dismiss, the allegations of material fact in the plaintiff's complaint are taken as true and construed in the light most favorable to the plaintiff. *Parks Sch. of Bus., Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Because Plaintiffs claims allege securities fraud, however, they are not subject to the general notice pleading standard of Federal Rule of Civil Procedure 8(a). Rather, Plaintiffs "must meet the higher, exacting pleading standards of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (PSLRA)." *Or. Pub. Emps. Retirement Fund v. Apollo Grp., Inc.*, 774 F.3d 589, 603-04 (9th Cir. 2014) (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313-14 (2007)). Nevertheless, dismissal is appropriate only where "the complaint fails to 'state a claim to relief that is plausible on its face." *Curry v. Yelp Inc.*, 875 F.3d 1219, 1224–25 (9th Cir. 2017) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Federal Rule of Civil Procedure 9(b), which demands heighted pleading standards for fraud or mistake, applies to all elements of a claim under Section 10(b). *Id.* at 605. Rule 9(b) requires that "[in] alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see also In re Cutera Sec. Litig.*, 610 F.3d 1103, 1108 (9th Cir. 2010) ("To surmount a motion to dismiss, the investors must thus plead facts sufficient to plausibly articulate with particularity the circumstances constituting fraud." (internal quotations and citations omitted)). The PSLRA requires that for any misleading statement or omission alleged in a securities fraud action, "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)(1); *Or. Pub. Emps. Retirement Fund,* 774 F.3d at 604. In addition, when

proving "that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission . . . 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); *Or. Pub. Emps. Retirement Fund,* 774 F.3d at 604.

III. REQUEST FOR JUDICIAL NOTICE

In support of their motion to dismiss, Defendants filed a request for judicial notice ("DRJN") of twenty-five documents attached as Exhibits A through Y thereto. (ECF No. 22-2; *see also* ECF Nos. 22-3 to 22-28.) Included therein are transcripts and a slide presentation from Regulus's various conference calls (Exs. A to G), press releases issued by Regulus (Exs. H & I), various filings submitted to the United States Securities and Exchange Commission ("SEC") (Exs. J to Q), analyst reports (Exs. R to X), and Regulus's historical stock price data (Ex. Y). In support of its response in opposition, Plaintiffs filed a request for judicial notice ("PRJN") of two documents attached as Exhibits 1 and 2 thereto. (ECF No. 23-1; *see also* ECF Nos. 23-2 to 23-4.) Included therein are two additional analyst reports (Exs. 1 & 2). Plaintiffs do not oppose the DRJN and Defendants do not oppose the PRJN.

A court presented with a motion to dismiss a securities class action complaint must consider the complaint in its entirety, "as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, including documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc.*, 551 U.S. at 323. The vast majority of the documents submitted with the DRJN are either judicially-noticeable SEC filings or historical stock prices, or, as in the case of the transcripts, press releases, and slide presentation, are incorporated by reference in the Complaint. *See Metzler Inv. GMBH v. Corinthian Colleges, Inc*., 540 F.3d 1049, 1064 n.7 (9th Cir. 2008) (SEC filings and historical stock price data subject to judicial notice on a motion to dismiss); *In re Amgen Inc. Sec. Litigation*, 544 F. Supp. 2d 1009, 1024

(C.D. Cal. 2008) (taking judicial notice of a transcript of a meeting, details of which were set forth in complaint, pursuant to doctrine of incorporation by reference). Further, courts have previously taken judicial notice of analyst reports "not in order to take notice of the truth of the matters asserted therein, but in order to determine what may or may not have been disclosed to the public." *Zamir v. Bridgepoint Educ., Inc.*, Case No. 15-CV-408-JLS-DHB, 2016 WL 3971400, at *4 (S.D. Cal. July 25, 2016) ("While the . . . analyst reports . . . may not be considered for the truth of their contents, the Court may properly look to those reports to understand the total mix of information available to investors over the class period." (internal quotations, citations, and alterations omitted)). Accordingly, the Court grants both Defendants' DRJN and Plaintiffs' PRJN.

IV. DISCUSSION

Section 10(b) makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered … any manipulative or deceptive device or contrivance…." 15 U.S.C. § 78j(b). Under Rule 10b–5, which implements section 10(b), it is unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5(b); *see also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37 (2011) ("We have implied a private cause of action from the text and purpose of § 10(b)." (citing *Tellabs*, 551 U.S. at 318)). To plead a claim under Section 10(b) and Rule 10b–5, "Plaintiffs 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." *Or. Pub. Emps. Retirement Fund*, 774 F.3d at 603 (citing *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). In their instant motion to dismiss, Defendants challenge whether Plaintiffs have sufficiently

pleaded the first (material misrepresentation or omission), second (scienter), and sixth (loss causation) elements of its claims under Section 10(b) and Rule 10b-5. The Court addresses each in turn.

A. Material Misrepresentation or Omission

To establish the first element of their Section 10(b)/Rule 10b-5 claims, Plaintiffs "must show that each defendant made a statement that was *misleading* as to a *material fact*." *Matrixx Initiatives*, 563 U.S. at 38 (internal quotations and citations omitted) (emphasis original); *see also* 15 U.S.C. § 78u–4(b)(1). "[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." *In re Cutera*, 610 F.3d at 1109 (citations omitted). A fact 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." *Matrixx Initiatives*, 563 U.S. at 38 (internal quotations and citations omitted).

Plaintiffs argue that "Defendants misled investors as to the safety of RG-101" when Defendants "severely downplayed the connection between RG-101 and liver toxicity and jaundice . . . [and] made statements to investors about the positive safety profile of RG-101." (ECF No. 23, at 16.) According to Plaintiffs, Defendants' statements were misleading because, at the time they were made, Defendants "had preclinical and nonclinical data linking RG-101 to liver toxicity, along with a conclusion from one of the company's investigators possibly linking RG-101 to Jaundice." (*Id.* at 23 (citing ECF No. 19, ¶¶ 61, 100, 103, 106, 109, 128).) And while not explicitly pleaded in their Consolidated Complaint, Plaintiffs argue that, based upon Regulus's purported assertion that "it did not investigate the mechanism for the jaundice until July 2016[ ] after they were forced to do so by the FDA[,]" Defendants' statements lacked sufficient factual basis because they were made "without looking into the preclinical information, nonclinical models, and

information already in Regulus'[s] possession" and were further misleading because Defendants failed to "disclose that they had not investigated or researched the mechanism of liver toxicity to determine whether RG-101 was the cause of the Jaundice SAE." (*Id*. at 18-19, 22 (citing ECF No. 22-1, at 12-13, 24).) Thus, Plaintiffs argue Defendants' statements created "the false impression that (a) Regulus had reviewed its preclinical and nonclinical information to research and investigate whether RG-101 could be the underlying cause of the Jaundice SAE; and (b) that the research indicated that the Jaundice SAE resulted from other issues with the patients and had no link to RG-101." (*Id.* at 15-16.) In response to Defendants' argument that the majority of the complained-of statements were statements of opinion rather than fact, Plaintiffs argue that such statements are nonetheless actionable because they "omitted material facts about how Defendants reached [their] conclusions" because they "did not disclose the existence of preclinical and nonclinical data that . . . suggested a link between RG-101 and liver toxicity . . . [or] that [Defendants] had not investigated or researched the mechanism of liver toxicity to determine whether RG-101 was the cause of the Jaundice SAE." (*Id.* at 19 (citing *In re Atossa Genetics Inc Sec. Litig.*, 868 F.3d 784, 802 (9th Cir. 2017) ("[F]or an opinion to be misleading by omission, (1) the statement must omit material facts about the defendant's inquiry into or knowledge concerning a statement of opinion, and (2) those facts must conflict with what a reasonable investor would take from the statement itself." (internal quotations, citations, and alterations omitted))).)

Given the vague and impressionistic nature of Plaintiffs' allegations regarding the contradictory preclinical and nonclinical results purportedly held by Defendants, the Court has difficulty concluding that Plaintiffs' allegations sufficiently establish the first element of their Section 10(b) claims. *See Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1230–31 (9th Cir. 2004) ("[A] proper complaint which purports to rely on the existence of internal

reports would contain at least some specifics from those reports as well as such facts as may indicate their reliability." (internal quotations and citations omitted)). Because Plaintiffs have failed to provide specifics as to how and to what extent these purported preclinical and nonclinical results "suggested a link between RG-101 and liver toxicity," the Court is unable to determine whether the complained-of statements differed materially from the actual state of affairs that existed at the time they were made and whether a reasonable investor would have considered the disclosure of such results to significantly alter the total mix of information made available. Indeed, the statements whose veracity is most strongly challenged by the purported existence of preclinical and nonclinical studies showing a link between RG-101, liver toxicity, and the Jaundice SAEs are Defendant Grint's June 27, 2016 statements that Defendants had not observed "any hint of bilirubin elevation" in the nonclinical studies or "chronic tox studies." (ECF No. 19, ¶ 96.) Without a particularized description of the relevant analysis and findings of the purported contradictory preclinical and nonclinical studies, however, the Court cannot determine whether such purported preclinical/nonclinical analysis or findings do in fact contradict these statements such that they became misleading and, even if they did, would have been considered material to a reasonable investor. *See Matrixx Initiatives*, 563 U.S. at 44 ("[Section] 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." (internal quotations, citations, and alterations omitted)). This is particularly true for Defendants' statements that are more appropriately classified as opinions. *See Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, ____ U.S. ____, 135 S. Ct. 1318, 1329 (2015) ("An opinion statement . . . is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way. Reasonable investors understand that opinions sometimes

rest on a weighing of competing facts . . . . [and a] reasonable investor does not expect that every fact known to an issuer supports its opinion statement."); *but see Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 706 (9th Cir. 2016) ("[O]nce defendants choose 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." (internal quotations, citations, and alterations omitted)). And while Defendants' appear to concede that a failure to conduct meaningful inquiries before making their complained-of statements could render such statements misleading (*see* ECF No. 24, at 7-8), the facts upon which such argument relies are not presently pled in Plaintiff's Consolidated Complaint and therefore such theories are unavailing. *See City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615 (9th Cir. 2017) ("A plaintiff cannot just say that the issuer failed to reveal the basis for the opinion at issue. Instead, an investor must call into question the issuer's basis for offering the opinion by identifying particular (and material) facts going to the basis for the issuer's opinion – facts about the inquiry the insurer did or did not conduct or the knowledge it did or did not have – whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." (internal quotations and alterations omitted) (citing *Omnicare*, 135 S. Ct. at 1332)).

Accordingly, the Court concludes that Plaintiffs have failed to sufficiently plead the falsity of each statement at issue.

B. Scienter

To establish the second element of their Section 10(b)/Rule 10b-5 claims, Plaintiffs "must plead facts that lead to a strong inference of scienter." *ESG Capital Partners, LP v. Stratos*, 828 F.3d 1023, 1035 (9th Cir. 2016) (citing *Tellabs*, 551 U.S. at 322); *see also* 15 U.S.C. § 78u–4(b)(2)(A). "To adequately demonstrate that the [Defendants] acted with the required state of mind, [Plaintiffs'] complaint

must allege that the [Defendants] made false or misleading statements either intentionally or with deliberate recklessness." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009) (internal quotations and citations omitted). "Deliberate recklessness is an extreme departure from the standards of ordinary care which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Align Tech.*, 856 F.3d at 619 (internal quotations, citations, alterations and emphasis omitted); *see also In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 390 (9th Cir. 2010) ("In the securities context, an actor is reckless if he had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort." (internal quotations and citations omitted). "[F]acts showing mere recklessness or a motive to commit fraud and opportunity to do so provide some reasonable inference of intent, but are not sufficient to establish a strong inference of deliberate recklessness." *Align Tech.*, 856 F.3d at 619.

"A securities fraud 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.'" *Curry*, 875 F.3d at 1226 (quoting *Tellabs*, 551 U.S. at 324)). "The inference that the defendant acted with scienter need not be irrefutable, i.e., of the 'smoking-gun' genre, or even the 'most plausible of competing inferences' . . . [but] must be more than merely 'reasonable' or 'permissible' – it must be cogent and compelling." *Id*. (alterations omitted) (quoting *Tellabs*, 551 U.S. at 324); *see also Stratos*, 828 F.3d at 1035 ("[The plaintiff] need not prove its case at the outset. Rather, it has to provide a narrative of fraud – facts which, if true, substantiate an explanation at least as plausible as a nonfraudulent alternative."); *but see Tellabs*, 551 U.S. at 326 ("[O]missions and ambiguities count against inferring scienter, for plaintiffs must state with particularity facts giving rise to a strong inference that the defendant acted with the

required state of mind." (internal quotations and citations omitted)). "We conduct a two-part inquiry for scienter: first, we determine whether any of the allegations, standing alone, are sufficient to create a strong inference of scienter; second, if no individual allegation is sufficient, we conduct a 'holistic' review of the same allegations to determine whether the insufficient allegations combine to create a strong inference of intentional conduct or deliberate recklessness." *Curry*, 875 F.3d at 1226; *cf. Tellabs,* 551 U.S. at 322–23 ("The inquiry . . . is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.").

Plaintiffs argue they have sufficiently demonstrated Defendants' scienter by alleging they "had nonclinical and preclinical information that indicated liver toxicity in their studies" and "received a report from their investigator that RG-101 was 'possibly' the cause of the reported Jaundice SAE" when they made their complained-of statements.[9] (ECF No. 23, at 24 (citing ECF No. 19, ¶¶ 61, 100, 103); *see also* ECF No. 19, ¶¶ 139-46.) Based thereon, Plaintiffs argue that

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[9] Plaintiffs argue that "Defendants even stated that Regulus already had most of the information later requested by the FDA that caused the FDA to put a clinical hold on RG-101 because it was unsafe." (ECF No. 23, at 24 (citing ECF No. 19, ¶ 103).) Plaintiffs misrepresent Defendants' statements. (*See* ECF No. 19, ¶ 103 (Defendant Grint's August 2, 2016 statements that "[m]uch of what is being asked of us is information we have or can obtain over the next couple of months," "we have conducted a significant formal toxicology program with RG-101. There is a lot of information in the IND that exists and I think to be helpful to the FDA we can take a lot of that information and put into a format that perhaps would be more helpful with regard to answering that question," and "there is a limited set of studies that we are contemplating conducting on top of, as I said, what we have already done which is a significant program"); *see also* id. ¶ 135 (Regulus's June 12, 2017 press release stating that "[c]omprehensive pre-clinical investigation and thorough evaluation of the clinical data from RG-101 has led to the identification of a bilirubin transport mechanism as the likely cause for the cases of hyperbilirubinemia in the RG-101 program").)

"Defendants either knew about the internal nonclinical models connecting RG-101 with liver toxicity, or deliberately disregarded the results of the nonclinical models altogether when discussing whether there could be a link between RG-101 and the Jaundice SAEs." (ECF No. 23, at 24 (citing ECF No. 19, ¶¶ 104, 139).) Plaintiffs also argue they have demonstrated Defendants were motivated to misrepresent the viability of RG-101 because "Regulus was able to obtain additional funds via debt financing that it otherwise would not have been unable to gain" and because the individual Defendants received lucrative salaries and other compensation that were related to Regulus's performance. (*Id*. at 26-27 (citing ECF No. 19, ¶¶ 132, 148); *see also* ECF No. 19, ¶¶ 147-53.) Finally, Plaintiffs argue that Defendant Grint's resignation from Regulus approximately five weeks prior to the announcement that Regulus would cease development of RG-101 after identifying it as the cause of the Jaundice SAE "suggests that Grint was in fact fired in connection with his reckless disregard to the false statements about the safety of RG-101." (ECF No. 23, at 27-28; *see also* ECF No. 19, ¶¶ 154-57.)

As an initial matter, Defendants publicly disclosed the existence of the investigator's conclusion that RG-101 was "possibly" the cause of one of the SAEs during the February 17, 2016 conference call and further elaborated upon that conclusion during the April 15, 2016 conference call. (ECF No. 19, ¶ 58, 61, 77, 78; ECF No. 22-4, at 11; ECF No. 22-5, at 5; ECF No. 22-6, at 16.) Thus, it is unclear to the Court how the existence of the investigator's conclusion cuts against Defendants given that any investors were in possession of the same information during the Class Period. Further, as to the alleged internal preclinical and nonclinical reports that indicated that RG-101 could cause liver toxicity, Plaintiffs fail to plead any particularized facts demonstrating the individual Defendants had actual knowledge of or access to the relevant reports and/or that the conclusion that RG-101 had a propensity to increase bilirubin levels was so obvious that Defendants' knowledge thereof may be presumed. *See Curry*, 875 F.3d at 1227

("[A]s a general matter, corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter – at least absent some additional allegation of specific information conveyed to management and related to the fraud or other allegations supporting scienter." (internal quotations, citations, and alterations omitted); *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008) ("Where a complaint relies on allegations that management had an important role in the company but does not contain additional detailed allegations about the defendants' actual exposure to information, it will usually fall short of the PSLRA standard. In such cases the inference that defendants had knowledge of the relevant facts will not be much stronger, if at all, than the inference that defendants remained unaware."); *cf. Align Tech.*, 856 F.3d at 620 ("[P]articularized allegations that defendants had actual access to the disputed information may raise a strong inference of scienter." (internal quotations and citations omitted)). Because of Plaintiffs' vague and impressionistic description of the reports and their attendant findings, the Court is left to speculate as to the parameters and import of the "link" between RG-101 and liver toxicity, bilirubin, and/or jaundice and thus whether such link would have been obvious to Defendants. *See Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002) ("[P]laintiffs merely assert in conclusory terms that the defendants had access to internal data demonstrating a decline in sales . . . . [but] do not identify any internal reports of 'sales data,' much less plead, in any detail, the contents of any such report or the purported data. Without this information . . . we cannot ascertain whether there is any basis for the allegations that the officers had actual or constructive knowledge of flat patient demand that would cause their optimistic representations to the contrary to be consciously misleading."). Indeed, the Court cannot tell whether the information allegedly contradicting the Defendants' complained-of statements were prominently and explicitly discussed within a major report's principal conclusions or received only a cursory and indirect mention

tucked away in an obscure footnote of a minor report. *See Zucco Partners*, 552 F.3d at 1001 ("[R]eporting false information will only be indicative of scienter where the falsity is patently obvious – where the facts are prominent enough that it would be absurd to suggest that top management was unaware of them." (internal quotations, citations, and alterations omitted)). Thus, these "negative characterizations of reports relied on by insiders, without specific reference to the contents of those reports, are insufficient to meet the heightened pleading requirements of the PSLRA." *See Lipton,* 284 F.3d at 1036 (citations omitted).

As to Plaintiffs' arguments concerning Regulus's debt financing activities, such routine corporate objectives are insufficient to establish a strong showing of scienter. *See In re Rigel Pharm., Inc. Sec. Litig*., 697 F.3d 869, 884 (9th Cir. 2012) ("[A]llegations of routine corporate objectives such as the desire to obtain good financing and expand are not, without more, sufficient to allege scienter; to hold otherwise would support a finding of scienter for any company that seeks to enhance its business prospects." (citations omitted); *Lipton*, 284 F.3d at 1038 ("[The defendants'] alleged desires to obtain favorable financing and to expand abroad are in themselves ordinary and appropriate corporate objectives. Such routine business objectives, without more, cannot normally be alleged to be motivations for fraud. To hold otherwise would be to support a finding of fraudulent intent for all companies that plan to lower costs and expand sales."). And while Plaintiffs assert that Regulus's motive in obtaining additional funds via debt financing "was not akin to the general corporate objective of raising capital shared by all companies" because "Regulus would not have been able to take out th[e] loan if the omitted information about RG-101 had been disclosed" (ECF No. 19, ¶ 151), the Court concludes that such distinction is illusory because Plaintiffs' instant argument could be made as to any company that sought financing after having purportedly made a material misrepresentation to the public as to any aspect of its business. *See In re Rigel Pharm*, 697 F.3d at 884.

Plaintiffs' arguments regarding the Defendants' compensation are unavailing for similar reasons. *See id.* ("[I]t is common for executive compensation, including stock options and bonuses, to be based partly on the executive's success in achieving key corporate goals . . . [and] we will not conclude that there is fraudulent intent merely because a defendant's compensation was based in part on such successes."); *Lipton*, 284 F.3d at 1038 ("If scienter could be pleaded merely by alleging that officers and directors possess motive and opportunity to enhance a company's business prospects, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions." (internal quotations and citations omitted)). And while it is true that "[a] strong correlation between financial results and stock options or cash bonuses for individual defendants may occasionally be compelling enough to support an inference of scienter," Plaintiffs have failed to plead particular facts demonstrating such strong correlation.[10] *See Zucco Partners,* 552 F.3d at 1004-05 ("Zucco's SAC makes only the bare assertion that executive-level bonuses were based in part on Digimarc's financial performance – the complaint fails to provide specifically, with comparisons to prior years bonuses, the correlation between Davis' and Ranjit's compensation and Digimarc's bottom line. Such generalized assertions of motive, without more, are inadequate to meet the heightened pleading requirements . . .").

As to Defendant Grint's May 2017 resignation, Plaintiffs have failed to plead facts indicating that Defendant Grint's resignation was accompanied by suspicious circumstances or otherwise related to his purported misstatements as opposed to

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[10] In the Consolidated Complaint, Plaintiffs allege that "[f]or the year 2016[, Defendant] Grint received a salary of $515,000 plus other awards resulting in $2,869,634. For 2015, [Defendant] Grint received a salary of $446,532 plus other awards resulting in total compensation of $5,006,729. [Defendant] Hagan received a 2016 salary of $413,610 plus other awards resulting in $3,950,279." (ECF No. 19, ¶ 152.)

the failure of the RG-101 development or other unrelated business or personal reasons. *See id*. at 1002 ("Where a resignation occurs slightly before or after the defendant corporation issues a restatement, a plaintiff must plead facts refuting the reasonable assumption that the resignation occurred as a result of restatement's issuance itself in order for a resignation to be strongly indicative of scienter," *e.g.*, the plaintiff must refute "the reasonable assumption that defendant's employee was fired simply because the errors that lead to the restatement occurred on his watch or because he failed adequately to supervise his department."); *see also Align Tech.*, 856 F.3d at 622 ("[A]n employee's resignation supports an inference of scienter only when the resignation at issue was uncharacteristic when compared to the defendant's typical hiring and termination patterns or was accompanied by suspicious circumstances. Otherwise, the inference that the defendant corporation forced certain employees to resign because of its knowledge of the employee's role in the fraudulent representations will never be as cogent or as compelling as the inference that the employees resigned or were terminated for unrelated personal or business reasons." (internal quotations and citations omitted)). For example, Plaintiffs' allegation that the report of Defendant Grint's resignation "did not contain any of the typical salutary words often found in corporate statements announcing high-level resignation" is directly contradicted by the press release issued that same day. (*Compare* ECF No. 19, ¶ 156; *with* ECF No. 22-12, at 2 ("We are very grateful for the leadership of Dr. Grint . . . ."). Further, while Plaintiff alleges "Regulus did not pay [Defendant] Grint a bonus for work performed during 2016, whereas [Defendant Hagan] received $100,000 and Wright received $110,000," Plaintiffs plead no facts that directly tie the non-receipt of this bonus to Defendant Grint's

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purportedly misleading statements, make no attempt to explain why Defendant Hagan received a bonus (and was in fact promoted to CEO) despite having allegedly made misleading statements, and ignore the significant severance package Defendant Grint received upon resignation. (*See* ECF No. 19, ¶¶ 131, 156.) Ironically, Plaintiffs themselves plead a innocent explanation for Defendant Grint's purported involuntary termination. (*See* ECF No. 19, ¶ 133 ("[F]ormer CEO Grint was fired in connection with cost saving . . . .").).

Finally, even upon a holistic review of all scienter allegations, the Court concludes that Plaintiffs have not adequately alleged a strong inference of scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs,* 551 U.S. at 322. As highlighted above, the investigator's report indicating that RG-101 may be related to the Jaundice SAE was disclosed contemporaneously to the public and thus investors were on the same footing as Defendants with regards to that information. Further, Plaintiffs description of purported contradictory internal reports are too vague and impressionistic to provide any indication of conscious misconduct or deliberate recklessness in the making of Defendants' complained-of statements. Additionally, Plaintiffs allegations that Defendants were motivated by improper financial motives are lacking particularized facts to indicate that Defendants' motivations were anything other than routine business objectives. Finally, Plaintiffs allegations regarding Defendant Grint's resignation add little to the scale given their failure to refute various innocent explanations for such resignation. Given the foregoing, Defendants' innocent explanation for its statements, namely that "Regulus began testing an experimental drug, encountered unexpected issues (as many pharmaceutical companies do), . . . worked backwards to find answers . . . . [and] when it identified a possible answer, it told the market and the FDA," is significantly more cogent and compelling than the narrative propounded by Plaintiffs on the facts as currently pled. (*See* ECF No. 23, at 29 (quoting ECF No.

22-1, at 24).)

C. Loss Causation

Loss causation is the causal connection between a defendant's material misrepresentation and a plaintiff's loss. *In re Oracle Corp.*, 627 F.3d at 392. "[T]o prove loss causation, the plaintiff must demonstrate a causal connection between the deceptive acts that form the basis for the claim of securities fraud and the injury suffered by the plaintiff." *Curry*, 875 F.3d at 1225 (internal quotations, citations, and alterations omitted); *see also In re Oracle Corp.*, 627 F.3d at 392 ("Loss causation is established if the market learns of a defendant's fraudulent act or practice, the market reacts to the fraudulent act or practice, and a plaintiff suffers a loss as a result of the market's reaction."). Generally, "the complaint must allege that the defendant's 'share price fell significantly after the truth became known.'" *Metzler Inv. GMBH*, 540 F.3d at 1062 (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)). Nevertheless, "[d]isclosure of the fraud is not a *sine qua non* of loss causation, which may be shown even where the alleged fraud is not necessarily revealed prior to the economic loss." *Mineworkers' Pension Scheme v. First Solar Inc.*, 881 F.3d 750, 753-54 (9th Cir. 2018), cert. denied, 139 S. Ct. 2741 (2019) ("A plaintiff may also prove loss causation by showing that the stock price fell upon the revelation of an earnings miss, even if the market was unaware at the time that fraud had concealed the miss. . . . because it is the underlying facts concealed by fraud that affect the stock price. Fraud simply causes a delay in the revelation of those facts." (internal quotations and citations omitted)). "The ultimate issue . . . is whether the defendant's misstatement, as opposed to some other fact, foreseeably caused the plaintiff's loss." *Id.* at 754. Yet a plaintiff is not required to demonstrate that a misstatement was "the sole reason for the investment's decline in value' in order to establish loss causation." *Metzler Inv. GMBH*, 540 F.3d at 1062 (internal quotations, citations, and emphasis omitted). Rather, a plaintiff need only "set forth allegations that if assumed true, are sufficient to provide the

defendant with some indication that the drop in defendant's stock price was causally related to the defendant's . . . misstatements." *Id*. (internal quotations, citations, and alterations omitted).

Here, Plaintiffs argue they have identified in their Consolidated Complaint several disclosures by Regulus that "related directly to the misrepresentations alleged by Plaintiffs[] and resulted in substantial declines in Regulus'[s] stock price." (ECF No. 23, at 31.) In contrast, Defendants argue that the drop in Regulus's share price was based upon what it describes as "six partial disclosures" that "revealed, at most, disappointing news." (ECF No. 22-1 (citing ECF No. 19, ¶¶ 92 ("FDA's initiation of the clinical hold"), 101 ("FDA's initial request for information"); 119 ("FDA's initiation of the clinical hold"); 122, 124, 127 ("sandwich trial's final results"); 133 ("Dr. Grint's resignation"); 136 ("Regulus's discontinuation of RG-101 program")). Yet this "disappointing news" concerns the revelation of the very facts that Plaintiffs claim were improperly withheld from the public, namely that RG-101 caused or was otherwise related to liver toxicity (including elevated bilirubin levels and/or jaundice) and therefore had little to no chance of receiving FDA approval. *See Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1120 (9th Cir. 2013) ("[A] plaintiff can satisfy loss causation by showing that the defendant misrepresented or omitted the *very facts* that were a substantial factor in causing the plaintiff's economic loss." (internal quotations and citations omitted) (emphasis original)). Further, contrary to Defendants' arguments, Plaintiffs have highlighted at least one disclosure that can be reasonably inferred as having corrected purported prior misstatements as to RG-101's safety and/or viability and having caused a material drop in Regulus's share prices. (*See*, *e.g.*, ECF No. 19, ¶¶ 91-92 (June 27, 2016 announcement of FDA's placement of clinical hold after second Jaundice SAE corrected prior misstatements that RG-101 was safe and first Jaundice SAE was no cause for worry as it was likely caused by comorbidities of relevant patient); 93 (share price

fell from $5.01 to $2.54 between June 27 and 28, 2016); 135-36 (June 12, 2017 announcement that RG-101 was likely cause of increased bilirubin levels and jaundice corrected prior misstatements that RG-101 was safe and Jaundice SAEs were no cause for worry and likely caused by comorbidities of relevant patients), 137 (share price fell from $1.40 to $1.10 between June 9 and 12, 2017).)

Accordingly, the Court concludes that Plaintiffs have sufficiently plead loss causation. Nevertheless, because Plaintiffs have failed to adequately plead the first and second elements of their claims under Section 10(b) and Rule10b-5, such claims are subject to dismissal.

D. Section 20(a) Claims

Because the Court concludes that the underlying Section 10(b) claims are subject to dismissal, Plaintiffs' § 20(a) claim also fails. *See Zucco Partners*, 552 F.3d at 990 ("Section 20(a) claims may be dismissed summarily . . . if a plaintiff fails to adequately plead a primary violation of section 10(b)."); *Lipton*, 284 F.3d at 1035 n.15 (9th Cir. 2002) ("[T]o prevail on their claims for violations of § 20(a) and § 20A, plaintiffs must first allege a violation of § 10(b) or Rule 10b 5." (citations omitted)).

E. Leave to Amend

In its response in opposition to Defendants' instant motion, Plaintiffs request leave to amend in the event the Court concludes the Consolidated Complaint is deficient. (*See* ECF No. 23, at 31 n.11.) Under Federal Rule of Civil Procedure 15, federal courts are instructed to "freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). "A district court, however, may in its discretion deny leave to amend due to undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, and futility of amendment." *Zucco Partners*, 552 F.3d at 1007. Nevertheless, dismissal with prejudice is generally "improper unless it is clear that

the complaint could not be saved by any amendment." *Id.* at 989 (internal quotations and citations omitted)).

Here, the Court concludes that while Plaintiffs' present Consolidated Complaint is subject to dismissal for failure to adequately plead the first and second elements of its claims under Section 10(b), it is not clear that Plaintiffs claims cannot be saved by amendment. Accordingly, the Court will grant Plaintiffs leave to amend their Consolidated Complaint. *See id.*

CONCLUSION

Based upon the foregoing, the Court **GRANTS** Defendants' Motion to Dismiss the Consolidated Complaint (ECF No. 22). Nevertheless, the Court **GRANTS** Plaintiffs leave to file an amended complaint that satisfies the deficiencies identified above. Plaintiffs must comply with CivLR 15.1(c). Plaintiffs shall file their amended complaint with the Court on or before **October 1, 2019**. Plaintiffs are warned that their failure to file an amended complaint on or before October 1, 2019 may result in the dismissal of this action without further notice. Defendants shall file their response to Plaintiffs' forthcoming amended complaint **within twenty-one (21) days after service of the amended complaint**. Alternatively, if Plaintiffs have nothing further to add or wish to appeal now, Plaintiffs may file a notice of no intent to further amend. Upon the filing of such notice, the Court will enter a final and appealable judgment.

IT IS SO ORDERED.

Dated: September 5, 2019

Honorable Barry Ted Moskowitz
United States District Judge