UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

SAMIT PATEL, individually and on behalf of all others similarly situated, Plaintiff, v. SEATTLE GENETICS, INC., CLAY B. SIEGALL, TODD E. SIMPSON, and JONATHAN DRACHMAN, Defendants.	CASE NO. C17-41 RSM ORDER GRANTING DEFENDANTS' MOTION TO DISMISS CONSOLIDATED SECOND AMENDED COMPLAINT AND DENYING REQUEST FOR JUDICIAL NOTICE

I. INTRODUCTION

This matter comes before the Court on Defendants' Motion to Dismiss Consolidated Second Amended Complaint and Defendants' Request for Judicial Notice. Dkts. ##34, 36. Plaintiff filed this putative class action on January 10, 2017. Dkt. #1. After the Court appointed a lead plaintiff and lead counsel, (Dkt. #8) Plaintiff filed a Consolidated Amended Complaint ("CAC"). Dkt. #18. The CAC sought remedies, under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934, for Plaintiff and all persons or entities who purchased or otherwise acquired Seattle Genetics, Inc.'s common stock between October 27, 2016, and December 27, 2016 (the "Class Period"). *Id.* On Defendants' motion to dismiss, the Court found that the CAC did not adequately plead Plaintiff's securities fraud claims, dismissed the CAC, and granted Plaintiff leave to file an amended complaint remedying the deficiencies. Dkt. #30. Plaintiff filed a Consolidated Second Amended Complaint ("CSAC") with additional factual allegations to

support his claims. Dkt. #31. Defendants now seek dismissal of Plaintiff's CSAC, arguing that Plaintiff failed to cure the deficiencies identified by the Court and that the CSAC still fails to adequately state a claim. Dkt. #34. For the reasons stated herein, the Court grants Defendants' Motion to Dismiss Consolidated Second Amended Complaint and denies Defendants' Request for Judicial Notice.

II. BACKGROUND[1]

Defendant Seattle Genetics, Inc. is a publicly traded biopharmaceutical company. The "Individual Defendants," Clay B. Siegall, Todd E. Simpson, and Jonathan Drachman, were executives at Seattle Genetics, Inc. during the relevant times.[2] Defendants attempted to develop a cancer treatment known as SGN-CD33A (Vadastuximab Talirine) ("33A") which was intended to treat Acute Myeloid Leukemia ("AML"). 33A, an antibody-drug conjugate ("ADC"), was intended to bind to cancerous cells and deliver a toxic payload to kill the cancerous cells. 33A utilized more potent payloads because it was intended to target and bind only to cancerous cells.

Defendants had successfully used ADC drug technology in an FDA approved drug (ADCETRIS). But the success of the technology was otherwise limited, with only one other FDA approved ADC drug. Among the failures was Defendants' own SGN-33, an ADC[3] and

[1] Relevant factual background is taken from Plaintiff's Consolidated Second Amended Complaint ("CSAC"), Dkt. #31, and accepted as true for purposes of ruling on Defendants' Motion.

[2] Defendant Clay B. Siegall is the co-founder, President, Chief Executive Officer, and Chairman of the Board of Directors. Defendant Todd E. Simpson was the Chief Financial Officer during the relevant times. Defendant Jonathan Drachman was the Chief Medical Officer and Executive Vice President of Research and Development during the relevant times.

[3] Plaintiff's CSAC is not clear, and the parties dispute, whether 33A is an ADC or even similar to 33A. *Compare* Dkt. #31 at ¶ 42 ("SGN-33, a predecessor to SGN-CD33, as an ADC . . .") *with* ¶ 68 (quoting statement by Defendant Siegall that indicates SGN-33 "was a naked anti-body"); Dkt. #34 at 10–11 (Defendants arguing SGN-33 was "completely different" than 33A);

predecessor to 33A. Defendants abandoned a clinical trial of SGN-33 in 2010 because the drug failed to extend overall survival of patients. Defendants also knew that Pfizer had previously developed and marketed Mylotarg, an ADC, but withdrew it from the market in 2010 because it was not a significantly more effective treatment than standard chemotherapy and resulted in more fatal treatment-related toxicity.

Before the Class Period, Defendants represented that 33A was a more sophisticated drug that would not suffer from the toxic side-effects that plagued previous ADCs. During the Class Period, Defendants continued to claim that 33A did not share the toxic side effects of Mylotarg and touted the promise of the treatment and the absence of liver disease in clinical trials. Specifically, Plaintiff alleges Defendants made the following misrepresentations:[4]

- On October 27, 2016, Defendant Drachman stated that a clinical study of 33A, in conjunction with a common treatment course ("7+3") that already had high complete remission rates, was in "a complicated space" but was "something that we're looking at really closely. We're excited about our interim data." Dkt. #31 at ¶ 81.
- On October 27, 2016, Defendant Siegall stated that while AML treatment was a competitive business environment "we're very happy with our positioning in this field

Dkt. #38 at 18 n.4 (Plaintiff arguing SGN-33 was a "predecessor" to 33A). While Plaintiff appears to concede that SGN-33 was not an ADC, the Court accepts the specific allegation of the CSAC and has treated SGN-33 as an ADC or at least highly related.

[4] The Court's earlier Order determined that Plaintiff's CSAC adequately alleged that these statements, now compiled at Dkt. #31 ¶¶ 81–90, contained material misrepresentations or omissions. Dkt. #30 at 10. Specifically, the Court focused on misrepresentations or omissions of hepatotoxic events because "even if the risk of hepatotoxicity was known to investors, the disclosure of an actual death could be viewable by the reasonable investor as having significantly altered the 'total mix' of information." *Id.*

and think that this could make a big difference for patients. . . . [because 33A] could be very user-friendly from a combination standpoint" with other treatments. *Id.* at ¶ 83.

- On November 8, 2016, Defendant Siegall stated that clinical trials of 33A combined with hypomethylating agents ("HMAs"), another common AML treatment, were encouraging and that Defendants were "excited with the data," the trials had a "low 30 and 60-day mortality rate," and Defendants knew that there was "a good safety profile." *Id.* at ¶ 85.
- On December 3, 2016, Defendants issued a press release announcing partial results from the clinical study of 33A with 7+3 treatment and indicated that it "was well-tolerated with a low early mortality rate" and showed "a high rate of remissions in younger newly diagnosed AML patients without significantly adding to the toxicity of treatment." Defendants included the most common adverse events experienced by patients and indicated that: "No veno-occlusive disease/sinusoidal obstruction syndrome or significant hepatotoxicity was observed on treatment." *Id.* at ¶ 87.
- On December 5, 2016, Defendants issued a press release indicating that Defendants were "pleased with the growing body of data demonstrating that [33A] has a promising overall tolerability." *Id.* at ¶ 89. The press release also presented details of ongoing clinical studies:
  - With regard to a clinical study of 33A with HMA treatment, Defendants represented that the results were promising with no 30- or 60-day "treatment-related deaths." Defendants identified the most common adverse events experienced by 20% or more of patients and did not list toxicity issues.
  - With regard to a study of 33A monotherapy, Defendants identified the most common adverse events experienced by 20% or more of patients and did not list toxicity issues.

Plaintiff alleges that during the Class Period, information known to Defendants unquestionably demonstrated that 33A was highly toxic and that patients exposed to 33A were experiencing serious adverse hepatotoxic events, including death. Despite this knowledge, Defendants either misrepresented or did not disclose 33A's hepatotoxicity risks. As a result, lead Plaintiff Carl Johnson and others acquired Seattle Genetics' common stock during the Class Period at artificially inflated prices.

On December 27, 2016, Seattle Genetics announced that the FDA had placed holds on Seattle Genetics' pending clinical trials. The announcement specified that "[s]ix patients have been identified with hepatotoxicity, including several cases of veno-occlusive disease, with four fatal events." The abrupt change of course stunned the market and analysts and stock prices dropped by over 15% on the news, resulting in Plaintiff suffering damages.

In March, 2017, the FDA lifted its holds on some 33A clinical trials and allowed them to resume with additional risk mitigation measures in place. However, in June 2017, Defendants announced they were abandoning several clinical trials and the FDA ultimately placed a hold suspending all clinical trials of 33A.

III. DISCUSSION

A. Request for Judicial Notice

Defendants have requested that the Court treat ten documents[5] as incorporated into the CSAC and that the Court take judicial notice of three documents[6] under Federal Rule of Evidence 201. Dkt. #36. Plaintiff objects only to the Court's incorporation of a 2010 press release related

[5] Dkt. #35-1, exhs. 1-7, 9-10, and 12.

[6] Dkt. #35-1, exhs. 8, 11, and 12.

to SGN-33[7] and to the Court taking judicial notice of SEC forms showing purchases of stock during the Class Period by Defendants' independent director.[8] Dkt. #37, at 1–2. Plaintiff also argues that the Court should only consider the existence and authenticity of the documents, not the truth of their contents. *Id.* at 2–4.

The Court finds that it may properly consider the documents presented by Defendants. *United States v. Ritchie*, 342 F.3d 903, 908–09 (9th Cir. 2003) (where a complaint incorporates a document, court can "assume that its contents are true for purposes of a motion to dismiss"); Fed R. Evid. 201(b) (court may take judicial notice of facts not subject to reasonable dispute and where fact "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned"). However, the Court does not find consideration of the documents to be necessary to its decision and therefore denies Defendants' request as moot on that basis.

B. 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) (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 facts "to state a claim to relief that is plausible on its face." *Id.* at 678. Absent facial plausibility, a plaintiff's claims must be dismissed." *Twombly*, 550 U.S. at 570.

[7] Dkt. #35-1, exh. 4.

[8] Dkt. #35-1, exh. 8.

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). To state a claim under the PSLRA, specifically 15 U.S.C. § 78j(b) and 17 C.F.R. § 240.10b-5, Plaintiff must 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*, 552 U.S. 148, 157 (2008). Defendants argue that Plaintiff has not adequately alleged scienter.

In the securities fraud context, scienter constitutes "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007). For a complaint to adequately allege scienter under the PSLRA, it must:

> "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). A "strong inference" that a defendant acted with scienter is not an irrefutable inference, though it "must be more than merely plausible or reasonable . . . ." *Tellabs, Inc.*[, 551 U.S. at 314]. A "strong inference" cannot be identified "in a vacuum," as "[t]he inquiry is inherently comparative[.]" *Id.* at 323[]. Rather, a "strong inference" is an inference that is "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324[]. To determine whether a "strong" inference has been pleaded, "the reviewing court must ask: When the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?" *Id.* at 326; *see also Matrixx Initiatives*[*, Inc. v. Siracusano*], 563 U.S. [27,] 48–50 [2011].
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> We have held that plaintiffs can meet this standard by alleging facts demonstrating an "intent to deceive, manipulate, or defraud" or "deliberate recklessness." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1144 (9th Cir. 2017) (quoting *Schueneman v. Arena Pharm.*, 840 F.3d 698, 705 (9th Cir. 2016)). "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." *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d

> 605, 619 (9th Cir. 2017) (alterations omitted) (quoting *Schueneman*, 840 F.3d at 705).

Webb v. Solarcity Corp., 884 F.3d 844, 850–51 (9th Cir. 2018) (alterations to text are in the original, alterations to citations are the Court's).

C. Scienter Allegations

The Court will first consider Plaintiff's major allegations individually, to determine whether any establish scienter on their own, before considering the allegations holistically. *See id.* at 851.

1. Confidential Witness Allegations

Plaintiff relies primarily on the testimony of two past employees of Seattle Genetics to establish scienter.

Confidential Witness 1 ("CW1") was employed as Seattle Genetics' Senior Environmental Health and Safety Engineer from March 2015 until February 2017. Dkt. #31 at ¶ 49. CW1's responsibilities were to provide employees with information about the risks in the work environment and proper handling requirements for toxic drug compounds. *Id.* In the course of his duties, CW1 became aware of animal studies previously initiated to assess safety risks that might be observed in a human clinical trial of a compound similar to 33A. *Id.* at ¶¶ 50–51. Those studies demonstrated a high risk of treatment-related hepatotoxicity. *Id.* 33A was similar to the earlier compound and 33A's safety protocols were developed from the compound's safety correlations and "data." *Id.* CW1 worked with Seattle Genetics' in-house toxicologist to prepare Safety Data Sheets, which indicated that 33A could damage the liver at specific levels of toxicity. *Id.* at ¶ 52. These Safety Data Sheets were available to all employees on Seattle Genetics' intranet. *Id.*

Following a mid-2016 risk assessment of 33A's toxicity by a third party, Defendants' contract manufacturer, Lonza, stopped manufacturing vital components for 33A. *Id.* at ¶ 53. CW1 and the in-house toxicologist were tasked with convincing Lonza to resume manufacturing. *Id.* at ¶ 53–54. Instead, CW1 "raised concerns about the risks of exposure" to 33A and CW1's manager threatened that he would be fired if he discussed the issue with the toxicologist. *Id.* at ¶ 55. CW1 attempted to raise "his concerns" with senior-level officers in compliance and HR and "these concerns were eventually communicated to Seattle Genetics' General Counsel." *Id.* at ¶ 57. At the same time, the toxicologist, who "initially also expressed concerns about [33A's] level of toxicity," was coerced by his managers, at the direction of Defendant Simpson, into "moderating" his concerns. *Id.* at ¶ 56. Lonza did ultimately resume manufacturing the necessary components.

CW1's testimony does not establish scienter on its own. Where a complaint relies on confidential witness testimony, the confidential witness "must be described with sufficient particularity to establish their reliability and personal knowledge" and the confidential witness's allegations "must themselves be indicative of scienter." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 995 (9th Cir. 2009). Here, CW1's allegations often lack detail and are not compelling evidence of scienter. *See id.* at 996–98 (discounting testimony that lacked detail, was based upon vague hearsay, or reported conclusory assertions).

Importantly and as noted by Defendants, CW1's testimony does not consistently indicate whether CW1 is addressing 33A's risks of hepatotoxicity in patients or its toxicity in the work environment. *See* Dkt. #31 at ¶¶ 50–51 (referring to "safety correlations" and "safety protocols"); ¶ 53 ("toxicity associated with [33A]"); ¶ 55 ("concerns about the risks of exposure to [33A]"). Nothing in CW1's allegations indicate that CW1 had access to any data related to

the clinical tests of 33A. CW1's allegations are not sufficiently particularized or compelling to infer there was a known risk of hepatotoxicity in the clinical trials of 33A.

CW1 also does not sufficiently establish that the Individual Defendants ever learned of CW1's concerns, environmental or otherwise.[9] CW1's allegation that information relating to the toxicity of 33A was available on Seattle Genetics' intranet does not establish that the Individual Defendants were required to review it, had reason to access it, or ever viewed the information. The allegations require a speculative jump as opposed to an inference. CW1 further alleges that CW1 approached "senior-level officials . . . about his concerns with no success" and was persistent in attempting to gain access. Dkt. #31 at ¶ 57. But, as discussed above, CW1 does not allege specifically what his "concerns" were or that the "concerns" were ever successfully communicated to anyone other than Seattle Genetics' General Counsel. *Id.* Even then, CW1 does not allege that CW1 spoke directly with the General Counsel, only that "these concerns were eventually communicated to Seattle Genetics' General Counsel." *Id.* CW1's allegations of the Individual Defendants' knowledge are not sufficiently particularized to demonstrate that they are made with personal knowledge, do not specify whether CW1's concerns were with the risk of toxicity in the work environment or the risk of hepatotoxicity in patients, and do not demonstrate that CW1's concerns were ever directly communicated to anyone, much less the Individual Defendants. As a whole, CW1's allegations do not create a compelling inference that

[9] Defendant points out that the Court's previous Order "found that Plaintiff 'lump[ed] together Dr. Drachman, Dr. Siegall, and Mr. Simpson' and therefore 'fail[ed] to satisfy the requirements that scienter be alleged with particularity as to each defendant separately.'" Dkt. #34 at 7 (quoting Dkt. #30 at 11, 13). Plaintiff contests this point. Dkt. #38 at 17 n.3. The Court does not find it necessary to address this issue as the CSAC fails to adequately allege scienter whether considering Defendants individually or collectively.

the alleged misrepresentations and omissions were made with an intent to deceive, manipulate, or defraud or with deliberate recklessness.

Confidential Witness 2 ("CW2") was employed at Seattle Genetics as a Senior Scientist and worked extensively on the chemistry to synthesize 33A for human trials. Dkt. #31 at ¶ 58. According to CW2, 33A is "the most toxic drug in the history of the world." *Id.* Because of the similarities to Mylotarg, CW2 and other employees were not surprised when hepatotoxic events occurred during clinical trials, especially because 33A was rushed to clinical trials with aggressive doses and without fully understanding the risk of hepatotoxicity. *Id.* at ¶ 58–59.

CW2 indicates that the Individual Defendants knew this information because they were micromanagers, "knew the most intimate details [about] Mylotarg," and attended company-wide meetings, also attended by CW2, where "deep concerns about the hepatotoxicity associated with" 33A were expressed "before the press releases about the trials were issued to the public."[10] *Id.* at ¶ 60. Further, employees that reported to Defendant Siegall were aware of the "risks of hepatotoxicity associated with" 33A, including the Senior Medical Director and Distinguished Clinical Scientist who oversaw the clinical trials. *Id.* at ¶ 60–61. Further, 33A was Seattle Genetics' "most advanced Phase III drug candidate, and its failure would mean that the [Seattle Genetics] 'would have nothing else in the pipeline.'" *Id.* at ¶ 62.

But CW2's allegations suffer the same defects as CW1's. CW2 does not allege a factual basis that would have allowed CW2 to know that the Individual Defendants "knew the most intimate details [about] Mylotarg." Nor does CW2 indicate what "deep concerns" were shared

[10] CW2 is not clear as to timing and whether these concerns predate press releases made prior to beginning clinical trials, prior to the December 27, 2016 press release announcing the FDA holds on clinical trials, or prior to the June 2017 press releases announcing that Seattle Genetics was suspending all clinical trials of 33A. Dkt. #31 at ¶¶ 91, 96–99.

at the company-wide meetings attended by the Individual Defendants or when the meetings took place. CW2's general allegations are not sufficiently particularized to demonstrate personal knowledge that individuals within Seattle Genetics were aware of the "risks of hepatotoxicity associated with" 33A's clinical trials.

Even so, the Court finds it unremarkable that individuals within Seattle Genetics may have had knowledge of or were aware of the risks of hepatotoxicity with 33A. The CSAC details that hepatotoxicity "is the most frequent single cause of safety-related drug marketing withdrawals in the last 50 years," that Mylotarg had been pulled from the market because of hepatotoxicity concerns, and that despite ADC drug technology being a fiercely competitive market, only two drugs have been approved by the FDA. Dkt. #31 at ¶¶ 5 n.1, 32–33, and 41. Even Seattle Genetics' approved ADC, ADCETRIS, had a label warning emphasizing hepatotoxic risk. *Id.* at ¶ 80. Hepatotoxicity was a risk from the start.[11]

CW2's allegations also are not sufficiently particularized to establish what the Individual Defendants knew and therefore do not support a compelling inference of scienter. "[T]he complaint must provide an adequate basis for determining that the witness in question have personal knowledge of the events they report." *See Zucco Partners, LLC*, 552 F.3d at 995 (requiring adequate basis for determining confidential witness's personal knowledge). But CW2's statements don't provide any dates or details of any discussions. These, "[o]missions and ambiguities count against inferring scienter, for plaintiffs must 'state with particularity facts

[11] Plaintiff lumps the risk of hepatotoxicity with the occurrence of hepatotoxic events during clinical trials. But the Court's previous Order focused on the occurrence of hepatotoxic events as providing the basis for the alleged statements misrepresenting or omitting material facts. *See supra* n.4. Regardless, the CSAC fails to adequately plead scienter whether considering the risks of hepatotoxicity or the occurrence of hepatotoxic events.

giving rise to a strong inference that the defendant acted with the required state of mind.'" *Tellabs, Inc.*, 551 U.S. at 325 (citing 15 U.S.C. § 78u04(b)(2)).

Without speculation, the confidential witness allegations do not answer "[t]he basic question of every scienter inquiry," according to Plaintiff, "what did the Defendants know, and when did they know about it." Dkt. #38 at 1.

2. Timing of Clinical Holds

Plaintiff argues that allegations of the CSAC "make it virtually impossible" that the Individual Defendants did not know about hepatotoxic events before making misleading statements during the Class Period, establishing scienter. *Id.* at 11–12. Plaintiff alleges that the clinical trials had been ongoing for several years, making it unlikely that the events were clustered within the last few weeks of the Class Period. Dkt. #31 at ¶ 74. Plaintiff alleges that "standard delays" in reporting events to the FDA[12] decrease the likelihood that the events occurred between Defendants' December 3 and 5 press releases and the December 27 press release announcing FDA holds on clinical trials. *Id.* at ¶¶ 75–78. Further, Plaintiff alleges that even after serious adverse events are reported to the FDA, there is dialogue between the company and the FDA before the FDA makes a decision to place a hold on the clinical trial, making it likely that the events occurred even earlier. *Id.* at ¶ 78.

[12] Plaintiff claims that data related to adverse events reported on a public FDA database and related to 33A indicates that 41 days is the "best benchmark" for reporting delays. Dkt. #38 at 12. But the Court finds this argument too speculative. The database does not appear to involve all serious adverse events related to 33A. The data only lists four events possibly occurring before 2017 and only three deaths while Plaintiff has alleged six serious adverse events and four deaths before 2017. This limited and unspecified data does not support an inference that 41 days is a "benchmark" that should be used to infer when the hepatotoxic events occurred. While the Court accepts the factual allegations as true, Plaintiff's argued inferences are not supported by those facts.

But Plaintiff's allegations must be more particularized to demonstrate scienter. The CSAC includes no allegations as to when the events actually occurred or which clinical trial they occurred in.[13] And while Plaintiff's allegations may make it more plausible that the events occurred before the December 3 and 5 press releases, they do not bear on when the Individual Defendants learned of the events. *Cf. Schueneman*, 840 F.3d 698 (finding adequate evidence of scienter for misleading statements that FDA approval was likely in part because of animal studies while the speaker knew that a rat study results made approval unlikely).

3. Internal Reports of Hepatotoxic Risks

Relying on the testimony of CW1, Plaintiff argues that the Court can infer scienter because the Individual Defendants must have known about the Safety Data Sheets showing toxicity because they had access to them and access alone is sufficient. Dkt. #38 at 15–16. Plaintiff relies on *In re Quality Systems* to argue that mere access to information is sufficient to impute knowledge of the information. 865 F.3d 1130. But this argument stretches *In re Quality Systems* too far. The complaint in that case alleged that the company's executives monitored the data and actually accessed the information. *Id.* at 1145 (confidential witnesses "had personal knowledge of executive-level management's real-time access" and use of sales information and one CW arranged sales data for delivery to CFO).

Similarly, Plaintiff argues that the Individual Defendants knew about the third-party risk assessment and CW1's internal complaints on the basis of CW1's allegations. Plaintiff argues that the risk assessment and internal complaints were so important that they must have been

[13] The Court is sympathetic to Plaintiff's explanation that "Defendants have not revealed precisely when during the course of the multi-year clinical trials the four deaths and two other serious hepatotoxic events occurred." Dkt. #38 at 7. Plaintiff has not had an opportunity to conduct discovery and is not required to prove its case at this stage of the action. But lack of access does not excuse Plaintiff from the need to adequately plead scienter.

shared with upper level management. Dkt. #38 at 16. But again, the specifics of the risk assessment and of CW1's concerns are not detailed enough to demonstrate that they were of sufficient concern and there are no allegations that the Individual Defendants accessed the information. These types of "generalized claims about corporate knowledge are not sufficient to create a strong inference of scienter." *Zucco Partners, LLC*, 552 F.3d at 998.

4. Predecessor Drugs

Plaintiff, again relying on the allegations of CW1 and CW2, argues that Defendants' earlier experiences with SGN-33 and knowledge of Mylotarg meant that Defendants knew 33A would likely be hepatotoxic. Dkt. #38 at 17–20. Plaintiff therefore argues that "having been on notice of the hepatotoxicity risk of this class of drugs," Defendants could not ignore the hepatotoxicity risk of 33A. Dkt. #38 at 18. Plaintiff is correct that some courts have found that notice of a risk can provide evidence of scienter. *See Makor Issues & Rights, Ltd. V. Tellabs, Inc.*, 513 F.3d 702, 704 (7th Cir. 2008) ("When the facts known to a person place him on notice of a risk, he cannot ignore the facts and plead ignorance of the risks."); *South Ferry LP #2 v. Killinger*, 687 F. Supp. 2d 1248 (W.D. Wash. 2009) (finding that individual defendant who represented access to necessary information and specific knowledge evidenced scienter when he made misleading statements in response to direct questioning). But at best the insufficient allegations of the confidential witnesses establish knowledge of general risks of hepatotoxicity, not specific hepatotoxic events. Under these facts, Defendants did not have a heightened duty to investigate, only to avoid deliberate recklessness or intentional misrepresentations.

5. Motive

Plaintiff correctly argues that "[t]he absence of a motive allegation, though relevant, is not dispositive." *Matrixx Initiatives*, 563 U.S. at 48 (citing *Tellabs, Inc.*, 551 U.S. at 325). Even

so, Plaintiff alleges that Defendants did have a motive because they were in a fiercely competitive landscape and needed 33A to be successful as they had nothing else in the pipeline. Dkt. #38 at 21–22. But "allegations 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." *In re Rigel Pharmaceuticals, Inc. Securities Litigation*, 697 F.3d 869, 884 (9th Cir. 2012) (citing *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002)). That Defendants needed 33A to be successful is not indicative of scienter, especially where the CSAC does not include allegations showing how the misrepresentations would aid Defendants in making 33A successful.

6. Core Operations

While not directly invoking the Core Operations Doctrine, Plaintiff does indirectly rely on it to fill many of the CSAC's gaps and demonstrate that the Individual Defendants must have known of the hepatotoxicity risks and hepatotoxic events as they occurred because 33A's importance to Seattle Genetics. Allegations that a defendant's role in the company meant the defendant must have been aware of relevant information may be sufficient to establish scienter on their own "where they are particular and suggest that defendants had actual access to the disputed information" or "where the nature of the relevant fact is of such prominence that it would be 'absurd' to suggest that management was without knowledge of the matter." *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 786 (9th Cir. 2008) (citations omitted).

But Plaintiff does not fully develop the argument other than relying on the generalized prior arguments about the importance of 33A, the Individual Defendants' involvement as "micromanagers," and knowledge of the hepatotoxicity risks of 33A within Seattle Genetics. Plaintiff's broad allegations are not sufficient to invoke the Core Operations Doctrine and do not

give rise to an inference of scienter that is cogent and compelling. *C.f. Berson v. Applied Signal Tech. Inc.*, 527 F.3d 982, 988, n.5 (finding scienter where specific allegations made it "hard to believe" that managers responsible for day-to-day operations did not know of stop-work orders halting millions of dollars of work and resulting contract renegotiations, reassignment of 50-75 employees, and massive amounts of paperwork).

7. Holistic Consideration of the Complaint

Having considered Plaintiff's individual allegations, the Court considers the CSAC as a whole, combining even vague or ambiguous allegations to determine whether a strong inference of scienter is established. *South Ferry LP, No. 2*, 542 F.3d at 784. Taken as a whole, Plaintiff's allegations are not sufficient to show that Defendants acted with an intent to deceive, manipulate, or defraud or that Defendants were deliberately reckless in making the alleged misrepresentations or omissions. Plaintiff has to "offer details that would bridge the gap between the existence of [material facts] and actual knowledge on the part of the defendants." *Id.* at 783 (citing *In re Vantive Corp. Securities Litigation*, 283 F.3d 1079, 1087–88 (9th Cir. 2002)). Even with the reliance on the Core Operations Doctrine, without "detailed allegations about the defendants' actual exposure to information, [a complaint] will usually fall short of the PSLRA standard." *Id.* at 784. As noted in the Court's earlier Order, "[t]he Core Operations Doctrine can only go so far." Dkt. #30 at 13.

Further, while motive is not required, every case must be considered on its facts and the Court finds the lack of motive highly relevant here. *See Tellabs, Inc.*, 551 U.S. at 325 ("the significance that can be ascribed to an allegation of motive, or lack thereof, depends on the entirety of the complaint"). Plaintiff alleges that Defendants expended significant time and money to develop "the most toxic drug in the history of the world," knowing that it was destined

to be hepatotoxic just like SGN-33 and Mylotarg. Knowing this, Defendants rushed it to clinical trials with excessive doses. When hepatotoxic events inevitably occurred, the Individual Defendants misled investors while cooperating with the FDA and knowing that the trials of "the most toxic drug in the history of the world" would ultimately be shut down. Without particularized allegations or some motive the Court cannot find that Plaintiff's allegations raise an inference of scienter that is at least as cogent and compelling as opposing inferences.

D. 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.*, 697 F.3d at 886. Because Plaintiff has failed to plead an underlying violation of the federal securities laws, this claim will be dismissed as well.

E. Leave to Amend

Ordinarily, leave to amend a complaint should be freely given following an order of dismissal, "unless it is absolutely clear that the deficiencies of the complaint could not be cured by amendment." *Noll v. Carlson*, 809 F.2d 1446, 1448 (9th Cir. 1987); *see also DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992) ("A district court does not err in denying leave to amend where the amendment would be futile.") (citing *Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990)).

Here, the Court concludes that granting leave to amend would be futile. Plaintiff has filed two consolidated amended complaints. Dkts. ##18, 31. Both have failed to survive motions to dismiss. Given that the Plaintiff has already been given the opportunity to remedy his Complaint's deficiencies and has failed to substantially do so, the Court finds that permitting Plaintiff to make further amendments would be futile and therefore denies leave to amend.

IV. CONCLUSION

Having reviewed the relevant pleadings and the remainder of the record, the Court hereby finds and ORDERS:

1. Defendants' Motion to Dismiss Consolidated Second Amended Complaint (Dkt. #34) is GRANTED.
2. Defendants' Request for Judicial Notice (Dkt. #36) is DENIED as moot.
3. Plaintiff's claims are DISMISSED.
4. This case is CLOSED.

DATED this 24th day of May 2018.

RICARDO S. MARTINEZ
CHIEF UNITED STATES DISTRICT JUDGE