UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JULIA JUNGE and RICHARD JUNGE, on behalf of themselves and a class of similarly situated investors,

Plaintiffs,

v.

GERON CORPORATION and JOHN A. SCARLETT,

Defendants.

No. C 20-00547 WHA

ORDER RE MOTION TO DISMISS AMENDED CONSOLIDATED CLASS ACTION COMPLAINT AND REQUESTS FOR JUDICIAL NOTICE

INTRODUCTION

In this securities action, defendants move to dismiss for failure to state a claim on which relief can be granted, and for judicial notice. For the following reasons, defendants' motions are **GRANTED IN PART AND DENIED IN PART**.

STATEMENT

The essence of the following long analysis is this: the amended complaint adequately alleges that Geron should have disclosed the bad news when it touted the good and that failure to do so was misleading.

The purportedly good news was that more than 50% of those enrolled in IMbark, the imetelstat Phase 2 study, remained alive at 19 months (a metric called "median OS"). Geron CEO Dr. John A. Scarlett announced this good news about median OS on March 19, 2018.

This 19-month longevity was promising for the myelofibrosis patients, even though Scarlett warned investors that this promising news was tempered by a lack of control arm.

The allegedly bad news was that other metrics under study — in particular, SVR, Total Symptom Score (TSS) reduction, and remission — did not look promising. TSS refers to patients' self-report about the level of debilitating symptoms that myelofibrosis causes, and whether those symptoms improved. Defendants disclosed that imetelstat's SVR result *was*, in fact, disappointing. But defendants failed to disclose the bad news about the other two metrics.

The most important time to give investors an accurate account of the drug's promise would have been the March 2018 investor call immediately following defendants' *final* analysis of the IMbark data. Instead, Scarlett said the following:

> [O]utcome measures for efficacy, including spleen volume responses and reductions in Total Symptom Score *remain consistent with the prior data reviews*; [and] with a median follow-up of approximately 19 months as of the January 2018 data cut, the median overall survival has not been reached in either dosing arm . . . .
>
> Janssen will amend the IMbark protocol to establish an extension phase of the trial to enable patients remaining in the treatment phase to continue to receive imetelstat per investigator discretion . . . . *Patients will continue to be followed for survival*

(Exh. 16 at 6, emphasis added).

"Prior data reviews" refer to defendants' earlier disclosures. About the co-primary endpoint SVR, defendants had previously revealed, "[T]he spleen volume response rate observed to date ***was less*** than that reported in front-line MF patients treated in trials with other drugs." (All prior front-line studies' SVR results ranged from 48% to approximately 26.5%.) In fact, defendants publicly cautioned investors about the SVR metric at least seven times before and during the class period. They did so by repeating that SVR seen was less than prior first-line studies, or by referencing the prior data reviews. This sufficiently disclosed the bad news *vis-a-vis* SVR (Exhs. 9 at 6; 11 at 9, 13; 12 at 23; 16 at 6; 19 at 16; 20 at 8; Amd. Compl. ¶¶ 82, 83, 98, 100, 113, 122).

This order turns now to prior data reviews of imetelstat's effect on patients' cancer symptoms, *i.e.* TSS. Geron disclosed, in its 2017 SEC Form 10K (released March 2018), and three more times, that IMbark patients in the study showed "reductions in" TSS. This statement suggested that the drug showed promise. Defendants neglected to mention, however, that the reduction in patients' symptom scores was much poorer that what was seen in the pilot study, giving the impression of unqualified optimism about TSS (Exhs. 15 at 8; 9 at 6; 11 at 13; 12 at 23; 16 at 6; 18 at 10).

Turning to remission, in March 2018, with the remission data already final, defendants warned investors that the very positive pilot study results "may not be seen." To accurately characterize the remission data, Scarlett should have revealed the truth once the data were no longer "interim" (Amd. Compl. ¶¶ 26, 36, 105; Exhs. 9 at 6; 8 at 14–15; 12; 16 at 6, 10–11; 12 at 3).

In summary, in the block quotation above, the company and Scarlett told investors that SVR results disappointed. They referenced early vague-but-positive assessments of TSS; the prior data reviews had not discussed remission results. Defendants did not reveal even the outlines of the true TSS and remission outcomes.

Of course, defendants also said Geron and Janssen were redesigning IMbark to study what was looking best, survival (median OS). Defendants never stated, however, that the one-year study extension would focus *exclusively* on median OS. Had defendants so clarified, the study extension alone might have tipped off investors that imetelstat failed with respect to the other metrics. But defendants stated publicly in their SEC filing in March 2018, for example, that after the study extension defendants would evaluate the data, "including" survival outcomes. In the block quote above, they stated simply that patients would "be followed" for survival. Since investors may have reasonably believed other metrics (including TSS and remission) were still being studied, the study design change alone could not have corrected investors' potentially inflated expectations of the TSS and remission results (Exh. 15 at 5; *see also* Exhs. 11 at 16; 16 at 6).

Ultimately, the TSS disclosure and remission nondisclosure may have misled investors because the undisclosed news was pretty disappointing: as of September 2018 (the close of the class period) only **10%** of IMbark patients showed a SVR reduction of at least 35% volume (compared to prior studies' results of between 48% and 25.6% volume), only **32%** (compared to 77% in the imetelstat pilot study) showed a TSS reduction of at least 50%, **zero** patients saw complete remission, and **one** saw partial remission (compared to 23% in the imetelstat pilot study). Geron did not disclose these specifics until September 27, 2018. Shortly thereafter, the bottom fell out for Geron's stock prices. The complaint adequately alleges that defendants had to give the contours, or perhaps even the specifics, of the unpromising metrics.

The reason Geron's stock price later cratered was that Janssen bailed on the partnership. Although Geron warned investors that Janssen had the right to quit at any time; that median OS climbed higher still (to 23 months by September 2018); and that that imetelstat could (and did) go to a Phase 3 study largely on the strength of the survival data, Janssen may have bailed out in part because of the undisclosed discouraging metrics. The complaint sufficiently alleges that the market *did not already know* that these metrics lacked the expected promise.

The complaint does not adequately allege, however, that Geron or Scarlett *knew* of Janssen's supposedly likely departure.

* * *

On January 23, 2020, individual investor Michael Tollen filed a putative class action against defendant Geron and Scarlett, alleging false and misleading statements in violation of federal securities laws. That same day, Tollen's counsel published a notice in PR Newswire informing investors that a class action lawsuit had been filed against Geron and that investors had 60 days from the publication of the notice to seek appointment as lead plaintiff. An individual, Eugene Connor, filed a second class action in this district in February 2020, which this Court later related. An earlier order herein appointed lead plaintiffs Julia and Richard Junge and consolidated the cases. Plaintiffs filed the first amended complaint and defendants responded with a motion to dismiss. They filed the second amended complaint in October 2020, and defendants now move to defeat it (Dkt. Nos. 84–85).

This order follows full briefing and oral argument (telephonic due to COVID-19).

ANALYSIS

1. SECTION 10(b)

When ruling on motions to dismiss brought under Section 10(b), "courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). To state a claim under Section 10(b), plaintiff must plead: (1) "a material misrepresentation or omission;" (2) "scienter;" (3) "connection with the purchase or sale of a security;" (4) "reliance;" (5) "economic loss;" and (6) "a causal connection between the material misrepresentation and the loss." *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 342 (2005). Defendants contest the first two elements.

A. MISREPRESENTATION.

The amended complaint identifies supposed misrepresentations about: (1) imetelstat's allegedly positive results regarding median OS; (2) imetelstat's effectiveness as to primary endpoints, SVR and TSS, and a secondary endpoint, remission; (3) the study's risk level to investors; and (4) Janssen's opinion of the IMbark study results. For the reasons that follow, this order agrees that Geron should have disclosed the outline, but not necessarily the data, for TSS and remission in light of the median OS disclosure (Opp. at 16; Exh. 16 at 6, 10–11; Amd. Compl. ¶¶ 27, 35, 110–11).

An actionable "omission" must do more than leave out a fact. It must "affirmatively create an impression of a state of affairs that differs in a material way from the" real one. *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002).

(i) Median OS.

The amended complaint fails to allege a material misrepresentation about median OS. The amended complaint calls the median OS result "essentially meaningless" because defendants allegedly failed to disclose: (1) bias in patient population; (2) bias in patient selection; and (3) the fact that "bias" in patient selection could render "study estimates" poor

"represent[atives] [for] the outcomes for the treated patient population" (Amd. Compl. ¶¶ 91, 97–111, 144).

The earliest disclosures about the data did not mislead: In April 2017 defendants twice told investors (on a conference call and at Geron's annual stockholder meeting), "[T]he data suggests [*sic*] a ***potential overall survival benefit***." Nor did those at the beginning of the class period. In March 2018 came the statement to which plaintiffs strenuously object: Geron's SEC Form 10-K informed investors that IMbark's patient cohort had ***failed to meet median OS after 19 months***. In other words, more than 50% of IMbark patients remained alive at 19 months, a favorable result. Three days later, Scarlett presided over an investor call and added that the study would continue another year to "look predominately at survival." In other words, defendants were disclosing the median OS figure to help explain why they would be extending the study. Defendants repeated similar disclosures of the median OS figure and the study extension several times, in its Form 10-Q filed in May 2018, in May 2018's conference call, and in Geron's Form 10-Q for the period ending in June 2018 (Exhs. 9 at 6; 16 at 6, 10–11; 19 at 16; 20 at 8, 11, 21; 21 at 14, 17; Amd. Compl. ¶¶ 119–34).

Disclosures contained adequate warnings of study limitations related to (3) in, for example, Scarlett's May 2017 and March 2018 conference calls (*see, e.g.*, Exhs. 11 at 15; 16 at 4).

Scarlett also elaborated on (1) and (2), related to bias in the March 2018 call:

> ***[Y]ou need a control arm in order to make a correct and an appropriate scientific assessment of overall survival because you can be surprised by relative changes in patient populations*** . . . . ***We don't have a control arm here*** . . . . [But] I think that you can make broad generalizations . . . . [Fourteen] to [sixteen] months appears to be the median OS for [other] patients in a number of different follow-up studies . . .

(emphasis added). Crucially, he did explain that earlier studies had examined patients with "earlier stage" illness while IMbark examined sicker patients. And, he cautioned that development depended upon the ultimate median OS result. Defendants adequately disclosed study limitations (Amd. Compl. ¶¶ 21, 77, 98–111; Exh. 11 at 9–10, 15–16; Exh. 16 at 10).

(ii) SVR.

Defendants did not mislead investors about imetelstat's promise to improve the SVR metric, because they never overstated the drug's promise. In September 2018, defendants revealed the final SVR results, that just **10%** of IMbark patients showed a SVR reduction of at least 35% (the study threshold).

The amended complaint calls the SVR data "materially adverse" because "the results of IMbark showed imetelstat did not produce the unprecedented and durable results seen in the" 2013 Mayo Clinic "pilot study of MF patients treated with imetelstat, or the outcomes produced in Phase 2 studies of other second-line MF treatments." The complaint also cites Geron and Janssen's initial enthusiasm about replicating the pilot studies' remission results to purportedly show that the remission data must have been materially adverse and that investors would have responded strongly to bad news on that front.

All of this fails to acknowledge that Geron informed investors that the SVR data were lower than previously seen in other front-line studies. (Researchers, to repeat, hoped to see significant reductions in spleen size in as many patients as possible.)

As discussed above, defendants publicly cautioned investors at least *seven times* before and during the class period that SVR results turned out worse, *i.e.* fewer IMbark patients' spleens shrank as compared to prior studies. This exact statement, or one extremely close to it, appeared in three conference calls, two slide decks/public presentations, and two SEC disclosures from April 2017 through June 2018:

> In those relapsed or refractory MF patients treated in the 9.4 milligram per kilogram dosing arm, the spleen volume response rate observed to date ***was less*** than that reported in front-line MF patients treated in trials with other drugs.

In May 2017, defendants had revealed the results of some prior front-line MF studies, which showed 48% to approximately 26.5%. Thus, the disclosures accurately revealed IMbark's ultimate SVR result was "less than" 26.5% (Exhs. 9 at 6; 11 at 9, 13; 12 at 23; 16 at 6; 19 at 16; 20 at 8).

Significantly, Scarlett also warned that the SVR rate did not "meet protocol-defined interim criteria at 12 weeks to continue enrollment in either arm." In other words, the SVR data were so poor that Geron would not give imetelstat to new patients. And, in explaining why they revealed the ballpark of the SVR figure (while not disclosing other figures), defendants emphasized that SVR results generally disappointed (Opp. at 4; Amd. Compl. ¶¶ 6, 20, 72, 100; Exhs. 9 at 6; 12 at 23; 15 at 8; 18 at 10; 19 at 16; 20 at 8; 21 at 17).

Defendants were not required to disclose the actual figure. They did accurately disclose this "bad" result, along with the "good" median OS figure. *See Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002).

(iii) TSS and Remission.

In contrast, defendants did not adequately disclose the bad TSS and remission outcomes alongside the good median OS result. The bad results plausibly contributed to Janssen's decision to quit the partnership.

The truth (released in September 2018) was: **32%** of IMbark patients showed a TSS reduction of at least 50%, a worse outcome than in the pilot study (77%). **Zero** patients saw complete remission (one saw partial remission), which was far less than the pilot (in which 21% saw complete or partial remission).

To repeat, developers and patients had hoped that imetelstat would decrease TSS (symptom scores), and cause remission in as many patients as possible.

In the April 2017 conference call, defendants revealed that "outcome measures included . . . ***decreases in total symptom scores***." While technically true that patients saw "decreases," the total percentage of patients who benefitted fell far short of the whopping 77% of patients in the pilot study. Later, after IMbark's final data calculation, Geron filed its SEC Form 10-K in March 2018, which stated that TSS results "remain consistent with the prior data reviews." "Prior data reviews" referred back to the revelation that patients saw "decreases" in TSS. Defendants repeated the same disclosure the day after the filing, in its slide deck presentation. At this pleading stage, the fact that the IMbark had a sicker patient population does not immunize defendants, who failed to explain that IMbark's TSS figure looked worse than in the

pilot study (Exhs. 9 at 6; 8 at 14–15; 12; 15 at 8; 16 at 6, 10–11; 17 at 10; Amd. Compl. ¶¶ 16, 20, 74, 80, 83, 110–24).

Concerning remission results, the amended complaint alleges that defendants should have disclosed the partial and complete remission data, already available in March 2018. The remission results disappointed and defendants failed to say so. For instance, defendants' SEC filing released in March 2018 stated that the 21% remission result seen in the pilot study *may* not be seen in IMbark, even though the poor results had already emerged. This plausibly misled investors (Amd. Compl. ¶¶ 7, 16, 103–06; Exhs. 12 at 3; 15 at 30).

In re Rigel Pharmaceuticals Inc. Sec. Lit., 697 F.3d 869, 878 (2012), does not bless defendants' remission and TSS disclosures/omissions. In that decision, plaintiffs contended that a pharmaceutical company failed to disclose the correct endpoints. Our court of appeals held that plaintiff's complaints implicated "study design" and methodology, not truth/falsehood. Here, however, defendants initially held out TSS and remission as important and never corrected that impression. Even assuming the study design had changed to devalue these endpoints, investors did not know as much, at least not on this record.

Plaintiffs urge that we follow *Miller v. Thane Int'l, Inc.*, 519 F.3d 879, 886 (9th Cir. 2008), *superseded in part on other grounds Miller v. Thane Int'l, Inc.*, 615 F.3d 1095, 1099 (9th Cir. 2010). There, a pre-merger prospectus contained a misleading statement. Shareholders relied on that statement in voting to merge. Our court of appeals found that the company's later disclosure, which modified but did not correct the earlier statement did not put shareholders on notice. "[I]nvestors are not generally required to look beyond a given document to discover" the truth. *Id.* at 887. Similarly, our amended complaint plausibly alleges that defendants failed to correct prior misleading statements. Defendants should have at least reported the outlines of the TSS and remission results (if not the figures), to faithfully report them.

Defendants did not sufficiently reveal the bad (TSS and remission) with the good (survival).

(iv) Risk Disclosures and "Derisking."

The amended complaint characterizes defendants' various risk statements to investors (detailed below) as false or misleading.

First, the amended complaint challenges the four "risk factors" that Geron disclosed in the 2017 Form 10-K released in March 2018: (1) Janssen may terminate the CLA at any time; (2) imetelstat clinical trials "may not" support further development; (3) complete and partial remissions observed in the pilot study may not be seen (Opp. at 16–17; Exh. 16 at 6, 10–11; Amd. Compl. ¶¶ 27, 35, 102–06, 110–11, 165).

The amended complaint contends that the risks in (1) and (2) "had already materialized" and thus these statements misrepresented the real state of affairs, *i.e.* that Janssen would abandon the partnership. But in January 2018, Janssen and Geron decided to continue the study for an additional year, suggesting they had some faith in imetelstat at that time. It remained a mystery at the time of the risk statements whether IMbark's median OS result would impress; therefore, its clinical prospects remained uncertain through the class period, at least on this record. As to (3): With respect to the risk statement about remission, defendants knew the final study results, so describing a hypothetical risks was misleading, at least at the pleadings stage. The risk of a poor TSS outcome had also already ripened, and defendants were duty-bound to disclose something about its true nature. For the reasons stated in the above sections, the disclosures about SVR and median OS did not mislead (Amd. Compl. ¶¶ 26, 29, 30, 86–92, 101–06).

The motion is, as to the risk statements released in March 2018, **GRANTED IN PART AND DENIED IN PART**.

Second, the amended complaint alleges that Scarlett's July 2018 statement, "[W]e believe the imetelstat program has been derisked by the collaboration with Janssen" misled. Opinions given to investors mislead only if "the statement is not actually believed" by the speaker or she "is aware of undisclosed facts tending seriously to undermine the statement's accuracy." *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 616 (9th Cir. 2017). De-risking refers to managing the time, risks, and costs of early drug

development. When Scarlett made the above statement, he was describing Geron's plans to proceed with imetelstat if Janssen bailed, and he warned imetelstat development would "take longer" without Janssen. Nothing suggests Scarlett dissembled. And, the concrete warning meant that investors could not have reasonably believed the de-risking statement literally (Amd. Compl. ¶ 34; Exh. 22 at 6–7).

As to the de-risking statement, the motion is **GRANTED**.

B. SCIENTER.

Under the PSLRA, a plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with [scienter]." 15 U.S.C. § 78u-4(b)(2)(A). A "strong inference" must be "cogent and at least as compelling as any plausible opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 314. The inquiry need not be limited to "individual allegations in isolation" if "the overwhelming evidence drawn from a holistic view" of the pleadings gives rise to a strong inference. *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 710 (9th Cir. 2012).

The complaint alleges that the following evince scienter: (1) at the January 2018 meeting of the Joint Steering Committee, Geron came to know that Janssen disliked the results of the study; (2) defendants closely monitored the study results; (3) Geron sold stocks in advance of Janssen's announcement; and (4) two executives (not named defendants) sold stocks suspiciously soon before Janssen's announcement.

First, the amended complaint has not alleged anything that memorialized Janssen's supposed disappointment in the IMbark results at the January 2018 meeting of the Joint Steering Committee. This speculation does not raise an inference of scienter.

Second, close access to study data may support a finding of scienter. *See In re Quality Sys., Inc.*, 865 F.3d 1130, 1145; *In re Daou Sys., Inc.*, 411 F.3d 1006, 1022-23 (9th Cir. 2005). Given that the amended complaint successfully alleges that defendants should have corrected TSS and remission statements, defendants' knowledge supports such an inference (Amd. Compl. ¶¶ 26, 87).

Third, while it is true that Geron, as a corporation, traded in stocks during the class period and made a profit, in a Form 10-Q dated May 10, 2018, Geron discussed the need to raise capital in anticipation of the next stage of Geron's partnership with Janssen: if Janssen decided to opt-in, Geron would need to decide to invest in imetelstat's further development (or not). If it opted out, Geron could be left holding the bag. Geron would need capital to go it alone. This alone does not necessarily reveal a strong inference of scienter. *Rigel*, 697 F.3d at 884 (Exh. 19 at 16; Amd. Compl. ¶¶ 59, 121–26).

Fourth, non-defendant executives' sales support an inference of scienter. The amended complaint names neither executive in this suit. Geron is small, with less than 20 employees. The complaint plausibly alleges that these two executives knew of Janssen's impending decision (due at the end of September) in which it would decide whether to continue the partnership. They sold 100% of their stocks at inflated prices at the end of August 2018 and in mid-September 2018, having never before sold any. A trading pattern by insiders "dramatically out of line" with previous patterns may support scienter. *In re UTStarcom, Inc. Sec. Litig.*, 617 F. Supp. 2d 964, 976 (N.D. Cal. 2009) (Judge James Ware). The timing and first-time, 100% sale support an inference of scienter. *See In re TUT Sys., Inc. Sec. Litig.*, 2002 WL 35462358, at *12 (N.D. Cal. Aug. 15, 2002) (Judge Claudia Wilken) (Amd. Compl. ¶¶ 151, 152, 162).

On balance, Geron's close monitoring of data and its executives' stock sales satisfy the heightened pleading standard for scienter.

2. CONTROL PERSON.

Lastly, defendants' motion seeks dismissal of plaintiff's claims under Section 20(a) because "Plaintiff's failure to plead a primary violation of Section 10(b) requires the dismissal." This argument fails, as the complaint pleads sufficient factual material. Defendants' motion to dismiss Section 20(a) claims against Scarlett is **DENIED** (Dkt. No. 105 at 25).

3. REQUESTS FOR JUDICIAL NOTICE.

Defendants request that the Court take judicial notice of or consider incorporated by reference 32 documents. Federal Rule of Evidence 201(b) permits courts to take judicial notice of any fact "that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." While a court may take judicial notice of matters of public record at the motion to dismiss stage, it cannot take judicial notice of disputed facts contained in such public records. *See Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018). Courts must specify what facts they judicially notice. *Ibid.*

This order relies only on Exhibits 6–9, 11–12, 15–16, and 18–23. The requests for judicial notice as to the remainder are **DENIED AS MOOT**.

Of these, plaintiffs object to Exhibits 7 and 12 because they "dispute facts alleged in the complaint and are offered for their truth." Exhibit 7, draft FDA guidance about the nature of Phase 2 and 3 trials, comes from an extremely reputable source, the FDA. This order relies on it only for its general discussion of the meaning and choice of study endpoints. Exhibit 12, a slide deck presentation, details the IMbark study design and the order relies on it for what notice it gave investors.

Plaintiffs object to 8 and 12 as "subject to varying interpretations" and disputes defendants' representation about what they establish. This order relies on both for Geron's public disclosures about the history of MF research and development of imetelstat.

This order will take judicial notice of defendants' public revelations, including Exhibits 6, 9, and 11 (all Geron investor calls). These documents form part of the basis of plaintiffs' claims. *See Orexigen*, 899 F.3d at 1002.

Plaintiffs do not oppose notice of 15–16 or 18–23. The Court will consider the investor presentation transcripts and investor presentation slide decks that plaintiffs allege contain false and/or misleading statements for the purpose of determining what was disclosed to the market. Because "the plaintiff refers extensively to the document[s] [and] the document[s] form[ ] the basis of the plaintiff's claim" with their public representations by Geron about imetelstat, this

order **GRANTS** the motion as to 6–9, 11–12, 15–16, and 18–23, finding these documents incorporated by reference. *See Khoja*, 899 F.3d at 1002 (quoting *United States v. Ritchie*, 342 F.3d 903, 907 (9th Cir. 2003)).

CONCLUSION

The motion to dismiss Section 10(b) and Rule 10b-5 claims against Geron, and 20(a) claims against Scarlett, is, with respect to median OS, SVR, and Scarlett's de-risking statement, **GRANTED**. With respect to overall TSS and remission omissions/disclosures, it is **DENIED**. With respect to the risk statements from March 2018 about SVR and median OS, it is **GRANTED**. With respect to the risk statements about TSS and remission, it is **DENIED**. The requests for judicial notice are **GRANTED IN PART AND DENIED IN PART**.

By **MAY 6, 2021, AT NOON**, plaintiffs may seek leave to amend the dismissed claims by a motion noticed on the normal 35-day calendar. Plaintiffs must plead their best case. Their motion should affirmatively demonstrate how the proposed amended complaint corrects the deficiencies identified in this order, as well as any other deficiencies raised in the defendants' motion but not addressed herein. The motion should be accompanied by a redlined copy of the amended complaint.

IT IS SO ORDERED.

Dated: April 12, 2021.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE

United States District Court
Northern District of California