IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

IN RE GERON CORPORATION STOCKHOLDER DERIVATIVE LITIGATION	)	Consolidated C.A. No. 2020-0684-SG

MEMORANDUM OPINION

Date Submitted: February 15, 2022
Date Decided: June 3, 2022

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GLASSCOCK, Vice Chancellor

This case is at its core quite simple. The Plaintiffs are stockholders of Geron Corporation ("Geron" or the "Company"). The Company at present has no products, but is attempting to develop and monetize an anti-cancer drug. It was party to a contract with Janssen Biotech Inc. ("Janssen") to assist in moving the drug, imetelstat, through clinical trials and, it was hoped, FDA approval and marketing. Janssen's impetus for entering the contract was based, in part, on results of a second-phase clinical trial (the "Phase Two Trial"). If those results proved disappointing, Janssen was likely to exit its agreement to develop imetelstat, which would be catastrophic for Geron.

Per the complaint (the "Complaint"), the Phase Two Trial was not successful. The board of directors was made aware of the ongoing failures (profound, but not complete) of the clinical trial. Nonetheless, the directors approved misleading disclosures in 10-K filings and in other public communications with investors, overstating the positive results and understating the risks. Eventually, Janssen exited the agreement.

The Plaintiffs bring this claim for breach of fiduciary duty. They allege that the Defendant directors' dissemination of "corporate lies" states a breach of duty claim based on two different theories. The most obvious is a false disclosure claim

under the theory of *Malone v. Brincat.*[1] The Plaintiffs also attempt to plead an oversight claim under the *Caremark* rubric.

The Defendants have moved to dismiss under Rule 23.1. That rule seeks to vindicate the fundamental principle that directors deploy corporate assets, including litigation assets. The Rule, accordingly, requires a demand for legal action on the board.

An exception to that requirement is recognized where demand would be futile. Where, as here, demand futility is alleged to rest on the Defendant directors themselves being liable in the litigation, demand may be excused, but the pleading standard is rigorous. A plaintiff must plead specific facts that raise a substantial likelihood that the directors would face liability before Rule 23.1 is satisfied, demand is excused, and the stockholder-plaintiff may proceed to litigate the claims on behalf of the entity.

In this action, the Plaintiffs allege that the Defendant directors intentionally misled investors and stockholders. That is a conclusion, not a factual pleading. The Plaintiffs also plead facts from which they contend I may infer the same conclusion, for purposes of the analysis under Rule 23.1. The Defendants point to different interpretations of the facts pled—as opposed to the conclusory allegations of the

[1] 722 A.2d 5 (Del. 1998).

Complaint—and seek a dismissal despite inferences being drawn in the Plaintiffs' favor.

I note that a separate securities action, based on the same facts and similar to the *Malone* theory here pled, is well-advanced in a California federal court.[2] That action, which is scheduled for trial in a few months, will establish a number of facts necessary to litigation here. It may obviate the need to address this motion to dismiss, or establish the predicate for successful assertion of demand futility. It may obviate the need for this action altogether.

I have said that the California securities action most nearly replicates the issues the Plaintiffs promote here under the common-law *Malone* claim. Again, the Plaintiffs also assert a cause of action under *Caremark*, asserting that the Defendant directors ignored "red flags" of the failure of the Phase Two Trial. The Plaintiffs repeat what has become the shibboleth of the "mission critical" nature of the subject of the directors' alleged misfeasance, here regarding the drug imetelstat. The viability of the drug is critical to Geron, no doubt. But I confess to not understanding the allegations of oversight liability. According to the Complaint, the directors were aware that the clinical trial was proceeding poorly. What could the Defendant

[2] I am mindful that this other matter differs somewhat in the parties to the suit (there pending solely against Defendant Scarlett and Defendant Geron) and the claims brought, but the factual and case theory overlap between the two actions remains significant. Verified Consolidated Am. Stockholder Derivative Compl. ¶ 28, Dkt. No. 38 [hereinafter "Compl."].

directors have done in good faith in the face of this knowledge to avert corporate trauma? The only thing the Plaintiffs point to is to not lie to investors. That, of course, is the *Malone* claim addressed above. I do not see how Plaintiffs may shoehorn this into a claim under *Caremark*. In essence, the Plaintiffs make a single claim—the Defendant directors knew the clinical trial results were bad, but misled investors into thinking all was well. If such actions were taken in bad faith, they are actionable, despite the rubric applied to the claim.

In any event, as stated above, this action is most efficiently handled after the imminent federal trial. And a stay will have the added advantage of avoiding potentially inconsistent rulings. Accordingly, I am staying further consideration of the matter. Should circumstances change—for instance, should a decision in the federal action be delayed—any party may seek to lift the stay.

I explain in more detail, below.

I. BACKGROUND

This Memorandum Opinion addresses a two-pronged motion to dismiss (the "Motion to Dismiss") premised upon demand futility and failure to state a claim.

A. Factual Overview[3]

1. The Parties, Relevant Non-Parties, and the Industry

Richard DiLaura, Ernesto Elizalde, Jr., and Joseph Oriente are the Plaintiffs in this action. DiLaura and Oriente have owned stock in Geron at all times pertinent.[4] Elizalde has held stock in Geron since March 22, 2018.[5]

Nominal Defendant Geron is a Delaware corporation and clinical-stage biopharmaceutical company.[6] Geron currently has a singular drug-product candidate, called imetelstat, which is intended to treat, among other things, myelofibrosis ("MF"), a deadly blood cancer.[7] Because Geron has no other product candidates, the Company, per the Plaintiffs, "was and (is) entirely dependent on the success of imetelstat," which would in turn require the drug to be approved for dispensation to customers.[8]

The remaining defendants are all current or former Geron senior officers or members of Geron's board of directors (the "Board") at the pertinent time: John

[3] Unless otherwise specified, the facts in this section are drawn from the Complaint. I consider the facts to be true as pled in the Complaint, in accordance with the applicable standard on a motion to dismiss. This section therefore does not constitute formal findings of fact.
[4] *Id.* ¶¶ 25, 27.
[5] *Id.* ¶ 26. The Defendants challenge Elizalde's status as a plaintiff in this action due to his alleged failure to satisfy the contemporaneous ownership requirement. *See* Defs.' Opening Br. Supp. Mot. Dismiss Pls.' Verified Consolidated Am. Stockholder Derivative Compl. Pursuant to Ct. of Chancery Rules 23.1 and 12(b)(6), at 5 n.1, Dkt. No. 46 [hereinafter "OB"]. I need not reach this argument at this juncture.
[6] Compl. ¶ 28; OB 5.
[7] OB 5.
[8] Compl. ¶ 46.

Scarlett, also the Chief Executive Officer and President of Geron; Karin Eastham; V. Bryan Lawlis; Susan Molineaux; Robert Spiegel; Daniel Bradbury; and Hoyoung Huh (collectively, the "Director Defendants" and together with Geron, the "Defendants").[9]

Non-party Janssen is a prior contractual counterparty of Geron's.[10]

2. Imetelstat Development

In 2013, Geron released positive results from a Mayo Clinic "pilot study" where MF patients received doses of imetelstat.[11] The participants in the pilot study fell into two groups: those who failed to respond to treatment with other MF drugs, and those who had not previously received treatment.[12] The pilot study provided a number of metrics to those following the development of imetelstat: 39% of patients with enlarged spleens experienced reduction in spleen size of at least 50%; 77% of patients showed at least a 50% reduction in symptoms; and finally, approximately 23% of patients experienced either complete or partial remission, with another 18% of patients showing some level of clinical improvement.[13]

In November 2014, Geron and Janssen entered into a Collaboration and Licensing Agreement (the "Agreement") to support the development of imetelstat.[14]

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[9] *Id.* ¶¶ 29–36.
[10] *See id.* ¶ 5.
[11] *Id.* ¶ 4.
[12] *Id.* ¶ 54.
[13] *Id.* ¶ 55.
[14] *Id.* ¶ 5.

Geron received $35 million in funding as a result of the Agreement, with potentially further funding to follow if imetelstat ultimately proved effective in treating MF.[15] The Agreement provided Janssen with the exclusive right to develop and commercialize imetelstat worldwide, but also made Janssen responsible for developing, manufacturing, obtaining regulatory approval for, and commercializing imetelstat.[16] The Agreement could be terminated by Janssen following the primary analysis of the second clinical study of imetelstat.[17]

After entry into the Agreement, Geron and Janssen began a Phase Two clinical trial for imetelstat as used to treat MF via a clinical study (defined above as the "Phase Two Trial").[18] The Phase Two Trial evaluated approximately 200 patients with intermediate or high-risk MF who had either relapsed after or were resistant to prior treatment with a different drug.[19] The Phase Two Trial was originally scheduled for a 24-week duration for measurement of the primary endpoints,[20] though the Complaint also states that the study was scheduled to continue until April 2018 or when a set number of patients had perished, whichever came first.[21]

[15] *Id.*
[16] *Id.* ¶ 57.
[17] *See id.* ¶ 67.
[18] *Id.* ¶¶ 6–7.
[19] *Id.* ¶ 7.
[20] *Id.* ¶ 12.
[21] *Id.* ¶ 65.

The Phase Two Trial set two "co-primary efficacy endpoints", measuring the percentage of patients who experienced (1) a reduction in spleen size/volume of 35% or more, and (2) reductions of 50% or more of a composite of various symptoms called the "Total Symptom Score."[22] These primary endpoints are identical to the endpoints used by a second pharmaceutical company that had obtained U.S. Food and Drug Administration ("FDA") approval of another drug treating MF.[23]

The Phase Two Trial also included fourteen secondary endpoints, including remission and "overall survival."[24] Overall survival is aptly named and refers to "the time for 50% of patients enrolled in the study to die."[25]

Primary endpoints, per the Plaintiffs, typically address the main research question, while secondary endpoints "are generally not sufficient to influence decision-making alone," but can demonstrate additional benefits or support causal analyses.[26]

Per the Plaintiffs, the results with respect to the primary endpoints "would determine whether the [Phase Two Trial] was successful or not and whether the FDA would approve imetelstat" for patient use in the United States.[27] Similarly, the Phase Two Trial would provide Janssen with information as to whether or not it wished to

[22] *Id.* ¶ 8.
[23] *Id.*
[24] *Id.* ¶ 9.
[25] OB 14.
[26] Compl. ¶ 10.
[27] *Id.* ¶ 11.

continue its partnership with Geron.[28] If the partnership were continued, Janssen would owe Geron an "upfront payment" of $65 million, with further milestone payments possible.[29]

a. The Phase Two Trial Results

The Phase Two Trial results were disappointing. Imetelstat failed to meet the co-primary endpoints as to the majority of patients who took part in the study.[30] The Plaintiffs allege that "90% of patients failed to experience a spleen size reduction of 35% or greater," and that "68% of patients failed to experience [Total Symptom Score] reduction of 50% or greater."[31] The Plaintiffs also note that no patients achieved *complete* remission, while one patient did achieve partial remission during the Phase Two Trial.[32] Per the Plaintiffs, consideration of the co-primary endpoints and remission data (the "Primary Endpoint Results") shows that imetelstat "was not effective in improving debilitating symptoms of MF or quality of life for patients,"[33] particularly as compared to the success of the pilot study.[34]

But the Phase Two Trial included fourteen secondary endpoints.[35] Certain of these secondary endpoints performed well. For example, median overall survival

[28] *Id.* ¶ 13.
[29] *Id.*
[30] *Id.* ¶ 14.
[31] *Id.* (emphasis omitted).
[32] *Id.* (emphasis omitted).
[33] *Id.*
[34] *Id.* ¶¶ 14–15.
[35] *Id.* ¶ 9.

had not been reached—that is, over 50% of patients remained alive—in either dosing arm of the Phase Two Trial as of March 2018—well over a year past the date on which the final patient was enrolled in the Phase Two Trial.[36] In fact, the overall survival rates were so good that Janssen amended the Phase Two Trial 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 be continued to be followed for survival."[37]

Notwithstanding this survival metric, the Plaintiffs aver that the Primary Endpoint Results "significantly reduced" imetelstat's prospects, both with respect to eventual FDA approval and with respect to the continuation of the Janssen partnership.[38]

b. The Geron Board and Janssen React to the Phase Two Trial Results

The Board started to receive negative information about the Phase Two Trial, including the Primary Endpoint Results, in mid-November of 2016.[39] Particularly, the 220 document production secured by the Plaintiffs shows that at a November 17 and 18, 2016, Board meeting, Defendant Scarlett told the Director Defendants more broadly that "without stronger interim [Phase Two Trial] data, we do not believe

[36] *Id.* ¶¶ 82, 7 (identifying October 2016 as the time of enrollment of the final patient).
[37] *Id.* ¶ 86.
[38] *Id.* ¶¶ 18–19.
[39] *Id.* ¶ 19.

there is currently a path to develop imetelstat for front-line MF."[40] That meeting also confronted the reality that the disappointing Primary Endpoint Results—interim in nature at this point—would likely affect Janssen's decision as to whether to remain party to the Agreement, and might affect imetelstat's ability to eventually receive FDA approval.[41]

At a meeting on February 8 and 9, 2017, the Director Defendants discussed a "pivot" in the Phase Two Trial's focus to the overall survival metric.[42] The Complaint indicates that the pivot was actually a reflection of Janssen's "focus on the development strategy."[43]

At a meeting on April 4, 2017, the Director Defendants received a presentation from Defendant Scarlett about the second data reviews.[44] Per the meeting minutes, the Director Defendants were made aware at this time that imetelstat was underperforming with respect to both of its co-primary endpoints.[45]

By May 2017, the entirety of the original 24 weeks allotted to the Phase Two Trial had run, and the Board at that time had "actual knowledge" that imetelstat's Primary Endpoint Results had failed to meet the trial threshold.[46] At a meeting on

[40] *Id.* ¶ 106.
[41] *Id.* ¶¶ 104–05.
[42] *Id.* ¶ 108.
[43] *Id.*
[44] *Id.* ¶ 109.
[45] *Id.*
[46] *Id.* ¶¶ 18, 21. At eight Board meetings between May 2017 and September 2018, the Board was provided with evidence of the Primary Endpoint Results' failure. *Id.* ¶ 22.

May 9 and 10, 2017, the Director Defendants were provided with "hard numerical data on imetelstat's primary endpoints," supporting the claim that the Board had actual knowledge of the failure.[47]

I do note, however, that the review at that point was described to the Board as "interim," and that the pertinent figures in the Complaint appear to change between the May 2017 Board meeting and a later September 2017 Board meeting.[48] The numbers associated with the Primary Endpoint Results shift repeatedly (but minorly) when reviewing the pleadings about a November 2017 Board meeting, a January 2018 Board meeting, and a May 2018 Board meeting.[49] These shifts suggest that even if all data had been collected as of May 2017, and even if interim results were available, that data underwent additional processing.

From the initiation of the Phase Two Trial through at least May 2017, the Director Defendants[50] continued promoting imetelstat publicly, including positive commentary about the Phase Two Trial.[51] The Complaint notes that the public statements made by the Director Defendants changed to focus more on overall

[47] *Id.* ¶¶ 111–12.
[48] *Id.* ¶¶ 110–11, 116.
[49] *Id.* ¶¶ 119, 120, 122.
[50] The Complaint alleges these actions were taken by the Director Defendants, not the Company. *See id.* ¶ 18. This particularity in allegation—noting that the Director Defendants caused the Company to take action—is consistent with the Complaint's allegations about Geron's public filings, discussed *infra*, as well.
[51] *Id.*

survival, one of the secondary endpoints, during this time, though the formal decision to refocus the study was not communicated to stockholders.[52]

Under the Agreement with Janssen, Janssen was required to analyze data from the Phase Two Trial and notify Geron as to whether it would terminate the Agreement.[53] Janssen elected to terminate the Agreement following the Phase Two Trial.[54]

3. Geron's Disclosures About the Phase Two Trial

a. Public Filings and Press Releases During the Phase Two Trial

On March 1, 2017—approximately three and a half months after the Complaint pleads Geron began receiving negative feedback about the Phase Two Trial—the Director Defendants caused Geron to file its Annual Report on Form 10-K for fiscal year 2016 with the Securities and Exchange Commission (the "2016 Form 10-K").[55] The 2016 Form 10-K discusses the Phase Two Trial in some detail, though it does not purport to deliver results to stockholders.[56] The summary provided by the 2016 Form 10-K discusses the co-primary endpoints in the most

[52] *Id.* ¶¶ 21, 108.
[53] *Id.* ¶ 67.
[54] *Id.* ¶ 68.
[55] *Id.* ¶ 72. The Complaint pleads two additional public filings made by Geron on November 3, 2016, *see id.* ¶¶ 70–71, but the Complaint also pleads that Geron began receiving negative information about the Phase Two Trial "at the latest by November 17–18, 2016." *Id.* ¶ 19. The Complaint is unclear, but it appears that the November 3, 2016 public filings predate the applicable time period.
[56] *Id.* ¶¶ 73–74.

detail, and while some secondary endpoints are mentioned, overall survival is not among them.[57]

The 2016 Form 10-K also states, as part of its "Risk Disclosures," that any failure by Janssen to perform under the Agreement could "terminate[] or substantially delay[]" commercialization of imetelstat, and Geron's business "would be severely harmed" as a result.[58]

Geron filed its Quarterly Report on Form 10-Q for the first quarter of fiscal year 2017 on May 9, 2017 (the "2017 Q1 10-Q").[59] The 2017 Q1 10-Q included a summary of the Phase Two Trial, stating:

> In these relapsed or refractory MF patients treated in the 9.4 mg/kg 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. However, activity within multiple outcome measures was observed with imetelstat treatment, which suggests potential clinical benefit . . . These outcome measures included a range of spleen volume reductions, reductions in Total Symptoms Score . . . In addition, the data suggest there may be a potential overall survival benefit associated with imetelstat treatment in these patients.[60]

True, per the Plaintiffs, but misleading. The Plaintiffs allege that the 2017 Q1 10-Q should have disclosed the final results of the Phase Two Trial—that is, that the

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[57] *Id.* ¶ 72, 73.
[58] *Id.* ¶ 74.
[59] *Id.* ¶¶ 76, 77. The Complaint also pleads details about the Company's press release regarding financial results for the first quarter, but that press release does not factor into my findings here. *Id.* ¶ 76.
[60] *Id.* ¶ 77.

Phase Two Trial's Primary Endpoint Results were a failure.[61] They also charge that Geron should have comparatively commented that the Primary Endpoint Results were in "stark contrast" to the pilot study.[62] Finally, the Plaintiffs believe that Geron should have disclosed that Janssen "likely would opt" to terminate the Agreement given the Primary Endpoint Results.[63]

I note that the Complaint does not provide me with precise dates. It alleges that the Board knew of the final Primary Endpoint Results of the Phase Two Trial in April or May 2017.[64] But it is not clear that the Board knew of the final results as of May 9, 2017.

The 10-Q Geron filed for the second quarter of 2017 reflects similar disclosure by the Company and nearly identical criticism by the Plaintiffs.[65] The third quarter 10-Q also contained similar discussion regarding the primary endpoints, but included additional disclosure, specifying: "We believe that without an adequate survival benefit in relapsed or refractory MF, Janssen would decide to discontinue the imetelstat program and terminate the [] Agreement, irrespective of any other data from [the Phase Two Trial]."[66]

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[61] *Id.* ¶ 78.
[62] *Id.*
[63] *Id.*
[64] *Id.* ¶ 18.
[65] *Id.* ¶¶ 79, 80.
[66] *Id.* ¶ 81.

The fiscal year 2017 Form 10-K (the "2017 Form 10-K") was filed on March 16, 2018.[67] That filing, along with the press release reporting on year-end financial results for 2017, listed a number of bullet points with respect to a third internal data review of the Phase Two Trial.[68] Those bullet points did not disclose the Primary Endpoint Results—they only report that "[o]utcome measures for efficacy, including spleen volume responses and reductions in Total Symptom Score remain consistent with the prior data reviews."[69] The bullet points focused repeatedly on overall survival.[70]

At this time, per the Complaint, the Board should have been in receipt of final negative information regarding the Primary Endpoint Results for months. However, as the press release and 2017 Form 10-K report, the Phase Two Trial was still ongoing at this time.[71]

On May 10, 2018, Geron filed its first-quarter 2018 Form 10-Q.[72] This 10-Q contained similar statements as the 2017 10-Qs, identifying the primary endpoints for imetelstat, and noting that Janssen had amended the trial protocol to include an

[67] *Id.* ¶ 83.
[68] *Id.* ¶¶ 82–83.
[69] *Id.*
[70] *Id.*
[71] *See id.* (emphasis omitted) ("The trial is officially being closed to new patient enrollment . . . . [T]he protocol-specified primary analysis, which includes an assessment of overall survival, will begin by the end of the second quarter of 2018. Upon the protocol-specified primary analysis, the main trial will be completed.").
[72] *Id.* ¶ 90.

assessment of overall survival.[73] But, again, the 10-Q did not reflect the Primary Endpoint Results.[74] The second-quarter 2018 Form 10-Q, filed on July 31, 2018, was much the same.[75]

b. Conferences and Presentations During the Phase Two Trial

On March 19, 2018, the Company held a conference call with stockholders, analysts, and the media to discuss 2017 financial results.[76] Defendant Scarlett spoke on the call about the Phase Two Trial at length,[77] purporting to summarize the results from the latest internal data review on Phase Two Trial. But his remarks did not disclose the disappointing Primary Endpoint Results.[78] Just like the bullet points for the 2017 Form 10-K and earnings press release, Scarlett stated that "outcome measures for efficacy, including spleen volume responses and reductions in Total Symptom Score remain consistent with the prior data reviews."[79] He also emphasized, repeatedly, the potential that the overall survival metrics were representing as part of the ongoing trial: "imetelstat potentially could address a significant unmet medical need if its use is associated with survival that is meaningfully longer than 14 to 16 months."[80]

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[73] *Id.*
[74] *Id.*
[75] *Id.* ¶ 91.
[76] *Id.* ¶ 85.
[77] *Id.*
[78] *Id.*
[79] *Id.*
[80] *Id.* ¶ 86.

Later that month, Defendant Scarlett made a presentation at a healthcare conference that purported to summarize the internal data reviews of the Phase Two Trial that Janssen had completed to date.[81] That summary listed "[r]ange of reductions in spleen volume" and decreases in Total Symptom Score, along with the fact that median overall survival had not yet been reached.[82]

c. The Primary Endpoint Results Are Disclosed

The Complaint states that the "truth" was not disclosed to Geron stockholders until September 27, 2018, at which time Geron issued a press release stating that the Phase Two Trial Primary Endpoint Results did not meet expectations.[83] 10% of patients showed decrease in spleen volume of at least 35%, and 32% of patients showed a reduction in Total Symptom Score of at least 50%.[84] No patients achieved full remission, though one did achieve partial remission.[85]

The pilot study had resulted in 39% of patients with enlarged spleens experiencing reduction in spleen size of at least 50%;[86] 77% of patients reporting at least a 50% reduction in symptoms; and finally, approximately 23% of patients

[81] *Id.* ¶ 87.
[82] *Id.*
[83] *Id.* ¶ 93.
[84] *Id.* ¶ 94.
[85] *Id.*
[86] I note that the target decrease-percentage the Complaint reports for the pilot study was 50%, while the target decrease-percentage the Complaint reports for the Phase Two Trial was 35%. *See id.* (Phase Two Trial); *id.* ¶ 4 (pilot study).

experiencing either complete or partial remission.[87] The Phase Two Trial had clearly enjoyed less success.[88]

According to the Plaintiffs, the Primary Endpoint Results were not disclosed to stockholders until over a year after the final data regarding those endpoints was collected.[89] For clarity, although the Phase Two Trial remained ongoing well after its initial 24-week schedule due to unexpected success in the overall survival metric,[90] the *primary endpoints* were tied to a hard-stop 24-week schedule.[91] Because the last patient was enrolled in the drug trial in October 2016,[92] per the Plaintiffs, this meant that all pertinent data for the Primary Endpoint Results had been collected and was known to the Board by April or May 2017.[93] Despite the availability of this data, it was not disclosed to stockholders until September 2018.[94]

The Director Defendants also notified stockholders in September 2018 that Janssen was discontinuing the Agreement.[95]

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[87] *See supra* note 13 and accompanying text.
[88] *See* Compl. ¶ 94.
[89] *See id.* ¶ 99.
[90] *See, e.g.*, *id.* ¶ 85 (Scarlett's remarks in March 2018 regarding the ongoing measurement of median overall survival).
[91] *Id.* ¶ 65.
[92] *Id.* ¶ 7.
[93] *See, e.g.*, *id.* ¶¶ 20–21 (emphasis omitted) ("By [May 2017], every [Phase Two Trial] participant had completed the full 24 weeks on imetelstat and the final results were known. The primary endpoint data simply cannot improve after this date.").
[94] *Id.* ¶ 93.
[95] *Id.* ¶ 68.

Geron's common stock price fell sharply upon the announcement, dropping from $3.92 per share to $2.31 at close on September 27, 2018.[96]

4. The Securities Action

A different action based on these same facts[97] has been filed against the Company and Defendant Scarlett in district court in the Northern District of California (the "Securities Action").[98] The Securities Action alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.[99] The Securities Action has survived "in large part" motion to dismiss practice from the defendants,[100] with the presiding judge, Judge William Alsup, finding that the plaintiffs had "adequately allege[d] that Geron should have disclosed the bad news . . . and that failure to do so was misleading."[101] Judge Alsup also found that the plaintiff had adequately alleged scienter.[102] A jury trial date, at the time the Complaint was filed on September 1, 2021, was set for October 31, 2022.[103]

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[96] *Id.* ¶ 98.
[97] *See* Stipulation and Proposed Order Staying Case Pending Resolution of the Mot. to Dismiss in the Related Securities Class Action 3, Dkt. No. 8 ("WHEREAS, the claims asserted in [this] Action . . . are based on similar factual allegations as those in the Securities Class Action; . . . WHEREAS, in light of the current status of the Securities Class Action, and in consideration of . . . the interests of preserving the parties' and the Court's resources, and efficient and effective case management, the parties have agreed to stay the Action until and through the resolution of the above-referenced motion to dismiss in the Securities Class Action.") [hereinafter "Stay Order"].
[98] Compl. ¶ 23.
[99] *Id.*
[100] Pls.' Answering Br. Opp'n Defs.' Mot. to Dismiss Verified Consolidated Am. Stockholder Derivative Compl. 19–21, Dkt. No. 58 [hereinafter "AB"].
[101] Compl. ¶ 130.
[102] *Id.* ¶ 134.
[103] *Id.* ¶ 135.

B. Procedural History

This action was originally filed on August 18, 2020.[104] It was shortly thereafter stayed via party stipulation pending resolution of a motion to dismiss filed in connection with the Securities Action.[105] This matter picked back up in May 2021, when a first amended complaint was filed.[106] The complaint was subsequently amended again in September 2021, and this second amended complaint is the operative Complaint.[107] The Complaint brings one count for breach of fiduciary duty against all Director Defendants.[108]

The Defendants moved to dismiss,[109] and following briefing I heard oral argument in February 2022.[110] I considered the matter fully submitted at that time.

II. ANALYSIS

This matter is before me on a motion to dismiss predicated upon a failure to plead demand futility under Court of Chancery Rule 23.1, and in the alternative, predicated upon a failure of the Complaint to state a claim.

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[104] Verified Stockholder Derivative Compl. for Breach of Fiduciary Duties, Dkt. No. 1.
[105] *See* Stay Order.
[106] Verified Consolidated Stockholder Derivative Am. Compl., Dkt. No. 20.
[107] *See* Compl.
[108] That same count also alleges a breach of the duty of loyalty by director Spiegel for selling Geron stock while in possession of material nonpublic information. *See id.* ¶ 159.
[109] Defs.' Mot to Dismiss Pls.' Verified Consolidated Am. Stockholder Derivative Compl. Pursuant to Ct. of Chancery Rules 23.1 and 12(b)(6), Dkt. No. 45.
[110] Tr. of 2-15-2022 Oral Arg. on Defs.' Mot. to Dismiss, Dkt. No. 73 [hereinafter "Oral Arg."].

I find it appropriate to reserve on these motions pending the upcoming securities trial in California federal court. I discuss the Rule 23.1 analysis below to explain my reasons for the stay. I do not reach the question of whether the Complaint has stated a claim under Rule 12(b)(6).

A. Demand Futility

Directors of a corporation are empowered to direct the use of that corporation's assets, including legal assets that a corporation may have assertable against its directors.[111] A plaintiff stockholder can pursue claims on a corporation's behalf in two situations: where the directors have wrongfully refused a demand for the corporation to bring the suit, or where demand would have been futile because "the directors were incapable of impartially considering the demand."[112]

Rule 23.1 requires that, where a plaintiff brings suit on basis of demand futility, the plaintiff's complaint "allege with particularity the efforts, if any, made by the plaintiff to obtain the action the plaintiff desires from the directors or comparable authority and the reasons for the plaintiff's failure to obtain the action or for not making the effort."[113] This is a heightened pleading requirement

[111] *See United Food & Com. Workers Union v. Zuckerberg*, 250 A.3d 862, 874–76 (Del. Ch. 2020), *aff'd*, 262 A.3d 1034 (Del. 2021).
[112] *In re Camping World Holdings, Inc. S'holder Deriv. Litig.*, 2022 WL 288152, at *6 (Del. Ch. Jan. 31, 2022) (quoting *Firemen's Ret. Sys. of St. Louis ex rel. Marriott Int'l, Inc. v. Sorenson*, 2021 WL 4593777, at *6 (Del. Ch. Oct. 5, 2021)).
[113] Ct. Ch. R. 23.1(a).

comparative to our otherwise permissive notice pleading standard.[114] "[T]he demand requirement is not excused lightly because derivative litigation upsets the balance of power that the [Delaware General Corporation Law] establishes between a corporation's directors and its stockholders."[115]

The pertinent test for assessing demand futility is a three-part, director-by-director analysis of the following questions:

> (i) whether the director received a material personal benefit from the alleged misconduct that is the subject of the litigation demand;
>
> (ii) whether the director would face a substantial likelihood of liability on any of the claims that are the subject of the litigation demand; and
>
> (iii) whether the director lacks independence from someone who received a material personal benefit from the alleged misconduct that is the subject of the litigation demand or who would face a substantial likelihood of liability on any of the claims that are the subject of the litigation demand.[116]

Demand is futile where the answer to any of the questions is "yes" for at least half of the members of the demand board.[117]

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[114] *Zuckerberg*, 250 A.3d at 876.
[115] *Zuckerberg,* 262 A.3d at 1049.
[116] *Id.* at 1058.
[117] *Camping World*, 2022 WL 288152, at *6.

The Geron Board, for purposes of assessing demand futility, consisted of seven directors.[118] The Plaintiffs, therefore, must have shown that the answer as to any of the questions articulated in *Zuckerberg* is "yes" for at least four of the Director Defendants. The Complaint alleges that they have successfully challenged at least five.[119]

The Plaintiffs say that the answer would be "yes" with respect to director Scarlett due to lack of independence,[120] and that the answer would be "yes" for director Spiegel, separate from the other directors, due to a substantial likelihood of liability for insider trading.[121] I do not address these allegations in detail here, for neither is dispositive of my opinion. Instead, I turn to the gravamen of the Plaintiffs' argument, which is that a majority of the Director Defendants faces a substantial likelihood of liability based on either a *Caremark* claim or a *Malone* disclosure claim.[122]

The first of these two theories is the pleading that a substantial likelihood of liability exists against a majority of the Board due to liability under *In re Caremark*.[123] Under *Caremark*, oversight liability may attach to directors under two prongs: (1) where the directors utterly failed to implement any reporting or

[118] Compl. ¶ 142.
[119] *Id.* ¶ 143.
[120] *Id.* ¶¶ 144, 145.
[121] *Id.* ¶ 155.
[122] *Id.* ¶¶ 146–154.
[123] *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996).

information system or controls; or (2) where directors, having implemented such a system or controls, consciously failed to monitor or oversee its operations, thus disabling themselves from being informed of risks or problems requiring their attention.[124] Both prongs require a showing of scienter.[125] *Caremark* liability is effectively simply an allegation of director bad faith, and falls within the broader camp of the duty of loyalty.[126]

The Plaintiffs have also advanced another theory that they assert demonstrates a substantial likelihood of liability: a disclosure claim under *Malone v. Brincat.*[127] *Malone* held that "directors who knowingly disseminate false information that results in corporate injury or damage to an individual stockholder violate their fiduciary duty."[128] The Plaintiffs say they have well-pled allegations that the Director Defendants knowingly approved false and misleading statements regarding the Phase Two Trial, and that, accordingly, the Director Defendants face a substantial likelihood of liability arising from *Malone* sufficient to excuse demand.

Because, to be candid, it is the most compelling on the facts alleged, I address the *Malone* theory first.

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[124] *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362, 370 (Del. 2006).
[125] *Id.*
[126] *See id.* at 369.
[127] 722 A.2d 5 (Del. 1998).
[128] *Id.* at 9.

1. Demand Futility Under *Malone v. Brincat*

The Plaintiffs' primary theory is that a majority of the Board faces a substantial likelihood of liability under *Malone* because the Director Defendants "participated in the issuance of false and misleading statements about imetelstat's performance as measured by its co-primary endpoints."[129]

The 2017 Form 10-K is the main document the Plaintiffs point to as containing false and misleading statements. Certain of the Director Defendants signed the 2017 Form 10-K, showing those directors' participation in the issuance.[130] The Plaintiffs say that certain of the Company's Form 10-Qs, quarterly earnings press releases, and earnings conference calls from 2016 to 2018 also demonstrate the Company's false and misleading statements about the Phase Two Trial's Primary Endpoint Results.[131]

The Defendants sought to cast this case as one regarding securities omissions.[132] The Plaintiffs clarified, however, that they believe that the directors caused Geron to engage in "corporate lies."[133] At oral argument, Plaintiffs' counsel pointed to two express statements they believe were affirmative false statements. I focus on these in addressing the substantial likelihood of liability argument.

[129] AB 40.
[130] *See, e.g.*, Compl. ¶ 153.
[131] AB 49–50.
[132] *See* Oral Arg. 5:23–6:13.
[133] *Id.* at 39:16–22.

Both of the purported false statements come from the 2017 Form 10-K, although I may infer that subsequent repetitions of similar statements were also false.[134] The stronger argument[135] stems from the "Business" section of the filing, which includes a subheading for "Imetelstat Clinical Trials Under the Collaboration [the Agreement] with Janssen."[136] The section further breaks into discussion of the Phase Two Trial under subheadings "Trial Design," "Preliminary Observations and Actions," and "Current Status of [the Phase Two Trial]."[137]

The exact language complained of is under the subheading "Current Status of [the Phase Two Trial]" and reads: "[o]utcome measures for efficacy, including spleen volume response and reductions in Total Symptom Score remain consistent with prior data reviews."[138]

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[134] I take judicial notice of the contents of the 2017 Form 10-K, as (1) it is incorporated into the Complaint and (2) its contents are not reasonably in dispute. Transmittal Decl., Pursuant to 10 *Del. C.* § 2937 of Sarah P. Kaboly Supp. Defs.' Mot. to Dismiss Pls.' Verified Consolidated Am. Stockholder Derivative Compl. Pursuant to Ct. of Chancery Rules 23.1 and 12 (b)(6), Ex. 37, Dkt. No. 61 [hereinafter "Kaboly Decl."].

[135] The second exemplar of challenged language stems from the risk factors outlined in the 2017 Form 10-K. Again, the 2017 Form 10-K was filed on March 16, 2018. *See* AB 40. The objected-to language is as follows: " . . . partial or complete remissions observed in the Pilot Study may not be seen in current or future clinical trials of imetelstat." Kaboly Decl., Ex. 37, at 30; Oral Arg. 40:11–20. The Plaintiffs argued in their answering brief and at oral argument that "the remission data from the [Phase Two Trial] at this time was also final and had been compiled by this time," *id.* at 40:15–20, so the language should have read "[p]artial or complete remissions observed in the Pilot Study *were not* seen in the current trial of imetelstat." *Id.* at 41:7–10 (emphasis added). But this argument is unsupported in the pleadings. While interim data may in fact have been compiled, the Primary Endpoint Result figures pled in the Complaint that were presented to the Board at meetings in November 2017, January 2018, and May 2018 were subject to movement. *See supra* note 49 and accompanying text.

[136] Kaboly Decl., Ex. 37, at 7.

[137] *Id.* at Ex. 37, at 7–8.

[138] *Id.* at Ex. 37, at 8.

The Plaintiffs read this language as suggesting that *the results relating to reductions in Total Symptom Score* (one of the primary endpoints) were "consistent" with prior data reviews.[139] They ask me to make the inference that the reference to "prior data reviews" is a reference to *the pilot study results* with respect to reductions in Total Symptom Score, which, of course, were considerably more successful than the Phase Two Trial.[140] Thus, they say, this disclosure was affirmatively misleading.

I make a couple of preliminary notes before addressing this proposal. First, I note that the section of the Complaint that deals with disclosures from the 2017 Form 10-K emphasized certain portions of the Business section's text, but notably did not emphasize this bullet point or outline the argument flowing therefrom.[141] Instead, this argument is made in the answering brief[142] and in the oral argument.[143] I need not decide now whether this failure to emphasize facts supporting the theory of the case in the Complaint meets the standard under Rule 23.1 for pleading with particularity.

Second, and more importantly, the Defendants argue that this sentence is taken out of context in the Plaintiffs' argument.[144] This is not concerning of itself—

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[139] *See* AB 40–41 (focusing on the challenged statement as relating to Total Symptom Score).
[140] *See id.*; *see also* Oral Arg. 43:15–44:6.
[141] *See* Compl. ¶ 82. Other bullet points in this paragraph are bolded and italicized, suggesting the Plaintiffs' focus and argument was previously built upon those bolded and italicized statements. *See id.*
[142] AB 40–46.
[143] Oral Arg. 39:3–22, 43:15–44:6.
[144] *Id.* at 57:3–58:17.

briefing and argument clearly cannot include full context if they are to be efficient in manner—but the benefit of context does, in my view, have a probative effect on the language in question. The paragraph preceding the challenged bullet point reads: "In March 2018, Janssen completed a *third internal data review* of [the Phase Two Trial], based on a January 2018 data cut, to enable a protocol amendment to allow the long-term treatment and follow up of patients, including for survival, and the [Joint Steering Committee] made the following observations[.]"[145] This language does much to ground the meaning of "prior data reviews." Further up on the same page, the previous subsection, labeled "Preliminary Observations and Actions," states that since the Phase Two Trial's initiation, Janssen "has conducted *internal data reviews in September 2016 and April 2017.* Based on these reviews, the [Joint Steering Committee] made the following observations[.]"[146] The Defendants argue that the challenged language refers to these reviews, and not to the pilot study.

I also note that it is not entirely clear what "[o]utcome measures for efficacy" means.[147] The language is ambiguous. It might refer to results—as the Plaintiffs seem to suggest—or it might refer to the measurements used to analyze efficacy (including spleen volume response and reductions in Total Symptom Score).

[145] Kaboly Decl., Ex. 37, at 8 (emphasis added).
[146] *Id.* at Ex. 37, at 8 (emphasis added).
[147] *Id.* at Ex. 37, at 8.

I note this because this motion must turn on my determination, based on the particularized pleadings in the Complaint aided by plaintiff-friendly inference, as to whether a substantial likelihood of liability should attach to the Director Defendants. That in turn will rest in part on my interpretation of the language of the disclosures. I note in this context the existence of and findings in the Securities Action. At oral argument, the Plaintiffs' counsel represented to me that Judge Alsup interpreted the statement's language "prior data reviews" as referencing "the pilot study and the Jakafi [a competitor] study."[148] This outcome may be warranted by applying the inferences in the Plaintiffs' favor applicable on a motion to dismiss in federal district court, but under our Rule 23.1 the Plaintiffs are only entitled to reasonable inferences on *particularized* facts.

This raises the possibility of inconsistent determinations in this case and the Securities Action, albeit under different pleading standards. I do note that the Securities Action is brought solely against the Company, Geron, and against Defendant Scarlett,[149] and that the Securities Action has survived a motion to dismiss. But this does not eliminate the duplicative nature of the claims or the possibility for inconsistency between the findings of this Court and the district court in California.

[148] Oral Arg. 43:15–44:12.
[149] *Id.* at 46:13–20.

Plaintiffs' counsel, at oral argument, commented that he believed a stay was not warranted here, and that the claims and "full-blown merits discovery" should proceed, noting that this case was previously stayed pending the ruling upon the motion to dismiss in the Securities Action.[150] Unsurprisingly, Defendants' counsel championed a stay, citing the Plaintiffs' heavy reliance upon the Securities Action and the burden of duplicative efforts.[151]

I noted at that time that I would only address a stay if needed.[152] But upon a review of the instant motion, and the possibility for divergence in analysis as to disclosure violations between this Court and the district court, I am convinced that a stay is in fact the best outcome here. I have the inherent authority to stay rather than dismiss a matter, where the litigants' efficiency so requires.[153] Until the Securities Action is resolved, in my view, the motion under Rule 23.1 is better deferred with respect to the *Malone* claim. Efficiency dictates it should be stayed.

I turn then to the *Caremark* argument in support of a substantial likelihood of liability put forth by the Plaintiffs.

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[150] *Id.* at 46:21–47:18.
[151] *Id.* at 64:3–19.
[152] *Id.* at 64:10–22.
[153] *In re Straight Path Commc'ns Inc. Consol. S'holder Litig.*, 2017 WL 5565264, at *3 (Del. Ch. Nov. 20, 2017).

2. Demand Futility Under *Caremark*

The Plaintiffs have pled a second theory they believe supports a finding of substantial likelihood of liability as to all Director Defendants, one born of *Caremark*. That issue, of course, is not present in the Securities Action, and I address it here. The Plaintiffs argue that a majority of the Board faces a substantial likelihood of liability for consciously failing to fulfill their oversight duties in connection with "red flags" raised by the Phase Two Trial. The Plaintiffs have not argued that the Board of Geron wholly failed to have a monitoring system in place with respect to the development of imetelstat, which, per the Complaint, was manifestly in place throughout.

The Plaintiffs' first theory is that, given that imetelstat was Geron's singular drug candidate (and sole product), "the . . . FDA Trial was a mission critical compliance issue and, thus, the Board's oversight of the trial had to be 'rigorously exercised.'"[154] The answering brief then discusses at length the importance of Board monitoring and oversight in connection with "externally imposed regulations," such as FDA regulations.[155]

But imetelstat was in the midst of its Phase Two Trial—it was not a product available to consumers for which Geron was out of compliance. Rather, the drug

[154] AB 26.
[155] *See id.* at 26–27 (quoting *In re Clovis Oncology, Inc. Deriv. Litig.*, 2019 WL 4850188, at *29 (Del. Ch. Oct. 1, 2019)).

was in the testing phases. The Plaintiffs have not pled that any actions undertaken or omitted in connection with the *implementation of the Phase Two Trial* violated any positive law, regulations, or testing protocol, nor suggested that corporate trauma resulted from any such actions. They have not suggested any action, moreover, that could have improved the outcome of the Phase Two Trial for the benefit of Geron.

Perhaps butting up against this realization, the Plaintiffs then shift to an argument that the Director Defendants' knowledge about the results of the Phase Two Trial was itself a red flag with respect to which directors "must [have taken] action in good faith to address."[156] This argument is predicated upon the theory that the Director Defendants made a conscious decision not to act "despite what they knew about Geron's misleading public reporting with respect to imetelstat's primary endpoint data."[157] Stated differently, the Plaintiffs argue that the Primary Endpoint Results were a red flag, and that the Board failed to "oversee" the Company's public statements in light of this knowledge, which they approved despite knowing the public statements were untrue and misleading.

Thus, the allegation here is that, with knowledge of the "red flags" of the failure of the Phase Two Trial, the Director Defendants caused or permitted Geron

[156] *Id.* at 27; *see also id.* at 31 ("Actual Knowledge of Imetelstat's TSS and SVR Failures Was a Red Flag the Board Ignored, Excusing Demand").
[157] *Id.* at 31 (emphasis omitted).

to lie to its investors, in bad faith.[158] That indeed states a fiduciary duty claim, already presumably addressed under the *Malone* doctrine, and in any case viable under Count One of the Complaint which alleges breach of fiduciary duty in this regard. It does not state a claim for failure to oversee the actions of Geron as I understand such a claim.[159]

I find that no directors are at risk of a judgment under the *Caremark* doctrine. This is not dispositive of the Motion to Dismiss, however. The potential for a failure to act in good faith leading to a substantial risk of liability, whatever the rubric, remains, as set out at length above. The Motion to Dismiss awaits assessment of that claim under Rule 23.1, in light of the conclusion of the Securities Action.

B. Assessing Failure to State a Claim

Because I have found above that the Defendants' Motion to Dismiss is properly stayed in light of the Securities Action, I do not reach the question, also briefed and argued, of whether the Plaintiffs have stated breach of fiduciary duty claims under Rule 12(b)(6) at this time.

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[158] Oral Arg. 30:20–31:10.

[159] The Plaintiffs point to *Clovis*, 2019 WL 4850188, as analogous. But *Clovis* involved a board ignoring red flags that the company was violating FDA regulations. *Id.* at * 15 (emphasis added) ("[The Plaintiffs] have well-pled that the Board consciously ignored red flags that revealed a mission critical failure *to comply with the RECIST protocol and associated FDA regulations*."). That is manifestly a *Caremark*-type cause of action.

III. CONCLUSION

The Defendants' Motion to Dismiss is STAYED. Any party may seek to lift the stay upon the ultimate resolution of the Securities Action, or as otherwise appropriate.

The parties should submit an appropriate form of order.