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Case No. 2022-0331-SG

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

IN RE FIBROGEN, INC. DERIVATIVE LITIGATION	)))))	C.A. No. 2022-0331-SG

MEMORANDUM OPINION

Date Submitted: May 9, 2024
Date Decided: October 2, 2024

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GLASSCOCK, Vice Chancellor

This matter is a natural securities action repurposed for equitable review. In fact, a federal securities action has been brought against the nominal defendant, FibroGen, Inc., and settled for over $28 million dollars.[1] FibroGen was accused of not disclosing to the market, or disclosing falsely, material information about the prospects of a drug it was developing, Roxadustat, for treatment of anemia in chronic kidney disease.[2] The instant litigation is brought by stockholders derivatively on behalf of the company, making similar allegations to those raised in the securities litigation; that management misled investors and the FDA by manipulating or misreporting data arising from the Phase 3 clinical trials of Roxadustat. If so, of course, that could lead to a cause of action against management arising as an asset of FibroGen. Deploying (or not) that litigation asset is, under our model of corporate governance, a matter for the Board of Directors of the company.[3] The stockholder Plaintiffs have made no demand on the Board requesting litigation, however.

Instead, they allege that, under Rule 23.1, demand should be excused, and Plaintiffs should be able to mount this litigation against corporate wrongdoers.[4] Stated simply, they aver that a majority of the Board is itself liable for the mal-

[1] *In re Fibrogen, Inc.*, 2022 WL 2793032, at *1 (N.D. Cal. July 15, 2022); Compl., No. 3:21-cv-02623-EMC, Dkt. No. 1; Ord. on Mot. for Settlement 6, No. 3:21-cv-02623-EMC, Dkt. 244.
[2] *Fibrogen, Inc.*, 2022 WL 2793032, at *1.
[3] *In re MetLife Inc. Deriv. Litig*, 2020 WL 4746635, at *11 (Del. Ch. Aug. 17, 2020) ("[I]t is typically the board's prerogative to determine whether the corporation initiates and maintains a lawsuit.").
[4] Verified Consol. S'holder Deriv. Compl. 245–66, Dkt No. 52 ("Compl.").

disclosures, for failing in bad faith to prevent misleading of investors, and for supplying manipulated data to the FDA.[5] The matter is before me on a motion to dismiss.

Because liability against the Director Defendants for breach of the duty of care is exculpated, in this instance Plaintiffs have the difficult task of showing that a majority of the Demand Board runs a substantial risk of liability for breach of the duty of loyalty; as alleged here, for acting in bad faith. Plaintiffs argue they have met their burden by sufficiently pleading that a majority of the Demand Board knew the disclosures and submissions to the FDA were false or misleading, or that lack of knowledge evinced willful blindness to the affairs of the company, amounting to bad faith.[6]

Upon review of the pleadings, however, and in light of the standard imposed by Rule 23.1, I cannot find a reasonable likelihood of liability for a majority of the Demand Board. Accordingly, I need not reach the other issues raised in the Motion; instead, the Motion to Dismiss must be granted.

[5] *Id.*
[6] Pls.' Omnibus Answering Br. in Opp'n to Defs.' Mot. to Dismiss, 31–61 Dkt. No. 65. ("Pls.' Opp'n").

I. BACKGROUND[7]

A. Factual Background

1. The Parties

Plaintiff Julie Williams is a stockholder of FibroGen, Inc. ("FibroGen" or the "Company") and has held stock in the company since April 2017.[8]

Plaintiff Fuying Zhao (together with Williams, "Plaintiffs") is a stockholder of FibroGen and has held stock in the company since September 2018.[9]

Nominal Defendant FibroGen is a biopharmaceutical company incorporated in Delaware and headquartered in San Francisco, California.[10] The Company's flagship product is Roxadustat, which is an oral treatment for anemia in patients with chronic kidney disease ("CKD").[11]

The individual defendants (the "Individual Defendants" and collectively with FibroGen, the "Defendants") are Enrique Conterno, James Schoeneck,[12] Dr. K.

[7] This Memorandum Opinion only contains facts necessary to my analysis. The facts, of course, are those alleged in the complaint.
[8] Compl. ¶ 30.
[9] *Id.* ¶ 31.
[10] *Id.* ¶¶ 32–33.
[11] *Id.* ¶ 33.
[12] Schoeneck served as Interim Chief Executive Officer from August 2019 to January 2020. *Id.* ¶ 34.

Peony Yu,[13] Dr. Mark Eisner,[14] Pat Cotroneo,[15] Christine Chung,[16] Suzanne Blaug, Aoife Brennan, Dr. Benjamin Cravatt, Jeffrey L. Edwards, Jeffrey W. Henderson, Dr. Maykin Ho, Gerald Lema, Thomas F. Kearns Jr., Dr. Kalevi Kurkijärvi,[17] and Rory B. Riggs.[18]

The eleven members of FibroGen's Board at the time this lawsuit was filed in April 2022 (the "Demand Board" or "Director Defendants") were Conterno, Schoeneck, Blaug, Brennan, Cravatt, Edwards, Henderson, Ho, Lema, Kearns, and Riggs.[19]

2. Standard Treatment for CKD

CKD is a disease that causes the loss of kidney function, which could lead to an individual requiring dialysis or a kidney transplant to survive.[20] Anemia is a common complication of CKD.[21] The standard treatment for anemia in patients with CKD is erythropoiesis-stimulating agents ("ESAs").[22]

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[13] Yu served as the Company's Chief Medical Officer from April 2016 to December 2020. *Id.* ¶ 36.
[14] Eisner served has served as the Company's Chief Medical Officer since December 2020. *Id.* ¶ 37.
[15] Cotroneo served as the Company's Chief Financial Officer from 2008 to September 2021. *Id.* ¶ 38.
[16] Chung has been Senior Vice President of China Operations at the Company since 2007. *Id.* ¶ 39.
[17] Kurkijärvi served as a director on the Company's Board from February 2021 until his resignation in June 2021. *Id.* ¶ 48.
[18] *Id.* ¶¶ 34–49.
[19] *Id.* ¶¶ 34, 35, 40–47, 49, 248.
[20] *Id.* ¶ 53.
[21] *Id.* ¶ 54.
[22] *Id.* ¶¶ 4, 56.

Epogen, the most widely prescribed ESA, is the current standard of care for anemia in patients with CKD.[23] But Epogen has drawbacks: (1) it has to be administered by injection or intravenously, which requires patients to visit their doctor or hospital for treatment, and (2) it increases the risk of a major adverse cardiac event ("MACE"), which includes myocardial infarction, stroke, and cardiovascular death.[24] Due to these drawbacks, Epogen is not recommended for use in mild CKD cases, including non-dialysis dependent ("NDD") and new-to-dialysis ("incident dialysis") patients.[25] Consequently, the U.S. Food and Drug Administration ("FDA") requires a "Black Box" warning on labels of Epogen and other ESAs.[26]

FibroGen produced Roxadustat, an oral treatment for anemia in patients with CKD.[27] FibroGen claimed that Roxadustat could deliver the benefits of Epogen without its severe drawbacks and could be administered to patients with mild cases of CKD, who are not viable candidates for ESAs like Epogen.[28]

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[23] *Id.* ¶ 56.
[24] *Id.* ¶ 57.
[25] *Id.*
[26] *Id.* ¶ 58. A Black Box warning is the strongest warning used by the FDA for prescription drugs and warns users of inherent deadly risks associated with drug products. *Id.*
[27] *Id.* ¶¶ 2, 52. Unlike ESAs, Roxadustat is intended to treat anemia as a hypoxia-inducible factor-prolyl hydroxylase ("HIF-PH") inhibitor, which stimulates the body's natural red blood cell production. *Id.* ¶¶ 2, 55–56.
[28] *Id.* ¶ 59.

3. FibroGen Enters into an Agreement with AstraZeneca to Develop Roxadustat and Begins Clinical Trials for Regulatory Approval

In 2013, FibroGen entered into an agreement with AstraZeneca in which AstraZeneca agreed to commercially develop Roxadustat.[29] The agreement was worth as much as $1.6 billion, contingent upon FibroGen reaching certain regulatory milestones in the drug's FDA approval process.[30] To obtain regulatory approval from the FDA, FibroGen had to demonstrate through Phase 3 clinical trial data that Roxadustat was at least as effective as Epogen, without causing the same safety issues that prevented Epogen from being used to treat incident dialysis and NDD patients.[31]

FibroGen conducted Phase 3 clinical trials of Roxadustat in three patient populations: (1) NDD patients; (2) dialysis-dependent ("DD") patients; and (3) incident dialysis patients.[32] For each patient population, the FDA used three key safety metrics during the clinical trial: (i) MACE; (ii) all-cause mortality, which analyzes deaths caused by Roxadustat for any reason; and (iii) MACE+, an evaluation relied on by European regulatory authorities (but not the FDA) that includes all MACE events, including those not requiring hospitalization.[33]

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[29] *Id.* ¶ 60.
[30] *Id.* At this time, FibroGen's revenue was primarily derived from this agreement. *Id.* ¶ 64.
[31] *Id.* ¶ 62.
[32] *Id.* ¶ 65
[33] *Id.* ¶ 67.

These metrics were measured by a "hazard ratio," which compared the relative risk between Roxadustat and Epogen.[34] A hazard ratio of less than 1.0 indicated that Roxadustat was safer than Epogen in DD and incident dialysis patients, or a placebo in NDD patients.[35] On the other hand, a hazard ratio above 1.0 (plus a statistical margin) would indicate that Roxadustat was less safe than Epogen or a placebo.[36] FibroGen had proposed a non-inferiority margin of 1.3 for assessing Roxadustat's hazard ratios, but the FDA had not agreed to that standard.[37] The FDA ultimately—exactly when is not pled—determined that a hazard ratio of 1.25 or greater would demonstrate that Roxadustat was less safe than Epogen or a placebo.[38] In other words, if Roxadustat yielded a hazard ratio of 1.25 or greater, it would not be approved by the FDA, even with a label warning.[39]

In a December 2018 press release announcing the top line Phase 3 trial results, Yu stated that Roxadustat had "achieved superiority in efficacy" over both Epogen and a placebo in FibroGen's studies.[40] The press release also stated that "preliminary safety analyses of each of [the Phase 3] individual studies show an overall safety profile consistent with the results observed in previous Roxadustat studies."[41]

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[34] *Id.* ¶ 68.
[35] *Id.*
[36] *Id.* ¶¶ 68–69.
[37] *Id.* ¶ 161.
[38] *Id.* ¶ 69.
[39] *Id.*
[40] *Id.* ¶ 73.
[41] *Id.* ¶ 74.

On May 9, 2019, FibroGen issued a press release announcing its results using safety data pooled across all studies in the Phase 3 clinical trials.[42] That same day, Yu communicated the results via a conference call and stated that FibroGen had shown "non-inferiority to placebo," which "really illustrates the strength of our drug's safety."[43] In addition, Yu stated that a hazard "ratio of below 1.3" was the "standard non-inferiority comparison" used to evaluate MACE results and that Roxadustat "achieved non-inferiority" under this standard.[44] Yu did not disclose that the FDA had not agreed to the "standard" 1.3 hazard ratio.[45] FibroGen also filed its first quarter 2019 report with the SEC, which stated that "there was a trend toward reduced risk of MACE for [incident dialysis] patients on [R]oxadustat, compared to [Epogen]."[46] Despite announcing the pooled results, FibroGen did not identify specific hazard ratios.[47]

4. Events Leading to Roxadustat's Rejection

On June 5, 2019, the Board met and discussed a "summary of the [R]oxadustat Phase 3 pooled cardiovascular safety analysis."[48] The Board did not ask for or

[42] *Id.* ¶ 78.
[43] *Id.* ¶ 80.
[44] *Id.* ¶ 81.
[45] *See id.* ¶¶ 81, 84. Rather, Yu stated that "[i]f we use that standard, the answer is yes, we have achieved non-inferiority." *Id.* ¶ 81.
[46] *Id.* ¶ 83.
[47] *Id.* ¶ 84.
[48] *Id.* ¶ 86. Of the Demand Board, Schoeneck, Edwards, Henderson, Ho, Kearns, Lema, and Riggs were present at the meeting. *Id.*

receive any information relating to the processes and procedures used to produce the data.[49]

In the second half of 2019, the members of the Demand Board repeatedly met and discussed with management the FDA New Drug Application ("NDA") submission and Phase 3 results for Roxadustat.[50] During this time, two separate short sellers published public reports that included questions about the Roxadustat's safety data.[51] But in a November 8, 2019 press release, FibroGen stated "Roxadustat cardiovascular safety [was] comparable to placebo in [NDD] patients," which had not been demonstrated in another anemia drug.[52] FibroGen also represented that Roxadustat "reduced risk of MACE by 30% and MACE+ by 34% compared to [Epogen]."[53]

FibroGen submitted the Roxadustat NDA to the FDA in December 2019.[54] While the NDA was under review, Conterno stated at a February 25, 2020

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[49] *Id.*
[50] For example, on July 25, 2019, Cotroneo, Schoeneck, Edwards, Henderson, Ho, Kearns, Lema, and Riggs, along with Yu and Kurkijärvi, met and discussed "the upcoming work in preparing the NDA." *Id.*¶ 89. On August 1, 2019, the Audit Committee discussed the Company's disclosures regarding the Phase 3 results in FibroGen's second quarter 2019 financial results. *Id.* ¶ 90. On August 2, Cotroneo, Schoeneck, Edwards, Henderson, Ho, Kearns, Lema and Rigs were present at a Board meeting to discuss FibroGen's pre-NDA meeting with the FDA. *Id.* ¶ 91. On September 5, 2019, Cotroneo Schoeneck, Blaug Edwards, Henderson, Ho Kearns, Lema, and Riggs were present at a Board meeting where they received an update by Dr. Yu on the Roxadustat programs. *Id.* ¶ 94. On October 17, 2019, Cotroneo, Schoeneck, Blaug, Edwards, Henderson, Ho, Lema, and Riggs were present at a Board meeting discussing an update on the Roxadustat program. *Id.* ¶ 100.
[51] *Id.* ¶¶ 101, 107.
[52] *Id.* ¶ 102.
[53] *Id.*
[54] *Id.* ¶ 108.

conference, "I do not believe that the data warrants a 'Black Box' warning."[55] On March 2, 2020, FibroGen filed its 2019 Form 10-K, signed by Conterno, Cotroneo, Schoeneck, Blaug, Edwards, Henderson, Ho, Kearns, Kurkijärvi, Lema, Riggs, Rosenkranz, and Tamura.[56] The filing restated previously-disclosed clinical trial results and stated that the cardiovascular safety analyses reflected the pooling strategy and analytical approach agreed upon with the FDA.[57]

On July 29, 2020, the Board met and discussed FibroGen's "takeaways from the Company's mid-cycle meeting with the FDA for the Roxadustat NDA."[58] One highlight presented to the Board was that the FDA had stated that Roxadustat was "consistently noninferior and not superior to ESA."[59] Thus, the Board learned, "the FDA believed [Roxadustat's] Warnings and Precautions would be reflected in the same way as ESAs, including the Black Box Warning."[60] During this meeting, the Board did not solicit or receive any information regarding the processes or procedures used to produce the data.[61]

In November 2020, a citizen petition ("Citizen Petition") was filed with the FDA urging the FDA to decline the Roxadustat NDA or issue a Black Box

[55] *Id.* ¶ 111.
[56] *Id.* ¶ 112.
[57] *Id.*
[58] *Id.* ¶ 124. Schoeneck, Conterno, Blaug, Edwards, Henderson, Ho, Kearns, Lema, and Riggs were present. *Id.*
[59] *Id.*
[60] *Id.*
[61] *Id.* ¶ 125.

warning.[62] Later that month, FibroGen announced Yu's retirement as Chief Medical Officer.[63]

At a Board meeting on December 18, 2020, the Board learned that the FDA had requested additional data, including additional safety analyses, and that the FDA would extend its review of Roxadustat.[64] On the same day, FibroGen announced that the FDA had extended its review period by three months.[65]

On April 6, 2021, FibroGen publicly revealed that the data submitted with the Roxadustat NDA "included post-hoc changes to the stratification factors."[66] In a press release showing both the analyses with post-hoc stratification factors and the pre-specified stratification factors, FibroGen stated that "based on these analyses we cannot conclude that [R]oxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to [Epogen]."[67]

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[62] *Id.* ¶ 135.
[63] *Id.* ¶ 136.
[64] *Id.* ¶ 140. Schoeneck, Conterno, Blaug, Brennan, Cravatt, Henderson, Ho, Kearns, Lema, Riggs, and Kurkijärvi were present. *Id.*
[65] *Id.* ¶ 141.
[66] *Id.* ¶ 147. *Post hoc* analyses, per the complaint, are inherently improper because they are selective analyses conducted in hindsight pursuant to cherry-picked criteria that are determined after all data is collected and fully unblinded. According to the FDA's guidance, *post hoc* analysis is considered "data-dredging" designed to "elicit a positive study result from a failed study," leading to "biased results[.]" *Id.* ¶ 148.
[67] *Id.* ¶ 149 (emphasis omitted).

5. The FDA Rejects Approval for Roxadustat

On August 11, 2021, FibroGen announced that it received a Complete Response Letter from the FDA stating that the FDA would not approve the Roxadustat NDA for any patient population.[68]

By June 2022, Conterno announced that FibroGen and AstraZeneca "had not been able to find a path forward for AstraZeneca to fund further Roxadustat development of anemia of CKD in the U.S."[69] Therefore, FibroGen did not expect to receive most or all of the remaining potential milestone payments—totaling more than $800 million—under the collaboration agreement.[70] Conterno also stated that, because AstraZeneca had exclusive rights for the development and commercialization of Roxadustat in the United States, the Company cannot proceed without AstraZeneca.[71]

On April 12, 2021, a securities class action claim ("Securities Class Action") was filed in the United States District Court for the Northern District of California.[72] The plaintiffs in the Securities Class Action filed the lawsuit against FibroGen, Yu, Eisner, Schoeneck, Conterno, and Cotroneo for violations of Section 10(b) of the Securities Exchange Act of 1934 for making allegedly false and misleading

[68] *Id.* ¶ 164.
[69] *Id.* ¶ 174.
[70] *Id.* ¶¶ 174–75, 179.
[71] *Id.* ¶ 175.
[72] *Fibrogen, Inc.*, 2022 WL 2793032, at *1; Compl., No. 3:21-cv-02623-EMC, Dkt. No. 1.

statements about Roxadustat's efficacy and safety data and prospects for FDA approval between December 20, 2018 and July 15, 2021.[73] In July 2022, the Court denied in part the defendants' motion to dismiss.[74] The court granted in part the plaintiffs' motion for class certification, certifying a class period shorter than the original class period proposed.[75] The parties agreed to settle the litigation for $28.5 million.[76]

6. Plaintiffs Bring this Derivative Action

Plaintiffs now bring this derivative action for the benefit of FibroGen against the Board and Individual Defendants. Plaintiffs bring derivative claims for breach of fiduciary duty against the Individual Defendants,[77] breach of fiduciary duty and unjust enrichment against Yu as a FibroGen officer,[78] and breach of fiduciary duty and misappropriation of information under *Brophy* against Yu, Schoeneck, Kurkijärvi, Kearns, Cotroneo, and Chung.[79]

[73] *Fibrogen, Inc.*, 2022 WL 2793032, at *1; Am. Compl. ¶¶ 2, 60–97, No. 3:21-cv-02623-EMC, Dkt. No. 97.
[74] *Fibrogen, Inc.*, 2022 WL 2793032, at *5; Ord. on Mot. to Dismiss, No. 3:21-cv-02623-EMC, Dkt. No. 126.
[75] Ord. Granting in Part Pls.' Mot. for Class Certification, No. 3:21-cv-02623-EMC, Dkt. 248.
[76] Ord. on Mot. for Settlement 6, No. 3:21-cv-02623-EMC, Dkt. 244.
[77] Compl. ¶¶ 267–77.
[78] *Id.* ¶¶ 278–85.
[79] *Id.* ¶¶ 286–93.

B. Procedural History

Plaintiffs filed their consolidated complaint on November 3, 2023.[80] Defendants, other than Yu, filed their Opening Brief in Support of their Motion to Dismiss the consolidated complaint pursuant to Court of Chancery Rule 23.1 on February 1, 2024.[81] Defendant Yu filed her Opening Brief in Support of its Motion to Dismiss pursuant to Court of Chancery Rule 12 (b)(6) that same day.[82] Plaintiffs filed their Answering Brief on March 28, 2024.[83] Defendants filed their Reply Brief on April 29, 2024[84] and Defendant Yu filed her reply brief that same day.[85] I heard oral argument on the Motion to Dismiss on May 9, 2024, and considered it submitted that date.[86]

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. I find that Plaintiffs have failed to plead facts from which I may infer demand futility, and that the complaint should be dismissed.

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[80] Compl.
[81] Defs.' Mot. to Dismiss Pls.' Verified Consolidated S'holder Deriv. Compl., Dkt. No. 58 ("Defs. OB").
[82] Def. K. Peony Yu, M.D.'s Mot. to Dismiss, Dkt. No. 60 ("Def. Yu OB").
[83] Pls.' Opp'n.
[84] Defs.' Reply Br. in Supp. of Their Mot. to Dismiss Pls.' Verified Consol. S'holder Deriv. Compl., Dkt. No. 68 ("Defs. RB").
[85] Reply Br. in Supp. of Def. K. Peony Yu, M.D.'s (1) Joinder in Other Defs.' Mot. to Dismiss Pursuant to Ct. of Chancery Rule 23.1; and (2) Mot. to Dismiss Pursuant to Ct. of Chancery Rule 12(b)(6), Dkt. No. 69 ("Def. Yu RB").
[86] Mot. to Dismiss before Vice Chancellor Sam Glasscock, Dkt. No. 74.

In their briefings, Plaintiffs plead demand futility under *Malone*, *Caremark*, and, as became clear at oral argument, a hybrid of the two. Plaintiffs begin by making a *Malone* claim, but ultimately fail to plead sufficient facts from which I can infer that a majority of the Demand Board faces a substantial likelihood for the breach of the duty of loyalty.[87] Perhaps sensing the weakness of the disclosure allegations, Plaintiffs then urge me to consider the facts under the lens of a *Caremark* oversight claim.[88] But at oral argument, it became clear that Plaintiffs did not advocate for a freestanding oversight claim.[89] Instead, their syllogism ran thus: Management communicated false and misleading statements to investors and the FDA; even if Plaintiffs have not adequately alleged that a majority of the Director Defendants participated in that dissemination knowingly or intentionally, these Director Defendants' failure to investigate and intervene, in the face of "red flags" indicating management wrongdoing, amounts to bad faith under a *Caremark* analysis.

At issue here is only this: Did a majority of the Demand Board act in such a way as to implicate the duty of loyalty? Humans are pattern-discerning animals, and

[87] Pls.' Opp'n 31–36.
[88] Pls.' Opp'n 37–67. In their briefing, Plaintiffs allege with respect to their *Caremark* theory that the Board "failed to investigate and remedy FibroGen's misleading [intent-to-treat] analysis[,] . . . the Company's use of *post hoc* stratification factors[, and] . . . the Company's misleading statements regarding the need for a Black Box warning." Pls.' Opp'n 61–62.
[89] Tr. of 5-9-2024 Hr'g on Defs.' Mot. to Dismiss Pls.' Verified Consol. S'holder Deriv. Compl. ("Tr.") 17:4–6, 20:8–21:15, Dkt. No. 75.

lawyers and judges among the most so inclined, perhaps, of the breed; it is not surprising that we group breach of loyalty claims accordingly. Have fiduciaries knowingly disseminated materially false information to stockholders? If so, we call that loyalty breach a *Malone* claim. Have directors failed to act to prevent corporate wrongdoing in the face of such strong evidence that a knowing failure to comply with duties, amounting to bad faith, is demonstrated? That is a prong two claim under *Caremark.*

Does the syllogism above state a *Caremark* claim? A *Malone* claim? I suppose if properly pled, it would state a "*FibroGen"* claim.[90] Inherent in that statement is the idea that a failure of a director to act in the face of sufficiently clear and vibrant notice that an employee is damaging the company or its stockholders through disseminating falsehoods could, given the proper hypothetical, amount to bad faith. Such a showing would require *scienter*, that is, would need to imply a knowing failure to perform a clear duty. Gross negligence in the neglect of duties

[90] Or, perhaps, a "*Geron*" claim. *See In re Geron Corp. S'holder Deriv. Litig.*, 2022 WL 1836238 (Del. Ch. June 3, 2022) (staying a motion to dismiss and rejecting an attempt to "shoehorn" a *Malone* claim "into a claim under *Caremark*"). It is also worth noting that this Court has previously examined false disclosure claims that "walk and talk like *Caremark*" under a *Caremark* analysis. *See, e.g.*, *In re GoPro, Inc.*, 2020 WL 2036602, at *11–12 (Del. Ch. Apr. 28, 2020) (addressing plaintiff's "*Caremark*-like allegations" and ultimately determining that "[w]hile Plaintiffs urge the Court to infer *scienter*, the Complaint pleads no facts that would allow a reasonable inference a majority of the Demand Board knew GoPro was misleading investors with any of its public statements").

would not suffice in the face of FibroGen's exculpation clause. Such a demonstration would be difficult; and is, in any event, not sufficiently pled here.

A. The Demand Futility Standard

When seeking to bring a derivative action on behalf of a corporation, a stockholder must either (i) seek to have the corporation bring the action itself by making a demand on the Board—and if the Board refuses, show that such refusal was wrongful—or (ii) demonstrate with particularity that such an effort would be futile.[91] If not, the derivative action will be dismissed.[92] Here, Plaintiffs have failed to make a pre-suit demand on the Demand Board. As such, the Court must dismiss the complaint unless Plaintiffs "state with particularity" within their complaint "the reasons for not . . . making the effort."[93]

The standard of review to assess demand futility is more stringent than that applicable to a motion to dismiss pursuant to Rule 12(b)(6). The reasoning for this heightened standard is that by circumventing making demand on a board, a plaintiff displaces the board of directors' decision-making role regarding whether to bring that suit.[94] To justify circumvention of the board's default role, Rule 23.1 requires

[91] *See United Food & Com. Workers Union & Participating Food Indus. Empls. Tri-State Pension Fund v. Zuckerberg*, 262 A.3d 1034, 1047, 1056 (Del. 2021).
[92] *See id.* at 1049; *Stone v. Ritter*, 911 A.2d 362, 366–67 (Del. 2006).
[93] Ct. Ch. R. 23.1(a).
[94] *See Zuckerberg*, 262 A.3d at 1047.

derivative complaints to allege demand futility with particularity, which "differ[s] substantially from . . . permissive notice pleadings."[95]

Although a plaintiff must plead facts with particularity, she is still entitled to the benefit of all reasonable inferences and the Court must accept as true all particularized and well-pled allegations contained in the complaint.[96] The reasonable inferences "must logically flow from particularized facts alleged by the plaintiff."[97]

This Court assesses demand futility on a director-by-director basis by considering the following:

> (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 faces a substantial likelihood of liability on any of the claims that would be 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 would be 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.[98]

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[95] *Id.* at 1048 (quoting *Brehm v. Eisner*, 746 A.2d 244, 254 (Del. 2000)).
[96] *Id.*
[97] *Wood v. Baum*, 953 A.2d 136, 140 (Del. 2008).
[98] *Zuckerberg*, 262 A.3d at 1058.

Demand is excused as futile "[i]f the answer to any of the questions is 'yes' for at least half of the members of the demand board."[99] This analysis is designed to answer a straightforward question with respect to each demand director: could she bring her business judgment to bear on behalf of the corporation in evaluating a demand?[100]

Here, Plaintiffs assert that demand is futile because a majority of the Demand Board faces a substantial likelihood of liability based on a *Malone* disclosure claim, a *Caremark* prong two claim, or a *Brophy* insider trading claim.[101] FibroGen's charter contains an exculpatory clause as authorized by 8 Del. C. § 102(b)(7).[102] As such, the question is whether the complaint adequately alleges that a majority of FibroGen's Demand Board face a substantial likelihood of liability for breaching the duty of loyalty.[103] Plaintiffs must provide "specific allegations of fact from which I may infer that the Director Defendants' actions or inaction were in bad faith; that is, in conscious disregard of their duties."[104]

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[99] *Id.* at 1059.
[100] *See Rales v. Blasband*, 634 A.2d 927, 934 (Del. 1993).
[101] Pls.' Opp'n 31; Compl. ¶ 248.
[102] I take judicial notice of FibroGen's certificate of incorporation. *See In re Baxter Int'l, Inc. S'holders Litig*., 654 A.2d 1268, 1270 (Del. Ch. 1995) ("The court may take judicial notice of the certificate [of incorporation] in deciding a motion to dismiss.") (citing *In re Wheelabrator Techs. Inc. S'holder Litig*, 1992 WL 212595, at *11 (Del. Ch. Sept. 1, 1992)).
[103] *See In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 124–25 (Del. Ch. 2009).
[104] *In re MetLife*, 2020 WL 4746635, at *2.

When this action was filed, FibroGen's Demand Board consisted of eleven directors,[105] four of whom served on the audit committee ("Audit Committee").[106] One director, Conterno, was also Chief Executive Officer ("CEO") at the time of filing, and therefore was not independent.[107] For the purpose of this analysis, I assume that Schoeneck is also not independent because he served as Interim CEO from August 2019 to January 2020.[108] Accordingly, the remaining independent directors on the Demand Board are Blaug, Brennan, Cravatt, Edwards, Henderson, Ho, Lema, Kearns, and Riggs (the "Independent Directors"). For Plaintiffs to prevail on demand futility, Plaintiffs have to plead that at least four Independent Directors face a substantial likelihood of liability for breaching the duty of loyalty.

Because Plaintiffs do not provide individualized pleadings as to each Director Defendant, I do not engage in a director-by-director analysis. Rather, the question is whether a majority of the Demand Board faces liability under any of Plaintiffs' theories. I determine that Plaintiffs have failed to plead particularized factual allegations that, through reasonable inferences, demonstrate that a majority of the

[105] Compl. ¶ 248. These directors are Conterno, Schoeneck, Blaug, Brennan, Cravatt, Edwards, Henderson, Ho, Kearns, Lema, and Riggs. *Id.*
[106] *Id.* ¶ 265. These directors are Schoeneck, Edwards, Ho, and Lema. *Id.* Kurkijärvi, who was not on the Board when this action was filed, was also a member of the Audit Committee. *Id.*
[107] *Id.* ¶ 35. Schoeneck previously served as Interim CEO of FibroGen from August 2019 to January 2020. *Id.* ¶ 34.
[108] *Id.* ¶ 34. I note that Plaintiffs have not argued that Schoeneck's service as interim CEO makes him fail to be independent. I need not analyze his independence as it does not alter the outcome of my determination.

directors of the Demand Board face substantial likelihood of liability under any of the three claims. Accordingly, Plaintiffs have failed to plead demand futility.

B. Plaintiffs Fail to Establish Demand Futility Under Malone or Caremark

Counting Conterno and Schoeneck as not independent, Plaintiffs' burden is to plead facts from which I may determine that four Independent Directors are unable to bring their business judgement to bear regarding a demand. Plaintiffs do not contend that self-interest or lack of independence taints any of the Independent Directors. Instead, Plaintiffs allege that a majority of the directors on the Demand Board face a substantial risk of liability for a bad-faith failure to disclose material facts to stockholders and issuing materially misleading statements regarding Roxadustat trials.[109] Specifically, Plaintiffs challenge essentially three categories of statements made: those made during conferences, conference calls, and in press releases; those made in FibroGen's Forms 10-Q; and those made in FibroGen's Forms 10-K.[110] After examining all three categories of statements, I determine that Plaintiffs have not established that a majority of the directors on the Demand Board face a substantial likelihood of liability for breaching the duty of disclosure under the duty of loyalty.

[109] Pls.' Opp'n 31.
[110] *Id.* at 31–37.

"[E]ven in the absence of a request for shareholder action, shareholders are entitled to honest communication from directors, given with complete candor and in good faith."[111] "When there is no request for shareholder action, a shareholder plaintiff can demonstrate a breach of fiduciary duty by showing that the directors 'deliberately misinform[ed] shareholders about the business of the corporation, either directly or by a public statement.'"[112] Such deliberate acts breach the duty of loyalty. Because FibroGen's directors are protected by an exculpatory charter provision, Plaintiffs "can demonstrate a substantial likelihood of liability that would excuse demand only by making 'particularized factual allegations that support the inference that the disclosure violation was made in bad faith, knowingly, or intentionally.'"[113] Thus, to sterilize a director, Plaintiffs must allege specific facts indicating that the director "prepared" the challenged language or was "directly responsible for the misstatements or omissions,"[114] that the statements were false or misleading, and that the director knew that the statements were false or misleading, or intended that they be so.[115]

[111] *Fisher ex rel. LendingClub Corp. v. Sanborn*, 2021 WL 1197577, at *17 (Del. Ch. Mar. 30, 2021) (quoting *In re InfoUSA, Inc. S'holders Litig.*, 953 A.2d 963, 990 (Del. Ch. 2007)).
[112] *Id.* (quoting *Citigroup*, 964 A.2d at 132) (emphasis removed).
[113] *Id.* (quoting *Citigroup*, 964 A.2d at 132).
[114] *Citigroup*, 964 A.2d at 134.
[115] *See id.* at 133–34.

1. Statements made during conferences, conference calls, and in press releases

Plaintiffs cite a slew of public statements made by FibroGen and its management team that they allege misled investors into believing that the FDA agreed to a hazard ratio of 1.3 and that Roxadustat would be approved without a Black Box warning.[116] Plaintiffs have failed to allege with particularity that any member of the Demand Board (other than Conterno or Schoeneck) played a role in making any of these statements. The complaint does not allege any facts from which I may infer that any Independent Director approved, prepared, caused, or were

[116] For example, on May 9, 2019, FibroGen announced its pooled safety results in a press release claiming that "there was 'no clinically meaningful difference' in MACE risk" between Roxadustat and Epogen/placebo. Compl. ¶ 78. FibroGen's then-CEO, Thomas Neff, echoed those positive results in a conference call the same day. *Id.* ¶ 79. On the same call, Yu reiterated those results, stated that a hazard ratio of below 1.3 was the "standard non-inferiority comparison" used to evaluate those results, that Roxadustat achieved non-inferiority "if we use that standard," that "we are pretty comfortable with safety," and that "[t]he adjudicated composite safety endpoint was something that we have discussed with the FDA." *Id.* ¶¶ 80–82. During an August 8, 2019 conference call, Neff stated that FibroGen had "reached an agreement with the [FDA] on the content of the NDA including cardiovascular safety analysis," and Yu stated that FibroGen had reached an agreement "on our proposed pooled MACE analysis." *Id.* ¶ 92.

In a November 8, 2019 press release, FibroGen announced the purported safety and efficacy results that had been presented at the American Society of Nephrology ("ASN") Kidney Week 2019 and stated, among other things, that "Roxadustat cardiovascular safety [was] comparable to placebo in [NDD] patients and that the positive Roxadustat MACE results the Company had presented were the result of the prespecified analyses they had "agreed [upon] with the FDA." *Id.* ¶¶ 102–03 (emphasis removed). On November 11, 2019, FibroGen held a conference call in connection with its third quarter 2019 financial results, during which Schoeneck and Yu repeated many of the statements from the November 8, 2019 press release. *Id.* ¶ 104. On an August 6, 2020 conference call, Conterno made statements to the effect that the data showed a "very positive benefit-risk profile" without sharing that the FDA believed a Black Box warning would be necessary. *Id.* ¶ 126. At a conference on September 9, 2020, Conterno stated that "we feel very good about our pool MACE data in NDD" and "we don't believe that the data that we have warrants a [Black Box] warning." *Id.* ¶ 128 (emphasis removed). Likewise, on November 5, 2020, Conterno made additional statements that FibroGen showed non-inferiority, without disclosing that the FDA believed that a Black Box warning would be necessary. *Id.* ¶ 132.

otherwise involved with the statements. As such, because Plaintiffs do not plead any particularized facts as to which, if any, Independent Directors were involved in the press releases and conferences, these statements do not support a *Malone* claim.

Even though they plead no particularized facts connecting these statements to the Demand Board, Plaintiffs argue that a majority the Demand Board nonetheless breached its disclosure duty by failing to correct the statements made by FibroGen's management team.[117] In light of the exculpation clause, it is not enough to allege that the misleading statements occurred on these directors' watch; nor is it enough to plead facts from which I may infer negligence, or even gross negligence, in the directors' failure to cure the misimpression caused by the statements. Instead, Plaintiffs' "burden is to plead non-conclusory facts from which (drawing all plaintiff-friendly inferences) I may infer bad faith."[118]

Plaintiffs have failed to plead facts from which I can infer bad faith here. As discussed above, Plaintiffs allege no particularized facts showing that the Independent Directors prepared, reviewed, or even knew about the statements at issue. For example, Plaintiffs allege that these Board members knew that the FDA believed a Black Box warning would be necessary, and yet, failed to stop Conterno from making misleading public statements indicating he believed that one would not

[117] Pls.' Opp'n 35–36.
[118] *Ellis v. Gonzalez*, 2018 WL 3360816, at *11 (Del. Ch. July 10, 2018).

be necessary.[119] But nowhere in the complaint do Plaintiffs plead particularized facts that any Independent Directors acted *with scienter* in failing to correct his statement. Without facts showing that the majority of the Demand Board reviewed or even knew about the statements made by FibroGen management, I cannot, even making plaintiff-friendly inferences, conclude that the Independent Directors acted in bad faith by failing to correct the statements made by FibroGen's management team in press releases and conference calls.

2. Statements made in FibroGen's Forms 10-Q

Plaintiffs also fail to sufficiently plead that any of the Independent Directors were involved in making misleading statements in FibroGen's Forms 10-Q. For instance, on August 8, 2019, FibroGen filed its second quarter 2019 Form 10-Q with the SEC, stating that the Company had reached an agreement on the content to be included in its NDA submission package.[120] Plaintiffs allege that two Independent Directors attended an Audit Committee meeting a week before the Form 10-Q was filed to approve FibroGen's second quarter 2019 financial results.[121] Additionally, Plaintiffs allege that there was a Board meeting on August 2, 2019 to discuss FibroGen's pre-NDA meeting with the FDA. [122]

[119] Compl. ¶¶ 118, 259.
[120] *Id.* ¶ 93.
[121] *Id.* ¶ 90. Edwards and Ho attended the meeting, along with Schoeneck (who I am assuming is not independent) and Cotroneo (who is not on the Demand Board). *Id.*
[122] *Id.* ¶ 91. Of the Independent Directors, Edwards, Ho, Henderson, Kearns, Lema, and Riggs were present at the meeting. *Id.*

As with the management-made comments discussed above, Plaintiffs do not plead sufficient facts from which I can infer that the Demand Board played a role in issuing the statements within the second quarter 2019 Form 10-Q. Assuming that the statements in the Form 10-Q are false or misleading, Plaintiffs do not provide sufficient particularized facts from which I can draw a reasonable inference that either the Audit Committee or the Demand Board knew as of August 8, 2019 that those statements were false or even that they were included in the Form 10-Q. Nor can I draw a reasonable inference that any of the Independent Directors (or even the minority of the directors who served on the Audit Committee) acted in bad faith in allowing these statements to be published.

The same conclusion applies to the other Forms 10-Q. On November 12, 2019 FibroGen filed its Form 10-Q for third quarter 2019 with the SEC, stating that the "cardiovascular safety analysis reflects the pooling strategy and analytical approach we agreed on with the FDA."[123] Plaintiffs allege that Independent Directors Blaug, Edwards, Henderson, Ho, Kearns, Lema, and Riggs knew as of September 15, 2019 facts from which they could have concluded that this Form 10-Q was false or misleading.[124] But again, Plaintiffs plead no particularized facts establishing that

[123] *Id.* ¶ 106.
[124] *Id.* ¶ 257.

any Independent Directors had a role in preparing the Form 10-Q.[125] And Plaintiffs plead no particularized facts establishing that any of the Independent Directors knew of the statements included in the Form 10-Q. With no particularized facts showing that the Board made or had any responsibility over the statements alleged to be false or misleading, I cannot draw a reasonable inference of any Independent Director's bad faith.

3. Statements made in FibroGen's Forms 10-K

More substantially, with regard to their theory under *Malone*, Plaintiffs rely on FibroGen's Forms 10-K to support their disclosure claims. On March 2, 2020, FibroGen filed its 2019 Form 10-K with the SEC.[126] The Form 10-K included the previously disclosed clinical trial results and stated that the cardiovascular safety analyses "reflect the pooling strategy and analytical approach we agreed on with the FDA."[127] FibroGen included essentially the same statements in its 2020 Form 10-K, filed on March 1, 2021.[128] Plaintiffs plead that a majority of the Demand Board signed the Forms 10-K that were based on post-hoc manipulated data and a non-inferiority margin of 1.3 (which, in fact, had not been agreed to by the FDA).[129]

[125] Of the Demand Board, only Schoeneck (who I consider not independent) signed and certified the Form 10-Q. *Id.* ¶ 106.
[126] *Id.* ¶ 112.
[127] *Id.*
[128] *Id.* ¶ 142.
[129] Of the Demand Board, Independent Directors Blaug, Edwards, Henderson, Ho, Kearns, Lema, and Riggs signed the 2019 Form 10-K. *Id.* ¶ 112. All members of the Demand Board signed the 2020 Form 10-K. *Id.* ¶ 142.

Again, Plaintiffs assert that a majority of the Demand Board knew that the FDA had not agreed to a non-inferiority margin as of September 2019.[130]

First, Plaintiffs plead no facts, other than the Demand Board's signatures on the Forms 10-K, showing that any Director Defendants were involved in preparing the statements. But "[a] statement that the documents were signed by the Director Defendants, or that they 'approved' the disclosures and 'caused' or 'consented to' their filing, is not—without more—a particularized allegation of fact."[131] Further, Plaintiffs only provide generalized allegations of board knowledge. Plaintiffs plead

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[130] Pls.' Opp'n 12–13.

[131] *See In re Zimmer Biomet Hldgs., Inc. Deriv. Litig.*, 2021 WL 3779155, at *15 (Del. Ch. Aug. 25, 2021) (finding an allegation that directors signed a registration statement inadequate to demonstrate director defendant involvement); *In re China Auto. Sys. Inc. Deriv. Litig*., 2013 WL 4672059, at *13 (Del. Ch. Aug. 30, 2013) (refusing to draw an inference that a company's directors acted in bad faith where all directors signed a misleading SEC filing, but did not "allege with particularity any direct or personal involvement by the Defendants in the Company's preparation of its financial statements"); *In re ProAssurance Corp. S'holder Deriv. Litig.*, 2023 WL 6426294, at *17 (Del. Ch. Oct. 2, 2023) (granting a motion to dismiss where the plaintiff's complaint "lack[ed] specific factual allegations reasonably suggesting 'sufficient board involvement' in preparing the disclosures" at issue where "[t]he only director involvement alleged is signing the SEC filings"); *see also In re TrueCar, Inc. S'holder Deriv. Litig.*, 2020 WL 5816761, at *12 (Del. Ch. Sept. 30, 2020) (dismissing a complaint where plaintiffs alleged that, by signing a company's 2016 Form 10-K, the directors on its' demand board "directly participated in" making misleading statements, on the grounds that plaintiffs failed to plead sufficient facts that the board had notice of illegality); *Citigroup*, 964 A.2d at 121–36 (holding that demand is not futile under disclosure allegations where plaintiffs fail to allege with sufficient specificity the actual misstatements that constituted a violation of the board's duty of disclosure, facts that suggest sufficient board involvement in the preparation of the disclosures, and facts that the director defendants had *knowledge* that any disclosures or omissions were false or misleading) (emphasis added). The surrounding facts presented here are not clear enough for me to reasonably draw an inference of directorial bad faith. *C.f. InfoUSA*, 953 A.2d at 990–91 (reasonably inferring scienter on behalf of directors who signed Form 10-Ks stating that payments involved "usage of aircraft and related services" shortly after being presented with a report with contradicting statements about the usage of the payments).

that at some point before December 2019, the FDA had communicated to "FibroGen" during pre-NDA meetings that the FDA's goal was a hazard ratio below 1.25,[132] but do not plead particularized facts showing that the *Demand Board* knew that the FDA had that goal. There are no specific factual allegations in the complaint that the Demand Board members knew that the FDA had rejected a hazard ratio of 1.3, had a "goal" of 1.25, or that the Demand Board members knew that management had been using modified stratification factors as would be rejected by the FDA.

Accordingly, while Plaintiffs have made allegations that Demand Board members had knowledge of information regarding the safety and efficacy of Roxadustat, Plaintiffs have failed to plead specific factual allegations from which one could reasonably infer that the Demand Board members had *actual knowledge* of, or intent to commit, dissemination of false or misleading information. Plaintiffs have not stated a claim under *Malone.*

Plaintiffs next argue that had the Demand Board looked to the red flags unfurled, and sufficiently investigated, it would have learned that management's statements were false.[133] I examine such assertions under the lens of *Caremark*, below.

[132] Compl. ¶¶ 161, 218, 253, 257.
[133] Pls.' Opp'n 3, 39–40.

To plead demand futility under *Caremark*, Plaintiffs must allege with particularity that corporate trauma arose from either "(a) the directors [having] utterly failed to implement any reporting or information system or controls; *or* (b) having implemented such a system or controls, [they] consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention."[134]

In making an argument under *Caremark*'s second prong,[135] Plaintiffs must provide particularized facts that the Demand Board "knew of evidence of corporate misconduct—the proverbial 'red flag'—yet acted in bad faith by consciously disregarding its duty to address that misconduct."[136] This Court has noted that "red flags are only useful when they are either waived in one's face or displayed so that they are visible to the careful observer,"[137] although "the careful observer is one whose gaze is fixed on the company's mission critical regulatory issues."[138]

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[134] *Stone*, 911 A.2d at 370.

[135] The complaint also attempted to plead a "first prong" Caremark claim, but that was abandoned in response to the Motion to Dismiss and is unsupported in the pleadings. Compl. ¶¶ 250–62.

[136] *Pettry ex rel. FedEx Corp. v. Smith*, 2021 WL 2644475, at *7 (Del. Ch. June 28, 2021) (quoting *Teamsters Local 443 Health Servs. & Ins. Plan v. Chou*, 2020 WL 5028065, at *17 (Del. Ch. Aug. 24, 2020)).

[137] *In re Clovis Oncology, Inc. Deriv. Litig.*, 2019 WL 4850188, at *13 (quoting *Wood*, 953 A.2d at 143).

[138] *Id.* (citing *Marchand v. Barnhill*, 212 A.3d 805 (Del. 2019)). In their complaint, Plaintiffs have sufficiently alleged that the FDA's approval of Roxadustat was mission critical to FibroGen. Compl. ¶¶ 209–22. However, this does not change the outcome of my determination. I note that none of the wrongdoing alleged against FibroGen itself caused the FDA's rejection of Roxadustat—that is, a failure of oversight did not lead to a "mission critical" corporate trauma.

In total, Plaintiffs allege that the Demand Board was faced with seven red flags signaling potential problems with Roxadustat's clinical trial data and related public disclosures.[139] These include:

> (i) Board meetings concerning pre-NDA discussions; (ii) two separate public investment reports questioning whether FibroGen's safety data was truthful; (iii) FibroGen's competitor drug failing its sensitivity analysis using a 1.25 hazard ratio; (iv) [a] Citizen's Petition demanding the FDA reject the NDA and, at minimum, mandate a Black Box warning; (v) Yu's suspicious retirement; (vi) the FDA's request for additional safety data analyses and unexpected extension of the review period; and (vii) the March 29, 2021 Board presentation and Defendants' subsequent efforts to destroy critical evidence, including data on Yu's laptop and hard copy documents.[140]

In oral argument, Plaintiffs identified two flags as most prominently displayed: The July 2020 Board meeting where the Board was told that the FDA had informed management that a Black Box warning would likely be required,[141] and the FDA's extension of the review period and request for additional safety analyses.[142] Accordingly, while I view all the red flags through a cumulative lens, I will begin with these two.

To start, Plaintiffs argue that, because the data previously presented to the Board pointed in the direction of Roxadustat being safer than Epogen, the

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[139] Pls.' Opp'n 39–40.
[140] *Id.*
[141] Tr. 28:15–30:21; Compl. ¶ 124. In addition to Schoeneck and Conterno, the following Independent Directors were present at the July 29, 2020 meeting: Blaug, Edwards, Henderson, Ho, Kearns, Lema, and Riggs. Compl. ¶ 124.
[142] Tr. 32:10–18; Compl. ¶ 140. In addition to Schoeneck and Conterno, the following Independent Directors were present at the December 18, 2020 meeting where the Board learned this information: Blaug, Brennan, Cravatt, Henderson, Ho, Kearns, Lema and Riggs. Compl. ¶ 140.

information regarding a probable Black Box warning should have put the Demand Board on notice that management had been misleading the Director Defendants, and investigation would have disclosed that management was similarly providing improper data to the FDA and misleading stockholders.[143] In light of this information, the Director Defendants, per Plaintiffs, acted in bad faith when they did not properly oversee management to prevent management from falsely telling stockholders that such a warning would be unnecessary, or from championing Roxadustat's safety profile.[144] According to Plaintiffs, the Demand Board's inaction in the face of this information rises to the level of bad faith.[145] I note that inaction in the face of *a known duty to act* is bad faith.[146]

Defendants dispute, however, that the information regarding a Black Box warning is a red flag at all,[147] and I agree. To start, the FDA's belief that a Black Box warning may be necessary is not clear evidence of management's misconduct. A Black Box warning requirement would only signal to the Board that the FDA viewed Roxadustat as comparable to Epogen, which itself had a Black Box warning. Plaintiffs fail to establish that this information was clear enough that, when presented to the Demand Board, it would put them on notice that management was issuing

[143] Pls.' Opp'n 62; Tr. 28:15–30:21.
[144] Compl. ¶¶ 144, 169, 259.
[145] Pls.' Opp. 62.
[146] *See In re Walt Disney Co. Deriv. Litig.*, 906 A.2d 27, 67 (Del. 2006).
[147] Tr. 45:9–47:14.

false or misleading public disclosures. Without evidence that the Demand Board was on notice, I cannot reasonably infer the Director Defendants disregarded a known duty to act, implying bad faith.

Plaintiffs also argue that the FDA's December 2020 extension of the Roxadustat review period and request for additional safety analyses was clear evidence presented to the Board that management must have been misleading stockholders or investors.[148] However, as Defendants point out, Plaintiffs fail to allege that the FDA's request for more information and further review was tied to the FDA's suspicion of illegality or corporate misconduct, let alone that the Director Defendants were so informed.[149] The FDA's decision to extend the study—when it could have ended the study and rejected the drug outright—does not to my mind represent clear evidence from which the Demand Board must have suspected that FibroGen management was providing false information or misleading stockholders. Plaintiff argues that it would have been prudent for the Board, given the FDA review extension and the probable Black Box warning, to have investigated more fully,[150] a supposition from which I do not dissent. These are not red flags from which I can infer that the Demand Board, with *scienter*, failed to address management's misconduct, however.

[148] Tr. 32:10–18; Compl. ¶ 140.
[149] Defs. RB 20.
[150] Pls.' Opp'n 57–58, 61–64.

Nor do the other proposed red flags vindicate Plaintiffs' theory. For example, Plaintiffs point to two short seller reports that questioned generally Roxadustat's safety data,[151] but do not plead particularized facts showing how these reports rise to the level of a red flag to the Demand Board. Plaintiffs similarly identify a meeting where Board members discussed analyst concerns relating to the news that Roxadustat's competitor failed its sensitivity analysis using a 1.25 hazard ratio as evidence of a red flag,[152] but do not plead particularized facts that give rise to a reasonable inference that this information about a *competitor's* drug was sufficient evidence of *FibroGen's* false or misleading disclosures to cause the Director Defendants to face a known duty to act.

Likewise, Plaintiffs aver that the Citizen Petition[153] filed with the FDA "raised serious questions about FibroGen's compliance risk."[154] The Citizen Petition contended that FibroGen's presentation of safety data at a conference had improperly "disguised" significant safety concerns.[155] Plaintiffs claim that "[h]ad the Board investigated [the Citizen Petition's claims], they would have discovered the data submitted to the FDA was misleading because it was manipulated using *pro*

[151] *Id.* 46–47; Compl. ¶¶ 101, 107.
[152] Pls.' Opp'n 50–51; Compl. ¶ 130.
[153] A citizen petition is a way for an individual or group to ask the FDA to take some sort of action. Defs. OB 17 n.15.
[154] Pls.' Opp'n 51.
[155] Compl. ¶ 135.

hoc stratification factors."[156] But Plaintiffs do not allege that the Demand Board viewed the Citizen Petition. Further, this "could-have" theory of knowledge is not sufficient under Rule 23.1's demanding pleading standard.[157]

Plaintiffs claim that Yu's retirement was another red flag.[158] Specifically, Plaintiffs allege that Yu's retirement was suspicious because it occurred shortly after the Citizen Petition (and because Yu joined a different company months later).[159] Yet, as with the other red flags, Plaintiffs do not provide sufficient particularized facts from which I could draw a reasonable inference that Yu's retirement was in and of itself evidence of management's corporate wrongdoing, or that a Board would view it as such.

Plaintiffs' final red flag is a Board presentation on March 29, 2021, which informed the Board of the misleading NDA.[160] But the Board met again on April 3,[161] and by April 6, FibroGen issued a press release informing investors that the previously presented safety data included post-hoc changes to the stratification factors.[162] Given these facts, I cannot reasonably infer that the Demand Board failed to respond to this red flag.

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[156] Pls.' Opp'n 52.
[157] *See MetLife*, 2020 WL 4746635, at *15–16.
[158] Pls.' Opp'n 54–55; Compl. ¶¶ 136–38.
[159] Pls.' Opp'n 54–55.
[160] *Id.* at 59–60.
[161] Defs. OB 19–20.
[162] Compl. ¶ 147.

Even viewing all these purported red flags cumulatively and in the light most favorable to Plaintiffs, I cannot reasonably infer that the Demand Board acted in bad faith. Even if a reasonable Board may have acted differently, Plaintiffs fail to establish particularized facts supporting the Demand Board's disloyalty to the Company.

Finally, even if Plaintiffs had established that the Demand Board was presented with red flags, they do not clearly identify a corporate trauma. To the extent that they allege that the corporate trauma is that AstraZeneca withdrew from the partnership, they plead no particularized facts connecting the withdrawal to their red flags, as opposed to the simple truth that *Roxadustat proved inferior to the existing treatment*. That would have become apparent with or without any management wrongdoing, and Plaintiffs do not suggest anything that the Board could have done in good faith in the face of the knowledge of the hazard ratios or post-hoc stratification that would have averted this withdrawal. It seems that the only colorable corporate trauma is the misleading statements themselves and resulting securities settlement liability, but as discussed above these facts fail to implicate a majority of the Demand Board under *Malone*. Plaintiffs have likewise failed to show that four of the Independent Directors face a substantial likelihood of liability under *Caremark* such that demand should be excused.

C. Plaintiffs Fail to Establish Demand Futility for their Brophy Claim

Given that Plaintiffs have failed to establish demand futility under either *Malone* or *Caremark*, Plaintiffs have also failed to establish that the Demand Board could not have disinterestedly and independently considered the *Brophy* claim (which would implicate only a minority of the Demand Board). Plaintiffs conceded this at oral argument.[163]

III. CONCLUSION

So long as FibroGen Directors act (or fail to take action) *loyally*, they are exculpated for resulting liability to the company, even in light of negligence or gross negligence. Taking the facts pled in the light most favorable to Plaintiffs, and assuming two Directors lacked independence, under the rigorous standards of Rule 23.1, I cannot infer disloyalty or bad faith on the part of a majority of the Demand Board. Demand is, therefore, not excused.

For the foregoing reasons, Defendants' Motion to Dismiss the Verified Shareholder Derivative Complaint is GRANTED. The parties should submit a form of order consistent with this Memorandum Opinion.

[163] Tr. 15:8–24; 39:14–40:1.