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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, vs. KIN-HUNG PEONY YU Defendant.	Case No. 3:25-cv-7593 **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Securities and Exchange Commission ("SEC") alleges:

SUMMARY

1. This case involves false and misleading statements about the safety of FibroGen, Inc.'s ("FibroGen") then-primary drug candidate roxadustat, a potential therapy for the treatment of anemia in patients with chronic kidney disease. During the period November 8, 2019 to March 1, 2021, FibroGen's Chief Medical Officer, Defendant Kin-Hung Peony Yu ("Dr. Yu"), repeatedly claimed that the results of key studies established roxadustat's

cardiovascular safety, including a superior safety profile to the primary existing treatment. Dr. Yu made these claims in a range of forums, including a high-profile industry presentation and accompanying press release, multiple SEC filings, an earnings call, and a published article in a leading industry journal.

2. Specifically, Dr. Yu told investors, analysts, and clinicians that statistical analyses of the study results showed roxadustat was a "potential game changer in anemia therapy," and that:

- the "results suggest potential long-term safety benefits in selecting roxadustat when initiating anemia therapy in dialysis patients";
- "in dialysis patients, roxadustat reduced the risk of [cardiovascular events] by 14%";
- for a key subgroup of dialysis patients, roxadustat was over 30% safer than the existing treatment, and could therefore be "viewed as a safer option for patients initiating chronic dialysis."

3. These claims were materially misleading. Dr. Yu did not tell investors that, at her direction, FibroGen generated those study results only *after* reviewing the study data and *after* initially receiving less favorable results. She omitted that information because the undisclosed initial analyses found that roxadustat's cardiovascular safety was, at best, no better than either the existing treatments or a placebo and because, as Dr. Yu knew, regulators and industry participants do not typically view "post-hoc" analyses – a method of analyzing data developed after the data has been reviewed – as sufficient to establish a study's primary conclusion.

4. Nor were the favorable results she announced a coincidence. Concerned by the unsatisfactory initial results and their impact on roxadustat's commercial viability and prospects for Food and Drug Administration ("FDA") approval, Dr. Yu directed FibroGen and two third-party firms to run numerous experimental analyses using different variables until she determined which set of key variables – or "stratification factors" – told what her subordinate described as "the most compelling story" about roxadustat. Simply put, Dr. Yu reverse-

engineered better results. Her conduct violated universally accepted industry and regulatory standards and roxadustat study guidelines. Her failure to disclose this conduct to investors and others rendered her and FibroGen's public statements regarding roxdustat's cardiovascular safety materially false or misleading.

5. Dr. Yu knew FibroGen changed the models after the data was unblinded, and she knew or was reckless in not knowing that, even putting aside these post-hoc changes, it is improper to publicly present exploratory, post-hoc analysis results as if they were the primary study outcome. Regulators, clinicians, and investors need to know the true nature of a statistical analysis to understand and evaluate clinical study results.

6. The nature of these statistical analyses was a key issue to analysts and investors. During FibroGen's key November 11, 2019 earnings call, analysts repeatedly pressed Dr. Yu on the statistical bases for her claims. Dr. Yu responded by insisting that the published results were "based on the agreed analysis plan that we have made with the FDA." That statement was false. The key numbers Dr. Yu presented and emphasized on the call were not based on an FDA-approved statistical analysis plan. Prior to the call, FibroGen had not disclosed to the FDA that its claims were based on the post-hoc use of revised stratification factors.

7. As Chief Medical Officer, with vast drug development experience and expertise, Dr. Yu personally directed the undisclosed post-hoc changes to the cardiovascular safety analyses, co-authored the publication of the results, and made false and misleading statements to investors and industry analysts. She engaged in this conduct despite repeated warnings by one of FibroGen's corporate partners in developing roxadustat that FibroGen needed to disclose publicly that it had improved the results by making post-hoc changes to the stratification factors used in its statistical analyses.

8. Dr. Yu's misleading statements were material. On November 8, 2019, the day FibroGen first disclosed the misleading results in a conference presentation prepared by Dr. Yu and a press release that quoted her extensively, FibroGen's stock rose more than 10 percent above its prior trading day closing price, with an intraday high of over 32 percent above the prior day's close immediately following the presentation.

9. After Dr. Yu's departure from FibroGen in March 2021, new FibroGen management issued a corrective disclosure in an April 6, 2021 press release. FibroGen admitted that its previously disclosed results were based on post-hoc changes to certain stratification factors and disclosed the less favorable pre-specified results, which showed roxadustat was merely comparable to the existing treatment. FibroGen's stock price promptly dropped over 43 percent. A leading industry journal also retracted an article, co-authored by Dr. Yu, touting roxadustat's results.

10. By this conduct, Defendant Dr. Yu violated Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Exchange Act Rule 10b-5(b) thereunder [17 C.F.R. § 240.10b-5(b)] and Section 17(a)(2) of the Securities Act [15 U.S.C. § 77q(a)(2)].

11. The SEC seeks permanent injunctions, an officer-and-director bar, disgorgement with prejudgment interest, and civil penalties against Dr. Yu.

JURISDICTION AND VENUE

12. The Court has jurisdiction over this action pursuant to Sections 21(d)(1), 21(d)(3)(A), 21(e), and 27(a) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. §§ 78u(d)(1), 78u(d)(3)(A), 78u(e), and 78aa].

13. The Defendant has, directly or indirectly, made use of the means or instrumentalities of interstate commerce, of the mails, or of the facilities of a national securities exchange in connection with the transactions, acts, practices and courses of business alleged in this complaint.

14. Venue is proper in this district pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)], and Section 27(a) of the Exchange Act [15 U.S.C. § 78aa(a)], because certain of the transactions, acts, practices and courses of conduct constituting violations of the federal securities laws occurred within this district, as described below. Specifically, FibroGen, the company at issue in this action, is headquartered in San Francisco, California and its personnel, including Defendant Dr. Yu, conducted business, including research and development, in this district during the relevant time period. Many of the events described below occurred in this district.

THE DEFENDANT

15. **Kin-Hung Peony Yu**, age 62, is a Bellevue, Washington resident, and was the Chief Medical Officer of FibroGen from April 2016 to December 2020. During the relevant time period, Dr. Yu was FibroGen's Global Project Leader for the roxadustat program and worked out of FibroGen's principal office in San Francisco. Dr. Yu also served on FibroGen's "Disclosure Committee," which reviewed press releases and other disclosures prior to publication. She resigned as Chief Medical Officer of FibroGen effective December 20, 2020 and departed from FibroGen on March 15, 2021. Since departing FibroGen, she has served as the Chief Medical Officer of another public pharmaceutical company although she does not currently serve in that role.

OTHER RELEVANT PARTIES

16. **FibroGen, Inc.** is a Delaware corporation with its principal place of business in San Francisco, California. FibroGen is a biopharmaceutical company that, at all relevant times, was engaged primarily in developing roxadustat. FibroGen's shares are registered with the Commission pursuant to Exchange Act Section 12(b) and are listed on the Nasdaq Global Select Market under the symbol "FGEN."

TERMINOLOGY

17. "Statistical Analysis Plan" ("SAP") is a document that sets forth the pre-specified statistical methods and procedures for analyzing clinical trial data. It serves as a blueprint for how the data will be analyzed. To minimize the risk of bias, the SAP is prepared prior to accessing or analyzing the data, without the knowledge of treatment group assignment. After the SAP is completed and the trial data are validated, cleaned, and analyzed, the treatment assignment is revealed to the researcher through a process referred to as "unblinding."

18. "Primary Analysis" refers to the analysis performed to test the study's primary hypotheses. Clinical trials are designed with the goal of delivering reliable results for its primary analysis. According to the FDA, "in general, results from the primary analysis form the basis of FDA's regulatory decisions."

19. "Post-Hoc Analyses" refers to analyses that were not specified in the SAP

and are based on changes to the statistical methods and procedures developed *after* the unblinding of the data from a clinical drug study.

20. "Hazard Ratio" is a ratio of the rate at which one study group experienced an event to the rate a comparator group experiences that same outcome. For safety events such as adverse cardiovascular events, a treatment-to-control group hazard ratio of 1 represents equal risk between the two groups, greater than 1 represents higher risk for the treatment group, and less than 1 represents lower risk for the treatment group.

21. "Superiority" trials are designed to determine whether one treatment is better than a placebo or another treatment. In the context of evaluating safety outcomes, if treatment A is "superior" to treatment B, this means that treatment A is associated with a lower risk of an adverse event than treatment B.

22. "Non-Inferiority" trials are designed to determine whether one treatment has a risk that is no higher than the comparator treatment.

FACTUAL ALLEGATIONS

I. Drug Safety – and a Drug's Commercial Viability – Depend on Appropriate, Fully Disclosed Statistical Analyses.

23. The safety and efficacy of medications is of paramount importance. Doctors must be able to accurately weigh the benefits of treatment with a medication versus its risks to a patient's health.

24. To minimize patient harm, the FDA and industry participants have established protocols for how to conduct and analyze the results of clinical drug studies. Such studies may involve thousands of participants over broad geographic areas and extended periods of time. The analysis of results may involve complex statistical analyses, especially when comparing the safety or efficacy of a new medication to an established treatment or a placebo. Study sponsors thus develop and rely on study protocols that lay out a detailed plan for conducting and analyzing data from the clinical trial to minimize the risk of bias in the study. Following established approaches to developing and relying on pre-specified study protocols and statistical analysis plans is critical for researchers, physicians, drug companies, and regulators to

have confidence in the study's findings.

25. The development of a study protocol, including a statistical analysis plan that outlines the statistical methods and procedures for analyzing data, is made before the study begins to minimize potential biases that can undermine the validity of the statistical inferences that can be drawn from the study's results. It should be approved by all investigators participating in a study prior to data collection and analysis. If changes are scientifically necessary, the investigators should clearly describe why they need to make these changes and propose specific amendments that will better answer the study's key questions.

26. Study sponsors must also make extensive disclosures about the study and its purported results. These disclosures may be made in a new drug application to the FDA, but the sponsor will typically also make extensive disclosures in presentations to conferences, manuscripts, and published articles. These disclosures further allow reviewers and regulators to verify that a study was conducted in a clinically and statistically appropriate manner.

27. One of the core principles is that a study's primary outcome must be based on a pre-specified analysis, set forth before the data and results are revealed to the sponsor. The dangers of using an analysis developed post-hoc – in other words, after reviewing the study data – are significant. Doing so invites study sponsors to cherry-pick or reverse-engineer the primary result, undermining the study's integrity. As a 2007 article in the *New England Journal of Medicine*, titled "Statistics in Medicine – Reporting of Subgroup Analyses in Clinical Trials," explained, post-hoc analyses "are of particular concern because it is often unclear . . . whether some were motivated by [sponsor] inspection of the data."

28. These principles do not prohibit post-hoc analyses. On the contrary, various types of post-hoc analyses may be appropriate and useful. They may generate new ways of looking at data or provide better insight into unexpected results.

29. But there is a clear consensus among industry participants and regulators that post-hoc analyses cannot be the basis for determining a study's primary outcomes. For example, referring to potential biases arising from post-hoc analyses, a well-known textbook in the field of clinical trial research – *Fundamentals of Clinical Trials* – noted that while post-hoc

analyses "may provide valuable insights into the harm of drugs and medical interventions, they should be specifically identified as separate from prospectively defined analyses."

30. A 2016 article in the journal *BMC Medical Research Methodology*, titled "Best Practice for Analysis of Shared Clinical Trial Data," summed up the key distinction between pre-specified and post-hoc analyses. It noted that the industry guidelines emphasize the importance of "pre-specification" of the statistical methodology "in order that unbiased decisions about the analysis methods can be made." In contrast, "[r]egardless of what motivates . . . post-hoc analyses, they are likely to produce biased results[.]" Post-hoc analyses are "of exploratory, rather than confirmatory, value." For confirmation of the primary objective, the article emphasized, "key statistical methods will be defined in the protocol prior to initiation of the trial, and a statistical analysis plan will be written prior to un-blinding of the data."

31. The well-recognized risks of post-hoc analyses require that their use must be fully disclosed. The Consolidated Standards of Reporting Trials ("CONSORT") 2010 Explanation and Elaboration on guidelines for reporting parallel group randomized trials emphasized at the outset that the "whole of medicine depends on the transparent reporting of clinical trials." The guidelines recognized that "Analyses that were pre-specified in the trial protocol . . . are much more reliable than those suggested by the data[.]" Accordingly, the CONSORT explanation insisted that study authors "should identify and explain" any changes to how "an outcome is assessed." Moreover, in reporting the analyses performed, authors must "distinguish[] pre-specified from exploratory."

32. FibroGen's own policies embraced these principles. Its 2014 standard operating procedure for a "Statistical Analysis Plan" stated that an "SAP [statistical analysis plan] is a *comprehensive and detailed description* of the methods and presentations of data analyses proposed for a clinical trial." (emphasis added). It continued that "[i]t is FibroGen's policy to prepare an SAP to document details of the planned analyses of clinical trial data." The procedures also emphasized that for "pivotal trials" any revisions to the SAP must be developed and documented in the same manner as the original SAP.

33. Further, in 2016, FibroGen worked with two other pharmaceutical companies, Pharmaceutical Company A ("Pharma Co. A") and Pharmaceutical Company B ("Pharma Co. B"), to develop roxadustat. The three companies drafted principles governing the publication of roxadustat study results. These included: "Secondary publications (such as . . . post-hoc analyses) should be accompanied by disclosure of its secondary nature and have a scientific need-based rationale." These principles also stated that "[p]ublications must be accurate, balanced, transparent and not otherwise misleading."

34. FibroGen, Pharma Co. A, and Pharma Co. B personnel involved in the roxadustat study, including Dr. Yu, all understood the industry customs and rules regarding the use and disclosure of post-hoc analyses. As confirmed by testimony before SEC staff during its investigation, they knew that the results of post-hoc analyses must be disclosed as such and that such results will be viewed with greater skepticism.

35. These core principles of statistical analysis help guide credible medical research and protect patient safety. Industry and regulatory guidance are united: post-hoc changes to a statistical analysis plan typically cannot support a study's primary conclusion. Moreover, the true nature of any such analyses must be disclosed.

36. As set forth below, Dr. Yu disregarded these guidelines. After the data was unblinded, and after she reviewed the initial, unpromising results, she (1) changed the pre-specified analysis, (2) reverse-engineered or cherry-picked a better result, and then (3) falsely and misleadingly told the investors, researchers, and clinicians that roxadustat was superior in key respects to the primary existing treatment, epoetin-alfa ("EPO") and comparable to a placebo. In doing so, she publicly disclosed neither the use of the key post-hoc analyses nor the initial results while, at her direction, FibroGen provided misleading information to the FDA.

II. FibroGen Developed Roxadustat, Which Was the Sole Source of Its Revenues.

37. FibroGen was incorporated in 1993. By 2019, it had only two products in development – roxadustat and another drug called pamrevlumab. Roxadustat is an oral medication meant to combat anemia in patients with chronic kidney disease ("CKD"). As of

2019, it was also being developed to treat anemia in cancer patients. According to FibroGen's third quarter 2019 10-Q, the development of pamrevlumab was far less advanced and highly uncertain, possibly requiring expertise and financial resources that FibroGen did not possess. That left roxadustat, which, as of 2019, was the sole source of FibroGen's revenues.

38. Virtually all those revenues derived from FibroGen's partnerships with Pharma Co. A and Pharma Co. B. The agreements with Pharma Co. A and Pharma Co. B each entitled FibroGen to receive substantial payments based on the achievement of developmental, regulatory, and commercial "milestone events." For example, in 2013, Pharma Co. B agreed to pay FibroGen "up to $325.0 million" for achieving various regulatory and milestones and a similar amount for achieving certain commercial milestones. These included a payment of $50 million for the "[f]irst acceptance by the FDA for filing of an NDA [New Drug Application]" for roxadustat's treatment of anemia in the United States, and $65 million for FDA approval of FibroGen's NDA.

39. Under its agreement with Pharma Co. A, FibroGen was entitled to certain payments based on roxadustat's development and commercialization, primarily in Europe and Japan. FibroGen had two agreements with Pharma Co. B. The first entitled FibroGen to potentially hundreds of millions of dollars depending on roxadustat's progress in the United States and certain other countries, except China. In the third quarter of 2019, FibroGen determined that the purported results of the study at issue in this case entitled it to payments of tens of millions of dollars. FibroGen also had an agreement with Pharma Co. B for the development and sale of roxadustat in China.

40. In 2019, roxadustat was completing Phase III clinical development for the treatment of anemia in CKD patients. Phase III is the final testing phase, often involving thousands of patients, before a drug's trial results are submitted to regulators. Phase III studies are typically referred to as "confirmatory," meaning that results based on the primary outcome are seen as confirming the efficacy and safety properties of the treatment. The goal of Phase III testing is often to evaluate the new medication in comparison to existing medications and usual care. Phase III testing may last several years.

41. For roxadustat, the Phase III study program consisted of a pooled analysis of seven studies involving patients with chronic kidney disease. A "pooled" analysis is an analysis that combines data from multiple studies or groups into a single analysis. The primary purpose or "endpoints" of these studies concerned roxadustat's impact on patients' cardiovascular health. Specifically, the studies measured: 1) the time to a patient's first Major Adverse Cardiovascular Event ("MACE"); 2) the time to a patient's first MACE+, which refers to MACE *plus* additional events, specifically hospitalization for heart failure and angina; and 3) the time to all-cause mortality ("ACM").

42. Of the seven studies, three were designed to test roxadustat's cardiovascular safety against a placebo in patients who were not dependent on dialysis treatment ("dialysis dependent"). Four were designed to test whether roxadustat was safer than a comparator drug, Epoetin Alfa ("EPO"), for dialysis-dependent patients.

III. Dr. Yu Led FibroGen's Roxadustat Development and Testing.

43. Dr. Yu was the global project leader for FibroGen's roxadustat program. She was also FibroGen's primary point of contact for coordinating with Pharma Co. A and Pharma Co. B. She oversaw the roxadustat Phase III studies from their outset. By 2019, as Chief Medical Officer, she managed the Biometrics group at FibroGen, which was responsible for the statistical analysis of the Phase III safety results. She also managed the Medical Affairs group, which was responsible for publishing those results.

44. Dr. Yu was a hands-on manager. She was intimately involved in the statistical analyses of the Phase III study, including discussions with Pharma Co. A and Pharma Co. B. She specifically selected the FibroGen statistician, Employee A, who worked on the statistical analyses. Dr. Yu and Employee A had been colleagues at a prior company.

45. Dr. Yu's tight control of Phase III study analyses and, in particular, the pooled cardiovascular safety analyses, extended to third parties, including Pharma Co. A, Pharma Co. B, and the firms assisting FibroGen's statistical team. For example, on April 12, 2019, Employee A emailed the two senior representatives of one of those two assisting firms regarding the cardiovascular safety analyses, copying Dr. Yu, to explain that: "All discussions

[concerning roxadustat's MACE results] will be limited to the 4 of us on this email until Peony [Yu] decides to involve a larger group. File sent to sftp site will be password protected. *Peony will decide when and who will be involved with the MACE results*." (emphasis added).

46. FibroGen also frequently slowed or stymied Pharma Co. A's and Pharma Co. B's attempts to obtain more information about roxadustat's clinical study data and analyses. For example, in 2019, FibroGen did not initially grant Pharma Co. A access to patient-level roxadustat study data, forcing Pharma Co. A to repeatedly request the data while preparing its submission to European regulators. Similarly, a senior Pharma Co. B representative stated that the company was routinely frustrated with its lack of involvement in the pooled analyses and collection of data.

47. Dr. Yu tightly managed – and eventually made – public statements about roxadustat. She appointed a subordinate, Employee B, to coordinate the drafting and editing of the presentations, manuscripts, and abstracts describing the Phase III study results. Employee B described Dr. Yu as "very detail-oriented" and provided "a very complete and thorough review" of all publication drafts. Employee B also regularly consulted with Dr. Yu about the review and editing of publications, including comments from Pharma Co. A and Pharma Co. B. Like Employee B, personnel from both companies viewed Dr. Yu as the ultimate decision-maker on FibroGen's public statements on roxadustat. Both Pharma Co. A and Pharma Co. B generally sent their comments on drafts to both Dr. Yu and Employee B.

IV. FibroGen Established a Statistical Analysis Plan and Initially Used It to Analyze Study Data.

48. At the outset of its Phase III roxadustat safety study, FibroGen established a set of pre-specified certain stratification factors for each of the seven studies. Stratification is a statistical tool that allows researchers and statisticians to compare study results for various groups of study participants. The categories used to divide – or stratify – the study participants are often clinically relevant. So, for example, in a study comparing two treatments for osteoporosis, the sponsor could compare the relative outcomes for patients over 50 and, separately, for patients under 50.

49. When analyzing data from a clinical trial, the sponsor often adjusts its statistical analyses to account for the impact of each stratification factor. These statistical adjustments may help control for "confounding variables," which, in simple terms, are variables that make it difficult to establish a cause-and-effect relationship between the treatment and outcome. For example, in the osteoporosis drug study, the sponsor may want to stratify by (and/or statistically adjust for) factors such as weight, age, and smoking status. By doing so, sponsors are better able both to discern real differences and to avoid erroneous inferences about causation.

50. It is accepted industry practice to ensure that the statistical analyses are adjusted for the same stratification factors used to randomize the study participants.

51. Here, consistent with industry practice, FibroGen pre-specified the stratification factors for each of the seven Phase III safety trials at the trials' outset. For the three trials where roxadustat's safety was being compared against a placebo – trials that involved patients not on dialysis – the stratification factors for each of the studies were:

- Baseline hemoglobin value (less than or equal to 8 versus greater than);
- History of cardiovascular disease (yes or no);
- Baseline kidney filtration rate (rate of less than 30 units versus greater than or equal to 30); and
- Geographic region (two studies U.S. versus non-U.S.; one study Western Europe versus others).

52. For each of the four trials where roxadustat's safety was compared to EPO, each involving patients that were dialysis dependent, the stratification factors were:

- Baseline hemoglobin value (stratified by 8 in one study and 10.5 in three others);
- History of cardiovascular disease (yes or no);
- Geographic region (U.S. versus non-U.S.);
- Incident versus stable dialysis (dialysis duration less than or equal to 4 months

versus more than four months at time of randomization); and

- In one study, average prescribed EPO dose (this was not a stratification in the three other studies).

53. FibroGen submitted its statistical analysis plans to the FDA in August and September 2018 for roxadustat's Phase III pooled cardiovascular safety analyses. Because these plans were submitted well before the data was unblinded in April 2019, they were pre-specified. The August 2018 submission concerned the three studies comprising patients that were not dialysis-dependent; the September submission described the analysis of the four studies with dialysis-dependent patients, where roxadustat's cardiovascular safety would be compared to EPO's. Dr. Yu and Employee B, along with a few other FibroGen employees, reviewed and signed both plans before they were submitted to the FDA.

54. The August 2018 statistical analysis plan ("August 2018 SAP") stated that the primary analysis was to "assess the cardiovascular safety of roxadustat relative to [a] placebo using pooled data from the Phase 3 program." It also explained that to achieve statistically significant results for that analysis, it was necessary to "pool" the data from the three Phase III roxadustat studies of participants who had CKD but were not dialysis dependent. It added that FibroGen would also conduct certain "[s]upportive analyses" on various patient subgroups to enhance the "range of evidence" regarding roxadustat safety. ("Supportive analyses" are analyses done to support the validity of the primary analysis and conclusion.)

55. The August 2018 SAP also defined the MACE endpoints used to assess roxadustat's cardiovascular safety and set forth how they would be determined. Crucially, in the section titled "statistical analysis," FibroGen "emphasize[d] the pre-specified nature of the key safety analyses and other supportive safety analyses" for non-dialysis dependent participants. The precise nature of the statistical analyses was unambiguous: to assess roxadustat's cardiovascular safety, as defined by MACE and MACE+, for the "primary analytic methods," FibroGen would "us[e] the study-specific stratification factors" referenced in paragraph 51 above.

56. The September 2018 statistical analysis plan ("September 2018 SAP") similarly explained that, for the four studies with dialysis-dependent participants, the "primary objective of the pooled analyses is to assess the CV [cardiovascular] safety of roxadustat relative to EPO[], as measured by the key analyses of composite endpoints of adjudicated . . . MACE and MACE+ using pooled data from the Phase 3 trials[.]" Like the August 2018 SAP, it noted that "supportive analyses across several secondary endpoints" would also be performed. The September 2018 SAP also noted that it "will be used to emphasize the pre-specified nature of the key safety analyses and other safety analyses in DD-CKD [dialysis-dependent chronic kidney disease]."

57. In the section titled "Statistical Analyses of the Key Safety Endpoints," the September 2018 SAP described the same "primary analytic method" as the August 2018 SAP – specifically, that FibroGen would "us[e] the study-specific stratification factors" referenced in paragraph 52 above. The purpose of the September 2018 analytical "framework" was to "determine whether there is an acceptable rate of [cardiovascular] events to support" the conclusion that roxadustat was safer than EPO.

58. In sum, consistent with (1) industry guidelines, (2) FibroGen policies, and (3) the agreement between FibroGen and its roxadustat partners, FibroGen pre-specified the statistical analyses it would use to determine the Phase III study's primary cardiovascular safety endpoints – i.e., how roxadustat compares to the placebo and EPO in terms of cardiovascular impact. It emphasized that the statistical calculations for the primary analyses would use the study-specific stratification factors, the precise nature of which had long since been determined. And, although Dr. Yu approved an addendum to the August 2018 SAP on April 11, 2019, that addendum changed nothing about the planned use of the stratification factors.

V. FibroGen and Dr. Yu Learned the Initial Study Results and Undertook an Effort to Make the Results Appear Better.

59. On April 12, 2019, the cardiovascular safety data from the seven studies was unblinded. Two days later, a third-party contractor ("Contractor I") provided FibroGen, including Dr. Yu, with the initial statistical results. Contractor I's calculations were based on the

study-specific stratification factors, as pre-specified in the August and September 2018 SAP's.

60. The original results showed the following, as disclosed some two years later in FibroGen's April 6, 2021 press release and corrective disclosure (discussed at greater length below):

	Hazard Ratio (95% Confidence Interval)
Non-Dialysis Dependent	
MACE	1.10 (0.96, 1.27)
MACE+	1.07 (0.94, 1.21)
ACM	1.08 (0.93, 1.26)
Dialysis Dependent	
MACE	1.02 (0.88, 1.20)
MACE+	0.91 (0.80, 1.05)
ACM	1.02 (0.84, 1.23)
Incident Dialysis (subset population of Dialysis Dependent)	
MACE	0.82 (0.60, 1.11)
MACE+	0.78 (0.59, 1.02)
ACM	0.82 (0.57, 1.18)

61. These results depict the hazard ratio and, in parentheses, confidence intervals for various MACE endpoints in the Phase III study's primary cardiovascular safety analysis. While some of the hazard ratios depicted were below 1.0 (e.g. statistically safer the EPO or placebo), the upper bound of the confidence interval was, in all cases, above 1.0. Therefore, from a statistical perspective, they do not support the conclusion that roxadustat is safer than EPO or the placebo for the primary analysis endpoints. As FibroGen later admitted in

its April 6, 2021 corrective press release, "[w]hile these hazard ratios remain below 1.0, based on these analyses we cannot conclude that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis, compared to [EPO]."

62. Between May 1 and 3, 2019, FibroGen shared the original results separately with Pharma Co. A and Pharma Co. B. Dr. Yu and other FibroGen personnel met with Pharma Co. B on or around May 1-2, 2019 and Pharma Co. A on or around May 3, 2019. One of Pharma Co. A's representatives summarized their meeting in a May 4, 2019 internal email. He recounted that, at the meeting, Dr. Yu "spent close to two hours reviewing the history of the [roxadustat] program" and that she argued FibroGen and Pharma Co. A "should adopt the statistical method that gives the best 'win' profile for [roxadustat]."

63. Dr. Yu and other FibroGen representatives sought Pharma Co. A's consent to certain claims it wanted to make in a press release to be issued shortly after the meeting. These included claims that roxadustat was non-inferior to the placebo for non-dialysis dependent patients and superior to EPO for MACE+ for incident dialysis patients. Pharma Co. A declined to consent to these claims "simply based on a cursory rapid presentation of the data."

64. FibroGen made the claims anyway. After trading closed on May 9, 2019, FibroGen issued a press release "Announc[ing] Positive Topline Results from Pooled Safety Analyses of Roxadustat Global Phase 3 Program." The press release mostly portrayed roxadustat as having a roughly equal cardiovascular safety profile to EPO and the placebo. FibroGen also claimed that, for one "subpopulation" of incident dialysis patients, roxadustat was superior to EPO "in the time to first MACE+." Unlike Dr. Yu's and FibroGen's later disclosures, this press release did not disclose any actual or purported data. (As shown, however, in FibroGen's April 2021 corrective disclosure, set forth in paragraphs 60-61above, the data from the prespecified analysis did not support even that modest claim.) The press release also claimed that FibroGen "will continue to discuss the specific statistical standards with the FDA."

65. The press release had a negative impact on FibroGen's stock price. On May 10, 2019, FibroGen's stock price closed down over 20 percent on massive volume. Equity analysts noted the lack of FDA approval for FibroGen's statistical plan as one of the factors

causing the market's unfavorable response. Roxadustat was FibroGen's only product; the negative consequences of mediocre Phase III cardiovascular safety results and lack of FDA approval were potentially substantial.

66. Dr. Yu sought to change the narrative. In a May 17, 2019 email summarizing a conversation with FibroGen, a Pharma Co. A employee said: "As expected FGN [FibroGen] was in shock after the decrease in stock price . . . The result is that key members for interpretation of the data (Peony [Yu], Ming [Employee A], [Employee B]) are now focusing on a better story instead of going through all the integrated tables that [Contractor I] has delivered[.]"

67. Accordingly, at Dr. Yu's direction, FibroGen decided to recalculate the primary outcome of the Phase III cardiovascular safety studies. The explicit purpose of this and other post-hoc changes was, as Employee A would later put it in an October 11, 2019 email to Pharma Co. A, copying Dr. Yu and Employee B, "to present the most compelling story that is told by the vast amount of data[.]" In her testimony before SEC staff, Employee A confirmed that FibroGen "tr[ied] to come up with a good story, [a] convincing story to tell[.]"

68. At Dr. Yu's direction, FibroGen wrote that story largely by changing the stratification factors in the statistical analyses. The recalculation of the primary outcome amounted to a massive trial-and-error project. Disregarding the August and September 2018 SAP's claim that FibroGen would use the "study-specific stratification factors," Dr. Yu directed Employee A to try different combinations of stratification factors until finding one that gave them the results they wanted. Employee A turned to multiple outside firms for assistance. For example, on May 6, 2019, Employee A emailed Contractor I to inform it that "We have decided to use the following model" with additional stratification factors, including "Black or African American." Employee A then instructed Contractor I to "re-run" its own calculations using the new stratification factors "as the source data for the press release." Contractor I's primary contact with FibroGen believed that these calculations were only to be used for an exploratory analysis, and later opined that it would be inappropriate to use the revised stratification factors for the primary analysis.

69. During May and early June 2019, Dr. Yu also employed a second third-party contractor ("Contractor II") based in China to run and validate additional calculations. Employee A's instructions to Contractor II resembled those to Contractor I. For example, on May 17, 2019, Employee A instructed Contractor II in an email to use a new "variable in the model and check if it makes any difference." This was a trial-and-error search for a better result. As Employee A put it in that email, "[w]e need to explore first before making any change." Employee A herself described the collective effort as: "So we look at this angle, we look at that angle, we adjust for this confounding factor and that confounding factor." She explained further that it was "a huge amount of data. . . . That's why we could cut into so many different ways."

70. In sum, between May and early June 2019, at Dr. Yu's direction, Employee A and two third-party contractors performed statistical analyses to try to determine which combination of stratification factors would make roxadustat appear to have a cardiovascular safety profile superior to EPO and, for non-dialysis dependent patients, at least comparable to a placebo.

71. Dr. Yu led this project. At one FibroGen staff meeting, she told staff to run countless analyses until they found the combination of stratification factors that worked. FibroGen's senior biostatistician at the time also overheard Dr. Yu state that FibroGen was "torturing the data until it complies," and that the goal was to cast roxadustat in the best possible light. Most critically, Dr. Yu told the biostatistician that FibroGen's goal was to achieve a hazard ratio less than one – the threshold for claiming that roxadustat is safer than EPO and the placebo.

72. Dr. Yu knew that in recalculating the primary outcomes for the Phase III cardiovascular safety studies, she was disregarding the August and September 2018 SAP's. Dr. Yu had been heavily involved in writing and finalizing those SAP's, both of which she signed.

73. FibroGen, at Dr. Yu's direction, eventually found a combination of stratification factors that achieved their desired result. For the studies with non-dialysis dependent participants, the stratification factors were modified as follows:

Original Factor:	Different?:
Baseline hemoglobin value of less than 8 or greater than or equal to 8	Yes. Participants with a hemoglobin value equal to 8 were now in a different group.
History of cardiovascular disease	No.
Geographic Region, Europe versus others	Yes. Had previously been U.S. versus others for two studies and Western Europe others for a third.
Baseline kidney filtration rate	Yes. Less than 10 units versus greater than or equal to 10 units, a substantially lower dividing line than original factor of 30 units.

74. For the dialysis-dependent studies, in which roxadustat would be compared to EPO, the changes were as follows:

Original Factor:	Different?:
Baseline hemoglobin values	No.
History of cardiovascular disease	No.
Gender	Yes. Completely new.
Body Mass Index	Yes. Completely new.
Race ("black vs. non-black")	Yes. Completely new.
Incident versus stable dialysis	Yes. No longer a factor.
EPO dose	Yes. No longer a factor.
Geographic Region, Europe vs. non-Europe	Yes. It was prespecified as US vs non-US.

75. On June 26, 2019, Dr. Yu emailed Pharma Co. A a draft of its submission for FibroGen's pre-NDA meeting with the FDA, scheduled for July 30, 2019. In her cover email, Dr. Yu informed Pharma Co. A that it intended to send the submission to the FDA just two days later, on June 28, 2019. The draft pre-NDA submission contained the following table ("py" = patient years):

Table xa: Summary of MACE, MACE+ and All-cause Mortality (OT-7*) in DD Studies (002, 063, 064)

	All DD Patients N=3880		**ID-DD Patients N=1526**	
	Roxadustat (n=1940)	EPO (n=1940)	Roxadustat (n=760)	EPO (n=766)
Total PY**	3315.3	3743.6	1098.2	1189.5
Mean PY	1.7	1.9	1.4	1.6
# pts with MACE events	303	339	74	97
# pts with MACE per 100 PY	9.1	9.1	6.7	8.2
HR* (95% CI) of MACE**	**0.95 (0.81, 1.12)**		**0.70 (0.51, 0.97)** ***P= 0.0301***	
# pts with MACE+ events	369	458	88	121
# pts with MACE+ per 100 PY	11.1	12.2	8.0	10.2
HR* (95% CI) of MACE+**	**0.84 (0.73, 0.97)** ***P=0.018***		**0.66 (0.50, 0.88)** ***P= 0.0054***	
Number of **deaths**	206	232	52	70
Deaths per 100 PY	6.2	6.2	4.7	5.9
HR*(95% CI) of deaths**	**0.96 (0.79, 1.16)**		**0.76 (0.52, 1.11)**	

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The table purports to show that for three of the bolded endpoints in the dialysis-dependent studies (including the subgroup for incident dialysis patients), the hazard ratios and the upper bound of the confidence interval are below 1. In other words, Dr. Yu intended to tell the FDA that in numerous respects roxadustat had a superior safety profile to EPO.

76. This claim – and the numbers that support it – contrasted sharply with the information FibroGen had provided Pharma Co. A and Pharma Co. B between May 1 and May 3, 2019. Pharma Co. A promptly responded to Dr. Yu that, because the draft "includes a wide range of analyses we have not seen yet," Pharma Co. A cannot meet Dr. Yu's requested deadline. Pharma Co. A's lead biostatistician on the roxadustat project then circulated internally a "side-by-side comparison . . . of what we just received vs what we saw in early May." As seen below, the Pharma Co. A chart showed that the numbers had all improved. (Pharma Co. A identified in red the numbers that improved.)

	Revised Numbers				**Original Numbers**			
	All DD Patients		**All ID-DD Patients**		**All DD Patients**		**All ID-DD Patients**	
	Roxadustat (n=1940)	EPO (n=1940)	Roxadustat (n=760)	EPO (n=766)	Roxadustat (n=1940)	EPO (n=1940)	Roxadustat (n=760)	EPO (n=766)
Total PY**	3315.3	3743.6	1098.2	1189.5				
Mean PY	1.7	1.9	1.4	1.6				
Number of MACE events	303	339	74	97	306	339	74	97
MACE Events per 100 PY	9.1	9.1	6.7	8.2				
HR (95% CI) of MACE	0.95 (0.81, 1.12)		0.70 (0.51, 0.97)		1.01 (0.86, 1.18)		0.79 (0.58, 1.08)	
Number of MACE+ events	369	458	88	121	373	458	88	121
MACE+ Events per 100 PY	11.1	12.2	8	10.2				
HR (95% CI) of MACE+	0.84 (0.73, 0.97)		0.66 (0.50, 0.89)		0.90 (0.78, 1.03)		0.74 (0.56, 0.98)	
Number of deaths	206	232	52	70	207	232	52	70
Deaths per 100 PY	6.2	6.2	4.7	5.9				
HR (95% CI) of deaths	0.96 (0.79, 1.16)		0.76 (0.52, 1.11)		1.00 (0.83, 1.21)		0.81 (0.56, 1.17)	

77. Dr. Yu made similar claims to Pharma Co. B. On June 19, 2019, Dr. Yu presented FibroGen's revised results to Pharma Co. B. With regard to dialysis-dependent patients and the sub-group for "incident dialysis" patients, the slide deck included assertions such as "Roxadustat Beats EPO In Efficacy & Safety" and "Potential for Taking Over EPO Market."

78. The slide deck also contained claims about roxadustat's safety profile relative to the placebo for the non-dialysis dependent patients. As with the dialysis-dependent numbers, the numbers showed statistical improvement. Although the revised numbers did not show that roxadustat was superior to the placebo for non-dialysis dependent patients, the improvement was, from Dr. Yu's perspective, still meaningful. That is because for a drug to be deemed "non-inferior," the upper bound to the confidence interval must be below a certain threshold. Here, before viewing the study results, Dr. Yu and FibroGen had initially proposed that the upper bound be 1.3, but the FDA had rejected that as too high. Dr. Yu was concerned the FDA would set the upper bound "between 1.2 and 1.3." When Dr. Yu viewed the initial results for the non-dialysis dependent patients, the upper bounds for two of the three endpoints were above 1.25. Accordingly, there was a risk that roxadustat would be deemed inferior. Accordingly, the revised numbers that Dr. Yu reverse-engineered all fell below 1.25.

79. In sum, by re-stratifying the Phase III study participants in its pooled statistical analyses for cardiovascular safety *after reviewing the study data*, FibroGen had, at Dr.

Yu's direction, made roxadustat look like a safer drug. Although the undisclosed post-hoc revisions to the stratification factors violated well-established industry and regulatory standards, Dr. Yu proceeded.

VI. Pharma Co. A and Pharma Co. B Questioned Dr. Yu's Approach Before FibroGen's July 30, 2019 Pre-NDA Meeting with the FDA.

80. After reviewing a draft of the pre-NDA meeting briefing materials sent to them, Pharma Co. B worried that FibroGen would neither clearly disclose its use of various post-hoc changes to the analyses set forth in the SAP's – nor the original results. In a June 20, 2019 internal email, a senior Pharma Co. B employee said that though the "situation may be atypical," it was, at a minimum, important for Dr. Yu and her team to be "transparent about the evolution of our thinking with regard to data analysis." Accordingly, they would need to "acknowledge the SAP . . . contents, [and] present data in line with those reference documents."

81. For its part, after reviewing the revised results in FibroGen's June 26, 2019 draft FDA pre-NDA submission, Pharma Co. A questioned the basis for the changes. In a July 23, 2019 slide deck Pharma Co. A prepared for its monthly meeting with FibroGen and Pharma Co. B, Pharma Co. A explained that it had responsibility "for ensuring data quality and integrity" in its upcoming submission to European Union regulators, seeking approval for roxadustat. (Pharma Co. A would ultimately not use FibroGen's post-hoc approach and would instead use the pre-specified protocols in its May 2020 submission to European regulators.) Accordingly, it needed "further insight" into the "[d]ifferences and changes in results" that Dr. Yu provided. Pharma Co. A then specified how virtually every hazard ratio had improved, many of them "quite substantially," between the May 3rd summary and FibroGen's June 26 draft submission.

82. Biostatisticians at Pharma Co. A and Pharma Co. B were deeply skeptical about this uniform improvement. Had FibroGen, at Dr. Yu's direction, selected new stratification factors based on clinical or analytical necessity, the biostatisticians would have expected to see variation in results. Instead, the across-the-board improvements revealed that FibroGen had selected the new stratification factors – and rejected others that may have clinical relevance – because that combination of stratification factors made all the numbers look better.

FibroGen also did not offer any explanation for why, if the new factors were relevant, they were not included in the original study protocols or SAP's.

83. In fact, a later Pharma Co. B analysis, conducted in March 2021, found that the stratification factors FibroGen used were "post-hoc, data-driven, best-case." As a result, the "final model is not possible to defend." In particular, Pharma Co. B concluded that there were too many stratification factors, leaving some strata with dozens of participants and others with zero. Moreover, several of the factors were not "informative regarding the risk for MACE." Pharma Co. B emphasized that the "model is very unstable," meaning that it lacked statistical "robustness" , i.e. the ability of a statistical model to produce consistent results under varying underlying assumptions. Here, FibroGen's model was largely driven by a specific set of reverse-engineered assumptions.

84. Pharma Co. A followed up on July 29, 2019, the day before FibroGen's meeting with the FDA. Its lead biostatistician sent a list of questions and requests to Employee A, including: "it would be great if you could provide the reason(s) for the difference in the stratification factors in the production model vs those in you[r] SAP for the [dialysis-dependent] pool." More generally, he asked if FibroGen could "provide additional insight if there were other factors that contributed to the changes in the analysis results?"

VII. Dr. Yu and FibroGen Misled the FDA at the July 2019 Pre-NDA Meeting.

85. FibroGen sent its pre-NDA submission to the FDA on June 30, 2019. Among other things, it included the chart, set forth in paragraph 75 above, purporting to show that roxadustat was in many respects safer than EPO. However, in presenting these results, Dr. Yu omitted several key pieces of information, including: 1) the original stratification factors; 2) the results of the analyses when FibroGen applied those stratification factors; 3) the fact that FibroGen, at Dr. Yu's direction, had replaced the original stratification factors after conducting countless analyses to find the most favorable combination; and 4) FibroGen's use of these post-hoc analyses to support its primary conclusions.

86. FibroGen continued to present a misleading picture at the July 30, 2019 pre-NDA meeting with the FDA. Dr. Yu led FibroGen's delegation. During the meeting, although

FibroGen did disclose certain post-hoc changes, such as eliminating one study from the pooled results, no one from FibroGen raised the issue of post-hoc changes to the stratification factors, and it was never discussed.

87. Importantly, the FDA emphasized during the meeting that post-hoc analyses could not be used for the primary conclusions. Regarding FibroGen's request to change the definition of a safety endpoint for its primary analyses, the FDA responded: "No. The Agency does not agree . . . Because you are already aware of the data, [the proposed change] should be considered a post-hoc analysis."

88. In sum, FibroGen disclosed certain of its post-hoc changes but did not disclose: 1) that the stratification factors it used differed from the pre-specified factors; 2) that the new factors had been selected after the data was unblinded; 3) the results using the original stratification factors; or 4) how and why FibroGen selected the new factors. Despite the lack of disclosure in FibroGen's written and oral presentations to the FDA, and despite the FDA's clear admonition that post-hoc analyses cannot be used for primary conclusions, Dr. Yu and. Employee A nonetheless chose to deem the FDA meeting as an implied acquiescence to FibroGen's post-hoc changes to the stratification factors. Following the pre-NDA meeting, Dr. Yu and her team began to prepare multiple, detailed public disclosures.

VIII. Dr. Yu Repeatedly Disregarded Pharma Co. A's and Pharma Co. B's Concerns While Preparing to Present FibroGen's Findings to Researchers and Investors.

89. Between August and October 2019, Dr. Yu led FibroGen's drafting of the abstracts, presentations, and NDA submission that would detail roxadustat's relative cardiovascular safety. FibroGen circulated various drafts of these documents to Pharma Co. A and Pharma Co. B. In response, Pharma Co. A repeatedly urged FibroGen to disclose that the results were based on post-hoc changes to the stratification factors. Dr. Yu and FibroGen declined.

90. In an August 9, 2019 email, Pharma Co. A's lead biostatistician asked Employee A for "change log(s) with regard to any changes in the datasets and models along with

the reasons thereof" – a standard document for a clinical sponsor to maintain, one that is typically signed by the senior medical officer and statistician. Pharma Co. A repeated the request in an August 28, 2019, follow up email from the lead biostatistician to Employee A. In the follow-up, he detailed Pharma Co. A's request and emphasized that "[w]e assume such changes are documented."

91. They were not. Dr. Yu and FibroGen maintained no coherent record of the changes they made, the results of any intermediate analyses, or the rationale for using certain stratification factors while discarding others. Employee A, on behalf of FibroGen, could offer only an "informal spreadsheet showing some iterations from SAP models to the final models." A few days later, Employee A elaborated in an email to the Pharma Co. A biostatistician: "We did not have a formal signed and dated document for the change in covariates. The excel file was all we had. I wish I did have such document before unblinding."

A. *The November 2019 American Society of Nephrologists Conference*

92. Between August and early November 2019, FibroGen, led by Dr. Yu, undertook substantial efforts to prepare for a November 8, 2019, conference held by the American Society of Nephrologists ("ASN Conference"). Dr. Yu intended to use the conference as a platform to highlight roxadustat's safety profile, including its purported superiority to EPO for dialysis-dependent patients. Dr. Yu planned to file two abstracts on behalf of FibroGen ahead of the ASN Conference and then to have FibroGen make a presentation at the conference. (An abstract is a concise summary of a drug study's key finding and methods.) The abstracts, which the ASN Conference required from presenters, were due September 4, 2019.

93. On August 26, 2019, Employee B emailed drafts of the roxadustat abstracts – one for the non-dialysis dependent and one for the dialysis-dependent analyses – to Pharma Co. A's and Pharma Co. B's lead representatives. She emphasized that she had spoken with Dr. Yu and that the abstracts "are a little different from other abstracts given how very, very important that they are."

94. Later the same day, Pharma Co. A's lead representative emailed its comments to Employee B, Dr. Yu, and Pharma Co. B's representatives. Pharma Co. A focused

on FibroGen's calculated hazard ratios, presented in support of its claims about roxadustat's superior – or at least non-inferior – safety profile. These comments included, for example: "This is a post-hoc analysis and should be presented as such"; "It should be acknowledged that this conclusion is only true using a post-hoc analysis"; and "*My understanding is that these results were generated from a model that included different stratification factors and covariates from the [September 2018 SAP]. If so, this modification should be acknowledged*." (emphasis added).

95. Similarly, in a September 4, 2019 email to Employee B, Pharma Co. A's lead representative stated his concerns with FibroGen's use and inadequate disclosure of its use of post-hoc analyses (not limited to the revised stratification factors). He also insisted that his name be removed as an author on the abstracts if FibroGen did not address his "MAJOR" comments (emphasis in original). Employee B twice forwarded this email only to Dr. Yu, the first time simply asking her: "I guess we need to remove his name?"

96. Dr. Yu monitored the abstracts closely. She spoke with Employee B every day to run through a list of issues to be addressed, and she provided guidance on points to emphasize. Indeed, Dr. Yu and Employee B limited most correspondence concerning the abstract to the two of them at FibroGen and a limited number of Pharma Co. A and Pharma Co. B representatives. Dr. Yu was also a meticulous and thorough editor. Employee B – who had the day-to-day role to draft and shepherd the abstracts – ensured that Dr. Yu reviewed any "major" comments from Pharma Co. A and Pharma Co. B. For example, the second time Employee B forwarded Pharma Co. A's September 4, 2019 email to Dr. Yu, she provided Dr. Yu additional context and emphasized that "I wanted to make sure that you were informed."

97. Despite Pharma Co. A's concerns, Dr. Yu did not revise the abstracts to disclose that their main conclusions were based on post-hoc analyses using revised stratification factors. Nor did she revise them to include the original results of the primary analyses, nor an explanation of how FibroGen selected the revised factors. Dr. Yu submitted the abstracts, containing the same claims about roxadustat's purported superiority, to conference organizers on September 4, 2019. No one from Pharma Co. A was listed as a co-author – though Dr. Yu was.

98. As the ASN Conference approached, Dr. Yu's team also prepared a slide

deck for a presentation of the pooled analyses. The presentation amounted to FibroGen's first public disclosure of roxadustat's purported cardiovascular safety results for the Phase III studies, and it had significant professional and personal meaning to Dr. Yu, as it concluded ten years of work. Because of this, according to Employee B, "Peony [Yu] took a more major role in preparing this presentation" and "played an instrumental role in developing the presentation" and directly coordinating with Pharma Co. A and Pharma Co. B. As with the abstracts, Dr. Yu limited drafting of the presentation to herself and Employee B at FibroGen and the senior representatives from Pharma Co. A and Pharma Co. B.

99. In October 2019, concerns continued to grow at Pharma Co. A that FibroGen's data analysis was unreliable. In an internal October 18, 2019 email, Pharma Co. A personnel considered whether to caution its roxadustat team to be skeptical of FibroGen data until Pharma Co. A can evaluate the data itself. The draft language they considered circulating to the team emphasized that if "we do decide to reference [FibroGen's] info, it is critically important to provide clear and objective caveats, e.g., post-hoc v. pre-specified, superiority v. non-inferiority, etc."

100. On October 28, 2019, Employee B emailed a draft conference presentation to Pharma Co. A and Pharma Co. B. Dr. Yu was the only person at FibroGen copied on the email. The draft slides included claims that patients on roxadustat "had lower . . . risk of MACE+ than [patients on EPO]," with corresponding data purporting to support that claim. It also said that for a "clinically important" subgroup, roxadustat "has 30% lower risk of MACE & 34% lower risk of MACE+ . . . relative to EPO." The draft slides did not disclose that these figures were based on post-hoc analyses using revised stratification factors; nor did they disclose the original results, which indicated that roxadustat had roughly equal cardiovascular risk to existing treatments or the placebo.

101. Dr. Yu directly oversaw the preparation of the slides and was the senior executive at FibroGen responsible for their content. She was directly involved in crafting the slides, ultimately approved the content of these slides at times over the objection of FibroGen's partners, and authorized their eventual inclusion in the ASN Conference presentation. As such,

she had ultimate authority over their content. She knew that the slides reflected post-hoc analyses using revised stratification factors.

102. Dr. Yu's communications with Pharma Co. B reflected her control. For example, on November 3, 2019, Dr. Yu sent an email to Pharma Co. B attaching a draft presentation. In the email, she noted that "to preserve the content and the flow, I needed to move things around." On November 7, 2019, the day before the presentation, she emailed Pharma Co. B to tell them she "had to spend hours fixing the changes from the last version . . ." These changes "included addressing questions [and] comments from [the conference], presenter, and others."

103. Pharma Co. A had provided comments to Dr. Yu and Employee B on October 30, 2019, insisting that the slides presenting the cardiovascular safety analyses "[s]hould also present pre-specified analyses (different approaches for NDD [non-dialysis dependent] and different stratification factors for DD)." These comments reiterated Pharma Co. A's long-running concerns. Neither Employee B nor Dr. Yu circulated another draft to Pharma Co. A before the November 8, 2019 ASN Conference presentation.

104. In addition to Pharma Co. A, Pharma Co. B expressed concerns about the content of the presentation. On November 2, 2019, Dr. Yu and Pharma Co. B's lead representative on the roxadustat project had an email exchange with the subject heading: "Pre-specified." Pharma Co. B's representative emphasized that the "main issue is the pre-specified randomization stratification factors and the change in covariates over time. We need to provide a good explanation of the evolution of the HR [hazard ratio] with consequent LB [lower bound] and UB [upper bound]."

105. Similar communications continued right up to the conference. On November 7, 2019, the roxadustat team – consisting of presenters and representatives from the pharmaceutical partners, including Employee B – called Dr. Yu (who was convalescing from a medical procedure and could not attend in person) to resolve a heated dispute. The issue was whether FibroGen's misleading claim that roxadustat was safer than EPO should be included even in a separate, ancillary conference presentation. The team viewed Dr. Yu as the ultimate

decider on this issue. Although she ultimately agreed not to include the claims in the ancillary presentation, Dr. Yu continued to feature the superiority claims in the primary presentation, as discussed below.

106. At around the same time, Pharma Co. B objected to FibroGen's intent to claim that the post-hoc results had true statistical significance by including a p-value. Dr. Yu vocally disagreed and ultimately overrode Pharma Co. B's objection. These and other debates continued until minutes before the presentation. Importantly, despite this ongoing dialogue, Dr. Yu never informed the primary outside presenters about the original results and post-hoc use of revised stratification factors.

107. FibroGen presented from the stage at the November 8, 2019 ASN Conference. Dr. Yu is listed on the first slide of the presentation as a co-author. The presentation did not disclose that FibroGen's claims about roxadustat as compared to EPO and a placebo were based on the post-hoc use of revised stratification factors. Nor did it disclose Dr. Yu's reverse-engineering of the results or that FibroGen's analyses could be considered, at most, exploratory.

108. Instead, the primary presentation emphasized, as in the draft slides described above, that roxadustat was at least as safe as a placebo for non-dialysis dependent patients, and materially (and statistically) safer than EPO for certain endpoints and patient groups. The slides presented graphics purporting to show that for certain featured groups and endpoints, the upper bound of the confidence interval was below 1. Accordingly, the slides claimed that "[r]oxadustat patients had a lower risk of MACE+ than [EPO] patients." They also claimed that for the incident dialysis group, "[r]oxadustat had 30% lower risk of MACE and 34% lower risk of MACE+ than [EPO] . . ." In an email the next day to outside affiliates that assisted in the Phase III study, Dr. Yu highlighted the key slides: "The crowd [at the ASN Conference] was somewhat in awe when the 4 CV safety slides were shown. . . . It was all followed by extended applause."

B. *The November 8, 2019 Press Release and 8-K*

109. FibroGen issued a press release and filed an 8-K the same day as the ASN presentation. Both quoted Dr. Yu saying: "The positive . . . cardiovascular safety results from

these pooled analyses . . . reaffirm the potential of roxadustat to improve treatment for anemia in CKD patients. There has not been much progress in treatment approaches for anemia in over 30 years, and more effective, safe, and convenient treatment options for patients are long overdue. We are privileged to be advancing this effort with roxadustat . . .”

110. Dr. Yu and Employee A were also the source of the statistical content in the press release and 8-K that purported to support these claims. Dr. Yu admitted she or someone on her clinical team was the “content provider” for public statements about clinical data. Dr. Yu’s role on FibroGen’s Disclosure Committee and position as FibroGen’s Chief Medical Officer and most senior clinical expert meant that FibroGen would not make a public statement about clinical results without Dr. Yu’s input and approval. Employee B confirmed that she “never let a publication out the door” without Dr. Yu’s authorization.

111. The press release and 8-K reiterated results from the pooled abstract and ASN Conference presentation that Dr. Yu had crafted and overseen, asserting that for dialysis-dependent patients generally, roxadustat had a 14% less risk of MACE+. It specified that for the incident-dialysis subgroup of dialysis-dependent patients, roxadustat caused 30-34% fewer adverse cardiovascular events than EPO. (The original results showed, at best, comparable safety.) The press release and 8-K also included the same charts with hazard ratios purporting to support these claims. And, consistent with Dr. Yu’s goal to cast roxadustat in the most favorable light, the press release asserted that incident dialysis patients – the group for which roxadustat is supposedly far safer than EPO – was the “appropriate setting for comparison of roxadustat versus [EPO.]”

112. In sum, between June and early November 2019, Dr. Yu was questioned by both Pharma Co. A and Pharma Co. B about the adequacy of FibroGen’s disclosures and the importance of disclosing that roxadustat’s positive results were based on post-hoc analyses. Nonetheless, in their pre-NDA meeting with the FDA, in two abstracts, in their presentations to the ASN Conference, and in their November 8, 2019 press release and 8-K, Dr. Yu and FibroGen repeatedly claimed that roxadustat was at least as safe as a placebo and, in many respects, much safer than EPO, without disclosing: 1) that these claims were based on post-hoc analyses using

revised stratification factors; 2) that the initial analyses, which were actually based on the SAPs and the pre-specified stratification factors, did not support many of these claims; and 3) that Dr. Yu had led a more than month-long effort to reverse-engineer a better result.

113. Investors were impressed by FibroGen's presentation and press release. FibroGen's stock jumped over 32% in intraday trading following the presentation on November 8, 2019, before closing up approximately 10% over its previous day's closing price on extremely high volume. Analyst reports were positive, with multiple analysts predicting that, in light of roxadustat's purported non-inferiority to the placebo and superiority to EPO, it would receive FDA approval.

114. Notably, the analyst reports focused at length on the specific hazard ratios and confidence intervals that FibroGen disclosed. For example, one report began a paragraph with: "We noted that we wanted to see a MACE HR [Hazard Ratio] of ≤ 1.1 (with an upper . . . bound CI ≤ 1.3) . . . Roxa delivered with an HR of 1.08 . . . (0.94, 1.24)[.]" The positive market reaction helped FibroGen set the stage for more payments under its contracts with Pharma Co. A and Pharma Co. B and for anticipated FDA approval.

C. *The November 11, 2019 Analyst Call*

115. FibroGen followed up the ASN Conference presentation and press release with an investor and analyst call on November 11, 2019, the Monday following its Friday presentation and 8-K. Dr. Yu represented FibroGen on the call, during which she described the purported results and answered analysts' questions. Dr. Yu often prepared her scripts for investor calls at the last minute.

116. Her headline claims during the November 11, 2019 call were that roxadustat's cardiovascular safety was comparable to a placebo for non-dialysis patients and 14% better than EPO for dialysis patients, including 30% to 34% better for a key subgroup. She repeated these claims in her initial presentation, using them as the basis for an argument about roxadustat's medical and commercial appeal. For example, Dr. Yu told listeners that the "results suggest potential long-term safety benefits in selecting roxadustat when initiating anemia therapy in dialysis patients." She also emphasized that with "a 30% reduction in MACE risk and a 34%

reduction in MACE+ risk compared with [EPO] in incident dialysis patients, we believe roxadustat could be viewed as a safer option for patients initiating chronic dialysis . . .” Dr. Yu did not disclose that post-hoc analyses using revised stratification factors generated the results she repeatedly touted. Nor did she disclose the original results based on the pre-specified stratification factors, or her efforts to improve thereon.

117. These were not her only misleading statements on the call. The first question posed by an industry analyst focused on the pre-NDA meeting with the FDA: “I would just like to understand, since there seems to be some investor concern about FDA agreements and FDA sign-off from statistical plans, how your general impression was of your meeting with the FDA? And why you feel confident about statistical protocols and their signing off of what you have . . .?” Dr. Yu replied: “we’ve also had a very productive dialogue with the FDA on the analysis of cardiovascular safety . . . And the most recent conversation with the FDA was at the end of July. And we had sent it to the FDA, a fairly comprehensive briefing package and had a very productive meeting. And walking out of it, we felt that we had all the guidance from the FDA we needed to put together a winning submission.”

118. Dr. Yu’s response was misleading. As described above, the June 30, 2019 pre-NDA “package” FibroGen submitted to the FDA – a submission crafted by Dr. Yu and her team – was not, in fact, “comprehensive.” Despite warnings from Pharma Co. A and Pharma Co. B, Dr. Yu omitted essential information from FibroGen’s submission and in the statements at the subsequent pre-NDA meeting. FibroGen did not disclose that its primary conclusions were based on post-hoc analyses using revised stratification factors. Nor did FibroGen share the initial analyses using the prespecified stratification factors or mention that Dr. Yu directed an intensive effort to re-stratify the data in pursuit of better results.

119. Dr. Yu gave other false and misleading responses to further analyst questions. After Dr. Yu’s initial answer, the analyst followed up: “So you feel no issue or no real concern about the hazard ratios and the upper bounds and all the things that people are talking about?” Dr. Yu responded: “No, we have no concerns about that. . . . And so based on our discussions and the historical precedents in this therapeutic area and the various conversations we’ve had

with the agency, we are very comfortable with our data where it is now."

120. Later in the call, another analyst asked a more specific question: "My second question is when are you going to talk about . . . the statistical analysis plan, including the non-inferiority margin. Is there any pre-planned FDA meeting in the coming weeks?" Dr. Yu answered: "So the answer to that question is that we had already talked with the FDA about analytical plan, and we had made the agreement on the analysis plan. The results that we have presented in the high-impact clinical session at the ASN [Conference], and the numbers I had just presented were based on the agreed analysis plan that we have made with the FDA."

121. Dr. Yu's response was false. The numbers she presented on the call were not based on an FDA-approved statistical analysis plan. In fact, the opposite was true: the FDA was not informed, and did not consent, to FibroGen's post-hoc use of revised stratification factors to re-calculate the study results. The numbers Dr. Yu presented on the call were not the product of an FDA-"agreed analysis plan."

IX. Dr. Yu Submitted FibroGen's NDA to the FDA and Continued to Make Misleading Public Statements.

A. *Statements to the FDA*

122. Dr. Yu submitted FibroGen's roxadustat NDA to the FDA on December 20, 2019. The Cardiovascular Safety Endpoint Report ("CV Safety Report"), which was just one component of the NDA submission, alone extended to over 2,100 pages and was not public. Prior to the submission of the CV Safety Report, on October 21, 2019, Pharma Co. B provided comments on a draft. In those comments – provided to Dr. Yu – Pharma Co. B insisted that there must be "absolute transparency of the pre-specified analyses. . . . Regarding why stratification factors were changed and whether they were made pre- or post- unblinding."

123. Dr. Yu and FibroGen only partially heeded this demand. In its December 2019 NDA submission, FibroGen disclosed to the FDA that it had changed the stratification factors for the roxadustat cardiovascular safety analyses, specified what the changes were, and – in a separate section – disclosed the original results. FibroGen also explained that it had simply switched the primary and post-hoc analyses, such that the post-hoc analyses using revised

stratification factors were now primary. Although this would have been highly material information to clinicians and investors, FibroGen did not disclose it publicly. The submission also appended the August and September 2018 SAP's.

124. FibroGen misleadingly described these changes as occurring "following database lock," which occurred before the data was unblinded. But as described above, FibroGen made the changes to the stratification factors *after* the data was unblinded and Dr. Yu reviewed the mediocre results. FibroGen never clarified this issue with the FDA, which did not know the full extent and timing of FibroGen's changes to the stratification factors until FibroGen's April 2021 corrective disclosure.

125. These disclosures were also defective in two other significant ways. First, FibroGen told the FDA that it changed the stratification factors to "harmonize" the factors among the different studies. That was not true. As described above, Dr. Yu and her team settled on the final set of stratification factors only after experimenting with numerous factor combinations and using the ones that made the results look better. Further, Pharma Co. B found in March 2021 that the final stratification factor model was "impossible to defend," with too many factors making statistically and clinically baseless distinctions.

126. Second, FibroGen and Dr. Yu did not make these disclosures public. That is especially significant because, as reflected by the analyst reports that followed the November 2019 ASN Conference and press release, described above, analysts and investors focused on precise hazard ratios and confidence intervals. Those analysts also questioned Dr. Yu on the November 11, 2019 call about FibroGen's statistical approach and whether it had received the FDA's support. But even after submitting the NDA, Dr. Yu chose to withhold from analysts and investors her team's post-hoc use of revised stratification factors.

127. Dr. Yu and FibroGen also withheld from the public information about the original results. This omission was significant and material because where clinical data has been analyzed using different models or assumptions, the FDA and industry participants will typically scrutinize the alignment between the outcomes. Where results are aligned, the primary conclusion may be considered more "robust." But where, as here, the results varied

significantly, industry participants will view a sponsor's claims with greater skepticism. By withholding the original results, then, Dr. Yu and FibroGen not only concealed their use of revised stratification factors but also deprived industry participants of a critical tool to evaluate their claims.

128. Following the NDA submission, the FDA engaged in a lengthy review process. On March 16, 2020, Dr. Yu presided over an "NDA Defense" meeting between FibroGen and Pharma Co. B to prepare to respond to FDA questions. The meeting outline listed anticipated questions that FibroGen "must have" a response to. These included a question about how FibroGen justifies its claim that roxadustat is superior to EPO in many respects when analyses "using pre-specified stratification factors demonstra[te] 95% CIs [confidence intervals] of the hazard ratio that cross 1" – in other words, how will FibroGen explain that the pre-specified analyses disclosed in the NDA do not support its headline claims? Another priority question addressed why FibroGen used certain stratification factors in its post-hoc analyses, but not "other factors potentially associated with CV risk . . . such as age, diabetes, baseline hemoglobin value . . . or baseline ESA dose?"

129. Dr. Yu knew that the answers to these questions might impact not only roxadustat's approval but also whether the drug would receive a so-called "black box" warning. The FDA uses black box warnings to alert the public that the medication may have serious side effects – such as, in roxadustat's case, risks to patients' hearts. To increase roxadustat's commercial appeal, Dr. Yu and FibroGen wanted to avoid having it receive such a warning. Accordingly, in subsequent meetings with the FDA, FibroGen sought to dissuade the FDA from requiring such a warning by citing the data purporting to show that roxadustat was safer than EPO – the same data used in the ASN Presentation and subsequent press release and investor call. These issues remained unresolved. By June 2020, the FDA was still reviewing FibroGen's "complex" submission and was still "evaluating the safety" of roxadustat.

130. Nonetheless, throughout 2020 and into 2021, Dr. Yu and FibroGen repeated the same misleading claims they made at the ASN Conference and in the ensuing press release and analyst call.

B. *Statements in SEC Filings*

131. FibroGen's November 12, 2019 Form10-Q, March 2, 2020 Form 10-K, and March 1, 2021 Form 10-K all repeated the same claims and charts that Dr. Yu included in FibroGen's ASN Conference presentation, and that she addressed in the November 11, 2019 analyst call. For example, the November 12, 2019 Form 10-Q and March 2, 2020 Form 10-K both asserted that roxadustat was 30% to 34% safer than EPO for incident dialysis patients, that this "subpopulation is the appropriate setting for comparison of roxadustat versus [EPO] . . .," and that the cardiovascular safety results "reflect the pooling strategy and analytical approach [FibroGen] agreed on with the FDA." The March 1, 2021 Form 10-K contained the same claims with slightly different wording.

132. Although these statements are not specifically attributed to Dr. Yu, she made them. She was Global Project Leader for FibroGen's roxadustat program with broad control over the conduct, analyses, and messaging for the roxadustat Phase III safety studies. The statements and charts that she authorized and included in the ASN Conference presentation slides – statements that she repeated and charts that she addressed on the November 11, 2019 analyst call – were repeated virtually verbatim in FibroGen's November 12, 2019 Form 10-Q, March 2, 2020 Form 10-K, and March 1, 2021 Form 10-K. In short, she had ultimate authority over the content of FibroGen's claims.

133. Further, while FibroGen did have a disclosure committee that reviewed draft publications of study results, Dr. Yu served on it, and the committee relied upon her clinical study expertise and knowledge. FibroGen deferred to Dr. Yu when came to roxadustat's clinical story, as that story remained largely unchanged between the ASN Conference and the March 1, 2021 Form 10-K. FibroGen would later claim, as described below, that the rest of its senior management was unaware that Dr. Yu was using post-hoc analyses. Indeed, FibroGen's newly-appointed, acting CEO at the time trusted and relied on Dr. Yu to provide accurate information about clinical trials.

C. *December 2020 Kidney International Reports Article*

134. FibroGen's March 2, 2020 10-K was not the only place Dr. Yu made her misleading claims in 2020. After announcing study results, it is common for trial sponsors to publish more detailed articles in peer-reviewed industry journals. Accordingly, at Dr. Yu's direction, FibroGen drafted manuscripts describing roxadustat's cardiovascular safety results and submitted them for publication in three different journals. On December 24, 2020, *Kidney International Reports* published an article with Dr. Yu, Employee A, and Employee B listed as co-authors, among others, and Dr. Yu listed as the point of contact. The article claimed, among other things, that roxadustat's risk of MACE was 30% lower than EPO for the incident-dialysis subgroup of dialysis-dependent CKD patients. Further, while the article disclosed the stratification factors used to calculate that figure, it did not disclose that those factors differed from the pre-specified factors. Nor did it disclose that those factors were the outcome of a Dr. Yu-led, post-hoc, effort to improve the initial results. (In its March 1, 2021 10-K, FibroGen highlighted that the pooled incident-dialysis data had been recently published in a *Kidney International Reports* manuscript and provided the website address where it was available.)

135. These omissions were all the more notable because Pharma Co. A had spent much of 2020 trying to persuade FibroGen that it must disclose its post-hoc use of revised stratification factors in the manuscripts. On July 30, 2020, Pharma Co. A told Employee B and Pharma Co. B personnel that Pharma Co. A had "MAJOR comments" (emphasis in original) on the manuscript for the dialysis-dependent studies, including: "[W]e noted that the stratification described is in contrast with the pooled DD SAP . . . We suggest that a justification [be] provided for deviation from this approach and/or provide additionally the outcomes using the pre-specified method."

136. On August 7, 2020, Pharma Co. A sent Employee B and Dr. Yu, among others, comments on a draft version of the above article. In the body of the email, Pharma Co. A emphasized: "The analysis descri[b]ed here appears to be a post-hoc defined analysis (e.g. no race, BMI, sex . . . used as stratification factors in studies). Please provide also results of the pre-defined analysis (e.g. in Suppl. Appendix) and provide justification for deviating from it[.]"

137. As reflected in the draft of the *Kidney International Reports* article described above, Dr. Yu and FibroGen effectively declined these requests. Pharma Co. A persisted. On August 17, 2020, it provided Employee B and Dr. Yu comments on a draft article addressing roxadustat's cardiovascular safety for non-dialysis dependent patients. Pharma Co. A wrote: "Hello . . . Please find attached comments from [Pharma Co. A] . . . which include[] a MAJOR comment in the main manuscript. . . . The [August 2018] SAP had pre-specified that the study-specific stratification factors will be used . . . The methodology described here is in deviation from the SAP. Please indicate this deviation and provide a justification for the deviation." Three days later, Employee B, copying Dr. Yu and others, responded misleadingly that "there is no deviation in the stratification factors. The analysis that is presented here was sent to the FDA and utilizes all the data with the stratification factors harmonized." Pharma Co. A promptly tried again, urging FibroGen to include text that would "add[] some transparency to the statistical approach."

138. That transparency would not come until April 6, 2021.

X. FibroGen Issued a Corrective Disclosure and Suffered Consequences.

139. Dr. Yu departed FibroGen in March 2021. After the markets closed on April 6, 2021, FibroGen issued a press release stating that as "members of senior management were preparing for the upcoming FDA . . . meeting, we became aware that the primary cardiovascular safety analyses included post-hoc changes to the stratification factors. . . . [W]e promptly decided to clarify this issue with the FDA and communicate with the scientific and investment communities." The press release then included a table comparing the analyses presented at the ASN Conference to the "analyses with the pre-specified stratification factors which have not been previously publicly reported." Thus, FibroGen dropped its claim that roxadustat was in any way superior to EPO or a placebo, and acknowledged that, instead, it is merely "comparable." FibroGen also committed to an internal review to determine how the lapse occurred.

140. This news was material to the market. One analyst said: "Bottom Line: Last night FibroGen . . . stunned us and investors by announcing a major 'oops', re-stating the statistical analysis of their pivotal cardiovascular safety meta analysis for Roxadustat." Analysts

opined that the corrective disclosure, which "erased [roxadustat's] appearance of superiority" over EPO, would make FDA approval much less likely. FibroGen's stock price dropped approximately 43% on April 7, 2021 from its prior day's closing price, on trading volume that nearly doubled its year-to-date high.

141. FibroGen also suffered damage to its clinical reputation. *Kidney International Reports* promptly retracted the article it published on roxadustat's purported superiority over EPO. In an April 13, 2021 email to Employee B, a FibroGen consultant who had been credited with co-authorship of the *Kidney International Reports* article emphasized that "the [outside] authors didn't have insight into this data issue. Given that the manuscript was focused on the original superiority data and that that is no longer true the impact of Roxadustat on [incidental dialysis] goes away." Further, in an April 12, 2021 email, another outside co-author told Pharma Co. B, that "pre-stratification and post-hoc stratification results . . . w[ere] not shared with me. I'm sure you all understand what a big problem that is." In the same email, the consultant also effectively renounced his relationship with FibroGen and asked to be removed as an author of the study. Both of these co-authors had also presented at the ASN Conference.

XI. Dr. Yu Acted with Scienter.

142. Dr. Yu knew that roxadustat's success was essential to FibroGen's business and her own success at the company. She also knew that the disclosure of mediocre results for the Phase III safety studies in an early May 2019 press release caused a sudden drop in FibroGen's stock price. A meticulous and highly involved manager, she directed Employee A and Contractors I and II to find new combinations of stratification factors that would make roxadustat's cardiovascular safety look superior to EPO and at least non-inferior to the placebo. Having achieved that goal by early June 2019, she led the preparation of FibroGen's public disclosures, many of which she drafted or made herself, including on the November 11, 2019 analyst call.

143. She withheld the truth about FibroGen's post-hoc use of revised stratification factors in the pre-NDA submission to the FDA and at the July 30, 2019 pre-NDA meeting. The

claims she made about FDA approval on the November 11, 2019 analyst call thus ranged from highly materially misleading to knowingly false. She also withheld the truth from, among others: the primary investigator for the Phase III study program who delivered FibroGen's pooled study presentation at the November 8, 2019 ASN Conference; other independent researchers who conducted the pooled studies and were listed as coauthors in the publication of the results; and the medical journals in which FibroGen hoped to, or did, publish manuscripts containing the same misleading claims. Indeed, Dr. Yu took great pains to restrict the number of people that worked on the statistical analyses and publications.

144. Dr. Yu engaged in all this behavior despite being questioned by Pharma Co. A and Pharma Co. B personnel about the adequacy of FibroGen's disclosures in communications that made clear that her conduct and statements were misleading and profoundly inconsistent with regulatory and industry norms. She also engaged in this misconduct while disclosing other post-hoc changes to FibroGen's analyses – in other words, she knew it was obligatory to disclose post-hoc analytical changes, but nonetheless misled the FDA, the public, and her fellow FibroGen executives about the revised stratification factors. Her and FibroGen's claims about "harmonizing" the stratification factors illustrate the extent to which she concealed from the FDA – and even from Pharma Co. A and Pharma Co. B – the true manner in which FibroGen determined which new stratification factors to use.

145. Between November 2019 and April 2021, while the materially misleading nature of her public statements regarding roxadustat had not yet been fully disclosed, Dr. Yu sold 23,472 shares of FibroGen stock, for net proceeds of approximately $1,097,333.

XII. Tolling Agreements.

146. Between September 2024 and June 2025, Dr. Yu entered into five separate tolling agreements with the SEC. Each tolling agreement specifies a period of time (a "tolling period") in which "the running of any statute of limitations applicable to any action or proceeding against Peony Yu authorized, instituted or brought by . . . the Commission . . . arising out of the [Commission's investigation of Dr. Yu's conduct], including any sanctions or relief that may be imposed therein, is tolled and suspended . . . ." Each tolling agreement further

provides that Dr. Yu "shall not include the tolling period in the calculation of the running of any statute of limitations or for any other time-related defense applicable to any proceeding, including any sanctions or relief that may be imposed therein, in asserting or relying upon any such time-related defense." Collectively, these agreements tolled the running of any limitations period or any other time-related defenses available to each of the Defendants for a period of approximately ten months, thereby preserving the timeliness of the Commission's claims for civil penalties as to all conduct in or after November 2019.

FIRST CLAIM FOR RELIEF

Fraud in Connection with the Purchase or Sale of Securities
Violations of Section 10(b) of the Exchange Act and Rule 10b-5(b)

147. The SEC realleges and incorporates by reference paragraphs 1 through 146 above.

148. As alleged above, Defendant Dr. Yu made numerous materially misleading statements and/or omitted to state material facts necessary to make her statements not misleading. As set forth above in paragraphs 23 to 36, the validity of clinical research requires full disclosure of analytical methods and results. Paragraphs 37 to 58 describe how FibroGen – under Dr. Yu's control and direction – prepared to follow those industry norms for analyzing the results of a Phase III clinical study for roxadustat, FibroGen's only revenue-generating product. Paragraphs 59 to 79 explain that Dr. Yu, disappointed with the study results and alarmed by investor reaction to an initial, more even-handed description of those results, led an effort to generate better results by re-doing the analyses using new stratification factors selected *after* reviewing the initial results. As set forth in paragraphs 80 to 106, Dr. Yu refused to disclose the true nature of FibroGen's analyses as well as the initial results, including in a presentation to the FDA. As set forth in paragraphs 107 to 137, Dr. Yu knowingly, or at least recklessly, made material misleading and untrue statements to the public to include investors, industry analysts, clinicians and others. Paragraphs 138 to 141 discuss FibroGen's April 2021 corrective disclosure and how the price of FibroGen's stock reacted.

149. By engaging in the conduct described above, Dr. Yu, in connection with the

purchase or sale of a security, and by the use of means or instrumentalities of interstate commerce, of the mails, knowingly and/or recklessly made untrue statements of a material fact or omitted to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

150. By engaging in the conduct described above, Dr. Yu violated, and unless enjoined will continue to violate, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b),)], and Rule 10b-5(b) thereunder [17 C.F.R. §§ 240.10b-5(b)].

SECOND CLAIM FOR RELIEF

Violations of Section 17(a)(2) of the Securities Act

151. The SEC realleges and incorporates by reference paragraphs 1 through 146above.

152. As alleged above, Defendant Dr. Yu made numerous materially misleading statements and/or omitted to state material facts necessary to make her statements not misleading. As set forth above in paragraphs 23 to 36, the validity of clinical research requires full disclosure of analytical methods and results. Paragraphs 37 to 58 describe how FibroGen – under Dr. Yu's control and direction – prepared to follow those industry norms for analyzing the results of a Phase III clinical study for roxadustat, FibroGen's only revenue-generating product. Paragraphs 59 to 79 explain that Dr. Yu, disappointed with the study results and alarmed by investor reaction to an initial, more even-handed description of those results, led an effort to generate better results by re-doing the analyses using new stratification factors selected *after* reviewing the initial results. As set forth in paragraphs 80 to 106, Dr. Yu refused to disclose the true nature of FibroGen's analyses as well as the initial results, including in a presentation to the FDA. As set forth in paragraphs 107 to 137, Dr. Yu knowingly, or at least recklessly, made material misleading and untrue statements to the public to include investors, industry analysts, clinicians and others. Paragraphs 138 to 141 discuss FibroGen's April 2021 corrective disclosure and how the price of FibroGen's stock reacted.

153. By engaging in the conduct that is described above, Defendant Dr. Yu, in connection with the offer or sale of securities, and by the use of the means or instrumentalities of

interstate commerce, of the mails, knowingly, recklessly, or negligently, directly or indirectly obtained money or property by means of untrue statements of material facts, or omitted to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

154. By engaging in the conduct described above, Defendant Dr. Yu violated, and unless enjoined will continue to violate, Securities Act Section 17(a)(2) [15 U.S.C. § 77q(a)(2)].

PRAYER FOR RELIEF

WHEREFORE, the SEC respectfully requests that the Court:

I.

Issue judgments, in forms consistent with Rule 65(d) of the Federal Rules of Civil Procedure, permanently enjoining Dr. Yu and her officers, agents, servants, employees and attorneys, and those persons in active concert or participation with any of them, who receive actual notice of the judgment by personal service or otherwise, and each of them, from violating Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)], Section 10(b) of the Exchange Act, [15 U.S.C. § 78j(b)], and Rule 10b-5(b) thereunder [17 C.F.R. § 240.10b-5(b)].

II.

Order Defendant Dr. Yu to disgorge all funds received from her illegal conduct, together with prejudgment interest thereon.

III.

Order Defendant Dr. Yu to pay civil penalties under Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)], and Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)(3)].

IV.

Issue an Order pursuant to Section 20(e) of the Securities Act [15 U.S.C. § 77t(e)], and Section 21(d) of the Exchange Act [15 U.S.C. § 78u(d)], permanently prohibiting Dr. Yu from serving as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78*l*], or that is required to file reports with the Commission pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78*o*(d)].

V.

Retain jurisdiction of this action in accordance with the principles of equity and the Federal Rules of Civil Procedure in order to implement and carry out the terms of all orders and decrees that may be entered, or to entertain any suitable application or motion for additional relief within the jurisdiction of this Court.

VI.

Grant such other and further relief as this Court may determine to be just and necessary.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the SEC demands trial by jury.

Dated: September 5, 2025

/s/ Daniel J. Maher
Daniel J. Maher
Attorney for Plaintiff
Securities and Exchange Commission