SAXENA WHITE P.A.
Maya Saxena (admitted *pro hac vice*)
msaxena@saxenawhite.com
Lester R. Hooker (SBN 241590)
lhooker@saxenawhite.com
Dianne M. Pitre (SBN 286199)
dpitre@saxenawhite.com
7777 Glades Road, Suite 300
Boca Raton, FL 33434
Tel.: 561.394.3399
Fax: 561.394.3382

Counsel for Lead Plaintiff Employees' Retirement System of the City of Baltimore, City of Philadelphia Board of Pensions and Retirement, and Plymouth County Retirement Association, and Lead Counsel for the Class

[Additional Counsel Listed on Signature Page]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE FIBROGEN, INC., SECURITIES LITIGATION	No. 3:21-cv-02623-EMC **CLASS ACTION** **[CORRECTED] CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

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TABLE OF ABBREVIATIONS

Abbreviation	Definition
ACM	All-Cause Mortality
AdCom	Advisory Committee
ASN	American Society of Nephrology
AstraZeneca or AZN	AstraZeneca AB
Baltimore Employees	Employees' Retirement System of the City of Baltimore
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CKD	Chronic Kidney Disease
Class Period	December 20, 2018 through July 15, 2021
CMO	Chief Medical Officer
Company, FGEN or FibroGen	FibroGen, Inc.
Conterno	Enrique Conterno, the current Chief Executive Officer of FibroGen
Cotroneo	Pat Cotroneo, the former Chief Financial Officer of FibroGen
CW	Confidential Witness
DD	Dialysis-Dependent
Defendants	FibroGen, Inc., Enrique Conterno, James A. Schoeneck, K. Peony Yu, Mark Eisner, and Pat Cotroneo
Eisner	Mark D. Eisner, the current Chief Medical Officer of FibroGen
ESA	Erythropoiesis-Stimulating Agent
ESRD	End Stage Renal Disease
Epogen or EPO	Epoetin Alfa
Exchange Act	Securities Exchange Act of 1934
FDA	United States Food and Drug Administration
Individual Defendants	Enrique Conterno, James A. Schoeneck, K. Peony Yu, Mark Eisner, and Pat Cotroneo
ITT Analysis	Intent-To-Treat Analysis
Lead Plaintiffs or Plaintiffs	Employees' Retirement System of the City of Baltimore, the City of Philadelphia Board of Pensions and Retirement, and the Plymouth County Retirement Association
MACE	Major Adverse Cardiovascular Events

Abbreviation	Definition
MACE+	MACE, Plus Hospitalization for Unstable Angina or Congestive Heart Failure
NDA	New Drug Application
NDD	Non-Dialysis-Dependent
Neff	Thomas B. Neff, the former CEO of FibroGen
PDUFA	Prescription Drug User Fee Act
Philadelphia Pension Fund	City of Philadelphia Board of Pensions and Retirement
Plymouth County	Plymouth County Retirement Association
Roxa	Roxadustat
Schoeneck	James A. Schoeneck, the former Interim Chief Executive Officer of FibroGen
SEC	United States Securities and Exchange Commission
Yu	K. Peony Yu, the former Chief Medical Officer of FibroGen

I. NATURE OF THE ACTION

1. Court-appointed Lead Plaintiffs the Employees' Retirement System of the City of Baltimore, the City of Philadelphia Board of Pensions and Retirement, and the Plymouth County Retirement Association ("Lead Plaintiffs" or "Plaintiffs"), on behalf of themselves and all others similarly situated, allege the following against Defendants (as defined below) upon personal knowledge as to themselves and their acts, and upon information and belief as to all other matters, based upon the ongoing investigation of the undersigned Lead Counsel. Lead Counsel's investigation included, among other things, review and analysis of: (i) the public filings of Defendant FibroGen, Inc. ("FibroGen" or the "Company") with the Securities and Exchange Commission (the "SEC"); (ii) information concerning FibroGen from the U.S. Food and Drug Administration ("FDA"); (iii) interviews with former executives of AstraZeneca AB, FibroGen's partner on the drug that is the subject of this action; (iv) in-depth research reports by securities and financial analysts concerning FibroGen; (v) transcripts of FibroGen's conference calls with analysts and investors; (vi) presentations, press releases, and media reports regarding FibroGen; (vii) consultation with various experts; and (viii) data reflecting FibroGen's stock price. Plaintiffs believe that substantial additional evidentiary support for their allegations will be developed after a reasonable opportunity for discovery, as many of the facts related to Lead Plaintiffs' allegations are known only by Defendants, or are exclusively within Defendants' custody or control.

2. Lead Plaintiffs assert claims under Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder, against FibroGen and its current Chief Executive Officer, Enrique Conterno ("Conterno"); former Interim Chief Executive Officer, James Schoeneck ("Schoeneck"); former Chief Medical Officer, K. Peony Yu ("Yu"); current Chief Medical Officer, Mark Eisner ("Eisner"); and former Chief Financial Officer, Pat Cotroneo ("Cotroneo" and, collectively, "Defendants"), and under Section 20(a) of the Exchange Act against the Individual Defendants, on behalf of all investors who purchased or otherwise acquired FibroGen securities, including options, between December 20, 2018 through July 15, 2021, inclusive (the "Class Period"), and who were damaged thereby (the "Class").

II. INTRODUCTION

3. As FibroGen and its senior-most officers have now ***admitted***, for over two years, Defendants lied to investors about the efficacy and safety of the Company's single most important drug, an anemia pill for kidney patients called Roxadustat. Specifically, Defendants repeatedly asserted that Roxadustat's critical Phase 3 trial results showed that the drug was "***superior***" to Epogen, the current standard of care, and even safer than placebo—what Defendants called "the gold standard for safety." Defendants went so far as to state that Roxadustat's "unbelievable" safety data would lead to FDA approval for less severe kidney disease patients, for which Epogen was not approved and which represented an untapped, multi-billion-dollar market. These statements were utterly false. As Defendants ultimately were forced to admit, they had manipulated Roxadustat's clinical trial data by making blatantly improper "*post hoc* changes" to that data in order to ***make the drug appear significantly better and safer than it really was***. In reality, Roxadustat's undisclosed, true data demonstrated that it was alarmingly *inferior* to Epogen and placebo due to severe safety issues, including increased deaths, that doomed the drug's chances for FDA approval. Significantly, the nature of Defendants' changes—including manipulations to ***every one of nine key analyses***, each of which was conveniently changed in Roxadustat's favor—made clear that they were no accident, and that they could only have been perpetrated by senior FibroGen officers. Indeed, when the "stunning" manipulations were revealed to investors, analysts uniformly excoriated management for committing "***the worst case of data manipulation in years***," which "***could [not have] happen[ed] accidentally***," as "***[t]he fact that all nine analyses [were changed] raises the suspicion that someone within FibroGen carefully selected the new criteria to make roxa's profile look better***." In response, FibroGen's stock price collapsed, losing 75% of its value in a few short months, wiping out billions of dollars in shareholder value.

4. FibroGen is a biopharmaceutical company whose flagship drug, Roxadustat, is an experimental pill that is designed to treat anemia in patients with chronic kidney disease ("CKD"). In 2013, FibroGen secured an agreement with AstraZeneca to commercially develop Roxadustat, which was contingent on FibroGen achieving various milestones in the drug's FDA new-drug-

application ("NDA") approval process. The current standard of care to treat anemia in CKD patients, Epogen, is only used in severe cases for patients already on dialysis ("DD patients") because it leads to an increased risk of major adverse cardiac events ("MACE"). As a result, Epogen is not used on patients with less severe CKD who have just begun dialysis ("incident dialysis" patients) or who have not yet started dialysis (non-dialysis or "NDD" patients). Accordingly, the key to securing critical FDA approval for Roxadustat was to demonstrate, through Phase 3 clinical trial data, that Roxadustat was at least as effective as Epogen, while avoiding the significant safety issues that prevented Epogen from being used to treat incident dialysis and NDD patients. If successful in these objectives, analysts estimated a potential ***$3.5 billion market*** for the drug—an extraordinarily material sum that was ***20 times*** FibroGen's total revenue for 2020.

5. Throughout the Class Period, Defendants repeatedly represented to investors that Roxadustat's "robust," "outstanding" and "extremely clean" Phase 3 clinical trial data demonstrated that the drug had in fact met these exact objectives, and that on the strength of this very data, Roxadustat's prospects for receiving FDA approval were "highly compelling," particularly in the all-important incident dialysis and NDD segments. For example, on December 20, 2018—the very first day of the Class Period—Defendant Yu emphasized that Roxadustat's top-line Phase 3 trial results had "***achieved superiority*** in efficacy not only against placebo but also over [Epogen]." When FibroGen released MACE safety results in May 2019, former CEO Thomas Neff[1] highlighted that the results demonstrated a "***statistically significant advantage over [Epogen]***" in the critical incident dialysis group, and Defendant Yu boasted that the results "***really illustrate[d] the strength of our drug's safety***" and set Roxadustat up to be the first anemia drug to avoid a "Black Box" warning on its label—the FDA's most severe safety warning. Defendants reaffirmed these results time and again through the end of the Class Period, with current CEO Defendant Conterno repeatedly asserting that "the data [was] ***extremely clean*** from my perspective when it comes to cardiovascular safety"; "we showed a 30% reduction in MACE risk" for incident dialysis patients, which was "***huge***" and "***differentiated***" Roxadustat from its competition; due to

[1] Neither Neff, the former CEO of FibroGen during the first nine months of the Class Period, nor his estate is named as a Defendant herein because Neff died in August 2019.

the "***compelling***" cardiovascular safety data "there's no warrant [for a] Black Box"; and Roxadustat had shown its safety was "comparable" to placebo, which was "very difficult to achieve" and "***critically important***." As late as November 2020—just months before Defendants' fraudulent manipulations were revealed—Conterno emphasized "the strength of our [Roxadustat] data" and FibroGen's "high level of conviction on the overall [NDA] submission."

6. Fueled by Defendants' representations, FibroGen's stock price skyrocketed by over 46%, from $41.00 per share at the start of the Class Period to a Class Period high of $59.91 per share on March 1, 2019. Tellingly, the Individual Defendants took full advantage of FibroGen's inflated stock prices, engaging in significant insider trading that yielded them proceeds of ***over $42 million***, with Neff alone selling $32 million worth of stock in less than one year, under highly suspicious circumstances with regard to the timing and magnitude of such sales. Moreover, the Individual Defendants also received highly lucrative compensation awards, including bonuses and awards of stock options worth an additional tens of millions of dollars, which were directly tied to FibroGen meeting regulatory and commercial milestones with respect to Roxadustat.

7. However, as Defendants themselves would ultimately be forced to admit, Defendants' Class Period statements were ***demonstrably false***. In reality, Roxadustat's data was not based on "prespecified" analyses that FibroGen had agreed upon with the FDA (meaning analyses and endpoints the FDA set in place *before* the results of the data were known), and the data did ***not*** support Defendants' claims about the supposed efficacy and safety of their key drug. To the contrary, Defendants admitted that they had deliberately manipulated the data, making a series of statistically significant and improper "*post hoc* changes" to ***every single one*** of nine clinical trial analyses *after* the data had been fully unblinded. The FDA has referred to this practice as after-the-fact "***data-dredging***" done in an "attempt to elicit a positive result from a failed study," and that is precisely what Defendants did here—all nine of the "*post hoc*" manipulated analyses made Roxadustat appear much better and safer than it actually was. Once Defendants' *post hoc* manipulations were corrected, the true data revealed that Roxadustat was so deficient and demonstrated such substantial safety concerns—including increased risk of serious afflictions such

as thrombosis, seizures, stroke and even death—that it showed the drug was ***significantly less effective and less safe*** than placebo or even Epogen, which already carried the dreaded "Black Box" warning. As a result, Roxadustat's true data failed to support FDA approval in ***any patient population at all***, effectively dooming its FDA approval prospects.

8. On March 1, 2021, Defendants' fraud began to unravel. On that day, FibroGen shocked investors by announcing that the FDA would hold an Advisory Committee ("AdCom") meeting to review Roxadustat's NDA—a surprising setback that late in the FDA approval timeline. On this news, FibroGen's stock price fell $16.18 per share, or over 32%, to close at $34.35 per share, on unusually heavy trading volume. Faced with the impending AdCom review that would ensure increased FDA scrutiny and possible public disclosure of the previously concealed Roxadustat safety data, just weeks later, on April 6, 2021, FibroGen was forced to admit, for the first time, that Defendants had made "***post-hoc changes to the stratification factors***" in Roxadustat's Phase 3 trial results—changes that were so significant that FibroGen needed to promptly "clarify this issue with the FDA" to "make sure that it was clear which analyses used which factors, prespecified and *post-hoc*." Significantly, Defendants admitted that, ***based on the actual "prespecified" FDA analyses, "we cannot conclude that Roxadustat reduced the risk of MACE… or is superior to … [Epogen]***," and confirmed that investors had been completely unaware of this material information, as Roxadustat's true FDA-prespecified data "***[had] not been previously publicly reported***." In response to this devastating news, FibroGen's share price was cut virtually in half in just two trading days, from $34.64 per share on April 6, 2021 to $18.81 per share on April 8, 2021, on extraordinary trading volume.

9. Significantly, sophisticated market participants and prominent members of the medical community uniformly excoriated FibroGen and its senior officers for presenting materially false information to the public for ***more than two years***. Indeed, numerous market analysts and nephrologists confirmed that Defendants' "*post hoc*" changes were highly material—fundamentally altering Roxadustat's safety and efficacy profile to the point that the drug's prospects for FDA approval were in jeopardy. For example, Dr. Geoffrey Porges, one of Wall

Street's most influential biotechnology analysts, called the disclosure "***nothing less than stunning***" given that "***[t]he re-statement reduced the benefit from [Roxadustat] vs controls in every case*** [and] erased the appearance of superiority over [Epogen] in incident dialysis patients." Similarly, a Jefferies report noted that "the fact that [Roxadustat's] Incident Dialysis is no longer 'statistically' superior – is ***a material change*** to the profile and [removed] one of the key prior advantages." William Blair highlighted that the admission "***will negatively affect management's credibility***" given that the data FibroGen had touted to investors for over two years was "inconsistent with analyses" that were "***requested by the FDA***," and which had "never been reported publicly to the medical or investment community."

10. Prominent nephrologists, analysts and medical journals further highlighted that the nature of the manipulations meant they could only have been intentionally implemented. For example, an article in one major pharmaceutical publication, *Evaluate Vantage*, underscored the magnitude of FibroGen's "***staggering admission***," and emphasized that management will "struggle to shake suspicions" for the "sorry debacle" because their explanation "***stretches the bounds of credibility***." Similarly, STAT+, another prominent pharmaceutical news outlet, excoriated Defendants for the "shocking revelation" that FibroGen had been "***touting false heart safety data for its experimental anemia pill for at least two years***," and called it "***the worst case of data manipulation in years***." *FiercePharma*, another major pharmaceutical publication, emphasized that "***[t]he fact that all nine analyses*** across the patient groups looked less favorable for [R]oxadustat after the change ***raises the suspicion that someone within FibroGen carefully selected the new criteria to make roxa's profile look better***." Likewise, a major article in the American Society of Nephrology ("ASN") emphatically criticized Defendants' "***statistical shenanigans***." The ASN article extensively quoted Dr. Daniel Coyne, a university professor and nephrologist who had personally worked as a site investigator in the Roxadustat trials. In striking commentary, Dr. Coyne concluded that Defendants' manipulations were indeed intentional, emphasizing: "This deeply damages the reputation of FibroGen . . . ***I feel very misled***, and I don't think there is any excuse for this. ***I don't know how this could happen accidentally***."

11. Remarkably, even at this point, Defendants did not reveal the full extent of their fraud. Rather, Defendants attempted to minimize the disclosure and continued to claim that Roxadustat was purportedly *still* just as safe as placebo and had comparable safety to Epogen. However, unbeknownst to investors, Defendants had in their possession *other* prespecified FDA analyses—known as "sensitivity" analyses—that revealed that Roxadustat's safety issues were so significant that the drug could not be approved ***at all***. These facts were not disclosed until July 15, 2021, when the FDA's AdCom met to review Roxadustat's NDA and the AdCom revealed that the drug's issues were even worse than what Defendants had previously represented. Indeed, as the AdCom unequivocally concluded that day, FibroGen's own undisclosed, prespecified sensitivity analyses of Roxadustat demonstrated that the drug's efficacy over Epogen was inconclusive at best, and with regard to safety, the drug caused "***greater rates of some important adverse events [] than even [Epogen]***," including a higher rate of death and other major side effects. As a result, the AdCom voted virtually unanimously ***against*** approval for Roxadustat ***for any patient population***, even with a "Black Box" warning.

12. Market analysts were again stunned by the true extent of Roxadustat's safety and efficacy deficiencies, noting that "***[t]hese signals were unknown from the company's disclosure to us and to investors before this week***." On this news, trading in FibroGen stock was halted on July 15, 2021, and the following day, the Company's stock price plummeted over 42%, or $10.49 per share, from $24.84 per share to $14.35 per share on July 16, 2021.

13. All told, the revelation of Defendants' fraud eviscerated FibroGen's stock price by ***over 75%*** from its Class Period high, wiping out billions in the Company's market capitalization. FibroGen's stock price has never recovered, and currently trades at approximately $11 per share, with investors suffering substantial losses from Defendants' violations of the federal securities laws. This action seeks redress on behalf of these aggrieved shareholders.

III. JURISDICTION AND VENUE

14. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R.

§ 240.10b-5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

15. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). FibroGen maintains its corporate headquarters in San Francisco, California, which is situated in this District, conducts substantial business in this District, and many of the acts and conduct that constitute the violations of law complained of herein, including the preparation and dissemination to the public of materially false and misleading information, occurred in this District. In connection with the acts alleged in this Corrected Consolidated Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

IV. PARTIES

A. Lead Plaintiffs

16. Lead Plaintiff the Employees' Retirement System of the City of Baltimore ("Baltimore Employees") is a public pension fund that provides retirement benefits to approximately 18,000 employees in the general administrative service of the City of Baltimore, Maryland and certain non-teacher employees of the Baltimore City Public School System. Baltimore Employees was established in 1926 and, as of June 30, 2021, had approximately $2.1 billion in assets under management. As reflected in its accompanying certification, Baltimore Employees purchased shares of FibroGen common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

17. Lead Plaintiff the City of Philadelphia Board of Pensions and Retirement ("Philadelphia Pension Fund") provides public pension fund benefits to approximately 64,000 police, fire, and civilian workers of the City of Philadelphia, Pennsylvania. Philadelphia Pension Fund was established in 1957 and, as of August 31, 2021, had approximately $7.3 billion in assets under management. As reflected in its accompanying certification, Philadelphia Pension

Fund purchased shares of FibroGen common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

18. Lead Plaintiff the Plymouth County Retirement Association ("Plymouth County") provides public pension fund benefits to approximately 12,000 current and retired municipal and county employees of Plymouth County, Massachusetts. Plymouth County was established in 1937 and, as of October 2021, had more than $1.2 billion in assets under management. As reflected in its accompanying certification, Plymouth County purchased shares of FibroGen common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

B. Defendants

19. Defendant Enrique Conterno ("Conterno") has served as the Chief Executive Officer of FibroGen since January 6, 2020 and is a member of the Company's Board of Directors. As CEO, Conterno is highly involved in the Company's day-to-day business. As stated in FibroGen's December 17, 2019 Offer Letter to Conterno filed with the SEC, he is "responsible for the general management of the affairs of the Company" and is required to devote his "full business time, skill and attention to the performance of [his] duties." In 2020, Conterno received $12,267,619 in total compensation. Conterno's 2020 compensation included $8,024,850 in option awards, $250,000 in bonus, $554,400 in non-equity incentive plan compensation, $790,909 in salary, $2,601,000 in stock awards, as well as $46,460 in other compensation. The Company's 2021 Proxy makes clear that Conterno's compensation depended on Roxadustat, stating that "Conterno was recognized for his efforts in leading the Company to achieve its corporate goals, ***including to ensure commercial readiness for [R]oxadustat***. . ."

20. During the Class Period, Defendant Conterno made materially false and misleading statements and omissions in press releases and during earnings calls, investor conferences and industry presentations, including on February 25, 2020, May 14, 2020, June 2, 2020, June 4, 2020, June 9, 2020, August 6, 2020, September 9, 2020, September 16, 2020, November 5, 2020, November 17, 2020, November 19, 2020, March 1, 2021, March 2, 2021, April 6, 2021, May 10,

2021, May 13, 2021, June 4, 2021, and June 10, 2021. Defendant Conterno also reviewed, approved, signed and certified FibroGen's quarterly and annual filings with the SEC on Forms 10-Q and 10-K, including on March 2, 2020 and August 6, 2020, which contained materially false and misleading statements and omissions.

21. Defendant James A. Schoeneck ("Schoeneck") is the current Chairperson of the Board of Directors of FibroGen and has served on the Board of Directors of the Company since April 2010. Schoeneck was appointed Chairperson in January 2020. In addition, Defendant Schoeneck served as interim Chief Executive Officer of FibroGen from August 2019 through January 2020. FibroGen's 2020 Proxy states, "[d]uring his time as Interim CEO, Mr. Schoeneck had several achievements, including, overseeing the submission of the [R]oxadustat New Drug Application."

22. During the Class Period, Defendant Schoeneck made false and misleading statements during the Company's November 11, 2019 conference call with investors, and also reviewed, approved, signed and certified FibroGen's false filing with the SEC on Form 10-Q on November 12, 2019, which contained materially false and misleading statements and omissions.

23. Defendant K. Peony Yu ("Yu") served as Chief Medical Officer of FibroGen from April 2016 through December 2020. According to Yu's biography, she "over[saw] all global and regional clinical development strategies and execution of the various clinical programs [at FibroGen]" and "provid[ed] leadership for the [R]oxadustat program." Prior to being CMO at FibroGen, Defendant Yu served as the Company's VP of Clinical Development from December 2008 until her promotion to CMO. On December 1, 2020, the Company announced Yu's "retirement" and stated that Yu would continue as CMO through December 20, 2020, the proposed date on which the FDA's final review of Roxadustat's NDA was scheduled. Yu remained with FibroGen through March 15, 2021, serving as Executive Advisor to the CEO, at which time she entered into a consulting agreement for a period of six months with FibroGen to provide services related to development, regulatory and commercialization. According to FibroGen's Transition, Separation, and Consulting Agreement with Yu dated November 27, 2020, as a consultant, Yu was

responsible for "clinical, regulatory and commercial matters relating to Roxadustat" and on other matters "as requested by the Company's CEO." Yu did not remain as a consultant for the full six months, as the Company terminated its agreement with Yu on August 24, 2021.

24. Yu's total compensation in 2019 was $5,856,451. Yu's 2019 compensation included $3,044,223 in stock awards, $1,886,018 in option awards, $590,000 in salary, $316,830 in non-equity incentive plan compensation, and $19,380 in other compensation. According to the Company's 2020 Proxy, Yu received that compensation in recognition "for her efforts in the completion of the [R]oxadustat pooled MACE safety data analyses" and "the [R]oxadustat New Drug Application submission to the U.S. Food and Drug Administration." Yu's total compensation in 2020 was $3,512,764. Yu's 2020 compensation included $1,201,950 in option awards, $1,188,450 in stock awards, $612,000 in salary, $459,000 in non-equity incentive plan compensation, and $51,364 in other compensation. Defendant Yu also received approximately $2 million in gross proceeds from insider sales in FibroGen stock during the Class Period.

25. During the Class Period, Defendant Yu made materially false and misleading statements and omissions in press releases and during earnings calls, investor conferences and industry presentations, including on December 20, 2018, February 27, 2019, May 9, 2019, June 12, 2019, August 8, 2019, November 11, 2019, March 2, 2020 and May 7, 2020.

26. Defendant Mark Eisner ("Eisner") is the current Chief Medical Officer of FibroGen and oversees all global clinical development and regulatory affairs for FibroGen. Eisner joined the Company in December 2020. Eisner's total compensation in 2020 was $3,917,657. Eisner's 2020 compensation included $1,919,616 in option awards, $1,443,750 in stock awards, $500,000 in bonus, $50,000 in salary, and $4,291 in other compensation.

27. During the Class Period, Eisner made materially false and misleading statements and omissions during earnings calls, investor conferences and/or industry presentations, including on March 1, 2021 and April 6, 2021.

28. Defendant Pat Cotroneo ("Cotroneo") served as the Company's CFO from 2008 to September 6, 2021. The Company announced his retirement on August 16, 2021, stating that he

would remain with FibroGen through March 31, 2022, serving as Executive Advisor to the CEO. Cotroneo's total compensation in 2019 was $4,326,386. Cotroneo's 2019 compensation included $1,769,851 in option awards, $1,782,963 in stock awards, $490,000 in salary, $264,600 in non-equity incentive plan compensation, and $18,972 in other compensation. Cotroneo's total compensation in 2020 was $2,916,018. Cotroneo's 2020 compensation included $1,061,723 in option awards, $1,056,400 in stock awards, $508,000 in salary, $230,937 in non-equity incentive plan compensation, and $58,959 in other compensation. Cotroneo received approximately $7 million in gross proceeds from insider sales of FibroGen stock during the Class Period.

29. During the Class Period, Cotroneo reviewed, approved, signed and certified FibroGen's quarterly and annual filings with the SEC on Forms 10-Q and 10-K, including on May 9, 2019, August 8, 2019, November 12, 2019, March 2, 2020 and August 6, 2020, which contained materially false and misleading statements and omissions.

30. Defendants Conterno, Schoeneck, Yu, Eisner and Cotroneo are collectively referred to herein as the "Individual Defendants." FibroGen and the Individual Defendants are collectively referred to as the "Defendants."

31. During the Class Period, the Individual Defendants, as senior executive officers and/or directors of FibroGen, were privy to confidential, proprietary and material adverse non-public information concerning FibroGen, its operations, finances, financial condition and present and future business prospects via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

32. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of Section 20(a) of the

Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of FibroGen's business.

33. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases and presentations to securities analysts, and through them, to the investing public. The Individual Defendants were provided with copies of the Company's reports and publicly disseminated documents alleged herein to be misleading, prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

34. As senior executive officers and/or directors and as controlling persons of a publicly traded company whose securities were, and are, registered with the SEC pursuant to the Exchange Act, and were traded on the NASDAQ and governed by the federal securities laws, the Individual Defendants had a duty to disseminate promptly accurate and truthful information with respect to FibroGen's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings, and present and future business prospects, to correct any previously issued statements that had become materially misleading or untrue, so the market price of FibroGen's securities would be based on truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

C. Relevant Non-Parties

35. Thomas B. Neff ("Neff") founded FibroGen in 1993. Neff was Chairman and CEO of FibroGen until his death on August 25, 2019. Probate closed a short time later, on October 30, 2019. Accordingly, Lead Plaintiffs only identify Neff as a relevant non-party in this action. Nevertheless, each and every one of the false and misleading statements and omissions issued by Neff during the Class Period, and the numerous facts supporting Neff's scienter, are attributable to

FibroGen as Neff served as the Company's Chief Executive Officer at all relevant times herein until his death in August 2019.

36. Neff's total compensation in 2019 was $11,407,472. Neff's 2019 compensation included $5,366,088 in stock awards, $5,333,469 in option awards, $687,115 in salary, and $20,800 in other compensation. Neff also received approximately $32 million in gross proceeds from insider sales in FibroGen stock during the Class Period. Neff was recognized for managing the Company purportedly to the successful achievement of its corporate objectives, including "the completion of the roxadustat global Phase 3 studies and the analysis and reporting of positive data from those studies," according to the Company's 2019 Proxy.

37. During the Class Period, Neff made materially false and misleading statements and omissions in press releases and during earnings calls, investor conferences and industry presentations, including on December 20, 2018, February 27, 2019, May 9, 2019, June 12, 2019, and August 8, 2019. Neff also reviewed, approved, signed and certified FibroGen's quarterly filings with the SEC on Form 10-Q, including on May 9, 2019 and August 8, 2019, which contained materially false and misleading statements and omissions.

38. AstraZeneca AB ("AstraZeneca") is a biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. On July 31, 2013, AstraZeneca announced that it had entered into a strategic collaboration with FibroGen to develop and commercialize a first-in-class oral compound in late stage development for the treatment of anemia associated with CKD and ESRD. AstraZeneca initially committed $350 million in cash and up to $465 million in milestone payments to FibroGen to fund the development and eventual FDA approval of Roxadustat. FibroGen has two agreements with AstraZeneca for the development and commercialization of Roxadustat, one for China, and one for the U.S. and all other countries not previously licensed. Under these agreements, FibroGen provides AstraZeneca the right to develop and commercialize Roxadustat for anemia in these territories. According to the Company's 2020 Form 10-K, FibroGen "share[s]

responsibility with AstraZeneca for clinical development activities required for U.S. regulatory approval of [R]oxadustat, and FibroGen will transfer the U.S. NDA to AstraZeneca upon approval."

V. FACTUAL OVERVIEW OF DEFENDANTS' FRAUD

A. Background of FibroGen and Its Single Most Important Drug, Roxadustat

39. FibroGen is a pharmaceutical company founded in 1993 that develops and commercializes drugs and therapies to treat anemia, fibrotic disease and cancer. During the Class Period, FibroGen's single most important drug prospect by far was Roxadustat, an oral treatment for anemia in patients with chronic kidney disease ("CKD") that works an HIF-PH inhibitor, which unlike other anemia drugs on the market is designed to stimulate the body's natural red blood cell production to treat anemia. CKD is a progressive disease characterized by the gradual loss of kidney function that eventually leads to kidney failure or end-stage renal disease requiring dialysis or a kidney transplant to survive. Anemia is a common complication of CKD and is associated with increased risk of death, in addition to causing severe fatigue and considerable reduction in quality of life. The standard treatment for anemia in CKD patients are erythropoiesis-stimulating agents ("ESAs")—which use a different mechanism to treat anemia than HIF-PH inhibitors—and the most prominent ESA representing the current standard of care is a drug called Epogen (also referred to as "epoetin alfa").

40. However, Epogen has two important drawbacks. First, since Epogen is administered by injection or intravenously, patients typically need to visit a doctor or a hospital to receive a treatment—and therefore it is not as easily administered to patients as an oral medication would be, particularly for patients who are not yet on dialysis. Second, and more importantly, Epogen is not recommended for use in less severe CKD cases, including non-dialysis dependent ("NDD") and new-to-dialysis patients (referred to as "incident dialysis" patients), because Epogen increases the risk of Major Adverse Cardiac Events ("MACE," a composite measure of serious cardiovascular events defined to include stroke, myocardial infarction, and cardiovascular death) and other serious adverse reactions such as thrombosis, hypertension and seizures. Accordingly, the FDA has required a so-called "Black Box" warning on the labels of Epogen and other ESAs—the strongest

warning the FDA can mandate for prescription drugs—stating that ESAs increase the risk of death, serious cardiac events, thrombosis, and tumors, among other serious risks.

41. FibroGen thus touted that Roxadustat was a drug that not only "could deliver the therapeutic benefits" of Epogen for dialysis-dependent ("DD") patients with "the convenience of a pill," but that it would also be safe for use by NDD and incident dialysis patients, for which Epogen was not recommended. In FibroGen's own words, as "an oral agent with a potentially more favorable safety profile" than Epogen, Roxadustat would "expand the market for anemia treatment by penetrating the NDD-CKD market," which was "substantially larger" than the DD market.

42. As a result, FibroGen represented to investors both before and throughout the Class Period that its development of a successful treatment for incident dialysis and NDD patients would represent a "***potential global multi-billion dollar market***" opportunity. On the strength of these representations, analysts such as Jefferies estimated that Roxadustat could represent a highly lucrative $3.5 billion market for FibroGen, with a staggering $3 billion of that amount coming from NDD and incident dialysis patients. The magnitude of this potential market for FibroGen was profound, as it dwarfed the Company's $176 million in revenues for all of 2020 ***by 20 times***. Indeed, analysts estimated that between 85-90% of FibroGen's $3.7 billion market value "***stem[med] primarily from [the financial prospects of FibroGen's] flagship drug Roxadustat***."

43. In 2013, FibroGen entered into a collaborative agreement with British-Swedish pharmaceutical company AstraZeneca to develop and commercialize Roxadustat for the crucial United States market. Pursuant to this agreement, FibroGen would be primarily responsible for the development of Roxadustat and the analysis of Roxadustat's critical clinical trial data, while AstraZeneca would cover the costs and provide highly substantial "milestone" payments to FibroGen as development and regulatory goals were met. For example, FibroGen disclosed that "[p]otential milestone payments" under its agreement with AstraZeneca "total[ed] $1.2 billion"—of which $571 million were for "development and regulatory milestones" and $652.5 million for "commercial-based milestones"—and that total consideration under the agreement could reach as high as $1.6 billion. Indeed, throughout the Class Period, FibroGen stated that its "revenue to date"

was "generated primarily from our collaboration agreements . . . for the development and commercialization of Roxadustat," with "substantially all" of its revenue being generated in this manner for the years covering the Class Period.

44. Significantly, FibroGen's agreement with AstraZeneca expressly designated FibroGen as the "lead regulatory party in the U.S. . . . through approval of the first NDA" for Roxadustat. The agreement further specified that, in that role, FibroGen would "be responsible for preparing and filing all Regulatory Materials" and would "have primary responsibility for interactions with [the FDA], including taking the lead role at all meetings with [the FDA]."

B. FibroGen's Phase 3 Clinical Trials For Roxadustat

45. In order to obtain FDA approval of a drug, a pharmaceutical company typically must conduct three sequential phased trials designed to demonstrate that a drug is both safe and effective. The FDA's goal is to evaluate the balance or ratio between the benefits a drug can offer (efficacy) and the risks or negative side effects the drug may cause (safety). Phase 1 trials typically evaluate safety, including adverse events and proper dosage. Phase 2 trials typically evaluate primarily efficacy and are used to determine the most optimal dosage of the drug. Phase 3 trials—which are typically much larger trials consisting of thousands of patients—are conducted just prior to FDA approval, and are designed to demonstrate efficacy, optimal dosage and safety within an expanded patient population. In other words, Phase 3 trials are used to confirm that a drug's benefits outweigh any adverse safety events before the FDA grants approval to a drug's NDA.

46. Just prior to the start of the Class Period, FibroGen completed its Phase 3 clinical trials for Roxadustat, which involved over 9,000 CKD patients across three key patient populations that were expected to use Roxadustat. These studies included the following: (i) four studies involving dialysis-dependent or DD patients; (ii) one study specifically focused on a subpopulation consisting of new-to-dialysis or "incident dialysis patients," in which Roxadustat was compared against Epogen; and (iii) three studies of NDD patients in which Roxadustat was compared to placebo (since Epogen was not typically used to treat anemia in NDD patients). All of these studies were randomized, double-blind studies, meaning that neither the researcher nor the patients knew

which patients were receiving Roxadustat and which were receiving placebo or Epogen. The purpose of a double-blind study of this nature is to eliminate possible bias or data contamination by preventing researchers from intentionally or unintentionally tipping off study participants that they are receiving the drug, or otherwise influencing researchers' evaluation of the results.

47. For Roxadustat to obtain FDA approval, it was critical for FibroGen to demonstrate not only that Roxadustat was at least as safe as the existing standard of care for DD patients, Epogen, but also that it was at least as safe as placebo and thus did not require a "Black Box" warning—meaning that it could be recommended to NDD and incident dialysis patients representing, in the words of market analysts, the "***key upside***" for Roxadustat. As FibroGen's then-CEO Neff explained, with respect to safety, the goal of these trials was to show that Roxadustat was "non-inferior" relative to the relevant comparator (*i.e.*, Epogen or placebo) in all three patient populations. In other words, FibroGen needed to demonstrate that, in DD and incident dialysis patients, Roxadustat did not cause more adverse safety events than Epogen, and in NDD patients, that it did not cause more adverse safety events than placebo. Defendants evaluated this by looking at three key safety endpoints in each patient population, namely (i) MACE, a crucial metric the FDA primarily evaluated when considering an NDA for anemia treatments; (ii) all-cause mortality, or "ACM," which evaluated deaths caused by Roxadustat for any reason and would also be a focus of the FDA; and (iii) "MACE+," a composite endpoint that included all MACE events in addition to hospitalizations, which was the primary focus of European regulatory authorities (and not the FDA). The resulting safety data for Roxadustat would therefore produce nine separate analyses of the safety of the drug—MACE, MACE+ and ACM for each of the three patient populations: DD, NDD and incident dialysis patients—which would purportedly unequivocally ensure that Roxadustat had shown its "non-inferiority" to placebo and Epogen.

48. These three endpoints, including the key MACE endpoint that would be the primary focus of the FDA, were measured by what is known as a "hazard ratio"—a metric that compared, on the one hand, the length of time until an adverse safety event occurred for patients on Roxadustat, and on the other, the length of time until an adverse safety event occurred for comparison patients

(*i.e.*, patients taking Epogen or placebo). For example, a hazard ratio of 0.5 meant that, for a given time period, half as many patients taking Roxadustat experienced an adverse safety event compared to Epogen or placebo. In contrast, a hazard ratio of 2.0 meant that, for a given time period, twice as many patients taking Roxadustat experienced an adverse safety event compared to Epogen or placebo. Thus, the smaller the hazard ratio, the safer the drug. Significantly, if the hazard ratio was below 1.0, the FDA could conclude that Roxadustat was actually ***safer*** than Epogen in DD/incident dialysis patients or placebo in NDD patients (provided the difference was statistically significant)—what Defendants described as the "holy grail" and a "big[] home run" for Roxadustat. In contrast, if the upper bound of the hazard ratio were to significantly exceed 1, the drug would be deemed less safe than placebo or Epogen, with the FDA deeming a hazard ratio of 1.25 or above as indicating that an anemia drug was ***less safe than*** or ***inferior to*** Epogen or placebo. Thus, if the studies showed that the hazard ratio for Roxadustat versus placebo was 1.25 or above, Roxadustat's prospects for approval with no "Black Box" warning and its ability to access the untapped $3.5 billion market would be doomed. Moreover, if the hazard ratio for Roxadustat versus Epogen was 1.25 or above, Roxadustat would be deemed too unsafe for approval ***for any patient population at all***, regardless of a label warning.

49. Accordingly, Roxadustat's future financial prospects in the U.S.—and, indeed, for FibroGen as a whole, given the drug's importance to the Company's bottom line and how critical the U.S. market was to its financial success—rested almost entirely on the drug's safety results across these endpoints in its Phase 3 trials, and especially the MACE endpoint that would primarily inform the FDA's decision of whether to approve Roxadustat and for which patient populations. As a result, market analysts such as Jefferies emphasized both prior to and during the Class Period that the "key cardiovascular MACE data" for the drug was what "the Street [was] focused on."

C. Throughout the Class Period, Defendants Falsely Touted that Roxadustat's Efficacy and Safety Were Purportedly "Superior" to Epogen and Just as Safe as Placebo, Fueling FibroGen's Stock Price to Class Period Highs

50. In the months leading up to the first day of the Class Period in December 2018—when FibroGen was scheduled to announce its "top-line" efficacy results for the Phase 3 trials for

Roxadustat—the market was keenly anticipating those results. Indeed, a March 2, 2018 Jefferies report stated that "Roxa could become a base case $2-4 [billion] franchise" if "Phase 3 data de-risks efficacy and shows 'non-inferiority' on CV [cardiovascular] risk" for the critical MACE safety endpoint. Similarly, another Jefferies report on September 20, 2018 noted that the market was "truly hyper-focused" on learning whether Roxadustat's efficacy was as good as Epogen and whether the MACE safety data FibroGen had seen thus far was "balanced" with "no major issues," while specifically noting that there was a potential downside for the stock as high as 50% if FibroGen were to report any "key [safety] imbalances that need further insight or clarity or add to the risk/benefit equation for [the] FDA to decide on." Accordingly, during FibroGen's third quarter 2018 earnings call held on November 8, 2018, analysts stated that they were looking for FibroGen to make a statement the following month on whether Roxadustat's "broad safety [was] similar to prior studies regarding balanced [adverse events]"—a key safety indicator that would "calm any recent [investor] concerns" that FibroGen had observed any negative safety issues for Roxadustat that would jeopardize FDA approval for the drug.

51. On December 20, 2018, the first day of the Class Period, FibroGen and its senior most officers gave the market the message it was hoping to hear, by making a series of unequivocally positive statements touting the safety and efficacy of Roxadustat. Specifically, with respect to efficacy, FibroGen announced that its Phase 3 trial results showed that Roxadustat had "***achieved superiority in efficacy not only against placebo but also over [Epogen]***." With respect to safety, Defendants provided the reassurance investors had been specifically looking for, stating that while FibroGen would not issue Roxadustat's "pooled" top-line MACE safety results until some time in the first half of 2019, "***[t]he preliminary safety analyses of each of [the Phase 3] individual studies show an overall safety profile consistent with the results observed in prior Roxadustat studies***"—indicating that the safety data for the large 9,000-patient Phase 3 trials had matched the safety data of much smaller prior trials that had purportedly shown no significant safety or cardiovascular issues for Roxadustat.

52. The market was highly encouraged by this news, with a December 20, 2018 Jefferies report expressing relief that the Company's "broad commentary says preliminary safety analyses of each of [FibroGen's] Phase 3 studies show overall safety profile consistent with results in prior Roxa studies and adverse events reported are consistent with those expected in these study populations," which the report stated "g[ave] a large picture of safety ***that should add comfort*** that these are truly robust studies with sufficient treatment experience." The report concluded that "we are buyers" in light of the "recent positive Phase 3 data and superiority on efficacy vs [Epogen]" and the purported "***minimal signs of cardiovascular risk***." A February 28, 2019 Jefferies report similarly emphasized that "***[t]hese are important and major de-risking events***, especially if the totality of the data suggest Roxa is safe (eg non-inferior) and does not increase CV risk."

53. By the spring of 2019, Defendants had completed their "pooled" analyses of the Roxadustat MACE safety data as planned, which pursuant to the Company's discussions with the FDA combined the drug's safety data across all studies in the Phase 3 trials, as opposed to evaluating each study individually. On May 9, 2019, after much market anticipation, FibroGen announced purportedly "Positive Topline Results" for the pooled Roxadustat MACE safety data, including for the key MACE endpoint on which the FDA was focused. The press release claimed that, based on an "ITT [intention to treat]" analysis, which FibroGen had supposedly discussed with the FDA, there was (i) "no clinically meaningful difference" in MACE risk between Roxadustat and placebo or Epogen; and (ii) ***Roxadustat had achieved "[s]uperiority in time to first MACE+ versus [Epogen] in incident dialysis patients***" with a "trend toward reduced [MACE] risk for patients on [R]oxadustat" compared to Epogen. On the Company's conference call with investors the same day, former CEO Neff asserted that these results were "***strongly supportive of the efficacy and safety of Roxadustat***" and stated that Roxadustat had "met the standards that people were looking for and that's why people are moving forward." Neff further emphasized that there were "***fewer [safety] events in Roxa versus [Epogen]***," including with respect to the crucial MACE events of deaths, myocardial infarctions, and strokes, and that the safety results for the "incident dialysis" sub-population in particular were supposedly extraordinary, demonstrating "***statistically***

significant advantage over [Epogen]." Defendants also emphasized Roxadustat's purportedly positive and unprecedented safety results showing that Roxadustat was just as safe as placebo in NDD patients, with Defendant Yu stating that "the fact that we . . . are able to show non-inferiority to placebo under such conditions"—which Yu stressed was "***the gold standard for safety***"—"***really illustrates the strength of our drug's safety.***"

54. Defendants also specifically reassured investors that the ITT analysis they had used to assess the top-line MACE data had been discussed with the FDA and was purportedly the standard non-inferiority analysis used by FDA—and that Roxadustat's non-inferiority had been easily established using that standard. Specifically, Yu assured investors that the ITT analysis was the "safety evaluation standard the FDA usually asks for" to establish non-inferiority, and that a "***[hazard] ratio of below 1.3***" represented the "***standard non-inferiority comparison in ITT***" that the FDA purportedly "***commonly applied***" and which the FDA would be looking for in reviewing Roxadustat's MACE results. While Defendants had not yet released any specific hazard ratios for the crucial MACE and ACM endpoints that the FDA would be focused on, Defendant Yu unequivocally told investors that "***[i]f we use that standard [of 1.3], the answer is yes, we have achieved non-inferiority***."

55. Significantly, Defendants' assurances that Roxadustat's data had "achieved non-inferiority" based on a 1.3 standard that the FDA purportedly "commonly applied" were completely false and intentionally misleading. In truth, Defendants knew full well that the FDA had ***never*** agreed to this standard for Roxadustat, and in fact had informed FibroGen of the exact opposite: as the FDA itself would ultimately confirm at the end of the Class Period, the FDA "***had a goal of 1.25***" for the Roxadustat trial data, "***that's what we discussed during meetings***" with FibroGen and "***that's why there was not an agreement on 1.3***." Even more damning, the FDA explicitly stated that it did "***not agree with [FibroGen's] proposed [non-inferiority margin] of 1.3***" because "***it was defined [by FibroGen] after the results of the study were known***." In other words, the FDA itself confirmed that FibroGen tried to set the 1.3 standard *after* Defendants already knew that Roxadustat's true, undisclosed trial results did not meet the FDA's 1.25 goal.

56. Despite Defendants' positive statements, there was nonetheless some concern among investors that FibroGen had failed to release any specific MACE hazard ratios that could confirm that Roxadustat had achieved statistical non-inferiority to placebo or Epogen. In reaction to this disclosure, FibroGen shares fell $9.28 per share, or 20%, to close at $36.39 per share on May 10, 2019, down from $45.67 per share on May 9, 2019, representing an $800 million decline in the Company's market capitalization. In response, FibroGen sought to strongly reassure the market that Roxadustat's MACE safety data supported FDA approval. For example, FibroGen's senior management met with a Jefferies analyst soon after the May 9, 2019 announcement of Roxadustat's top-line MACE safety data to assert that "[t]he Company feels very confident about Roxa's numerically lower [MACE] event rate profile," and claimed that the only reason that FibroGen could not yet confirm statistical non-inferiority was because the Company purportedly had not yet reached any official final "statistical agreement [with the FDA] on upper and lower bounds" for the MACE hazard ratios. Defendants' assurances successfully assuaged the market's concerns. For example, the Jefferies analyst explained that, following discussions with FibroGen's management, Jefferies had "a very clear picture" of Roxadustat, and investors would "soon realize the data is positive and Roxa's risk/benefit is favorable."

57. In the wake of FibroGen's announcement of purportedly "positive" top-line Roxadustat MACE safety data, and as the Company's planned release of the detailed MACE safety data at the American Society of Nephrology conference on November 8, 2019 approached, Defendants made numerous additional highly positive statements about what the detailed MACE safety data would show. For example, Defendants asserted that the MACE data they had seen showed "***compelling evidence confirming [R]oxadustat's cardiovascular safety to support our regulatory filings***,"; that "our MACE results in dialysis and in non-dialysis [] support the conclusion of ***no increased cardiovascular safety risk***"; that the Company had "***safety data and efficacy data that's superior to [Epogen] in a U.S. setting***"; that the Company had showed Roxadustat was "as safe as the placebo control arm" such that the FDA would likely conclude that "it shouldn't have a Black Box" warning; and that the Company had demonstrated "***outstanding***

results" in the crucial incident dialysis population that had poised Roxadustat to "become first-line therapy" for that highly significant market segment.

58. As Defendants would ultimately be forced to admit, and as the FDA expressly determined, all of Defendants' statements about Roxadustat's purportedly "compelling" and "superior" MACE data were false. In reality, as FibroGen expressly admitted on April 6, 2021, Defendants had manipulated Roxadustat's clinical trial data by making significant and improper "*post hoc* changes" in order to make the drug appear safer and better than it really was. Indeed, the true data demonstrated the exact opposite: there was no evidence whatsoever to support Defendants' claims that Roxadustat was safer or better than Epogen. In FibroGen's own words, "based on these [FDA prespecified] 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 [Epogen]***."

D. In Addition to Falsely Touting Roxadustat's Safety and Efficacy Data, Defendants Also Falsely Assured Investors That the Drug's Safety Data Was Derived Pursuant to Purportedly FDA-Sanctioned Analyses

59. In addition to providing analysts with the detailed positive and manipulated MACE data that would purportedly confirm the safety of Roxadustat, the market was also keenly anticipating confirmation from Defendants that the FDA had agreed to the specific analyses that FibroGen would be presenting at the November 2019 ASN conference. On August 8, 2019, FibroGen held its second quarter earnings call in which it provided the market with this exact confirmation. Specifically, during the call, FibroGen announced that it had held its pre-NDA meeting with the FDA at the end of July, during which the Company had purportedly obtained the FDA's full blessing of its analyses of the positive pooled topline MACE safety data that FibroGen previously announced on May 9, 2019. FibroGen proclaimed this was a "very good" development, and that as a result of reaching this agreement with the FDA, the Company's "level of confidence is very high" that its "Phase 3 results confirm[ed] cardiovascular safety of Roxadustat in the CKD population in both [the] [DD] and [NDD]" patient populations.

60. Analysts responded very favorably to the news. For example, an August 8, 2019 Jefferies report reiterated FibroGen's commentary that the Company had "very high" confidence in Roxadustat's safety profile as a result of its meeting with the FDA, and commented that this meant that "the CV [MACE cardiovascular] safety was confirmed" and that the FDA was clearly "receptive" and "***on board***" with FibroGen's proposed statistical analyses that had resulted in the Company's claim of Roxadustat's non-inferiority, thus setting the stage for FDA approval:

> We think based on our conversations [with FGEN management], ***the read-through is FGEN proposed statistical plans and analyses [to the FDA] (including for non-inferiority for MACE which has been an investor debate) and the FDA has indeed agreed, is receptive, on board*** and ready to review the filing.

61. On November 8, 2019, FibroGen presented the false MACE safety data at the ASN conference as planned, which purportedly confirmed what Defendants had been telling investors all along about the success of the Roxadustat MACE safety data—namely, that the data showed that Roxadustat was dramatically more safe than Epogen and, remarkably, even as safe as placebo. Although the actual data showed the exact opposite—that, as Defendants would later admit, the Company had no basis or evidence to "conclude that Roxadustat reduces the risk of (or is superior to)" Epogen—the press release claimed that: (i) Roxadustat's "cardiovascular safety [was] comparable to placebo in [NDD] patients," a feat no anemia drug had ever achieved before; (ii) Roxadustat "did not increase the risk of MACE . . . compared to [Epogen] in [DD] patients" and had in fact lowered the risk of MACE+ in DD patients by 14% compared to Epogen; and (iii) Roxadustat had remarkably "reduced the risk of MACE by 30% and MACE+ by 34% compared to [Epogen]" by a statistically significant margin in the crucial incident dialysis population.

62. Defendants emphasized that they had reached these conclusions based on the "ITT [intention to treat] analysis ***agreed [upon] with the FDA***" during the pre-NDA meeting, and by using "a reference non-inferiority margin of 1.3," which FibroGen had told investors was the FDA's standard measure against which Roxadustat would be measured (while concealing that the FDA had in fact informed FibroGen that the agency would be looking for a 1.25 margin instead). Defendants' assurances to investors that the results they were presenting had satisfied the prespecified analysis they had agreed upon with the FDA were absolutely critical, as investors knew

that Roxadustat had to show non-inferiority to both Epogen and placebo based on those prespecified analyses in order to obtain FDA approval and a favorable label that could compete with Epogen.

63. To unequivocally confirm to investors that Roxadustat had indeed achieved statistical non-inferiority for the safety endpoints the FDA would be focused on—including most critically the MACE and ACM endpoints—the press release also disclosed the specific hazard ratios for each endpoint across each of the three study populations, reflected in the chart below. Just as Defendants had emphasized to investors, for all nine analyses, the upper bound of the reported hazard ratios (shown in the chart below as the second number in parenthesis next to each estimated hazard ratio) were all well below the 1.3 non-inferiority margin FibroGen had told investors the FDA would use. Additionally, the MACE and ACM hazard ratios for the NDD population in particular—for which Defendants had to show Roxadustat was comparable to placebo, the purported "gold standard" for safety, in order avoid the Black Box warning attached to Epogen—were tellingly conveniently just below the FDA's true non-inferiority margin of 1.25.

Hazard Ratios Reported in November 8, 2019 Press Release

	NDD	DD	Incident Dialysis
MACE	1.08 (0.94, 1.24)[1]	0.96 (0.82, 1.13)	0.70 (0.51, 0.96)
MACE+	1.04 (0.91, 1.18)	0.86 (0.74, 0.98)	0.66 (0.50, 0.89)
ACM	1.06 (0.91, 1.23)	0.96 (0.79, 1.17)	0.76 (0.52. 1.18)

[1] For each endpoint, the estimated hazard ratio is shown with the hazard ratio range at a 95% confidence interval shown in parens, *i.e.*, for NDD, the MACE hazard ratio is 1.08 with a hazard ratio range of 0.94 to an upper bound of 1.24 at a 95% confidence interval.

64. Significantly, even in the face of investors' direct questions about whether the FDA would accept Defendants' analyses of the data presented on November 8, 2019, Defendants firmly maintained that the positive MACE safety results they had disclosed conformed to the prespecified statistical plan FibroGen had agreed upon with the FDA. For example, when the Company held its November 11, 2019 third quarter earnings call following the ASN conference and analysts raised recent "investor concern about FDA agreements and FDA sign-off," Defendant Yu quickly reassured investors that the Company had long had a clear understanding of the statistical analyses of MACE data the FDA wanted to see. Specifically, Yu stated that FibroGen had "been in dialogue

with the FDA" over the prior six years about the Phase 3 trials for Roxadustat, and thus had "a very good understanding" of the "analysis of cardiovascular safety" that the FDA would require for approval and was "very comfortable with our data where it is now." Yu stated that she therefore had "no concern" about the MACE hazard ratios FibroGen had presented being below the upper bounds the FDA wanted to see, and made crystal clear that the safety data presented at the ASN conference did in fact reflect the ***prespecified statistical plan FibroGen had supposedly agreed upon with the FDA***:

> [W]e had already talked with the FDA about [the] 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, and the numbers I had just presented, were based on the agreed analysis plan that we have made with the FDA***.

65. Defendants' adamant reassurances that the positive Roxadustat MACE results the Company had presented were the result of the prespecified analyses they had agreed upon with the FDA had their intended effect. Leading up to FibroGen's submission of the Roxadustat NDA in December 2019, FibroGen's stock price surged by over 22%, from $37.01 on November 4, 2019 to $45.30 on December 20, 2019.

E. In the Wake of Submitting the Roxadustat NDA to the FDA and Throughout 2020, Defendants Continued to Falsely Tout Roxadustat's Purportedly Remarkable Efficacy and Safety Results

66. Pursuant to FibroGen's agreement with AstraZeneca, the Company stood to receive highly lucrative "milestone" payments for achieving certain regulatory goals for Roxadustat, with one of the most significant of these goals being FibroGen's submission of the Roxadustat NDA to the FDA. Indeed, when FibroGen announced that it had submitted the Roxadustat NDA to the FDA on December 23, 2019, this triggered a substantial milestone payment from AstraZeneca amounting to $50 million, which would comprise approximately 20% of the Company's annual revenues for 2019. Defendants further announced that the FDA's final review date for the Roxadustat NDA was scheduled approximately one year later, on December 20, 2020 (known as the "PDUFA" date in reference to the Prescription Drug User Fee Act).[2]

[2] Once the FDA accepts a filing for the approval of a drug, the agency must complete its review process before a specific scheduled date—typically 10 months or a year in most cases. The date at the end of the review period is referred to as the "PDUFA" date.

67. Throughout 2020 and as the December 20, 2020 PDUFA date approached, FibroGen continued to strongly and repeatedly tout Roxadustat's purportedly "very compelling" efficacy and MACE safety data without abatement. For example, on a February 25, 2020 analyst call, new CEO Defendant Conterno assured the market that he had personally reviewed the Roxadustat MACE safety data, and that based on his extensive experience "conduct[ing] and be[ing] a part of a number of cardiovascular studies in my previous roles," the Roxadustat safety data was "***extremely clean***" and "***highly compelling***" because they had definitively shown "***safety against what I think is a very high hurdle of placebo***" in every single MACE category.

68. Defendants also repeatedly and specifically touted the purportedly "***unbelievable***" safety results in incident dialysis patients, for which they emphasized Roxadustat had extraordinarily lowered the MACE risk by a statistically significant 30%—resulting in unprecedented market share prospects for the drug. For example, during a May 14, 2020 investor conference, Defendant Conterno stressed that "***we need to highlight the incident dialysis data, whereby we basically show a reduction in risk of MACE events at a time that is critical"*** because "[t]his is the time when a treatment decision is made when it comes to anemia." On a June 9, 2020 investor call, Defendant Conterno similarly touted Roxadustat's safety results in the incident dialysis population, emphasizing that they were precisely what "***differentiated***" Roxadustat and what would cause it to be chosen as a first-line therapy upon a CKD patient's initiation of dialysis:

> [A]s I think you know, ***I've been very excited about our incident dialysis data and the fact that we showed a 30% reduction in MACE risk and 34% when it comes to MACE plus. Honestly, that's huge and that's an anchor.*** Because as patients start dialysis, clearly part of that dialysis initiation is going to be treatment of anemia. And ***I believe that we have the very best data. It's quite compelling and differentiated.***

69. As late as the fall of 2020 and just prior to the PDUFA date, Defendants also repeatedly emphasized to investors that their conversations with the FDA about the Company's "excellent data" were going extremely well, setting the stage not only for FDA approval, but also for the FDA to allow a highly favorable label that would avoid the "Black Box" warning. For example, at a September 9, 2020 investor conference, Defendant Conterno asserted that FibroGen felt "very good about where we are in terms of the review with the FDA," and that due to the

Company's "excellent data," "***[w]e don't believe that the data that we have warrants a [Black Box] warning***." Similarly, during a November 19, 2020 conference—"with the PDUFA date [for Roxadustat] coming up quickly"—Conterno again stressed FibroGen's "***high level of conviction on the overall [NDA] submission***," and that "the cadence [with the FDA] is good." Conterno then firmly announced that "***we expect, quite frankly, [FDA] approval . . . by the PDUFA date***."

70. Fueled by Defendants' repeated representations concerning Roxadustat's purportedly astoundingly positive safety and efficacy results, FibroGen's stock price closed at $55.72 per share on February 12, 2021, more than 30% higher than its price at the start of the Class Period. However, unbeknownst to investors, and as explained below, all of Defendants' statements about Roxadustat being as safe as placebo, and purportedly having a "superior" efficacy and safety profile to Epogen, were completely false. In reality, Roxadustat's safety issues were so severe and so numerous that, as the FDA would expressly determine, the drug could not be approved at all—for any patient population, and regardless of any "Black Box" warning.

F. The Truth Regarding Defendants' Fraud Slowly Emerges

71. As discussed above, throughout the Class Period, Defendants repeatedly assured investors that the extraordinarily positive Roxadustat efficacy and safety data they had presented to the market—including unprecedentedly low hazard ratios across each of nine analyses in all three patient populations—were the result of the "prespecified" analyses that they had purportedly agreed upon with the FDA. These representations were false. In truth, the data that Defendants had touted for two years was *not* the "prespecified" analyses agreed upon with the FDA, but was in fact data that Defendants had changed "*post-hoc*"—*i.e.*, meaning that Defendants altered the data after it had been fully unblinded (so Defendants knew which patients had received Roxadustat and which had not) by manipulating certain variables in the data to make the drug appear better and safer than it really was. Significantly, Roxadustat's true, "prespecified" data was materially worse than FibroGen had disclosed across ***each of the nine analyses***, and demonstrated such severe and alarming safety signals in patients—including increased deaths and major adverse ailments such as thrombosis, stroke and seizures—that they rendered Roxadustat *materially inferior* to both placebo

and Epogen, thereby dooming Roxadustat's chances for FDA approval in any patient population. As a result, every single one of Defendants' positive public statements concerning Roxadustat's efficacy and safety made during the Class Period was ***demonstrably false***, as explained below.

1. After Defendant Yu Suddenly "Retires," the FDA Announces a Delay in Roxadustat's Approval Process, and then Calls for an Unexpected Advisory Committee Meeting to Review Roxadustat's NDA

72. FibroGen's fraud began to unravel beginning in the fall of 2020, as the truth regarding Roxadustat's true inferior safety profile slowly emerged. First, on November 27, 2020, FibroGen abruptly announced the sudden "retirement" of FibroGen's Chief Medical Officer, Defendant Yu, who would be replaced by Defendant Eisner. Thus, while ostensibly on the cusp of gaining regulatory approval for its flagship drug after years of development, the Company pushed out its Chief Medical Officer who was directly responsible for this very data, under highly suspicious circumstances. Tellingly, Defendant Yu did not stay "retired" for long at all, as she assumed a new position at a different company just three months later, on March 9, 2021.

73. Then, on December 18, 2020, just three weeks after Defendant Yu's unexpected "retirement," FibroGen issued a press release after trading hours announcing that the FDA had "extended the review period of the [NDA] for Roxadustat . . . by three months," with a new PDUFA date of March 20, 2021. Analysts expressed concern over the delay: for example, a December 18, 2020 Raymond James report stated that "[w]hile there are numerous explanations for the PDUFA delay, none of them are good (especially considering how late it came in the review cycle)," and that the FDA's request for "new data analyses could very likely translate to higher risk (otherwise, why weren't they included in the original filing?)." A December 18, 2020 Jefferies report likewise opined that "[w]e expect investors will be slightly more nervous about the FDA regulatory on Roxadustat" as "any additional analysis required by the FDA generally makes investors worried, when it should generally be straightforward." On this news, FibroGen's stock price fell 9%, from $43.97 per share on December 18, 2020 to close at $40.01 per share on December 21, 2020. To directly quell investor concerns, Defendants expressly asserted that the FDA's review delay was of

no moment, claiming that FibroGen was merely "submitting additional analyses of existing Roxadustat clinical data," which "require[d] an extension of the original PDUFA date."

74. Despite FibroGen's efforts to downplay the news about the FDA's delay, less than three months later, it became evident that the FDA's delay was not benign. Specifically, on March 1, 2021, FibroGen shocked investors by unexpectedly announcing that the FDA "will hold an advisory committee (AdCom) meeting to review the [NDA]" for Roxadustat. The fact that the FDA had called for the AdCom so late in the regulatory process signaled a significant setback for Roxadustat's approval timeline, and analysts immediately expressed concern about the news, and what it could mean for Roxadustat's approval. For example, a March 1, 2021 Jefferies report stated that, as a result of the AdCom, the "[r]isk went up and [made approval] timelines longer," which "[a]dds uncertainty around approvability and a possible 'Black Box' label" and "will bring into question what the FDA concerns are, what theoretical CV risks are outstanding." Similarly, a SVB Leerink analyst wrote "[t]his announcement, and the complete lack of clarity about its implications, significantly lowers our confidence in overall approval for Roxa[dustat] . . . particularly in the non-dialysis setting where the risk-benefit tradeoff may be less clear to regulators."

75. As a direct result of FibroGen's disclosure of the AdCom meeting, FibroGen's stock price fell $16.18 per share over the next two days, or 32%, from a close of $50.53 on March 1, 2021, to close at $34.35 per share on March 3, 2021—representing a $1.48 billion decline in the Company's market capitalization.

76. Faced with the precipitous decline in the Company's stock price, Defendants attempted to reassure investors that Roxadustat's trial results remained sound, that its NDA submission was complete and strong, and that the drug was still on track for FDA approval. Specifically, during FibroGen's first quarter earnings call on March 1, 2021, Defendant Conterno assured investors that FibroGen "continue[d] to have confidence in the completeness of the NDA submission and the strength of the [R]oxadustat data" and that "[c]learly, the efficacy and safety of [R]oxadustat were established by the global Phase 3 programs." FibroGen's new CMO Eisner further emphasized that the Company was "very confident in our data for both [NDD and DD]

populations" as well, stating that "the data are the same today as they were yesterday . . . [s]o we continue to feel very confident in the data." Significantly, Conterno also continued to strongly highlight the blatantly false MACE results for the incident dialysis population in particular, stating "***of course, the data that we have on incident dialysis, we believe, is some of our strongest data[,] [a]s we think about MACE and MACE+ significance in that population***."

2. FibroGen Shocks the Market by Admitting to "Devastating" Manipulations of Roxadustat Data that Made the Drug Appear Better and Safer Than It Really Was

77. With increased scrutiny by the FDA bearing down on them, and public disclosure of their data manipulations imminent, Defendants could no longer conceal the truth. On April 6, 2021, after the market closed, FibroGen issued a press release in which it made the shocking admission that the Company had manipulated Roxadustat's Phase 3 trial results, and that those manipulations—which Defendants had made to ***each and every one of the nine analyses*** of the key Roxadustat safety endpoints across all three studied patient populations—had made the drug appear significantly safer than it really was. Indeed, FibroGen admitted that the clinical trial results it had repeatedly touted to investors throughout the Class Period as purportedly being the results of the prespecified analyses agreed upon with the FDA in fact "***included post-hoc changes to the stratification factors***" in Roxadustat's Phase 3 trial. These changes were not insignificant. As, FibroGen's own CMO Defendant Eisner admitted, these "*post-hoc* changes" included changes to "the cut point for GFR [which measures kidney function] based on hemoglobin"—a critical measure that would significantly alter the level of CKD severity of the patient population being analyzed, therefore dramatically altering trial results—and changes to "additional variables of sex, race and body mass index," which would also significantly recategorize patients in a way that would substantially obscure the real data.

78. The nature of Defendants' "*post hoc*" manipulations—and the significant way in which they altered the Roxadustat safety data—confirmed that they were no accident, and that they could only have been orchestrated by FibroGen's most senior officers. Indeed, as Defendants were well aware, the FDA has expressly stated that there is a highly significant and well-known

difference between a *prespecified* statistical analysis for a clinical trial—meaning one that it is agreed upon with the FDA ***in advance***, with parameters that are set ***before*** the unblinding of the clinical trial data—and *post hoc* analyses, which are the exact opposite and thus inherently unreliable. Stated simply, in contrast to prespecified analyses, *post hoc* analyses are selective analyses done in hindsight pursuant to cherry-picked criteria that are determined *after* all trials are completed and only *after* the data have been *fully unblinded—i.e.*, *after* FibroGen was able to fully see which patients had received Roxadustat and which had not, and what their results were under the prespecified criteria that the Company could now selectively alter.

79. As such, *post hoc* analyses are notoriously highly suspect, and cannot support FDA approval—which was precisely why investors kept seeking assurances from FibroGen that the data it was presenting was based on the prespecified FDA analyses. In fact, the FDA has drafted guidance describing *post hoc* analyses as little more than after-the-fact "***data-dredging***" designed to "elicit a positive study result from a failed study," with the agency specifically stating that such analyses cannot be trusted due to the drug sponsor's "desire for success":

> In the past, it was not uncommon, after the study was unblinded and analyzed, to see a variety of ***post hoc adjustments*** of design features (e.g., endpoints, analyses), usually plausible on their face, ***to attempt to elicit a positive study result from a failed study — a practice sometimes referred to as data-dredging*** . . . Although post hoc analyses of trials that fail on their prospectively specified endpoints may be useful for generating hypotheses for future testing, they do not yield definitive results. ***The results of such analyses can be biased because the choice of analyses can be influenced by a desire for success***.[3]

80. The chart below—which is based on information given in Defendants' April 6, 2021 press release revealing the *post hoc* changes and essentially restating Roxadustat's clinical trial results—demonstrates the significant manipulations Defendants made to Roxadustat's data across ***all nine*** safety analyses. The chart compares (i) Defendants' *post-hoc* manipulated data underlying Defendants' public statements throughout the Class Period; (ii) the actual FDA pre-specified data

[3] *See* "Multiple Endpoints in Clinical Trials, Guidance For Industry," *available at* https://www.fda.gov/media/102657/download. The FDA has further made clear that post hoc adjustments are especially improper with respect to the non-inferiority trials at issue here. For example, the agency's official "Non-Inferiority Clinical Trials to Establish Effectiveness, Guidance For Industry" (available at https://www.fda.gov/media/78504/download) states that "[a]pplying post hoc adjustments developed at the time of analyzing the NI [non-inferiority] trial"—i.e., precisely what Defendants improperly did here—"would not be appropriate."

for each of the nine analyses; and (iii) the percentage difference for each analysis. As depicted in the chart, the greatest manipulations occurred in the critical MACE endpoint for the all-important incident dialysis segment, which Defendants had repeatedly touted as key to launching Roxadustat into a multi-billion-dollar market specifically because Epogen was too unsafe for that population.

81. Specifically, Defendants had manipulated that data to appear ***over 17%*** safer than it actually was under the FDA's primary prespecified analysis. As disclosed on April 6, 2021, Roxadustat's true FDA pre-specified data unequivocally demonstrated that, in reality, there was no evidence whatsoever to support Defendants' assertions that Roxadustat was safer than Epogen. Indeed, as ***Defendants themselves admitted in the April 6, 2021 press release***, "based on these [FDA prespecified] 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 [Epogen]*** " ***at all***:

Analyses	*Post-Hoc* Manipulated Analysis	True, Undisclosed FDA Pre-Specified Analysis	% Difference
Incident Dialysis			
MACE	0.70 (0.51, 0.96)	0.82 (0.60, 1.11)	**17.14%**
MACE+	0.66 (0.50, 0.89)	0.78 (0.59, 1.02)	**18.18%**
ACM	0.76 (0.52, 1.11)	0.82 (0.57, 1.18)	**7.89%**
Dialysis Dependent			
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)	**6.25%**
MACE+	0.86 (0.74, 0.98)	0.91 (0.80, 1.05)	**5.81%**
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)	**6.25%**
Non Dialysis			
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)	**1.85%**
MACE+	1.04 (0.91, 1.18)	1.07 (0.94, 1.21)	**2.88%**
ACM	1.06 (1.91, 1.23)	1.08 (0.93, 1.26)	**1.88%**

82. It is difficult to understate the magnitude of the *post hoc* changes Defendants made to Roxadustat's clinical trial data. Significantly, ***each and every one of the nine analyses*** that Defendants had touted to investors for over two years as purportedly confirming Roxadustat's safety and efficacy had been manipulated in this manner to make the drug look better and safer than it really was under the FDA's prespecified analyses—an indisputable fact that could not have been

carried out without the express participation of the Individual Defendants. Indeed, sophisticated market analysts and prominent members of the nephrology community concluded exactly that, stating that the manipulations "***could [not have] happen[ed] accidentally***," and emphasizing that "***[t]he fact that all nine analyses across the patient groups looked less favorable for [R]oxadustat after the change raises the suspicion that someone within FibroGen carefully selected the new criteria to make roxa's profile look better***."

83. The fact that Defendants' manipulations were intentional is further demonstrated by the results in the NDD population, another crucial patient population for which Epogen was too dangerous to be prescribed, and for which it was key for Roxadustat to be comparable to the "gold standard" of placebo in order for it to avoid the "Black Box" warning. As shown in the chart above, Defendants' *post hoc* manipulated analysis in the NDD group resulted in an upper bound hazard ratio for the key MACE and ACM endpoints of 1.24 and 1.23, respectively—*i.e.*, just under the upper bound threshold of 1.25 that the FDA had told FibroGen it was looking for (a fact FibroGen was still misleadingly withholding from investors, who were still under the false impression that the FDA was using a higher non-inferiority threshold of 1.3). Significantly, however, under the actual FDA prespecified analysis, the upper bound for those endpoints ***exceeded 1.25***, with the real upper bounds for the MACE and ACM endpoints being ***1.27 and 1.26***, respectively—meaning Defendants had long known that Roxadustat had exceeded the FDA's contemplated non-inferiority margin of 1.25 and therefore could not avoid a Black Box warning.

84. Tellingly, Defendants further admitted in the April 6, 2021 press release that they had not only presented the manipulated data to investors, nephrologists, patients and other industry stakeholders throughout the Class Period—and had falsely told investors that the false data was actually the proper FDA prespecified analyses—***but Defendants had also submitted the manipulated data to the FDA in the Roxadustat NDA submission***, necessitating that FibroGen "promptly . . . clarify this issue with the FDA" to "make sure that it was clear which analyses used which factors, prespecified and *post-hoc*." In other words, Defendants had doctored the Roxadustat data in an attempt to not only defraud investors and artificially inflate FibroGen's stock price, but

also to obtain FDA approval for large, undertreated patient populations for whom they knew the drug was fundamentally unsafe. In addition, Defendants had submitted the manipulated data to multiple prestigious medical journals, including "a particular publication of the pooled incident dialysis data" in *Kidney International*—the official journal of the International Society of Nephrology—that Defendants admitted would now have to be *retracted*.

85. Also on April 6, 2021, Defendants held a "Business Update Call" with investors, specifically to address the manipulated data. During the call, Defendants confirmed that the manipulated and false *post hoc* data was what they had touted to investors all along—***not*** the prespecified analysis agreed upon with the FDA, as Defendants had represented throughout the Class Period. Defendants further confirmed that they were publicly disclosing the ***real*** analysis for the ***first time***, stating "the analysis with the prespecified stratification factors ***[had] not been previously publicly reported***." Tellingly, Defendants announced during the call that the AdCom meeting to review Roxadustat's NDA had been scheduled for July 15, 2021—thus, ***Defendants only came clean once the FDA had formally scheduled the AdCom review***.

86. Moreover, during the call, notwithstanding the fact that (i) Roxadustat was FibroGen's single most important drug; (ii) Defendants had made dozens of public statements touting Roxadustat's clinical trial data for ***years***; and (iii) Defendants expressly assured investors that this very data were the results of prespecified analyses agreed upon with the FDA, Defendant Conterno implausibly attempted to claim that the fraudulent manipulation of the data was news to FibroGen's senior management, asserting that it only "recently came to the attention of members of our senior management team, including myself, during our preparation for the upcoming [AdCom]." Tellingly, Defendant Conterno provided no further information on how the *post hoc* changes were made, who made them, when they were made, or how they all could have cut in the Company's favor. Defendant Conterno further attempted to blame prior management by claiming that their failure to detect the issue was the result of management changeover—meaning, by implication, the now-deceased former CEO Neff and the purportedly "retired" Defendant Yu.

87. However, analysts immediately lambasted this obvious spin as "***stretch[ing] the bounds of credibility***," particularly because FibroGen had been representing to investors for over a year, since at least the spring of 2020, that it was rigorously preparing for a potential AdCom review. Indeed, Conterno had commenced his role as CEO in January 2020—more than a year earlier—and he had repeatedly touted to investors that he was intimately familiar with this very data. Significantly, Conterno had specifically highlighted to investors that based on his own personal review of the cardiovascular safety data and his own extensive prior experience with cardiovascular safety trials, he was convinced that Roxadustat's safety data was "***very compelling***," "***extremely clean***," and precisely what "***differentiated***" the drug's approval prospects from competitor treatments, especially with respect to the incident dialysis population—the most important segment and the one that experienced the greatest manipulation among the three patient populations. Accordingly, it defied credulity that Defendant Conterno and the rest of FibroGen management could have been unaware of the fact that the Company had been presenting and repeatedly touting to investors a significantly altered *post hoc* analysis of the Roxadustat data.

88. As a result of Defendants' stunning admissions that they had been touting false Roxadustat clinical trial data to investors for ***over two years***, FibroGen's share price was virtually halved, falling 45% over the next two days, or $15.83 per share, to close at $18.81 per share on April 8, 2021—representing another $1.45 billion decline in market capitalization.

3. In Extraordinary Commentary, Analysts Excoriate Defendants for the "Staggering Admission" That They Had Been "Touting False Heart Safety Data" for Roxadustat "For At Least Two Years"

89. In the wake of Defendants' stunning admissions, many of the world's most prominent market analysts, medical journals and respected doctors in the nephrology community reacted with shock and anger. Significantly, these sophisticated market commentators unequivocally emphasized, in no uncertain terms, that the nature of Defendants' "***data doctoring***" could not have happened by accident or have been carried out by lower-level employees, but were necessarily orchestrated by senior FibroGen officers, thereby fundamentally destroying Roxadustat's value, management's credibility and the Company's future financial prospects.

90. Wall Street analysts uniformly excoriated the Company for the disclosure, noting that it completely contradicted Defendants' prior statements, constituted a "material change" to the drug's safety and efficacy profile, and dramatically decreased the drug's chances for obtaining FDA approval. For example, STAT+—one of the world's preeminent publications covering biotechnology, pharmaceutical, policy and life science analysis—published an article immediately following Defendants' disclosures on April 6, 2021, which underscored the material nature of the data manipulations. The article stated: "the company has been ***touting false heart safety data*** for its experimental anemia pill ***for at least two years—a shocking revelation*** that raises even more questions about the drug's approvability."

91. Similarly, analysts emphasized that the true data established the "the prior conclusion of MACE superiority of roxa" in the critically important incident dialysis population was "no longer supported by the new analysis." For example, an April 7, 2021 Jefferies report cut estimates for FibroGen's share of future sales by $2 billion, and emphasized that the "***key takeaway***" from Defendants' admission was that Roxadustat's true data represented a "***material change***" to the drug's safety profile:

> FGEN announced an important change to prev reported CVOT safety data whereby new analyses pre-specified by FDA show the CV benefit is no longer statistically superior in incident dialysis pts - an important group. . .
>
> Big Picture: We previously lowered our rating (here) due to uncertainty about the regulatory filing and FDA questions which have led to a planned Adcom (now announced for pot'l July 15) and today's news is consistent w/ our view there remains risk and unknowns . . . ***the fact that Incident Dialysis is no longer "statistically" superior - is a material change to the profile and one of the key prior advantages*** for pts. This lowers peak sales and lowers Pos for approval(risk/benefit) and our PT. We believe new disclosures to the Street on statistics of the CVOT safety analyses ***do not give us or investors confidence*** about the rest of the filing (they said an internal review of all other data is underway...) and probability of approval. In our discussions w/ mgmt - it appears both analyses have been in the FDA NDA filing but ***the interpretation (administrative errors or otherwise back in 2019 filing) of the pre-specified and post-hoc analysis was incorrect by the co and was presented incorrectly at conferences and to the Street***.

92. Similarly, on April 7, H.C. Wainwright published a report in which it specifically highlighted that Roxadustat's true data was "weaker than the data the company previously announced and published," that such data was only now released "for the first time to the public,"

and that it was "unclear why the company only 'became aware' of this issue at this point in time." The report specifically emphasized:

> Yesterday after market close, Fibrogen released, for the first time to the public, "analyses with pre-specified stratification factors" of the pooled roxa MACE safety data. ***The new dataset is weaker than the data the company previously announced and published***. Based on the newly released data, the earlier assessment of the roxa clinical profile and market potential have to be modified. ***For instance, the prior conclusion of MACE superiority of roxa in the incident dialysis population is no longer supported by the new analysis***. ***This unfavorable disclosure changes our view on roxa approvability and potential market uptake***, thus we downgrade our FGEN rating from Buy to Neutral, with no price target.
>
> ***
>
> New analyses with the pre-specified stratification factors result in higher hazard ratios (point estimates of relative risk) and 95% confidence intervals . . . ***which do not support the previous conclusions that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to [Epogen]***. Prior analyses (with post-hoc stratification factors) were first presented at ASN in Nov.2019, and the same data have appeared in company presentations and journal publications ever since. According to Fibrogen, all the analyses in the table below, "including the differences in the stratification factors, were included in the NDA", which was submitted in Dec. 2019 (>15months ago). ***We are unclear why the company only "became aware" of this issue at this point in time***, nor do we fully understand how the changes to the stratification factors affect the overall pooled MACE outcome between the two datasets.

93. Other analysts echoed these same exact conclusions. On April 6, 2021, a Raymond James report aptly entitled, "***The Roxa Saga Continues: The Episode We Find Out The MACE Data We Were Presented Aren't Real***," stated that "the prespecified dataset for the primary analysis looks ***meaningfully worse*** than what was presented in the past." The Raymond James report further "question[ed] the willingness of the FDA to overlook this pretty ***significant misstep***," and specifically highlighted FDA approval backlash in light of the fact that FibroGen management "had multiple prior opportunities to 'clarify' the dataset" with the FDA, which "certainly doesn't help in the credibility department." A William Blair analyst report from April 7, 2021 similarly emphasized that FibroGen's disclosure "***will negatively affect management's credibility***"; that the data Defendants reported throughout the Class Period was "inconsistent with analyses with prespecified stratification factors ***as requested by the FDA***"; and that the "more objective unbiased characterization of [R]oxadustat's clinical profile [had] ***never been reported publicly to the medical or investment community***."

94. Similarly, prominent pharmaceutical publications excoriated management for their fraudulent data manipulations. An article published in a major pharmaceutical news outlet, *Evaluate Vantage*, on April 7, 2021, entitled "***FibroGen Stretches the Bounds of Credibility***," directly questioned management's explanation for the data manipulations and underscored the magnitude of the changes. The article noted that Defendants' fraudulent manipulations "concern[] pooled safety data ***first presented back in 2019***" that FibroGen "claimed [] cleared up doubt about [Roxadustat's] safety profile" in CKD patients, and that "FibroGen's claim that [R]oxadustat was safer than [Epogen] formed a big part [of] the project's perceived value." Indeed, the article emphasized that "the real value" of Roxadustat was in its purported safety advantage over Epogen, which would lead to approval for use in non-dialysis patients, and that "the new data cuts make this outcome highly improbable." The article stated that as a result of Defendants' manipulations, "[t]hat value, already diminished by the [C]ompany's opaque disclosure of complex datasets, ***was seriously dented [by] Fibrogen's staggering admission***," which "leaves [R]oxadustat looking like a considerably weaker proposition." The article placed the blame squarely on FibroGen management, noting that during a conference call the prior day "executives studiously avoided analysts' enquiries" regarding the implications of the data manipulations, and that Defendants would "***struggle to shake suspicions***" regarding their role in the "***sorry debacle***."

95. Also on April 7, 2021, *FiercePharma*—a major news outlet that provides regular analysis on news and data on pharmaceutical drug companies—published an article entitled, "Fibrogen Admits To Messing With Roxadustat Safety Data, Upending Hopes For The AZ-Partnered Anemia Drug." The article made crystal clear the magnitude of Defendants' admissions and the intention behind the manipulations: "***In a stunning revelation, FibroGen admitted to presenting roxadustat data manipulated to make the anemia drug look safer than it is***." The article noted that "CEO Enrique Conterno immediately distanced senior management from the ***data doctoring***," but this strained explanation was not credible because the Roxadustat NDA submission was "a do-or-die FDA filing"—and as a result of the "damning" data manipulations, "FibroGen's public credibility is without doubt seriously damaged." Indeed, the article unequivocally

concluded that the nature of FibroGen's data manipulations confirmed that they were intentionally doctored, specifically emphasizing: "***[t]he fact that all nine analyses*** across the patient groups looked less favorable for [R]oxadustat after the change ***raises the suspicion that someone within FibroGen carefully selected the new criteria to make roxa's profile look better***."

96. In addition to market analysts, the country's most prominent nephrologists and medical journals similarly excoriated management for intentionally misleading the investing public and the scientific community for years. For example, a high-profile article published in the American Society of Nephrology entitled, "Did Roxadustat's Results Change From Blockbuster to Lackluster?,"[4] noted that "the net effect" of the "***statistical shenanigans***" was "***to remove [R]oxadustat's evident safety advantage compared with the drugs it would presumably replace***." Significantly, the article directly quoted one of the leading nephrologists in the country, Dr. Daniel W. Coyne, a professor of medicine at Washington University in St. Louis, who had served as a site investigator for Roxadustat trials—meaning that he was the nephrologist assigned to conduct a Roxadustat clinical trial at a particular site. Dr. Coyne emphasized the magnitude of Defendants' changes, stating that "[a]ll the superiority claims have now gone away" and that "the noninferiority claims . . . are a little bit worse." Dr. Coyne was emphatic that Defendants had actively misled the scientific community and had done so intentionally, emphasizing that "[t]his deeply damages the reputation of FibroGen going forward. ***I feel very misled, and I don't think there is any excuse for this. I don't know how this could happen accidentally***."

97. In addition to Dr. Coyne, other prominent members of the scientific community also underscored the magnitude of the changes to Roxadustat's trial data and the apparent intentional nature of Defendants' manipulations. For example, a *TipRanks* article dated April 8, 2021,[5] quoted extensive assessments from Dr. Geoffrey Porges, one of Wall Street's most influential biotechnology analysts. Dr. Porges called FibroGen's admission "***nothing less than stunning***"

[4] http://onlinedigeditions.com/publication/?i=709259&article_id=4045453&view=articleBrowser&ver=html5

[5] https://www.tipranks.com/news/article/is-fibrogen-still-a-buy-following-data-analysis-faux-pas-analyst-weighs-in/.

given that "[t]he re-statement reduced the benefit from [Roxadustat] vs controls in every case, erased the appearance of superiority over ESAs in incident dialysis patients, and increased the apparent risk of a negative effect of [Roxadustat] on CV safety in non-dialysis patients."

98. Other articles further highlighted other indicia of Defendants' knowledge concerning the data manipulations, including the nature of the changes, the lack of insider buying of FibroGen stock, Defendant Yu's sudden "retirement" just months prior to the admissions, and Defendants' failure to specifically acknowledge who was responsible for the manipulations.

99. For example, on May 13, 2021, STAT+ published another article entitled, "FibroGen's Data Manipulation Scandal Came With Questions. There Need To Be Answers." The article specifically emphasized that FibroGen was "reeling from ***the worst case of data manipulation in years***," flatly concluding that "***FibroGen cheated***" and that the "charade lasted nearly two years." In an extraordinary rebuke from a prominent industry publication, the STAT+ article specifically questioned: "***how can anyone – investors, physicians, regulators – trust a company that spent nearly two years touting cardiovascular data that turns out to have been falsified***?" The article also quoted Dr. Coyne, the nephrologist who worked as a site investigator in the Roxadustat trials, who characterized Defendants' Class Period statements concerning Roxadustat's data as "wildly misleading" and stated that he no longer trusted the Company's management after he and other kidney disease specialists "were thrown under the bus" when the Company provided them with false safety data for publication. Noting that Defendant Conterno was "unable to acknowledge the seriousness of the situation" because he failed to explain how the data manipulations occurred, the article concluded that Defendants would be unable to "fully repair the damage to FibroGen, or restore its credibility with investors and physicians" until they were "a lot more transparent about who ordered and carried out the manipulation of safety data – and why."

100. Days later, on May 17, 2021, *SeekingAlpha* published an article titled, "FibroGen's Cardiovascular Data Mess," which further underscored investors' outrage over the manipulations and their skepticism concerning Defendants' explanation. The article explained that FibroGen's "acknowledged manipulation" of Roxadustat's data was "***stark, if not devastating***," and that in

"simple, easy to understand English," this meant that FibroGen executives thought that the data "wasn't good enough . . . [s]o they decided to change the 'stratification factors' . . . nearly 2 years ago ***to make the data look better***." The article noted that Defendants' explanation for the manipulations completely lacked credibility, as it meant that "[t]he 13-member, highly-qualified management team at FibroGen – who earn millions of dollars every year – failed to do their jobs of detecting such hocus pocus before it became public." Underscoring the implausibility of such a scenario, the article highlighted that there was an "***absolute lack of insider buying of a stock which once had so much promise***"—and which Defendants repeatedly trumpeted for two years as on the cusp of capitalizing on a largely untapped, potential $3.5 billion market.

101. The article further emphasized that FibroGen management lost all credibility as a result of the false data, as "the confidence intervals have changed, as has ***the confidence levels in whatever this management says***." The article further noted the suspicious circumstances of this disclosure coming on the heels of Defendant Yu's retirement, noting that "[n]o reason was given" for her departure, that Yu was the lead author of the specific scientific paper regarding the Roxadustat trial data that was now going to be retracted in light of the data manipulations, and that "***[i]t was strange that the Chief Medical Officer would retire just before the most important PDUFA of the company***." The article concluded that "***[Defendant Yu was] responsible*** – just as, being executive management, ***the CEO is responsible for the entire fiasco***."

4. The FDA AdCom Votes Against Approval of Roxadustat After It Reveals, For the First Time, that the Drug Showed a Greater Risk of "Severe" and "Major Adverse Cardiovascular Events" than Epogen

102. Remarkably, even after admitting that they had made significant "*post hoc*" manipulations to Roxadustat's trial data that materially altered the drug's safety and efficacy profile, Defendants continued to falsely insist that the drug's data was sound and that there remained a good chance for FDA approval. Indeed, during the April 6, 2021 Business Update Call, Defendants claimed that "this hasn't changed our confidence in Roxadustat's benefit risk profile," and attempted to reassure investors by stating that they were going to begin "a comprehensive internal review" to "understand how this happened"—even as FibroGen clearly already knew the

extent of Defendants' data manipulations.[6] Accordingly, from April 2021 through the July 15, 2021 FDA AdCom meeting, Defendants repeatedly and falsely asserted and reasserted that "our conclusions that . . . we're comparable to placebo in NDD and comparable in DD to [Epogen] have not changed from a safety perspective"; "we can clearly state that the results with the prespecified stratification factors continue to support comparable cardiovascular safety between Roxadustat and placebo and a positive benefit risk profile"; and "when we look at Roxadustat we view it as . . . comparable to ESAs on [DD] and to placebo on [NDD]." Defendants also expressly represented that the prior efficacy results they had touted—such as the purportedly lower rate of red blood cell transfusions and improvements to quality of life—were still true, stating "we've been able to confirm all those results and that has not changed."

103. The full extent of Defendants' fraud was finally revealed on July 15, 2021, when investors learned that Defendants had ***completely withheld*** from public disclosure *additional* critical prespecified "sensitivity" analyses that had been mandated by, and ultimately revealed by, the FDA. These critical analyses conclusively demonstrated that the true data results for Roxadustat were even *worse* than what Defendants publicly revealed on April 6, 2021—and showed that the drug was in fact ***materially inferior*** to both placebo and Epogen—thereby dooming Roxadustat's FDA approval prospects in their entirety, for any patient population at all.

104. Specifically, on July 15, 2021, the AdCom held a meeting to evaluate Roxadustat's NDA. In the FDA briefing document published for the AdCom meeting, the FDA stated that "[t]he principal issue before the Committee is the drug's safety," and noted that "the drug was hoped to achieve efficacy at least comparable to ESAs, with fewer safety issues." With respect to efficacy, after reviewing Roxadustat's trial data, ***the AdCom concluded that Roxadustat's "benefits are difficult to calculate here***," including the purported red cell blood transfusion benefit which the FDA briefing document found was inconclusive at best. With respect to safety, the AdCom concluded that Roxadustat's safety data demonstrated numerous severe and alarming risks. Indeed, the briefing document noted that "***[t]he rate of death was higher in patients who had received***

[6] As of the date of this filing—a full six months after the Company's disclosure—FibroGen has not released the results or conclusions from this "comprehensive internal review."

[R]oxadustat" as compared to Epogen, with the "leading causes of death [being] infections, 'renal' deaths, and sudden cardiac deaths." The briefing document further highlighted numerous signals for major adverse events associated with Roxadustat use, including "serious thromboembolic events," sepsis, stroke, seizures, congestive heart failure, and hypoglycemia, among several others.

105. Tellingly, it quickly became clear that FibroGen's main strategy for the AdCom meeting was not to defend its Phase 3 trial data, but to present a "dose mitigation strategy" for Roxadustat—*i.e.*, FibroGen was making a last-ditch proposal to lower the dose of Roxadustat in a desperate effort to decrease what it knew were serious safety issues with the drug. However, FibroGen had never tested the proposed lower dosing, and as the AdCom would determine, the reason for that was because it was very likely that if the Roxadustat dose was lowered—while it was possible it could make the drug safer—the drug would likely lose efficacy, particularly compared to Epogen, which was in fact *safer* than Roxadustat despite its "Black Box" warning.

106. After hearing both the FDA's and FibroGen's presentations, AdCom members cited numerous serious safety concerns for Roxadustat, and especially highlighted that "***there were greater rates of some important adverse events with Roxadustat than even epoetin alfa [Epogen]***," in addition to "thrombotic events in particular," which were a significant issue for CKD patients since "vascular access . . . is a lifeline in dialysis patients." With respect to the dose mitigation strategy FibroGen had proposed in a last-ditch effort to calm panelists' concerns and obtain FDA approval for at least some segment of anemia patients, the AdCom members were likewise unconvinced, commenting that it was suspect that even though FibroGen had already completed extensive full Phase 3 clinical trials "using a very specific strategy," it suddenly "now would like approval for a strategy which has been developed only as a simulation." In the end, the panel felt that there was a good chance that at lower doses Roxadustat would "***not match the efficacy of [Epogen]***"—especially considering that the trials already showed that "the retention rate is higher in the [Epogen] group than the Roxadustat group" (meaning patients stayed on Epogen longer than Roxadustat), "and if we lowered the dose of Roxadustat, will that retention difference become even greater."

107. The AdCom's conclusions were derived in large part from additional prespecified "sensitivity" analyses that the FDA had also required and which FibroGen had submitted to the FDA as part of the NDA submission nearly two years earlier, but which Defendants ***never disclosed to investors***. Specifically, Defendants had claimed that the FDA had agreed to the ITT analysis as the primary prespecified analysis for NDD patients (which evaluates patients for safety events long after patients have stopped actively taking the drug), and the OT+7 ("on treatment plus 7 days") analysis as the primary prespecified analysis for DD and incident dialysis patients (which in contrast to ITT evaluates patients for safety events only while they are actively taking the drug). However, Defendants had wholly concealed the fact that the FDA had *also* required prespecified *sensitivity* analyses that were critical for confirming the drug's safety in both populations. For NDD patients, the sensitivity analysis was the OT+7 analysis, because ITT analyses can often result in the artificial dilution of safety events due to the long period of time patients are followed. In DD patients, it was the reverse—the ITT analysis was the sensitivity analysis to account for latent safety events that may materialize long after a patient has stopped taking the drug.

108. Significantly, it was the FDA AdCom—and not Defendants—that finally revealed these FDA-mandated sensitivity analyses to the investing public, and it quickly became clear why the Company had concealed them from investors. Tellingly, these analyses specifically demonstrated that Roxadustat's clinical trial data, including hazard ratios in both the NDD and DD populations, were not only materially worse than the "*post-hoc*" manipulated analysis that Defendants had been falsely touting to investors throughout the Class Period, but also dramatically worse than even the primary prespecified analysis revealed in April 2021, and by a substantial margin. The chart below shows these specific endpoints under (i) Defendants' *post-hoc* manipulated analyses; (ii) the prespecified analyses Defendants revealed in April 2021; and (iii) the "sensitivity" analyses mandated by the FDA, which Defendants never revealed and which were only revealed by the FDA AdCom in July 2021:

Non-Dialysis Dependent (NDD)			
Endpoint	*Post-Hoc* Manipulated Analysis	True, Undisclosed FDA Pre-Specified Analysis	True, Undisclosed FDA Pre-Specified "Sensitivity" Analysis
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)	1.38 (1.11, **1.70**)
ACM	1.06 (0.91, 1.23)	1.08 (0.93, 1.26)	1.40 (1.08, **1.82**)

Dialysis Dependent (DD)			
Endpoint	*Post-Hoc* Manipulated Analysis	True, Undisclosed FDA Pre-Specified Analysis	True, Undisclosed FDA Pre-Specified "Sensitivity" Analysis
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)	1.14 (1.00, **1.30**)
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)	1.17 (1.02, **1.35**)

109. Roxadustat's true, undisclosed FDA prespecified sensitivity analyses irrefutably established that each and every one of Defendants' positive Class Period statements concerning the drug's safety and efficacy were demonstrably false. Indeed, these analyses demonstrated that the hazard ratios that Defendants repeatedly touted during the Class Period were not true representations of Roxadustat's safety, as under the sensitivity analyses, the upper bound hazard ratios for each analysis were all at or significantly above 1.3. This was significant because throughout the Class Period, Defendants had told investors that the FDA's purportedly commonly used upper bound for hazard ratios—the "non-inferiority" margin that the FDA would be looking for in the trial results—was 1.3.

110. Moreover, the FDA confirmed in connection with the AdCom that Defendants' representations concerning the non-inferiority margin of 1.3 that the FDA purportedly "commonly applied" were also false. Indeed, the FDA explicitly stated that the agency ***never "agree[d] with [FibroGen's] proposed [non-inferiority] margin of 1.3***" because "***it was defined [by FibroGen] after the results of the study were known***"—in other words, FibroGen had set the 1.3 target for itself, *post hoc* and after the data were fully unblinded, with no agreement from the FDA. In fact, the FDA further revealed that, during its pre-NDA meetings with FibroGen, the FDA "had a goal of ***1.25***"—*i.e.*, a significantly lower non-inferiority margin than 1.3, ***which Defendants had concealed from investors***—with the FDA specifically noting that "***that's what we discussed during meetings[,] [s]o that's why there was not an agreement on 1.3***." Thus, every statement Defendants

had made during the Class Period about how they had shown "non-inferiority" relative to the upper bound hazard ratio threshold of 1.3, unbeknownst to investors, was materially misleading, since that threshold was completely meaningless as far as the FDA was concerned and in fact, the FDA had expressly told FibroGen that the agency was looking for a goal of 1.25 instead.

111. Given the alarming and severe safety issues that these sensitivity analyses had revealed, the FDA AdCom would ultimately vote overwhelmingly against approving Roxadustat ***for any patient population***. Indeed, citing to the data from the sensitivity analyses, AdCom members noted numerous serious safety concerns for Roxadustat, and especially highlighted that "***there were greater rates of some important adverse events with Roxadustat than even epoetin alfa [Epogen]***." As one doctor and AdCom panel member commented, Roxadustat's decidedly *inferior* safety to Epogen—which itself already had the most severe "Black Box" warning the FDA could give—was especially alarming and raised concerns that Roxadustat had significant *additional* safety risks that caused *additional* deaths than what Epogen would cause:

> [H]ere we have a comparison with a drug [Epogen] which is already labeled for increase in mortality and increase in risks and ***we're seeing estimates here that are either similar to or greater than those seen with [Epogen].*** I guess I'm really concerned about Study 613. 613, as [FibroGen] said, had a little bit higher dose of Roxadustat and maybe a little bit lower dose of [Epogen], and the mortality differences became even more marked**.** So there's something this drug is doing that is maybe different than [Epogen]. And we already know about [Epogen's] risks, and they're in the label, ***so this is a source of concern***.

112. Based on these significant concerns in the efficacy and safety of Roxadustat that were revealed by the previously undisclosed prespecified sensitivity analyses and true trial results, the AdCom panel voted virtually unanimously against approval for Roxadustat. Specifically, the panel voted 13-1 against approval of Roxadustat in NDD patients, with the AdCom meeting minutes stating that committee members had cited in support of their decision, among other things, "***concerning safety risks***" including "risks of thrombosis and mortality" and "untested proposed mitigation dosing strategy with unknown efficacy." The panel further noted in support of their "no" vote that despite Defendants' numerous statements that Roxadustat had shown statistically significant improvement in quality of life, in truth, "members noted a surprising lack of improvement in quality of life." With respect to the DD patients, the panel voted 12-2 against

approval of Roxadustat, with panelists again universally concerned with the drug's safety profile in light of the "***increased mortality when compared to [Epogen]***" and the committee's conclusion that it was "unclear whether the drug's benefit would be maintained with a lower Roxadustat dose."

113. As a result of this development, trading in FibroGen's stock was halted on July 15, 2021. When trading reopened the following day and the market digested what the FDA Advisory Committee had disclosed, investors finally understood the full extent of Defendants' prior misrepresentations concerning Roxadustat's safety profile and the drug's exceedingly slim prospects for FDA approval. In response, the Company's stock price plummeted, falling over 42%, or $10.49 per share, from a prior close of $24.84 per share to close at $14.35 per share on July 16, 2021, on extraordinary volume of over 16 million shares traded.

5. Analysts Expressed Utter Shock Over Roxadustat's True Safety and Efficacy Profile, Which Was "Unknown from the Company's Disclosure [] to Investors Before This Week"

114. Following the FDA AdCom's revelation of Roxadustat's true safety and efficacy profile, analysts were again stunned at Defendants' lack of candor and immediately recognized the severe implications that this information would have on FibroGen's business.

115. For example, a July 16, 2021 article in *BioPharma Dive* entitled, "FDA Advisers Push Back on FibroGen Anemia Drug," noted that "Roxadustat was developed to be a safer, more convenient alternative to Epogen," but that after Defendants' manipulations were revealed and the FDA AdCom "voted against approval of the pill," Roxadustat "doesn't appear to have lived up to the promise of a safer alternative." The article highlighted that Roxadustat's true studies "showed a greater risk of major adverse cardiovascular events than Epogen and similar drugs," and that "some experts on the panel said the data suggest [Roxadustat] may itself create a major risk for blood clots." The article also extensively quoted Dr. Porges, the prominent Wall Street biotechnology analyst who had closely reported on Roxadustat during the Class Period. After reviewing the true data disclosed at the AdCom meeting, Dr. Porges concluded that, "when reviewed in the cold harsh light of day," Roxadustat's true data demonstrated severe and dangerous

risks for CKD patients, and that it was highly unlikely that an additional Phase 3 trial would be funded for the drug, effectively dooming any hope for FDA approval.

116. Significantly, Dr. Porges emphasized that FibroGen management had kept investors completely in the dark regarding these severe risks during the Class Period—and even after the April 2021 admissions regarding Defendants' *post hoc* manipulations—and that investors were only now learning the truth through the damning disclosure by the AdCom:

> We do not believe that AstraZeneca, or FibroGen's investors, will be willing to fund an additional Phase 3 trial . . . When reviewed in the cold harsh light of day, the drug has a positive dose association with mortality, and has signals for severe infection risk, seizures and major cardiovascular events. ***These signals were unknown from the company's disclosure to us and to investors before this week***.

117. Dr. Porges further suggested that, in light of the gravity of Defendants' fraudulent conduct, investors should no longer trust FibroGen management. Specifically, Dr. Porges was quoted in a *FiercePharma* article on August 11, 2021, warning investors of the "***perils of trusting FibroGen's data, management and board***."

118. Other analysts expressed similar shock at the information disclosed by the AdCom. For example, a July 16, 2021 H.C. Wainwright report further stated that the AdCom had "deliver[ed] a strong 'No' to roxa" by delivering "***an overwhelmingly one-sided vote***." The report specifically noted that "[t]he Panel raised ***serious safety concerns on Roxadustat*** in MACE, all-cause death, thrombosis, and seizures among other safety signals" and found that (1) in NDD patients, "risks of myocardial infarction, stroke and systemic hypertension, as well as serious and fatal infections, are ***higher in roxa than placebo***"; and (2) in DD patients "thrombosis, seizures and vascular thrombosis (critical for dialysis patients) are prominent for roxa treatment, and ***these risks are higher in roxa group compared to [Epogen], which already has a safety warning for thrombosis***." The report also noted the issues the panel had cited with respect to Roxadustat's efficacy, including "hemoglobin overcorrection or overshoot," which was "particularly concerning for NDD patients with limited or no [hemoglobin] monitoring," and the "lack of evidence of improvement in quality of life, which is generally associated with improved [hemoglobin] level."

119. Following the end of the Class Period, on August 11, 2021, FibroGen announced what the market had already been expecting: that it had received a "Complete Response Letter" from the FDA confirming that the FDA would not approve Roxadustat for ***any*** patient population. The press release stated, without actually disclosing the Complete Response Letter itself, that "[t]he letter indicates the FDA will not approve the Roxadustat NDA in its present form and has requested additional clinical study of Roxadustat to be conducted." Analysts were unmoved, with an August 11, 2021 Mizuho report stating that after the abysmal FDA AdCom, the FDA's Complete Response Letter for Roxadustat was "widely expected" and thus already "priced into shares following the negative AdCom votes last month." On August 12, 2021, an H.C. Wainwright report similarly stated that "[t]he regulatory rejection came as no surprise to the Street, due to the recent negative AdCom." The report further commented on the incredible nature of Defendants' data manipulations and lack of disclosure and transparency with the investing public, specifically highlighting that there was "***[s]o much to learn from this Roxa saga***, including trial design, regulatory communication, and ***disclose/transparency (esp. to investors)***."

G. Former AstraZeneca Employees Confirm that FibroGen's Most Senior Officers Directly Orchestrated the Fraudulent Data Manipulations

120. In connection with Lead Plaintiffs' independent investigation of Defendants' fraud, Lead Plaintiffs interviewed several former employees of AstraZeneca, FibroGen's corporate partner for the development and commercialization of Roxadustat.[7] These former employees occupied senior positions at AstraZeneca during the Class Period, had direct knowledge of FibroGen's control over the Roxadustat clinical trial data, and interacted on numerous occasions with FibroGen executives regarding the development of the drug. These employees uniformly confirmed that (i) FibroGen had exclusive control over the Roxadustat clinical trials, and the *post hoc* changes to the data were made by the Company's most senior officers and were unknown to AstraZeneca prior to Defendants' admissions at the end of the Class Period; (ii) Defendants' data manipulations destroyed the drug's potential and FibroGen's credibility; and (iii) AstraZeneca and

[7] Former AstraZeneca employees are referred to herein as Confidential Witness "CW __" and are referenced in the feminine form to maintain their confidentiality.

FibroGen became aware of issues regarding Roxadustat's safety data, to the point that a "Black Box" warning, at the very least, was virtually inevitable, ***as early as the fall of 2020***—*i.e.*, several months *before* Defendants were forced to reveal the truth at the end of the Class Period, and at the same time that Defendants were telling investors the exact opposite.

121. *First*, former AstraZeneca employees uniformly recounted that FibroGen—and not AstraZeneca—maintained complete control over the Roxadustat clinical trial data, its NDA submission to the FDA, and its public data presentation throughout the Class Period. For example, CW 1, a former Senior Director of Global Marketing Roxadustat-Global Product Portfolio Strategy ("GPPS") Cardio Renal at AstraZeneca from February 2014 until May 2021,[8] confirmed that "***FibroGen was in control of the data and when the data was released***." CW 1 further confirmed that the process of submitting the Roxadustat data to the FDA "***was all driven by FibroGen***" and "was not normal" given her highly limited visibility into the drug's data, which based on her past experience at AstraZeneca, "was very unusual given the role that I had." CW 1 stated that FibroGen limited the extent to which the Company shared the complete Roxadustat data to AstraZeneca, and that FibroGen had the final say on most data decisions. CW 1 explained that there was a great deal of angst among AstraZeneca managers, who were used to full clinical trial data being readily available to them, because that was not the case with FibroGen.

122. Similarly, CW 2, a former AstraZeneca Renal Sales Specialist from January 2019 until January 2021 who was part of the team preparing to commercialize Roxadustat, also corroborated FibroGen's direct control of the clinical trial data.[9] CW 2 recounted having numerous discussions with Leigh Ann Bradley, another member of the AstraZeneca marketing team for

[8] CW 1 worked for AstraZeneca in Maryland from February 2014 until May 2021 in various roles throughout her tenure, including Senior Director Global Marketing-GPPS Renal Franchise from 2015 through January 2017 and Senior Director, Global Marketing Roxadustat-GPPS Cardio-Renal from January 2017 until May 2021. CW 1 was a senior member of the global launch of Roxadustat in China and the United States. Regarding Roxadustat, CW 1 was responsible for leading the cross functional team in development of the drug's Global commercial strategy and was responsible for collaborating with FibroGen to lead development of global disease and branded message platforms.

[9] CW 2 worked for AstraZeneca in Texas from January 2019 until January 2021 as a Renal Sales Specialist. CW 2 was preparing to sell Roxadustat while FibroGen awaited FDA approval. CW 2 had several years' experience selling anemia drugs, such as Procrit, and she joined AstraZeneca specifically to market Roxadustat.

Roxadustat who attended frequent, and sometimes daily, meetings with FibroGen during 2019 and 2020 in preparation for the commercial launch of the drug. CW 2 recalled discussing with Bradley that FibroGen executives were being "***shady***" during those meetings with respect to Roxadustat's clinical trial data—to the point that Bradley described dealing with FibroGen on data topics as a "***herculean task***"—and that this behavior on the part of FibroGen executives led Bradley to question whether there were issues regarding the data of which AstraZeneca was not aware.

123. CW 3, a former AstraZeneca Global Vice President of Renal and Anemia Therapeutic Areas from November 2013 until January 2021,[10] corroborated the accounts of CW 1 and 2 regarding FibroGen's direct control over the Roxadustat clinical trial data and its submission to the FDA, stating that "FibroGen were the ones managing the [NDA] submission and answering the FDA's questions." CW 3 further stated that FibroGen was laser focused on Wall Street's approval of Roxadustat information, as FibroGen was very much aware that any Roxadustat data that was released could have a major impact on its stock price—in contrast to AstraZeneca, for which Roxadustat had significantly less of an impact and less materiality due to AstraZeneca's dramatically larger and more diverse drug portfolio. CW 3 stated that "FibroGen folks always wanted to make sure that their story got told and they were very aggressive to make sure that as much positive information was put out there as possible. ***They put information and data out there that AstraZeneca would never have done . . . investor confidence was the main game here***."

124. CW 3 further confirmed that it was the most senior officers of FibroGen who personally orchestrated the manipulations to Roxadustat's clinical trial data. For example, CW 3 stated that FibroGen "was Tom [Neff's] company, and ***they were all over every bit of this***. ***The senior people at FibroGen had to have been all over this information, Peony [Yu] had to have been all over the data sets . . . there were [only] a handful of people making all of the decisions***."

[10] CW 3 worked for AstraZeneca in Delaware from November 2013 until January 2021 in various roles throughout her tenure, including most recently, Commercial Business Director, Diabetes Sales Division from October 2016 through May 2018; Executive Director, Marketing-Renal Therapeutic Areas from May 2018 through July 2019; and Global Vice President, Renal and Anemia Therapeutic Areas, US and Global Head from June 2020 through January 2021. In her last role, CW 3 was responsible for expanding the global anemia team delivering the first launch of Roxadustat. CW 3 also put together a team to deliver CKD, oncology, heart failure, and inflammation indications specifically for Roxadustat.

CW 3 also recalled that whenever FibroGen did share information about the clinical trial data with AstraZeneca's commercial team, it was always FibroGen's slides and FibroGen's story being told. CW 3 recalled first-hand attending boardroom meetings during her tenure where Defendant Yu presented data from FibroGen slide decks that appeared incomplete—Defendant Yu "***played fast and loose*** and she had a story to tell even in [those] boardroom meetings."

125. CW 3 further confirmed that AstraZeneca employees held deep reservations concerning FibroGen's presentation of the Roxadustat data. CW 3 stated that "we were asking these questions" and making arguments to see additional data but were not getting any answers from FibroGen. CW 3 stated: "We were never able to get there until right at the end," and thus the feeling at AstraZeneca was an overall lack of belief in the data FibroGen was presenting. CW 3 stated that it was "very tough from that perspective" and created "tension" between the two companies: "***We always felt like there was more data they weren't sharing***." CW 3 stated that when she read about the Roxadustat data manipulations in April 2021, she thought that senior FibroGen officers, and in particular Defendant Yu, spearheaded those manipulations, and that the prior slides AstraZeneca had been shown during those "boardroom meetings" during CW 3's tenure reflected the altered *post hoc* analyses—such that the accurate, prespecified analyses was the data being withheld from AstraZeneca. Indeed, CW 3 confirmed that, at the time, she was made to believe that the data FibroGen was providing to AstraZeneca was the same data being presented to the FDA. "I was always under the assumption that the data we were operating under was considered incredible data and ***that it was agreed to by the FDA***."

126. *Second*, these former AstraZeneca employees confirmed that Defendants manipulated the data to make Roxadustat look better and safer than the drug actually was, and once the true data was revealed, it destroyed the drug's potential and FibroGen management's credibility. For example, CW 2, the former AstraZeneca Renal Sales Specialist who was part of the team preparing to commercialize Roxadustat, stated that upon seeing FibroGen's revelations of the *post hoc* changes, FibroGen lost all credibility at that point given the significance of the data manipulations: "***How can you believe the data now that we have seen what FibroGen has done?***

The relative significance of its efficacy in light of its safety changes everything." CW 2 commented that FibroGen's manipulations of the data had far-reaching implications for the Company's overall reputation and any future prospects for Roxadustat, stating that her father, who has been a nephrologist for over 40 years, had never seen anything like this in medical research where a pharmaceutical company had manipulated clinical trial data in this manner. CW 2 stated that in light of FibroGen's significant safety data manipulations, nephrologists and patients would never trust FibroGen management or their data enough to use Roxadustat. CW 2 stated: "Roxadustat has been very tarnished. ***Once the data was manipulated, [Roxadustat] was lost forever***. Once you burn the trust in the medical community, the nephrologists have to question every piece of data… Approval or not, FibroGen severed their trust in the nephrology space."

127. CW 3 similarly emphasized the magnitude of Defendants' data manipulations and the fact that they completely changed the prospects for Roxadustat. For example, CW 3 stated that, in the end, the difference between the *post hoc* and prespecified analyses was starkly different, especially with respect to the crucial incident dialysis population. CW 3 stated that FibroGen executives had really "***hung their hat***" on the incident dialysis population, and specifically on their assertions that Roxadustat's clinical trial data for this critical group would be significantly better from a safety perspective: "We were statistically significant in a very important population in dialysis and all of a sudden we weren't, ***that's a huge change*** . . . [w]e were touting Roxa as an oral agent as being able to take all of [the safety issues] away, and now suddenly we were not able to take all of that away . . . [it had] all of the same baggage." CW 3 emphasized that the major goal for Roxadustat was to show that the drug was "as safe as placebo," which was "a really big deal," but that its true data confirmed the opposite: "Our story was that we were not only effective, but we did it in a more physiologic way, it was safer. ***If it is not safer, what are you***?"

128. *Third*, these former AstraZeneca employees also gave mutually corroborating accounts of the fact that AstraZeneca first realized that there was something seriously wrong with the Roxadustat trial data when the FDA began raising numerous red flags about Roxadustat's negative safety profile and the definite need for, at the very least, a "Black Box" warning ***in the***

fall of 2020—*i.e.*, several months *before* Defendants would reveal the truth about Roxadustat's safety deficiencies, and *at the same time* that they were touting to investors the purported "strength" of Roxadustat's trial data and their "conviction" regarding FDA approval for the drug.

129. For example, CW 2 stated that around November of 2020 and just before the FDA announced that it would have to delay the PDUFA date by three months, AstraZeneca received its first indication that "something was going on" and the FDA may not approve Roxadustat. CW 2 stated that this was made evident by the fact that AstraZeneca suddenly backed off the training of Roxadustat for its sales reps at that time, despite Roxadustat's purportedly imminent commercial launch. CW 2 stated "[w]e were going hot and heavy with the [Roxadustat] training," and then "they backed off completely on the training, which told us that something was going on with the FDA approval." AstraZeneca switched its sales team to training for a drug called Farxiga instead, which was never mentioned in its original plans. As CW 2 concluded at the time: "***AstraZeneca was trying to pivot realizing that Roxadustat was not coming to market***."

130. CW 3 corroborated CW 2's account, explaining that in the fall of 2020, the FDA began giving clear signals to FibroGen and AstraZeneca that it had become aware of significant safety issues with respect to Roxadustat that, at the very least—and directly contrary to Defendant Conterno's simultaneous public statements stating the opposite—would indeed necessitate a "Black Box" warning: "When they were negotiating the label in the fall of 2020 and getting close to December, we were going back and forth with iterations of the label, it became clear that we were likely going to have a [Black Box] warning." CW 3 explained that, in her role, she was briefed on the safety data as interactions with the FDA were contemporaneously occurring: "I would get a briefing on what it was looking like. I was part of the team that reviewed the label that went to the FDA and was on the calls with other senior leaders [who] were given updates on the sticking points and how we were going to address them through negotiation." CW 3 specifically recalled that the FibroGen development team told the AstraZeneca team during their briefing sessions that the questions the FDA was asking suggested that the agency was concerned about Roxadustat's safety data, including most significantly thrombosis and infection, things that would end up in a Black

Box warning. CW 3 stated: "We sat down with the [FibroGen] team and got an update on where things were and the direction where they were heading, and ***we were told that we are likely going to end up with a [Black Box] warning***."

131. CW 3 stated that news of the Black Box warning was "***a total shock to [AstraZeneca]***," and that, up until that point in the fall of 2020, the FibroGen development team had conveyed to AstraZeneca's commercial team that Roxadustat was an approvable drug from all indications it had received from the FDA, and that the FDA was accepting FibroGen's analyses of the data. CW 3 made clear that because of the materiality of this news, it was shared with a very limited group of senior people between the two companies: "When we got close to the PDUFA [date], we had to come to terms that we were likely going to have a box warning. ***To be very clear, this was not something that was widely known because of the materiality of it. It was kept to a very small group***." As a result, the teams working on Roxadustat continued to operate on scenarios that did not include a Black Box warning, which challenged CW 3's team because her team knew the truth: "So few people were in the know and we could not say anything or tell the teams that were working on it that we were going to have a [Black Box] warning." CW 3 added: "It was hard doing all of this work with the scenarios when we knew in the back of our mind that we were likely going to prepare for a world with a [Black Box] warning. This was shocking but it became more and more apparent that we were going to have one."

132. CW 3 also commented that she thought Defendant Yu's departure announcement in November 2020, right before Roxadustat ostensibly was supposedly set to receive FDA approval for its NDA, was telling. CW 3 recalled that she and others at AstraZeneca read between the lines regarding Yu's purported "retirement" and saw Yu's departure as a way for Defendant Conterno to attempt to right what he knew was a sinking ship. CW 3 recalled that, just weeks later, when the FDA extended its review timeline by three months, things began eroding rapidly. CW 3 explained that the FDA's request for the AdCom meeting to review Roxadustat's NDA, announced shortly thereafter in March 2021, was indicative that the FDA felt that it was dealing with a public relations

issue, and that there were "questions that [the FDA has] been unable to answer, and ***they want outside people to answer these questions***."

133. Accordingly, these accounts from former AstraZeneca employees confirm not only that FibroGen and its senior-most officers maintained complete control over the doctored Roxadustat data throughout the Class Period, but that it was readily apparent at AstraZeneca that the drug's safety profile was an issue for the FDA at the exact same time that Defendants were publicly representing the opposite—representations that were knowingly false.

H. The Individual Defendants Capitalized On FibroGen's Inflated Stock Price, Obtaining $42 Million From Insider Sales and Tens of Millions of Dollars in Compensation Awards During The Class Period

134. As set forth above, in direct response to Defendants' repeated statements falsely touting the purportedly unprecedented efficacy and safety of Roxadustat, FibroGen's stock price skyrocketed from opening at $41.00 per share on the first day of the Class Period to a Class Period high of $59.91 per share on March 1, 2019—a highly significant increase of over 46%.

135. FibroGen insiders took full advantage of this stock price surge, profiting off of FibroGen's artificially inflated stock by engaging in coordinated and substantial insider sales that yielded them ***over $52 million*** in profits. Significantly, the Individual Defendants' sales comprised the lion's share of this amount, totaling ***over $42 million***, or ***over 80%*** of the total insider sales for the entire Company that occurred during the Class Period. Tellingly, former CEO Neff was the largest seller by far, with his sales alone comprising ***over $32 million***, and Neff increased the amount of his sales right as the Class Period was starting. Specifically, while Neff had been selling shares in increments of 19,818 shares leading up to the Class Period, on December 6, 2018—just a few days before the start of the Class Period, when Neff and Defendant Yu would falsely tout Roxadustat's efficacy and safety stemming from the drug's topline Phase 3 clinical trial results—Neff increased his sales to 30,000 shares. In so doing, Neff took full advantage of the run-up in the stock price following Defendants' false statements on the first day of the Class Period, with the stock price increasing by approximately 46% in a few short months. Moreover, Neff's Class Period sales—a total of 683,448 shares sold for proceeds of $32,485,157—constituted a highly material

14% of his total vested securities held as of April 1, 2018, per FibroGen's 2018 Proxy Statement.

136. Defendant Cotroneo, FibroGen's Chief Financial Officer, also made significant insider sales that were suspicious in both timing and amount. Specifically, Cotroneo sold 149,226 shares for gross proceeds of $6,916,517, which constituted nearly 40% of his total vested securities as of April 1, 2018, per FibroGen's 2018 Proxy Statement. Moreover, Defendant Cotroneo made his largest sale of the class period on December 20, 2019, when he made three transactions totaling 59,456 shares sold for proceeds of $2,715,517—a large deviation from his prior sales, when he made sales of 3,201 shares each on June 18, 2019 and September 17, 2019. The December 2019 sale was also exceedingly well-timed to take advantage of a 22% increase in the stock price following FibroGen's release of false safety data on November 8, 2019 at the ASN conference, and Defendants' subsequent adamant reassurances to investor questions regarding the veracity of that data and whether the data was derived pursuant to analyses that were agreed upon by the FDA.

137. Defendant Yu, FibroGen's former CMO, and Defendant Schoeneck, FibroGen's interim CEO, similarly made substantial insider sales, yielding them approximately $2 million and $500 thousand in proceeds, respectively, constituting 14% and 9.5%, respectively, of their total vested holdings as of April 1, 2018 per FibroGen's 2018 Proxy Statement. The chart below shows the total insider sales carried out by the four most senior officers of FibroGen—totaling nearly $42 million, and comprising over 80% of the $52 million in total insider sales effectuated by Company employees during the Class Period—which were sold under highly suspicious circumstances:

Insider Name	Shares Sold During Class Period	Gross Proceeds from Sale	Total Vested Securities Held as of 4/1/18 Per 2018 Proxy Statement	Pct. Sold
Yu, K. Peony	39,456	$1,892,184	280,943	14.0%
Schoeneck, James A.	10,000	$515,457	105,000	9.5%
Neff, Thomas B.	683,448	$32,485,157	4,845,507	14.1%
Cotroneo, Pat	149,226	$6,916,517	384,669	38.8%
Total	**882,130**	**$41,809,315**	**5,616,119**	**15.7%**

138. In addition to these significant insider sales, Defendants also received highly lucrative compensation awards, including bonuses and awards of stock options, that were directly

tied to the Company meeting regulatory and commercial milestones with respect to Roxadustat. For example, former CEO Neff received total compensation of $9.2 million in 2018, which was significantly increased to $11.4 million in 2019, the year FibroGen submitted the Roxadustat NDA. Defendant Yu, the CMO of FibroGen who was primarily overseeing the Roxadustat trials, received $4.5 million in total compensation in 2018, which was significantly increased to $5.8 million in total compensation for 2019. Tellingly, the Company's Class Period Proxy statements confirm that Defendant Yu received over $10 million in Restricted Stock and Option awards that were based in large part on her efforts "in the completion of the Roxadustat MACE safety analysis" and the submission of the Roxadustat NDA to the FDA. Significantly, this non-cash compensation accounted for the lion's share of Defendant Yu's Class Period compensation (79% in 2018; 84% in 2019; and 68% in 2020). Defendant Schoeneck received over $5.2 million in total compensation for his short role as interim CEO of FibroGen in 2019, and Defendant Cotroneo received over $4.3 million in total compensation for his role as CFO (significantly increased from $3.5 million the prior year). Finally, Defendant Conterno, despite having just begun his role as the new CEO of FibroGen upon former CEO Neff's passing in August 2019, received over $12.2 million in total compensation in 2020—and Defendant Eisner, who had just begun his role as the new CMO of FibroGen, received over $3.9 million in total compensation that year.

139. Defendants' insider sales, which were highly suspicious in both timing and amount—and the highly lucrative compensation awards they received due to the purported success of Roxadustat and its supposed unprecedented market prospects—further confirms that the *post hoc* changes Defendants made to the Roxadustat data, and their complete concealment of critical prespecified analyses mandated by the FDA that showed Roxadustat to be inferior to placebo and Epogen in alarming ways, were no accident and were in fact the result of an intentional fraud.

VI. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS

140. Defendants made false and misleading statements and material omissions during the Class Period in violation of Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder. Throughout the Class Period, FibroGen's press releases, investor

presentations, and public filings made with the SEC included material misstatements and/or omissions concerning the Company's financial condition, which included, among other misrepresentations, statements concerning Roxadustat's purported safety and efficacy, its Phase 3 trial results, the drug's NDA approval process, and its prospects for FDA approval.

141. Defendants' representations concerning Roxadustat were false. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of FibroGen's business, operational status, and future growth prospects as, in truth, Defendants had falsely presented to investors a materially misleading portrayal of Roxadustat throughout the Class Period.

A. December 2018 False Statements

142. On December 20, 2018, the first day of the Class Period, FibroGen issued a press release, also filed as a Form 8-K with the SEC, announcing "Positive Topline Results from Three Global Phase 3 Trials of Roxadustat," which included studies of NDD, incident dialysis and DD patients. In the press release, FibroGen's most senior officers made materially false statements regarding the purported efficacy and safety of Roxadustat. For example, FibroGen's then-CEO Neff was quoted as stating "***[t]his is the first well-controlled CKD anemia program that has shown improved efficacy in incident and stable dialysis patients relative to ESA standard of care therapy***." Similarly, Defendant Yu claimed that Roxadustat had "***achieved superiority in efficacy not only against placebo but also over active comparator [Epogen] in our studies,***" and emphasized that "***[t]hese results support [R]oxadustat's potential to bring clinical benefit over current standard of care***." The press release further highlighted certain specific efficacy results, such as that "***in the pre-specified secondary efficacy analysis, Roxadustat-treated patients had a 33% reduction in the risk of blood transfusion compared to [Epogen].***"

143. The press release also included a statement about preliminary safety results being consistent with prior results in other trials, which assured investors that the Company had not observed any concerning safety issues. Specifically, the press release stated: "***The preliminary safety analyses of each of these three individual studies show an overall safety profile consistent***

with the results observed in prior Roxadustat studies. The adverse events reported are consistent with those expected in these study populations with similar background diseases."

144. The statements in ¶¶142-43 were materially false and misleading, and omitted material facts when made because, unbeknownst to investors, the Phase 3 trials of Roxadustat did not show "improved efficacy" and "superiority in efficacy" over placebo or Epogen. To the contrary, the purportedly positive Roxadustat efficacy and safety data Defendants touted was based on Defendants' own improper *post hoc* manipulations of the data that were designed to make the drug look significantly better and safer than it was, and not on any prespecified analyses required by the FDA. In reality, as Defendants would be forced to admit and as the FDA would ultimately determine, Roxadustat's safety signals were so alarming that it was more dangerous than placebo and decidedly *inferior to* and caused *more deaths than* Epogen—rendering Roxadustat too dangerous to be approved *at all.* Thus, there was in fact no proof of *any* efficacy for Roxadustat because at the dosage level FibroGen used in the Phase 3 clinical trials, there were far too many serious safety signals for Roxadustat to warrant approval for any patient population, regardless of any "Black Box" warning.

B. February 2019 False Statements

145. On February 27, 2019, FibroGen held a conference call with analysts and investors to discuss the Company's earnings and operations results for the fourth quarter and full year 2018. During the conference call, former CEO Neff stated that ***all of the Phase 3 Roxadustat studies "have positive top line results" and "support our NDA [to the FDA]."*** Neff further asserted that "***based on our review of the data . . . there is a strong conviction to move ahead to file the NDA . . . this year***." In addition, Defendant Yu stated that "***superiority [to Epogen] was demonstrated in all 3 dialysis studies***," and that ***of "much clinical importance" was the fact that "Roxadustat was [] shown to have a lower [red blood cell] transfusion risk than ESA,"*** which Defendants Yu emphasized was a "big deal" and "could be of great significance to CKD patients." With respect to the preliminary safety data from the trials, Defendant Yu reiterated that the "***[r]esults in individual studies are consistent with what one would expect in the study patient population,"***

and stated that FibroGen was "***encouraged by the robust efficacy results, the preliminary safety data in individual Phase 3 studies and the ongoing pool efficacy and safety analyses***."

146. The statements in ¶145 were materially false and misleading, and omitted material facts when made because, unbeknownst to investors, Defendants had made improper *post hoc* manipulations of the Roxadustat data that were designed to make the drug appear significantly better and safer than it was, and not on any prespecified analysis discussed or agreed upon with the FDA. Indeed, Defendants knew that Roxadustat's efficacy was questionable at best, if it existed at all, and that its safety signals—rather than being "consistent" with prior trials or "expect[ed]" in the study population—were in reality so numerous and "very concern[ing]" under the FDA's mandated prespecified analyses that the FDA would not be able to approve the drug at all. Moreover, Defendants' claims concerning red blood cell transfusion risk in DD patients was false, as the FDA determined that claim to be inconclusive at best based on the drug's true data.

C. May 2019 Statements

147. On May 9, 2019, FibroGen issued a press release, also filed as a Form 8-K with the SEC on the same day, announcing "Positive Topline Results From Pooled Safety Analyses of Roxadustat Global Phase 3 Program," including MACE results (the "May 2019 Press Release"). In that press release, the Company claimed that (i) there was "***no clinically meaningful difference in [MACE] risk***" between the two treatment arms for DD and NDD patients; and that (ii) ***Roxadustat had achieved "[s]uperiority in time to first MACE+ versus [Epogen] in incident dialysis patients"*** and that there was "***a trend toward reduced [MACE] risk for patients on [R]oxadustat***" compared to Epogen. The May 2019 Press Release further stated that "ITT [intention-to-treat]" method was "among the several statistical methods that we will discuss with the FDA," and that ***"[i]n these analyses, Roxadustat was comparable based on a commonly applied non-inferiority margin of 1.3***."

148. The press release also quoted Defendant Yu as stating that "***[w]e are particularly excited about the results indicating a reduction of risk of MACE+ events in incident dialysis patients***," and former CEO Neff as stating that "[w]e are very pleased with what we believe are

important positive results of MACE and MACE+ analyses in the dialysis-dependent, incident dialysis, and non-dialysis dependent CKD patients, supporting the safety of Roxadustat in CKD patients . . . ***these positive safety data give us confidence as we progress in preparation for the U.S NDA*** . . ." The press release further quoted Neff as touting certain Roxadustat efficacy results, namely a "***reduction of transfusion, and the encouraging results from the pooled analyses of Quality of Life***." Defendant Yu similarly was quoted as touting the "additional potential clinical benefits of Roxadustat," including data concerning purported "***improvement of quality of life***," which the press release claimed was "statistically significant" in NDD patients.

149. The statements in ¶¶147-48 were materially false and misleading, and omitted material facts when made. *First*, Defendants' claim that there was no "clinically meaningful difference in risk of MACE between Roxadustat" and placebo in NDD patients—or between Roxadustat and Epogen in DD patients—was false. To the contrary, Defendants improperly manipulated the Roxadustat safety data *post hoc* in order to make the drug appear significantly better and safer than it was. As the FDA would reveal at the end of the Class Period, under the FDA's prespecified analyses, Roxadustat's safety signals were so alarming and "serious" that the drug was more dangerous than placebo and decidedly *inferior to* and caused *more deaths than* Epogen, rendering Roxadustat too dangerous to be approved *at all*.

150. *Second,* as Defendants were well aware, under the FDA's prespecified analyses, there was no statistically significant "superiority" of Roxadustat over Epogen for the MACE+ endpoint in the crucial incident dialysis population, nor was there "a trend toward reduced [MACE] risk for patients on Roxadustat." To the contrary, FibroGen could only claim this result after manipulating the data *post hoc* to make the drug seem much safer than it was. Indeed, based on the *actual* prespecified FDA analyses, Defendants *admitted* in the April 6, 2021 press release that they "***[could not] conclude that Roxadustat reduces the risk of (or is superior to) . . . MACE and MACE+ in incident dialysis compared to [Epogen]***."

151. *Third*, rather than there being any "statistically significant improvements" in quality of life data for NDD patients taking Roxadustat, the exact opposite was true—as the FDA AdCom

would expressly determine, based on the drug's true, undisclosed analyses, there was in fact "a surprising lack of improvement in quality of life" in NDD patients taking Roxadustat.

152. Finally, Defendants' assertion in ¶147 that under the ITT analysis—which Defendants claimed was one of several prespecified analyses discussed with the FDA—Roxadustat had achieved non-inferiority because its hazard ratio was below the "commonly applied" 1.3 threshold was also false. Indeed, as the FDA would reveal during the July 15, 2021 AdCom, in FibroGen's private negotiations with the FDA about the prespecified non-inferiority margin, the FDA in fact ***did "not agree with [FibroGen's] proposed [non-inferiority] margin of 1.3" because "it was defined [by FibroGen] after the results of the study were known"***—in other words, FibroGen had defined the 1.3 margin for itself, *post hoc* and after the data were fully unblinded, with no agreement from the FDA. Moreover, the FDA revealed that, during its pre-NDA meetings with FibroGen, the FDA in fact "had a goal of ***1.25***, and that's what we discussed during meetings[,] [s]o that's why there was not an agreement on 1.3."

153. Also on May 9, 2019, the Company held its first quarter earnings call for 2019. In response to analyst questions about the meaning of the "clinically meaningful" statement, Neff stated that it "***mean[t] that [Roxadustat] met the safety standards that people were looking for and that's why people are moving forward"*** and ***"the message there is we're trending favorably***." Neff and Defendant Yu also further emphasized the purported numerical advantage in MACE+ of Roxadustat versus Epogen, asserting that in "***[e]very one of [the MACE+ categories]***"—which they explained encompassed MACE all events—"***we have a numeric advantage over [Epogen]… Fewer events in Roxa versus ESA in deaths. Fewer events in Roxa versus ESA in myocardial infarction. Fewer strokes in Roxa than ESA. Fewer unstable angina hospitalizations. Fewer congestive heart failures resulting in hospitalizations***."

154. The statements in ¶¶152-53 were materially false and misleading, and omitted material facts when made. Defendants' claims that Roxadustat "met the safety standards that people were looking for" and that there were "fewer" MACE events for the Roxadustat arm than the Epogen arm were plainly false, as Defendants failed to disclose the extraordinarily material

information that they had manipulated the Roxadustat safety data *post hoc* in order to make the drug look significantly better and safer than it was. In truth, as the FDA would reveal at the end of the Class Period, Roxadustat's safety signals were so alarming and "concerning" that the drug was much more dangerous than placebo and decidedly *inferior to* Epogen, rendering Roxadustat too dangerous to be approved *at all*, for any patient population, and regardless of any "Black Box" warning.

155. On the May 9, 2019 call, Defendant Yu continued to strongly tout the Roxadustat results in the NDD and incident dialysis groups in particular. For NDD patients, Yu stated that "***because our drug is so efficacious and so well tolerated, patients really like staying on our drug***," and that, under the purportedly "conservative" ITT analysis, "***the fact that . . . we are able to show non-inferiority to placebo under such conditions***"—which Yu stressed was "***the gold standard for safety***"—"***really illustrates the strength of our drug's safety***." For incident dialysis patients, Yu emphasized that Roxadustat had "superior" safety to Epogen on the MACE+ endpoint by a statistically significant margin, stating "***that we are superior in time to MACE+ analysis in incident dialysis, what I mean is the upper bound of the 95% confidence interval is less than 1***," such that "***when you compare the hazard between Roxadustat to that of [Epogen], we have a very significant p value.***" Furthermore, in response to a question from noted biotech analyst Dr. Porges seeking "reassurance" regarding the "number of deaths, MIs and strokes" (*i.e.*, MACE events) in the overall DD patient population as opposed to the incident dialysis subpopulation, Yu replied, "***we are quite comfortable with the safety result when looking at MACE and MACE+***" and verified that the rates of events in each of the MACE and MACE+ categories were at least comparable as between Roxadustat and Epogen. Specifically, Yu stated: "***[W]hen we tested time to—for example, MACE+ and MACE, Roxadustat was at least non-inferior to [Epogen] even in the conversion stable dialysis patients***."

156. The statements in ¶155 were materially false and misleading, and omitted material facts when made. Defendants' claims that Roxadustat had achieved non-inferiority compared to placebo and statistically significant superiority compared to Epogen in incident dialysis patients

were plainly false, as these statements were based on Defendants' own improper and undisclosed *post hoc* manipulations of the Roxadustat safety data that were designed to make the drug look significantly better and safer than it was, and not on any prespecified analyses agreed upon with the FDA. Indeed, as Defendants were well aware, under the FDA's prespecified analyses, there was no "superiority" of Roxadustat over Epogen for the MACE+ endpoint in the crucial incident dialysis population. To the contrary, and as Defendants would expressly *admit* in the April 6, 2021 press release, FibroGen could only claim this result after manipulating the data *post hoc* to make the drug seem much safer than it was. Indeed, based on the *actual* prespecified FDA analyses, Defendants "***cannot conclude that Roxadustat reduces the risk of (or is superior to) . . . MACE and MACE+ in incident dialysis compared to [Epogen].***"

157. Additionally, during the May 9, 2019 call, Neff and Defendant Yu repeatedly asserted in response to analysts' questions that they were confident in FDA approval due to Roxadustat purportedly achieving statistical non-inferiority using the non-inferiority margin of 1.3, which Defendants stated was the "standard non-inferiority comparison" the "FDA usually asks for." For example, in response to analyst questions regarding the FDA prespecified analysis, Neff stated that the Company felt the ITT results were what "describe[ed] the situation most effectively," and asserted that an upper bound on the hazard ratio of 1.3 under the ITT analysis was the "safety evaluation standard the FDA usually asks for":

> ***[I]n thinking about how to describe the situation most effectively, we decided to describe the ITT results***. This is MACE, MACE+, MACE CV, time to MACE+, time to MACE . . . And ***in each case, the result of the analysis was at a [hazard] ratio of below 1.3, which is a standard non-inferiority comparison in ITT*** . . .

158. Defendant Yu similarly emphasized this point later in the call in response to a direct analyst question about whether Roxadustat had achieved statistical non-inferiority on the FDA's MACE endpoint:

> ***[W]e are using the conventional standards of noninferiority, which is widely published for assessment of CKD anemia and have previously been used by [the FDA] for assessment of cardiovascular safety*** in similar types of composite endpoints…***that standard has been 1.3 for upper bound of 95% confidence interval. If we use that standard, the answer is yes, we have achieved non-inferiority.***

159. The statements in ¶¶157-58 regarding Defendants' assertions that Roxadustat had achieved statistical non-inferiority because it had cleared the 1.3 non-inferiority hazard ratio margin that the FDA would purportedly measure the Roxadustat data against were materially false and misleading, and omitted material facts when made. As Defendants knew but failed to inform investors, the FDA had ***expressly rejected a margin of 1.3*** because it was proposed by FibroGen to the FDA only after-the-fact, *i.e.*, *post hoc* and after the unblinding of the data, and had instead told FibroGen that the FDA needed to see a non-inferiority margin of 1.25. FibroGen therefore could not establish the non-inferiority of Roxadustat by clearing the 1.3 hazard ratio margin in either the NDD or DD patient populations. Moreover, as set forth in the chart in ¶108 above, under the true, undisclosed prespecified analysis (with no *post hoc* changes), for NDD patients, the Roxadustat MACE data in fact ***exceeded*** the upper bound of 1.25 discussed with the FDA, as it was in truth 1.27—and the same was true for the DD population, for which the upper bound MACE hazard ratio under the prespecified ITT analysis also ***exceeded 1.25 and in fact reached 1.3***.

160. Finally, when directly asked by an analyst whether FibroGen believed it would avoid the dreaded "Black Box" warning on Roxadustat's label based on the MACE safety data, Defendant Yu responded: "***[B]ased on what we have seen, we are pretty comfortable with safety. The adjudicated composite safety endpoint was something that we have discussed with the FDA***."

161. The statements in ¶160 were materially false and misleading, and omitted material facts when made. Defendants' assertion that FibroGen was "comfortable with safety" and believed that there would be no need for a "Black Box" warning were materially false, because unbeknownst to investors, Defendants had engaged in fraudulent *post hoc* manipulations of the Roxadustat data that were designed to make the drug appear significantly safer than it was. Indeed, as the FDA would ultimately reveal, Defendants knew that under the actual prespecified analyses agreed upon with the FDA, the Roxadustat safety data showed that the drug had far too numerous serious safety issues to be approved at all, for any patient population, and regardless of any "Black Box" warning.

162. The same day, FibroGen filed with the SEC FibroGen's Form 10-Q for Q1 2019—which was signed and certified by Neff and Defendant Cotroneo—in which the Company reiterated

the topline MACE safety results set forth in the May 2019 Press Release. Specifically, for DD patients, the 10-Q again stated that "[f]or the U.S., where the focus will be on MACE, based on the collective results of the various MACE analyses, we believe there is ***no clinically meaningful difference in MACE risks between roxadustat and epoetin alfa***." For incident dialysis, "there was a trend toward ***reduced risk of MACE for patients on roxadustat, compared to epoetin alfa***." For NDD, "[f]or the U.S., where the focus will be on MACE, based on the collective results of the various MACE analyses, we believe there is ***no clinically meaningful difference in MACE safety between roxadustat and placebo in this same non-dialysis population***." These statements were materially false and misleading, and omitted material facts when made, for the same reasons set forth in ¶¶149-151 above.

D. June 2019 Statements

163. On June 12, 2019, FibroGen participated in the Goldman Sachs 40th Annual Global Healthcare Conference. During the conference, Defendants continued to make unequivocally positive—and false—statements regarding the safety and efficacy of Roxadustat. For example, Defendant Yu once again touted Roxadustat's Phase 3 trial results and the "***compelling evidence confirming [R]oxadustat's cardiovascular safety to support our regulatory filings***." Defendant Yu further reiterated that "***our MACE results in dialysis and in non-dialysis also support the conclusion of no increased cardiovascular safety risk***." Yu also "emphasize[d] [the] MACE+ superiority in [the] incident dialysis pool," and touted certain "efficacy benefits" of Roxadustat, including "transfusion reduction" and "improvement in quality of life."

164. Neff added that the Company was "in a place now ***where we have safety data and efficacy data that's superior to [Epogen] in a U.S. setting"*** and specifically emphasized how Roxadustat was "differentiated" from the competition because it was just as safe as placebo and due to its "outstanding" results in the critical incident dialysis population:

> In the U.S., there are a couple of factors related to ***how we've differentiated ourselves*** and I think in one respect doing the work to do [a] placebo study in CKD ***and show that we are as safe as the placebo control arm is a very exciting place to be*** for purposes of trying to build a marketplace . . . And in the dialysis setting . . . we've ended up creating a pool of almost 1,600 patients in an incident dialysis setting . . . ***we've had outstanding results in this area.*** We think it's the most fair

> comparison of [Epogen] to Roxa. ***We think it opens the door to Roxa being recommended as a first medicine . . . [I]t looks very, very promising at this point.***

165. Neff also asserted that, based on the MACE data the Company had seen, Roxadustat "shouldn't have a 'Black Box'" warning:

> [A] key goal in the U.S. was—with CKD population, a placebo study was to show non-inferior to placebo, to show that there isn't any incremental risk measure so that it ***opens the door to the logic [that Roxadustat] shouldn't have a 'Black Box' for placebo. Therefore, Roxa should not have a 'Black Box'*** and go from there in dealing with dialysis. ***And it's turned out as we hoped for.***

166. The statements in ¶¶163-65 were materially false and misleading, and omitted material facts when made. *First*, Defendants' claims of "compelling evidence confirming Roxadustat's cardiovascular safety"; that they had "safety and efficacy data that's superior to Epogen"; and that Roxadustat was "differentiated" because it was "as safe as placebo" were plainly false, as Defendants had secretly engaged in blatantly improper *post hoc* manipulations to the Roxadustat clinical trial data which were designed to make the drug appear significantly better and safer than it was. As Defendants would *admit* in the April 6, 2021 press release, under the actual prespecified analyses and once the *post hoc* changes Defendants had made were corrected, there was no "superiority" of Roxadustat over Epogen in the crucial incident dialysis population. Moreover, as the FDA would reveal at the end of the Class Period, under the FDA's prespecified sensitivity analyses which Defendants never disclosed during the Class Period, Roxadustat's safety signals were so alarming and "very concern[ing]" that the drug was in truth much more dangerous than placebo and decidedly *inferior to* and causing *more deaths than* Epogen, rendering Roxadustat too dangerous to be approved *at all*, for any patient population. Accordingly, Defendants' statement that Roxadustat's safety data would not warrant any "Black Box" warning was also materially false and misleading—as Defendants knew, their own undisclosed analyses showed that Roxadustat was *less safe* than Epogen, which already had the "Black Box" warning. *Second*, as Defendants knew, and as the FDA would reveal at the end of the Class Period, there was in fact no "statistically significant improvements" in quality-of-life measures for NDD patients taking Roxadustat—to the contrary, the FDA saw no signs of any such improvements at all.

E. August 2019 Statements

167. On August 8, 2019, FibroGen held a conference call with analysts and investors to discuss the Company's earnings and operations results for the second quarter of 2019. On that call, Neff announced that Company had "reached an agreement with the [FDA] on the content of the NDA including the cardiovascular safety analysis." Defendant Yu then emphasized Roxadustat's MACE safety results, stating that "***Phase 3 results confirmed the cardiovascular safety of [R]oxadustat***." Yu further touted FibroGen's interactions with the FDA, highlighting that the Company had a "very good pre-NDA meeting with the FDA on [R]oxadustat" where FibroGen and the FDA reached an agreement "on our proposed pooled MACE analysis." Yu claimed that FibroGen was "***very pleased with the agreement [with the FDA] on the primary safety analysis of our primary cardiovascular safety endpoint in NDD***."

168. In response to an analyst question on the August 8 conference call about whether FibroGen had "confidence around the statistics" in light of the agreement reached with the FDA, Defendant Yu expressed FibroGen's "***confidence on non-inferiority of MACE***," stating that the Company's "***level of confidence is very high***, and we do believe . . . that ***our Phase 3 results confirm cardiovascular safety of [R]oxadustat in the CKD population in both dialysis and non-dialysis***." Yu also further emphasized that "***on the safety side – the ability to demonstrate a drug is as safe as placebo which is a very high bar,*** because placebo is considered to give the drug an opportunity to show how safe it is based on its own merit."

169. The same day, FibroGen filed with the SEC its Form 10-Q for Q2 2019, which was signed and certified by Defendant Cotroneo and Neff. The 10-Q stated that the Company "reached agreement on the content to be included in our NDA submission package for Roxadustat for treatment of anemia in CKD, including the cardiovascular safety analyses for both CKD-dialysis and CKD-non-dialysis. The agreement for non-dialysis is an approach to account for the differential dropout between roxadustat and placebo observed in our Phase 3 studies. ***We are confident we have sufficient data for FDA review of our NDA in both CKD dialysis and CKD non-dialysis*** and we are planning to submit the NDA in October of 2019."

170. The statements in ¶¶167-69 were materially false and misleading, and omitted material facts when made. Specifically, the Phase 3 clinical trials did not "confirm[] the cardiovascular safety of Roxadustat," nor did Defendants have "very high" confidence in Roxadustat's MACE non-inferiority based on the agreement FibroGen had reached with the FDA on the statistical analyses. To the contrary, Defendants had manipulated the Roxadustat data *post hoc* in order to make the drug appear significantly safer than it was. As the FDA would reveal at the end of the Class Period, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "very concern[ing]" that the drug was much more dangerous than placebo and decidedly *inferior to* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population.

F. November 2019 Statements

171. Throughout 2019, FibroGen continued to falsely tout the safety and efficacy results of its studies, claiming that those studies uniformly and unequivocally established that Roxadustat was as safe as placebo and safer than Epogen—all without ever disclosing to investors that they had improperly manipulated Roxadustat's results in all nine studies *post hoc* to make the drug appear safer and better than it in fact was. Thus, for example, on November 8, 2019, FibroGen issued a press release announcing "Positive Phase 3 Pooled Roxadustat Safety and Efficacy Results" that had been presented at the American Society of Nephrology Kidney Week 2019. In the press release, which was also filed with the SEC on Form 8-K, FibroGen announced that (i) ***"Roxadustat cardiovascular safety [was] comparable to placebo in [NDD] patients" under MACE***; (ii) ***it "did not increase risk of MACE and reduced risk of MACE+ compared to [Epogen]" in DD patients***; and (iii) that it purportedly ***"reduced risk of MACE by 30% and MACE+ by 34% compared to [Epogen]" in the crucial incident dialysis population.*** The press release also announced specific MACE hazard ratios. Specifically, the Company reported a MACE hazard ratio of 0.96 (95% confidence interval, 0.82 to an upper bound of 1.13) for DD patients; a MACE hazard ratio of 1.08 (95% confidence interval, 0.94 to an upper bound of 1.24) in NDD patients.; and a MACE hazard ratio of 0.70 (95% confidence interval, 0.51 to an upper bound of

0.96) in incident dialysis patients. The press release proclaimed that, in total, "[t]he pooled safety analyses. . . demonstrate a cardiovascular safety profile comparable with placebo in [NDD] patients, and comparable or in some cases better than that of [Epogen] in patients on dialysis."

172. The press release also purported to expressly clarify that for NDD patients, the results were based on the ***"ITT analysis agreed with the FDA" and that the "[r]isks of MACE, MACE+, and all-cause mortality in Roxadustat patients were comparable to placebo in the ITT analyses based on a reference non-inferiority margin of 1.3."*** In the DD patient population, the release stated that ***"[r]isks of MACE and all-cause mortality in Roxadustat patients were not increased compared to those for patients receiving [Epogen] based on a reference non-inferiority margin of 1.3"*** and further claimed that "[r]isk of MACE+ was 14% lower in Roxadustat-treated patients than in those receiving [Epogen.]." Finally, for the crucial incident dialysis population, the release stated that the ***"[r]isk of MACE was 30% lower in Roxadustat patients than in epoetin alfa patients, and risk of MACE+ was 34% lower."***

173. The statements in ¶¶171-72 were materially false and misleading, and omitted material facts when made. *First,* as Defendants would *admit* in the April 6, 2021 press release, the statements Defendants made about the safety and efficacy results for Roxadustat—including the specific MACE hazard ratios and Defendants' claims that they had achieved "non-inferiority" compared to placebo and statistical superiority compared to Epogen in the crucial incident dialysis population—were materially false because Defendants had *post hoc* manipulated the data to make the drug appear significantly better and safer than it was. Thus, as Defendants would be forced to admit in the April 6, 2021 press release, rather than Roxadustat lowering the MACE risk in the crucial incident dialysis population by a statistically significant 30%, once the *post hoc* changes were corrected ***Defendants could not "conclude that Roxadustat reduces the risk of (or is superior to) MACE+ in [DD], and MACE and MACE+ in incident dialysis compared to [Epogen]" at all***.

174. *Second*, as Defendants well knew, under the prespecified analyses Defendants had agreed upon with the FDA—and in particular the prespecified sensitivity analyses Defendants concealed from investors throughout the Class Period—Roxadustat's cardiovascular safety was not

"comparable to placebo" in NDD patients, nor was it comparable to Epogen in DD patients. To the contrary, Roxadustat's safety signals were so alarming and "very concern[ing]" that the drug was in fact much more dangerous than placebo, and decidedly *inferior to* and caused *more deaths than* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population.

175. *Finally*, Defendants' claims that Roxadustat had achieved inferiority in the MACE endpoint by referencing the non-inferiority margin of 1.3 were also false. As set forth above, the FDA's goal for the Roxadustat trials was a non-inferiority margin of 1.25, not 1.3—and in fact, the FDA had expressly *rejected* FibroGen's proposal of the 1.3 non-inferiority margin because it had chosen that margin for itself *post hoc*, *after* the data had been fully unblinded. Moreover, under the FDA prespecified analyses that FibroGen *never disclosed*—and which were in fact disclosed ***by the FDA*** during the July 15, 2021 AdCom—Roxadustat's hazard ratio margins actually greatly *exceeded* 1.3, with the NDD margin reaching 1.70 under MACE and 1.82 under all-cause mortality, and the DD margin reaching 1.3 under MACE and 1.35 under all-cause mortality. These undisclosed analyses were highly material, as the FDA's AdCom meeting minutes and hearing transcript confirmed that they contributed significantly to the AdCom panel's overwhelming vote recommending against the approval of Roxadustat for any patient population.

G. After Investors Question Whether Roxadustat's Safety Results Were Accurate and Derived From Analyses Agreed Upon by the FDA, Defendants Respond by Vehemently Denying That There Were Any Issues With the Drug's Data

176. Despite Defendants' repeated statements over the previous months concerning the safety and efficacy of Roxadustat, leading up to FibroGen's presentation at the ASN conference, short sellers questioned the veracity of Roxadustat's safety data and whether the data was derived pursuant to analyses that were agreed upon by the FDA, including a November 4, 2019 report authored by short seller Plainview Capital LLC, which caused the Company's stock price to drop approximately 7.5%, from $40.02 on November 1, 2019 to $37.01 on November 4, 2019.

177. In response, on November 11, 2019, FibroGen held a conference call with analysts and investors to discuss the Company's 3Q19 results. During that call, Defendant Schoeneck, the

Company's Interim CEO at the time following former CEO Neff's passing, reaffirmed that Roxadustat's "***cardiovascular safety was comparable to placebo in [NDD] patients***"; "***in [DD] patients, roxa[] did not increase the risk of MACE and reduce[d] the risk of MACE+ compared to [Epogen]***"; and in "***incident dialysis patients, roxa[] reduced MACE by 30% and MACE+ by 34% compared to [Epogen]***," which was purportedly "unlike anything currently on the market in the U.S. or Europe." Schoeneck's statements were materially false and misleading, and omitted material facts when made, for the same reasons set forth in ¶¶173-75 above.

178. During the call, Defendant Yu responded to specific questions about recent "investor concern about FDA agreements and FDA signoff," and reassured investors by stressing that the Company had "a very productive dialogue with the FDA on the analysis of cardiovascular safety" and "***walking out of [the pre-NDA meeting with the FDA], we felt that we had all the guidance from the FDA we needed to put together a winning submission***." When further pressed by analysts on the call about whether she had any concern "about the hazard ratios and the upper bounds" the Company had presented, ***Yu responded that she had "no concern about that" and that FibroGen was "very comfortable with our data where it is now***." Later on the call, when Yu was directly asked again about whether the FDA had signed off on the analyses the Company had presented, Yu responded by unequivocally confirming that the Company's publicly announced results "***were based on the agreed analysis plan that we have made with the FDA***":

> So the answer to that question is that we had already talked with the FDA about [the] 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, and ***the numbers I had just presented, were based on the agreed upon analysis plan that we have made with the FDA*** . . . [W]e are confident that we do have what it takes for this drug to be favorably evaluated.

179. Similarly, in an email published on November 14, 2019 in response to a separate short seller report by BuyersStrike that also questioned whether Roxadustat's data reflected FDA-required analyses, FibroGen unequivocally stated: "We do not agree with this report … ***The data presented at [ASN] reflect the analytical methods and study pools agreed upon with the FDA***."

180. Defendants' vehement denials of these short sellers' concerns, and their adamant reassurances that the positive Roxadustat MACE results the Company had presented were the result

of the prespecified analyses they had agreed upon with the FDA, had their intended effect. Leading up to FibroGen's submission of the Roxadustat NDA in December 2019, FibroGen's stock price surged by over 22%, from $37.01 on November 4, 2019 to $45.30 on December 20, 2019.

181. On November 12, 2019, Defendants filed with the SEC FibroGen's Form 10-Q for Q3 2019, which was signed and certified by Defendants Schoeneck and Cotroneo. The 10-Q further presented ***how the "cardiovascular safety analysis reflects the pooling strategy and analytical approach we agreed on with the FDA***." The 10-Q added that in FibroGen's "pre-NDA meeting, the ***FDA agreed that the ITT-analysis would be our primary cardiovascular safety analysis method for non-dialysis in the U.S***. as it uses on-treatment and post-treatment long term follow-up (until a common study end date) to account for the higher drop-out rate in the placebo arm. ***The figure below shows that in the 4,270 pooled non-dialysis patients (OLYMPUS, ANDES, and ALPS), the risk of MACE, MACE+, and all-cause mortality in Roxadustat patients were comparable to that in placebo patients based on a reference non-inferiority margin of 1.3."***

182. The statements in ¶¶178-81 were materially false and misleading, and omitted material facts when made. *First,* as Defendants well knew, the detailed MACE safety results they had presented were not "based on the agreed upon analysis plan that we have made with the FDA," as the exact opposite was true. In reality, they were based on FibroGen's own *post hoc* analysis of the Roxadustat trial data conducted *after* the data was unblinded and manipulated to make the data appear significantly better than it was. Indeed, Defendants would admit on April 6, 2021 that the hazard ratios for each of the patient populations under the prespecified FDA analyses were in fact, in the words of market analysts, "***meaningfully worse***" in every patient population. Defendants therefore knew that they did not have what they needed for a "winning submission" to the FDA for Roxadustat. Moreover, under the FDA's actual prespecified analyses, Roxadustat's safety signals were so alarming and "serious" that the drug was in fact much more dangerous than placebo, and decidedly *inferior to* and caused *more deaths than* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population.

183. *Second*, Defendants' claims that Roxadustat had achieved non-inferiority in the MACE endpoint by referencing the non-inferiority margin of 1.3 was also false. As set forth above, the FDA revealed during the AdCom that it had never agreed with FibroGen on a non-inferiority hazard ratio margin of 1.3—to the contrary, based on prior experience with ESAs, the FDA's goal was a non-inferiority margin of 1.25. Moreover, under the FDA prespecified sensitivity analyses that FibroGen ***never disclosed***—and which were in fact disclosed ***by the FDA*** during the July 15, 2021 AdCom—Roxadustat's hazard ratio margins were significantly worse and in fact greatly ***exceeded*** 1.25 *and* 1.3 in every key endpoint.

H. February 2020 Statements

184. On February 25, 2020, Defendant Conterno presented at the SVB Leerink Global Healthcare Conference, where he made a series of false statements touting the purported safety of Roxadustat. For example, at the conference, Defendant Conterno stated that "***the [Roxadustat] data that we have on cardiovascular safety is very compelling***." Defendant Conterno went on to say that "***when we look at the data, basically – we basically show to be comparable to placebo***" and that "***our data [is] extremely clean … from my perspective when it comes to cardiovascular safety***." Conterno emphasized that "***we have a trial that, in my view, basically, shows safety against what I think is a very high hurdle of placebo***." Defendant Conterno further asserted that, based on his review of the data, "***I do not believe that the data warrants a 'Black Box'" warning,*** and while not receiving the warning would require Roxadustat to meet "a pretty high standard," Conterno was "***very excited and delighted with the results that we got . . . out of cardiovascular safety***." Conterno further asserted that based on the only guidance the Company had purportedly received from the FDA, which was for diabetes***, there was "a 1.3 upper bound" for non-inferiority***, and ***"when we looked at the pooled analysis . . we do basically see hazard ratios, about 1—slightly higher than 1, but the upper bound in each one of these cases, is below 1.3***."

185. The statements in ¶184 were materially false and misleading, and omitted material facts when made. *First*, Defendants' claims of "very compelling" cardiovascular safety data for Roxadustat, and that Roxadustat was "comparable to placebo," were plainly false because they

were based on Defendants' *post hoc* manipulations of the Roxadustat data that were designed to make the data appear significantly better and safe than it was. In truth, under the FDA's prespecified analyses, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo and decidedly *inferior to* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. For this reason, Defendants' suggestion that Roxadustat's safety data would not warrant any "Black Box" warning was also materially false and misleading—as Defendants knew, Roxadustat was already *less safe* than Epogen, which itself already had the "Black Box" warning.

186. *Second*, Defendants' claims that Roxadustat had achieved inferiority in the MACE endpoint by referencing the non-inferiority margin of 1.3 was also false. As set forth above, the FDA revealed during the AdCom that it had never agreed with FibroGen on a non-inferiority hazard ratio margin of 1.3—to the contrary, based on prior experience with ESAs the FDA's goal was a non-inferiority margin of 1.25. Moreover, under the FDA prespecified analyses that FibroGen *never disclosed*—and which were in fact disclosed *by the FDA only* during the July 15, 2021 AdCom—Roxadustat's hazard ratio margins were significantly worse and reached or *exceeded* 1.3 in every key endpoint.

I. March 2020 Statements

187. On March 2, 2020, FibroGen reported financial results for the fourth quarter and full year of 2019. Once again, Defendants raved about the safety and efficacy of Roxadustat. For example, during FibroGen's March 2 analyst call, Defendant Yu stated that "[R]oxadustat can potentially better address CKD anemia than what is currently available to CKD patients on dialysis and those not on dialysis" due to "***the robust efficacy and safety profile demonstrated***." In particular, Yu referenced the purported "***lower transfusion risk than [Epogen] patients, while lowering MACE+ risk in the dialysis patient pool***" and highlighted that FibroGen was "***particularly excited about the cardiovascular safety results of the incident dialysis population***," which purportedly "***demonstrated a meaningful reduction in cardiovascular safety risk, as Roxadustat-treated incident dialysis patients had a 30% lower MACE risk and a 34% lower***

MACE+ than [Epogen]-treated patients." Yu further stated that, ***"with respect to cardiovascular safety, Roxadustat was comparable to placebo in risk of MACE and MACE+***" and that "we have designed a program to demonstrate safety in comparison to placebo and with the hope and ***confidence of gaining clean safety label for non-dialysis***." FibroGen reiterated these results in its 2019 Form 10-K filed the same day, which was signed by Defendants Conterno and Cotroneo.

188. The statements in ¶187 were materially false and misleading, and omitted material facts when made. *First*, Defendants' claims of Roxadustat's "robust" safety and efficacy data, and that Roxadustat had "demonstrated a meaningful reduction" in MACE and MACE+ risk over Epogen for the incident dialysis population, were plainly false as these statements were based on Defendants' *post hoc* manipulations of the Roxadustat data that were designed to make the drug appear significantly safer than it was. As Defendants admitted on April 26, 2021—and contrary to Defendants' statements above—under the actual prespecified analyses agreed upon with the FDA, "we cannot conclude that Roxadustat reduces the risk of (or is superior to) MACE+ in [DD], and MACE and MACE+ in incident dialysis compared to [Epogen]." Moreover, under the FDA's prespecified sensitivity analyses that Defendants never disclosed during the Class Period, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than (and not at all comparable to) placebo and decidedly *inferior to* and causing *more deaths than* Epogen, the current standard of care for which there was already a "Black Box" warning—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. For this reason, Defendants' suggestion that Roxadustat's safety data would warrant a "clean safety label" for NDD patients was similarly false—as Defendants knew, Roxadustat was already *less safe* than Epogen, which itself already had the "Black Box" warning.

J. May 2020 Statements

189. On May 7, 2020, FibroGen held a conference call to discuss the Company's financial results for the first quarter 2020. Regarding Roxadustat safety, Defendant Yu stated that "[i]mportantly, ***we have demonstrated cardiovascular safety in the overall dialysis population and in MACE*** . . . In our 1,530-incident dialysis patient pool, where the comparison between Roxadustat

with epoetin alpha started within the first 4 months of dialysis initiation, ***Roxadustat had a 30% lower risk of MACE and 34% lower risk of MACE+ than [Epogen], with a trend towards lower or cause mortality, relative to [Epogen]***." With respect to DD patients, Yu stated "looking at safety -- ***cardiovascular safety, it does not change any of the conclusions that we have on the -- about Roxadustat being safe and efficacious."*** With respect to NDD patients, Yu asserted that ***"placebo is the gold standard. With -- in comparison to placebo, we have demonstrated that cardiovascular safety in the MACE endpoint and MACE+ endpoint.***" Yu stated that, ***"in conclusion, Roxadustat, excellent cardiovascular safety profile***, coupled with the statistically significant and clinically meaningful, higher hemoglobin efficacy results and ***lower transfusion rate relative to epoetin alfa,*** together makes Roxadustat potentially a better treatment option for dialysis-dependent patients. ***We like the hand that we have and expect the product label to reflect the results of clinical trials*** on our compound."

190. On May 14, 2020, FibroGen participated in the Bank of America Securities 2020 Health Care Conference. During the conference, Defendant Conterno stated that "lower transfusions," the "compelling" "overall cardiovascular data" and the "quite meaningful" results in the incident dialysis population ***differentiated***" Roxadustat from its competitors:

> [A]s I think about the differentiation of Roxa, number one, I think you have to start with efficacy . . . ***We actually had lower transfusions with Roxa than with [Epogen] . . . So that benefit to me, I think, is pretty significant***. Clearly, in the—when we look at the totality of the data, ***I find our overall cardiovascular data pretty compellin***g. And in particular, I think ***we need to highlight the incident dialysis data, whereby we basically show a reduction in risk of MACE events at a time that is critical***. And this is—incident dialysis, basically, covers those patients within the first 4 months of starting dialysis. That is the time when a treatment decision is made when it comes to anemia . . . So that I find also quite meaningful. And clearly the data is highly—it was—***compared to [Epogen], it's highly differentiated based on what we can see.***

191. The statements in ¶¶189-90 were materially false and misleading, and omitted material facts when made. In reality, Defendants knew that they had not "demonstrated cardiovascular safety" for Roxadustat, that Roxadustat was not comparable to placebo or Epogen, and that it was not statistically superior to Epogen in the incident dialysis population, because unbeknownst to investors, Defendants' had improperly *post hoc* manipulated the Roxadustat data

to make the drug appear significantly better and safer than it was. Indeed, as Defendants were forced to admit on April 6, 2021—and contrary to Defendants' statements above highlighting the purported statistically significant 30% and 34% reduction in MACE and MACE+ risk in the crucial incident dialysis population—under Roxadustat's true, undisclosed prespecified analyses, there was no evidence of any purported reduction of MACE risk in this population *at all.* Furthermore, as the FDA would determine during the July 15, 2021 AdCom, under the prespecified sensitivity analyses that Defendants had concealed from investors, Roxadustat was decidedly *inferior* to placebo and Epogen, despite Epogen's "Black Box" warning." Moreover, Defendants knew that Roxadustat's efficacy was also not superior to Epogen. As the DFA would determine, Roxadustat's efficacy benefits compared to existing therapies were, at best, "unclear" and "difficult to calculate," with the FDA stating that the claimed reduction in blood transfusions versus Epogen was inconclusive at best and ***likely nonexistent*** at the untested lower doses that the Company was ultimately forced to propose in order to address significant safety issues.

K. June 2020 Statements

192. In June of 2020, Defendants attended numerous investor conferences specifically to tout the supposed extraordinary benefits and safety results of Roxadustat. For example, on June 2, 2020, the Company participated in the Jefferies 2020 Healthcare Conference. At the conference, with respect to Roxadustat, Defendant Conterno again touted the Company's "data," without disclosing the highly material fact that FibroGen had improperly manipulated that data to make the drug appear safer and better than it really was:

> [W]hen we look at our data, ***I feel it basically shows that the product is safe because of the safety profile when it comes to CV comparable to placebo*** . . . [I]n [DD], ***when it comes to incident dialysis, we do show an actual significant benefit, well, with a 30% reduction in MAC***E . . . When I put those two reasons together, ***I look at the compelling nature of our data, and I feel that . . . there's no warrant [for a] Black Box*** . . .

193. On June 4, 2020, FibroGen held its 2020 Annual Meeting of Stockholders for FibroGen, Inc. Defendant Conterno stressed to investors the importance of the MACE safety results in incident dialysis patients, stating:

> ***Importantly, CV safety was demonstrated across all studied populations. Non-***

> ***dialysis-dependent, incident dialysis and dialysis dependent.. . In incident dialysis patients, Roxadustat reduced risk of major adverse cardiovascular events or MACE by 30%***. And reduce[d] the risk of MACE+ by 34% compared to [Epogen]. ***Both results were statistically significant . . . Roxadustat clearly provides a large clinical benefit in the incident dialysis patient population***, and we believe this is a natural decision point for health care professional[s] when selecting which therapeutic agent will be utilized in the treatment of anemia.

194. The statements in ¶¶192-93 were materially false and misleading, and omitted material facts when made. Defendants' statements that Roxadustat was "safe," "comparable to placebo," and had shown a "significant benefit" in incident dialysis patients by lowering the MACE and MACE+ risk by a statistically significant 30% and 34%, respectively, were plainly false, as all of these statements were based on Defendants' *post hoc* manipulations of the Roxadustat data to make it appear significantly better and safer than it was. Indeed, the purported "statistically significant" and "unbelievable" MACE benefit in incident dialysis patients was only present under Defendants' *post hoc* analysis manipulating the safety data to look much better than it was— as Defendants *admitted* on April 6, 2021, under the actual prespecified analyses agreed upon with the FDA, Defendants could not "conclude that Roxadustat reduces the risk of . . . MACE and MACE+ in incident dialysis compared to [Epogen]." Moreover, rather than the Roxadustat data not warranting a "Black Box" warning, in truth, under the FDA's prespecified sensitivity analyses that Defendants never disclosed to investors, Roxadustat's safety signals were so alarming and "serious" that the drug was *inferior to* Epogen, which already carried a "Black Box" warning— rendering Roxadustat too dangerous to be approved *at all*. Finally, as the FDA would determine, Roxadustat's efficacy benefits compared to existing therapies were, at best, "unclear" and "difficult to calculate," with the FDA stating that the claimed reduction in blood transfusions versus Epogen Defendant Conterno touted was in fact inconclusive at best and ***likely nonexistent*** at the untested lower doses that the Company was ultimately forced to propose in order to address significant safety issues.

195. On June 9, 2020, FibroGen participated in the Goldman Sachs 41st Annual Global Healthcare Conference. During the conference, Defendant Conterno again emphasized the "***huge***" and "***compelling***" results in the incident dialysis population, which "***differentiated***" the drug:

> I think as you know, I've been very excited about our incident dialysis data and ***the***

> ***fact that we showed a 30% reduction in MACE risk and 34% when it comes to MACE plus. Honestly, that's huge and that's an anchor***. Because as patients start dialysis, clearly part of that dialysis initiation is going to be treatment of anemia. And I believe that ***we have the very best data. It's quite compelling and differentiated.***

196. Defendant Conterno later reiterated again on the June 9, 2020 call that ***Roxadustat had "showed a significant benefit when it comes to MACE in [the incident dialysis] population, 30% reduction in MACE,"*** which was an ***"unbelievable result"*** and ***"probably the most compelling data that we have."*** Defendant Conterno further represented that ***"given that [FibroGen] showed [Roxadustat had] basically comparable safety to placebo"—which was "very difficult to achieve"—the Company had "the very best chance basically to have a label without a 'Black Box."***

197. The statements in ¶¶195-96 were materially false and misleading, and omitted material facts when made. Indeed, the purported "statistically significant" and "unbelievable" MACE benefit in incident dialysis patients taking Roxadustat was only present because Defendants manipulated the safety data to look much better than it was. As Defendants *admitted* on April 6, 2021, rather than lowering the MACE and MACE+ risk in incident dialysis patients by a statistically significant 30% and 34%, respectively, the actual prespecified analyses agreed upon with the FDA showed the exact opposite, to the point that Defendants were forced to admit that they "cannot conclude that Roxadustat reduces the risk of . . . MACE and MACE+ in incident dialysis compared to [Epogen]." In other words, there was no evidence of any purported reduction of MACE risk in this population *at all.* Moreover, rather than the Roxadustat data not warranting a "Black Box" warning, the exact opposite was true. Under the FDA's prespecified sensitivity analyses that Defendants never disclosed to investors, Roxadustat was decidedly *inferior to* Epogen, and too dangerous to be approved *at all*.

L. August 2020 Statements

198. On August 6, 2020, FibroGen held a conference call with investors, where Defendant Conterno further discussed the FDA's review, stating that Defendants continued to expect an FDA decision on the Roxadustat NDA by the PDUFA date of December 20, 2020 and that the FDA had indicated that an advisory committee meeting was not planned at that time. While

Conterno stated that moving forward, there would be no public discussion regarding labeling, he stated "clearly, ***we view that Roxadustat will be successful*** -- I think I've mentioned this to you and others in the past, ***very successful regardless*** … ***We continue to view that our data shows a very positive benefit-risk profile for the product."*** Conterno added, ***"our engagement and our interaction with the FDA was positive***. ***So we feel good about the progress that we are making."***

199. Also on August 6, 2020, FibroGen filed its 2Q 2020 Form 10-Q, which was signed and certified by Defendants Conterno and Cotroneo, and which stated that "***the Company received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials for Roxadustat, enabling the Company's NDA submission to the FDA***."

200. The statements in ¶¶198-99 were materially false and misleading, and omitted material facts when made. Defendants' claim that "Roxadustat will be successful," that FibroGen had "positive" "engagement with the FDA," and that the Company had "positive" MACE results for Roxadustat that supported the NDA submission were plainly false because all of these statements were entirely dependent upon Defendants' own *post-hoc* manipulations that completely altered the actual Roxadustat MACE results and made the drug seem much safer than it was. In truth, as the FDA would reveal at the end of the Class Period, under the FDA's prespecified analyses—which Defendants were not "pleased" with and in fact attempted to desperately conceal throughout the Class Period—Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo and decidedly *inferior* to Epogen, the current standard of care for which there was already a "Black Box" warning—rendering Roxadustat too dangerous to be approved *at all*, for any patient population.

M. September 2020 Statements

201. In the fall of 2020, Defendants continued on their tour of investor conferences, during all of which they further touted the purportedly "highly compelling" efficacy and safety of Roxadustat. For example, on September 9, 2020, FibroGen participated in the Citigroup 15th Annual BioPharma Conference, during which a Citigroup analyst asked how investors should think about Roxadustat in light of its main competitor's negative safety results released the prior week.

Specifically, competitor Akebia's anemia drug Vadadustat had failed to show non-inferiority in the NDD group compared to ESAs, with a hazard ratio above 1.25. Defendant Conterno responded by reaffirming Roxadustat's MACE results in the NDD population, citing ***"the significant level of evidence that we have already with Roxadustat around NDD,"*** and how the Company was ***"able to show non-inferiority relative to placebo, which is a higher bar than a comparison to a product that had – or product [that has] box warnings. So we feel very good about our pool MACE data in NDD."*** Defendant Conterno further stated that the Company's "excellent data" did not warrant a "Black Box" warning, and that FibroGen's engagement with the FDA on the issue was positive:

> I think what I can say is ***we feel very good about where we are in terms of the review with the FDA,*** the level of engagement that we have. I know this question about a [Black Box] warning comes often, which is are going to get one or not . . . But we feel very good about the level of energy that we have. ***I think what I've said before is that we have excellent data. We don't believe that the data that we have warrants a [Black Box] warning.***

202. The Company participated in the Morgan Stanley 18th Annual Global Healthcare Conference on September 16, 2020. Conterno commenced the conference by touting the MACE data for Roxa, stating "Roxadustat has a very significant data set in NDD . . . ***when we look at MACE, we were non-inferior relative to placebo, which is a higher bar than ESAs would be. So we feel very good about our data there***."

203. The statements in ¶¶201-202 were materially false and misleading, and omitted material facts when made. *First*, all of Defendants' statements that the Company had shown Roxadustat was "non-inferior" to placebo, that no Black Box warning would be required, and that conversations with the FDA were going well due to the Company's "excellent" Roxadustat data were false because they were entirely dependent upon Defendants' own *post-hoc* manipulations that completely altered the actual Roxadustat clinical trial results and made the drug seem much better and safer than it was. In reality, Roxadustat was not "comparable to placebo," as under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo *and* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. For this reason, Defendants' statement that Roxadustat's safety data would not warrant any "Black Box"

warning was also materially false and misleading—as Defendants knew, under prespecified analyses, Roxadustat was already *less safe* than Epogen, which itself already had the "Black Box" warning. Indeed, as CW 3 would confirm, the FDA concluded as much by no later than the fall of 2020, when it directly informed Defendants that—at the very least—Roxadustat would most definitely require a "Black Box" warning, if it could be approved at all.

204. *Second*, Defendants knew but failed to reveal in response to the analyst's direct question that, just like Akebia's drug Vadadustat, in NDD patients, Roxadustat had also failed to reach the MACE safety non-inferiority margin the FDA was looking for—which, unbeknownst to investors and as the FDA would reveal during the July 15, 2021 AdCom, was 1.25 and not 1.3. Indeed, as FibroGen would admit on April 6 ,2021, the FDA's prespecified ITT analysis showed a hazard ratio for NDD patients with an upper bound of ***1.27***—and as the FDA would reveal on July 15, 2021, the undisclosed prespecified sensitivity analysis for NDD patients on Roxadustat was even *worse*, as it showed ***an overall hazard ratio of 1.38 with an upper bound reaching 1.7.***

N. November 2020 Statements

205. On November 5, 2020, FibroGen held a conference call with investors during which Defendant Conterno stated that the "Roxadustat ***clinical data demonstrated consistent efficacy and reassuring safety results across the continuum of CKD patients with anemia.***" Regarding NDD patients, Conterno stated that Roxadustat "has the ***right efficacy safety profile to be able to have a really good uptake in the NDD setting and be able to be a catalyst for the overall expansion of that market."*** Further discussing NDD, Conterno told investors that "I think what's important is when -- first, when we look at the overall trial, we basically see that in ***NDD, we were comparable to placebo. So that's when it comes to MACE. So that's critically important. We showed non-inferiority."*** Regarding incident dialysis patients, Conterno stated, "I think if we think about straight off the bat, in incident dialysis, ***the excellent data that we have with – showing basically reduced cardiovascular outcomes in this population***, ***so that's extremely important***."

206. The statements in ¶205 were materially false and misleading, and omitted material facts when made. Defendants' statements that Roxadustat's clinical trial data "demonstrated

consistent efficacy and reassuring safety" across the tested patient populations, that it was "comparable" to placebo, and that there were "reduced cardiovascular outcomes" in incident dialysis patients were false. In reality, these statements were entirely dependent upon Defendants' own *post-hoc* manipulations that completely altered the actual Roxadustat data and made the drug seem much better and safer than it really was. Indeed, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo *and* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population.

207. Later that month, FibroGen also participated in the Stifel 2020 Virtual Healthcare Conference on November 17, 2020. During the conference, analysts queried whether the fact that the FDA had never called an Advisory Committee—or a committee of external experts the FDA would often call to assist it in evaluating new drugs that may require particular expertise--to review the Roxadustat NDA was a positive sign. In response, Defendant Conterno cited FibroGen's "very compelling" data the Company had previously shared with the FDA that had "[c]learly . . . demonstrated both the efficacy and the safety" of Roxadustat:

> Given the chance of an AdCom, ***we had to prepare for one but that's really water under the bridge***… at this stage, I think what I can say is basically we have to ***rely on the data that we've shared.*** And I feel that ***the data that we shared,*** I think is ***very compelling when it comes to Roxadustat***…the broad safety data that we have first thing in DD where we look at both our safety data there when we compare to ESAs. As you know ***we had pretty compelling data when it comes to incident dialysis we had statistics in terms of a reduction in the number of MACE events in that setting.*** And then when we look ***at NDD, we were compared to placebo and we basically had comparability when it comes to overall safety***. So, feel very good about the overall package that we had . . . ***Clearly we've already said and have demonstrated both the efficacy and the safety of the product***.

208. FibroGen also participated in the Jefferies Virtual London Healthcare Conference on November 19, 2020. As in the conference two days before, Conterno told investors: "***Clearly, we have a high level of conviction on the overall submission, the strength of our data***…" Conterno reiterated, "Clearly, I think the -- ***when we look at our data, we continue to feel that the data basically offers a very favorable risk-benefit profile for patients across the continuum***." "[W]here ESAs are really not working very well," Conterno stated that "Roxadustat will be an

excellent option there, okay? ***What about the incident dialysis population, where we basically showed a very significant benefit when it comes to MACE and MACE+***."

209. The statements in ¶¶207-208 were materially false and misleading, and omitted material facts when made. Defendants' statements they had "[c]learly . . . demonstrated both the efficacy and the safety" of Roxadustat, and that the "compelling" Roxadustat data and its "very favorable risk-benefit profile" gave them a "high level of conviction" in FDA approval, were plainly false because Defendants had *post hoc* manipulated the Roxadustat data in order to make the drug appear significantly better and safer than it was. Nor had Roxadustat shown "a very significant benefit" in the incident dialysis population. As Defendants *admitted* on April 6, 2021, rather than lowering the MACE and MACE+ risk in incident dialysis patients by a statistically significant 30% and 34%, respectively, the actual prespecified analyses agreed upon with the FDA showed the exact opposite, to the point that Defendants were forced to admit that they could not "conclude that Roxadustat reduces the risk of . . . MACE and MACE+ in incident dialysis compared to [Epogen]"—meaning that there was no evidence of any purported reduction of MACE risk in this population *at all*. Furthermore, as Defendants were well aware, Roxadustat's cardiovascular safety data did not support FDA approval. Rather, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug decidedly *inferior to* placebo *and* Epogen—rendering Roxadustat too dangerous to be approved *at all*. Indeed, as confirmed by Plaintiffs' CWs, by November 2020 the FDA had already informed Defendants that due to numerous safety concerns with Roxadustat, at the very least, a "Black Box" warning would be required for Roxadustat.

O. December 2020 Statements

210. In mid-November 2020, an FDA Citizen Petition—which is a process provided by the FDA for individuals and community organizations to provide input on the FDA's evaluation of New Drug Applications—was filed requesting that the FDA decline approval of Roxadustat pending more data demonstrating that the drug's benefits outweighed the risks and asking for a "Black Box" warning indicating that the MACE risk was similar to Epogen. The Citizen Petition

further alleged that Defendants' presentation of the detailed MACE safety data at the November 8, 2019 ASN conference had improperly "disguised" significant safety concerns for Roxadustat.

211. On December 9, 2020, Senior Vice President Frost sent a letter to the FDA on behalf of FibroGen providing a strong rebuttal to the claims made in the Citizen Petition. Specifically, Frost unequivocally asserted that "***[c]ardiovascular safety of Roxadustat was also carefully evaluated, and demonstrated in the Phase 3 program,*** by assessment of major adverse cardiovascular events (MACE) from pooled analyses of Phase 3 studies," and claimed that "***[R]oxadustat demonstrated non-inferiority compared to [Epogen], and in the NDD-CKD pool, Roxadustat demonstrated non-inferiority to placebo with respect to MACE.***"

212. Regarding whether the Company's NDA contained accurate and complete data, Frost asserted that ***the NDA submission "was complete and transparent"***:

> ***FibroGen's NDA submission was complete, complied with all FDA guidance, and included data from all clinical and preclinical studies.*** The Integrated Summary of Safety cardiovascular safety report includes the pooled cardiovascular safety analyses of the DD-CKD, and NDD-CKD patient populations. In addition, for completeness and full transparency, FibroGen included certain cardiovascular safety sensitivity analyses, including the stable dialysis subgroup, and the DD-CKD pool including the PYRENEES study. ***The results from these sensitivity analyses do not change the conclusions with respect to MACE of non-inferiority of roxadustat to epoetin-alfa in DD-CKD patients, and non-inferiority of roxadustat to placebo in NDD-CKD patients. In conclusion, FibroGen's NDA submission was complete and transparent. The data supporting the safety and effectiveness of roxadustat is robust and compelling.***

213. The statements in ¶¶211-212 were materially false and misleading, and omitted material facts when made. *First*, Defendants' statements in response to the Citizen Petition that the "cardiovascular safety" of Roxadustat was "demonstrated in the Phase 3 program," and that Roxadustat had demonstrated "non-inferiority" compared to Epogen and placebo in the Phase 3 trials, were plainly false. In reality, all of these statements were entirely dependent upon Defendants' *post hoc* manipulations of the Roxadustat data, which made the drug appear significantly better and safer than it was, and they were not based on any prespecified analyses agreed upon with the FDA. Rather, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo *and* Epogen. Indeed, as confirmed by Plaintiffs' CWs, by the fall of 2020

the FDA had already informed Defendants that, at the very least, a "Black Box" warning would be required for Roxadustat due to the FDA's growing safety concerns.

214. *Second*, as Defendants would themselves soon admit, FibroGen's NDA submission to the FDA was *not* "complete and transparent"—to the contrary, and as FibroGen admitted in the April 6, 2021 press release, the Company had misleadingly submitted manipulated *post hoc* safety analyses in the NDA as the primary safety analyses, forcing FibroGen to have to rush to "clarify" the issue with the FDA and identify what *post hoc* changes were made to which analyses.

215. *Third*, while the Company claimed in its response to the Citizen Petition that "sensitivity analyses" did not change any conclusion that the MACE risk of Roxadustat was non-inferior to placebo or Epogen, in truth, the FDA's prespecified sensitivity analyses—which Defendants wholly concealed from investors throughout the Class Period—revealed highly alarming safety results for Roxadustat showing that Roxadustat was inferior to placebo *and* Epogen.

P. March 2021 Statements

216. On March 1, 2021, FibroGen issued a press release announcing that the FDA would hold an AdCom meeting "to review the [NDA] for Roxadustat" on a date to be determined later. The fact that the FDA was requesting an AdCom so late in the regulatory approval process signaled a significant setback for the approval of Roxadustat. On this news, FibroGen's share price fell 32% over the next two days, from $50.53 per share to $34.35 per share. Analysts immediately reacted with alarm, stating that this development had "[a]dd[ed] uncertainty around approvability and a possible 'Black Box' label" and would "bring into question what the FDA concerns are, what theoretical CV risks are outstanding."

217. In response to this development, rather than admit the truth about Roxadustat's true efficacy and safety profile, Defendants made a series of public statements asserting that they remained fully confident in Roxadustat's data and its prospects for FDA approval. For example, while FibroGen stated in the March 1, 2021 press release that it was "disappointed" with the news, Defendant Conterno was quoted in that release as stating: "***We continue to be confident in the***

efficacy and safety profile of [Roxadustat] based on positive results from a global Phase 3 program encompassing more than 8,000 patients."

218. On the same day, FibroGen held an earnings call during which the AdCom was discussed, with CMO Eisner stating: "***We continue to have confidence in the completeness of our NDA submission, the strength of our data***," later adding that "we're very willing and able to have this discussion in public and present our data, which, as we alluded to before, ***we're quite confident in."*** Defendant Conterno added: "***[T]he data that we have on incident dialysis, we believe, is some of our strongest data. As we think about MACE and MACE+ significance in that population. So clearly, very, very important data***."

219. On March 2, 2021, Defendant Conterno participated in the 41st Annual Cowen Healthcare Conference. Conterno assured investors that there was no concern despite the previous day's news regarding the AdCom meeting, again stating that: "We continue to have confidence in ***the completeness of the NDA submission and the strength of the roxadustat data.***" Conterno called the AdCom "an opportunity to basically showcase, I think, the ***strength of our data***, and we continue to have ***confidence on the strength of the data of Roxadustat across both DD and NDD."*** Conterno further asserted that the totality of the data for DD and NDD patients "***supports -- the benefit risk profile***." Conterno added that "I know because we've discussed in the past, and I think ***I've been pretty clear in terms of what has been agreed with the FDA and what hasn't been agreed with FDA. I think that's known***."

220. The statements in ¶¶217-19 were materially false and misleading, and omitted material facts when made. *First*, contrary to Defendants' statements about their unwavering "confidence" in the Roxadustat data, as Defendants were well aware, Roxadustat's cardiovascular safety data did not support FDA approval. Rather, Defendants had made significant *post hoc* manipulations to the Roxadustat data in order to make the drug appear much better and safer than it was, and the manipulated data that they presented to the public were not based on any prespecified analyses that had been agreed upon with the FDA. In reality, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and

"serious" that the drug was too dangerous to be approved *at all*, for any patient population. *Second*, as Defendants would themselves admit only one month later, FibroGen's NDA submission to the FDA was *not* "complete"—to the contrary, and as the Company would soon admit on April 6, 2021, FibroGen had misleadingly submitted its manipulated *post hoc* safety analyses in the NDA to the FDA as the primary analyses, forcing the Company to immediately "clarify" the issue with the FDA.

Q. April 2021 Statements

221. Under the pressure of increased FDA scrutiny and the approaching AdCom, on April 06, 2021, FibroGen issued a press release *admitting* that the Roxadustat safety analyses the Company had presented to investors had "included post-hoc changes to the stratification factors" that had dramatically altered the data and made Roxadustat appear much better and safer than it was. Analysts were shocked by this "stunning revelation," stating that FibroGen's "acknowledged manipulation" of the Roxadustat data was "stark, if not devastating" and meant that FibroGen executives had clearly thought that the data "wasn't good enough . . . [s]o they decided to change the 'stratification factors' . . . nearly 2 years ago to make the data look better." In response to this "devastating" news, FibroGen's stock price was decimated, falling 45% over the next two days to close at a price of $18.81 per share on April 8, 2921.

222. Despite Defendants' shocking admission, Defendants continued to staunchly maintain that the Roxadustat data was positive and that the drug would obtain FDA approval. For example, Defendant Conterno was quoted in the press release as stating that "***this does not impact our conclusion regarding the comparability, with respect to cardiovascular safety, of Roxadustat to [Epogen] in dialysis-dependent (DD) patients and to placebo in non-dialysis dependent (NDD) patients. We continue to have confidence in Roxadustat's benefit risk profile***." The press release reiterated that "[t]hese analyses do not change the Company's assessment that ***Roxadustat is comparable to placebo in non-dialysis dependent patients and to [Epogen] in dialysis dependent patients using MACE to measure cardiovascular safety***."

223. On the same day, the Company held a special "Business Update Call" to discuss the Roxadustat's true cardiovascular safety analyses. During the call, Conterno specifically attempted to rebut concerns regarding the cardiovascular safety of Roxadustat:

> Our conclusion regarding ***the comparability with respect to cardiovascular safety of Roxadustat to [Epogen] in dialysis-dependent patients and to placebo in nondialysis-dependent patients is not impacted***. So let me be very clear. We continue to have ***confidence in Roxadustat's benefit risk profile, and we're committed to working closely with the FDA to bring this important new treatment to patients living with anemia of CKD.***

224. Defendant Eisner also stressed that "these analyses do not change the Company's assessment that ***Roxadustat is comparable to placebo in nondialysis-dependent patients and to [Epogen] in dialysis-dependent patients using MACE to measure cardiovascular safety***."

225. In response to another analyst inquiry from Dr. Porges regarding whether the upper bound of the confidence intervals that was pre-agreed with the FDA was 1.25 or 1.3 for noninferiority, Defendant Conterno stated that "***in non-dialysis, we basically show comparability relative to placebo***. With regards to the 1 point to any measures of excess risk***, you mentioned 1.25 or 1.3, I think I said in a number of different occasions that we do not have a pre-agreed non-inferiority margin with the FDA***." Conterno further assured investors that the "***critically important message***" was that the conclusions "***have not changed from a safety perspective***":

> But clearly, ***our conclusions when it comes, as I mentioned, to -- in NDD and DD that we're comparable to placebo in NDD and comparable in DD to EPO have not changed a from a safety perspective***. I think that's a ***critically important message.*** When it comes to incident dialysis, the ***numbers continue to be quite positive***.

226. Eisner added that "the ***overall analysis are consistent with comparable safety to placebo in the NDD population and to ESA in the dialysis-dependent population.*** And overall, we feel ***very good about the overall benefit-risk profile of the drug."*** Further, in response to analyst inquiry regarding Roxa's safety profile, Eisner reiterated that "still, ***the overall results are very comparable in the NDD population to -- for Roxadustat to placebo and in the DD and the incident dialysis subpopulation, comparable to ESA's in terms of cardiovascular safety.*** So overall, we continue to believe that ***the benefit risk profile of Roxadustat is favorable***." Eisner again stressed that they could "clearly state that ***the results with the prespecified stratification***

factors continue to support comparable cardiovascular safety between [R]oxadustat and placebo and a positive benefit risk profile." Eisner concluded that "[a]t the end of the day, we do believe that ***the benefit/risk profile of roxadustat is positive and that the review will likely conclude that***."

227. The statements in ¶¶222-26 were materially false and misleading, and omitted material facts when made. Specifically, Defendants knew that Roxadustat was not comparable to placebo or Epogen, nor did it have a "favorable" risk-benefit profile. Rather, in truth, while Defendants purported to come clean on April 6, 2021 by releasing data showing the real hazard ratios under the FDA's prespecified *primary* analyses, Defendants *still* did not disclose the FDA's prespecified and equally important *sensitivity* analyses—*i.e.*, analyses that were indisputably a key part of the "totality" of the data—which Defendants had wholly withheld from investors throughout the Class Period. These critical sensitivity analyses made clear that Roxadustat was significantly inferior to placebo *and* Epogen in the MACE *and* ACM endpoints in numerous and alarming ways. Indeed, based on the data from the FDA's prespecified sensitivity analyses, the FDA AdCom would conclude that "there were greater rates of some important adverse events with Roxadustat than even [Epogen]"—including deaths—and that Roxadustat could "not match the efficacy of [Epogen]" even if the Roxadustat dose were lowered to potentially lessen the safety issues. As a result of these "serious" safety concerns, the FDA AdCom would vote overwhelmingly *against* the approval of Roxadustat for *any* patient population, and even with a Black Box warning.

228. The chart below demonstrates what the FDA described as the "considerable difference" between the results in the crucial MACE and ACM endpoints as between (i) FibroGen's *post hoc* manipulated analysis; (ii) the primary prespecified FDA analysis Defendants belatedly revealed on April 6, 2021; and (iii) the prespecified FDA sensitivity analyses Defendants ***never revealed***. For endpoints, the estimated hazard ratio is shown first, with the lower and upper bounds listed in parenthesis. Significantly, for NDD patients, under the undisclosed FDA prespecified sensitivity analyses the estimated MACE hazard ratio was ***1.38***, or nearly ***30% higher*** than the estimated MACE hazard ratio of 1.08 Defendants had originally disclosed pursuant to the doctored *post hoc* analysis—and the upper bound for that endpoint was higher still, at ***1.7, or nearly 40%***

higher than the upper bound of 1.24 Defendants had originally disclosed. The same was true for the ACM endpoint in the NDD patient population, for which the FDA's sensitivity analysis showed an estimated hazard ratio of ***1.4, or over 30% higher*** than the estimated hazard ratio Defendants originally disclosed of 1.06, with the upper bound for that endpoint reaching as high as ***1.82—or 48% higher*** than the upper bound of 1.23 Defendants had disclosed pursuant to the manipulated *post hoc* analysis. The prespecified sensitivity results for the DD population also showed a significant difference, as the upper bound for the MACE endpoint was ***1.3, or over 15% higher*** than the upper bound of 1.13 Defendants originally disclosed—and for the ACM endpoint, the prespecified sensitivity analysis showed an upper bound of ***1.35, which was also over 15% higher*** than the upper bound of 1.17 Defendants had presented under the manipulated *post hoc* analysis.

Non-Dialysis Dependent (NDD)			
Endpoint	*Post-Hoc* Manipulated Analysis	True, Undisclosed FDA Pre-Specified Analysis	True, Undisclosed FDA Pre-Specified "Sensitivity" Analysis
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)	1.38 (1.11, **1.70**)
ACM	1.06 (0.91, 1.23)	1.08 (0.93, 1.26)	1.40 (1.08, **1.82**)

Dialysis Dependent (DD)			
Endpoint	*Post-Hoc* Manipulated Analysis	True, Undisclosed FDA Pre-Specified Analysis	True, Undisclosed FDA Pre-Specified "Sensitivity" Analysis
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)	1.14 (1.00, **1.30**)
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)	1.17 (1.02, **1.35**)

229. Furthermore, Defendant Conterno's statement that FibroGen had no agreement with the FDA on whether the upper bound for the non-inferiority margin should be 1.3 or 1.25 was materially false because Conterno omitted the critical fact—as the FDA would reveal during the July 15, 2021 AdCom—that the reason for the lack of agreement was that the FDA had stated all along that an upper bound of ***1.25*** (and ***not*** 1.3) was what it was looking for. Indeed, the FDA stated that it had explicitly *rejected* the Company's proposal of 1.3 as the upper bound because FibroGen had attempted to choose that non-inferiority margin for itself, *post hoc*, *i.e.*, after the results of the Roxadustat safety data were fully known to FibroGen. As a result, and as shown

above, the true upper bound hazard ratios for the Roxadustat safety data under the FDA's prespecified sensitivity analyses Defendants never disclosed far exceeded the upper bound of 1.25 the FDA was focused on in the key MACE and ACM endpoints across both patient populations, in addition to also reaching or exceeding the 1.3 non-inferiority margin Defendants claimed the FDA wanted to see and that Roxadustat had purportedly cleared. Moreover, as shown above, for NDD patients, even under the FDA's slightly more favorable *primary* prespecified analysis Defendants belatedly revealed on April 6, 2021, the MACE and ACM hazard ratios still exceeded 1.25—as they were at 1.27 and 1.26, respectively—thus failing the actual non-inferiority margin the FDA was using, but that Defendants concealed from investors throughout the Class Period.

R. May 2021 Statements

230. On May 10, 2021, FibroGen held a conference call with analysts and investors to discuss the Company's Q1 2021 financial results. During the call, Defendant Conterno stated that the *post hoc* update the Company had provided on April 6, 2021 "***does not impact our overall conclusions regarding the comparability with respect to cardiovascular safety of Roxadustat to [Epogen] in [DD] patients and to placebo in [NDD] patients***." Conterno stressed that he "want[ed] to reiterate that we continue to have ***confidence in the Roxadustat data and in the safety and efficacy profile demonstrated in the Phase 3 program."***

231. On May 13, 2021, Defendant Conterno participated in the Bank of America Annual Healthcare Conference. During the conference, Conterno stressed that Roxadustat was "***comparable on both dialysis dependent and non-dialysis dependent comparable to ESAs on dialysis dependent onto placebo on non-dialysis dependent***" and "***can be an ideal choice there given the strength of our data, in particular in incident dialysis***." Conterno assured investors that he was "***quite confident on what Roxadustat can deliver***," and added that for Roxa, "***when it comes to MACE non-inferior to ESAs on DD and non-inferior comparable to placebo on NDD***. . . all in all, I think it should help understand I think the overall profile of the product better, and I'm optimistic about ***given our preparation that we will have a good showing***."

232. The statements in ¶¶230-31 were materially false and misleading, and omitted material facts when made, as Roxadustat's MACE safety results were not in fact comparable to placebo nor Epogen. *First*, under the true prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo and decidedly *inferior to* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. *Second,* while Defendants purported to come clean by releasing data showing the real hazard ratios under the FDA's prespecified *primary* analyses on April 6, 2021, significantly, Defendants still had not disclosed the FDA's prespecified and equally important *sensitivity* analyses—*i.e.*, indisputably a key part of the "totality" of the data—which unequivocally confirmed that, contrary to Defendants' public statements, Roxadustat was significantly inferior to placebo *and* Epogen in the MACE *and* all-cause mortality endpoints.

S. June 2021 Statements

233. On June 4, 2021, Defendant Conterno participated in the Jefferies Healthcare Conference. During the call, Defendant Conterno again stated that it was "important [to] highlight" "that ***Roxadustat has shown comparability when it comes to both placebo in NDD and relative to EPO in DD***." Conterno further claimed that the hazard ratio estimate for DD patients was ***"still below 1 and it looks very, very positive***."

234. On June 10, 2021, Defendant Conterno presented at the Goldman Sachs 42nd Annual Global Healthcare Conference. In response to analyst inquiry regarding the safety of the updated Roxadustat data, Conterno stated again that "what the data shows is -- what the analogy shows is basically the ***Roxadustat is comparable to ESAs to EPO in the DD setting and comparable to placebo in the NDD setting***."

235. The statements in ¶¶233-34 were materially false and misleading, and omitted material facts when made, as Roxadustat's MACE safety results were in fact not comparable to placebo or Epogen. Rather, in reality, under the FDA's prespecified analyses, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo *and* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population.

Indeed, Defendants knew that they had still not disclosed the FDA's prespecified and equally important *sensitivity* analyses showing that, contrary to their public statements, Roxadustat was significantly inferior to placebo *and* Epogen in the MACE *and* all-cause mortality endpoints, in addition to causing a host of other undisclosed risks and side effects. Moreover, contrary to Defendant Conterno's assertion that the estimated hazard ratio for DD patients was less than 1, under the FDA's undisclosed prespecified sensitivity analyses in that population, the estimated hazard ratios for MACE and ACM—in addition to having upper bounds of 1.3 and above—exceeded 1 by notable margins (1.14 and 1.17, respectively).

VII. ADDITIONAL ALLEGATIONS OF DEFENDANTS' SCIENTER

236. As alleged above, numerous factors raise a strong inference that Defendants knew, or were severely reckless in disregarding, the true facts concerning Roxadustat's Phase 3 trial results and the drug's prospects for receiving FDA approval. Specifically, Defendants were obviously well aware that FibroGen had made "*post-hoc* changes" to the underlying "stratification factors" for Roxadustat's trials that made the drug appear safer and better than it really was, and Defendants were further aware that the actual Roxadustat safety data using the FDA's prespecified analyses was materially worse—and, indeed, statistically inferior to both Epogen and placebo—which rendered the drug's FDA approval prospects highly unlikely. In addition to the allegations set forth above, these particularized facts demonstrating Defendants' scienter include the following.

237. *Defendants' admissions on April 6, 2021 that they had made* post-hoc *manipulations to the critical Roxadustat safety data that made the drug appear to be much safer and better than it actually was raise a strong inference of scienter*. On April 6, 2021, Defendants issued the "***nothing less than stunning***" admission that they had made *post-hoc* manipulations to each of nine analyses of Roxadustat's safety data, and ***in all nine analyses*** Defendants had manipulated the results to make the drug appear better and safer than it actually was. Moreover, Defendants had misleadingly presented the false data to investors, the scientific community and the FDA as the data resulting from the FDA's *prespecified* analysis, and as a result, Defendants were forced to "clarify" the issue with the FDA and *retract* publications of the data in prominent peer-reviewed

medical journals. Significantly, when the true, prespecified analyses were revealed, in the words of one market analyst, Roxadustat's data was "***meaningfully worse***" and removed the "key prior advantage" of the drug. Notably, Defendants were forced to admit that they could no longer claim that Roxadustat lowered the MACE and MACE+ risk for the crucial incident dialysis population—which was set to launch Roxadustat into a $3.5 billion market—by a statistically significant 30 and 34%, and in fact, Defendants could no longer claim that Roxadustat lowered the MACE or MACE+ risk for that population *at all*. Defendants' specific admission that they had manipulated the crucial clinical trial results for FibroGen's single most important drug, and that such manipulations were effectuated across the board on all nine analyses that Defendants had been incessantly touting to investors for over two years as indicative of Roxadustat's efficacy and safety superiority over comparison treatments, raises a strong inference of Defendants' knowing or reckless disregard regarding their false and misleading statements and omissions.

238. *The uniform reactions of prominent analysts, medical journals and renowned members of the scientific community to Defendants' admissions, including specific recriminations of management's credibility, support a strong, cogent and compelling inference of scienter*. After Defendants admitted in April 2021 that they had blatantly manipulated and misrepresented Roxadustat's trial data for over two years, and after the FDA AdCom revealed in July 2021 that such manipulations rendered the drug materially inferior in both efficacy and safety than its comparison treatments, market analysts, prominent doctors in the nephrology community, and major medical journals uniformly reacted with shock and anger. These sophisticated market participants confirmed that Defendants' manipulations were not only material and effectively decimated Roxadustat's likelihood of receiving FDA approval and FibroGen's financial prospects, but they also made clear that the manipulations could not have happened accidentally, but were spearheaded by senior Company officers.

239. Indeed, noted medical, pharmaceutical and biotechnology journals and publications explicitly concluded that FibroGen management was complicit in the scheme. For example, an article by the American Society of Nephrology noted that "the net effect" of the "***statistical***

shenanigans" was "to remove [R]oxadustat's evident safety advantage compared with the drugs it would presumably replace." An article published in pharmaceutical news outlet *Evaluate Vantage* likewise emphasized that management's explanation for "FibroGen's staggering admission" "***stretches the bounds of credibility***," and underscored that Defendants would "struggle to shake suspicions" regarding their role in the "sorry debacle."

240. Another prominent biotechnology publication, STAT+, underscored that "the company has been touting false heart safety data [] for at least two years—***a shocking revelation***." STAT+ further underscored that Defendants perpetrated the "***worst case of data manipulation in years***," concluding that "FibroGen cheated" and that the "charade lasted nearly two years." The publication also excoriated management for failing to admit who was responsible for the manipulations, ultimately questioning: "***how can anyone – investors, physicians, regulators – trust a company that spent nearly two years touting cardiovascular safety data that turns out to have been falsified***?" And the major pharmaceutical and biotechnology publication, *FiercePharma*, emphasized that the "data doctoring" was a "stunning revelation"; that "FibroGen admitted to presenting roxadustat data manipulated to make the anemia drug look safer than it is"; and that "[t]he fact that all nine analyses across the patient groups looked less favorable for [R]oxadustat after the change ***raises the suspicion that someone within FibroGen carefully selected the new criteria to make roxa's profile look better***."

241. Similarly, prominent nephrologists who were exceedingly knowledgeable about Roxadustat and the Company's representations during the Class Period concerning the drug's safety and efficacy profile excoriated management for misleading investors and the scientific community. For example, Dr. Daniel Coyne, a nephrologist and Washington University in St. Louis professor who directly worked as a site investigator in the Roxadustat clinical trials, emphasized that "[t]his deeply damages the reputation of FibroGen . . . ***I feel very misled, and I don't think there is any excuse for this. I don't know how this could happen accidentally***." Similarly, one of Wall Street's most prominent biotechnology analysts, Dr. Geoffrey Porges, specifically highlighted the magnitude of Defendants' data manipulations, emphasizing that "[t]he re-statement reduced the

benefit from Roxa vs controls in every case, erased the appearance of superiority over ESAs in incident dialysis patients, and increased the apparent risk of a negative effect of Roxa on CV safety in [NDD] patients." Moreover, after the FDA AdCom revealed Roxadustat's true safety profile at the end of the Class Period and voted against the drug's approval, Dr. Porges emphasized that "[t]hese signals were unknown from the company's disclosure to us and to investors before this week," and warned investors of the "***perils of trusting FibroGen's data, management and board***."

242. Numerous sophisticated market analysts also excoriated management for the data manipulations. For example, Jefferies opined that the manipulations were "a material change to the profile" and removed one of the drug's "key prior advantages." Raymond James emphasized that "the MACE data we were presented ***[wasn't] real***." William Blair noted that Defendants' admissions "will negatively affect management's credibility" given that the true, and inferior, analyses had "never been reported publicly to the medical or investment community." And a *SeekingAlpha* article explained that in "simple, easy to understand English," FibroGen executives thought that the data "wasn't good enough . . . [s]o they decided to change the 'stratification factors' . . . nearly 2 years ago ***to make the data look better***," and that in light of the manipulations, there was no longer "***confidence [] in whatever this management says***."

243. In sum, analysts, nephrologists and medical journals all uniformly made crystal clear that Defendants' data manipulations were no accident, and that Defendants intentionally misrepresented Roxadustat's data to make the drug appear better and safer than it really was.

244. *Defendants' withholding of Roxadustat safety results from the FDA prespecified analyses, which Defendants indisputably had in hand throughout the Class Period, and their touting of the manipulated* post hoc *safety data instead as representative of the FDA prespecified analyses, is highly probative of scienter.* Pursuant to FibroGen's contract with AstraZeneca, FibroGen was the regulatory "lead" for the U.S. development of Roxadustat, for which duties included being the primary party interfacing with the FDA. Defendants were thus fully aware of what the FDA's prespecified analyses were for Roxadustat's trial data throughout the Class Period.

245. Indeed, Defendants referenced throughout the Class Period their direct participation in extensive meetings and discussions with the FDA regarding the proper statistical methods to use to analyze the Roxadustat MACE safety data, and confirmed their personal participation in the pre-NDA meeting with the FDA. The FDA itself confirmed during the AdCom that there were numerous discussions, the majority of which occurred "pre-data," in which the FDA made clear that it required certain statistical methods and was looking for a non-inferiority margin of 1.25 and not 1.3, a number FibroGen attempted to unilaterally chose only later, after the unblinding of the data. Moreover, Defendant Conterno *admitted* that the NDA submitted to the FDA included *both* the *post-hoc* manipulated data *and* the key data from the FDA's prespecified analyses—meaning ***Defendants admitted they had those analyses in hand the entire time***. As Defendant Conterno commented: "In its NDA, the Company calculated accurately and described *both sets of analyses* including the statistical methodologies and the stratification factors used." However, remarkably, and despite the market's repeated requests for this information, Defendants not only ***fully withheld*** this information from investors—disclosing only *a portion* of the FDA prespecified analyses on April 6, 2021 *for the first time anywhere*—they also misleadingly presented the manipulated *post hoc* analysis ***as the primary FDA analysis*** to investors, the FDA, and the medical community. There can be no more damning evidence of scienter.

246. *Roxadustat's development and approval was FibroGen's single most important drug and indisputably its material, core operation, that directly drove FibroGen's stock price throughout the Class Period.* Market analysts estimated that FibroGen derived approximately 90% of its value from Roxadustat, and analysts further widely and repeatedly commented on how "the most important catalyst" for FibroGen's stock during the Class Period was news about the Roxadustat Phase 3 clinical trial data and the MACE safety data in particular. Indeed, throughout the Class Period, FibroGen disclosed that "substantially all" of its revenue was derived from its collaboration agreements involving Roxadustat. For example, of the $256 million the Company recognized as revenue in 2019, the entire $256 million was tied to achieving various regulatory milestone for Roxadustat, with $50 million (or nearly 20%) of that amount consisting of a milestone

payment from AstraZeneca for the filing of the NDA for Roxadustat. Underscoring how critical Roxadustat was to the Company's overall valuation, in the wake of the July 15, 20121 FDA AdCom recommending against the approval of Roxadustat for any patient population, analysts began asking the Company about its options "for significantly reducing the Company's cash burn so that you don't need to refinance the Company at this greatly impaired valuation level." The fact that FibroGen's future financial prospects were virtually entirely dependent on Roxadustat's regulatory and commercial success supports a finding of Defendants' scienter.

247. *Defendants repeatedly spoke about and indeed touted Roxadustat's clinical trial data to the investing public throughout the Class Period, at a time when they undisputedly had already manipulated the drug's trial data and misrepresented the nature and results of that data*. Throughout the Class Period, Defendants made innumerable statements to investors boasting about Roxadustat's clinical trial data each and every quarter, all of which specifically touted the purportedly "superior" safety and efficacy of the drug, ***for over two years***—and at a time that Defendants obviously knew about the true prespecified analyses for Roxadustat that demonstrated that the drug was materially inferior to both Epogen and placebo. The fact that Defendants spoke so often and in such detail about the Roxadustat data makes clear that the data was critically important to them and that they had fully analyzed that data and were intimately familiar with all of the clinical trial results. Indeed, Defendants had submitted the true prespecified analyses to the FDA in the Roxadustat NDA, but never publicly disclosed them, and instead attempted to pass off their "*post-hoc*" manipulated data to investors as the real data for over two years. The longstanding nature of Defendants' fraudulent misrepresentations—and the degree to which those representations sharply conflicted with the actual Roxadustat data Defendants had in hand—directly supports a strong inference of scienter.

248. *Defendants' strong affirmative responses to analysts' direct questions about whether the data FibroGen was presenting was sanctioned by the FDA is highly probative of scienter.* In the days leading up to FibroGen's presentation of the detailed Roxadustat MACE safety data at the ASN conference on November 8, 2019, analysts and investors had questioned whether

the data was presented pursuant to FDA prespecified analyses. On FibroGen's November 11, 2019 earnings call following the ASN conference, analysts again raised questions about "investor concern" regarding "FDA agreements and [whether] FDA signed off on statistical plans." In response, Defendant Yu strongly affirmed that "the results we have presented in the High-Impact Clinical session at the ASN and ***the numbers I had just presented were based on the analysis plan that we have made with the FDA***." However, as Defendants would *admit* on April 6, 2021, the opposite was true—the numbers FibroGen presented at the ASN conference and during the November 11, 2019 earnings call in fact resulted from Defendants' own manipulated *post hoc* analysis of the data that concealed the numerous safety issues with Roxadustat. Tellingly, FibroGen would later reiterate that "[t]he data presented at [ASN] reflect the analytical methods and study pools agreed upon with the FDA." Defendants' plainly false responses to these direct investor questions are highly probative of scienter.

249. *The fact that Defendants did not themselves reveal the full truth about the highly negative safety profile for Roxadustat that doomed its approval prospects—such that it was revealed by the FDA only during the July 15, 2021 AdCom—strongly supports an inference of scienter.* FibroGen only admitted that it had made "*post-hoc* changes" to Roxadustat's safety data on April 6, 2021, which was tellingly just approximately one month after the FDA had "surprised" the Company by informing FibroGen that it would hold an AdCom regarding Roxadustat. Indeed, Defendants had repeatedly publicly reported that they were no longer expecting an AdCom, meaning Defendants saw the writing on the wall when the FDA suddenly called for one, forcing them to come clean. However, significantly, Defendants *still* did not tell the full truth in the April 6, 2021 press release or the Business Update Call. Specifically, while Defendants finally disclosed for the first time results of the FDA prespecified *primary* analyses—which they admitted they had in hand the entire time—they *still* did not disclose the results of the equally important FDA prespecified *sensitivity* analyses. This was highly significant, and telling, because as Defendants well knew, those sensitivity analyses showed that Roxadustat was decidedly *inferior* to both placebo *and* Epogen, which itself already had the most severe "Black Box" warning. Indeed, the

results from those analyses were so alarming that the AdCom would conclude it was unable to approve Roxadustat *at all*, for *any* patient population. Moreover, before the FDA revealed those analyses, Defendants *continued* to make *numerous* misrepresentations about their "confidence" in Roxadustat being non-inferior to placebo in NDD patients and non-inferior to Epogen in DD patients. Defendants' blatant refusal to reveal the full truth is highly probative of scienter.

250. *Plaintiffs' CWs confirmed that Defendants had first-hand knowledge, and control, of the Roxadustat safety data; they were hyper focused on market response to the data; and they misrepresented the true data.* Plaintiffs' CWs confirmed that FibroGen's senior most officers were directly in charge of the Roxadustat clinical trials and the resulting data. Indeed, CW 3, the former AstraZeneca Global Vice President of Renal and Anemia Therapeutic Areas during the Class Period, stated that Neff and Defendant Yu "were all over every bit of [the Roxadustat data]. The senior people at FibroGen had to have been all over this information, Peony [Yu] had to have been all over the data sets" because there were only "a handful of people making all of the decisions" at FibroGen. CW 3 also stated that FibroGen made all of the public announcements regarding the Roxadustat data because, under the contract with AstraZeneca, FibroGen was the holder of the NDA and had most of the interactions with the FDA. CW 3 stated that FibroGen very deliberately sought to tell a very clear and favorable story to the market about the Roxadustat data—even when the data stated otherwise—because "FibroGen folks . . . were very aggressive to make sure that as much positive information was put out there as possible." CW 3 explained that because FibroGen essentially had only one product, Roxadustat, "investor confidence was the main game here."

251. Plaintiffs' CWs also gave mutually corroborating accounts that Defendants had such a vice grip on the Roxadustat clinical trial data that they took pains to hide the full data from partner AstraZeneca, with every former AstraZeneca employee Plaintiffs interviewed corroborating that FibroGen was being "shady" about the clinical trial data and unwilling to share it, such that obtaining any data from FibroGen even when AstraZeneca needed it to plan for commercialization of the drug was a "***herculean task***." Furthermore, CW 3, who directly participated in boardroom meetings with FibroGen and Defendant Yu about the data, described Defendant Yu as "***play[ing]***

fast and loose" during those meetings with one-sided slide decks prepared by FibroGen that made AstraZeneca feel as if it was only being told part of the story. CW 3 stated that, as a result, AstraZeneca never was able to get a full picture if of the data "until right at the end." FibroGen's control of the Roxadustat trial data, and its efforts to conceal part of the data from partner AstraZeneca, are highly probative of Defendants' scienter.

252. *Plaintiffs' CWs gave mutually corroborating accounts that by the fall of 2020—months before Defendants would reveal the truth and at the same time Defendants were assuring investors that Roxadustat safety data did not warrant a "Black Box"—the FDA had already informed FibroGen that a "Black Box" warning would be required as the FDA became aware of more and more safety issues with Roxadustat.* CW 3, the former AstraZeneca Global Vice President of Renal and Anemia Therapeutic Areas during the Class Period, stated that in the fall of 2020, the FDA began giving clear signals to FibroGen and AstraZeneca that it had become aware of significant safety issues that, at the very least, would warrant a "Black Box" warning. CW 3 stated that she was directly informed of this by the FibroGen development team, who told AstraZeneca's team at this time that "we are likely going to end up with a [Black Box] warning." CW 2, a former AstraZeneca Renal Sales Specialist during the Class Period, likewise stated that around November 2020, there were indications that something had gone wrong and that the FDA was not going to approve Roxadustat, as AstraZeneca suddenly pivoted its entire sales team away from Roxadustat to focus on another drug instead. Despite these facts confirming that the FDA had clearly indicated to FibroGen by the fall of 2020 that a "Black Box" warning would be required—if approved at all—at this same time and through the end of the Class Period, Defendants continued to make material misstatements about Roxadustat's data, approval prospects and the likelihood of a "Black Box" warning. These accounts demonstrating that Defendants had simultaneous knowledge of negative information about Roxadustat's FDA approval prospects that directly conflicted with their public statements are highly probative of Defendants' scienter.

253. *The Individual Defendants engaged in highly significant coordinated insider trading and received substantial compensation tied to Roxadustat performance goals.* During the Class

Period, the Individual Defendants engaged in substantial and coordinated stock sales that were highly suspicious in both timing and amount, collectively selling approximately ***$42 million worth of FibroGen stock***—over 80% of the entire insiders sales by all Company employees during the Class Period. Significantly, the largest insider seller by far was FibroGen's former CEO Neff, who Plaintiffs' CWs affirmed was running the show with respect to the Roxadustat clinical trials and who made the majority of the Company's misstatements during the Class Period. Specifically, Neff sold over $32 million alone during the Class Period, while significantly increasing his selling right as the Class Period was starting and during a time that Defendants' false and misleading statements caused a significant run-up in FibroGen's stock. Roxadustat's CFO, Pat Cotroneo, also made significant sales of $7 million during the Class Period, which constituted nearly 40% of his total vested securities as of as of April 1, 2018, per FibroGen's 2018 Proxy Statement, and which likewise were the product of a suspicious trading pattern in which Cotroneo made his largest sale just weeks after Defendants adamantly denied any issues with Roxadustat's trial data, leading to a 22% increase in the Company's stock. Defendant Yu, FibroGen's former CMO, and Defendant Schoeneck, FibroGen's interim CEO, also made substantial insider sales, yielding them approximately $2 million and $500 thousand in proceeds, constituting 14% and 9.5%, respectively, of their total vested holdings as of April 1, 2018 per FibroGen's 2018 Proxy Statement.

254. Moreover, the Company's Class Period Proxy statements confirm that the Individual Defendants received tens of millions of dollars in compensation during the Class Period and at a time that the Company's financial and operational performance was directly tied to the appearance of Roxadustat's developmental and commercial success. For example, former CEO Neff received total compensation of $9.2 million in 2018, which was significantly increased to $11.4 million in 2019, the year FibroGen submitted the Roxadustat NDA. Defendant Yu, the CMO of FibroGen who was primarily overseeing the Roxadustat trials, received $4.5 million in total compensation in 2018, which was significantly increased to $5.8 million in total compensation for 2019. Defendant Yu also received over $10 million in Restricted Stock and Option awards that were based in large part on her efforts "in the completion of the Roxadustat MACE safety analysis" and the submission

of the Roxadustat NDA to the FDA. Significantly, this non-cash compensation accounted for the lion's share of Defendant Yu's Class Period compensation (79% in 2018; 84% in 2019; and 68% in 2020). Defendant Schoeneck received over $5.2 million in total compensation for his short role as interim CEO of FibroGen in 2019, and Defendant Controneo received over $4.3 million in total compensation for his role as CFO (significantly increased from $3.5 million the prior year). Finally, Defendant Conterno, despite having just begun his role as the new CEO of FibroGen upon former CEO Neff's passing in August 2019, received over $12.2 million in total compensation in 2020—and Defendant Eisner, who had just begun his role as the new CMO of FibroGen, received over $3.9 million in total compensation that year.

255. These lucrative compensation awards coupled with substantial coordinated insider selling by the Individual Defendants is highly probative of their scienter.

256. *The Company stood to receive highly lucrative milestone payments from partner AstraZeneca if it could obtain FDA approval of Roxadustat.* According to FibroGen's 2020 Annual Report filed on a Form 10-K with the SEC on March 1, 2021, FibroGen's agreements with AstraZeneca for the commercial development of Roxadustat provided for total potential milestone payments of $1.2 billion, of which $571million were "development and regulatory" milestones. In addition, the Company was eligible to receive from AstraZeneca $875 million in milestone payments consisting of (i) $65 million for the achievement of specified clinical and development milestones (which were fully received as of April 2020); (ii) $325 million for achievement of specified regulatory milestones; (iii) $160 million related to activity by potential competitors; and (iv) $325 million upon the achievement of commercial sales events. According to the Company's Form 10-Q for the second quarter of 2021, filed with the SEC on August 9, 2021, by that time FibroGen had received $439 million in these milestone payments. The highly lucrative milestone payments FibroGen stood to receive from AstraZeneca if it could establish Roxadustat as a regulatory and commercial success are highly probative of Defendants' scienter.

257. *The magnitude and duration of Defendants' fraud is indicative of scienter.* In the face of public scrutiny of the validity and accuracy of the Roxadustat Phase 3 clinical trial data

Defendants had provided to investors, for more than *two years* Defendants maintained the ruse that the manipulated *post hoc* data they had presented to the market was in fact the real, prespecified data required by the FDA. Given that Defendants' fraud spanned such a long period, and involved several instances of Defendants specifically refuting questions regarding the very Roxadustat safety data that they had manipulated, is highly probative of Defendants' scienter.

258. *Defendant Yu's suspicious and abrupt departure at a critical time for Roxadustat is highly probative of scienter.* Defendants announced the abrupt departure of Defendant Yu in a November 27, 2020 Form 8-K filed with the SEC, less than one month prior to the scheduled PDUFA date of December 20, 2020 for Roxadustat—with the Company announcing that Yu's official last day would in fact be December 20, 2020—and at the exact same time Plaintiffs' CWs stated the FDA was informing FibroGen that Roxadustat would most definitely require a "Black Box" warning and was expressing increasing concerns about numerous safety issues concerning the drug. Defendant Yu's abrupt and unexplained departure at a critical time for Roxadustat is highly probative of Defendants' scienter.

VIII. LOSS CAUSATION

259. During the Class Period, shares of FibroGen's publicly traded securities traded on the NASDAQ. The market for shares of FibroGen's securities was open, well-developed and efficient at all relevant times.

260. Throughout the Class Period, the price of FibroGen's securities was artificially inflated as a result of Defendants' materially false and misleading statements and omissions identified above. Defendants engaged in a scheme to deceive the market, and a course of conduct that operated as a fraud or deceit on Class Period purchasers of FibroGen securities, by failing to disclose and misrepresenting the adverse facts detailed herein. When Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the price of FibroGen securities fell precipitously as the prior artificial inflation dissipated. As a result of their purchases of FibroGen securities during the Class Period, Lead Plaintiffs and the other Class members suffered economic loss, i.e., damages, under the federal securities laws.

261. By issuing materially false and misleading financial statements, among other adverse facts detailed herein, Defendants presented a misleading picture of FibroGen's business. Defendants' false and misleading statements had the intended effect and caused FibroGen's securities to trade at artificially inflated levels throughout the Class Period. Indeed, FibroGen's stock price traded at a Class Period high of $59.91 on March 1, 2019, and FibroGen's common stock was trading in the months prior to Defendants' revelation of the fraud near its Class Period highs, closing as high as $55.72 per share on February 12, 2021. Between February 12, 2021 and July 16, 2021, FibroGen's stock price dropped $41.37 per share, or 74.25%, wiping out over $3.8 billion in market capitalization.

262. Among the disclosures in this action that establish loss causation are the following.

263. On May 9, 2019, after the market closed, FibroGen issued a press release disclosing topline results from the pooled safety analyses from its Phase 3 Roxadustat trials, including MACE results. In the press release, FibroGen revealed that the largest three patient populations in its Global Phase 3 Program did not meet the requisite statistical threshold to claim that Roxadustat was not inferior to Epogen. In reaction to this disclosure, FibroGen shares fell $9.28 per share, or 20%, to close at $36.39 per share on May 10, 2019, down from $45.67 per share on May 9, 2019, representing an $800 million decline in the Company's market capitalization.

264. On March 1, 2021, after the market closed, FibroGen announced that the FDA would unexpectedly hold an AdCom meeting to review Roxadustat's NDA, well over a year after its initial submission. The FDA decision was a significant setback to the Company's much anticipated March 20, 2021 FDA approval of the drug and indicated a problem with the application. In reaction to the disclosure about the AdCom meeting and delayed PDUFA date, FibroGen's stock price fell $16.18 per share over the next two days, or 32%, from a close of $50.53 on March 1, 2021, to close at $34.35 per share on March 3, 2021—representing an approximate $1.48 billion drop in market capitalization.

265. On April 6, 2021, after the market closed, FibroGen issued a statement "provid[ing] clarification of certain prior disclosures of U.S. primary cardiovascular safety analyses from the

roxadustat Phase 3 program for the treatment of anemia of [CKD]." Specifically, the Company stated that the primary cardiovascular safety analyses "included post-hoc changes to the stratification factors." FibroGen further revealed that, based on analyses using the pre-specified stratification factors, the Company "cannot conclude that [R]oxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to epoetin alfa." On this news, the Company's share price fell over 45% over the next two days, or $15.83 per share, from a close of $34.64 per share on April 6, 2021 to closing at $18.81 per share on April 8, 2021—representing an approximate $1.45 billion decline in market capitalization.

266. On July 15, 2021, after the markets closed, FibroGen announced that the FDA CRDAC "voted to recommend not approving [R]oxadustat." Specifically, at the AdCom meeting, the Committee panel voted virtually unanimously against approval for Roxadustat. The panel voted 13-1 against approval of Roxadustat in non-dialysis CKD patients given the serious and concerning safety signals, particularly mortality. With respect to the DD patients, the panel voted 12-2 against approval of Roxadustat, with panelists again universally concerned with the drug's safety profile, in particular the increased risk over the current standard of care.

267. As a result of this development, trading in FibroGen's stock was halted on July 15, 2021. When trading reopened the following day and the market understood the full extent of Defendants' prior misrepresentations concerning Roxadustat's safety profile and the drug's exceedingly slim prospects for FDA approval, the Company's stock price plummeted, falling over 42%, or $10.49 per share, from a prior close of $24.84 per share to close at $14.35 per share on July 16, 2021, wiping out $971 million of market capitalization on extraordinary volume of over 16 million shares traded.

268. The drastic and continuing decline in FibroGen's stock price was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the decline in the Company's share price negates any inference that the loss suffered by Plaintiffs and the other Class members was caused by changed market conditions,

macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct.

IX. PRESUMPTION OF RELIANCE

269. At all relevant times, the market for FibroGen's securities was an open, efficient and well-developed market for the following reasons, among others:

a. FibroGen's stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

b. As a regulated issuer, FibroGen filed periodic reports with the SEC and the NASDAQ;

c. FibroGen regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services, and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

d. FibroGen was followed by numerous securities analysts employed by major brokerage firms who wrote reports which were distributed to those brokerage firms' sales force and certain customers. Each of these reports was publicly available and entered the public market place.

270. As a result of the foregoing, the market for FibroGen's securities reasonably and promptly digested current information regarding the Company from all publicly available sources and reflected such information in the price of FibroGen's securities. All purchasers of the Company's securities during the Class Period suffered similar injury through their purchase of FibroGen's securities at artificially inflated prices, and a presumption of reliance applies.

271. A Class-wide presumption of reliance is also appropriate in this action under the U.S. Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class' claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding FibroGen's business and operations—information that Defendants were obligated to disclose— positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND THE BESPEAKS CAUTION DOCTRINE

272. The statutory safe harbor or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the false and misleading statements pleaded in this Complaint. The statements alleged to be false or misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false or misleading may be characterized as forward-looking, they were not adequately identified as forward-looking statements when made, and there were no meaningful cautionary statements identifying important facts that could cause actual results to differ materially from those in the purportedly forward-looking statements.

273. To the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, each of these Defendants had actual knowledge that the particular forward-looking statement was materially false or misleading. Defendants are liable for the statements pleaded because, at the time each of those statements was made, Defendants knew the statement was false, and the statement was authorized and/or approved by an executive officer and/or director of FibroGen who knew that such statement was false when made.

XI. CLASS ACTION ALLEGATIONS

274. Lead Plaintiffs bring this action as a class action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) on behalf of a Class consisting of all those who purchased, or otherwise acquired FibroGen securities, including options, between December 20, 2018 and July 15, 2021, inclusive (the "Class"), and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of FibroGen at all relevant times, members of their immediate families, and their legal representatives, heirs, agents, affiliates, successors or assigns, Defendants' liability insurance carriers, and any affiliates or subsidiaries thereof, and any entity in which Defendants or their immediate families have or had a controlling interest.

275. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, FibroGen shares were actively traded on the NASDAQ. As of April 30, 2021, there were over 92.1 million shares of FibroGen common stock outstanding. While the exact number of Class members is unknown to Lead Plaintiffs at this time, and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that there are at least hundreds-of-thousands of members of the proposed Class. Class members who purchased FibroGen securities may be identified from records maintained by the Company, or its transfer agent(s), and may be notified of this class action using a form of notice similar to that customarily used in securities class actions.

276. Lead Plaintiffs' claims are typical of Class members' claims, as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal laws, as complained of herein.

277. Lead Plaintiffs will fairly and adequately protect Class members' interests, and have retained competent counsel experienced in class actions and securities litigation.

278. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of fact and law common to the Class are:

a. whether the federal securities laws were violated by Defendants' acts, as alleged herein;

b. whether the Defendants made statements to the investing public during the Class Period that were false, misleading or omitted material facts;

c. whether Defendants acted with scienter; and

d. the proper way to measure damages.

279. A class action is superior to all other available methods for the fair and efficient adjudication of this action because joinder of all Class members is impracticable. Additionally, the damage suffered by some individual Class members may be relatively small so that the burden and expense of individual litigation make it impossible for such members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

COUNT I

For Violations of Section 10(b) of the Exchange Act, and SEC Rule 10b-5 Promulgated Thereunder

(Against All Defendants)

280. Lead Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

281. This Count is asserted on behalf of all members of the Class against FibroGen and the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

282. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew were, or they deliberately disregarded as, misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

283. Defendants violated Section 10(b) of the Exchange Act and Rule 10b5 promulgated thereunder in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Lead Plaintiffs and other investors similarly situated in connection with their purchases of FibroGen securities during the Class Period.

284. Defendants, individually and in concert, directly and indirectly, by the use of means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Lead Plaintiffs and the other members of the Class; made various untrue and/or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; made the above statements intentionally or with a severely reckless disregard for the truth; and employed devices and artifices

to defraud in connection with the purchase and sale of FibroGen securities, which were intended to, and did: (a) deceive the investing public, including Lead Plaintiffs and the other members of the Class, regarding, among other things, FibroGen's business and operations; (b) artificially inflate and maintain the market price of FibroGen securities; and (c) cause Lead Plaintiffs and the other members of the Class to purchase the Company's securities at artificially inflated prices, and to suffer losses when the true facts became known.

285. Defendants are liable for all materially false and misleading statements made during the Class Period, as alleged above.

286. As described above, Defendants acted with scienter throughout the Class Period, in that they acted either with intent to deceive, manipulate, or defraud, or with severe recklessness. The misrepresentations and omissions of material facts set forth herein, which presented a danger of misleading buyers or sellers of FibroGen securities, were either known to the Defendants, or were so obvious that the Defendants should have been aware of them.

287. Lead Plaintiffs and the other members of the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for FibroGen securities, which inflation was removed from its price when the true facts became known. Lead Plaintiffs and the other members of the Class would not have purchased FibroGen securities at the prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by these Defendants' misleading statements.

288. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages attributable to the material misstatements and omissions alleged herein in connection with their purchases of FibroGen securities during the Class Period.

COUNT II

For Violations Of Section 20(a) of the Exchange Act (Against the Individual Defendants)

289. Lead Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

290. This Count is asserted on behalf of all members of the Class against the Individual Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

291. During their tenures as officers and/or directors of FibroGen, each of these Individual Defendants was a controlling person of the Company, within the meaning of Section 20(a) of the Exchange Act. *See* ¶¶19-34. By reason of their positions of control and authority as officers and/or directors of FibroGen, these Individual Defendants had the power and authority to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein. These Individual Defendants were able to and did control, directly and indirectly, the content of the public statements made by FibroGen during the Class Period, including its materially misleading statements, thereby causing the dissemination of the false and misleading statements and omissions of material facts as alleged herein.

292. In their capacities as senior corporate officers of the Company, and as more fully described above, the Individual Defendants had direct involvement in the day-to-day operations of the Company, in reviewing and managing its regulatory compliance, clinical and commercial matters, including overseeing, reviewing and managing the NDA and trial data for Roxadustat. The Individual Defendants signed the Company's SEC filings during the Class Period, and were directly involved in providing false information, and in certifying and approving the false statements disseminated by FibroGen during the Class Period. The Individual Defendants were also directly involved in providing false information, and they certified and approved the false statements disseminated by FibroGen during the Class Period. As a result of the foregoing, the Individual Defendants, together and individually, were controlling persons of FibroGen within the meaning of Section 20(a) of the Exchange Act.

293. As set forth above, FibroGen violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint.

294. By virtue of their positions as controlling persons of FibroGen, and as a result of their own aforementioned conduct, the Individual Defendants are liable pursuant to Section 20(a)

of the Exchange Act, jointly and severally with, and to the same extent as, the Company is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Lead Plaintiffs and the other members of the Class, who purchased or otherwise acquired FibroGen securities. As detailed above in ¶¶19-34, during the respective times these Individual Defendants served as officers and/or directors of FibroGen, each of these Individual Defendants was culpable for the material misstatements and omissions made by the Company.

295. As a direct and proximate result of these Individual Defendants' conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their purchase or other acquisition of FibroGen securities.

XIII. PRAYER FOR RELIEF

296. WHEREFORE, Lead Plaintiffs pray for relief and judgment as follows:

a. Declaring the action to be a proper class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;

b. Awarding all damages and other remedies available under the Securities Exchange Act in favor of Lead Plaintiffs and all other members of the Class against Defendants in an amount to be proven at trial, including interest thereon;

c. Awarding Lead Plaintiffs and the other members of the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

d. Such other and further relief as the Court may deem just and proper.

XIV. JURY DEMAND

297. Lead Plaintiffs hereby demand a trial by jury.

Dated: November 19, 2021

SAXENA WHITE P.A.

/s/ Lester R. Hooker
Maya Saxena (admitted *pro hac vice*)
msaxena@saxenawhite.com
Lester R. Hooker (SBN 241590)
lhooker@saxenawhite.com
Dianne M. Pitre (SBN 286199)
dpitre@saxenawhite.com
7777 Glades Road, Suite 300
Boca Raton, FL 33434
Tel.: 561.394.3399
Fax: 561.394.3382

Steven B. Singer
Kyla Grant
10 Bank Street, 8th Floor
White Plains, New York 10606
Tel: (914) 437-8551
ssinger@saxenawhite.com
kgrant@saxenawhite.com

David R. Kaplan (SBN 230144)
dkaplan@saxenawhite.com
12750 High Bluff Drive, Suite 475
San Diego, California 92130
Telephone: (858) 997-0860
Facsimile: (858) 369-0096

Counsel for Lead Plaintiff Employees' Retirement System of the City of Baltimore, City of Philadelphia Board of Pensions and Retirement, and Plymouth County Retirement Association, and Lead Counsel for the Class

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on November 19, 2021, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel or parties of record.

Dated: November 19, 2021

SAXENA WHITE P.A.

/s/ Lester R. Hooker
Lester R. Hooker (SBN 241590)