UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

_____, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. FIBROGEN, INC., ENRIQUE CONTERNO, JAMES SCHOENECK, and K. PEONY YU, Defendants.	Case No. CLASS ACTION **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** JURY TRIAL DEMANDED

INTRODUCTION

Plaintiff, by his undersigned attorneys, alleges upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, based on the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the public documents and announcements issued by FibroGen, Inc. ("FibroGen" or the "Company"), filings with the U.S. Securities and Exchange Commission ("SEC"), wire and press releases published by and regarding the Company, securities analysts' reports and advisories about the Company, and other information readily obtainable on the Internet.

NATURE OF THE ACTION

1. This is a federal class action brought individually and on behalf of all other persons and entities who purchased or otherwise acquired FibroGen securities and/or sold put options from November 8, 2019, through and including April 6, 2021 (the "Class Period"), seeking to recover damages pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder (the "Class").

JURISDICTION AND VENUE

2. The claims alleged 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 (17 C.F.R. § 240.10b-5)

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

4. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), as a substantial part of the acts events or omissions giving rise to the claims pleaded herein occurred in this District and defendants named herein maintain their residence or principal places of business in this District.

5. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited

to, the United States mails, interstate telephone communications and the facilities of the NASDAQ National Securities Market ("NASDAQ").

PARTIES

6. Plaintiff purchased and sold FibroGen securities, as set forth in the accompanying certification, which is incorporated by reference herein, and has been damaged thereby.

7. FibroGen is a Delaware corporation and maintains its principal executive offices in San Francisco, California. The Company's common stock is listed on the NASDAQ under the ticker symbol "FGEN".

8. Defendant Enrique Contero ("Contero") has served as the Company's Chief Executive Officer ("CEO") since January 3, 2020.

9. Defendant James Schoeneck ("Schoeneck") served as interim CEO from August 2019 to January 3, 2020.

10. Defendant K. Peony Yu ("Yu") served as Chief Medical Officer from April 2016 until December 20, 2020.

11. Defendants Contero, Schoeneck and Yu are collectively referred to herein as the "Individual Defendants."

12. 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. By reason of their management positions and their ability to make public statements in the name of the Company, the Individual Defendants were and are controlling persons, and had the power and influence to cause (and did cause) the Company to engage in the conduct complained of herein.

CLASS ACTION ALLEGATIONS

13. Plaintiff brings this action as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of all persons and entities that purchased or otherwise acquired FibroGen securities and/or sold put options in FibroGen from November 8, 2019, through and including April 6, 2021. The members of the Class are located in geographically diverse areas and are so numerous that joinder of all members is impracticable. Throughout the

Class Period, the Company's common stock was actively traded on the NASDAQ. Although the exact number of Class members is unknown at this time and can only be ascertained through appropriate discovery, Plaintiff believes there are thousands of members of the Class who traded the Company's common stock during the Class Period.

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

(a) Whether Defendants violated federal securities laws based upon the facts alleged herein;

(b) Whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management;

(c) Whether the Individual Defendants caused the Company to issue false and misleading statements during the Class Period;

(d) Whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

(e) Whether the prices of the Company's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) Whether the members of the Class have sustained damages and, if so, the proper measure of damages.

15. Plaintiff's claims are typical of the claims of the members of the Class as Plaintiff and members of the Class sustained damages arising out of Defendants' wrongful conduct in violation of federal laws as complained of herein.

16. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to, or in conflict with, those of the Class.

17. A class action is superior to alternative methods for the fair and efficient adjudication of this controversy since joinder of all members of this Class is impracticable. Furthermore, because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for the Class members individually to redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

18. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the Company's common stock traded in an efficient market;

(d) the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

(e) the Company traded on the NASDAQ and was covered by multiple analysts;

(f) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(g) Plaintiff and members of the Class purchased, acquired and/or sold the Company's securities between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

19. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

SUBSTANTIVE ALLEGATIONS

20. FibroGen is a biopharmaceutical company that develops medicines for the treatment of anemia, fibrotic disease, and cancer. Its most advanced product is roxadustat, an oral small molecule inhibitor of hypoxia-inducible factor-prolyl hydroxylase ("HIF-PH") activity that acts by stimulating the body's natural pathway for red cell production. In 2019, the Company filed its New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for the approval of roxadustat for the treatment of anemia due to chronic kidney disease ("CKD").

21. Anemia can be a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin, a protein in red blood cells that carries oxygen to cells throughout the body. Anemia in CKD is associated with increased risk of hospitalization, cardiovascular complications and death, also frequently causing significant fatigue, cognitive dysfunction, and reduced quality of life. Severe anemia is common in patients with CKD, cancer, myelodysplastic syndromes ("MDS"), inflammatory diseases, and other serious illnesses.

22. Anemia is particularly prevalent in patients with CKD. The prevalence of CKD in the adult population is estimated at 10-12% globally and is generally a progressive disease characterized by gradual loss of kidney function that may eventually lead to kidney failure, or end stage renal disease, requiring dialysis or kidney transplant to survive. Blood transfusion is used for treating life-threatening severe anemia. However, blood transfusions reduce the patient's opportunity for kidney transplant, and increase the risk of infections and the risk of complications such as heart failure and allergic reactions.

23. According to the United States Renal Data System ("USRDS"), over 14% of the U.S. adult population is affected by CKD, and a majority of dialysis-eligible CKD patients are currently on dialysis. It is estimated that approximately 509,000 patients are receiving dialysis in the U.S. as of 2016.

24. Roxadustat (FG-4592) purports to be an orally administered small molecule HIF-PH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, improving iron regulation, and overcoming the negative impact of inflammation on hemoglobin syntheses and red blood cell production by downregulating hepcidin. The Company states that administration of roxadustat has been shown to induce coordinated erythropoiesis, increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of CKD patients, including in the presence of inflammation and without a need for supplemental intravenous iron.

MATERIALLY FALSE & MISLEADING STATEMENTS

25. The Class Period begins on November 8, 2019. On November 8, 2019, FibroGen issued a press release announcing "Positive Phase 3 Pooled Roxadustat Safety and Efficacy Results". The press release stated in relevant part as follows:

> [The Company] today announced results from the pooled analyses of data from six global pivotal Phase 3 trials investigating roxadustat, a first-in-class, orally-administered inhibitor of hypoxia-inducible-factor (HIF) prolyl hydroxylase activity. The pooled analyses assessed the safety and efficacy of roxadustat as a treatment for anemia in chronic kidney disease (CKD) compared to placebo in Non-Dialysis-Dependent (NDD) patients and to standard of care epoetin alfa in Dialysis-Dependent (DD) patients, including the clinically important Incident Dialysis (ID) patient subgroup. These Phase 3 trials conducted by FibroGen and collaboration partners AstraZeneca and Astellas Pharma, Inc., enrolled over 8,000 CKD patients from more than 50 countries.
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> "The pooled safety analyses assessing roxadustat as a treatment for anemia in chronic kidney disease demonstrate a cardiovascular safety profile comparable with placebo in patients not on dialysis, and comparable or in some cases better than that of epoetin alfa in patients on dialysis," said Robert Provenzano, MD, Associate Professor of Medicine, Wayne State University, Detroit, Michigan, U.S. and a primary investigator on the global Phase 3 program. "It is exciting to see this application of the groundbreaking science on oxygen sensing and adaptation to hypoxia recently awarded the 2019 Nobel Prize in Physiology or Medicine, and championed by FibroGen's late founder and CEO, Tom Neff, who sadly passed away earlier this year. These positive safety results, coupled with roxadustat's well-defined efficacy in CKD patients, and its oral formulation, support the potential for roxadustat to become an important new treatment option for patients with anemia associated with CKD."
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> These late-breaking data were featured in the High-Impact Clinical Trials oral abstract session on Friday, November 8, at the American Society of Nephrology Kidney Week 2019 in Washington, D.C. (Presentation FR-OR131)
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> ***Pooled Efficacy Results***
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> Individually, all six Phase 3 trials included in these pooled analyses (OLYMPUS, ANDES, ALPS, HIMALAYAS, SIERRAS, and ROCKIES) achieved the primary efficacy endpoint of mean hemoglobin (Hb) change from baseline compared to placebo in patients not on dialysis and to epoetin alfa in patients on dialysis.
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> In the pooled analysis of Non-Dialysis Dependent (NDD) patients (n=4277):
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> - Roxadustat was statistically superior to placebo, demonstrating an improvement of 1.85 g/dL in patients' Hb levels from baseline to the average over 28-52 weeks compared to 0.13 g/dL among patients in the placebo arm, for an overall treatment difference of 1.72 g/dL ($p<0.001$).
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> - The rate of rescue therapy required in the first year of treatment among patients treated with roxadustat (8.9%) was less than one third of the rate of the placebo arm (31.1%) $p<0.0001$; HR=0.19 (95% CI: 0.16, 0.23).

- The rate of red blood cell (RBC) transfusions required in the first year of treatment was also lower with roxadustat (5.2%) than placebo (15.4%) p<0.0001; HR=0.26 (95% CI: 0.21, 0.32).

In the pooled analysis of Dialysis Dependent (DD) patients (n=3880):

- Roxadustat was statistically superior to epoetin alfa, demonstrating an improvement of 1.22 g/dL in patients' Hb levels from baseline to the average over 28-52 weeks compared to 0.99 g/dL, for an overall treatment difference of 0.23 g/dL (p<0.0001).

- Roxadustat was superior to epoetin alfa across patients regardless of inflammation status, categorized by the baseline CRP levels (CRP > 4.9 mg/L), demonstrating an improvement of 1.29 g/dL and 1.27 g/dL in Hb levels from baseline in patients with and without inflammation, respectively, compared to 0.96 g/dL and 1.05 g/dL with epoetin alfa.

- The rate of RBC transfusions required in the first year of treatment was also lower with roxadustat (9.5%) than with epoetin alfa (12.8%) in DD patients (p=0.046). HR=0.82 (95% CI: 0.679, 0.997).

Across the NDD and DD patient populations, roxadustat was effective in raising Hb levels regardless of whether patients were iron-replete (i.e., shown to have sufficient stores of iron in their body, TSAT% ≥20% and Ferritin ≥100 ng/mL) at baseline. NDD patients experienced a mean change of 1.94 g/dL from baseline with roxadustat in both iron-replete and non-replete subpopulations, compared to 0.13 g/dL in iron-replete and 0.33 g/dL in non-replete patients receiving placebo.

Pooled Safety Results

Across these pooled safety analyses, the studies evaluated several different patient populations, including:

- Non-Dialysis Dependent (NDD) patients;

- Dialysis Dependent (DD) patients; and

    - Incident Dialysis (ID) patients, who are patients who recently initiated dialysis (within 4 months). This ID subpopulation is the appropriate setting for comparison of roxadustat versus epoetin alfa, as this period of initial dialysis treatment is associated with substantially increased levels of safety events and patient mortality; whereas the stable DD patients have survived this period and thus are responsive to stable doses of erythropoiesis stimulating agents (ESA) such as epoetin alfa.

Cardiovascular (CV) endpoints were defined as:

- Time to first Major Adverse Cardiovascular Event (MACE): a composite endpoint of all-cause mortality, myocardial infarction, stroke;

- Time to first MACE+, a composite endpoint which includes MACE plus unstable angina and heart failure requiring hospitalization; and

- Time to all-cause mortality

- In the Non-Dialysis Dependent (NDD) patient population:
    - Risks 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 a post hoc subgroup analysis of 2,438 non-dialysis patients with baseline eGFR≥15,
    - The one-year decline in eGFR in roxadustat treated patients (-2.8) was significantly less than that in placebo treated patients (-4.4), with a treatment difference of 1.6 mL/min/1.73m2 ($p<0.0001$).
- In the Dialysis Dependent (DD) patient population:
    - Risks of MACE and all-cause mortality in roxadustat patients were not increased compared to those for patients receiving epoetin alfa based on a reference non-inferiority margin of 1.3.
    - Risk of MACE+ was 14% lower in roxadustat-treated patients than in those receiving epoetin alfa.
- The Incident Dialysis (ID) patient sub-group of the Dialysis Dependent (DD) patient population:
    - Risk of MACE was 30% lower in roxadustat patients than in epoetin alfa patients, and risk of MACE+ was 34% lower.
    - Roxadustat-treated patients' risk showed a trend towards lower all-cause mortality relative to epoetin alfa-treated patients.

"**The positive efficacy and cardiovascular safety results from these pooled analyses, in a population with a broad range in both CKD and anemia severity in over 8,000 patients across six Phase 3 global trials, reaffirm the potential of roxadustat to improve treatment for anemia in CKD patients.**" said K. Peony Yu, MD, Chief Medical Officer, FibroGen. "There has not been much progress in treatment approaches for anemia in over 30 years, and more effective, safe, and convenient treatment options for patients are long overdue. We are privileged to be advancing this effort with roxadustat and plan to file the NDA in the U.S. by the end of this quarter for both dialysis and non-dialysis patients with our partner AstraZeneca and the MAA in Europe by the end of first quarter 2020 with our partner Astellas, followed by submissions to other regulatory authorities."

26. On December 23, 2019, FibroGen announced that it had submitted its NDA for roxadustat to the FDA and stated in pertinent part:

> [The Company] today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for roxadustat for the treatment of anemia of chronic kidney disease (CKD), in both non-dialysis-dependent (NDD) and dialysis-dependent (DD) CKD patients.
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> Roxadustat is the first orally administered small molecule hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor submitted for FDA regulatory approval for the treatment of anemia of CKD. Regulatory approval of roxadustat is supported by positive results from

> a global Phase 3 program encompassing 15 trials that enrolled more than 10,000 patients, worldwide.
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> "The submission of this NDA is a major step toward our goal of bringing this novel oral medicine to U.S. patients suffering from anemia in CKD," said Jim Schoeneck, Interim Chief Executive Officer, FibroGen. "We, in collaboration with our partner AstraZeneca, look forward to working with the FDA during the NDA review, and to the potential of roxadustat as a new therapeutic option for treating CKD anemia, in patients on dialysis and not on dialysis."

27. On February 11, 2020, FibroGen announced in a press release that the FDA had completed its filing review of its NDA for roxadustat. The Company stated in relevant part:

> "The FDA's acceptance of the roxadustat new drug application is a critical step towards providing a new treatment option in the United States for chronic kidney disease patients suffering from anemia, a serious and often life-threatening disease," said Enrique Conterno, Chief Executive Officer, FibroGen.
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> "There is significant unmet medical need for patients with anemia of CKD, who have seen only limited advances in the last three decades," said Peony Yu, M.D., Chief Medical Officer, FibroGen. "We intend to work closely with the FDA, in collaboration with our partner, AstraZeneca, to make this novel oral therapy available as soon as possible."
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> The filing of the roxadustat NDA triggers a $50 million milestone payment from AstraZeneca (LSE/STO/NYSE: AZN) to FibroGen.

28. On December 18, 2020, Fibrogen issued a press release providing a regulatory update on roxadustat, stating in relevant part as follows:

> FibroGen, Inc. (Nasdaq: FGEN) today announced that the U.S. Food and Drug Administration (FDA) has extended the review period of the New Drug Application (NDA) for roxadustat for the treatment of anemia of chronic kidney disease (CKD) by three months. The updated Prescription Drug User Fee Act (PDUFA) action date is March 20, 2021.
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> The FDA is close to finalizing its review of the NDA and FibroGen is submitting additional analyses of existing roxadustat clinical data, which require an extension of the original PDUFA date.
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> "FibroGen is working closely with the FDA, in collaboration with our partner, AstraZeneca, to support the final review of the new drug application for roxadustat," said Enrique Conterno, Chief Executive Officer, FibroGen. "There is significant unmet medical need for the treatment of anemia of CKD, and we are committed to bringing roxadustat to patients in the U.S. as soon as possible."

29. The above statements identified in ¶¶ 25-28 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (i) that the Company's prior disclosures of U.S. primary cardiovascular safety analyses from the roxadustat Phase 3 program

for the treatment of anemia certain safety analyses submitted in connection with CKD included post-hoc changes to the stratification factors; (ii) that FibroGen's analyses with the pre-specified stratification factors result in higher hazard ratios (point estimates of relative risk) and 95% confidence intervals; (iii) that, based on these analyses the Company could not conclude that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to epoetin-alfa; (iv) that, as a result, the Company faced significant uncertainty that its NDA for roxadustat as a treatment for anemia of CKD would be approved by the FDA; and (v) that, as a result of the foregoing, Defendants' statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

THE TRUTH IS REVEALED

30. On April 6, 2021, after the market closed, FibroGen issued a press release providing additional information on Roxadustat which stated in pertinent part as follows:

> FibroGen, Inc. (Nasdaq: FGEN) (the "Company") today provided clarification of certain prior disclosures of U.S. primary cardiovascular safety analyses from the roxadustat Phase 3 program for the treatment of anemia of chronic kidney disease ("CKD").
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> "As members of senior management were preparing for the upcoming FDA Advisory Committee meeting, we became aware that **the primary cardiovascular safety analyses included post-hoc changes to the stratification factors**," said Enrique Conterno, Chief Executive Officer, FibroGen. "While all of the analyses set forth below, including the differences in the stratification factors, were included in the NDA, we promptly decided to clarify this issue with the FDA and communicate with the scientific and investment communities."
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> Mr. Conterno continued, "It is important to emphasize that this does not impact our conclusion regarding the comparability, with respect to cardiovascular safety, of roxadustat to epoetin-alfa 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."
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> FibroGen continues to prepare for the FDA Advisory Committee meeting and will work closely with the FDA to bring this important new treatment to patients living with anemia of CKD.
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> There is no change in the underlying roxadustat data, or to the efficacy analyses from the Phase 3 program. The Company has begun a comprehensive internal review to ensure such issues do not occur in the future.
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> **Pooled Cardiovascular Safety Data**
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> As previously disclosed, the Company agreed with the FDA in the pre-NDA meeting that the primary analysis in non-dialysis would be ITT (intention to treat with long-term follow up) and in dialysis would be OT-7 (on-treatment plus 7 days). MACE, a composite endpoint of all-cause mortality, stroke, and myocardial infarction, was the primary safety endpoint agreed on with the FDA.
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> The table below describes the cardiovascular safety results using the post-hoc stratification factors reported at the American Society of Nephrology conference in November 2019, as well as the analyses with the pre-specified stratification factors which have not been previously publicly reported.

	Analyses with post-hoc stratification factors	Analyses with pre-specified stratification factors
	HR (95% Confidence Interval)	HR (95% Confidence Interval)
Non Dialysis (OLYMPUS, ANDES, ALPS N=4,270); ITT		
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)
MACE+	1.04 (0.91, 1.18)	1.07 (0.94, 1.21)
ACM	1.06 (0.91, 1.23)	1.08 (0.93, 1.26)
Dialysis Dependent (HIMALAYAS, SIERRAS, ROCKIES N=3,880); OT-7		
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)
MACE+	0.86 (0.74, 0.98)	0.91 (0.80, 1.05)
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)
Incident Dialysis (N=1,526); OT-7		
MACE	0.70 (0.51, 0.96)	0.82 (0.60, 1.11)
MACE+	0.66 (0.50, 0.89)	0.78 (0.59, 1.02)
ACM	0.76 (0.52, 1.11)	0.82 (0.57, 1.18)

ITT: intention to treat with long-term follow up
OT-7: on-treatment plus 7 days
Major Adverse Cardiovascular Event (MACE): a composite endpoint of all-cause mortality, stroke, and myocardial infarction.
(MACE+): in addition to the components in MACE, includes hospitalization due to heart failure or unstable angina.
(ACM): all-cause mortality.

> As reflected in the table, the analyses with the pre-specified stratification factors result in higher hazard ratios (point estimates of relative risk) and 95% confidence intervals. For MACE+ in dialysis and for MACE and MACE+ in incident dialysis, the 95% confidence intervals include 1.0. **While these hazard ratios remain below 1.0, based on these analyses we cannot conclude that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to epoetin-alfa.**

31. On this news, the Company's share price fell $14.90, or 43%, to close at $19.74 per share on April 7, 2021, on heavy volume. Shares continued to fall on April 8, 2021, to close at $18.81 per share (a decline of $0.93 per share or 4.7%), on heavy volume.

32. On April 6, 2021, STAT+ published an article titled "Fibrogen admits false heart-safety data for experimental anemia pill shared with FDA, investors." The article noted:

> **Fibrogen acknowledged Tuesday that 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**. Shares of Fibrogen fell 27% to $25 in Tuesday's after-hours trading session as investors questioned the credibility of the company's management team and mulled the ramifications of revised heart-safety data that may no longer be strong enough to pass muster with the Food and Drug Administration…Fibrogen was expecting the FDA to complete its review of roxadustat and render an approval decision by March 20. But in a surprising — and concerning — move announced just three weeks before that deadline, the FDA instead decided to convene a meeting of outside experts to review the drug's clinical data. The FDA advisory panel meeting is tentatively scheduled for July 15.
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> But Tuesday, Fibrogen said that while preparing for the FDA advisory panel, it discovered the post-hoc changes to the heart safety "stratification factors." **When those changes were removed and roxadustat's heart-safety data were analyzed as pre-specified in the analysis plan, the results are less robust.**

Across three studies involving dialysis patients, Fibrogen said it can no longer conclude that roxadustat reduces the risk of cardiovascular events or hospitalization compared to a currently approved anemia injection used as a control.

33. Analysts covering FibroGen we stunned by this revelation:

- An analyst from Raymond James said "the dataset is messy and indicates that overall risk/benefit profile of roxa is questionable, at best."
- A Mizuho analyst cut FibroGen to Neutral from a Buy and slashed the price target to $29 from $72, commenting "we were surprised by this update and find it difficult to understand if this was a one-off unintentional mistake, or more."
- An HC Wainwright analyst downgraded the stock to Neutral from Buy stating, "this unfavorable disclosure changes our view on roxa approvability and potential market uptake."

ADDITIONAL *SCIENTER* ALLEGATIONS

34. The Individual Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information that they caused to be disseminated to the investing public. The ongoing fraudulent scheme described herein could not have been perpetrated over a substantial period of time without the knowledge and complicity of the personnel at the highest level of the Company, including the Individual Defendants. The Individual Defendants were motivated to materially misrepresent the true nature of the Company's business, operations, and financial affairs to the public and regulators in order to keep the Company's share price artificially high.

LOSS CAUSATION / ECONOMIC LOSS

35. During the Class Period, as detailed herein, the Individual Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the Company's common stock, and operated as a fraud or deceit on acquirers of the Company's common stock. As detailed above, when the truth about the Company's financial situation was revealed, the Company's common stock declined as the prior artificial inflation came out of its common stock price. That decline in Company's common stock was a direct result of the nature and extent of the fraud finally being revealed to investors and the market. The timing and magnitude of the common stock price decline negates any inference that the loss suffered by Plaintiff and other members of the Class was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the fraudulent conduct. The economic loss, *i.e.,* damages, suffered by the Plaintiff and other Class members was a direct result of the fraudulent scheme to

artificially inflate the Company's common stock and the subsequent significant decline in the value of the Company's common stock when the prior misrepresentations and other fraudulent conduct were revealed.

36. At all times relevant, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and other Class members. Those statements were materially false and misleading because they failed to disclose a true and accurate picture of Company's business, operations and financial condition, as alleged herein. Throughout the Class Period, Defendants publicly issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing Company's common stock price to be artificially inflated. Plaintiff and other Class members purchased Company's common stock price at artificially inflated prices, causing them to suffer the damages complained of herein.

NO SAFE HARBOR

37. The statutory safe harbor under the Private Securities Litigation Reform Act of 1995, which applies to forward-looking statements under certain circumstances, does not apply to any of the allegedly false and misleading statements pleaded in this complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false 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 factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor is intended to 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, the particular speaker had actual knowledge that the particular forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false, misleading or omitted necessary information when they were made.

COUNT I
Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder
(Against All Defendants)

38. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

39. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

40. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of these Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for the Company's securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company's finances and business prospects.

41. By virtue of their positions the Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, these Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to these defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

42. Information showing that the Defendants acted knowingly or with reckless disregard for the truth is within these Defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants each had knowledge of the details of the Company's internal affairs.

43. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the

Company. As officers and/or directors of a publicly held company, Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to the Company's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of the Company's securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company's business and financial condition which were concealed by these defendants, Plaintiff and the other members of the Class purchased or otherwise acquired the Company's securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by these Defendants, and were damaged thereby.

44. During the Class Period, the Company's securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which these Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of the Company's securities at prices artificially inflated by these Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of the Company's securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of the Company's securities declined upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

45. By reason of the foregoing, the Individual Defendants knowingly or recklessly, directly or indirectly violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder in that they: (a) employed devices, schemes and artifices to defraud; (b) failed to disclose material information; or (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class in connection with their purchases of the Company's securities and/or sale of put options during the Class Period.

46. As a direct and proximate result of the Individual Defendants wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II
Violations of Section 20(a) of the Exchange Act
(Against the Individual Defendants)

47. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

48. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about the Company's misstatement of income and expenses and false financial statements.

49. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

50. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period concerning the Company's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company securities.

51. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on his own behalf and on behalf of the Class, prays for judgment as follows:

(a) Determining this action to be a proper class action and certifying Plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for the damages sustained as a result of the wrongdoings of Defendants, together with interest thereon;

(c) Awarding Plaintiff the fees and expenses incurred in this action including reasonable allowance of fees for Plaintiff's attorneys and experts;

(d) Granting extraordinary equitable and/or injunctive relief as permitted by law, equity and federal and state statutory provisions sued on hereunder; and

(e) Granting such other and further relief as the Court may deem just and proper.

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JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(B) Plaintiff hereby demands a trial by jury.