UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 11387 / September 5, 2025

SECURITIES EXCHANGE ACT OF 1934
Release No. 103897 / September 5, 2025

ADMINISTRATIVE PROCEEDING
File No. 3-22528

In the Matter of **FIBROGEN, INC.,** **Respondent.**	**ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS, PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933 AND SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER**

I.

The Securities and Exchange Commission ("Commission" or "SEC") deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 ("Securities Act") and Section 21C of the Securities Exchange Act of 1934 ("Exchange Act"), against FibroGen, Inc. ("FibroGen" or "Respondent" or the "Company").

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the "Offer") which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission's jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings, Pursuant to Section 8A of the Securities Act of 1933 and Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order (the "Order"), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds[1] that:

Summary

This matter involves false and/or materially misleading statements about the results of certain cardiovascular safety analyses of FibroGen's then-primary drug candidate Roxadustat, a potential therapy for the treatment of anemia in patients with chronic kidney disease. From November 8, 2019 to April 6, 2021, FibroGen, through its then-Chief Medical Officer Dr. Kin-Hung Peony Yu ("Dr. Yu"), reported cardiovascular safety results for Roxadustat, including, with respect to certain results, its superior safety profile compared to the existing treatment on the market without disclosing that these claims relied on post-hoc changes (i.e. changes made after unblinding of the data) to the stratification factors for certain analyses. In addition, in an earnings call following the reporting of the cardiovascular safety results, Dr. Yu represented that the FDA had agreed with FibroGen's statistical approach when FibroGen had not discussed the post-hoc changes to the stratification factors with the FDA. FibroGen's and Dr. Yu's public statements were false and/or materially misleading in light of these facts.

FibroGen and/or Dr. Yu made the false and/or materially misleading disclosures in a range of forums, including a high-profile industry presentation, multiple SEC filings, an earnings call, and a published manuscript. After Dr. Yu's departure from FibroGen in March 2021, then-new FibroGen management issued an April 6, 2021 press release informing investors that its previously disclosed results were based on post-hoc changes to the stratification factors and also disclosed the results utilizing pre-specified stratification factors, which showed that, for certain results, Roxadustat was merely non-inferior to the existing treatment.

Respondent

1. **FibroGen, Inc.** is a Delaware corporation with its principal place of business in San Francisco, California. FibroGen's shares are registered with the Commission under Exchange Act Section 12(b) and are listed on the Nasdaq Global Select Market under the symbol "FGEN."

Other Relevant Person

2. **Dr. Kin-Hung Peony Yu**, age 62, is a resident of Bellevue, Washington. During the relevant period, Dr. Yu was FibroGen's Chief Medical Officer. Dr. Yu resigned as Chief Medical Officer of FibroGen effective December 20, 2020 and departed from FibroGen on March 15, 2021.

[1] The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

Facts

Background on FibroGen

3. During the relevant period, FibroGen was a biopharmaceutical company developing its then-most advanced drug candidate Roxadustat, a potential therapy for treatment of anemia in chronic kidney disease patients.

4. Between April 2016 and December 2020, Dr. Yu oversaw all areas of clinical development for Roxadustat, including statistical analyses and publication of clinical results. Dr. Yu was directly involved in the drafting, editing, and approval of the misstatements described herein.

5. During the relevant period, FibroGen offered and sold securities, including by issuing FibroGen shares through an employee stock purchase plan.

False and/or Materially Misleading Public Statements Concerning Pooled Cardiovascular Safety Results of Roxadustat

6. Consistent with industry practice and guidance, and its own written policies, in 2018, FibroGen pre-specified the methods and protocols that would be used to analyze the pooled cardiovascular safety data in documents called pooled statistical analysis plans ("Analysis Plans"), which Dr. Yu reviewed and signed. In its Analysis Plans, FibroGen pre-specified that the stratification factors for the individual studies would be used for the primary analysis of the pooled cardiovascular studies.

7. In or around April 2019, the cardiovascular safety data from the pooled studies, using the pre-specified stratification factors, was unblinded and viewed by FibroGen. The results showed Roxadustat was merely non-inferior, but not superior, in cardiovascular safety risk to the existing treatment on the market.

8. In or around early May 2019, FibroGen, through Dr. Yu and her team, conducted various analyses of the unblinded data, including certain analyses utilizing post-hoc stratification factors. In some of those analyses, the results utilizing the post-hoc stratification factors showed that Roxadustat had a superior cardiovascular safety profile to the existing treatment on the market.

9. Between November 8, 2019 and April 6, 2021, FibroGen knowingly and/or recklessly, made numerous false and/or materially misleading public statements concerning the pooled cardiovascular safety analyses for Roxadustat. Specifically, FibroGen (i) reported its pooled cardiovascular safety results for Roxadustat's Phase 3 Studies, including touting, for certain analyses, Roxadustat's superior profile to the existing treatment, without disclosing that FibroGen relied on a post-hoc analysis utilizing post-hoc changes to stratification factors for such results; and (ii) represented, during a November 11, 2019 earnings call, that the FDA had agreed to the statistical approach underlying those reported results when, in fact, FibroGen had never sought the FDA's input on the post-hoc changes to the stratification factors.

10. As FibroGen's Chief Medical Officer, Dr. Yu personally directed the effort and ultimately approved post-hoc changes to the stratification factors. Dr. Yu also managed the drafting of the publication of the results, coordinated the review process with partners, and co-authored and approved the final version. As a result of the conduct of Dr. Yu, FibroGen is responsible for the false and/or materially misleading statements referenced herein.

11. As reflected by statements made internally and to representatives of a pharmaceutical partner, Dr. Yu was motivated to make the post-hoc changes in order to improve clinical study results, and in particular, to show Roxadustat was superior in cardiovascular safety to the existing treatment and ensure its results demonstrated non-inferiority relative to the placebo. The false and/or materially misleading public statements include:

a. a November 8, 2019 American Society of Nephrology Conference presentation in which FibroGen reported the results of its pooled cardiovascular safety studies for Roxadustat, including touting that certain results showed superiority relative to the existing treatment;

b. a November 8, 2019 press release and Form 8-K containing similar false and/or materially misleading statements about the results of FibroGen's pooled cardiovascular safety studies for Roxadustat as the American Society of Nephrology Conference presentation, including falsely touting results showing superiority relative to the existing treatment;

c. a November 11, 2019 earnings call in which Dr. Yu (i) repeatedly touted, for certain analyses, Roxadustat's superior cardiovascular safety results relative to the existing treatment without disclosing that the results utilized post-hoc changes to the stratification factors and (ii) represented that the FDA had agreed to the statistical analytical methods underlying those purported results, when the changes to the stratification factors had not been communicated to the FDA;

d. a quarterly report on Form 10-Q filed on November 12, 2019 and annual reports on Form 10-K filed on March 2, 2020 and March 1, 2021 containing the same false and/or materially misleading reporting of results for its pooled cardiovascular safety studies for Roxadustat; and

e. a December 24, 2020 *Kidney International Reports* journal article co-authored by Dr. Yu which contained the same false and/or materially misleading reporting of results for FibroGen's pooled cardiovascular safety studies for Roxadustat and provided a detailed explanation of the statistical analyses without disclosing the post-hoc changes to the stratification factors.

12. Citing industry guidance and practice, a pharmaceutical partner of FibroGen objected to FibroGen's use of an undisclosed analysis utilizing post-hoc changes to stratification factors to publish results showing superiority. The pharmaceutical partner also insisted that

FibroGen disclose the original results, based on the pre-specified stratification factors. Dr. Yu disregarded their concerns and FibroGen published the results of its pooled cardiovascular safety studies for Roxadustat without disclosing they utilized post-hoc changes to the stratification factors or disclosing the original results using the pre-specified stratification factors.

13. The publication of the results of the pooled cardiovascular safety analyses was highly anticipated by the medical and financial communities, which viewed the results as critical to determining whether the drug candidate would be approved by the FDA and if approved, whether a black box warning label would be required. In addition, the market viewed the publication of the results as significant, as reflected by the significant increase (approximately 10%) in FibroGen's share price when the false and/or materially misleading results were first reported. Likewise, equity analysts uniformly reacted positively to the initial reporting of the pooled cardiovascular safety results. The failure to disclose the post-hoc changes to stratification factors was particularly important because these changes led to results showing that Roxadustat had a superior cardiovascular safety profile relative to the existing treatment on the market.

14. On April 6, 2021, FibroGen issued a press release in which it disclosed that its previously disclosed results had been based on post-hoc changes to stratification factors and disclosed, for the first time, the additional results that were based on the pre-specified stratification factors. This disclosure resulted in a steep decline of approximately 43% in FibroGen's stock price. Equity analysts reacted overwhelmingly negatively to the corrective disclosure.

15. Between November 2019 and April 2021, FibroGen raised approximately $5.6 million in proceeds from its employee stock purchase plan.

Violations

16. As a result of the conduct described above, Respondent violated Sections 17(a)(2) of the Securities Act and Section 10(b) of the Exchange Act and Rule 10b-5(b) thereunder. These provisions prohibit fraudulent statements in the offer or sale of securities and in connection with the purchase or sale of securities, respectively.

Respondent's Remedial Efforts and Cooperation

17. In determining to accept the Offer, the Commission considered FibroGen's cooperation with the staff's investigation and agreement to cooperate in a Commission investigation and related enforcement action and its remedial efforts.

Undertakings

18. Respondent (including its officers, directors, and employees, and third-party consultants within its control) shall continue to cooperate fully with the Commission with respect to this action or any related judicial proceeding or administrative proceeding or investigation commenced by the Commission or to which the Commission is a party and subject to compliance with applicable law. Respondent agrees that such cooperation shall include, but is not limited to:

a. upon reasonable notice, agreeing to truthfully and completely disclose all non-privileged information in its possession, custody or control requested by the Commission staff;

b. upon reasonable notice, agreeing to produce any non-privileged document, record, or other tangible evidence in its possession, custody or control requested by the Commission staff and to take steps to render documents or records produced by FibroGen admissible in any court proceedings;

c. upon reasonable notice, agreeing to appear and be interviewed by Commission staff at such times and places as the staff requests;

d. accepting service by mail or facsimile transmission of notices or subpoenas issued by the Commission for documents or testimony at depositions, hearings, or trials, or in connection with any related investigation by Commission staff;

e. appointing Respondent's attorney as agent to receive service of such notices and subpoenas;

f. with respect to such notices and subpoenas, waiving the territorial limits on service contained in Rule 45 of the Federal Rules of Civil Procedure and any applicable local rules, provided that the party requesting the testimony reimburses Respondent's travel, lodging, and subsistence expenses at the then-prevailing U.S. Government per diem rates; and

g. consenting to personal jurisdiction over Respondent in any United States District Court for purposes of enforcing any such subpoena.

In determining whether to accept the Offer, the Commission has considered these undertakings.

IV.

In view of the foregoing, the Commission deems it appropriate and in the public interest to impose the sanctions agreed to in Respondent FibroGen's Offer.

Accordingly, it is hereby ORDERED that:

A. Pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, Respondent shall cease and desist from committing or causing any violations and any future violations of Section 17(a)(2) of the Securities Act and Section 10(b) of the Exchange Act and Rule 10b-5(b) thereunder.

B. Respondent shall pay a civil money penalty in the amount of $1,250,000 to the Securities and Exchange Commission. Payment shall be made in the following installments: $100,000 within 30 days of the entry of this Order; $250,000 within

120 days of the entry of this Order; $250,000 within 180 days of this Order; and $650,000 within one year of the entry of this Order. Payments shall be applied first to post-order interest, which accrues pursuant to 31 U.S.C. § 3717. Prior to making the final payment set forth herein, Respondent shall contact the staff of the Commission for the amount due. If Respondent fails to make any payment by the date agreed and/or in the amount agreed according to the schedule set forth above, all outstanding payments under this Order, including post-order interest, minus any payments made, shall become due and payable immediately at the discretion of the staff of the Commission without further application to the Commission. The Commission may distribute civil money penalties collected in this proceeding if, in its discretion, the Commission orders the establishment of a Fair Fund pursuant to 15 U.S.C. § 7246, Section 308(a) of the Sarbanes-Oxley Act of 2002. The Fair Fund may be added to or combined with any other fund created in a related proceeding arising out of the same facts that are the basis of this Order. The Commission will hold funds paid pursuant to this paragraph in an account at the United States Treasury pending a decision whether the Commission, in its discretion, will seek to distribute funds or, subject to Exchange Act Section 21F(g)(3), transfer them to the general fund of the United States Treasury. If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. § 3717.

Payment must be made in one of the following ways:

(1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;

(2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at http://www.sec.gov/about/offices/ofm.htm; or

(3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying FibroGen, Inc. as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Pei Chung, Associate Director, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549.

C. Monies paid in this proceeding may be combined with any other Distribution Fund

or Fair Fund in a related proceeding arising out of the same underlying facts that are the basis of this Order.

D. Regardless of whether the Commission in its discretion orders the creation of a Fair Fund for the penalties ordered in this proceeding, amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

By the Commission.

Vanessa A. Countryman
Secretary