# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): April 6, 2021**

# FibroGen, Inc.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-36740** | **77-0357827** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**FibroGen, Inc.**
**409 Illinois Street**
**San Francisco, CA 94158**
**(Address of principal executive offices, including zip code)**

**(415) 978-1200**
**(Registrant's telephone number, including area code)**

**Not Applicable**
**(Former name or former address, if changed since last report.)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.01 par value | FGEN | The Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 8.01 Other Events.**

On April 6, 2021, FibroGen, Inc. issued a press release providing additional information clarifying 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.

A copy of such press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release titled "FibroGen Provides Additional Information on Roxadustat" dated April 6, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**FIBROGEN, INC.**

Dated: April 6, 2021

By: /s/ Michael Lowenstein
Michael Lowenstein
Chief Legal Officer

**FibroGen Provides Additional Information on Roxadustat**

*Company Continues to be Confident in the Benefit / Risk Profile of Roxadustat*

*Company to Host Investor Call Today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time)*

SAN FRANCISCO – April 6, 2021 – 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").

"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."

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."

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.

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.

**Pooled Cardiovascular Safety Data**

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.

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+: the components of MACE, plus 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.

These analyses do not change the Company’s assessment that roxadustat is comparable to placebo in non-dialysis dependent patients and to epoetin-alfa in

dialysis dependent patients using MACE to measure cardiovascular safety.

As previously announced, roxadustat has been launched in China and Japan for the treatment of anemia of CKD in both NDD and DD adult patients. These approvals were based on different studies conducted in the relevant geographies. In Europe, the Marketing Authorization Application for roxadustat for the treatment of anemia of CKD in patients both on dialysis and not on dialysis was filed by FibroGen's partner Astellas and accepted by the European Medicines Agency for review in May 2020.

**Conference Call and Webcast Details**

FibroGen will host a conference call and webcast today, April 6, 2021, at 5:00 pm Eastern Time (2:00 p.m. Pacific Time) to discuss this matter. Interested parties may access a live audio webcast of the conference call via the FibroGen website at https://fibrogen.gcs-web.com/events-and-presentations/events. It is recommended that listeners access the website 15 minutes prior to the start of the call to download and install any necessary audio software.

Dial-In Information
Live (U.S./Canada): (877) 658-9081
Live (International): (602) 563-8732
Confirmation number: 5297733

A replay of the webcast and investor presentation will be available shortly after the call for a period of 30 days. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international), and use passcode 5297733.

**About Anemia of CKD**
Chronic kidney disease (CKD) 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. CKD is estimated to occur in approximately 10-12% of adults worldwide and is predicted to become the fifth most common cause of premature death globally by 2040.

Anemia, a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin, is a common early complication of CKD, affecting approximately 20% of CKD patients. Anemia of CKD is associated with an increased risk of hospitalization, cardiovascular complications, and death, and

can also cause significant fatigue, cognitive dysfunction and reduced quality of life. Blood transfusions are used for treating severe anemia, however, they may reduce a patient's opportunity for kidney transplant and can increase the risk of infection and/or complications such as heart failure and allergic reactions.

**About Roxadustat**

Roxadustat, an oral medicine, is the first in a new class of medicines, HIF-PH inhibitors that promote erythropoiesis, or red blood cell production, through increased endogenous production of erythropoietin; improved iron absorption and mobilization; and downregulation of hepcidin. Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA).

Roxadustat is approved in China, Japan, and Chile for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). In Europe, the Marketing Authorization Application for roxadustat for the treatment of anemia of CKD in patients both on dialysis and not on dialysis was filed by our partner Astellas and accepted by the European Medicines Agency for review in May 2020. Several other licensing applications for roxadustat have been submitted by Astellas and AstraZeneca to regulatory authorities across the globe, and are currently in review.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in territories including Japan, Europe, Turkey, Russia and the Commonwealth of Independent States, the Middle East, and South Africa. FibroGen and AstraZeneca are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in the U.S., China, other markets in the Americas, in Australia/New Zealand, and Southeast Asia.

**About FibroGen**

FibroGen, Inc. is a biopharmaceutical company committed to discovering, developing, and commercializing a pipeline of first-in-class therapeutics. The Company applies its pioneering expertise in hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology to advance innovative medicines for the treatment of unmet needs. The Company is currently developing and commercializing roxadustat, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, for anemia associated with chronic kidney disease (CKD).

Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA). Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF). For more information, please visit www.fibrogen.com.

**Forward Looking Statements**

This release contains forward-looking statements regarding the Company's prospects, including statements regarding the safety and efficacy profile of our product candidates and regulatory results, strategy and interactions, including those of our partners. Forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "will", "should," "on track," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of our various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the Securities and Exchange Commission (SEC), and the risk factors set forth therein, including without limitation, risks related to obtaining regulatory approval and the planned FDA Advisory Committee meeting. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release, except as required by law.

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