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): August 11, 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 August 11, 2021, FibroGen, Inc. ("FibroGen") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has issued a complete response letter regarding the New Drug Application ("NDA") for roxadustat for the treatment of anemia of chronic kidney disease. The 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, prior to resubmission.

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 Receives Complete Response Letter from the FDA for Roxadustat for Anemia of Chronic Kidney Disease" dated August 11, 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.

Dated: August 11, 2021

FIBROGEN, INC.

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

FibroGen Receives Complete Response Letter from the FDA for Roxadustat for Anemia of Chronic Kidney Disease

SAN FRANCISCO, AUGUST 11, 2021 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) today announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter regarding the New Drug Application (NDA) for roxadustat for the treatment of anemia of chronic kidney disease (CKD).

The letter indicates the FDA will not approve the roxadustat NDA in its present form and has requested additional clinical study of roxadustat be conducted, prior to resubmission.

“We are deeply disappointed with this result, and this is an unfortunate day for patients suffering from anemia of CKD in the United States,” said Enrique Conterno, Chief Executive Officer, FibroGen. “Roxadustat is changing the lives of patients around the world, and we and our partner AstraZeneca will discuss next steps in the U.S.”

Roxadustat is approved in China, Japan, Chile, and South Korea for the treatment of anemia of CKD in both non-dialysis-dependent (NDD) and dialysis-dependent (DD) adult patients and has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP), the European Medicines Agency’s committee responsible for human medicines. The European Commission decision is expected by the end of August.

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 percent 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 percent 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, Chile, and South Korea for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). In Europe, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion relating to the use of roxadustat for the treatment of adult patients with symptomatic anemia associated with chronic kidney disease (CKD). 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 of CKD 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 of CKD 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 of 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 our strategy, future plans and prospects, including statements regarding the development and commercialization of the company’s product candidates and product, the potential safety and efficacy profile of our product candidates and product, our clinical programs and regulatory events, and those of our partners, and the commercial and clinical success of HIFRENZO (roxadustat) in anemia of CKD. These 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 and our Quarterly Report on Form 10-Q for quarter ended June 30, 2021 filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. 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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