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): December 18, 2020

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 December 18, 2020, FibroGen, Inc. ("FibroGen") issued a press release announcing 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 by three months and the new Prescription Drug User Fee Act action date set by the FDA is March 20, 2021. The FDA is close to finalizing its review of the NDA and FibroGen is submitting additional analyses of existing roxadustat clinical data, which is considered a major amendment, thus granting the FDA three months for review.

A copy of such press release is furnished 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 Regulatory Update on Roxadustat" dated December 18, 2020
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: December 18, 2020

FIBROGEN, INC.

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

FibroGen Provides Regulatory Update on Roxadustat

SAN FRANCISCO, December 18, 2020 (GLOBE NEWSWIRE) – 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.

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.

“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.”

Roxadustat, an oral small molecule hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor, is the first HIF-PH inhibitor accepted by the FDA for review for the treatment of anemia of CKD. The NDA for roxadustat is based on positive results from a global Phase 3 program encompassing more than 8,000 patients.

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 called HIF-PH inhibitors that promotes erythropoiesis, or RBC 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 MDS syndromes and for chemotherapy-induced anemia.

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 in CKD in NDD and DD patients was filed by Astellas Pharma Inc. (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, which 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 and in Australia/New Zealand as well as 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 idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and coronavirus (COVID-19). 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 development and commercialization of the Company's product candidates, including roxadustat regulatory events. 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, 2019 and our Quarterly Report on Form 10-Q for quarter ended September 30, 2020 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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