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 7.01 Regulation FD Disclosure

On April 6, 2021, FibroGen, Inc. ("FibroGen") announced that the U.S. Food and Drug Administration (the "FDA") informed FibroGen late on Tuesday, April 6, 2021, that the FDA has tentatively scheduled a Cardiovascular and Renal Drug Advisory Committee meeting on July 15, 2021 to review the New Drug Application for roxadustat for the treatment of anemia of chronic kidney disease in both dialysis-dependent and non-dialysis-dependent patients.

The information in this Item 7.01 is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Item 7.01 of this report will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this report is not intended to, and does not, constitute a determination or admission by the Company that the information in this report is material or complete, or that investors should consider his information before making an investment decision with respect to any security of the Company.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen Announces FDA Advisory Committee to Review Roxadustat New Drug Application Tentatively Scheduled for July 15, 2021" 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 Announces FDA Advisory Committee to Review Roxadustat New Drug Application Tentatively Scheduled for July 15, 2021

SAN FRANCISCO, APRIL 6, 2021 (GLOBE NEWSWIRE) -- FibroGen, Inc. (NASDAQ: FGEN) announced that the U.S. Food and Drug Administration (FDA) has informed the Company late today it has tentatively scheduled a Cardiovascular and Renal Drug Advisory Committee (CRDAC) on July 15, 2021 to review the New Drug Application (NDA) for roxadustat for the treatment of anemia of chronic kidney disease (CKD) in both dialysis-dependent and non-dialysis-dependent patients.

The NDA submission was supported by positive results from a global Phase 3 program encompassing more than 8,000 patients. Roxadustat is approved and launched in China and Japan for the treatment of anemia of CKD in patients on dialysis and not on dialysis.

About Cardiovascular and Renal Drugs Advisory Committee
The Cardiovascular and Renal Drugs Advisory Committee (CRDAC) reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational drug products for use in the treatment of cardiovascular and renal disorders, and makes appropriate recommendations to the Commissioner of Food and Drugs. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of a product is made solely by the FDA.

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.

Contacts:
FibroGen, Inc.

Investors:
Michael Tung, M.D.
Corporate Strategy / Investor Relations
1.415.978.1434
mtung@fibrogen.com

Media:
Jennifer Harrington
1.610.574.9196
Jennifer.Harrington@gcihealth.com

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