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): February 11, 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 February 11, 2020, FibroGen, Inc. ("FibroGen") announced acceptance by the U.S. Food and Drug Administration (the "FDA") of FibroGen's New Drug Application (the "NDA") for roxadustat for the treatment of anemia of chronic kidney disease, in both non-dialysis-dependent and dialysis-dependent patients. The FDA notified us that it has completed its filing review, and the NDA will be considered filed on February 18, 2020. The FDA has set a Prescription Drug User Fee Act goal date of December 20, 2020. The filing of the NDA triggers a $50 million milestone payment to FibroGen from AstraZeneca, its collaboration partner for the U.S.

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 Announces U.S. FDA Acceptance of New Drug Application for Roxadustat for the Treatment of Anemia of Chronic Kidney Disease" dated February 11, 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: February 11, 2020

FIBROGEN, INC.

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

Exhibit 99.1

FibroGen Announces U.S. FDA Acceptance of New Drug Application for Roxadustat for the Treatment of Anemia of Chronic Kidney Disease

SAN FRANCISCO, February 11, 2020 (GLOBAL NEWSWIRE) – FibroGen, Inc. (NASDAQ:FGEN) today announced that the U.S. Food and Drug Administration (FDA) has completed its filing review of its New Drug Application (NDA) for roxadustat for the treatment of anemia of chronic kidney disease (CKD), in both non-dialysis-dependent (NDD) and dialysis-dependent (DD) patients. The application will be considered filed on February 18, 2020. The FDA has set a Prescription Drug User Fee Act (PDUFA) date of December 20, 2020.

"The FDA's acceptance of the roxadustat new drug application is a critical step towards providing a new treatment option in the United States for chronic kidney disease patients suffering from anemia, a serious and often life-threatening disease," said Enrique Conterno, Chief Executive Officer, FibroGen.

"There is significant unmet medical need for patients with anemia of CKD, who have seen only limited advances in the last three decades," said Peony Yu, M.D., Chief Medical Officer, FibroGen. "We intend to work closely with the FDA, in collaboration with our partner, AstraZeneca, to make this novel oral therapy available as soon as possible."

The filing of the roxadustat NDA triggers a $50 million milestone payment from AstraZeneca (LSE/STO/NYSE: AZN) to FibroGen.

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

Roxadustat is currently approved in China for the treatment of anemia in patients with CKD, regardless of whether they require dialysis, and in Japan for the treatment of dialysis patients with anemia of CKD. FibroGen's partner Astellas also intends to file a marketing authorization application with the European Medicines Agency in the first half of 2020.

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About Anemia Associated with CKD

Anemia results from the reduced oxygen-carrying capacity of the blood, in which patients typically have insufficient red blood cells and/or low levels of hemoglobin, a protein in red blood cells that carries oxygen to cells throughout the body. CKD anemia, which can be associated with increased risk of hospitalization, cardiovascular complications, and death, also frequently causes significant fatigue, cognitive dysfunction, and reduced quality of life. Severe anemia is common in patients with CKD, cancer, myelodysplastic syndromes (MDS), inflammatory diseases, and other serious illnesses.

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 to survive. The prevalence of CKD in the adult population is estimated at 10-12% globally. Anemia is particularly prevalent in patients with CKD, and life-threatening severe anemia in CKD patients is often treated with blood transfusions. However, such transfusions reduce the patient's opportunity for kidney transplant, increase risk of infections, and carry the risk of complications such as heart failure and allergic reactions.

According to the United States Renal Data System (USRDS), over 14% of the U.S. adult population is affected by CKD, and a majority of dialysis-eligible CKD patients are currently on dialysis. It is estimated that approximately 509,000 patients are receiving dialysis in the U.S. as of 2016.

About Roxadustat

Roxadustat (FG-4592) is a first-in-class, orally administered small molecule HIF-PH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, as well as improving iron regulation and overcoming the EPO-suppressive effects of inflammation on hemoglobin syntheses and red blood cell production.

Roxadustat is currently approved in China for the treatment of anemia in CKD patients on dialysis and patients not on dialysis and approved in Japan for the treatment of anemia in CKD patients on dialysis. Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes (MDS), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia.

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

About FibroGen

FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, is a leading biopharmaceutical company discovering and developing 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, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, the company's most advanced product, is an oral small molecule inhibitor of HIF prolyl hydroxylase (HIF-PH) activity, completing worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), is approved by the National Medical Products Administration (NMPA) in China for CKD patients on dialysis and not on dialysis, and by the Ministry of Health, Labour and Welfare (MHLW) in Japan for CKD patients on dialysis. The NDA for roxadustat for treatment of CKD anemia was submitted to the U.S. FDA in December 2019. Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes (MDS), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). FibroGen is also developing a biosynthetic cornea in China. For more information, please visit www.fibrogen.com.

Forward-Looking Statements

This release contains forward-looking statements regarding the timing, our strategy, future plans, and prospects regarding the development and commercialization of the company's product candidates. These forward-looking statements include, but are not limited to, statements about the timing of regulatory events, the potential of roxadustat to treat CKD anemia patients, receipt of funds from our collaboration partner, 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, 2018 and our quarterly report on 10-Q for the fiscal quarter ended September 30, 2019 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.

Exhibit 99.1

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