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): September 20, 2019

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 September 20, 2019, FibroGen, Inc., together with its collaboration partner Astellas Pharma Inc., announced that the Ministry of Health, Labour and Welfare in Japan has approved Evrenzo® (generic name: roxadustat) for the treatment of anemia associated with chronic kidney disease in dialysis patients.

A copy of such press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibits

Exhibit No.	Description
99.1	Press Release titled "Roxadustat Approved in Japan for the Treatment of Anemia Associated with Chronic Kidney Disease in Dialysis Patients" dated September 20, 2019
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: September 20, 2019

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

Press Release

Roxadustat Approved in Japan for the Treatment of Anemia Associated with Chronic Kidney Disease in Dialysis Patients

SAN FRANCISCO and Tokyo, September 20, 2019- FibroGen, Inc. (Nasdaq: FGEN, Interim CEO: James A. Schoeneck, "FibroGen") and Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) approved Evrenzo® (generic name: roxadustat; tradename Evrenzo® in Japan) for the treatment of anemia associated with chronic kidney disease (CKD) in dialysis patients.

Roxadustat is a first-in-class orally administered inhibitor of hypoxia-inducible factor (HIF) prolylhydroxylase that corrects anemia by a mechanism of action that is different from that of erythropoiesis-stimulating agents (ESAs). As a HIF-PH inhibitor, roxadustat activates a response that occurs naturally when the body responds to reduced oxygen levels in the blood. The response activated by roxadustat involves the regulation of multiple, complementary processes to promote erythropoiesis and increase the blood's oxygen-carrying capacity.

"Evrenzo® is a valuable new treatment option for dialysis patients with CKD anemia," said Bernhardt G. Zeiher, M.D., Chief Medical Officer, Astellas. "Astellas is committed to improving the health of people worldwide and expanding treatment options, especially within the dialysis community where there is high-unmet need. We are delighted to bring this important new treatment option to both patients suffering from, and healthcare professionals treating, this debilitating condition."

CKD anemia can severely worsen the outcomes of kidney disease, increasing the rate of progression to renal failure[1] and the likelihood of cardiovascular complications.[2] It also significantly reduces patients' quality of life and their cognitive ability.[3] Reaching and maintaining target hemoglobin levels can present challenges and roxadustat provides an alternative therapeutic option.

"We appreciate the commitment and focus of our partner Astellas as we work together to bring a new therapy to CKD anemia patients on dialysis in Japan," said K. Peony Yu, M.D., Chief Medical Officer, FibroGen. "With this approval in Japan, NDA approval in China, and EU MAA and U.S. NDA preparations underway, we are another step closer to our goal of addressing the significant unmet medical need of patients living with anemia associated with CKD, worldwide."

The approval is based on four Phase 3 studies conducted in CKD anemia patients on dialysis in Japan.[4,5,6,7] The studies demonstrated that roxadustat was effective at raising hemoglobin and that it was well-tolerated. This marks the first approval for roxadustat through the Astellas and FibroGen collaboration.

Product Information

PRODUCT NAME	Evrenzo® Tablets 20mg Evrenzo® Tablets 50mg Evrenzo® Tablets 100mg
GENERAL NAME	Roxadustat
INDICATIONS	Renal anemia in patients on dialysis
DOSAGE AND ADMINISTRATION	*Patients not on erythropoiesis-stimulating agent treatment.* For adults, the usual dosage is 50mg, the starting dose, as roxadustat orally administered three times weekly. The dosage thereafter should be adjusted according to the patient's condition; however, the maximum dose should not exceed 3.0mg/kg. *Patients switching from erythropoiesis-stimulating agents.* For adults, the usual dosage is 70 or 100mg, the starting dose, as roxadustat orally administered three times weekly. The dosage thereafter should be adjusted according to the patient's condition; however, the maximum dose should not exceed 3.0mg/kg.
APPROVAL DATE	September 20, 2019

About Chronic Kidney Disease (CKD) and Anemia
CKD is a progressive loss of kidney function caused by damage to the kidneys resulting from conditions such as hypertension, diabetes, or immune-regulated inflammatory conditions.[8] Worldwide, more than 1 in 10 people are living with CKD.[9] In Japan, specifically, the prevalence of CKD has increased significantly over time.[10] Although CKD can occur at any age, it becomes more common in aging populations, and the prevalence is increasing. CKD is a critical worldwide healthcare issue that represents a large and growing unmet medical need.

Anemia is a common early complication of CKD,[11] affecting approximately 20% of patients with CKD.[12] It results from the failing kidneys' diminished ability to produce erythropoietin that stimulates red blood cell production from the bone marrow, and is associated with significant morbidity and mortality in dialysis and non-dialysis populations, increasing in both prevalence and severity as kidney disease worsens.[13] CKD anemia increases the risk of adverse cardiovascular events, worsens renal outcomes and negatively impacts patients' quality of life.[14,15] In addition, CKD can be both a cause and a consequence of cardiovascular disease and is now a critical worldwide healthcare issue that represents a large and growing unmet medical need.

About Roxadustat
In addition to receiving approval from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, roxadustat is approved in China for treatment of anemia associated with CKD in both dialysis-dependent and non-dialysis-dependent CKD patients. U.S. NDA and EU MAA preparation is underway. Roxadustat is also 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. For information about roxadustat studies, please visit www.clinicaltrials.gov at: https://clinicaltrials.gov/ct2/results?term=roxadustat&Search=Search.

Astellas and FibroGen are collaborating on the development of roxadustat for the potential treatment of anemia in territories including Japan, Europe, 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, and other markets.

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 candidate, 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), and is approved by the National Medical Products Administration (NMPA) in China, and by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. 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). 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.

About Astellas
Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit https://www.astellas.com/en.

FibroGen Forward-looking Statements
This release contains forward-looking statements regarding FibroGen strategy, future plans and prospects, including statements regarding the development of the company's product candidates, the potential safety and efficacy profile of our product candidates, and our clinical and regulatory plans, and those of our partners. 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, 2018 and our quarterly report on 10-Q for the fiscal quarter ended June 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.

Astellas Cautionary Notes
In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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