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): January 30, 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 January 30, 2020, FibroGen, Inc. and its collaboration partner, Astellas Pharma Inc., issued a press release in which they announced the submission of a supplemental New Drug Application to Japan's Ministry of Health for marketing approval for Evrenzo® (roxadustat) in Japan for the treatment of anemia associated with chronic kidney disease (CKD) in non-dialysis dependent patients. Roxadustat was approved in Japan for the treatment of anemia associated with CKD in dialysis dependent patients in September 2019.

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 "Astellas Submits Supplemental New Drug Application for Approval of Evrenzo® (roxadustat) for the Treatment of Anemia Associated with Chronic Kidney Disease in Non-Dialysis Dependent Patients in Japan" dated January 30, 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.

FIBROGEN, INC.

Dated: January 30, 2020

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

Press Release

Astellas Submits Supplemental New Drug Application for Approval of Evrenzo® (roxadustat) for the Treatment of Anemia Associated with Chronic Kidney Disease in Non-Dialysis Dependent Patients in Japan

TOKYO and San Francisco, January 30, 2020 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and FibroGen, Inc. (Nasdaq: FGEN, CEO: Enrique Conterno, "FibroGen") today announced the submission of a supplemental New Drug Application (sNDA) to Japan's Ministry of Health, Labour and Welfare to gain marketing approval for Evrenzo® (generic name: roxadustat) for the treatment of anemia associated with chronic kidney disease (CKD) in non-dialysis dependent (NDD) patients. Roxadustat was approved in Japan for the treatment of anemia associated with CKD in dialysis dependent (DD) patients in September 2019 and launched for use in this indication in November 2019.

The sNDA for the use of roxadustat in NDD-CKD patients is supported by three studies in more than 500 Japanese patients, which establish the profile within this group of patients.[1,2,3] The first, an open-label Phase 3 conversion study versus active comparator, darbepoetin alfa (genetical recombination) ("darbepoetin alfa"), met the primary efficacy endpoint of non-inferiority and continued to demonstrate maintenance of hemoglobin (Hb) levels over time.[1] Roxadustat was well tolerated and the safety profile of roxadustat was comparable to that of darbepoetin alfa.[1] The other two studies (one Phase 3 and one Phase 2) supports the safety and efficacy in patients naïve to erythropoiesis-stimulating agents (ESAs).[2,3]

"The data demonstrates that roxadustat is effective in increasing and maintaining Hb levels within the target range in patients with anemia associated with CKD who are not on dialysis," said Bernhardt G Zeiher, MD, Chief Medical Officer, Astellas. "This submission is an important next step to bringing roxadustat to even more patients with this condition in Japan, and this is particularly pertinent in the non-dialysis setting where many patients' anemia is currently not treated, or not treated to target."

"We are excited to reach another important milestone for roxadustat and appreciate the joint team's commitment to addressing the significant unmet medical need of patients living with anemia associated with CKD," said K Peony Yu, MD, Chief Medical Officer, FibroGen.

About Clinical Trials
For more information about the clinical trials associated with this submission (1517-CL-0310[1], 1517-CL-0314[2], 1517-CL-0303[3]), please visit www.clinicaltrials.gov.

About 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.[4] Worldwide, 1 in 10 people are living with CKD.[5] In Japan, specifically, the prevalence of CKD has increased significantly over time.[6] CKD is predicted to become the fifth most common cause of premature death globally by 2040.[7] It is a critical worldwide healthcare issue that represents a large and growing unmet medical need.

Anemia is a common early complication of CKD,[8] affecting approximately 20% of patients with CKD.[9] It results from the failing kidneys' diminished ability to produce erythropoietin, which stimulates red blood cell production from the bone marrow. It is associated with significant morbidity and mortality in dialysis and non-dialysis populations, increasing in both prevalence and severity as kidney disease worsens.[10] Anemia associated with CKD increases the risk of adverse cardiovascular events, worsens renal outcomes and can negatively impact patients' quality of life.[10,11,12]

About Roxadustat
Roxadustat is a first-in-class orally administered inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase (PH) that corrects anemia by a mechanism of action that is different from that of 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. Roxadustat is approved and launched for the treatment of anemia associated with CKD in Japan in DD patients and in China in both DD and NDD patients. An NDA has been submitted in the US. Also, roxadustat is in Phase 2 for chemotherapy-induced anemia.

Astellas Pharma Inc., and FibroGen, Inc. 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, Inc. and AstraZeneca are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in the US, China and other markets.

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.

About FibroGen
FibroGen, Inc., headquartered in San Francisco, with subsidiary offices in Beijing and Shanghai, is a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in HIF, connective tissue growth factor biology and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease and cancer. For more information, please visit www.fibrogen.com.

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) that is included in this press release is not intended to constitute an advertisement or medical advice.

FibroGen Forward-Looking Statements
This release contains forward-looking statements regarding FibroGen's 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, 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 September 30, 2019 filed with the

Securities and Exchange Commission, 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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