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): August 21, 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 August 21, 2019, FibroGen, Inc. announced that the National Medical Products Administration ("NMPA") in China has approved expansion of the marketing authorization of roxadustat, a first-in-class hypoxia-inducible factor prolyl hydroxylase inhibitor for the treatment of patients with anemia caused by chronic kidney disease ("CKD"), to include treatment in CKD patients who are not dialysis-dependent. Marketing authorization for roxadustat for the treatment of anemia associated with CKD in patients who are dialysis-dependent was granted by the NMPA in December 2018.

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.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "Roxadustat Approved in China for Treatment of Anemia in Chronic Kidney Disease Patients Not Receiving Dialysis" dated August 21, 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: August 21, 2019

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

ROXADUSTAT APPROVED IN CHINA FOR TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE PATIENTS NOT RECEIVING DIALYSIS

SAN FRANCISCO, August 21, 2019 -- FibroGen, Inc. (NASDAQ:FGEN) today announced that the National Medical Products Administration (NMPA) in China has approved expansion of the marketing authorization of roxadustat, a first-in-class hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the treatment of patients with anemia caused by chronic kidney disease (CKD) to include treatment in CKD patients who are not dialysis-dependent (NDD).

Marketing authorization for roxadustat for the treatment of anemia associated with CKD in patients who are dialysis-dependent (DD) was granted by the NMPA in December of 2018.

Anemia commonly develops in the presence of CKD, and is associated with cardiovascular disease, hospitalization, increased mortality risk, cognitive impairment, and reduced quality of life.[1] NDD-CKD patients in China include CKD Stage 3, Stage 4, and Stage 5 patients who are not eligible for dialysis, as well as a sizeable population of end-stage renal disease patients who are eligible for, but who are not receiving, dialysis. The prevalence rate of anemia (defined as Hb <12g/dL for women and <13g/dL for men) in this population in China is estimated to be approximately 50% for Stage 3 and 80% for Stage 4, and higher for Stage 5 and dialysis-eligible patients. Anemia in the NDD-CKD population is largely untreated in China.

“The NMPA approval of roxadustat for treatment of anemia in both dialysis-dependent and non-dialysis-dependent CKD patients is an important milestone in our multi-year commitment to bringing critically-needed and innovative medicines to a growing CKD population in China,” said Ms. Chris Chung, Senior Vice President, China Operations, FibroGen. “Roxadustat, as an oral treatment for anemia, represents an efficacious, safe, and accessible treatment for CKD patients in China, including the millions of CKD patients not receiving dialysis who are not reached by current therapies.”

Results of FibroGen’s Phase 3 study of roxadustat for the treatment of non-dialysis-dependent CKD patients, and a Phase 3 study in dialysis-dependent CKD patients, were reported in two articles recently published in the *New England Journal of Medicine*.[2, 3]

FibroGen’s partner AstraZeneca and FibroGen (China) Medical Technology Development Co., Ltd. (FibroGen China) are collaborating on the development and commercialization of roxadustat in China. FibroGen China, a Beijing-based subsidiary of FibroGen, Inc., sponsored the development and registration of roxadustat as a Domestic Class 1 Innovative Drug. FibroGen China conducted the China Phase 3 clinical trials and submitted the New Drug Application for registration of roxadustat to the Chinese regulatory authorities. Following this approval, AstraZeneca manages commercialization

activities in China, and FibroGen China manages commercial manufacturing and medical affairs, as well as clinical development and regulatory affairs.

About Anemia Associated with CKD in China
Anemia commonly develops in association with chronic kidney disease and is linked to significant morbidity and mortality in both the dialysis and non-dialysis populations. Although CKD may occur at any age, it is more common in aging populations, and its prevalence is increasing. CKD can be both a cause and a consequence of cardiovascular disease and is a critical healthcare issue. There is no treatment available that is curative or can stop kidney deterioration.

In China, 120 million people have chronic kidney disease. [4] Anemia is a complication of chronic kidney disease, is associated with morbidity and mortality [5, 6] and remains undertreated in non-dialysis chronic kidney disease patients worldwide due to delayed nephrology referral [7] and concerns over erythropoiesis stimulating agent safety. [8-10]

About Roxadustat
Roxadustat (FG-4592), discovered by FibroGen, is a first-in-class, orally administered small molecule currently approved in China for the treatment of anemia in CKD patients on dialysis. Roxadustat is a HIF-PH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, improving iron regulation, and overcoming the negative impact of inflammation on hemoglobin syntheses and red blood cell production by downregulating hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis, increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of CKD patients, including in the presence of inflammation and without a need for supplemental intravenous iron.

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), 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. Together with our collaboration partners Astellas and AstraZeneca, preparation for regulatory submissions for the treatment of anemia in chronic kidney disease (CKD) to the U.S. FDA, the EMA, and other regulatory authorities is underway. Roxadustat is approved for treatment of anemia associated with CKD in China in both dialysis-dependent and non-dialysis-dependent CKD patients. Our partner Astellas submitted an NDA for the treatment of anemia in CKD patients on dialysis in Japan in September 2018, which is currently under review by the Pharmaceuticals and Medical Devices Agency (PMDA). 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 for the treatment of pancreatic cancer. Pamrevlumab is also 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 our strategy, future plans and prospects, including statements regarding the development of the company's product candidates pamrevlumab and roxadustat, 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.

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Contact
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