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): July 24, 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 July 24, 2019, FibroGen, Inc. (“FibroGen”) issued two press releases announcing two publications in the New England Journal of Medicine. The first is of results from its China Phase 3 clinical study of the efficacy and safety of roxadustat for the treatment of anemia in chronic kidney disease for patients receiving dialysis. The second publication is of results from FibroGen’s China Phase 3 trial of the efficacy and safety of roxadustat for the treatment of anemia in patients with chronic kidney disease not on dialysis. Copies of such press releases are attached as Exhibit 99.1 and Exhibit 99.2 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 “The New England Journal of Medicine (NEJM) Publishes Roxadustat China Phase 3 Results for the Treatment of Anemia in Chronic Kidney Disease Patients Receiving Dialysis” dated July 24, 2019
99.2	Press Release titled “Roxadustat China Phase 3 Trial for Treatment of Anemia in Chronic Kidney Disease Patients Not on Dialysis Published in the New England Journal of Medicine (NEJM)” dated July 24, 2019

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: July 24, 2019

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

THE NEW ENGLAND JOURNAL OF MEDICINE (NEJM) PUBLISHES ROXADUSTAT CHINA PHASE 3 RESULTS FOR THE TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE PATIENTS RECEIVING DIALYSIS

-- One of Two Concurrent Publications of Roxadustat China Phase 3 Results in The New England Journal of Medicine --

SAN FRANCISCO, July 24, 2019 - FibroGen, Inc. (NASDAQ: FGEN) today announced the publication of clinical study results in the *New England Journal of Medicine (NEJM)*[1] from the China Phase 3 trial of the efficacy and safety of roxadustat treatment for anemia in chronic kidney disease patients receiving dialysis and were receiving epoetin alfa prior to study participation. In this study, the primary efficacy endpoint was the mean change from the baseline in the hemoglobin level, averaged over Weeks 23 through 27. Roxadustat treatment resulted in a numerically greater mean increase in the hemoglobin level from baseline compared to epoetin alfa, and was non-inferior to epoetin alfa.

Inflammation is a well-known cause of suppression of hemoglobin response in the erythropoiesis-stimulating agents (ESAs) in dialysis patients, reported in published literatures and was observed in the active comparator arm in this study. In contrast, inflammation, measured by elevated baseline C-reactive protein (CRP, a measure of inflammation) levels, did not appear to affect the hemoglobin response with roxadustat treatment in this study. Favorable changes in iron metabolism markers, such as transferrin, hepcidin, and serum iron, were noted with roxadustat as compared to epoetin alfa; this could result in reduced use of intravenous iron therapy and improved efficacy of oral iron supplementation with roxadustat.

Roxadustat, is the first-in-class oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) achieved the first in world approval in China in December 2018 for the treatment of anemia associated with chronic kidney disease (CKD) in dialysis-dependent patients.

“The treatment of anemia associated with chronic kidney disease remains a serious need in China, with limited access to anemia therapy and blood transfusions, as well as limited ESA effectiveness in this population where inflammation is highly prevalent,” said Professor Chen Nan, Department of Nephrology, Institute of Nephrology, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai. “As the first oral medication approved for anemia in dialysis dependent CKD patients, we are hopeful roxadustat will make a significant contribution to a patient care.”

Anemia caused by CKD is associated with cardiovascular disease, hospitalization, cognitive impairment, and reduced quality of life, and has been shown consistently to be associated with an increased mortality risk[2]. Anemia becomes increasingly common among individuals with CKD as their kidney function declines, affecting nearly all CKD patients at the dialysis-eligible stage[2].

The trial (FGCL-4592-806) was a randomized open-label, active controlled study designed to compare

the efficacy and safety of oral roxadustat to intravenous epoetin alfa (ESPO®, Kyowa Hakko Kirin) in treatment of anemia patients receiving chronic dialysis who were previously on epoetin alfa treatment.

In this China Phase 3 study, a total of 305 patients were randomized to roxadustat (n=204) and epoetin alfa (n=101) for a 26-week treatment period. The primary endpoint was the average change in hemoglobin from baseline to Week 23-27. The average baseline hemoglobin level was 10.4 g/dL. Notably, use of parenteral iron was restricted in these patients except as a rescue therapy.

- Roxadustat treatment resulted in a numerically greater mean hemoglobin change from baseline to Weeks 23-27 (0.7 g/dL$\pm$1.1) than epoetin alfa, (0.5 g/dL $\pm$1.0), and was non-inferior to EPO, in Full Analysis Set (FAS).
- Roxadustat-treated patients with elevated CRP had the similar hemoglobin response and dose requirement as in patients with normal CRP, and achieved higher Hb level than EPO-treated patients with elevated CRP level. EPO-treated patients with elevated CRP achieved lower hemoglobin response than those with normal CRP despite receiving higher doses of epoetin alfa.
- % patients maintain Hb response (hemoglobin level not <1.0 g/dL below baseline value): 92.5% in both the roxadustat and EPO study arms.
- Roxadustat increased transferrin, maintained serum iron, and attenuated transferrin saturation (TSAT) decreases versus epoetin alfa.
- Roxadustat was associated with a reduction in hepcidin (by a mean of 30.2 ng/ml (95% CI (-64.8, -13.6)) compared to 2.3 ng/ml with epoetin alfa (95% CI -51.6, 6.2)), the central regulator of iron homeostasis.

Of note, the previously reported mean hemoglobin level increase in the roxadustat arm higher than the comparator EPO arm (0.75g/dL vs. 0.46g/dL; p=0.037) was based on Per Protocol analysis per regulatory guidance.

The Phase 3 results importantly demonstrated roxadustat's ability to correct anemia in patients with high levels of inflammation, a population known for poor response to ESA therapy.

The adverse events observed during treatment were consistent with those expected in patients undergoing dialysis.

"Publication of the data from China Phase 3 anemia study in CKD patients on dialysis in the *New England Journal of Medicine* highlights the potential impact of roxadustat as the first oral anemia therapy, an effective therapy in maintaining hemoglobin levels in end-stage renal disease patients on dialysis, with or without comorbidity of inflammation," said K. Peony Yu, M.D., Chief Medical Officer of FibroGen. "We are grateful for the opportunity to improve anemia care for a growing patient population as the number of patients requiring anemia therapy is expected to grow steadily as the CKD population and access to dialysis care continue to expand in China and globally."

Roxadustat was approved by the National Medical Products Administration (NMPA) in China for patients with chronic kidney disease receiving dialysis in December 2018 and is currently under review for approval for the treatment of anemia in CKD patients not receiving dialysis (China Approved Drug Name: □□□□; Chinese brand name: □□□®).

In addition, FibroGen today announced publication of the results in the NEJM from the China Phase 3 trial of the efficacy and safety of roxadustat treatment compared to placebo for anemia in non-dialysis dependent (NDD) CKD patients [3].

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 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, and 500,000 receive dialysis [4,5]. Anemia is present in >90% of dialysis patients [6] contributing to morbidity and mortality [7]. Anemia treatment is recommended by clinical practice guidelines [8-11], however, studies link high-dose erythropoiesis-stimulating agents to an increased risk of cardiovascular events and death [12-14] with only half the patients in China receiving dialysis achieving hemoglobin level of 10.0 g/dL or greater using recombinant erythropoietin. This apparent undertreatment may result from the medication's cost, hypo-responsiveness from inflammation, or iron-depletion[15].

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, completing Phase 3 clinical development worldwide for the treatment of anemia in chronic kidney disease (CKD), with a New Drug Application (NDA) now approved by the National Medical Products Administration (NMPA) in China. 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 advancing towards Phase 3 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, 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 March 31, 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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ROXADUSTAT CHINA PHASE 3 TRIAL FOR TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE PATIENTS NOT ON DIALYSIS PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE (NEJM)

-- One of Two Concurrent Publications of Roxadustat China Phase 3 Results in The New England Journal of Medicine --

SAN FRANCISCO, July 24, 2019 - FibroGen, Inc. (NASDAQ: FGEN) today announced publication of results from the Phase 3 trial of the efficacy and safety of roxadustat treatment compared to placebo for anemia in non-dialysis patients (NDD) with chronic kidney disease (CKD) in the People's Republic of China (China) in the *New England Journal of Medicine (NEJM)*[1]. In this study, roxadustat met its primary efficacy endpoint for anemia correction by achieving a statistically significant increase in mean hemoglobin level from baseline to hemoglobin level averaged over Weeks 7 through 9. The efficacy of roxadustat in hemoglobin correction and maintenance was maintained during the open-label period of Weeks 9 through 26.

"In China, there is a growing advanced stage CKD population. Anemia management, especially in those patients not receiving dialysis, has been challenging as the current injectable therapies require frequent administration at medical facilities, leaving a significant proportion of patients untreated. This orally available medicine, roxadustat, the first-in-class HIF-PHI, has the potential to address this medical need," said Professor Nan Chen, Department of Nephrology, Institute of Nephrology, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai.

"An accessible anemia therapy like roxadustat is much needed for anemic CKD patients in both urban and countryside areas. We look forward to the addition of the treatment of anemia in non-dialysis dependent CKD patients to the roxadustat label," said Professor Chuanming Hao, M.D., Ph.D., Division of Nephrology, Huashan Hospital Fudan University, Shanghai.

Anemia in CKD is associated with cardiovascular disease, hospitalization, cognitive impairment, and reduced quality of life, and has been shown consistently to be associated with an increased risk of mortality [2].

The trial (FGCL-4592-808) featured an 8-week double-blind placebo-controlled initial treatment period in which roxadustat was compared to placebo in non-dialysis dependent CKD patients with anemia in China[1]. Following this initial period, all patients continuing the study received roxadustat for an 18-week open-label treatment period. Notably, parenteral iron was restricted in these patients except as a rescue therapy. The primary endpoint was the average change in hemoglobin from baseline to Week 7 through 9.

Randomized Double-Blind Phase (First 8 Weeks)

For the initial double-blind period, 154 patients were randomized to roxadustat (n=102) and placebo (n=52), respectively.

- The primary endpoint was met, as the mean change in hemoglobin from baseline (8.9 g/dL) to Weeks 7-9 was +1.9 g/dL in the roxadustat group, significantly greater improvement compared to the placebo group with -0.4 g/dL ($p<0.001$) .

- Secondary endpoints:
    - A higher percentage of patients showed hemoglobin response (defined as a hemoglobin increase of ≥1.0 g/dL from baseline) at Week 9, with a responder rate of 84% (85 of 101) of roxadustat-treated patients compared to 0% (none of 50) in the placebo group , for a between-group difference of 84 percentage points (95% CI, 75 to 91).
    - A higher percentage of roxadustat-treated patients achieved average hemoglobin level of ≥10 g/dL at Weeks 7–9, with 67% in the roxadustat group compared to 6% in the placebo group, for a between-group difference of 61 percentage points (95% CI, 47 to 72).
    - Patients receiving roxadustat had a significant reduction in hepcidin with a change from baseline to Week 9 of -56.14 ng/mL, compared to -15.10 ng/ml in the placebo group, for a between-group difference of -49.77 ng per milliliter (95% CI, -66.75 to -32.79).
    - Significant reduction of LDL cholesterol level with a change from baseline to Week 9 of -25.3 mg/dL was seen in the roxadustat group, compared to -5.8 mg/dL in the placebo group, for a between-group difference of -21.2 mg/L (-0.5 mmol/L; 95% CI, -0.8 to -0.3).

Open-Label Phase (Weeks 9 through 26)
Following completion of the 8-week randomized period, 87 patients from the roxadustat group and 44 patients from the placebo group participated in the 18-week open-label phase, in which all the patients received roxadustat.

- In those patients initially randomized to the roxadustat group (n=87), efficacy was maintained. The mean hemoglobin at Weeks 23-27 was maintained at +1.9 g/dL above baseline, and 84% of those patients achieved hemoglobin ≥11.0 g/dL during the 26-week treatment period.
- In those patients crossed over from the placebo group (n=44), anemia correction was demonstrated by achieving a 2.0 g/dL increase in hemoglobin from baseline averaged over Weeks 23-27, with 72% of the patients achieving hemoglobin ≥11.0 g/dL during the treatment period.

The most frequent treatment-emergent serious adverse events were typical of those among patients with chronic kidney disease.

“Publication of these data in the New England Journal of Medicine underscores the potential of roxadustat as an innovative and critically needed therapy for CKD patients not on dialysis, as well as for CKD patients on dialysis, for whom the National Medical Products Administration in China has already approved use of roxadustat to treat anemia of CKD,” said K. Peony Yu, M.D., Chief Medical Officer of FibroGen. “We are grateful for the collaboration and commitment shown by the investigators and patients who participated in the study.”

Roxadustat was approved by the National Medical Products Administration (NMPA) in China for patients with chronic kidney disease receiving dialysis in December 2018, and is currently under review by the NMPA for the treatment of anemia in CKD patients not receiving dialysis (China Approved Drug Name: □□□□; Chinese brand name: □□□®).

In addition, FibroGen today announced a second publication in the NEJM of results from the China Phase 3 trial of the efficacy and safety of roxadustat treatment compared to epoetin alfa for anemia in dialysis-dependent CKD patients [3].

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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.

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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 Study FGCL-4592-808
FGCL-4592-808 is a double-blind, placebo-controlled multi-center Phase 3 study in 154 patients not on dialysis, who were randomized 2:1 to roxadustat or placebo for the first eight weeks, during which 102 patients received roxadustat (initial dose of 70 mg or 100 mg, based on body weight) and 52 patients received placebo three times weekly (TIW), followed by dose titration to hemoglobin levels every four weeks as needed. After the initial eight-week period, placebo-treated patients were crossed over to receive 18 weeks of roxadustat treatment, while the active arm continued on roxadustat for the same period. The primary efficacy endpoint is hemoglobin change from baseline at the end of Week 8. A subset of roxadustat-treated patients entered the ongoing open-label extension for safety assessment and received roxadustat for up to 52 weeks of continuous exposure.

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, completing Phase 3 clinical development worldwide for the treatment of anemia in chronic kidney disease (CKD), with a New Drug Application (NDA) now approved by the National Medical Products Administration (NMPA) in China. 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 advancing towards Phase 3 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, 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 March 31, 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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References:

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