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): October 25, 2018

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))

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 October 25, 2018, FibroGen, Inc. issued a press release in which it announced the presentation of results from its Phase 3 studies of roxadustat for the treatment of anemia associated with chronic kidney disease conducted in China at the American Society of Nephrology Kidney Week 2018 in San Diego, California.

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 Presents Results from Two Phase 3 Studies of Roxadustat for the Treatment of Anemia Associated with Chronic Kidney Disease Conducted in China at American Society of Nephrology Kidney Week 2018 Annual Meeting" dated October 25, 2018

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: October 25, 2018

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

FibroGen Presents Results from Two Phase 3 Studies of Roxadustat for the Treatment of Anemia Associated with Chronic Kidney Disease Conducted in China at American Society of Nephrology Kidney Week 2018 Annual Meeting

San Francisco, CA – October 25, 2018 — FibroGen, Inc. (NASDAQ: FGEN), a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics, and FibroGen China Medical Technology Development Co., Ltd. (FibroGen China), today announced the presentation of results from two Phase 3 multi-center, randomized, controlled clinical trials of roxadustat (FG-4592 or □□□□1) for the treatment of anemia associated with chronic kidney disease (CKD) conducted in China at the American Society of Nephrology (ASN) Kidney Week 2018 annual meeting in San Diego, California. Roxadustat is a first-in-class oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) in late-stage development for the treatment of anemia associated with CKD both in patients on dialysis and in patients not on dialysis.

“The results of two Phase 3 trials in dialysis-dependent and non-dialysis-dependent CKD patients in China showed roxadustat effectively corrected and maintained hemoglobin levels, and are the basis of our new drug application currently under review by the National Medical Products Administration. These results are consistent with findings from multiple Phase 3 clinical studies reported to date by FibroGen and our partners, supporting roxadustat as the potential first oral drug for the treatment of anemia associated with chronic kidney disease, a serious and potentially life-threatening condition,” said Peony Yu, M.D., Chief Medical Officer of FibroGen. “If approved in China, roxadustat will be the first HIF-PHI available to help CKD patients with anemia, and patients in China could be first to gain access to treatment with roxadustat.”

Highlights of China Phase 3 Results Presented

Title: A Phase 3, Randomized, Open-Label, Active-Controlled Study of Efficacy and Safety of Roxadustat for Treatment of Anemia in Subjects with CKD on Dialysis

Presenters: Chen Nan, Shanghai Ruijin Hospital and Hao Chuanming, Shanghai Huashan Hospital

Abstract: TH-PO1152

Results

304 CKD patients on chronic dialysis were randomized and received treatment in this study (204 roxadustat, 100 Kirin brand epoetin alfa); 256 patients (162 roxadustat, 94 epoetin alfa) completed the 26-week treatment period. The average baseline hemoglobin overall was 10.4 g/dL. Roxadustat produced a numerically greater mean change in hemoglobin from baseline to Weeks 23-27 of 0.8 g/dL (±1.1) as compared to epoetin alfa, (0.5 g/dL ±1.0) and was statistically non-inferior. Roxadustat increased transferrin, maintained serum iron, and attenuated decreases in TSAT versus epoetin alfa (all $p<0.01$). At Week 27, the decline from baseline in both total and LDL cholesterol was greater with roxadustat (both

p<0.0001). Roxadustat reduced hepcidin from baseline by a mean of 30.2 ng/ml (p=0.003) compared to a reduction of 2.3 ng/ml in the epoetin alfa group (p=0.12).

In subgroup analysis based on the baseline CRP levels, which indicates the patient's inflammation status, roxadustat demonstrated consistent efficacy in hemoglobin control regardless of CRP levels without increase in roxadustat dose requirements, while epoetin alfa patients with elevated baseline CRP levels showed lower hemoglobin response despite receiving higher average doses of epoetin alfa compared to the doses patients with normal baseline CRP levels received. In the subgroup of inflamed patients (as measured by elevated CRP), mean change in hemoglobin from baseline to Weeks 23-27 were significantly higher in roxadustat than EPO, p=0.0034.

Roxadustat appeared to be well-tolerated in this study, there were no safety signals, and the most frequent treatment emergent adverse events were typical for this population.

Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Efficacy and Safety of Roxadustat (FG-4592) for Treatment of Anemia in Subjects with CKD Not on Dialysis

Presenters: Chen Nan, Shanghai Ruijin Hospital and Hao Chuanming, Shanghai Huashan Hospital

Abstract: TH-PO1153

Results

152 patients were randomized and received either roxadustat (n=101) or placebo (n=51) in the initial eight weeks. Subjects in the roxadustat arm had a greater mean (+SD) change from baseline in hemoglobin of 1.9 g/dL (±1.2) (mean baseline hemoglobin 8.9 (±0.8) g/dL), as compared to the mean change in the placebo group of -0.4 g/dL (±0.8) from a mean baseline of (8.9 (±0.7) g/dL (p<0.0001). At Week 9, patients in roxadustat group had a greater mean reduction in hepcidin of -56.14 (±63.40) (p<0.0001) vs. -15.10 (±48.06) ng/ml (p=0.17) in the placebo group (p<0. 0001 between groups). At Week 9, the decline from baseline in total cholesterol and LDL cholesterol in the roxadustat arm were larger than placebo (p<0.0001).

Following the initial eight-week period, all subjects continuing on study received roxadustat for an 18-week, open-label treatment period enabling patients initially randomized to placebo to have crossover to roxadustat. Among subjects treated with roxadustat during the initial eight weeks, hemoglobin remained stable for the subsequent 18-week, open-label period with an overall change from baseline of +1.9 (±1.3) g/dL over Weeks 23-27, with 79.7% of subjects achieving a hemoglobin ³11.0 g/dL during the 26-week treatment, and 71.1% achieved a mean hemoglobin ³10.0 g/dL averaged over Weeks 23-27. Among patients treated with placebo during the initial double-blind period, hemoglobin increased from baseline by 2.0 (±1.5) g/dL upon crossing over to roxadustat treatment (p<0.0001), 72.1% of subjects achieved a hemoglobin >11.0 g/dL during the last 18-weeks of treatment, and 86.0% achieved a mean hemoglobin >10.0 g/dL averaged over Weeks 23-27.

Roxadustat appeared to be well-tolerated in this study, there were no safety signals, and the most frequent treatment emergent adverse events were typical for this population.

About Studies FGCL-4592-808 and FGCL-4592-806 in China

FGCL-4592-806 is a multi-center, randomized, epoetin alfa-controlled, open-label Phase 3 study in 304 patients on dialysis conducted over 26 weeks. CKD patients on chronic dialysis (whose anemia was

previously treated with stable doses of one or more of nine brands of commercially available epoetin alfa) were randomized 2:1 to roxadustat or Kirin EPO, with 202 patients receiving roxadustat (initial dose of 100 mg or 120 mg TIW, based on body weight) and 100 patients receiving Kirin EPO, followed by dose titration to hemoglobin levels every four weeks as needed. 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.

FGCL-4592-808 is a double-blind, placebo-controlled multi-center Phase 3 study in 151 patients not on dialysis, who were randomized 2:1 to roxadustat or placebo for the first eight weeks, during which 101 patients received roxadustat (initial dose of 70 mg or 100 mg, based on body weight) and 50 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 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. CKD affects an estimated 119.5 million patients in China. 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. With the exception of kidney transplantation, there is no treatment available that is curative, or has the ability to stop kidney deterioration.

The dialysis population in China, which is estimated to be more than 400,000 patients, has been growing at a double-digit rate. The number of patients that require anemia therapy in China is expected to increase steadily, as the CKD population continues to grow and the number of dialysis patients increases. There is a significant opportunity for roxadustat to treat patients on dialysis (both hemodialysis and peritoneal dialysis) and not on dialysis, as well as to address unmet need in the large number of currently treated patients whose anemia remains undertreated or untreated in China.

About Roxadustat

Roxadustat (FG-4592) is a first-in-class, orally administered small molecule completing global Phase 3 clinical development as a potential therapy for anemia associated with chronic kidney disease (CKD). Roxadustat is a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) that promotes erythropoiesis through increasing endogenous erythropoietin, improving iron regulation, and reducing 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.

FibroGen and collaboration partners are pursuing four approval pathways in major jurisdictions to prepare for commercialization worldwide:

- 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, other markets in the Americas, Australia/New Zealand, as well as Southeast Asia.

FibroGen and its partners have completed 35 Phase 1 and Phase 2 studies. The Phase 2 clinical studies have consistently demonstrated anemia correction and maintenance of hemoglobin levels in multiple subpopulations across a wide spectrum of CKD patients.

Globally, the Phase 3 program encompasses a total of 15 Phase 3 studies of roxadustat in both non-dialysis-dependent and dialysis-dependent CKD patients to support independent regulatory approvals in the U.S., Europe, Japan, and China. To date, positive topline results have been announced for seven of the Phase 3 studies, with two supporting the China NDA for treatment of anemia in CKD patients on dialysis and not on dialysis, four supporting the Japan NDA for treatment of anemia in CKD patients on dialysis, and one supporting the U.S./EU submissions. The China and Japan NDAs are both under review by the respective regulatory agencies.

Roxadustat is currently in Phase 3 clinical development for the treatment of anemia associated with myelodysplastic syndromes (MDS) in the U.S. and in Phase 2/3 development for MDS in China.

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 activity, completing worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), with a New Drug Application (NDA) currently under review by the National Medical Products Administration in China. Our partner Astellas submitted a NDA for the treatment of anemia in CKD patients on dialysis in Japan and 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 advancing towards 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 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, 2017, and our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018 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

FibroGen, Inc.
Karen L. Bergman
Vice President, Investor Relations and Corporate Communications
1 (415) 978-1433
kbergman@fibrogen.com