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): December 20, 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 December 20, 2018, FibroGen, Inc. issued a press release in which it reported positive topline results from three pivotal Phase 3 studies of roxadustat, its potential first-in-class, orally administered small molecule for the treatment of anemia in chronic kidney disease patients. These three trials, ANDES, HIMALAYAS, and SIERRA, studied anemia in chronic kidney disease patients on dialysis, not on dialysis, and initiating dialysis.

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 Announces Positive Topline Results from Three Global Phase 3 Trials of Roxadustat for Treatment of Anemia in Patients with Chronic Kidney Disease" dated December 20, 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: December 20, 2018

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

FibroGen Announces Positive Topline Results from Three Global Phase 3 Trials of Roxadustat for Treatment of Anemia in Patients with Chronic Kidney Disease

Primary efficacy endpoints met in all three studies: non-dialysis, incident dialysis, and stable dialysis studies

SAN FRANCISCO, December 20, 2018 – FibroGen, Inc. (NASDAQ:FGEN), a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics, today announced that roxadustat, an inhibitor of hypoxia-inducible-factor (HIF) prolyl hydroxylase activity (HIF-PHI), met all primary efficacy endpoints in the three global pivotal Phase 3 trials conducted by FibroGen: ANDES in non-dialysis-dependent (NDD) chronic kidney disease (CKD) patients, HIMALAYAS in incident (newly initiated) dialysis patients, and SIERRAS in dialysis-dependent (DD) CKD patients.

“Anemia in CKD is a serious condition for which a significant number of patients are left without treatment options in many markets,” said Thomas B. Neff, Chief Executive Officer, FibroGen. “These Phase 3 results demonstrate the potential for roxadustat to be a first-in-class oral anemia therapeutic for CKD patients. This is the first well-controlled CKD anemia program that has shown improved efficacy in incident and stable dialysis patients relative to ESA standard of care therapy.”

Each of the three studies had a pre-specified primary efficacy endpoint for meeting U.S. regulatory requirements and another pre-specified primary efficacy endpoint for meeting EU regulatory requirements, which also served as a secondary efficacy endpoint for the U.S. Both the U.S. and EU primary efficacy endpoints were met in all three studies.

Non-Dialysis CKD Patients Study (ANDES[1])

ANDES is a 922-patient global Phase 3, randomized, double-blinded, placebo-controlled trial designed to evaluate the efficacy and safety of roxadustat versus placebo for the treatment of anemia in patients with later-stage CKD (stages 3, 4 or 5) who are not dialysis-dependent.[1] This study was conducted in the U.S. and 14 other countries. Treatment duration was up to 4.5 years, with average duration of 1.7 years. Baseline hemoglobin (Hb) levels averaged 9.1 g/dL in both the roxadustat (N=616) and the placebo (N=306) arms.

a. U.S. primary efficacy endpoint: Roxadustat was superior to placebo in mean Hb change from baseline to the average over Weeks 28-52 (2.00 vs 0.16 g/dL, respectively, $p<0.0001$).

b. EU primary efficacy endpoint: A higher proportion of roxadustat-treated patients (86.0%) achieved a Hb response in the first 24 weeks (defined as achieving a Hb level of at least 11 g/dL and a Hb increase of at least 1 g/dL) as compared to placebo (6.6%), p=0.0007.

Furthermore, in a pre-specified secondary efficacy analysis, roxadustat reduced the risk of rescue therapy by 81% (hazard ratio (HR)=0.19) defined as the time to first use of blood transfusion, administration of an erythropoiesis stimulating agent (ESA) or IV iron in the first 52 weeks of treatment, p<0.0001. In addition, roxadustat reduced the risk of blood transfusion by 74% (HR = 0.26) in the time to first blood transfusion during the first 52 weeks of treatment, p<0.0001.

Incident Dialysis CKD Patients Study (HIMALAYAS[2])

HIMALAYAS is a 1,043-patient global Phase 3 randomized, open-label, active-controlled trial to assess the efficacy and safety of roxadustat compared to epoetin alfa, an ESA, for the treatment of anemia in CKD patients who have newly initiated dialysis treatment for end stage renal disease and have had minimal or no exposure to ESA prior to study participation.[2] This study was conducted in the U.S. and 17 other countries. Treatment duration was up to 4.4 years, with mean duration of 1.8 years. Mean baseline Hb was 8.43 g/dL in the roxadustat arm (N=522) and 8.46 g/dL in the epoetin alfa arm (N=521).

a. U.S. primary efficacy endpoint: The mean Hb change from baseline to the average over Weeks 28-52 was 2.57 g/dL (roxadustat) vs. 2.36 g/dL (epoetin alfa), a least squares mean difference of 0.18 g/dL, with the 95% confidence interval (CI) of (0.08, 0.29). The non-inferiority criteria was met as the lower bound of the 95% CI was well above the non-inferiority margin of -0.75 g/dL, and superiority over epoetin alfa was also achieved, p=0.0005.

b. EU primary efficacy endpoint: Roxadustat met the non-inferiority criteria compared to epoetin alfa: 88.2% of the roxadustat-treated patients achieved a Hb response in the first 24 weeks (defined as achieving a Hb level of at least 11 g/dL and a Hb increase of at least 1 g/dL) compared to an 84.5% responder rate in the epoetin alfa arm; lower bound of the 95% CI (-0.9%, 7.6%) of the treatment difference in responder rate is well above the non-inferiority margin of -15%.

Stable Dialysis CKD Patients Study (SIERRAS[3])

SIERRAS is a 741-patient U.S. Phase 3, randomized, open-label, active-controlled trial to assess the efficacy and safety of roxadustat compared to epoetin alfa for the treatment of anemia (in maintaining Hb level) in DD-CKD patients who were receiving stable doses of ESA prior to study participation.[3] Treatment duration was up to 3.5 years, with a mean duration of 1.9 years. Mean baseline Hb levels were 10.3 g/dL in both roxadustat and epoetin alfa arms.

a. U.S. primary efficacy endpoint: The mean Hb change from baseline to the average over Weeks 28-52 was 0.39 g/dL (roxadustat) vs -0.09 g/dL (epoetin alfa), a least squares mean treatment difference of 0.48 g/dL (95% CI 0.37, 0.59). Roxadustat met the non-inferiority criteria as the lower bound of 95% CI was well above the non-inferiority margin of -0.75 g/dL. Roxadustat also achieved superiority, p<0.0001.

b. EU primary efficacy endpoint: The mean Hb change from baseline to the average over Weeks 28-36 was 0.54 g/dL (roxadustat) vs -0.02 g/dL (epoetin alfa), a least squares mean treatment difference of 0.53 g/dL with a 95% CI (0.39, 0.67). Roxadustat met the non-inferiority criteria as the lower bound of the 95% CI was well above the non-inferiority margin of -0.75 g/dL. Roxadustat also achieved superiority over epoetin alfa, p<0.0001.

In addition, in the pre-specified secondary efficacy analysis, roxadustat-treated patients had a 33% reduction in the risk of blood transfusion compared to epoetin alfa (HR=0.67) in the time to first blood transfusion during treatment, p=0.0337.

The preliminary safety analyses of each of these three individual studies show an overall safety profile consistent with the results observed in prior roxadustat studies. The adverse events reported are consistent with those expected in these study populations with similar background diseases.

These three Phase 3 studies sponsored and conducted by FibroGen are part of FibroGen's co-development collaboration with AstraZeneca AB and with Astellas Pharma Inc. These studies are part of the roxadustat global Phases 3 program, which consists of multiple global studies in more than 50 countries.

Results of the pooled safety analyses, including the major adverse cardiovascular events (MACE) for both NDD-CKD and DD-CKD in the global Phase 3 program is anticipated prior to U.S. NDA submission in the first half of 2019.

"We are excited to have achieved superiority in efficacy not only against placebo but also over active comparator in our studies," said K. Peony Yu, MD, Chief Medical Officer, FibroGen. "These results support roxadustat's potential to bring clinical benefit over current standard of care, such as reducing blood transfusion risk in patients on dialysis and those not on dialysis, and to improve patient access to anemia therapy with a new convenient oral therapeutic."

AstraZeneca also announced positive topline results today from its roxadustat phase 3 trials; OLYMPUS[4] in NDD-CKD and ROCKIES[5] in DD-CKD.

About Anemia Associated with CKD

Anemia can be a serious medical condition in which patients have insufficient red blood cells and low levels of Hb, a protein in red blood cells that carries oxygen to cells throughout the body.[6,7] Anemia in CKD is associated with increased risk of hospitalization, cardiovascular complications and death,[8] also frequently causing significant fatigue, cognitive dysfunction and reduced quality of life.[9] Severe anemia is common in patients with CKD, cancer, myelodysplastic syndromes (MDS), inflammatory diseases, and other serious illnesses.

Anemia is particularly prevalent in patients with CKD. The prevalence of CKD in the adult population is estimated at 10-12% globally,[10] and is generally a progressive disease characterized by gradual loss of kidney function that may eventually lead to kidney failure, or end stage renal disease, requiring dialysis or kidney transplant to survive. Blood transfusion is used for treating life-threatening severe anemia. However, blood transfusions reduce the patient's opportunity for kidney transplant, increase risk of infections and the risk of complications such as heart failure and allergic reactions.

According to the United States Renal Data System (USRDS), over 14% of the U.S. adult population is affected by CKD, and a majority of dialysis-eligible CKD patients are currently on dialysis. It is estimated that approximately 507,000 patients are receiving dialysis in the U.S. as of 2016.[11]

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-PHI 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.

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, and other markets in the Americas and in 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 12 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 six supporting the U.S./EU submissions including today's announcement of 3 studies by FibroGen. Roxadustat was approved by China National Medical Products Administration (NMPA) in December 2018, for treatment of anemia in CKD patients on dialysis. The Japan NDA submitted by Astellas is under review by the Japan Pharmaceuticals and Medical Devices Agency (PMDA).

Roxadustat is currently in Phase 3 clinical development for the treatment of anemia associated with 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) now approved by the National Medical Products Administration (NMPA) in China. Our partner Astellas submitted a 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 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 September 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.

References

1. Data on File. A Phase 3, Randomized, Double-Blind, Placebo Controlled Study of the Efficacy and Safety of Roxadustat (FG-4592) for the Treatment of Anemia in Chronic Kidney Disease Patients not on Dialysis. December 2018.
2. Data on File. A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Study of the Efficacy and Safety of FG-4592 in the Treatment of Anemia in Incident-dialysis Patients. December 2018
3. Data on File. A Phase 3, Open-Label, Randomized, Active-Controlled Study of the Efficacy and Safety of Roxadustat (FG-4592) in the Maintenance Treatment of Anemia in Subjects with End Stage Renal Disease (ESRD) on Stable Dialysis. December 2018.
4. Clinicaltrials.gov. Safety and Efficacy Study of Roxadustat to Treat Anemia in Patients with Chronic Kidney Disease (CKD), Not on Dialysis. [Online]. Available at: https://clinicaltrials.gov/ct2/show/record/NCT02174627. Last accessed: December 2018.
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6. National Kidney Foundation. “Managing Anemia When You Have Kidney Disease or Kidney Failure.” 2014.
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8. Babitt JL, Lin HY. Mechanisms of Anemia in CKD. J Am Soc Nephrol (2012); 23:1631-1634.
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10. Mills et al. Kidney International 2015; 88: 950–957
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