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 11, 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 7.01 Regulation FD Disclosure

On October 11, 2019, FibroGen, Inc. (FibroGen) issued a press release announcing that results from the global Phase 3 roxadustat clinical program will be presented at the American Society of Nephrology Kidney Week 2019 (ASN), taking place from November 5-10 in Washington D.C. A total of nine presentations of roxadustat clinical results (one late-breaker oral presentation, three additional oral presentations, and five poster presentations) will be presented by FibroGen, or its collaboration partners AstraZeneca and Astellas Pharma, Inc., at this year's meeting. A copy of such press release, which includes a link to the ASN website containing the accepted abstracts of the individual Phase 3 roxadustat studies, is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Item 7.01 of this report will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this report is not intended to, and does not, constitute a determination or admission by the Company that the information in this report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "Roxadustat Global Phase 3 Results for Treatment of Chronic Kidney Disease (CKD) Anemia to be Presented at American Society of Nephrology Kidney Week 2019" dated October 11, 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: October 11, 2019

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

Roxadustat Global Phase 3 Results for Treatment of Chronic Kidney Disease (CKD) Anemia to be Presented at American Society of Nephrology Kidney Week 2019

Pooled efficacy and cardiovascular safety of roxadustat, compared to epoetin alfa (EPO) in CKD patients on dialysis and compared to placebo in CKD patients not on dialysis, to be presented as late-breaker

SAN FRANCISCO, October 11, 2019 - FibroGen, Inc. (NASDAQ: FGEN), today announced that results from the global Phase 3 roxadustat clinical program will be presented at the American Society of Nephrology Kidney Week 2019 taking place from November 5-10 in Washington D.C. A total of nine presentations of roxadustat clinical results (one late-breaker oral presentation, three additional oral presentations, and five poster presentations) will be presented by FibroGen, or its collaboration partners AstraZeneca and Astellas Pharma, Inc., at this year's meeting.

The accepted abstracts on the individual Phase 3 roxadustat studies are now available on the ASN website at *https://www.asn-online.org/education/kidneyweek/2019/program-annual.aspx*

Presentation data include:

- Primary efficacy endpoint met in each of the three placebo-controlled Phase 3 studies (OLYMPUS, ANDES, ALPS) in patients with CKD anemia not on dialysis
- Primary efficacy endpoint met comparing roxadustat to erythropoiesis-stimulating agents (ESAs) in CKD patients with anemia on dialysis (ROCKIES, HIMALAYAS, SIERRAS, and PYRENEES):
    - Significant reduction in red blood cell transfusion is demonstrated in roxadustat-treated patients compared with epoetin alfa in SIERRAS
    - In subgroup analysis of patients with inflammation (increased C-reactive protein levels), roxadustat-treated patients achieved statistically larger increase in hemoglobin level from baseline than epoetin alfa-treated patients in ROCKIES
- Confirmed global Phase 3 pooled efficacy and cardiovascular safety results to be presented at late-breaker session on Friday, November 8, at 2pm

"We are excited to present results from our global Phase 3 studies, including the pooled cardiovascular safety results," said Dr. K. Peony Yu, M.D., Chief Medical Officer, FibroGen. "We believe roxadustat, a first-in-class oral treatment for anemia, may provide an efficacious and well-tolerated treatment option to physicians and to their patients suffering from CKD anemia."

Key roxadustat oral and poster presentations at ASN Kidney Week 2019:

Lead Author	Abstract / Presentation Title	Date / Time
Provenzano	HIMALAYAS: A Phase 3, Randomized, Open-Label, Active-Controlled Study of the Efficacy and Safety of Roxadustat in the Treatment of Anemia in Incident-Dialysis Patients *FibroGen-sponsored*	Oral Presentation TH-OR021 Nov 7, 2019 4:30-4:42PM
Fishbane	ROCKIES: An International, Phase 3, Randomized, Open-Label, Active-Controlled Study of Roxadustat for Anemia in Dialysis-Dependent CKD Patients *AstraZeneca-sponsored*	Oral Presentation TH-OR022 Nov 7, 2019 4:42-4:54 PM
Fishbane	OLYMPUS: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, International Study of Roxadustat for Anemia in Patients with Non-Dialysis-Dependent (NDD) Chronic Kidney Disease (CKD) *AstraZeneca-sponsored*	Oral Presentation TH-OR023 Nov 7, 2019 4:54-5:06 PM
Charytan	SIERRAS: A Phase 3, Open-Label, Randomized, Active-Controlled Study of the Efficacy and Safety of Roxadustat in the Maintenance Treatment of Anemia in Subjects with End Stage Renal Disease (ESRD) on Stable Dialysis *FibroGen-sponsored*	Poster SA-PO227 Nov 9, 2019 10:00 AM-12:00 PM
Coyne	ANDES: A Phase 3, Randomized, Double-Blind, Placebo Controlled Study of the Efficacy and Safety of Roxadustat for the Treatment of Anemia in Chronic Kidney Disease Patients Not on Dialysis *FibroGen-sponsored*	Poster SA-PO228 Nov 9, 2019 10:00 AM-12:00 PM
Esposito	Two Phase 3, Multicenter, Randomized, Studies of Intermittent Oral Roxadustat in Anemic CKD Patients on (PYRENEES) and Not on (ALPS) Dialysis *Astellas-sponsored*	Poster SA-PO225 Nov 9, 2019 10:00 AM-12:00 PM
Akizawa	Phase 3, Multicenter, Randomized, Open-Label, Non-Comparative Study of Intermittent Oral Roxadustat in ESA-Naive CKD Patients Not on Dialysis in Japan *Astellas-sponsored*	Poster SA-PO226 Nov 9, 2019 10:00 AM-12:00 PM
Barranco	An Open-Label Extension Study to Evaluate the Efficacy and Safety of Roxadustat for the Long-Term Maintenance Treatment of Anemia in Dialysis and Non-Dialysis Patients with Chronic Kidney Disease *FibroGen-sponsored*	Poster SA-PO230 Nov 9, 2019 10:00 AM-12:00 PM

Roxadustat is approved by the National Medical Products Administration (NMPA) in China for the treatment of anemia in CKD patients on dialysis and not on dialysis, and by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan for the treatment of anemia in CKD patients on dialysis. Submission of the U.S. New Drug Application (NDA) is expected in Q4 2019, with the European Marketing Authorization Application (MAA) submission to follow.

About Anemia Associated with Chronic Kidney Disease (CKD)

Anemia can be a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin, a protein in red blood cells that carries oxygen to cells throughout the body. Anemia in CKD is associated with increased risk of hospitalization, cardiovascular complications and death, also frequently causing significant fatigue, cognitive dysfunction and reduced quality of life. 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, 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.

About Roxadustat

Roxadustat (FG-4592) is a first-in-class, orally administered small molecule 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 chronic kidney disease (CKD) patients, including in the presence of inflammation and without a need for supplemental intravenous iron. Roxadustat is currently approved in China for the treatment of anemia in CKD patients on dialysis and patients not on dialysis and approved in Japan for the treatment of anemia in CKD patients on dialysis. 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), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia.

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) and 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 worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), is approved by the National Medical Products Administration (NMPA) in China for CKD patients on dialysis and not on dialysis and by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan for CKD patients on dialysis.

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), and in a Phase 2 U.S. trial for treatment of chemotherapy-induced anemia. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in 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 roxadustat, our interpretation of the pooled safety analyses and other analyses of the global Phase 3 program for roxadustat, the expected endpoints and potential standards for safety assessments of such data by the FDA and the EMA, the potential for and timing of an NDA submission to the FDA and an MAA submission to the EMA for potential marketing approval for 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 Form 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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