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): November 7, 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 November 7, 2019, FibroGen, Inc. ("FibroGen") issued a press release announcing results of its Phase 3 HIMALAYAS trial evaluating roxadustat for the treatment of anemia of chronic kidney disease ("CKD") in incident dialysis patients, a clinically important subgroup of dialysis-dependent CKD patients, that were presented at the American Society of Nephrology Kidney Week 2019 in Washington, D.C.

A copy of such press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and a copy of the HIMALAYAS presentation will be posted on FibroGen's website.

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 "FibroGen Presents Phase 3 Efficacy and Safety Results for Roxadustat Versus Epoetin Alfa as Treatment of Anemia in Incident Dialysis Patients with Chronic Kidney Disease" dated November 7, 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: November 8, 2019

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

FibroGen Presents Phase 3 Efficacy and Safety Results for Roxadustat Versus Epoetin Alfa as Treatment of Anemia in Incident Dialysis Patients with Chronic Kidney Disease

Roxadustat met both primary efficacy endpoints of mean hemoglobin (Hb) change from baseline and proportion of patients achieving Hb response in HIMALAYAS

WASHINGTON, D.C., November 07, 2019 (GLOBAL NEWSWIRE) – FibroGen, Inc. (NASDAQ:FGEN), today announced results from the Phase 3 HIMALAYAS trial evaluating roxadustat for the treatment of anemia in incident dialysis (ID) patients with chronic kidney disease (CKD), a clinically important subgroup of dialysis-dependent CKD patients. Incident dialysis was defined as those who initiated dialysis within 4 months before randomization to roxadustat or epoetin alfa. In this trial of 1,043 patients, believed to be the largest trial to date investigating an anemia medicine in the ID population, roxadustat achieved both primary efficacy endpoints. The safety profile of roxadustat observed in the HIMALAYAS trial was consistent with results observed in previous roxadustat studies.

This incident dialysis subpopulation is appropriate for comparison of roxadustat versus epoetin alfa, as patients experience high rates of morbidity and mortality during the period of initial dialysis treatment, whereas the stable dialysis population consists of patients who have survived this period and are already shown to be responsive to stable ESA doses.

“Roxadustat is the first of a new class of medication, applying the groundbreaking science on oxygen sensing and adaptation to hypoxia recently awarded the 2019 Nobel Prize in Physiology or Medicine,” said Robert Provenzano, MD, Associate Professor of Medicine, Wayne State University, Detroit, Michigan, U.S. and lead investigator of the HIMALAYAS study. “The positive HIMALAYAS results highlight the potential of roxadustat as an attractive new treatment option for anemia in these highly vulnerable patients who are new to dialysis care. This study provides useful insights and clinically relevant data for consideration in clinical practice, as most patients start anemia treatment when they begin dialysis.”

HIMALAYAS is an open label, active controlled, global Phase 3 study in which 1,043 incident dialysis patients were randomized 1:1 to receive roxadustat or epoetin alfa for up to 4.4

years, with mean treatment duration of 1.8 years. The U.S. primary efficacy endpoint of mean change in hemoglobin (Hb) levels from baseline to the average over 28-52 weeks was met as roxadustat was shown to be non-inferior to epoetin alfa, followed by demonstration of superiority (p=0.0005). The mean Hb increased from 8.4 g/dL to 11.0 g/dL in roxadustat-treated patients vs. 8.4 g/dL to 10.8 g/dL in epoetin alfa-treated patients. Roxadustat was non-inferior to epoetin alfa in the EU primary efficacy endpoint of proportion of patients achieving a Hb response (defined as Hb ≥11.0 g/dL and Hb increased by ≥1 g/dL from baseline) during the first 24 weeks of treatment: 88.2% in the roxadustat arm vs. 84.4% in the epoetin alfa arm. Further, patients treated with roxadustat required lower average monthly intravenous iron use than those treated with epoetin alfa (p=0.00028).

The most frequently observed adverse events (AEs) with roxadustat in the HIMALAYAS trial were hypertension, diarrhea, and muscle spasms.

“We are encouraged by these HIMALAYAS efficacy and safety results which suggest roxadustat to be a promising treatment for anemia in incident dialysis CKD patients who have newly initiated dialysis therapy,” said K. Peony Yu, MD, Chief Medical Officer, FibroGen. “These results create the opportunity to potentially improve anemia care in dialysis patients initiating treatment by offering a novel and effective oral therapy.”

These data (TH-OR201) were featured in the oral abstract session, Anemia and Iron Metabolism: Clinical Research, at the American Society of Nephrology (ASN) Kidney Week 2019 in Washington, D.C.

In the same oral abstract session as HIMALAYAS, FibroGen’s collaboration partner AstraZeneca will present study results from the Phase 3 OLYMPUS and ROCKIES trials, assessing roxadustat as a treatment for anemia in non-dialysis and dialysis-dependent patients with CKD, respectively.

Data from the HIMALAYAS trial is included in pooled efficacy and cardiovascular safety analyses of the roxadustat Phase 3 clinical development program, which will be presented during the ASN Kidney Week High-Impact Clinical Trials oral abstract session on Friday, November 8 at 2:00 PM EST.

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About Anemia Associated with 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 509,000 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, 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 Ministry of Health, Labour and Welfare (MHLW) 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, for the commercial potential of roxadustat, the potential safety and efficacy profile of our product candidates, aspects of roxadustat that could affect its commercial prospects, 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 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.

Contact:
FibroGen, Inc.

Media Inquiries:
Sara Iacovino
1.703.474.4452
sara.iacovino@gcihealth.com

Investors:
Michael Tung, M.D.
Investor Relations
1.415.978.1433
ir@fibrogen.com