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): September 26, 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 September 26, 2019, FibroGen, Inc. (the "Company") issued a press release announcing dosing of the first patient in the Company's Phase 2 clinical study of roxadustat for the treatment of chemotherapy-induced anemia in cancer patients receiving chemotherapy. A copy of such press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen Announces Initiation of Phase 2 Clinical Trial of Roxadustat for the Treatment of Anemia in Cancer Patients Receiving Chemotherapy" dated September 26, 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: September 26, 2019

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

FibroGen Announces Initiation of Phase 2 Clinical Trial of Roxadustat for the Treatment of Anemia in Cancer Patients Receiving Chemotherapy

SAN FRANCISCO, CA September 26, 2019 — FibroGen, Inc. (NASDAQ: FGEN) today announced first patient dosed in the company's Phase 2 clinical study of roxadustat, a first-in-class hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the treatment of chemotherapy-induced anemia (CIA) in cancer patients receiving chemotherapy.

"There is a significant unmet need among cancer patients experiencing anemia," said John Glaspy, M.D., M.P.H., professor of medicine and co-chair of the Division of Hematology/Oncology at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA). "Investigation of roxadustat as a potential therapy that may be able to overcome the shortcomings of current treatments and alleviate the challenges faced by cancer patients undergoing chemotherapy is welcome."

"Chemotherapy-induced anemia is a devastating side effect of chemotherapy that can interfere with quality-of-life, exposes patients to risks associated with red blood cell transfusion, and may even set limitations on the dose of chemotherapeutic agents that can be used; yet, it is undertreated," said Nashat Gabrail, M.D., Gabrail Cancer Center, Canton, Ohio.

Chemotherapeutic agents are known suppressors of red cell production by the bone marrow, and 30% to 90% of patients treated with myelosuppressive chemotherapy develop anemia, resulting in decreased functional capacity, and impaired quality of life. In contrast to other common side effects experienced by patients undergoing treatment for cancer, CIA is often a "silent" side effect with insidious symptoms. CIA can be one of the most common underlying etiologies of the fatigue in cancer patients, and is associated with cognitive dysfunction, dyspnea, and depression. As a result of such reduced quality of life, some patients choose to discontinue or delay chemotherapeutic treatment, increasing the potential for suboptimal outcomes.

"Roxadustat has been studied in anemia associated with chronic kidney disease in global Phase 3 studies enrolling over 9,000 patients, and is approved for treatment of anemia in CKD patients on dialysis and not on dialysis in China, and in CKD patients on dialysis in Japan, with preparation of the U.S. NDA submission and the European MAA submission underway," said K. Peony Yu, M.D., Chief Medical Officer of FibroGen. "We and our partners, AstraZeneca and Astellas, are committed to investigating roxadustat's potential in the treatment of anemia that currently affects a majority of cancer patients undergoing chemotherapy."

This 16-week Phase 2 study is designed to evaluate the efficacy and safety of roxadustat in anemic subjects undergoing chemotherapy treatments when the anticipated outcome is non-curative. The trial will enroll up to 100 anemic cancer patients with non-myeloid malignancy (solid tumor) having a hemoglobin level at or below 10 g/dL, while undergoing myelosuppressive chemotherapy and continuing such chemotherapy for at least another 8 weeks. Patients are to receive oral roxadustat three times a week for

16 weeks. The primary efficacy endpoint is maximum change in hemoglobin level from baseline without red blood cell transfusion. Secondary endpoints include hemoglobin change from baseline, number (%) of patients with hemoglobin response, and % of patients that require red blood cell transfusion(s).

For more information regarding this study please visit www.clinicaltrials.gov (NCT04076943).

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 Chemotherapy-Induced Anemia

Although chemotherapy-induced anemia is one of the most common side effects of chemotherapy, it is often not recognized and is frequently undertreated. CIA can adversely affect long-term patient outcomes, as the anemic environment may limit the effectiveness of some chemotherapy agents. The incidence and severity of CIA depend on a variety of factors, including the type, schedule, and intensity of therapy administered, or whether the patient has received prior myelosuppressive chemotherapy, radiation therapy, or both. An estimated 30% to 90% of cancer patients receiving chemotherapy develop anemia. Approximately 1.3 million cancer patients undergo chemotherapy every year in the United States.

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 the company's product candidates, 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 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.

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