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): July 22, 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 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 July 22, 2019, FibroGen, Inc. ("FibroGen") issued a press release announcing dosing of the first patient in ZEPHYRUS, FibroGen's Phase 3 clinical study of pamrevlumab in patients with idiopathic pulmonary fibrosis. 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.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "FibroGen Announces First Patient Dosed in ZEPHYRUS, a Phase 3 Clinical Trial of Pamrevlumab for the Treatment of Patients with Idiopathic Pulmonary Fibrosis" dated July 22, 2019

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: July 22, 2019

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

Exhibit 99.1

FibroGen Announces First Patient Dosed in ZEPHYRUS, a Phase 3 Clinical Trial of Pamrevlumab for the Treatment of Patients with Idiopathic Pulmonary Fibrosis

SAN FRANCISCO, CA July 22, 2019 -- FibroGen, Inc. (NASDAQ: FGEN), today announced dosing of the first patient in the ZEPHYRUS Phase 3 clinical study of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF).

“There is an urgent need for new treatments that will help IPF patients, who have limited or no treatment options,” said Luca Richeldi, M.D., Ph.D., Head of the Division of Pulmonary Medicine at Agostino Gemelli University Hospital of the Catholic University of the Sacred Heart in Rome, Italy. “Pamrevlumab has demonstrated positive efficacy and safety results with statistically significant treatment effects in slowing IPF progression as well as promising findings in improving lung function and lung fibrosis in prior studies. It is exciting to see pamrevlumab, as a potential new therapy, begin the ZEPHYRUS Phase 3 study.”

“IPF patients today face a poor prognosis and must endure devastating losses in lung function and the quality of their lives. Pamrevlumab represents an innovative therapeutic approach to treating IPF,” said Elias Kouchakji, M.D., Senior Vice President, Clinical Development and Drug Safety. “By addressing the underlying pathology of IPF, pamrevlumab has the potential to reduce the burden and progression of this chronic, progressive, and fatal lung disease.”

ZEPHYRUS is a randomized, double-blind, placebo-controlled, multi-center Phase 3 trial designed to evaluate the efficacy and safety of pamrevlumab in subjects with IPF over a 52-week period. Approximately 565 subjects will be enrolled into the global study. The primary endpoint of the study is the change in forced vital capacity (FVC) from baseline. Subjects who complete the 52-week study may be eligible for rollover into a separate study offering open-label, extension treatment with pamrevlumab.

The design of ZEPHYRUS is supported by safety and efficacy data from two Phase 2 studies. In a Phase 2, randomized, double-blind, placebo-controlled trial of pamrevlumab in IPF (Study 067/PRAISE), pamrevlumab demonstrated a statistically significant difference over placebo in the primary efficacy endpoint of FVC percent predicted change from baseline to Week 48 (Gorina, ERS 2017). Pamrevlumab achieved superiority over placebo in the following secondary endpoints: the proportion of subjects with disease progression (defined as a change from baseline in FVC percent predicted decline ≥10% or death), time to disease progression, change from baseline to Week 48 in quantitative lung fibrosis (QLF) score to Week 48 measured by quantitative HRCT. In addition, there was a trend towards improvement in patient-reported quality of life measurements assessed by the SGRQ (positive trends) and the UCSD-SOBQ, as well as favorable trend in all-cause mortality.

In a prior single-arm, open-label FGCL-3019-049 study, the treatment of patients with IPF given 15 mg/kg and 30 mg/kg IV of pamrevlumab every three weeks was associated with improvement or stability in quantified scores of whole lung fibrosis in approximately 35% of subjects at Week 48 (Raghu, 2012). Changes from baseline in these scores were significantly correlated with changes in FVC percent predicted value (Raghu, 2012).

For more information regarding this study please visit www.clinicaltrials.gov (NCT03955146).

About Pamrevlumab
Pamrevlumab is a first-in-class antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Pamrevlumab is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and for the treatment of locally advanced unresectable pancreatic cancer (LAPC), and in Phase 2 clinical development for the treatment of Duchenne muscular dystrophy (DMD). The U.S. Food and Drug Administration has granted Orphan Drug Designation (ODD) to pamrevlumab for the treatment of patients with IPF, LAPC, and DMD. Pamrevlumab has also received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with IPF and LAPC. Across all clinical studies, pamrevlumab has consistently demonstrated a good safety and tolerability profile to date. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

About Idiopathic Pulmonary Fibrosis (IPF)
Idiopathic pulmonary fibrosis is a chronic lung disease characterized by a progressive and irreversible decline in lung function when lung tissue becomes damaged, stiff, and scarred. As tissue scarring progresses, transfer of oxygen into the bloodstream is increasingly impaired, leading to irreversible loss of lung function, as well as high morbidity and mortality rates. Average life expectancy is estimated to be three to five years from diagnosis with approximately two-thirds of patients dying within five years. Survival rates are comparable to those of some of the deadliest cancers.

Patients with IPF experience debilitating symptoms, including shortness of breath and difficulty performing routine functions, such as walking and talking. Other symptoms include chronic dry, hacking cough, fatigue, weakness, discomfort in the chest, loss of appetite, and weight loss. Over the last decade, refinements in diagnosis criteria and enhancements in high-resolution computed tomography imaging technology (HRCT) have enabled more reliable diagnosis of IPF without the need for a lung biopsy.

U.S. prevalence and incidence of IPF is estimated to be 135,000 cases (defined by ICD-9 code) and 21,000 new cases per year, respectively, based on Raghu et al. (Am J Respir Crit Care Med, 2006) and on data from the United Nations Population Division. We believe the number of patients will continue to grow due to heightened awareness and improved methods for detection and diagnosis.

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), with a New Drug Application (NDA) now approved by the National Medical Products Administration (NMPA) in China. Our partner Astellas submitted an 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, 2018 and our quarterly report on 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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Contact
FibroGen, Inc.
Karen L. Bergman
Vice President, Investor Relations and Corporate Communications
1 (415) 978-1433
ir@fibrogen.com