# 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): May 21, 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 May 21, 2018, FibroGen, Inc. issued a press release in which it announced presentations of additional data from its randomized, double-blind, placebo-controlled Phase 2b PRAISE study of pamrevlumab in patients with idiopathic pulmonary fibrosis. The posters were presented at the American Thoracic Society 2018 in San Diego, California.

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 Presents Latest Data from PRAISE Phase 2b Study of Pamrevlumab in Idiopathic Pulmonary Fibrosis at American Thoracic Society" dated May 21, 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: May 21, 2018

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

FibroGen

NEWS RELEASE

**FIBROGEN PRESENTS LATEST DATA FROM PRAISE PHASE 2B STUDY OF PAMREVLUMAB IN IDIOPATHIC PULMONARY FIBROSIS AT AMERICAN THORACIC SOCIETY 2018**

**San Diego, CA – May 21, 2018 —** FibroGen, Inc. (NASDAQ: FGEN), a biopharmaceutical company, today announced that updated results from the company's randomized, double-blind, placebo-controlled Phase 2b PRAISE study of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF) were presented in several poster presentations at the American Thoracic Society (ATS) 2018 in San Diego, California. In total, the company is presenting four abstracts on pamrevlumab.

Pamrevlumab, a proprietary first-in-class antibody targeting connective tissue growth factor (CTGF) currently being developed for the treatment of fibrotic and fibroproliferative disorders, has demonstrated favorable results in slowing disease progression as measured by forced vital capacity (FVC) in IPF patients in two Phase 2 trials. The poster presentation at ATS presents additional results demonstrating that pamrevlumab treatment achieved a statistically significant reduced rate of progression of lung fibrosis compared to placebo using quantitative high resolution computed tomography (qHRCT). The pamrevlumab findings are consistent with reported results from a prior Phase 2 study in IPF.

Quantitative lung fibrosis (QLF) measurements appear to be an objective method for quantifying the change in lung fibrosis captured by HRCT (a non-invasive imaging tool). In PRAISE, the change in QLF volumes in pamrevlumab-treated patients over 48 weeks was significantly less than in patients on placebo, and the treatment difference between pamrevlumab vs placebo was observed as early as six months. The change from baseline in QLF volume for pamrevlumab-treated patients was 24.8 ml vs 86.4 ml for placebo at Week 24, with a treatment difference of -61.6 ml, p=0.0090. The change in QLF volume from baseline to 48 weeks was 75.4 ml in pamrevlumab-treated patients vs 151.5 ml from baseline to 48 weeks in patients on placebo, with a treatment difference of -76.2 ml, p=0.038. These QLF results on pamrevlumab's reduction of fibrotic build up in the lungs of IPF patients correlate with attenuation of the rate of decline in FVC % predicted, the primary endpoint of this study, with Spearman's correlation coefficient of -0.64, p=0.0001.

"Data from HRCT analysis show a strong correlation between changes in fibrosis with the changes in FVC in patients treated with pamrevlumab, suggesting the promise of this antibody as an effective and well-tolerated therapy for IPF patients," said lead author Jonathan G. Goldin, M.D., Ph.D., Professor of Radiology, UCLA Medical Center. "These exciting results in a placebo-controlled Phase 2 study clearly demonstrate that quantitative imaging can be incorporated into IPF clinical trials and show that pamrevlumab appears to have a positive and measurable effect on disease pathology."

The PRAISE Phase 2b study is a randomized, double-blind, placebo-controlled trial designed to evaluate the safety and efficacy of pamrevlumab in patients with mild-to-moderate IPF. One hundred and three (103) patients were randomized (1:1) to receive either 30 mg/kg of pamrevlumab or placebo intravenously every three weeks. Lung function assessments (FVC) were conducted at baseline and at Weeks 12, 24, 36, and 48. Quantitative HRCT assessments were performed at baseline and at Weeks 24 and 48. Additional secondary endpoints of the study were disease progression, health-related quality of life, and safety.

“We are excited to present additional analyses of the PRAISE Phase 2b trial that confirm and expand our understanding of positive safety and efficacy results with pamrevlumab, with statistically significant treatment effects in slowing IPF progression with encouraging results in both lung function (FVC) and in lung fibrosis (QLF) for the first time in a controlled study,” said Elias Kouchakji, M.D., Senior Vice President, Clinical Development and Drug Safety. “This study demonstrates the therapeutic potential of pamrevlumab and, brings us one step closer to helping IPF patients.”

**HRCT Quantitative Imaging of Lung Fibrosis Results**

**Title:** Lung Fibrosis Measured by Quantitative High Resolution Computed Tomography (qHRCT) in Idiopathic Pulmonary Fibrosis (IPF) Patients Treated with Pamrevlumab (FG-3019)

**Presenter:** Jonathan G. Goldin, M.D., Ph.D., Professor of Radiology, UCLA Medical Center

**Publication ID:** #P810

- QLF results in the PRAISE study demonstrated a clear reduction in the rate of progression of pulmonary fibrosis in pamrevlumab-treated patients compared to placebo.
- There was a significant difference in the change in QLF volume from baseline in the pamrevlumab group compared to the placebo group at Weeks 24 and 48.
- The treatment effect on change in fibrosis correlated to a change in pulmonary function.

The following posters were also presented at ATS:

**PK/PD Dose Analysis Results**

**Title:** PK and PK/PD Modeling to Inform Dosing Optimization for Pamrevlumab in Idiopathic Pulmonary Fibrosis (IPF)

**Presenter:** Eduard Gorina, M.D., Executive Director Clinical Development, FibroGen, Inc.

**Publication ID:** #P1240

- The results from PK modeling predict pamrevlumab dosing at 30 mg/kg q3weeks has a >90% probability of reaching superiority to placebo in the change of FVC % predicted over 48 weeks.

**CTGF Inhibition Effect on Pulmonary Gene Expression**

**Title:** Radiation-Induced Pulmonary Gene Expression Changes Are Attenuated by the CTGF Antibody Pamrevlumab

**Presenter:** Kenneth Lipson, Ph.D., Executive Director, Drug Research, FibroGen, Inc.

**Publication ID:** #908

- Gene expression changes in irradiated lungs during active remodeling identified transcripts modulated by irradiation and were partially normalized by the anti-CTGF antibody pamrevlumab.
- Results suggest pamrevlumab disrupts autocrine signaling and decreases chemokine secretion.

New results from the PRAISE study quality-of-life assessments using the St. George's Respiratory Questionnaire will be presented on Monday, May 21, 2018.

**St. George's Respiratory Questionnaire Results**

**Title:** St. George's Respiratory Questionnaire (SGRQ) Results in the PRAISE Trial in Idiopathic Pulmonary Fibrosis (IPF)

**Presenter:** Eduard Gorina, M.D., Executive Director Clinical Development, FibroGen, Inc.

**Publication ID:** B103/A4254 Poster Discussion #203

**Date and Time:** Monday, May 21, 2018, 2:15 p.m. PDT

**Location:** Room 6D (Upper Level)

- SGRQ is designed to measure the effect of respiratory disease on overall health, daily life, and perceived well-being. These are meaningful outcomes for patients with chronic and progressive diseases like IPF.
- The SGRQ results from the PRAISE study suggest that pamrevlumab treatment may improve health-related quality of life in patients with IPF and are supportive of additional testing in larger trials.

**About Idiopathic Pulmonary Fibrosis (IPF)**

IPF is a form of progressive pulmonary fibrosis, or abnormal scarring of the lungs. 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.

IPF is designated as an orphan disease by the U.S. Food and Drug Administration, with U.S. prevalence and incidence 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 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 advancing towards Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), for which FibroGen was granted Orphan Drug Designation (ODD), and pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). Pamrevlumab recently received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with locally advanced unresectable pancreatic cancer. Evaluated in multiple Phase 2 clinical studies, pamrevlumab has also demonstrated a good safety and tolerability profile. For information about pamrevlumab studies currently recruiting patients, please visit www.clinicaltrials.gov.

**About FibroGen**

FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, is a leading science-based 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 in worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), with a New Drug Application currently under review in China by the State Drug Administration, or SDA (formerly the China Food and Drug Administration, or CFDA). Roxadustat is in Phase 3 clinical development in the U.S. and Europe, and expected to enter 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, and commercial 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 March 31, 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.

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**Contact**

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