# 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 12, 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 September 12, 2018, FibroGen, Inc. (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has granted Fast Track designation for the Company's anti-CTGF antibody, pamrevlumab, for the treatment of patients with idiopathic pulmonary fibrosis.

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 Receives Fast Track Designation from the U.S. FDA for Pamrevlumab for the Treatment of Idiopathic Pulmonary Fibrosis" dated September 12, 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.

Dated: September 12, 2018

**FIBROGEN, INC.**

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

FibroGen

**FIBROGEN RECEIVES FAST TRACK DESIGNATION FROM THE U.S. FDA FOR PAMREVLUMAB FOR THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS**

SAN FRANCISCO, California, September 12, 2018 – FibroGen, Inc. (NASDAQ: FGEN), a biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the company's anti-CTGF antibody, pamrevlumab, for the treatment of patients with idiopathic pulmonary fibrosis (IPF). This follows review of the Phase 2 clinical data evaluating pamrevlumab in a placebo-controlled trial and represents recognition by the FDA that pamrevlumab has the potential to address an unmet medical need for this disease.

"This Fast Track designation reflects recognition of the great need for a new therapeutic to help patients diagnosed with IPF to reduce the burden and progression of this debilitating disease and another positive step in developing pamrevlumab for the treatment of IPF," said Elias Kouchakji, M.D., Senior Vice President, Clinical Development and Drug Safety. "We look forward to advancing pamrevlumab into Phase 3 studies early next year."

**About Fast Track Designation**

Fast Track designation is intended to facilitate the development and review of drugs used to treat serious conditions and to fill an unmet medical need. Fast Track designation enables the company to have more frequent interactions with the FDA throughout the drug development process, so that an approved product can reach the market expeditiously.

**About Idiopathic Pulmonary Fibrosis**

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 (HRCT) imaging technology 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) and pancreatic cancer and has been granted Orphan Drug Designation (ODD) in each of these indications, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). Pamrevlumab has received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with locally advanced unresectable pancreatic cancer. Across all trials, 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 FibroGen**

FibroGen, Inc., headquartered in San Francisco, with subsidiary offices in Beijing and Shanghai, 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), 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, completing worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), with a New Drug Application (NDA) currently under review in China by the State Drug Administration (SDA). 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, 2017, and our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 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.

# # #

**Investor and Media Contact**
Karen L. Bergman
Vice President, Investor Relations and
Corporate Communications
FibroGen, Inc.
kbergman@fibrogen.com
(415) 978-1433