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): April 15, 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))

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 April 15, 2019, FibroGen, Inc. (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has granted Orphan Drug Designation status to the Company's anti-CTGF antibody, pamrevlumab, for the treatment of patients with Duchenne muscular dystrophy.

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 Orphan Drug Designation from the U.S. FDA for Pamrevlumab for the Treatment of Duchenne Muscular Dystrophy" dated April 15, 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: April 15, 2019

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

Exhibit 99.1

FIBROGEN RECEIVES ORPHAN DRUG DESIGNATION FROM THE U.S. FDA FOR PAMREVLUMAB FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY

SAN FRANCISCO, California, April 15, 2019 – FibroGen, Inc. (NASDAQ: FGEN), a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for the company's anti-CTGF antibody, pamrevlumab, for the treatment of patients with Duchenne muscular dystrophy (DMD).

"We are pleased to have received Orphan Drug Designation from the FDA for pamrevlumab in the treatment of DMD. There is high unmet medical need for patients suffering from this debilitating disease needing a new treatment option," said Elias Kouchakji, M.D., Senior Vice President, Clinical Development and Drug Safety. "All 21 non-ambulatory DMD patients in our ongoing phase 2 study with pamrevlumab have completed the first 52 weeks of treatment. We are evaluating a number of clinical parameters in this study, including lung function, cardiac function, and upper extremity muscle function, and tissue fibrosis. We look forward to the continued development of this investigational therapeutic."

Duchenne muscular dystrophy is a rare and debilitating neuromuscular disease that affects between approximately 1 in every 3,500 to 5,000 newborn boys. About 20,000 children are diagnosed with DMD globally each year. Progression to non-ambulatory status typically occurs between the ages of 6 and 13 years. Once becoming non-ambulatory, joint contractures and scoliosis develop rapidly, and may lead to cardiomyopathy and respiratory failure with fatality in young adulthood. While most DMD drugs in development target ambulatory DMD patients, the majority of DMD patients are non-ambulatory. Pamrevlumab's clinical program currently targets the unmet medical need in these patients.

About Orphan Drug Designation

Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. This designation qualifies the sponsor for various development incentives of the Orphan Drug Act, including tax credits for qualified clinical testing, to advance the evaluation and development of products that demonstrate promise for the diagnosis and treatment of rare diseases or conditions. Orphan Drug Designation can also convey up to seven years of marketing exclusivity if the compound receives regulatory approval from the FDA.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a rare and debilitating neuromuscular disease that affects between approximately 1 in every 3,500 to 5,000 newborn boys. About 20,000 children are diagnosed with DMD globally each year. The fatal disease is caused by a genetic mutation leading to the absence or defect of dystrophin, a protein necessary for normal muscle function. The absence of dystrophin results in muscle weakness, muscle loss, fibrosis, and inflammation. Patients with DMD are often wheelchair-bound before the age of 12, and their progressive muscle weakness may lead to serious medical problems relating to respiratory and cardiac muscle.

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. Pamrevlumab has been granted Orphan Drug Designation in idiopathic pulmonary fibrosis (IPF), pancreatic cancer, and Duchenne muscular dystrophy (DMD). Pamrevlumab has also received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with IPF and for patients with locally advanced unresectable pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy. 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, 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), 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 Phase 3 clinical development worldwide 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, 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, the potential safety and efficacy profile of our product candidates, and our clinical and regulatory plans. 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 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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