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): March 1, 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 March 1, 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 locally advanced unresectable pancreatic cancer.

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 Granted Fast Track Designation by U.S. FDA for Pamrevlumab Treatment of Patients with Locally Advanced Unresectable Pancreatic Cancer" dated March 1, 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: March 1, 2018

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

FibroGen

NEWS RELEASE

FIBROGEN GRANTED FAST TRACK DESIGNATION BY U.S. FDA FOR PAMREVLUMAB TREATMENT OF PATIENTS WITH LOCALLY ADVANCED UNRESECTABLE PANCREATIC CANCER

SAN FRANCISCO, California, March 1, 2018 – FibroGen, Inc. (NASDAQ: FGEN), a science-based 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 locally advanced unresectable pancreatic cancer. This follows review of the Phase 2 clinical trial evaluating pamrevlumab in combination with gemcitabine and nab-paclitaxel and represents recognition by the FDA that pamrevlumab has the potential to address an unmet medical need for this disease.

"There are no approved treatment options for patients with locally advanced pancreatic cancer, who face a short life expectancy. We are encouraged by our Phase 2 study results, where the combination of pamrevlumab with chemotherapy changed eligibility for surgical resection in a majority of treated patients who were previously not candidates for surgery," said Peony Yu, M.D., FibroGen's Chief Medical Officer. "This designation is an important milestone for our pamrevlumab program and has the potential to speed our ability to advance pamrevlumab to patients."

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 Locally Advanced Pancreatic Cancer

In locally advanced pancreatic cancer (LAPC), the patient's tumor typically involves structures, particularly blood vessels that are closely associated with the pancreas such as the superior mesenteric artery and superior mesenteric vein. Involvement of the cancer around these blood vessels precludes surgical removal of the tumor. Patients with unresectable LAPC have a median survival of six to 10 months, only slightly better than patients with metastatic pancreatic cancer, and only 20 percent of newly diagnosed patients are classified as having resectable disease. Patients who have their tumor surgically removed have a much better prognosis with median survival of approximately 23 months with some patients being cured.

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. Fibrosis is characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. In desmoplastic, or fibrotic cancers, such as pancreatic cancer, fibrous tissue promotes abnormal proliferation of tumor cells and associated stromal cells. Pamrevlumab 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). In Phase 2 clinical studies conducted to date, pamrevlumab has 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) 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 activity in worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD); in China, our New Drug Application is currently under review by the CFDA for regulatory approval. Roxadustat is in Phase 3 clinical development in the U.S. and Europe, and expected to shortly enter Phase 2/3 development in China, for anemia associated with myelodysplastic syndromes (MDS). Pamrevlumab, a fully-human monoclonal anti-CTGF 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 the potential advantages of having Fast Track designation in pancreatic cancer. 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," "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, 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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