# 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): June 3, 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 June 3, 2018, FibroGen, Inc. issued a press release in which it announced results from its clinical trial of pamrevlumab in combination with standard-of-care chemotherapy in patients with locally advanced unresectable pancreatic cancer. The results were presented in a discussion poster session at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois.

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 Clinical Results of Pamrevlumab Treatment in Patients with Locally Advanced Unresectable Pancreatic Cancer at ASCO 2018 Annual Meeting" dated June 3, 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: June 4, 2018

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

FibroGen

NEWS RELEASE

**FibroGen Presents Clinical Results of Pamrevlumab Treatment in Patients with Locally Advanced Unresectable Pancreatic Cancer at ASCO 2018 Annual Meeting**

**Demonstrates Enhanced Rate of Surgical Resection with Pamrevlumab in Patients with Previously Unresectable Disease**

SAN FRANCISCO, Calif., June 3, 2018 – FibroGen, Inc. (NASDAQ: FGEN), a biopharmaceutical company, today announced Phase 1/2 clinical trial results of pamrevlumab in combination with standard-of-care chemotherapy in patients with locally advanced unresectable pancreatic cancer (LAPC). Principal investigator Vincent J. Picozzi, Jr., M.D., Director, Pancreas Center of Excellence, Virginia Mason Cancer & Digestive Diseases Institutes, presented the results in a discussion poster session at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. Pamrevlumab is a proprietary first-in-class antibody targeting connective tissue growth factor (CTGF) under development for the treatment of fibrosis and fibroproliferative disorders.

“These are some of the most exciting clinical trial results in locally advanced pancreatic cancer I have seen since I began treating pancreatic cancer patients,” said Dr. Picozzi. “The data suggest that pamrevlumab in combination with chemotherapy has the potential to become a neoadjuvant treatment regimen for locally advanced unresectable pancreatic cancer patients that has not existed before.”

Patients with locally advanced pancreatic cancer (without metastasis) tend to have a poor prognosis with a median survival of 9–18 months. In patients who have undergone resection of their tumor, median survival and five-year survival rates have been reported to be higher than those without resection. Therefore, treatment to achieve a surgical resection in this patient population is a meaningful treatment goal to potentially achieve a favorable overall survival outcome.

In this open-label, randomized Phase 1/2 study, pamrevlumab was administered in combination with standard-of-care chemotherapy (gemcitabine and nab-paclitaxel) and compared to treatment with chemotherapy alone in patients with locally advanced pancreatic ductal adenocarcinoma, who were not eligible for surgical resection based on histology, computerized tomography (CT) scans, and laparoscopy criteria, prior to randomization. Upon completion of the six months of study drug treatment, patients underwent surgical eligibility assessment based on pre-specified objective criteria. The study enrolled 37 patients: 24 received pamrevlumab + chemotherapy: 13 received chemotherapy alone.

At ASCO 2018, FibroGen reported that a higher proportion of patients whose tumor was previously considered unresectable became eligible for resection (based on protocol pre-specified post-treatment surgical eligibility criteria) after receiving pamrevlumab and chemotherapy than after receiving chemotherapy alone (at the end of 6 months of treatment), 70.8% vs. 15.4%. For those patients who met these surgical resection eligibility criteria at post-treatment assessment, individual patient condition and circumstance contributed to whether resection subsequently occurred. A higher proportion of pamrevlumab-treated patients achieved surgical resection than those received chemotherapy alone, 33.3% vs. 7.7%.

In the study, patients were followed for survival after evaluation for eligibility for resection and, when applicable, after resection. Patients who had successful resections in this study had a statistically significant longer median survival benefit as compared to patients who did not undergo resection, 40 months vs.18.6 months (p=0.0141), as of May, 2018. FibroGen is continuing to monitor study patients for survival.

“Patients with unresectable locally advanced pancreatic cancer are in need of an innovative and effective treatment with the potential to transform non-operable cancer into resectable disease,” said Elias Kouchakji, M.D., Senior Vice President, Clinical Development and Drug Safety. “The updated clinical results we are reporting at ASCO suggest that pamrevlumab may improve the treatment outcomes for patients who are currently deemed unresectable.”

**About Locally Advanced Pancreatic Cancer**

In locally advanced pancreatic cancer (LAPC), tumors typically encase 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. Approximately 80% of newly diagnosed LAPC patients are classified as having unresectable disease, and patients with unresectable LAPC have a median survival only slightly better than that of patients with metastatic pancreatic cancer. Patients with resectable cancer whose tumors are surgically removed have a much better prognosis, with median survival of approximately 23 months, and 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 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 recently received Fast Track designation from the U.S. Food and Drug Administration for the treatment of patients with locally advanced unresectable pancreatic cancer. Pamrevlumab has demonstrated a good safety and tolerability profile in multiple Phase 2 trials conducted 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 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). Roxadustat is in Phase 3 clinical development in the U.S. and Europe 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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