



VIA EDGAR

December 13, 2019

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549
Attn: Sasha Parikh
Rolf Sundwall

**RE: FibroGen, Inc.
Form 10-K for the Year Ended December 31, 2018
Filed February 27, 2019
File No. 001-36740**

Ladies and Gentlemen:

FibroGen, Inc. ("**FibroGen**" or the "**Company**" or "**we**") is submitting this letter via electronic submission in response to a letter (the "**Comment Letter**"), dated December 3, 2019, from the Division of Corporation Finance, Office of Life Sciences, of the Securities and Exchange Commission (the "**Commission**") with respect to the Company's Form 10-K for the year ending December 31, 2018 (the "**2018 10-K**"), filed on February 27, 2019.

For the Commission's convenience, we have incorporated your comments into this response letter in italics. Capitalized terms used in this letter but otherwise not defined herein shall have the meanings ascribed to such terms in the 2018 10-K.

ITEM 1. BUSINESS
PAMREVLUMAB FOR THE TREATMENT OF FIBROSIS AND CANCER
Clinical Development of Pamrevlumab, page 28

1. Please address the following regarding your disclosure of certain serious adverse events (SAEs) experienced by patients in the clinical development of Pamrevlumab:

- You disclose on page 31 that there have been 45 SAEs in 31 patients, four of which were considered possibly related by the principal investigator to study treatment.*

409 Illinois Street, San Francisco, CA 94158

415.978.1200

www.fibrogen.com



- Further, on page 34, you disclose that there were 99 TSAEs; six of which were assessed as possibly related by the principal investigator, and 93 as not related to study treatment.

Please provide us proposed disclosure to be provided in future filings identifying each treatment related SAE "possibly" related to Pamrevlumab.

Response:

The Company acknowledges the Commission's comment but we believe that the particular serious adverse events ("**SAEs**") that a principal investigator cannot rule out as unrelated to the study drug (i.e. "possibly related to study treatment") are not material to an investor's decision to buy or sell the Company's stock as discussed below.

Pursuant to U.S. Food and Drug Administration ("**FDA**") regulations, clinical study sponsors do not report to the FDA SAEs deemed by a principal investigator to be possibly related to a study drug. Such a designation by the investigator did not lead to modification of the drug administration during the study, does not necessarily affect the safety of the drug or whether a clinical study is allowed to continue by the FDA, or even the chances of U.S. regulatory approval of the study drug. Upon evaluation of these events, there was no evidence of a causal relationship between the drug and these adverse events. The Company therefore feels that disclosing these events would not help, and could confuse, an investor's understanding of the value of the product candidate and the results of the Company's clinical development.

In contrast, we believe the more relevant and informative disclosure is regarding whether there have been any safety signals discovered during a clinical trial or other unusual or material safety issues. Therefore, the Company proposes to modify the applicable language in the Company's next Form 10-K for the year-ending 2019 to the following:

Page 31 - Study 049 – Open-label Phase 2 trial of pamrevlumab in idiopathic pulmonary fibrosis ("IPF")

"Eighty-nine patients had at least one adverse event. The most common reported events were cough, fatigue, shortness of breath, upper respiratory tract infection, sore throat, bronchitis, nausea, dizziness, and urinary tract infection. No safety signal was identified in this study and adverse events observed to date are consistent with typical conditions observed in this patient population."

Page 34 - Study 028 – Open-label dose finding trial of pamrevlumab combined with gemcitabine plus erlotinib in patients with previously untreated locally advanced (stage 3) or metastatic (stage 4) pancreatic cancer



“In the study, the majority of adverse events were mild to moderate, and were consistent with those observed for erlotinib plus gemcitabine treatment without pamrevlumab. We did not identify any evolving dose-dependent pattern or safety signal, and higher doses of pamrevlumab were not associated with higher numbers of SAEs or greater severity of the SAEs observed.”

The Company would note that the two studies at issue are earlier-stage completed trials and the FDA has since allowed us to progress to more advanced clinical trials in each of these diseases and very sick patient populations, although we chose to study a slightly different patient population within pancreatic cancer. The IPF study (049) referenced on page 31 of our 2018 10-K was followed by a randomized, double-blind, placebo-controlled Phase 2 trial (067) of pamrevlumab in IPF (see page 30 of the 2018 10-K). The pancreatic cancer study (028) referenced on page 34 was followed by an open-label, randomized Phase 1/2 trial (069) in patients with inoperable locally advanced pancreatic cancer (see page 33 of the 2018 10-K).

The Company believes its proposed revised disclosure is also consistent with the rest of (and the more recent) safety disclosures in the 2018 10-K. For example in the more recent IPF study (067), our safety disclosure on page 30 of the 2018 10-K is as follows:

“Pamrevlumab was well-tolerated in the placebo-controlled study. The TEAEs were comparable between the pamrevlumab and placebo arms and the adverse events in the pamrevlumab arm were consistent with the known safety profile of pamrevlumab.”

The Commission will find similar safety language for our other clinical trials on pages 6, 7, 18 and 22 of the 2018 10-K:

“The preliminary safety analyses of each of these three studies show an overall safety profile consistent with the results observed in prior roxadustat studies. The adverse events reported are consistent with those expected in these study populations with similar background diseases.”

“The preliminary safety analysis for this trial shows an overall event profile consistent with the results seen in previous roxadustat studies in CKD patients with anemia.”

“Roxadustat was generally well tolerated and there were no safety signals observed in the China Phase 3 clinical trials, including through the 52-week safety extension periods.”

“Roxadustat was well tolerated in this study, and the safety profile of roxadustat was consistent with that observed in previous studies both in dialysis and non-dialysis patients.”

The Company appreciates the Commission’s comments on this topic and believes the proposed disclosures above will provide more relevant, informative and less confusing disclosure for investors.



Please contact me at (415) 978-1522 with any questions or further comments regarding our responses to the Commission's comments.

Sincerely,

/s/ John Alden

John Alden

Vice President, Legal

cc: Pat Cotroneo, FibroGen, Inc.
Michael Lowenstein, FibroGen, Inc.
Greg Vlahos, PricewaterhouseCoopers LLP

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