



VIA EDGAR

January 20, 2022

U.S. Securities and Exchange Staff  
Division of Corporation Finance  
Office of Life Sciences  
100 F Street, N.E.  
Washington, D.C. 20549  
Attn: Jane Park  
Christine Westbrook

**RE: FibroGen, Inc.**  
**Form 10-K for the Fiscal Year Ended December 31, 2020**  
**Filed March 1, 2021**  
**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 January 5, 2022, from the Staff of the Division of Corporation Finance, Office of Life Sciences (the "***Staff***") of the Securities and Exchange Commission with respect to the Company's Form 10-K for the year ending December 31, 2020 (the "***2020 10-K***"), filed on March 1, 2021.

For the Staff's convenience, we have incorporated its 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 2020 10-K.

In addition to the disclosures we proposed in our December 16, 2021 letter, we have proposed further changes to our Form 10-K for the year ending December 31, 2021 as noted below under "Proposed Disclosures".

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Cover Page

**1.** We note your response to our prior comment 1. At the onset of Part 1, please provide prominent disclosure that you are a U.S. holding company that conducts its operations in China through a wholly-owned subsidiary and joint venture, as referenced in your response to comment 1, and that investors will not hold direct investments in the Chinese operating companies.

**Response:**

The Company advises the Staff that it is not a U.S. holding company but has extensive business in the United States and around the world, including China. However, in response to the Staff's Comments 1 through 4, the Company will add the following "CHINA OPERATIONS" section on the 2nd page of Part 1, Item 1 in our next Annual Report on Form 10-K, following the one-page "OVERVIEW" of our development and commercialization programs.

As part of this additional section at the outset of our Business Section in Part 1, Item 1, we will move the paragraph we originally proposed in response to the Staff's prior Comment 3 to the first paragraph of the proposed disclosure below:

**Proposed Disclosure:****"CHINA OPERATIONS"**

We are incorporated in the state of Delaware. The Company operates within the China market through FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing"), a wholly-owned subsidiary established in Beijing. FibroGen Beijing consists of development and commercialization operations as well as a drug product manufacturing facility. FibroGen Beijing holds the regulatory licenses issued by the Chinese regulatory authorities in respect of roxadustat. FibroGen Beijing has two branch offices located in Shanghai and Cangzhou, China. The branch office in Cangzhou operates a drug substance manufacturing facility. FibroGen Beijing also owns 51.1% of Beijing Falikang Pharmaceutical Co. Ltd. ("Falikang"), a joint venture established by the Company and operated in conjunction with AstraZeneca Investment (China) Co., Ltd. ("AZ China") for purposes of distributing our sole drug product approved for sale in China, roxadustat. Falikang conducts distribution activities for roxadustat within China while AZ China, AstraZeneca AB (PUBL) ("AstraZeneca") and AstraZeneca (Wuxi) Trading Co., Ltd. ("AZ China Trading Co" and together with AZ China and AstraZeneca, "AZ") provide sales and marketing services in support of roxadustat. Thus, stockholders of FibroGen, Inc. have an ownership interest in the joint venture, Falikang, through the FibroGen, Inc. equity ownership in our subsidiaries, including FibroGen Beijing.

For a full discussion of our business in China, please see the section below titled "ROXADUSTAT FOR THE TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE IN CHINA" as well as the section titled "ROXADUSTAT FOR THE TREATMENT OF CHEMOTHERAPY-INDUCED ANEMIA AND ANEMIA ASSOCIATED WITH MYELODYSPLASTIC SYNDROMES". We summarize certain risks associated with our operations in China in this section, however, please refer also to the section of this Annual Report captioned "Item 1A. Risk Factors" for additional risks related to our international operations.

To operate our general business activities currently conducted in China, each of our Chinese subsidiaries (and our joint venture with AstraZeneca, Falikang) is required to and does obtain a business license from the local counterpart of the State Administration for Market Regulation, or SAMR. Such business licenses list the business activities we are authorized to carry out and we would be noncompliant if we act outside of the scope

of business activities set forth under the relevant business license. Due to China's regulatory framework in general and for the pharmaceutical industry specifically, we are required to apply for and maintain many approvals or permits specific to many of our business activities, including but not limited to manufacturing, distribution, environmental protection, workplace safety and cybersecurity, from both national and local government agencies. For certain of our clinical trials conducted in China, we need to obtain, through the clinical sites, permits from the Human Genetic Resource Administrative Commission to collect samples that include human genetic resources, such as blood samples. We may also be required to obtain certain approvals from Chinese authorities before transferring certain scientific data abroad or to foreign parties or entities established or actually controlled by them. If we are unable to obtain the necessary approvals or permissions in order to operate our business in China, or if we inadvertently conclude that such approvals or permissions are not required, or if we are subject to additional requirements, approvals, or permissions, it could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our common stock.

Due to our operations in China and the United States, any unfavorable government policies on cross-border relations and/or international trade (including increased scrutiny on companies with significant China-based operations, capital controls or tariffs) may affect the competitive position of our drug products, the hiring of personnel, the demand for our drug products, the import or export of products and product components, our ability to raise capital, the market price of our common stock, or prevent us from selling our drug products in certain countries. While we do not operate in an industry that is currently subject to foreign ownership limitations in China, China could decide to limit foreign ownership in our industry, in which case there could be a risk that we would be unable to do business in China as we are currently structured.

Cash flows from Falikang and cash flows into FibroGen Beijing are currently intended to remain onshore in China. Our long-term plans for distributing cash flows from FibroGen Beijing may involve any number of scenarios including keeping the money onshore to fund future expansion of our China operations or paying down certain debt obligations. To date, no such debt repayments have occurred, nor have there been any other payments or distributions from FibroGen Beijing to entities or investors outside of China. Our capital contributions to FibroGen Beijing and the liquidity position of FibroGen Beijing depend on many factors, including those set forth under Part II, Item 1A "Risk Factors" in this Annual Report on Form 10-K."

*2. We note your response to our prior comment 2, which we reissue. We note your disclosure that 42% of revenue for the fiscal year ended December 31, 2020 was from roxadustat commercial sales in China and that you own manufacturing facilities in China to produce your lead product. Please expand your disclosure at the onset of Part 1 to provide prominent disclosure about the legal and operational risks associated with having a significant portion of the company's operations in China.*

**Response:**

The Company advises the Staff that, while most of our operations are in the United States, we have significant operations for our lead product, roxadustat, in China, as well as sales of roxadustat in Europe and Japan. Our other product candidate, pamrevlumab, is in Phase 3 clinical trials in idiopathic pulmonary fibrosis, pancreatic cancer and Duchenne muscular dystrophy, and such development is not highly dependent on operations in China.

As a result, and taking into consideration the relative significance of our operations in China, we will include the additional disclosure above, and in particular, the fourth paragraph of our proposed disclosure to Comment 1.

**3.** We note your response to our prior comment 4 and proposed disclosure to be provided in the Management's Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors section. Please also provide revised disclosure at the onset of Part 1. We will not object to expanded disclosure under the heading "ROXADUSTAT FOR THE TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE IN CHINA," as referenced in response to prior comment 3.

**Response:**

In response to the Staff's comment, the Company will include some of its previously proposed disclosure on the second page of Part 1, Item 1 as set forth above, and in particular, the fifth paragraph of our proposed disclosure to Comment 1.

**4.** We note your response to our prior comment 7, which we reissue in part. We note your proposed additional risk factor. Please also provide related disclosure at the onset of Part 1. Additionally, please revise your proposed disclosure to explicitly address the consequences to you and your investors if you, your subsidiaries or Falikang inadvertently conclude that such permissions or approvals are not required.

**Response:**

In response to the Staff's comment, the Company will include some of its previously proposed disclosure on the second page of Part 1, Item 1 as set forth above, and in particular, the third paragraph of our proposed disclosure to Comment 1.

In addition, we will revise the last paragraph of the new risk factor titled "We may be subject to additional Chinese requirements, approvals or permissions in the future" that we proposed in response to the Staff's prior comment 7 as follows (and redlined against the proposed disclosure from our December 16, 2021 letter):

**Proposed Disclosure:**

"If we are unable to obtain the necessary approvals or permissions in order to operate our business in China, if we inadvertently conclude that such approvals or permissions are not required, or if we are subject to additional requirements, approvals, or permissions, it could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our common stock."

**5.** At the onset of Part 1, please disclose whether your auditor is subject to the determinations announced by the PCAOB on December 16, 2021 and whether and how the Holding Foreign Companies Accountable Act and related regulations will affect your company.

**Response:**

The Company advises the Staff that our independent registered public accounting firm, PricewaterhouseCoopers LLP, is headquartered in the United States and was not identified in the report issued by the PCAOB on December 16, 2021 of firms that they were unable to inspect.



That report identified PCAOB-registered public accounting firms headquartered in mainland China and in Hong Kong because of positions taken by China authorities in those jurisdictions.

As indicated in Form AP filed with the PCAOB, an affiliate of PricewaterhouseCoopers LLP, PricewaterhouseCoopers Zhong Tian LLP, did perform part of the audit relating to our financial statements. PricewaterhouseCoopers Zhong Tian LLP was identified in the report issued by the PCAOB on December 16, 2021 of firms that they were unable to inspect. However, the Commission stated in Securities Exchange Act Release 93701 that only the principal accountant – as defined by Rule 2-05 of Regulation S-X and PCAOB AS 1205 is “deemed ‘retained’ for purposes of Section 104(i) of the Sarbanes-Oxley Act and the Commission’s determination of where the registration statement should be a Commission Identified Issuer.” The principal accountant, as defined, that we have retained is PricewaterhouseCoopers LLP.

The Holding Foreign Companies Accountable Act (“HFCA Act”) does not apply to registrants that retain a principal accountant that is headquartered in the United States. Accordingly, the HFCA Act does not apply to us.

As we are a U.S. incorporated company that is headquartered in the U.S. and our critical financial reporting process is also U.S. based, we plan to retain for purposes of Section 104(i) of the Sarbanes-Oxley Act a registered public accounting firm headquartered in the U.S. for the foreseeable future.

As the HFCA Act does not apply to us and we do not expect it to apply to us in the foreseeable future, we do not believe any incremental disclosure relating to the HFCA Act is currently required in Part 1.

In response to the Staff’s request that we state whether our auditor is subject to the determinations announced by the PCAOB on December 16, 2021 and whether the HFCA Act affects us, we will include this information in Part 2, Item 9C., as follows:

**Proposed Disclosure:**

**“ITEM 9C. HOLDING FOREIGN COMPANIES ACCOUNTABLE ACT**

Our independent registered public accounting firm, PricewaterhouseCoopers LLP, is headquartered in the United States and was not identified in the report issued by the PCAOB on December 16, 2021 of firms that they were unable to inspect. Therefore, the Holding Foreign Companies Accountable Act does not apply to us.”

**6.** We note from the audit opinion that you have a U.S. based auditor that is registered with the PCAOB and currently subject to PCAOB inspection. Please disclose any material risks to the company and investors if it is later determined that the PCAOB is unable to inspect or investigate completely your auditor because of a position taken by an authority in a foreign jurisdiction. For example, disclose the risk that lack of inspection could cause trading in your securities to be prohibited under the Holding Foreign Companies Accountable Act and as a result an exchange may determine to delist your securities.

**7.** Please expand your risk factors to disclose that the United States Senate has passed the Accelerated Holding Foreign Companies Accountable Act, which, if enacted, would decrease the number of "non-inspection years" from three years to two years, and thus, would reduce the time before your securities may be prohibited from trading or delisted. Additionally, disclose that the Commission adopted rules to implement the HFCAA and that, pursuant to the HFCAA, the PCAOB has issued its report notifying the Commission of its determination that is unable to inspect or investigate completely accounting firms headquartered in mainland China or Hong Kong.

#### **Response to Comments 6 and 7:**

The Company reiterates its response to Comment 5. To address the Staff's Comments 6 and 7, the Company will add the following risk factor:

#### **Proposed Disclosure:**

**"A portion of our audit is conducted by an independent registered public accounting firm that is not subject to PCOAB inspection, which may negatively impact investor sentiment towards our Company or our China operations which could adversely affect the market price of our common stock.**

The majority of audit work incurred for the audit report included in this Annual Report was performed by our independent registered public accounting firm, PricewaterhouseCoopers LLP, which is headquartered in the United States and was not identified in the report issued by the PCAOB on December 16, 2021 of firms that they were unable to inspect.

However, [between 10 and 20%] of the total audit hours for our December 31, [2020] audit were provided by PricewaterhouseCoopers Zhong Tian LLP, which is headquartered in the People's Republic of China. PricewaterhouseCoopers Zhong Tian LLP was identified in the report issued by the PCAOB on December 16, 2021 as a Firm they were unable to inspect.

Inspections of auditors conducted by the PCAOB in territories outside of China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China prevents the PCAOB from evaluating such audits and such auditors' quality control procedures. The component of our audit that was performed by PricewaterhouseCoopers Zhong Tian LLP and the work papers associated with such audit work is not currently subject to inspection by the PCAOB. As a result, investors are deprived of the potential benefits of such PCAOB inspections for this portion of our audit, which may negatively impact investor sentiment towards our Company or our China operations, which in turn could adversely affect the market price of our common stock."



The Company appreciates the Staff's comments on this topic and believes the proposed disclosures above, in addition to the disclosures proposed in our December 16, 2021 letter, (which we propose to make in our Form 10-K for the year ending December 31, 2021) will provide additional information that will be helpful to an investors' understanding of our business and the risks associated with operating in China.

Please contact me at (415) 978-1522 and [jalden@fibrogen.com](mailto:jalden@fibrogen.com) with any questions or further comments regarding our responses to the Staff's comments.

Sincerely,

/s/ John Alden

John Alden  
Vice President, Legal

cc: Juan Graham, FibroGen, Inc.  
Michael Lowenstein, FibroGen, Inc.

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