



VIA EDGAR

December 15, 2021

U.S. Securities and Exchange Staff
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549
Attn: Sasha Parikh
Kevin Vaughn
Suzanne Hayes

**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 November 8, 2021, 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 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 2020 10-K. We propose to make these changes in our Form 10-K for the year ending December 31, 2021.

Before we address the specific comments, we would like to summarize some key points that we discuss in detail below. The Company appreciates the discussion with the Staff via telephone on November 19, 2021. We are aware of the statements that Chair Gensler and the Securities and Exchange Commission has made regarding Cayman Island holding companies that conduct substantially all of their operations in China and have substantially all of their assets in China. These entities use a Variable Interest Entity ("VIE") structure whereby they enter into contracts in order to control an entity located in China in which they have no share ownership

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because foreign ownership is not allowed. While China is an important market for us, we are fundamentally different from those entities.

- We are incorporated in the state of Delaware with headquarters in the state of California and most of our operations are in the United States. We and our subsidiaries currently generate revenue from sales in China, Europe, and Japan.
- Beijing Falikang Pharmaceutical Co. Ltd. (“Falikang”) (the entity referred to as a VIE in the Comment Letter) is a joint venture between two multi-national companies, in which each party owns shares. It is accounted for as a VIE only for U.S. GAAP accounting purposes.
- Falikang does not operate in an industry in which foreign ownership is prohibited.

Cover Page

1. At the onset of Part 1, provide prominent disclosure that you are not a Chinese operating company but a United States holding company with operations conducted by your subsidiary and through contractual arrangements with a variable interest entity (VIE) based in China and that this structure involves unique risks to investors. Explain whether the VIE structure is used to replicate foreign investment in Chinese-based companies where Chinese law prohibits direct foreign investment in the operating companies, and disclose that investors may never directly hold equity interests in the Chinese operating company. Your disclosure should acknowledge that Chinese regulatory authorities could disallow this structure, which would likely result in a material change in your operations and/or value of your common stock, including that it could cause the value of such securities to significantly decline or become worthless. Provide a cross-reference to your detailed discussion of risks facing the company as a result of this structure.

Response:

Further to our discussion on November 19, 2021, the Company advises the Staff that the Company does not employ a variable interest entity (VIE) structure for purposes of replicating foreign investment in China-based companies. The Company also does not operate in a business sector where Chinese law prohibits direct foreign investment. Furthermore, the Company is not a U.S. holding company with operations conducted through contractual arrangements with a VIE based in China.

The Company operates internationally, including in the United States, as a biotechnology research, development, and commercialization Company. The Company operates within the China market through FibroGen (China) Medical Technology Development Co., Ltd. (“FibroGen Beijing”), our wholly-owned subsidiary established in Beijing, and Falikang, a joint venture established by the Company and operated in conjunction with AstraZeneca Investment (China) Co., Ltd. (“AZ China”) for purposes of distributing the Company’s sole pharmaceutical product approved for sale in China, roxadustat. FibroGen Beijing holds the regulatory licenses issued by the Chinese regulatory authorities in respect of roxadustat and also manufactures roxadustat. Falikang (the entity referred to as a VIE in the Comment Letter) 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.

Falikang is 51.1% owned by FibroGen Beijing, with the remaining 48.9% owned by AZ China.

No third party holds any operating permit or business license issued by the Chinese government; nor is any third party required to do so under the laws of China for Falikang to conduct its drug distribution activities within China.

The Company's disclosure in Note 3 to the Notes to the Consolidated Financial Statements regarding its treatment of Falikang as a variable interest entity for which it is not the primary beneficiary of arises from final decision-making authority granted to AstraZeneca under the terms of the China Agreement, China Amendment and governance arrangements of Falikang which provides AZ with the power and economic criteria under ASC 810. As a result, the Company accounts for its investment in Falikang under the equity method and does not consolidate the Falikang into the Company's consolidated financial statements. The power and economic rights granted to AZ are in furtherance of the 50/50 profit-sharing arrangement with AstraZeneca as required under the terms of the China Agreement and China Amendment, under which AstraZeneca is responsible for roxadustat commercialization (including distribution). These AstraZeneca agreements are described in Part 1, Item 1 of the 10-K. For clarity, the variable interest entity classification of Falikang does not arise from any restriction imposed by the Chinese government on the part of the Company or AZ from holding direct ownership interests in Falikang. The variable interest entity classification of Falikang is solely for accounting purposes under the U.S. generally accepted accounting principles ("GAAP").

While Falikang is accounted for under the equity method, it is currently not significant using the criteria in Rule 1-02(w) of Regulation S-X to require disclosures under Rule 4-08(g) of Regulation S-X.

As a result, the Company advises the Staff that it does not believe that it is necessary to provide prominent disclosure at the onset of Part 1 of its Annual Report on Form 10-K that the Company is not a Chinese operating company. In fact, we believe such disclosure would be confusing and misleading to investors as an investor may mistakenly believe that our operating structure is prohibited by Chinese law. If in the future the Company employs a VIE structure for purposes of replicating foreign investments in Chinese-based companies where Chinese law prohibits direct foreign investment in operating companies, it will provide prominent disclosure of the risks associated with such structure.

However, in response to the Staff's comment, the Company will clarify its disclosure in Note 3 to the Notes to the Consolidated Financial Statements in our next Annual Report on Form 10-K, as outlined below and as redlined against our most recent relevant disclosures in our Form 10-Q for the period ended September 30, 2021:

Proposed Disclosure:

Note 3 to the Notes to the Consolidated Financial Statements

“3. [Equity method investment - Variable Interest Entity](#)

Falikang is a distribution entity jointly owned by AstraZeneca and FibroGen Beijing. FibroGen Beijing owns 51.1% of the outstanding shares of Falikang.

Pursuant to the guidance under ASC 810, *Consolidation* (“ASC 810”), the Company concluded that Falikang qualifies as a VIE [for U.S. GAAP purposes under ASC 810](#). As Falikang is a distribution [joint venture between FibroGen Beijing and AstraZeneca, entity](#) and AstraZeneca is the final decision maker for all the roxadustat commercialization activities, the Company lacks the power criterion while AstraZeneca meets both the power and economic criteria under the ASC 810, to direct the activities of Falikang that most significantly impact its performance. Therefore, the Company is not the primary beneficiary of this VIE for [U.S. GAAP](#) accounting purposes. As a result, the Company accounts for its investment in Falikang under the equity method, and Falikang is not consolidated into the Company’s ~~condensed~~ consolidated financial statements. Accordingly, the Company records its total investments in Falikang as an equity method investment in an unconsolidated VIE in the ~~condensed~~ consolidated balance sheet. In addition, the Company recognizes its proportionate share of the reported profits or losses of Falikang as [investment income \(loss\) in unconsolidated variable interest entity](#), ~~investment gain or loss in unconsolidated VIE~~ in the ~~condensed~~ consolidated statement of operations, and as an adjustment to its investment in Falikang in the ~~condensed~~ consolidated balance sheet. Falikang has not incurred material profit or loss to date. The Company may provide shareholder loans to Falikang to meet necessary financial obligations as part of its operations. To date, these loans have been immaterial.”

2. At the onset of Part 1, provide prominent disclosure about the legal and operational risks associated with being based in or having a significant portion of the company’s operations in China. Your disclosure should make clear whether these risks could result in a material change in your operations and/or the value of your common stock or could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. Your disclosure should address how recent statements and regulatory actions by China’s government, such as those related to the use of variable interest entities and data security or anti-monopoly concerns, has or may impact the company’s ability to conduct its business, accept foreign investments, or list on an U.S. or other foreign exchange. Your Business section should address, but not necessarily be limited to, the risks highlighted in Part 1.

Response:

The Company advises the Staff that it operates internationally and, while most of our operations are in the United States, a significant portion of our future revenue for our lead product roxadustat depends on not only sales in China but also sales of roxadustat in Europe, Japan, and potentially the United States. 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, the Company advises the Staff that it does not believe that prominent disclosure at the onset of Part 1 of its Annual Report on Form 10-K is necessary. In fact, we believe such disclosure would be confusing and misleading to investors, highlighting risks that are not the most material to the Company.



However, in response to the Staff's comment, we will include additional risk factors in our next Annual Report on Form 10-K. Please see our response to Comment 6 for proposed disclosure.

In addition, while risks associated with our operations in China are present, we do not believe they are the most material risks for the Company. Being an international biotechnology company with multiple programs in research, development, and commercialization, the most material risks for our Company are those related to development and commercialization of our product candidates, followed by risks related to intellectual property and government regulation.

However, in response to the Staff's comment, we will relocate our international operations risk factors such that they would be prior to the risk factors related to COVID-19, general business operations, and our common stock in future periodic reports. Please see also our additional and revised risk factors below, including in response to Comment 6.

3. At the onset of Part 1, clearly disclose how you will refer to the holding company, subsidiaries, and VIE when providing the disclosure throughout the document so that it is clear to investors which entity the disclosure is referencing and which subsidiaries or entities are conducting the business operations. Refrain from using terms such as "we" or "our" when describing activities or functions of a VIE. Disclose clearly the entity (including the domicile) in which investors are purchasing their interest.

Response:

The Company advises the Staff that investors purchase common stock of FibroGen, Inc., a business incorporated in the state of Delaware with headquarters in the state of California. As previously mentioned, we have an equity ownership in the joint venture, Falikang, and are not merely a holding company doing business in China through contractual arrangements with a VIE. In response to the Staff's comment, because the majority of the Company's business does not operate in China, we will add additional disclosure (as set forth below) in the China-related portion of our Business Section (Item 1 of Part I), titled "ROXADUSTAT FOR THE TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE IN CHINA". In response to the Staff's comment, we will also refrain from using terms such as "we" or "our" when describing activities or functions of Falikang, our joint venture in China, in our next Annual Report on Form 10-K.

Proposed Disclosure:

ROXADUSTAT FOR THE TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE IN CHINA

"The Company operates within the China market through FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing"), our wholly-owned subsidiary established in Beijing. FibroGen Beijing consists of development and commercialization operations as well as a drug substance manufacturing facility. FibroGen Beijing also 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 product 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."

4. *At the onset of Part 1, provide a clear description of how cash is transferred through your organization. Disclose your intentions to distribute earnings or settle amounts owed under the VIE agreements. Quantify any cash flows and transfers of other assets by type that have occurred between the holding company, its subsidiaries, and its VIE, and direction of transfer. Quantify any dividends or distributions that a subsidiary or VIE have made to the holding company and which entity made such transfer, and their tax consequences. Similarly quantify dividends or distributions made to U.S. investors, the source, and their tax consequences. Describe any restrictions on foreign exchange and your ability to transfer cash between entities, across borders, and to U.S. investors. Describe any restrictions and limitations on your ability to distribute earnings from your businesses, including subsidiaries and/or VIEs, to the parent company and U.S. investors as well as the ability to settle amounts owed under the VIE agreements.*

Response:

The Company advises the Staff that a majority of the Company's business does not operate in China and we do not currently rely on revenue from China to fund our operations outside of China. At September 30, 2021, we have \$629 million in cash and investments, of which only 9% is in China.

Cash flows from the Falikang joint venture to FibroGen Beijing are currently intended to remain onshore in China. All cash flows generated from the joint venture to date have remained onshore in China to help fund operations of FibroGen Beijing. This joint venture is not designed to facilitate moving money out of China but instead to support distribution and the growth of our operations in the country. One of the two partners in this joint venture is FibroGen Beijing, our Chinese wholly foreign owned entity. 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.

The Company also advises the Staff that we disclose information about our cash holdings in China in the "Financial Conditions" section under LIQUIDITY AND CAPITAL RESOURCES. For example, in our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, we disclose as follows:

"As of September 30, 2021, we had cash and cash equivalents of \$274.5 million. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting of available-for-sale debt investments and marketable equity investments, and stated at fair value, are also available as a source of liquidity. As of September 30, 2021, we had short-term and long-term investments of \$211.9 million and \$142.6 million, respectively. As of September 30, 2021, a total of \$77.4 million of our cash and cash equivalents was held outside of the U.S. in our foreign



subsidiaries, including \$56.0 million of our cash and cash equivalents is held in China, to be used primarily for our China operations.”

Proposed Disclosure:

While we do not expect cash flow to be repatriated from China in the near future, in response to the Staff’s comment we will add the following additional disclosure in LIQUIDITY AND CAPITAL RESOURCES under MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS in our next Annual Report on Form 10-K.

“Cash flows from Falikang, a distribution joint venture between FibroGen Beijing and AstraZeneca, 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.”

In addition, we have a risk factor that describes regulations involved with transferring cash across borders titled “FibroGen (China) Medical Technology Development Co., Ltd. (“FibroGen Beijing”) would be subject to restrictions on paying dividends or making other payments to us, which may restrict our ability to satisfy our liquidity requirements.” We propose the following edits to this risk factor:

“We plan to conduct all of our business in China through FibroGen China Anemia Holdings, Ltd., FibroGen Beijing and its branch offices, and our joint venture distribution entity, Beijing Falikang Pharmaceutical Co. Ltd. (“Falikang”). We do not currently rely on revenue from China to fund our operations outside of China. However, we may in the future rely on dividends and royalties paid by FibroGen Beijing for a portion of our cash needs, including the funds necessary to service any debt we may incur and to pay our operating costs and expenses. The payment of dividends by FibroGen Beijing is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0% of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of September 30, 2021, approximately \$56.0 million of our cash and cash equivalents is held in China.”

5. In a separate summary discussion, disclose clearly that the company uses a structure that involves a VIE based in China and what that entails and provide early in the summary a diagram of the company's corporate structure, including who the equity ownership interests are of each entity. Describe all contracts and arrangements through which you purport to obtain economic rights and exercise control that results in consolidation of the VIE's operations and financial results into your financial statements. Identify clearly the entity in which investors are purchasing their interest and the entity(ies) in which the company's operations are conducted. Describe the relevant contractual agreements between the entities and how this type of corporate structure may affect investors and the value of their investment, including how and why the contractual arrangements may be less effective than direct ownership and that the company may incur substantial costs to enforce the terms of the arrangements. Disclose the uncertainties regarding the status of the rights of the United States holding company with respect to its contractual arrangements with the VIE, its founders and owners, and the challenges the company may face enforcing these contractual agreements due to uncertainties under Chinese law and jurisdictional limits.

Response:

Further to our discussion on November 19, 2021, the Company advises the Staff that the Company does not employ a VIE structure for purposes of replicating foreign investment in Chinese-based companies where Chinese law prohibits direct foreign investment in operating companies within our business sector. Investors are purchasing common stock of FibroGen, Inc., a business incorporated in the state of Delaware with headquarters in the state of California. The Company is not a U.S. holding company with operations conducted through contractual arrangements with a VIE based in China. FibroGen, Inc. owns a true equity interest in the joint venture Falikang through owning our wholly foreign-owned entity FibroGen Beijing, which owns 51.1% of Falikang. FibroGen is not consolidating results from this joint venture. There is no third-party ownership of Falikang, which is owned solely by AstraZeneca and FibroGen Beijing.

We have detailed disclosure regarding the contractual arrangements with AstraZeneca and the Company's and AstraZeneca's joint venture, Falikang, in Part II Item 7 of our Annual Report on Form 10-K, Management's Discussion and Analysis of Financial Condition and Results of Operations, as well as in Note 3 to the Notes to the Consolidated Financial Statements.

Based on the above, the Company does not believe any additional disclosure is necessary in our periodic reports.

6. *In your summary of risk factors, disclose the risks that your corporate structure and being based in or having a significant portion of the company's operations in China poses to investors. In particular, describe the significant regulatory, liquidity, and enforcement risks with cross-references to the more detailed discussion of these risks. For example, specifically discuss risks arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws and that rules and regulations in China can change quickly with little advance notice; and the risk that the Chinese government may intervene or influence your operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in your operations and/or the value of your common stock. Acknowledge any risks that any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.*

Response:

The Company advises the Staff that investors are purchasing common stock of FibroGen, Inc., a business incorporated in the state of Delaware with headquarters in the state of California. FibroGen, Inc. owns a true equity interest in the joint-venture Falikang through ownership of its subsidiaries and the Company is not a China-based issuer or a U.S. holding company operating in China through contractual arrangements with a VIE.

While we have already included risk factors related to: the legal system in China, enforcement of laws, rules and regulations in China, changes in laws in China, and risks related to the pharmaceutical industry in China (which is highly regulated and subject to change), based on the Staff's comment in our next Annual Report on Form 10-K we will include the following additional risk factors and additional disclosure regarding the risk that the Chinese government may intervene or influence our operations unexpectedly which could result in a material change in our operations and/or the value of our common stock. We will also include these changes in our summary risk factors.

Proposed Additional Disclosure:

“Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U.S. or to China, our industry or on us. We



conduct manufacturing and development activities and have business operations both in the United States and China. 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 scientists and other research and development 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. In addition, the Company's periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and this additional scrutiny could affect our ability to effectively raise capital in the United States.

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes 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."

Proposed Additional Disclosure redlined against its most recent disclosures in its Form 10-Q for the period ended September 30, 2021

"Uncertainties with respect to the China legal system and regulations could have a material adverse effect on us.

The legal system of China is a civil law system primarily based on written statutes. Our financial condition and results of operations may be adversely affected by government control, perceived government interference and/or changes in tax, cyber and data security, capital investments, cross-border transaction and other regulations that are currently or may in the future be applicable to us. Recently, Chinese regulators have announced regulatory actions aimed at providing China's government with greater oversight over certain sectors of China's economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China's government may in the future take regulatory actions that materially adversely affect the business environment and financial markets in China as they relate to us, our ability to operate our business, our liquidity and our access to capital.

Unlike in a common law system, prior court decisions may be cited for reference but are not binding. Because the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules are not always uniform and enforcement of these laws, regulations and rules involve uncertainties, which may limit legal protections available to us. Moreover, decision makers in the China judicial system have significant discretion in interpreting and implementing statutory and contractual terms, which may render it difficult for FibroGen Beijing to enforce the contracts it has entered into with our business partners, customers and suppliers. Different government departments may have different interpretations of certain laws and regulations, and licenses and permits issued or granted by one government authority may be revoked by a higher government authority at a later time. Furthermore, new laws or regulations may be passed, in some cases with little advance notice, that affect the way we or our collaboration partner do business in China (including the manufacture, sale, or distribution of roxadustat in China). Our business may be affected if we rely on laws and regulations which are subsequently adopted or interpreted in a manner different from our understanding of these laws and regulations. Navigating the uncertainty and change in the China legal and

regulatory systems will require the devotion of significant resources and time, and there can be no assurance that our contractual and other rights will ultimately be maintained or enforced.”

“Changes in China’s economic, governmental, or social conditions could have a material adverse effect on our business.

Chinese society and the Chinese economy continue to undergo significant change. Changes in the regulatory structure, regulations, and economic policies of the Chinese government could have a material adverse effect on the overall economic growth of China, which could adversely affect our ability to conduct business in China. The Chinese government continues to adjust economic policies to promote economic growth. Some of these measures benefit the overall Chinese economy, but may also have a negative effect on us. For example, our financial condition and results of operations in China may be adversely affected by government control over capital investments or changes in tax regulations. [Recently, Chinese regulators have announced regulatory actions aimed at providing China’s government with greater oversight over certain sectors of China’s economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China’s government may in the future take regulatory actions that materially adversely affect the business environment and financial markets in China as they relate to us.](#) As the Chinese pharmaceutical industry grows and evolves, the Chinese government may also implement measures to change the regulatory structure and structure of foreign investment in this industry. We are unable to predict the frequency and scope of such policy changes and structural changes, any of which could materially and adversely affect FibroGen Beijing’s development and commercialization timelines, liquidity, access to capital, and its ability to conduct business in China. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to develop and commercialize our product candidates in China. In addition, the changing government regulations and policies could result in delays and cost increases to our development, manufacturing, approval, and commercialization timelines in China.”

7. On page 1 and as a separate risk factor under Item 1A, disclose each permission that you or your subsidiaries are required to obtain from Chinese authorities to operate and issue these securities to foreign investors, including approvals needed to transfer scientific data. State whether you or your subsidiaries are covered by permissions requirements from the CSRC, CAC or any other entity, and state affirmatively whether you have received all requisite permissions and whether any permissions have been denied, including those related to the transfer of scientific data. Revise for the consequences to you and your investors if you do not receive or maintain the approvals, inadvertently conclude that such approvals are not required, or applicable laws, regulations, or interpretations change and you are required to obtain approval in the future.

Response:

We are not currently required to obtain approval or prior permission from the China Securities Regulatory Staff or Cyberspace Administration of China. However, we are subject to a number of government approvals, and we propose to add the additional risk factor described below:

Proposed Disclosure:

“We may be subject to additional Chinese requirements, approvals or permissions in the future.

We are incorporated in the state of Delaware. 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, environment protection, workplace safety, cybersecurity, from both national and local government agencies. For example, FibroGen Beijing is required to maintain a Drug Product Production Permit that allows it to manufacture API and roxadustat capsules. Falikang, our joint venture with AstraZeneca, is required to maintain a Drug Product Distribution Permit in order to be able to distribute our drug product roxadustat in China. For certain of our clinical trials conducted in China, we need to obtain, through the clinical sites, permits from 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.

None of our subsidiaries or joint venture in China are required to obtain approval or prior permission from the China Securities Regulatory Staff, Cyberspace Administration of China, or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to our investors. However, the approvals and permits we do have to comply with are numerous and there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented. There can be no assurance that we will not be subject to new or changing requirements, approvals or permissions in the future in order to operate in China.

If we are unable to obtain the necessary approvals or permissions in order to operate our business in China, 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.”

8. Revise your risk factors to acknowledge that if the PRC government determines that the contractual arrangements constituting part of your VIE structure do not comply with PRC regulations, or if these regulations change or are interpreted differently in the future, your shares may decline in value or become worthless if you are unable to assert your contractual control rights over the assets of your PRC subsidiaries that conduct a significant portion of your operations.

Response:

The Company advises the Staff that it is not a U.S. holding company operating in China through contractual arrangements with a VIE for the purposes of replicating foreign investment in Chinese-based companies where Chinese law prohibits direct foreign investment in operating companies within our business sector. FibroGen, Inc. owns a true equity interest in the joint venture Falikang through owning our wholly foreign-owned entity FibroGen Beijing, which owns 51.1% of Falikang, not through contractual rights.

Therefore, we do not believe the Chinese government would disallow our joint venture structure in China. However, in response to the Staff's comment, we will include the following additional risk factor in our next Annual Report on Form 10-K:

Proposed Disclosure:

"If the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently in the future, the value of our common stock may decline in value.

In July 2021, the Chinese government provided new guidance on China-based companies raising capital outside of China, including through arrangements called variable interest entities, or VIEs. We do not employ a VIE structure for purposes of replicating foreign investment in Chinese-based companies where Chinese law prohibits direct foreign investment. We do not operate in an industry that is currently subject to foreign ownership limitations in China. However, there are uncertainties with respect to the Chinese legal system and there may be changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented. If in the future the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently, the value of our common stock may decline."

9. Given the Chinese government's significant oversight and discretion over the conduct of your business, please revise to separately highlight the risk that the Chinese government may intervene or influence your operations at any time, which could result in a material change in your operations and/or the value of your common stock.

Response:

Please see the additional disclosures we have proposed in response to Comments 6, 7, and 8.



10. For your summary risk factor discussion and the full risk factor section, please provide the risk factors related to China prior to your other risk factor discussions.

Response:

The Company advises the Staff that while risks associated with our operations in China are important, we do not believe they are the most material risks for the Company. Being an international biotechnology company with multiple programs in research, development, and commercialization, we believe the most important risks for our Company are those related to development and commercialization of our product candidates, followed by risks related to intellectual property and government regulation.

However, in response to the Staff's comment, we will relocate our international operations risk factors such that they would be prior to the risk factors related to COVID-19, general business operations, and our common stock in our next Annual Report on Form 10-K.

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The Company appreciates the Staff's comments on this topic and believes the proposed disclosures above (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 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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