

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

July 9, 2014

Via E-Mail
Michael Lowenstein
Vice President, Legal Affairs
FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158

Re: FibroGen, Inc.

Confidential Draft Registration Statement on Form S-1

Submitted June 11, 2014 CIK No. 0000921299

Dear Mr. Lowenstein:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

General

- 1. If our comments are applicable to portions of the filings that we have not cited, please make the appropriate changes elsewhere in the filing in accordance with our comments.
- 2. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 3. Please confirm that the graphics included in your registration statement are the only graphic, visual, or photographic information you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.

- 4. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.
- 5. We note that you have submitted a request for confidential treatment of portions of Exhibits 10.19, 10.20, 10.23, and 10.24, and that your exhibit index indicates that you have requested or will be requesting confidential treatment of portions of certain other exhibits. We will provide any comments on your confidential treatment request(s) and the related disclosure in one or more separate comment letters.

"We will incur increased costs as a result of operating as a public company..." page 56

6. Please expand this risk factor to include an estimate of the annual costs you expect to incur as public company.

Use of Proceeds, page 64

- 7. Please revise your disclosure to identify:
 - the product candidates the development of which you may fund with proceeds from the offering;
 - the approximate amount intended to be used for each program; and
 - the anticipated stage of development that you estimate the proceeds from this offering will allow you to reach

Management's Discussion and Analysis and Results of Operations Research and Development Expenses, page 75

8. Please disclose the total research and development expenses incurred from inception to date for the four product candidates presented in the table.

<u>Critical Accounting Policies and Significant Judgments and Estimates</u> <u>Stock-Based Compensation, page 79</u>

9. Please disclose the methods used and the nature of your material assumptions in determining the fair value of your common stock. Please note we may have additional comments on your accounting for stock compensation once you have disclosed an estimated offering price. Please supplementally provide us with a quantitative and qualitative analysis explaining the difference between the estimated offering price and the

fair value of each equity issuance through the date of effectiveness for the preceding twelve months.

Business, page 91

- 10. Please amend your disclosure to describe the INDs submitted for roxadustat, FG-3019, and FG-6874 by indication and specify when these INDs were filed and by whom. Additionally, if an IND has not been filed for each product candidate for each of the indications you are currently investigating, please explain why.
- 11. In this section, as well as in the prospectus summary, please explain what "physiologic range" means the first time the term it appears, as in "This coordinated erythropoietic response includes both the stimulation of red blood cell progenitors by erythropoietin, or EPO, typically within or near physiologic range..."
- 12. We note throughout your prospectus you occasionally characterize roxadustat as "effective" or "demonstrating efficacy" when discussing your clinical observations. Because FDA approval is dependent on the agency making a formal determination (according to criteria specified in law and agency regulations) that a drug, biologic or, in certain cases, a medical device, is both safe and effective, it is premature for you to describe your clinical stage products as either safe or effective. It is also inappropriate to state that the results of any of your trials demonstrated or established safety or efficacy. Accordingly, please remove or modify this wording, as necessary, throughout your prospectus.
- 13. In the discussion of each of your ongoing Phase 3 studies, please indicate whether you have begun patient enrollment and, if so, the date such enrollment began and the number of patients enrolled to date.

Roxadustat for the Treatment of Anemia in Chronic Kidney Disease Reimbursement Challenges Associated with ESAs, page 97

- 14. Please amend your disclosure to explain briefly CMS's bundled ESRD payment approach under Medicare Part B the first time you introduce this concept in your Business section and prospectus summary.
- 15. On page 106, where you discuss statistical significance and p-values, please explain the relevance of statistical significance to the FDA's evidentiary standards for drug approval.
- 16. On page 113, under the subheading "Study 053," your statement that "Incident dialysis patients are at increased risk of serious cardiovascular events and death as compared to incident dialysis patients" appears to be in error. Please revise this sentence as necessary.

Status with Regulatory Agencies, page 120

17. Please amend your disclosure to provide the dates of your meeting with the FDA regarding your Phase 3 development program and the confirmation from the EMA of your Phase 3 development program.

Roxadustat for the Treatment of Anemia in Chronic Kidney Disease in China Commercialization – Reimbursement, page 127

18. You state that you intend to apply for reimbursement by the Chinese government, and that such pricing for drugs under reimbursement is determined by the government rather than the drug manufacturer. However, you then state that you believe you will have flexibility to price roxadustat competitively. Please revise your disclosure to clarify this apparent discrepancy.

Reversal of Lung Damage in Preclinical Models with FG-3019 in Pulmonary Fibrosis, page 137

19. In the chart that appears at the top of page 138 illustrating the results of the FG-3019 study, please provide appropriate legends that identify the triangle and circle data markers associated with the placebo-treated animals and those treated with FG-3019, respectively.

Collaborations

Our Collaboration Partnerships for Roxadustat – Astellas, page 148

20. Please revise your description of your agreements with Astellas here to disclose the aggregate amount of payments received to date.

AstraZeneca, page 149

21. Please revise your description your agreements with AstraZeneca here to disclose the aggregate amount of payments received to date.

Manufacture and Supply, page 152

22. If you are substantially dependent on any of your manufacturing-related agreements with WuXi STA, Caatalent, IRIX, or Boehringer Ingelheim, please file a copy of such agreement as an exhibit to your registration statement.

Intellectual Property

<u>In-License Agreements – University of Miami, page 171</u>

23. Please revise your description of your license agreement with the University of Miami to disclose the amount of the upfront licensing fee, if material.

Bristol-Myers Squibb Company (Medarex, Inc.), page 171

24. Please revise your description of your license agreement with Madarex to disclose the amount of development-related milestone payments paid to date.

Notes to Consolidated Financial Statements
Note 3—Collaboration Agreements
Accounting for the Astellas Agreements, page F-14

- 25. Please address the following regarding your Astellas collaboration agreements:
 - Disclose the co-development payments for the Europe agreement that were included in the consideration for the arrangements.
 - Disclose the amount of consideration that was allocated to each deliverable and any remaining deferred revenue.
 - Tell us what the license revenue recorded in 2012 and 2013 represent.
 - Tell us why you recognize revenue for co-development services when the reimbursement is contractually due as opposed to when it is earned.
 - Clarify for us the precise payments you are referring to when you state that any
 upfront consideration received after the initial proceeds on the agreement signing date
 were allocated to co-development services based on relative selling price. For
 instance does this include any non-contingent payments made after signing date, and
 if so why.
 - Provide us with a detailed analysis supporting your conclusion that the license in Japan provides stand-alone value to the customer despite the lack of manufacturing rights. In this regard, we are unsure how the compensation under the arrangement would impact the stand-alone value conclusion.

Accounting for the AstraZeneca Agreements, page F-15

- 26. Please address the following regarding your AstraZeneca collaboration agreements:
 - Disclose the total arrangement consideration and separately quantify the fixed and determinable amounts.
 - Disclose the amount of consideration that was allocated to each deliverable and any remaining deferred revenue.
 - Tell us what the license revenue recorded in 2014 represents.

- Tell us why you recognize revenue for co-development services when the reimbursement is contractually due as opposed to when it is earned.
- Clarify for us the precise payments you are referring to when you state that any
 upfront consideration received after the initial proceeds on the agreement signing date
 were allocated to co-development services based on relative selling price. For
 instance does this include any non-contingent payments made after signing date, and
 if so why.
- In the footnote to your tabular disclosure on page 20 you state that co-development, information sharing, and committee services have been combined into a single unit of accounting. Please disclose why this is the case pursuant to ASC-605-25-50-2f.

Item 16. Exhibits and Financial Statement Schedules, page II-5

- 27. Please file a copy of each of the following as an exhibit to your registration statement:
 - the individual offer letter agreements with your executive officers;
 - the TEKES promissory note(s) and any related agreement(s);
 - the September 2012 Credit Facility; and
 - the January 2013 FibroGen China note
- 28. We note that you have incorporated Exhibit 10.21 by reference to Exhibit 10.2 to a Form 8-K filed by Medarex, Inc., and that Medarex has redacted portions of these exhibits pursuant to a confidential treatment order granted to it. Please be advised that you may only satisfy your obligation to file required exhibits by: (1) filing your own properly marked, redacted exhibit and submitting a request for confidential treatment in your own name for any redacted portions; or (2) incorporating by reference a complete, unredacted copy of an exhibit filed by a third party.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Tabatha McCullom at (202) 551-3658 or Joel Parker at (202) 551-3651 if you have questions regarding comments on the financial statements and related matters. Please contact Amy Reischauer at (202) 551-3793, Daniel Greenspan at (202) 551-3623 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: <u>Via E-Mail</u>
Michael E. Tenta
Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304