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

DIVISION OF
CORPORATION FINANCE

June 23, 2023

Pete O'Heeron
Chief Executive Officer
FibroBiologics Inc.
455 E. Medical Center Blvd.
Suite 300
Houston, TX 77598

Re: FibroBiologics Inc.
Draft Registration Statement on Form S-1
Submitted May 18, 2023
CIK No. 0001958777

Dear Pete O'Heeron:

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.

Draft Registration Statement on Form S-1 submitted May 18, 2023

Cover Page

1. Please disclose on your cover page whether your listing is contingent on the final approval of NASDAQ.

Prospectus Summary, page 2

2. Please balance the Summary discussion of the opportunity you see in your market, your value proposition and your growth strategy with equally prominent disclosure of the challenges you face and the risks and limitations that could harm your business or inhibit your strategic plans regarding development of fibroblast therapy products. For instance,

we note your risk factor disclosure on page 24 indicating that to date no fibroblast therapy products have been approved and that only a small number of clinical trials involving fibroblasts have been conducted.

Our Current Pipeline, page 3

3. We note your disclosure stating that you have completed a Phase 1 study of your drug candidate, CYMS01. However, your pipeline chart on pages 3 and 78 appears to show that this drug candidate is in still in the preclinical stage. Please advise.

4. Please revise the pipeline table to remove the CYW628, TBC190 and CYTER915 candidates from the table. In this regard, your disclosures indicate that your work on these candidates is early-stage and, as such, these candidates should not be highlighted in the Summary pipeline table.

5. We note your disclosure on page 3 highlighting your belief that CybroCell will prove superior to existing treatments because you expect it will be less invasive, and will regenerate the disc, restore function and reduce pain without debilitating long-term effects. Given that you have not conducted human clinical trials, please revise to provide balance and context to your beliefs and expectations regarding the potential performance of the product under development.

Pipeline Table, page 3

6. Please revise your pipeline table to make the columns for each phase the same size.

Risk Factors, page 9

7. Please revise your risk factor on page 61 regarding exclusive forum jurisdiction to include discussion of Section 27 of the Exchange Act, which grants exclusive federal jurisdiction, and Section 22 of the Securities Act, which grants concurrent jurisdiction for federal and state courts.

Results of Operations
Comparison of Fiscal Years December 31, 2022 and 2021
Research and Development Expenses, page 70

8. Please expand your disclosure of research and development expenses to provide a breakout of expenses by product candidate. To the extent that you do not track expenses by product candidate, please so state.

Business, page 76

9. We note your disclosure on page 12 indicating that your existing capital will enable you to fund operations through at least June 30, 2024. Please revise the Business section, where appropriate, to discuss your plans to fund development work for each product candidate. Quantify the funds that you plan to allocate to each candidate(s) and discuss whether such

allocation is planned to reach a specific stage in the development process (e.g., through phase 1, phase 2, etc.).

Fibroblasts Technology Platform, page 76

10. Please revise your disclosure at the top of page 77 to identify and discuss the studies that have "demonstrated that allogeneic fibroblasts, much like mesenchymal stem cells, are immune-privileged and do not provoke an immune response *in vitro* and *in vivo*."

CybroCell for Degenerative Disc Disease, page 79

11. Please revise to include narrative disclosure explaining the illustrative diagram depicted on page 79 so it is clear how this diagram support the claims made in this section.

Our Solution, page 81

12. Please revise to disclose when you received IND clearance for the Phase 1/2 trial. Explain the trial design, including the number of participants and the clinical endpoints. Clarify whether the drug will be injected into the degenerating disc, which we note was the method of administration in the rabbit studies that you reference. Discuss the work involved in submitting and gaining approval for a master cell bank, including whether material costs are required for that process.

13. Please revise to present the data from each of the animal studies. From the discussion, it should clear how many animals were tested and whether the data is statistically significant. Revise the Summary on page 3 to explain briefly how the results were "positive."

14. Please revise to present Dr. An's consent for the summarization attributed to him on page 82. Refer to Rule 436.

Our Solution, page 83

15. Please revise to explain briefly the four efficacy-related tests used in the trial. Present the data for each of the five participants.

16. Please revise to explain why you are conducting further research into the mode of action prior to filing the Phase 2 IND application. Clarify whether the IND filing is planned for the US or Mexico.

Intellectual Property, page 86

17. Please revise to specify how many granted patents are covered by the license agreements and clarify the applicable jurisdictions for these patents. Clarify whether you have composition of matter patents covering your lead candidates.

18. We note that you have issued Series A Preferred Stock to Fibrogenesis in exchange for a

patent assignment agreement. Please revise your disclosure here to clarify how much preferred stock was provided in exchange for the patent assignment agreement.

Management
Executive Officers, page 99

19. Please revise your disclosure in this section to include the dates for current and prior positions held by Pete O'Heeron and Dr. Hamid Khoja.

Principal and Registered Stockholders, page 112

20. Please revise your registration statement to clearly state that shareholders or registered holders may elect to sell their shares in connection with this listing and in market transactions following the listing. Please also include the number of shares held by the registered holders and the portion of those shares that may be freely sold upon effectiveness of the registration statement, as well as the number of shares that may be freely sold in reliance on an exemption from registration such as Rule 144.

21. Please revise to identify the natural person(s) who have voting and/or dispositive control of the shares beneficially owned by Golden Knight Incorporated.

Sale Price History of Our Capital Stock, page 118

22. Please revise this section to explain why the bonus shares were paid in each instance.

Plan of Distribution, page 123

23. With reference to your disclosure on page 124, please revise to discuss NASDAQ direct listing rules as they relate to the Advisor's ability to affirmatively direct/request NASDAQ to delay the opening cross until the Advisor feels there is sufficient trading volume.

Financial Statements, page F-1

24. Please explain to us your basis for presenting carve-out financial statements for the years ended December 31, 2022 and 2021. Specifically address the following in your response:
    - You disclose that you were formed on April 8, 2021 through the issuance of 35,000,000 shares of Series A Preferred Stock to your former parent, FibroGenesis, in return for rights to certain intellectual property. As such, it is unclear why you have not presented stand-alone financial statements for FibroBiologics from April 8, 2021 (inception) through December 31, 2021 and for the year ended December 31, 2022. Please advise.
    - It is unclear why you would present financial statements on a carve-out basis for FibroBiologics after the date of its formation when it became a separate stand-alone legal entity. In this regard, you disclose that "prior to its formation" the Company operated as a line of business of FibroGenesis and that your expenses included certain allocations from the parent for the company's portion of general and administrative and research and development expenses originally incurred by the parent "prior to the

Company's formation on April 8, 2021". You further disclose in MD&A that since inception your operations have included business planning, hiring personnel, raising capital, building your intellectual property portfolio and performing research and development on your product candidates and our fibroblast technology. It is therefore unclear why carve-out financial statements would be appropriate for the period from April 8, 2021 (inception) through December 31, 2021 and for the year ended December 31, 2022.

- Please ensure that all agreements related to your company formation, including the Patent Assignment Agreement and the Intellectual Property Cross-License Agreement, are filed as we may review them as part of our analysis.

Note 7- Share Subscription Agreement, page F-11

25. We note your disclosure stating that, on November 12, 2021, you entered into a Share Purchase Agreement with certain investors for the sale of up to $100,000 thousand of common stock, which is contingent upon you achieving a public listing of your common stock. Please tell us how you accounted for this agreement and the accounting literature you relied upon in your determination.

Note 11- Share-based Compensation, page F-14

26. Given the significance of your stock-based compensation expense to your financial statements, please tell us how you considered the guidance in Item 303(b)(3) of Regulation S-K in determining not to include it as a critical accounting estimate in your Management's Discussion and Analysis of Financial Condition and Results of Operations.

27. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances. Please discuss with the staff how to submit your response.

You may contact Tracie Mariner at (202) 551-3744 or Angela Connell at (202) 551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Cindy Polynice at (202) 551-8707 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Kelvin Kesse, Esq.