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August 16, 2023

**VIA EDGAR AND OVERNIGHT COURIER**

Office of Life Sciences
Division of Corporation Finance
Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549
Attention:Cindy Polynice
Joe McCann
Tracie Mariner
Angela Connell

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

Ladies and Gentlemen:

This letter is submitted on behalf of FibroBiologics, Inc. (the "***Company***") in response to comments of the staff (the "***Staff***") of the U.S. Securities and Exchange Commission (the "***Commission***") with respect to the Company's Draft Registration Statement on Form S-1 confidentially submitted on May 18, 2023 (the "***Draft Registration Statement***"), as set forth in the Staff's letter dated June 23, 2023 (the "***Comment Letter***").

Set forth below are the Company's responses to the Staff's comments in the Comment Letter. For reference purposes, the text of the Staff's comments are reproduced in bold below, followed by the Company's response to the comment. The numbered paragraphs below correspond to the numbered comments in the Comment Letter.

Additionally, the Company is concurrently confidentially submitting Amendment No. 1 to the Draft Registration Statement ("***Amendment No. 1***"), which reflects revisions in response to the Comment Letter and certain other updates. For the convenience of the Staff, we are also sending, by overnight courier, copies of this letter and copies of Amendment No. 1, marked to show changes to the Draft Registration Statement as originally confidentially submitted.

**Cover Page**

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

Company Response: In response to the Staff's comment, the Company has revised the cover page of Amendment No. 1 to disclose that the Company's listing is contingent on 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.**

Company Response: In response to the Staff's comment, the Company has revised the Prospectus Summary in Amendment No. 1 to include disclosure of certain challenges the Company faces and certain risks and limitations that could harm the Company's business or inhibit the Company's strategic plans regarding development of fibroblast therapy products.

**Our Current Pipeline, page 3**

3. **We note your disclosure stating that you have completed a Phase 1 study of your drug candidate, CYMS101. However, your pipeline chart on pages 3 and 78 appears to show that this drug candidate is still in the preclinical stage. Please advise.**

Company Response: In response to the Staff's comment, the Company has revised the headings and corresponding columns in the pipeline chart on pages 3 and 78 of Amendment No. 1 to show that the Company has completed a Phase 1 study of CYMS101.

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.**

Company Response: In response to the Staff's comment, the Company has revised the pipeline table in Amendment No. 1 to remove the TBC190 and CYTER915 candidates. However, the Company respectfully submits that CYWC628 should remain in the pipeline table because the Company is completing one preclinical study and preparing to submit an IND for this candidate.

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.**

Company Response: In response to the Staff's comment, the Company has supplemented its disclosure with results obtained to date for CybroCell in the "Our Solution" section on page 82 of Amendment No. 1 to support our beliefs regarding the potential benefits of this candidate.

**Pipeline table, page 3**

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

Company Response: In response to the Staff's comment, the Company has revised the pipeline table in Amendment No. 1 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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1.

**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.**

Company Response: In response to the Staff's comment, the Company advises the Staff that it does not track research and development expenses by product candidate. The Company has included disclosure to this effect in Amendment No. 1. In the Company's discussion of its results of operations, the Company has quantified the material causes of period-over-period changes in research and development expense. As several of the Company's research and development activities benefit more than one product candidate or opportunity, the Company does not believe additional breakout would provide meaningful insight into its results of operations.

**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.).**

Company Response: In response to the Staff's comment, the Company has revised the Business Section of Amendment No. 1 to provide an overview of the development work the Company plans to complete with its existing capital through June 30, 2024.

**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."**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1 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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1 to remove the illustrative diagram depicted in the Draft Registration Statement. In light of such removal, the Company respectfully submits that inclusion of the requested narrative disclosure is not necessary.

**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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1 to (i) disclose the date the Company received IND clearance for the Phase 1/2 trial, (ii) explain the trial design, including the number of participants and the clinical endpoints, (iii) clarify that the drug will be injected directly into a damaged intervertebral disc and (iv) discuss the work involved in submitting and gaining approval for a master cell bank.

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."**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1.

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

Company Response: In response to the Staff's comment, Dr. An's consent for the summarization attributed to him has been filed as an exhibit to Amendment No. 1.

**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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1 to explain the four efficacy-related tests used in the trial and to 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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1 to explain why it is conducting further research into the mode of action prior to filing the Phase 2 IND application and to clarify that the IND application will be filed in the United States.

**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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1 to provide the requested information.

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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1 to clarify the number of preferred stock 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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure in Amendment No. 1 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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure 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.

The Company respectfully acknowledges the Staff's request for inclusion of 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. The Company undertakes to revise the registration statement on Form S-1 to include such disclosure, once such information is available.

**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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure to identify the natural persons 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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure 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.**

Company Response: In response to the Staff's comment, the Company has revised the referenced disclosure 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.**

Company Response:

The Company was spun out of its former parent company, FibroGenesis, on April 8, 2021. The initial audited periods for the Company included the two years ended December 31, 2020 and 2021. In its creation of the carve-out financial statements, the Company followed the guidance from SAB 1.B.1 (codified in ASC 220-10-S99-3), which includes the following guidance:

- The staff believes that the historical statements of a registrant should reflect all of its costs of doing business. Therefore, in specific situations, the staff has required the subsidiary to revise its financial statements to include certain expenses incurred by the parent on its behalf.

- The staff expects any expenses clearly applicable to the subsidiary to be reflected in its income statements. However, the staff understands that in some situations a reasonable method of allocating common expenses to the subsidiary must be chosen because specific identification of expenses is not practicable.

Consistent with this guidance, the Company used a reasonable method to allocate expenses incurred on behalf of the Company by its parent up to the point at which the Company was spun out (April 8, 2021) and began incurring all of its own expenses. Allocating expenses was required because specific identification of expenses incurred by the parent was not practicable. These allocated expenses are included in the Company's carve-out financial statements. Expenses allocated to the Company for the period from January 1, 2021, to April 8, 2021, total $171 thousand in research and development expenses and $121 thousand in general and administrative expenses. Furthermore, the Company recorded a total of $1,461 thousand in net parent investment for expenses allocated from the parent company from January 1, 2020, to April 8, 2021.

Including these allocated expenses for the period from January 1, 2021, to April 8, 2021, in the Company's financial statements makes the comparison of fiscal years 2022 and 2021 more meaningful for investors because 2021 financial statements reflect a full year of activity with the allocated expenses.

No expenses have been allocated from the parent beyond April 8, 2021. In other words, the Company's financial statements are standalone from April 8, 2021, and beyond.

To avoid confusion and maximize comparability, the Company has included the carved-out allocated expenses through April 8, 2021, along with the appropriate disclosures, in its audited financial statements, but has removed "Carve-Out" from the title of these financial statements. The revised audited financial statements for the years ended December 31, 2022 and 2021, with "Carve-Out" removed from the title are included in Amendment No. 1.

The agreements related to the Company's formation, including the Patent Assignment Agreement and the Intellectual Property Cross-License Agreement, have been filed as exhibits to Amendment No. 1.

**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.**

Company Response:

The Share Purchase Agreement contains provisions for a Registration Rights Agreement, a Purchase Agreement, a Commitment Fee, Warrants, and a Private Transaction Fee. The accounting for each of these provisions was determined as follows:

- ***Registration Rights Agreement***. The contingent payments that may become due under the Registration Rights Agreement are accounted for separately and without regard to the potential shares or warrants that may be issued under the Purchase Agreement. The contingent obligation to provide a cash payment to the Purchaser if the Filing Deadline or Effectiveness Deadline is not met should only be recorded as a liability if such payment is both probable and reasonably estimable. At inception, there is no accounting for the contingent consideration that may become due under the Registration Rights Agreement because the Company has not completed a Public Listing so a transfer of consideration under this Registration Rights Agreement is not probable. (ASC 825-20, *Registration Payment Arrangements*)
- ***Purchase Agreement***. The Purchase Agreement is not accounted for as a liability under ASC 480 because it neither embodies an obligation to buy back the Company's shares nor embodies an obligation to issue a variable number of shares. The sales and timing of any sales of the Company's common stock is solely at the Company's election. However, the Purchase Agreement does meet the definition of a derivative and should be recognized at fair value, but the fair value prior to Public Listing is $0. (ASC 480, *Distinguishing Liabilities from Equity*; ASC 815, *Derivatives and Hedging*)
- ***Commitment Fee***. The Commitment Fee represents a payment to the Purchaser rather than an issuance cost and will be recorded as a reduction to additional paid-in capital when it becomes probable upon Public Listing. (ASC 340, *Other Assets and Deferred Costs*)
- ***Warrants***. At inception, the warrants are an embedded component of the Purchase Agreement, which is valued at $0, as they are not legally detachable or separately exercisable from the host contract at inception until a Public Listing occurs. However, upon Public Listing the warrants will become freestanding financial instruments because they will at that point be legally detachable and separately exercisable from the Share Purchase Agreement. When the warrants become freestanding financial instruments upon Public Listing, they will be recorded as derivative liabilities at fair value on that date, and subsequent changes in fair values going forward for the next year will be recognized in earnings. At the end of one year after Public Listing, the warrants will be classified as equity because the number of shares will become fixed. (ASC 480, *Distinguishing Liabilities from Equity*; ASC 815, *Derivatives and Hedging*)
- ***Private Transaction Fee***. The Private Transaction Fee is an embedded feature of the host Purchase Agreement that is clearly and closely related to the host contract and therefore requires no separate accounting at inception under ASC 815. The fee represents a loss contingency and will only be accrued as a liability if payment becomes probable (i.e., upon the occurrence of a Private Transaction). (ASC 450, *Contingencies*; ASC 815, *Derivatives and Hedging*)

**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.**

Company Response: In response to the Staff's comment, the Company has revised the disclosure in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of Amendment No. 1 to include stock-based compensation as a critical accounting estimate.

**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.**

Company Response: The Company respectfully acknowledges the Staff's comment and will provide the Staff with the requested information, once an estimated offering price or range is available.

*Remainder of page intentionally blank. Signature page follows.*

Should the Staff have additional questions or comments regarding this submission, please do not hesitate to contact the undersigned at (713) 651-5557 or brian.fenske@nortonrosefulbright.com.

Sincerely,

NORTON ROSE FULBRIGHT US LLP

*/s/* Brian P. Fenske

Enclosure
cc: Pete O'Heeron, Chief Executive Officer
Mark Andersen, Chief Financial Officer
**FibroBiologics, Inc.**

Kelvin Kesse
**Norton Rose Fulbright US LLP**