



DIVISION OF
CORPORATION FINANCE

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

April 26, 2021

Jeff Ross
Chief Executive Officer
Miromatrix Medical Inc.
10399 West 70th Street
Eden Prairie, MN 55344

Re: Miromatrix Medical Inc.
Draft Registration Statement on Form S-1
Submitted March 29, 2021
CIK No. 0001527096

Dear Mr. Ross:

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

Prospectus Summary

Overview, page 1

1. We note your statement here and on page 75 that you have generated human clinical data to demonstrate the safety of your decellularized porcine liver scaffold. Please revise your disclosure to clarify, if true, that this safety data was obtained from your clinical studies of Miromesh and Miroderm, rather than from studies or trials of a bioengineered human organ.

Our Strengths, page 3

2. We note your statements here and on page 80 that you have proven perfusion

decellularization technology. Please revise to clarify that the marketing approval process for a BLA differs significantly from the approval process for medical devices and that there is no guarantee that (i) you will be able to leverage the approvals for Miroderm and Miromesh in seeking marketing approvals for your bioengineered organs or (ii) the FDA will deem your technology to be safe or effective for the purpose of developing bioengineered organs.

3. We note your statement here and on page 80 that you have demonstrated the "potential efficacy" of your recellularization technology. "Efficacy" is a determination that is solely within the purview of the FDA and foreign regulators. Please revise your statement to remove any implication that your preclinical studies have demonstrated efficacy.
4. We note your statements here and on page 81 describing your patent portfolio. Please revise to include the expiration dates of your patents.

Our Growth Strategy, page 4

5. We note your references here and on page 81 to your "technology leadership position". Please revise your disclosure to explain the basis for this claim.
6. We note your statement here and on page 82 that you intend to "rapidly advance" the clinical development of your products. Please remove these statements or revise to provide appropriate balance and context so that these statements do not imply that you will be successful in developing and progressing your products in a rapid or accelerated manner.
7. We note your statements in this section and on page 82 that you intend to pursue an efficient regulatory pathway and that you intend to leverage your experience with the Miroderm and Miromesh products to efficiently advance your organ programs. Please balance this disclosure to reflect your disclosure on pages 14-15 that (i) you will need to obtain an exemption from the FDA for the cGTP prohibition against pooling cells from two or more donors during manufacturing and (ii) that the FDA could view your bioengineered organs as combination products.

Implications of Being an Emerging Growth Company , page 6

8. 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.

Use of Proceeds, page 54

9. We note the use of proceeds to fund research and development activities and for expenditures related to a new facility. Please revise to specify how far the proceeds of the offering will take the Company in (i) research and development, including whether the proceeds will be sufficient to complete any clinical trials and (ii) developing the new

facility. If any material amounts of other funds are necessary to accomplish the specified purposes for which the proceeds are to be obtained, state the amounts and sources of such other funds needed for each such specified purpose and the sources thereof. Refer to Instruction 3 of Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Liquidity and Capital Resources, page 66

10. The end of the second paragraph in this section appears to contemplate that the timing and amount of your operating expenditures will depend on various factors, but no such factors are listed. Similarly, the end of your third paragraph references an estimate that is based on assumptions that may prove to be wrong, but no such estimate appears in the preceding disclosure. Please revise to clarify your disclosure.

Critical Accounting Policies and Significant Judgments and Estimates
Stock-Based Compensation, page 70

11. 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 including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

Business, page 75

12. Please revise to explain the pictures presented on pages 77, 78, 83 and 88. In this regard, it should be clear whether these pictures depict a prototype of your product(s) or something else. Also, revise page 78 to explain what is shown in each of the three pictures and tell us whether they depict a clinical trial.
13. Please revise to identify the publications and studies referenced in the second paragraph on page 78.

Our Growth Strategy, page 81

14. We note your statement that you believe that your technology will yield "best-in-class" functionality. This term suggests that your product candidates are effective and likely to be approved. Please revise your disclosure to remove this term or, alternatively, revise to explain the term and provide context so that the disclosure does not make these suggestions.

Product Pipeline, page 83

15. Please revise your pipeline chart to include separate columns for Phase 1, Phase 2 and Phase 3 trials. We also note that the arrow for the External Assist Liver is drawn nearly to

the end of the IND-Enabling Study column, but your disclosure on page 85 indicates that you will need to initiate further IND-Enabling Studies later in 2021 or early in 2022 to support an IND. Please revise the arrow in your pipeline chart to reflect the External Assist Liver's current development status.

Collaborations and Partnerships, page 91

16. Please revise your description of the Mayo Clinic, Mount Sinai and Texas Heart Institute agreements described in this section to:
 - quantify all payments made to date;
 - disclose separately the aggregate amount of all potential development, regulatory and commercial milestone payments;
 - disclose when royalty provisions expire, if the expiration is based on a number of years following commercialization, disclose the number of years;
 - disclose the expiration date; and
 - describe any termination provisions.
17. Your disclosure on page 76 indicates that you have an exclusive license agreement with the University of Minnesota and your disclosure on page 94 indicates that you exclusively license U.S. and foreign patents. Please revise this section to disclose the terms of all material license agreements. In your description of the terms of these agreements, please:
 - include each parties' rights and obligations under the agreement;
 - quantify all payments made to date;
 - disclose separately the aggregate amount of all potential development, regulatory and commercial milestone payments;
 - disclose the amount of option fees for any additional license or targets;
 - quantify the royalty rate, or a range no greater than 10 percentage points per tier;
 - disclose when royalty provisions expire, if the expiration is based on a number of years following commercialization, disclose the number of years;
 - disclose the expiration date; and
 - describe any termination provisions.

Certain Relationships and Related Party Transactions

Policies and Procedures for Related Party Transactions, page 127

18. Please disclose the standards that will be applied in determining whether to approve any of the transactions described in this section. Refer to Item 404(b)(1)(ii) of Regulation S-K.

Description of Capital Stock

Registration Rights, page 131

19. Please revise this section to disclose how many shares of your common stock will have registration rights following the consummation of the offering. Please also revise to disclose the terms of the demand and S-3 registration rights including the percentage of

shares required to be held by demanding holders in order for a registration rights request to be valid, whether there is any minimum offering size and whether there is any limit on the number of registrations that you will be obligated to effect.

Financial Statements

Note 3. Discontinued Operations, page F-12

20. In regards to the spin-out transaction which took place related to the Acellular Business with Reprise Biomedical, Inc. as well as the corresponding equity method investment held in Reprise Biomedical, Inc, please address the following:
- Tell us what percentage of ownership you held in Reprise Biomedical, Inc. prior to the spin-out transaction, if any. We note that you owned 100% of the Acellular Business but it is not clear if you also had ownership in Reprise Biomedical, Inc. Please also tell us how you determined it was appropriate to record a gain on this equity investment as part of this transaction if you did not have an ownership interest in Reprise Biomedical, Inc. prior to the transaction; and
 - Disclose all the significant terms of the spin-out transaction in June 2019. For example, we note that you received proceeds from the sale of your Acellular business of \$2.5 million based on your statement of cash flow for the year ended December 31, 2019.

Note 13. Commitments and Contingencies, page F-22

21. It is not clear based on your disclosures on page 112 whether you are currently subject to material legal proceedings. We remind you of the disclosure requirements of ASC 450 as applicable. For example, if there is at least a reasonable possibility that a loss exceeding amounts already recognized may have been incurred related to any matter, please either disclose an estimate (or, if true, state that the estimate is immaterial in lieu of providing quantified amounts) of the additional loss or range of loss, or state that such an estimate cannot be made pursuant to ASC 450-20-50.

You may contact Nudrat Salik at (202) 551-3692 or Brian Cascio at (202) 551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at (202) 551-4224 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Jonathan Zimmerman