



DIVISION OF
CORPORATION FINANCE

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

January 10, 2022

Vlad Vitoc, M.D., M.B.A.
Chief Executive Officer
MAIA Biotechnology, Inc.
4444 West Lake Street, Suite 1700
Chicago, IL 60606

**Re: MAIA Biotechnology, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted December 22, 2021
CIK No. 0001878313**

Dear Dr. Vitoc:

We have reviewed your amended 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.

Amendment No. 1 to Draft Registration Statement on Form S-1 submitted December 22, 2021

Cover page

1. Please revise to remove the graphics that appear before the Summary as these graphics are presented without appropriate context for an investor to be able to evaluate your disclosure. We refer to our prior comment 3, which we reissue in part. Please revise to disclose in the Summary that you are working with experts to evaluate the extent and quality of the existing data supporting THIO, as referenced on page 89. Make clear in the Summary the extent to which you intend to rely on clinical data generated by third parties and the basis for your belief that you will be permitted to do so.

Our Lead Product Candidate, page 2

2. We note your response to our prior comment 4, which we reissue in part. We note your statement that "Similar high and durable anti-cancer activities of THIO have been consistently demonstrated in multiple preclinical models..." It is inappropriate to present conclusions that data establishes safety and/or efficacy. Please revise your disclosure accordingly. As additional examples, we note the following:
- We believe we will generate favorable clinical safety data...
 - We believe this drug discovery program will lead to the development of additional proprietary drug candidates, more specifically with increased efficacy and a better safety profile across multiple cancer types.
- Additionally, please revise to explain what you mean by "conditional approval," as referenced at the top of page 3.

Our Science--Driven Telomere Targeting Approach, page 3

3. We note your response to our prior comment 5, which we reissue. Please revise your presentation to present all of the necessary phases of clinical development and an accurate representation of how far along you are in the development process or remove this graphic in its entirety. Your revised presentation should make clear, if true, that you have not yet initiated your Phase 2 study of THIO-101 and that you plan to conduct this study in Australia and Europe. Please also delete from your pipeline table the projected FDA approval for THIO in NSCLC as such projection is premature and speculative. Additionally, we note your revised disclosure stating that you have initiated an early-stage research and discovery program aimed at identifying new compounds capable of acting through similar mechanisms of activity as THIO. However, you have not provided any additional detail regarding these efforts or discussion of your platform elsewhere. Please revise to remove from the graphic the row corresponding to your next generation telomere targeting agents as this program does not appear currently material. We will not object to a narrative discussion of your early-stage programs.

Risk Factors

Risks Related to Our Initial Public Offering and Ownership of Our Common Stock

Our amended and restated bylaws will designate the Court of Chancery of the State of Delaware as the sole and exclusive forum..., page 52

4. We note your response to our prior comment 10 and your disclosure that "the exclusive forum provisions shall not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction, for which the federal district courts of the District of Delaware shall be the sole and exclusive forum unless the Company consents in writing to the selection of an alternative forum." Please revise to make clear that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Critical Accounting Policies and Significant Judgments and Estimates

Fair value of common stock, page 70

5. We acknowledge the changes made in response to comment number 15. Please revise throughout the filing to clarify what methodology was used to determine the fair value of your common stock (e.g. market or income approach) for each valuation date. Reference to the third-party valuation firm is not sufficient and the straight-line interpolation for your common stock is not an acceptable methodology.

Our Strategy, page 75

6. We note your response to our prior comment 17 and reissue. You still make statements implying that you will be advancing your product candidates in a "rapid" manner. For example, we note your statements on pages 4 and 75 that "[Y]our initial focus is to leverage the existing preclinical and clinical data available for THIO to support rapid and cost-efficient development." Clinical development is a lengthy process and statements that imply you will be successful in developing your product candidates in a rapid or accelerated manner are inappropriate and speculative. Please revise your disclosure accordingly.

Current Landscape of the Checkpoint Inhibitor Franchises, page 76

7. We note your revisions and response to our prior comment 19. Please revise to make clear that THIO has not been tested in combination with any other check-point inhibitor and your current development plans are to initiate a Phase 2 study in combination with cemiplimab only. Please also clarify the significance of the years under the indication columns. If the dates are meant to indicate when the product was either approved or commercialized for the respective indication, please remove from the table references to checkpoint inhibitors that are in clinical development. Given the inherent uncertainty of drug development, it is speculative to imply that THIO could be used in combination with check-point inhibitors that have not been approved by the FDA.

Intellectual Property, page 77

8. We note your revisions and response to our prior comment 20 and reissue in part. Please expand your discussion of your intellectual property to disclose the types of patents you hold (i.e., composition of matter, use or process) for each patent.

Our Programs, page 80

9. We note your response to our prior comment 23. Please explain whether earlier clinical trials were powered for statistical significance. Where applicable, disclose the relevant p-values and explain how statistical significance relates to FDA standards of efficacy.

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Differentiated Activity of THIO, a Telomere-Targeting Agent, page 81

10. We your revisions in response to our prior comment 26 and reissue in part. Please explain the basis for your claim that "To our knowledge, THIO's cancer-specific and direct telomere targeting mechanism of action using telomerase is different from all other available cancer therapies and those currently in clinical trials."

THIO Program, page 92

11. We note your revisions in response to our prior comment 29. Please revise to disclose the dollar amount of the aggregate potential milestones segregated by development, regulatory and commercial sales milestones.

You may contact Eric Atallah at 202-551-3663 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Jordan Nimitz at 202-551-6001 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Mitchell S. Nussbaum, Esq.