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

DIVISION OF
CORPORATION FINANCE

November 15, 2021

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.
Draft Registration Statement on Form S-1
Submitted October 15, 2021
CIK No. 0001878313

Dear Dr. Vitoc:

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 October 15, 2021

Prospectus Summary, page 6

1. We note your statement on page 6 that your lead product candidate is a "potential first-in-class telomere targeting agent" and several other references to "first-in-class" on pages 65, 71, 78, 80, and elsewhere in the prospectus. This term suggest that the product candidate is effective and likely to be approved by the FDA. Please delete these references throughout your registration statement. To the extent your use of this term was intended to convey your belief that the product is based on a novel technology or approach and/or is further along in the development process, you may discuss how your technology differs from technology used by competitors and, as applicable, that you are not aware of competing products that are further along in the development process. Statements such as

these should be accompanied by cautionary language that the statements are not intended to give any indication that the product candidate has been proven effective or that it will receive regulatory approval.

2. We note your statement that "The unique primary activity of THIO is based on two distinct Nobel Prize winning discoveries." Please revise to clarify that THIO was not the subject of Nobel Prizes and that the prizes relate to telomere discoveries. The statement currently implies that THIO was the subject of the Nobel Prizes.

Our Company, page 6

3. 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 86. Your Summary should present a factual and balanced presentation of your business. Please revise to provide a discussion of the challenges you face in implementing your business strategy, including, but not limited to, that earlier clinical trials of THIO were abandoned, as referenced on page 80, and that you may face early generic competition for THIO, as referenced on page 29. To the extent that you intend to rely on clinical data generated by third parties, revise to make this clear and provide the basis for your belief you will be able do so. Where you discuss earlier preclinical and clinical studies, revise to disclose who conducted such studies, when the studies were conducted and whether endpoints were met.

   Where you discuss your supply agreement with Regeneron, revise to make clear the nature of Regeneron's obligations and avoid characterizing this agreement as a co-development collaboration. As examples only, we note your reference on page 8 to "strategic collaborations…similar to and potentially more broadly than [your] existing agreement with Regeneron" and on page 88 to "using this technology in collaboration with Regeneron…."

Our Lead Product Candidate , page 6

4. We note your disclosure in the second paragraph of this section. Please revise to remove your conclusions here and throughout your registration statement that earlier data establishes efficacy or proof-of-concept. You may describe the data collected in preclinical and clinical studies and any observations that support continued development efforts but may not imply that the data establishes efficacy or proof-of-concept.

Our Development Pipeline, page 7

5. Given the lengthy timeline and uncertainty with regard to clinical development, it appears premature and inappropriate to present completion dates for your planned Phase 2 studies. 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. We will not object to a narrative discussion of your clinical development plans. Be sure to include separate columns for each phase of

development. Please make similar revisions to the chart on page 88. Additionally, please tell is why you believe your "2nd Generation Telomeres Targeting Agents" program is sufficiently material to warrant inclusion. In this regard, we note that you have not provided additional detail concerning your activities to date in the Business section.

6. The graphic provided on page 7 contains text that is illegible. Please revise this figure accordingly. In addition, several graphics on pages 83-85 contain abbreviations that are not defined. Please define abbreviations in all graphics here and elsewhere. Additionally, all graphics throughout the prospectus, including those on pages 83-85, should be accompanied by narrative disclosure that clearly explains the context for the graphic.

Implications of Being an Emerging Growth Company, page 8

7. Please 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. Please contact the staff member associated with the review of this filing to discuss how to submit such copies.

Summary of Risk Factors, page 12

8. Please add a bullet point highlighting the risk that the FDA may require the approval of a companion diagnostic in order for your to market THIO, as referenced on pages 25-26.

Risk Factors
We Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval
We may face future business disruption and related risks resulting from the recent outbreak..., page 17

9. Please revise to update your risk factor disclosure concerning the impact COVID-19 has had or is anticipated to have on your clinical development plans. In this regard, we note your disclosure on page 65 that you plan to enroll up to 164 patients in your Planned Phase 2 study in Australia. Similarly, please update your related disclosure on page 66.

Risks Relating to Our Initial Public Offering and Ownership of our Common Stock
Our amended and restated bylaws will designate the Court of Chancery, page 55

10. We note your disclosure that your amended and restated bylaws will designate the Court of Chancery of the State of Delaware as the exclusive forum for certain actions, including any "derivative" action. However, you also state that the federal district courts of the U.S. will be the sole and exclusive forum for the resolution of any action arising under the Securities Act, the Exchange Act or the rules and regulations thereunder. Further, you state on page 126 that your bylaws will not apply to any suits brought to enforce any duty or liability created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Please reconcile your disclosure for consistency and disclose in your Risk Factors whether the exclusive forum provision

applies to actions arising under the Securities Act or Exchange Act. In this regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and 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. If this provision does not apply to actions arising under the Securities Act or Exchange Act, please also ensure that the exclusive forum provision in the governing documents states this clearly.

Industry and Other Data, page 59

11. Your statement that you have not independently verified statistical, market and other industry data may imply an inappropriate disclaimer of responsibility with respect to this information. Please either delete this statement or specifically state that you are responsible for such information.

Use of Proceeds, page 60

12. Please revise your disclosure to include the estimated amount of proceeds you plan to allocate for each of the uses identified. In addition, provide an estimate of how far in the clinical development process for THIO the allocated proceeds of the offering will enable you to reach. Please also disclose the sources of other funds needed to reach regulatory approval and commercialization for THIO. Refer to Instruction 3 to Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Operating Expenses, page 66

13. We note in your discussion of General and administrative expenses, you cite factors such as increased compensation expense and payroll expense, but you do not discuss the underlying factors contributing to the increased expenses. Please revise to expand your disclosure to describe the underlying reasons in quantitative and qualitative terms that impacted your operating expenses.

Critical Accounting Policies and Significant Judgments and Estimates
Fair value of common stock and Stock-based compensation, page 69

14. 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 initial public offering 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.

15. Disclose the specific methodologies and the nature of assumptions used to determine the

fair value of your common stock for the periods presented. State that the estimates are highly subjective and once the company's initial public offering is effective these estimates will no longer be necessary since the fair value will be based on the trading value of the company's common stock.

Business, page 71

16. You make several assertions regarding the safety and efficacy of your product candidate. Safety and efficacy determinations are solely within the authority of the FDA or applicable foreign regulator. You may present clinical trial end points and objective data resulting from trials without concluding efficacy and you may state that your product candidate has been well tolerated, if accurate. Please revise or remove statements/inferences throughout your prospectus that your product candidate is safe and/or effective. As a non-exhaustive list of illustrative examples only, we note the following:

- On page 6, "When THIO was administered to mice at low doses... complete tumor regression with no recurrence was achieved, representing a curative or nearly curative effect."
- On page 65, "THIO...has demonstrated curative or near-curative effect in preclinical models of telomerase positive cancers when administered in advance..."
- On page 78, "THIO inhibited the cancer cell viability of colon and lung cancers while normal human cells were largely unaffected."
- On page 79, "In 2019, further non-clinical research in synergic and humanized mouse models of telomerase-expressing cancers uncovered previously unknown activity of THIO, specifically resulting from its efficient killing of cancer cells."
- On page 80, "As a result of these prior human studies, THIO has a well-established safety profile," "In addition to a well-established safety profile, THIO has shown a promising efficacy profile in prior clinical and human studies...", " We believe there is reduced safety risk (compared to higher doses used in early clinical studies) and increased chance of efficacy based on the previously shown clinical effects of THIO combined with the current insights from the recently identified evidence of its immune-activating effects. "
- In the graphic on page 81, "Newly discovered unprecedented immunogenic activity."
- On page 81, "although...results of unrelated clinical trials of different drugs cannot be relied upon as proof of comparative efficacy or safety, these results are promising."
- On page 82, "Extensive preclinical studies have been performed to validate THIO's primary mechanism of action: targeting telomeres directly, killing cancer cells via telomerase-mediated DNA damage."
- On page 82, "in vivo, THIO....followed by an immune checkpoint inhibitor ...resulted in cures in NSCLC and CRC syngeneic tumor models."
- On page 82 and 85, "we hypothesized that THIO...will effectively 'prime' the tumor environment and initiate an overall anti-tumor immune response," and "THIO alone has shown high anti-cancer activity."

- On page 83, "THIO appears to be highly effective in vitro at selectively killing cancer cells with active enzyme telomerase versus normal cells," and "THIO, as a single agent, showed in vitro activity in cancer cells "
- On page 86, "We believe there is reduced safety risk (compared to higher doses used in early clinical studies) and increased chance of efficacy based on the previously shown clinical effects of THIO combined with the current insights from the recently identified evidence of its immune-activating effects."

Our Strategy, page 72

17. We note your disclosure in this section that you intend to "rapidly advance...THIO, through clinical studies and toward accelerated approval". We also note your disclosure on page 7 that your focus is to leverage THIO's history to support "rapid" development. Please revise these statements to remove any implication that you will be successful in advancing your product candidates in a rapid or accelerated manner as such statements are speculative.

18. We note your intention to pursue an accelerated approval pathway. Please revise to include balancing disclosure that an accelerated approval pathway may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that your product candidate will receive marketing approval.

Current Landscape of Checkpoint Inhibitor Franchises, page 74

19. We note that you have included in the table on page 74 sales of checkpoint inhibitor franchises marketed by third parties. Please tell us why the information presented in the table is material to an understanding of your business. Alternatively, please remove this graphic.

Intellectual Property, page 74

20. We note your disclosure of your license agreements with UTSW, as well as your disclosure on page 65 of your provisional patent application. Please expand your discussion of your intellectual property to disclose the types of patents you hold (i.e., composition of matter, use or process), whether they are owned or licensed, patent expiration dates or expected expiration dates for your patent applications, the applicable jurisdictions where patents are granted or where patent applications are pending.

Our Team, page 75

21. Please revise to briefly discuss the roles and responsibilities of your “Special Advisory Board” and any related compensation arrangements.

Our Programs, page 77

22. Please expand your disclosure on pages 85-86 to provide a textual discussion of the clinical trials listed in your chart, including a material description of the studies, including

when they were conducted, the endpoints of the trials, whether or not the trials achieved those endpoints, whether or not the data from the trial was found to be statistically significant, including the P-value, and drug related serious adverse events and the number of patients who experienced them. Address in your revisions how ORR, PR and CR were measured.

23. We note use of p-values on page 80. At first use, please explain how "p-value" is used to measure statistical significance and the relevance of statistical significance to the FDA's evidentiary standards for drug approval.

Targeting Telomeres via Telomerase to Kill Cancer, page 77

24. Please provide narrative disclosure explaining the graphic on page 78. As currently presented, it is not clear what the graphic is intended to represent.

Differentiated Activity of THIO, a Telomere-Targeting Agent, page 78

25. Your graphic representation of your theoretical method of action on page 79 suggests that you are farther along in the development process. Please remove it.

THIO: A Potential First-in-Class Telomere Targeting Agent, page 80

26. We note your statement on page 81 that "To [y]our knowledge, THIO’s cancer-specific telomere targeting by using telomerase is different from all other available cancer therapies and those currently in clinical trials," as well as your use of "novel" and "unique" throughout the prospectus. Please expand your disclosure to provide the basis for these claims.

27. We note your comparison of THIO to approved drugs marketed by third parties. To the extent you did not conduct head-to-head comparisons in your trials, please remove this disclosure or tell us why you believe it is appropriate. Address in your response whether you expect to be able to rely on such comparisons for purposes of securing marketing approval for THIO.

Clinical Supply Agreement with Regeneron Pharmaceuticals, Inc. , page 88

28. To the extent not disclosed, please expand your disclosure to include the material terms of your agreement with Regeneron, including the parties' respective rights and obligations, financial terms, term and termination provisions.

Strategic Collaborations and Key Agreements, page 88

29. To the extent not disclosed, please expand your disclosure concerning your license agreements to include the material terms of such agreements, including:
- the technology or product candidates subject to the agreement;
- each parties' rights and obligations;

- quantify any upfront payments;
- quantify all payments made to date;
- disclose separately the aggregate amount of all potential development, regulatory and commercial milestone payments;
- disclose any milestones you are required to achieve;
- quantify the royalty rate or range not to exceed ten percentage points per tier;
- disclose when the royalty provisions expire, if the expiration is based on a number of years, disclose the number of years;
- the duration of the agreement; and
- termination provisions.

30. We note your statement that you expect strong partnership interest from other pharmaceutical companies who have developed checkpoint inhibitor franchises or those with cancer immunotherapy interest. Please revise to provide the basis for this claim or state such claims are management's belief.

Competition, page 90

31. Revise to identify specific competitors for your target indications. Refer to Item 101(h)(4)(iv) of Regulation S-K. Please also remove your statement that competition is expected "given the magnitude of anticipated clinical effect and revenue stream," as such disclosure suggests that your product candidate is likely to be approved.

Certain Relationships and Related Party Transactions, page 123

32. Please expand your disclosure to describe the consulting services provided by Mr. Klohs and Ms. Durant.

Financial Statements
THIO Asset Acquisition, page F-12

33. We also note that you acquired all outstanding stock of THIO through a share exchange agreement for 631,822 shares of your common stock with an estimated fair value of $1,137,342. Please tell us how you determined the fair value for this transaction, including your consideration of SAB Topic 5G.

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.