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

FORM 8-K

Current Report
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

April 11, 2023
Date of Report (Date of earliest event reported)

MAIA Biotechnology, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41455**	**83-1495913**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

444 West Lake Street, Suite 1700 Chicago, IL	**60606**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(312)** 416-8592

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	MAIA	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □

Item 7.01. Regulation FD Disclosure.

On April 11, 2023, MAIA Biotechnology, Inc. (the "Company") issued a press release announcing it has received positive topline data from the completed Part A safety lead-in of the Company's THIO-101 Phase 2 go-to-market trial in advanced Non-Small Cell Lung Cancer and has commenced recruitment in Part B randomized efficacy/dose selection. Pursuant to Regulation FD, the press release is furnished with this Current Report as Exhibit 99.1.

The information set forth in Item 7.01 of this Current Report on Form 8-K and in the attached Exhibit 99.1 is deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information set forth in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press release, dated as of April 11, 2023.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 11, 2023

MAIA BIOTECHNOLOGY, INC.

By: */s/ Vlad Vitoc*
Name: Vlad Vitoc
Title: Chief Executive Officer

Exhibit 99.1

MAIA Biotechnology Reports Positive Topline Data from Part A Safety Lead-In of THIO-101 Phase 2 Trial for Non-Small Cell Lung Cancer

CHICAGO – April 11, 2023 – MAIA Biotechnology, Inc. (NYSE American: MAIA) today announced positive topline data from the completed Part A safety lead-in of the Company's THIO-101 Phase 2 go-to-market trial in advanced Non-Small Cell Lung Cancer (NSCLC) and has commenced recruitment in Part B randomized efficacy/dose selection.

Topline data from Part A demonstrated that MAIA's telomere-targeting agent, THIO, administered in sequential combination with Regeneron's anti-PD-1 therapy, Libtayo® (cemiplimab), were generally well-tolerated. No dose-limiting toxicities (DLTs) or significant treatment-related adverse events were observed.

Part A was designed to assess the safety and tolerability of the highest dose of 360 mg/cycle in six patients. Mild toxicities, such as grade 1 fatigue, and muscle pain, were reported, as well as only one occurrence of grade 3 nausea, but no grade 4 adverse events, reported.

"Part A's safety profile is in sharp contrast with the typical safety profile of chemotherapy treatment where 70-80% of NSCLC patients experience grade 3 and 4 toxicities," said MAIA's Chief Medical Officer Mihail Obrocea, M.D. "The next dose levels of THIO in Part B are lower compared to Part A. Based on the initial safety profile seen at the highest dose in Part A, we are optimistic about the safety profile of THIO."

"We are pleased with the completion of the safety lead-in portion, which is a very important milestone and catalyst that marks the continued progression of our Phase 2 THIO-101 trial. Recruitment has commenced in the Part B efficacy/dose selection portion of our go-to-market trial, and we anticipate reporting preliminary efficacy data later this year," said MAIA's Chairman and Chief Executive Officer Vlad Vitoc, M.D.

Part B of the study will allow randomization of patients to three THIO dose levels, including 60 mg, 180 mg and 360 mg, followed by cemiplimab treatment every 3 weeks. Safety and tolerability will continue to be monitored across all THIO doses. The objective of Part B is to determine the most efficacious and safe dose, which will guide Part C of the trial.

THIO-101 is a multicenter, open-label, dose-finding Phase 2 clinical trial designed to evaluate THIO's potential direct anticancer and immune system activation effects in NSCLC patients by administering THIO in advance of Regeneron's anti-PD-1 therapy, Libtayo® (cemiplimab), thus allowing for immune system activation and sensitivity to the PD-1 inhibitor to take effect. The primary objectives of the trial are to evaluate the safety and tolerability of THIO administered as

a direct anti-cancer and priming immune system agent followed by cemiplimab administration, as well as preliminary clinical efficacy of THIO in patients with advanced NSCLC, who either progressed or relapsed through the initial treatments with an immune-check point inhibitor alone, or in combination with chemotherapy. The clinical trial is currently enrolling patients in Australia and the European Union. For more information on this Phase II trial, please visit ClinicalTrials.gov using the identifier NCT05208944.

About Toxicity Grading in Cancer Treatments
Toxicity is graded 0-5. Toxicity of grade 1 is mild, grade 2 is moderate, grade 3 is severe, grade 4 is life-threatening, and grade 5 is death.

About THIO
THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a telomere-targeting agent currently in clinical development to evaluate its activity in non-small cell lung cancer (NSCLC), in sequential administration with Regeneron's anti-PD-1 therapy, Libtayo® (cemiplimab). Telomeres play a fundamental role in the survival of cancer cells and their resistance to current therapies. THIO is being developed as a second or later line of treatment for NSCLC for patients that have progressed beyond the standard-of-care regimen of existing checkpoint inhibitors.

About MAIA Biotechnology, Inc.
MAIA is a targeted therapy, immuno-oncology company focused on the development and commercialization of potential first-in-class drugs with novel mechanisms of action that are intended to meaningfully improve and extend the lives of people with cancer. Its lead program is THIO, a potential first-in-class cancer telomere targeting agent in clinical development for the treatment of NSCLC patients with telomerase-positive cancer cells. For more information, please visit www.maiabiotech.com.

Forward Looking Statements
MAIA cautions that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels or activity, performance or achievements to be materially different from those anticipated by such statements. The use of words such as "may," "might," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward looking statements. However, the absence of these words does not mean that statements are not forward-looking. For example, all statements we make regarding (i) the initiation, timing, cost, progress and results of our preclinical and clinical studies and our research and development programs, (ii) our ability to advance product candidates into, and successfully complete, clinical studies, (iii) the timing or likelihood of regulatory filings and approvals, (iv) our ability to develop, manufacture and commercialize our product candidates and to improve the manufacturing process, (v) the rate and degree of market acceptance of our product candidates, (vi) the size and

growth potential of the markets for our product candidates and our ability to serve those markets, and (vii) our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates, are forward looking. All forward-looking statements are based on current estimates, assumptions and expectations by our management that, although we believe to be reasonable, are inherently uncertain. Any forward-looking statement expressing an expectation or belief as to future events is expressed in good faith and believed to be reasonable at the time such forward-looking statement is made. However, these statements are not guarantees of future events and are subject to risks and uncertainties and other factors beyond our control that may cause actual results to differ materially from those expressed in any forward-looking statement. Any forward-looking statement speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. In this release, unless the context requires otherwise, "MAIA," "Company," "we," "our," and "us" refers to MAIA Biotechnology, Inc. and its subsidiaries.

Investor Inquiries

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