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

Date of Report (Date of earliest event reported): January 17, 2024

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 with Zip Code)

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

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 8.01 Other Events.

On January 17, 2024, MAIA Biotechnology, Inc. (the "Company") issued a press release announcing new interim data for THIO-101, a Phase 2 clinical trial evaluating THIO in patients with non-small cell lung cancer, and outlining key clinical milestones achieved for 2024.

In the latest available data from THIO-101 as of November 13, 2023, 60 patients had been dosed with THIO in sequential combination with Libtayo®. The patients received either 60mg, 180mg, or 360mg of THIO per dose, and 42 had at least one post baseline assessment completed. The Company's key findings from THIO-101 included an observed 100% preliminary disease control rate ("DCR") in second-line and 88% in third-line, in highly difficult-to-treat patients who already progressed through previous lines of treatment. Additionally, the Company determined that DCR across all dose levels met pre-determined statistical requirements earlier than expected to proceed to next stage of the trial.

The Company's key clinical milestones for 2024 include its second-generation telomere-targeting program focused on the research and development of new prodrugs derived from lipid-modified THIO molecules, which compounds the Company believes are capable of acting through similar mechanisms of activity as THIO with higher potency at lower dose levels.

A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Forward-looking Statements

The Company cautions that all statements, other than statements of historical facts, contained in this Current Report on Form 8-K, or furnished herewith, 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. 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, including, but not limited to: (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. Any forward-looking statement speaks only as of the date on which it was made. The Company undertakes 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press release, dated January 17, 2024
104	Cover Page Interactive Data File (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: January 18, 2024

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Biotechnology Provides Positive Phase 2 Clinical Updates for Lead Anticancer Agent and Outlines Targeted Milestones for 2024

- Lead candidate THIO maintains unprecedented disease control rates in Phase 2 non-small cell lung cancer (NSCLC) clinical trial
- Multiple clinical milestones ahead for THIO-101 Phase 2 trial
- Company enters 2024 with robust clinical pipeline in multiple hard-to-treat cancer indications

CHICAGO, IL – January 17, 2024 - MAIA Biotechnology, Inc., (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, announced new interim data for its ongoing THIO-101 Phase 2 trial in non-small cell lung cancer (NSCLC) and outlined key clinical milestones for 2024.

In the latest available data from THIO-101 (November 13, 2023), 60 patients had been dosed with THIO in sequential combination with Libtayo®. The patients received either 60mg, 180mg, or 360mg of THIO per dose, and 42 had at least one post baseline assessment completed. The observed disease control was well sustained compared to previous scans.

"We are entering 2024 with strong momentum and great excitement about our programs and pipeline," said Vlad Vitoc, M.D., MAIA's Chairman and Chief Executive Officer. "To date, preliminary Phase 2 data on THIO in NSCLC has demonstrated unprecedented rates of disease control and response - measures that vastly outperform the standard of care."

"In addition to NSCLC, our pipeline of immuno-oncology therapies includes THIO orphan drug designations for multiple hard-to-treat cancers, and our research includes THIO-like second-generation telomere-targeting agents. The main objective for the second-generation program is to discover new compounds with potentially improved specificity towards cancer cells relative to normal cells and with potentially increased anticancer activity," Dr. Vitoc continued.

"Multiple milestones are on target for 2024 as enrollment continues in THIO-101, including long-term efficacy as a major clinical inflection point."

Key 2023 Achievements

Positive Preliminary Efficacy Data: Key findings from THIO-101 included:

- 100% preliminary disease control rate (DCR) in second-line and 88% in third-line, in highly difficult-to-treat patients who already progressed through previous lines of treatment.
- DCR across all dose levels met pre-determined statistical requirements earlier than expected to proceed to next stage of the trial.

Third orphan drug designation (ODD) granted to THIO: MAIA's portfolio of immuno-oncology therapies with ODDs now includes a third hard-to-treat cancer, glioblastoma, the most aggressive and most common type of brain cancer with only limited treatment options.

U.S. FDA Investigational New Drug (IND) Clearance: The FDA cleared U.S.-based evaluation for THIO as part of THIO-101. The trial drew a strong pace of enrollment in 2023 compared with previous NSCLC trials by other drug developers.

Dose Selection: A 180mg/cycle dose of THIO was selected for THIO-101 based on stronger efficacy compared to other doses. The selected dose showed unprecedented disease control and overall response rates for a NSCLC clinical trial.

Next Generation Telomere Targeting Agents: MAIA's second-generation telomere-targeting program is engaged in research and development for new prodrugs derived from lipid-modified THIO molecules. Capable of acting through similar mechanisms of activity as THIO, the higher potency of these compounds at lower dose levels will be investigated further in 2024.

THIO is the only direct telomere targeting agent currently undergoing clinical development in the field of cancer drug discovery and treatment.

About THIO

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a first-in-class investigational telomere-targeting agent currently in clinical development to evaluate its activity in Non-Small Cell Lung Cancer (NSCLC). Telomeres, along with the enzyme telomerase, play a fundamental role in the survival of cancer cells and their resistance to current therapies. The modified nucleotide 6-thio-2'-deoxyguanosine (THIO) induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. THIO-damaged telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment with THIO followed by PD-(L)1 inhibitors resulted in profound and persistent tumor regression in advanced, in vivo cancer models by induction of cancer type–specific immune memory. THIO is presently 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 THIO-101, a Phase 2 Clinical Trial

THIO-101 is a multicenter, open-label, dose finding Phase 2 clinical trial. It is the first trial designed to evaluate THIO's anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of THIO administered prior to cemiplimab (Libtayo®) will enhance and prolong immune response in patients with advanced NSCLC who previously did not respond or developed resistance and progressed after first-line treatment regimen containing another checkpoint inhibitor. The trial design has two primary objectives: (1) to evaluate the safety and tolerability of THIO administered as an anticancer compound and a priming immune activator (2) to assess the clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. Treatment with cemiplimab (Libtayo®) followed by THIO has been generally well-tolerated to date in a heavily pre-treated population. For more information on this Phase II trial, please visit ClinicalTrials.gov using the identifier NCT05208944.

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. Our 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.

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