# 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): October 24, 2023**

# 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 October 24, 2023, MAIA Biotechnology, Inc. (the "Company") issued a press release announcing that it reported positive preliminary efficacy data from its ongoing Phase 2 clinical human trial, THIO-101, which evaluates THIO (our drug candidate that provides for an investigational dual mechanism of action that incorporates telomere targeting and immunogenicity) in patients with advanced Non-Small Cell Lung Cancer ("NSCLC") in sequential combination with Regeneron's anti-PD-1 cemiplimab (Libtayo®), which is administered a few days after patients with advanced NSCLC are treated with THIO. The Company intends to continue providing updates on our THIO-101 clinical trial as they become available.

On October 30, 2023, the Company issued a press release announcing that an investigational new drug-enabling study of the Company's second-generation telomere-targeting agents derived from lipid-modified THIO molecules generated positive results. The Company intends to continue to further study THIO conjugates as second generation cancer therapies. THIO's telomere-centric action is currently being evaluated in Phase 2 of the THIO-101 clinical human trial, as described above.

A copy of the press release, dated October 24, 2023, and the press release, dated October 30, 2023, are filed herewith as Exhibits 99.1 and 99.2, respectively, and are 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 October 24, 2023 |
| 99.2 | Press Release, dated October 30, 2023. |
| 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: October 30, 2023

**MAIA BIOTECHNOLOGY, INC.**

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

**Exhibit 99.1**

**MAIA Biotechnology Announces 100% Disease Control in Second-Line Non-Small Cell Lung Cancer Demonstrating Impressive Positive Preliminary Efficacy Data for Ongoing THIO-101 Phase 2 Trial**

- Unprecedented disease control rate (DCR) of 100% in second-line of treatment far surpasses standard of care (SoC) DCR of 53-64%
- DCR is far stronger than overall response rate (ORR) in predicting overall survival benefit, as shown in recent meta-analysis of 74 clinical trials worldwide[1]

CHICAGO, IL – October 24, 2023 – MAIA Biotechnology, Inc. (NYSE American: MAIA), a clinical stage company developing telomere-targeting immunotherapies for cancer, today reported positive preliminary efficacy data from its ongoing Phase 2 clinical trial, THIO-101, evaluating THIO in patients with advanced Non-Small Cell Lung Cancer (NSCLC) in sequential combination with Regeneron's anti-PD-1 cemiplimab (Libtayo®).

Key findings:

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

"In NSCLC patients who received at least one line of therapy, DCRs have shown to be excellent predictors of overall survival.[1] Observing 100% DCR to date in second-line treatment is unprecedented compared to DCRs for the SoC ranging from 53-64%,[2]" said Vlad Vitoc, M.D., MAIA's Chief Executive Officer. "We have also observed unprecedented high DCRs in third-line, with an 88% control rate, with treatment of THIO followed by cemiplimab. The results are even more remarkable given patients in this population have previously failed treatment with a checkpoint inhibitor. Currently, there is no SoC for third-line, but previous studies have reported an approximate 30% DCR.[3] These exceptional preliminary results underscore our confidence in advancing the trial to bring our novel treatment to advanced stage NSCLC patients."

**Study Disease Control Rates by Line of Treatment**

| Treatment Line | Standard of Care Treatment | DCR | Treatment Line | THIO + Libtayo® (cemiplimab) DCR |
|---|---|---|---|---|
| NSCLC-1 | pembrolizumab (KEYNOTE-024) | 71% | NSCLC-1 | TBD |
| NSCLC-2 | ramucirumab + docetaxel (REVEL)<br>docetaxel monotherapy (REVEL) | 64%<br>53% | NSCLC-2 | 100% |
| NSCLC-3 | chemotherapy (RWD) | 25-35% | NSCLC-3 | 88% |

The Company presented the data at the European Society for Medical Oncology (ESMO) Congress 2023 in Madrid, Spain, on October 23, 2023. Full preliminary data is detailed in the poster available here.

**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

1 Matsumoto H et al. Transl Lung Cancer Res. 2021 May; 10(5): 2278–2289
2 REVEL https://www.cyramza.com/hcp/nsclc-treatment/revel-response-rate-efficacy
3 Journal of Thoracic Oncology (VOLUME 16, ISSUE 10, OCTOBER 2021), T. Beninato et al.

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, 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 Regeneron's anti-PD-1 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 a 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 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**

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**MAIA Biotechnology Reveals Higher Anticancer Potency of Telomere-Targeting Compounds Derived from THIO**

***Study results warrant further in vivo in-depth investigation of THIO conjugates as second generation cancer therapies.***

CHICAGO, IL – October 30, 2023 – MAIA Biotechnology, Inc. (NYSE American: MAIA), a clinical stage company developing telomere-targeting immunotherapies for cancer, today announced positive results from an investigational new drug-enabling study of the Company's second-generation telomere-targeting agents derived from lipid-modified THIO molecules. MAIA's second-generation telomere-targeting molecule program seeks to discover new compounds with improved specificity towards cancer cells relative to normal cells, potentially increased anticancer activity, and stronger chemistry manufacturing control characteristics.

"In this study we demonstrated broad-spectrum therapeutically-attractive opportunities for specific telomeric stress-inducing treatments. The results demonstrate an increase in innate sensing and adaptive antitumor immunity via the self-produced chemical modification of cancer cell telomeres by THIO," said MAIA's Chief Scientific Officer Sergei Gryaznov, Ph.D.

The new THIO prodrugs are lipid conjugated compounds derived from THIO. The prodrugs are pharmacologically inactive compounds that, after intake, are metabolized into a pharmacologically active drug. In vitro, these compounds were able to induce telomeric DNA damage responses that were similar or more profound than those for THIO, as assessed by quantitative Telomere Damage Induced Foci assays (TIF formation). Efficient formation of micronuclei structures was also observed. Initial in vivo evaluation of the anticancer activity, conducted in human xenografts and murine syngeneic models of colorectal cancer, demonstrated potent anticancer activity at relatively low dose levels for one of the lead lipid conjugates.

"Our findings from this study demonstrate the significance of telomeric DNA structural and functional integrity for cancer cell survival. The high potency of these THIO-like agents warrants further in vivo in-depth investigation as a potential next generation of telomerase-mediated telomere-targeting compounds," said Vlad Vitoc, M.D., MAIA's Chief Executive Officer.

The findings were presented by Dr. Gryaznov at the International Biochemistry Congress 2023, organized by the Turkish Biochemical Society and held in Turkey. The findings are detailed in the abstract available in the event website under Speakers, Sergei M. Gryaznov and Lecture Abstract sections.

The telomere-centric action of MAIA's lead candidate THIO is being evaluated in Phase 2 clinical trials (THIO-101) in non-small-cell lung carcinoma (NSCLC) patients.

**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.

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