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): March 6, 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)	**(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 March 6, 2024, MAIA Biotechnology, Inc. (the "Company") issued a press release announcing positive efficacy data in its Phase 2 THIO-101 clinical trial.

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

On March 6, 2024, the Company issued a press release announcing that the Company and Nationwide Children's Hospital will be presenting at the American Association for Cancer Research Annual Meeting taking place April 5–10, 2024 in San Diego, California.

A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

On March 7, 2024, the Company issued a press release announcing that the Company will be participating in the 36th Annual ROTH Conference taking place March 17-19, 2024 in Dana Point, California.

A copy of the press release is attached hereto as Exhibit 99.3 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 March 6, 2024
99.2	Press Release dated March 6, 2024
99.3	Press Release dated March 7, 2024
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: March 8, 2024

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Biotechnology Announces Strong Efficacy of THIO as Third-Line Treatment for Non-Small Cell Lung Cancer Patients

- Combination THIO 180mg + cemiplimab achieved 38% overall response rate (ORR) in difficult-to-treat, third-line non-small cell lung cancer (NSCLC)
- ORR of 38% significantly exceeds standard of care ORR in NSCLC third-line in patients without a targetable mutation who progressed on checkpoint inhibitors and chemotherapy

CHICAGO, IL – March 6, 2024 - MAIA Biotechnology, Inc., (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced positive efficacy data for third-line treatment in its Phase 2 THIO-101 clinical trial evaluating THIO sequenced with the immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in advanced non-small cell lung cancer (NSCLC).

As of January 8, 2024, overall response rate (ORR), characterized as partial or complete response to therapy, was 38% (3 out of 8 patients) in the efficacy evaluable population for combination THIO 180mg + cemiplimab in third-line treatment for NSCLC patients who failed treatment with immune checkpoint inhibitors in prior lines of therapy, with or without chemotherapy.

"As an impressive measure of efficacy, the strong response rate of 38% in third-line treatment supports our premise that THIO administration prior to cemiplimab can improve tumor responses to immunotherapy in advanced NSCLC patients resistant to CPIs and other standard treatments," said Vlad Vitoc, M.D., MAIA's Chairman and Chief Executive Officer. "Around 60-70% of NSCLC patients do not have a targetable mutation and cannot benefit from a biomarker-targeted therapy, making it the greatest unmet medical need population in lung cancer. In currently available treatments for these patients in third-line, response rates range around 6%.[1] We are encouraged by the excellent efficacy findings in THIO-101 to date, adding impressive ORR to unprecented disease control rates (DCR), and further demonstrating the potential of our first-in-class treatment to redefine the standard of care for NSCLC patients."

[1] Journal of Thoracic Oncology, Volume 4, Number 12, December 2009. *Note: no updated 3rd line NSCLC data in recent years.

The efficacy evaluable population defined in the THIO-101 protocol considers all subjects who received at least one dose of THIO treatment and have at least one postbaseline tumor assessment (scans). Two third-line patients in the 180mg dose cohort did not have recorded scans at the data cutoff. Safety remained consistent with previous reports.

The Company recently announced early completion of enrollment in the THIO-101 trial. THIO-101 is expected to be the first completed clinical study of a telomere-targeting agent 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

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Exhibit 99.2

MAIA Biotechnology and Nationwide Children's Hospital Announce Presentation of THIO's Potency in Pediatric Brain Tumors at American Association of Cancer Research Annual Meeting

- THIO and ionizing radiation combination shown to significantly decrease cell proliferation and produce potent anticancer effects in highly aggressive, treatment-resistant childhood brain cancer

CHICAGO, IL – March 06, 2024 - MAIA Biotechnology, Inc., (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced that Dr. Rachid Drissi, Principal Investigator at the Center for Childhood Cancer Research, Nationwide Children's Hospital, and Associate Professor at Ohio State University, will present an abstract detailing the potency of THIO, MAIA's telomere-targeting agent, as treatment for pediatric brain cancers at the American Association for Cancer Research (AACR) Annual Meeting taking place April 5–10, 2024 in San Diego, California.

The research was conducted in collaboration with Nationwide Children's Hospital and led by Dr. Drissi. The study explored the combination of THIO and ionizing radiation (IR) treatments to induce direct anticancer effects and stimulate anti-tumor immunity in diffuse intrinsic pontine glioma (DIPG).

DIPG, a very difficult-to-treat and high-risk childhood cancer, is a central nervous system (CNS) tumor that forms in the brainstem. Scientists from Nationwide Children's Hospital and MAIA have shown that THIO synergistically sensitizes DIPG cells to ionizing radiation (IR), significantly decreasing cell proliferation.

"At the AACR Annual Meeting, we will present study results demonstrating the potential for THIO and IR combinational treatments to stimulate anti-tumor immunity through activation of the STING pathway, one of the key regulators of immune responses in a DIPG model," said Sergei M. Gryaznov, PhD., MAIA's Chief Scientific Officer. "Unfortunately, prognosis for DIPG is dismal with a survival rate of less than one year, and radiotherapy, the only standard of care for DIPG, extends survival by only a few months. Immunotherapy is emerging as a potential alternative. Novel therapies that activate the immune system while evading tumor immunosuppression are in high demand in the field of cancer research."

"MAIA is excited to see that the results of our scientific collaborative work with the Nationwide Children's Hospital were accepted for presentation at the AACR Annual Meeting, a gathering of many of the best minds in cancer research from institutions all over the world," added Vlad Vitoc, M.D., CEO of MAIA.

MAIA's presentation at the 2024 AACR Annual Meeting

Abstract #:
5108

Abstract title:
Immunomodulatory and Antitumor Effect of Radiation and Induced Telomere Damage to Treat Pediatric High-grade Gliomas

Authors:
- Banlanjo Umaru, Shiva Senthil Kumar (Center for Childhood Cancer Research, Nationwide Children's Hospital, Columbus, OH)
- Sergei M. Gryaznov (MAIA Biotechnology, Inc., Chicago, IL)
- Rachid Drissi (Center for Childhood Cancer Research, Nationwide Children's Hospital, Columbus, OH; The Ohio State University College of Medicine, Columbus, OH)

Presenter:
Rachid Drissi

Session date and time:
Tuesday April 09, 2024, 09:00AM – 12:30PM (Section 43)

About THIO

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About Nationwide Children's Hospital

Named to the Top 10 Honor Roll on U.S. News & World Report's 2023-24 list of "Best Children's Hospitals," Nationwide Children's Hospital is one of America's largest not-for-profit free-standing pediatric health care systems providing unique expertise in pediatric population health, behavioral health, genomics and health equity as the next frontiers in pediatric medicine, leading to best outcomes for the health of the whole child. Integrated clinical and research programs, as well as prioritizing quality and safety, are part of what allows Nationwide Children's to advance its unique model of care. NationwideChildrens.org

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Exhibit 99.3

MAIA Biotechnology to Participate in the 36th Annual ROTH Conference

CHICAGO, IL – March 07, 2024 - MAIA Biotechnology, Inc., (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced its participation in the 36th Annual ROTH Conference being held March 17-19, 2024 in Dana Point, California. Chief Executive Offer Vlad Vitoc, M.D. will host one-on-one meetings with institutional investors and analysts on Monday, March 18th and Tuesday, March 19th.

Conference Details:

Location:	The Ritz Carlton, Laguna Niguel in Dana Point, California.
Registration:	Available on the conference website.
1x1 meetings:	Investors may request a meeting by contacting a ROTH representative at 800.678.9147 or by contacting MAIA investor Relations.

MAIA's lead candidate is THIO, a small molecule telomere-targeting anticancer agent that acts by producing direct telomeric DNA damage and inducing cancer-specific immune responses. THIO's efficacy in non-small cell lung cancer (NSCLC) is being evaluated in THIO-101, a Phase 2 go-to-market clinical trial nearing completion, which is expected to be the first completed clinical study of a telomere-targeting agent in the field of cancer drug discovery and treatment. MAIA plans to pursue the FDA's accelerated approval program for THIO.

Recent news from MAIA's THIO-101 trial includes:

- Early completion of enrollment; trial nears completion with topline data expected in second half of 2024; (press release, February 22, 2024)
- Strong response rate of 38% in third-line treatment efficacy data; (press release, March 6, 2024).
- Multiple paths to potential commercial approval of THIO under consideration; MAIA anticipates a final FDA decision on THIO in 2026; (MAIA Shareholder Letter 2024).

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