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): June 5, 2025

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** **(Address of principal executive offices)**	**60606** **(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 June 5, 2025, MAIA Biotechnology, Inc. (the "Company") issued a press release entitled "MAIA Biotechnology Announces Positive Efficacy Update for Phase 2 THIO-101 Clinical Trial in Non-Small Cell Lung Cancer." A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On June 5, 2025, MAIA Biotechnology, Inc. (the "Company") issued a press release entitled "MAIA Biotechnology Announces New Responder in Non-Small Cell Lung Cancer Phase 2 Clinical Trial." A copy of the press release is attached hereto as Exhibit 99.2 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 June 5, 2025 entitled "MAIA Biotechnology Announces Positive Efficacy Update for Phase 2 THIO-101 Clinical Trial in Non-Small Cell Lung Cancer"
99.2	Press Release dated June 5, 2025 entitled "MAIA Biotechnology Announces New Responder in Non-Small Cell Lung Cancer Phase 2 Clinical Trial."
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: June 5, 2025

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Biotechnology Announces Positive Efficacy Update for Phase 2 THIO-101 Clinical Trial in Non-Small Cell Lung Cancer

Median overall survival (OS) from ateganosine (THIO) treatment extends to 17.8 months in latest data

CHICAGO – June 5, 2025 – *MAIA Biotechnology, Inc.* (NYSE American: **MAIA**) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today announced updated data from its THIO-101 pivotal Phase 2 clinical trial evaluating its lead clinical candidate, ateganosine (THIO), sequenced with Regeneron's immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced non-small cell lung cancer (NSCLC) who are resistant to immune therapy and chemotherapy.

As of May 15, 2025, third line (3L) data showed median overall survival (OS) of 17.8 months for the 22 NSCLC patients who received at least one dose of ateganosine (the intent-to-treat population) in parts A and B of the trial. The updated analysis continues to demonstrate a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months. The treatment has been generally well-tolerated to date in this heavily pre-treated population.[1] Studies of standard-of-care (SOC) chemotherapy treatments for NSCLC in a similar setting have shown OS of 5 to 6 months.[2-3]

"It is gratifying to see that our treatment further extend lives for these hard-to-treat patient population, especially in third-line NSCLC treatment where patients are most resistant to therapy," said MAIA Chairman and CEO Vlad Vitoc, M.D. "This new benchmark of 17.8 months median OS is nearly triple the recognized SOC data for third-line NSCLC found in medical literature. We believe this is a substantial indicator of the potential ateganosine has to shift the NSCLC treatment landscape."

MAIA's multiple potential regulatory pathways for ateganosine could provide accelerated FDA approval and robust exclusivity in NSCLC, with a potential FDA decision as early as next year.

About Ateganosine

Ateganosine (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 induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. Ateganosine-damaged telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment of ateganosine 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. Ateganosine 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.

[1] Details on safety can be found on the previously announced ASCO 2025 poster available on MAIA's website.

[2] Girard N, et al. J Thorac Onc 2009;12:1544-1549.

[3] A.T. Freeman et al. Curr Oncol. 2020 May 1;27(2):76–82

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 ateganosine (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 Relations Contact

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ir@maiabiotech.com

Exhibit 99.2

MAIA Biotechnology Announces New Responder in Non-Small Cell Lung Cancer Phase 2 Clinical Trial

CHICAGO – June 5, 2025 – MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today announced a new partial response (PR) was identified in a patient after 20 months of treatment in its Phase 2 THIO-101 clinical trial evaluating ateganosine (THIO), sequenced with Regeneron's immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced non-small cell lung cancer (NSCLC) who are resistant to immune therapy and chemotherapy. A partial response is defined as a decrease in tumor size of at least 30%.

"The patient remained on treatment and we observed stable disease for more than twenty months before the partial response was identified, highlighting the efficacy, safety and low toxicity of the treatment. Extended-term responses like this are not often seen in heavily pretreated patients in hard-to-treat diseases such as NSCLC, where the prognosis for the advanced-stage of the disease is typically poor," said MAIA Chairman and CEO Vlad Vitoc, M.D. "We confirmed this response with a second scan, and we are highly confident that ateganosine could become an outstanding therapeutic alternative for third-line NSCLC patients."

THIO-101 third line (3L) data cutoff from May 15, 2025, showed median overall survival (OS) of 17.8 months for the 22 NSCLC patients who received at least one dose of ateganosine in parts A and B of the trial. At the data cutoff, the patient with the longest survival in the trial had completed 32 cycles of therapy and had 24.3 months survival. Studies of standard-of-care (SOC) chemotherapy treatments for NSCLC in a similar setting have shown OS of 5 to 6 months.[1]

MAIA has announced the trial design for an expansion of its THIO-101 pivotal Phase 2 trial in NSCLC to assess overall response rates (ORR) in advanced NSCLC patients receiving third line (3L) therapy who were resistant to previous CPI treatment and chemotherapy.

About Ateganosine

Ateganosine (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 induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. Ateganosine-damaged telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment of ateganosine 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. Ateganosine 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.

[1] Girard N, et al. J Thorac Onc 2009;12:1544-1549.

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