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): April 16, 2026

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 April 16, 2026, MAIA Biotechnology, Inc. (the "Company") issued a press release entitled "MAIA Biotechnology Activates First U.S. Site for Ongoing International Phase 2 Expansion Trial of Novel Telomere Targeting Treatment Targeting Advanced Non-Small Cell Lung Cancer" A copy of the press release is attached hereto 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, (vii) our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and (ix) the ability to source a larger talent pool for our clinical trials due to our current and expected U.S. expansion for testing sites. 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 April 16, 2026
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: April 16, 2026

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Biotechnology Activates First U.S. Site for Ongoing International Phase 2 Expansion Trial of Novel Telomere Targeting Treatment Targeting Advanced Non-Small Cell Lung Cancer

Exceptional measures of efficacy observed in THIO-101 Phase 2 trial to date include disease control, response rates, and survival data well above standard of care benchmarks

50,000 advanced NSCLC diagnoses in the U.S. annually

CHICAGO – April 16, 2026 – MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today announced that it has activated the first U.S. clinical site in its Phase 2 THIO-101 expansion trial of its lead investigational therapy as a third-line (3L) treatment for non-small cell lung cancer (NSCLC).

"We are thrilled to activate the expansion of our Phase 2 THIO-101 trial in the U.S., bringing our novel treatment to our country's broad underserved NSCLC patient population. Every year, we estimate approximately 50,000 patients resistant to chemo and CPIs alone advance to third-line NSCLC in the U.S. The medical need is extensive," said Vlad Vitoc, M.D., Founder and Chief Executive Officer of MAIA.

The trial's expansion into the U.S. marks a key milestone for MAIA, which is expected to open a significantly larger patient pool for evaluation of ateganosine, a novel dual mechanism of action drug candidate incorporating telomere targeting and immunogenicity. In addition to the first location, Summit Medical Group in New Jersey, MAIA intends to open four additional sites in U.S. in 2026. The trial is ongoing in Europe and Asia with 44 active sites in 6 countries.

MAIA's THIO-101 expansion study evaluates ateganosine in heavily pre-treated patients in 3L NSCLC who have previously failed treatment with checkpoint inhibitors (CPIs) and chemotherapy. Two treatment arms are being studied: ateganosine sequenced with cemiplimab (Libtayo®) and ateganosine monotherapy. Third-line treatment evaluation in the U.S. is funded by a prestigious $2.3 million grant from the National Institutes of Health (NIH).

"The activation of Summit Medical Group as our first U.S. clinical site is a landmark moment for the THIO-101 study. This is expected to further advance ateganosine as a potential best-in-class therapy for third-line NSCLC," said Matthew Failor, MAIA's Director of Clinical Operations. "Partnering with a premier institution like Summit should allow us to bring this highly innovative telomere-targeting approach to U.S. patients who have limited options."

"We are proud to be the first U.S. site to offer patients access to MAIA's innovative THIO-101 expansion trial and contribute to advancing a promising new treatment strategy in lung cancer," added Charles J. Kim, M.D., Summit Health oncologist and principal investigator for the THIO-101 trial in New Jersey.

MAIA holds FDA Fast Track designation for its lead drug targeting advanced NSCLC. The Fast Track process is designed to facilitate development and expedite the review of drugs for serious conditions with no treatment options or limited low-efficacy therapies. If relevant criteria are met during the Fast Track process, a drug is eligible for FDA Accelerated Approval and Priority Review (FDA decision within six months).

In 2025, THIO-101 delivered exceptional efficacy data for MAIA's lead investigational drug sequenced with a checkpoint inhibitor including disease control, response rates, and survival data well above standard of care benchmarks. MAIA recently reported overall survival (OS) beyond two years for eight patients treated with ateganosine sequenced with cemiplimab in Parts A and B of the trial. The eight patients include one with survival of 33 months and four with survival over 30 months. The measures of 3L OS beyond 24 months exceed all known benchmarks for advanced NSCLC treatment. The THIO-101 treatment regimen has shown an acceptable safety profile to date in a heavily pre-treated population.

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.

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 ateganosine's anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of ateganosine 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 ateganosine administered as an anticancer compound and a priming immune activator (2) to assess the clinical efficacy of ateganosine using Overall Response Rate (ORR) as the primary clinical endpoint. The expansion of the study will assess overall response rates (ORR) in advanced NSCLC patients receiving third line (3L) therapy who were resistant to previous checkpoint inhibitor treatments (CPI) and chemotherapy. Treatment with ateganosine followed by cemiplimab (Libtayo®) has shown an acceptable safety profile 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 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

+1 (872) 270-3518
ir@maiabiotech.com