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): February 24, 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 February 24, 2026, MAIA Biotechnology, Inc. (the "Company") issued a 2026 Letter to Shareholders detailing the Company's development pipeline.

A copy of the 2026 Letter to Shareholders is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On February 24, 2026, the Company issued a press release entitled "MAIA Biotechnology's Phase 3 Momentum Demonstrates Potential Breakthrough Anticancer Opportunity in $50 Billion Immunotherapy Market" which press release also announces the release of the 2026 Letter to Shareholders detailing the Company's development pipeline

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 (including all exhibits), 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	2026 Letter to Shareholders
99.2	Press Release dated February 24, 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: February 24, 2026

MAIA BIOTECHNOLOGY, INC.

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

MAIA BIOTECHNOLOGY

Letter to Shareholders 2026
NYSE American: MAIA

Key Takeaways

Strong momentum in clinical trials of lead molecule, ateganosine, as a treatment for non-small cell lung cancer (NSCLC)

- *Phase 3 THIO-104 full approval trial underway with high probability of technical success on both interim and full analysis*
- *Phase 2 THIO-101 expansion (Part C) nearing completion with potential for accelerated approval*
- *Unprecedented interim measures of efficacy*
- *FDA Fast Track designation as a third-line therapy for NSCLC*

Ateganosine is the only direct telomere-targeting anticancer agent in clinical development anywhere

- *Potential breakthrough therapy with substantial commercial opportunity in a ~$50 billion global immunotherapy market*

MAIA Biotechnology, Inc. • 444 West Lake Street, Suite 1700, Chicago, IL 60606 • maiabiotech.com

MAIA Letter to Shareholders

February 2026

Dear fellow shareholders,

MAIA's lead commercial candidate, ateganosine (THIO), is expected to continue its exceptional outcomes in the clinic as it proceeds through ongoing Phase 3 and Phase 2 trials as a treatment for advanced non-small cell lung cancer (NSCLC). Measures of efficacy to date are unprecedented in third-line (3L) treatment in patients resistant to immune and chemotherapy. The most recent interim data for our Phase 2 THIO-101 trial, evaluating ateganosine sequenced with the immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in 3L therapy, shows:

- **88% disease control rate (DCR):** ~3x chemotherapy treatment, the standard of care (SOC) for NSCLC, at a 25–35% DCR
- **38% overall response (ORR):** 4 – 6x SOC of 6–10%
- **17.8 months median overall survival (OS):** 3x SOC of 5.8 months

As an all-new science for cancer therapy with a dual mechanism of action (MoA)—telomere targeting and immunogenicity—*ateganosine is the only direct telomere-targeting anticancer agent in clinical development that we are aware of.*

Ateganosine could mark the start of a new therapeutic category in cancer treatment and could become the standard of care for multiple cancer indications. The commercial opportunity for ateganosine is immense.

Strategic Third-Line Treatment Focus

The market size for checkpoint inhibitors is estimated at $50 billion in global sales in 2025 and is expected to reach over $107 billion by 2030, growing at a compound annual growth rate of 16.5% during the forecast period.[1]

CPIs and chemotherapy are the standard of care in first- and second-line treatment for NSCLC patients without actionable mutations. Patients who do not respond to these therapies become eligible for third-line treatment. No established standard of care exists in 3L treatment, with most oncologists currently treating 3L patients with chemotherapy, leading to particularly poor clinical outcomes.

Our development strategy intentionally targets this third-line NSCLC population, where the unmet need is urgent. In clinical studies, ateganosine sequenced with a CPI has demonstrated outcomes that exceed those historically achieved with either CPI-based therapy or chemotherapy alone. These findings position ateganosine not as a competitor to CPIs, but as the foundation of a new treatment category designed specifically for advanced NSCLC following CPI and chemotherapy failure.

By focusing on a third-line population with no defined standard of care, we are seeking to address an underserved group of approximately 50,000 patients annually in the United States and creating a differentiated, incremental revenue opportunity outside of the CPI market.

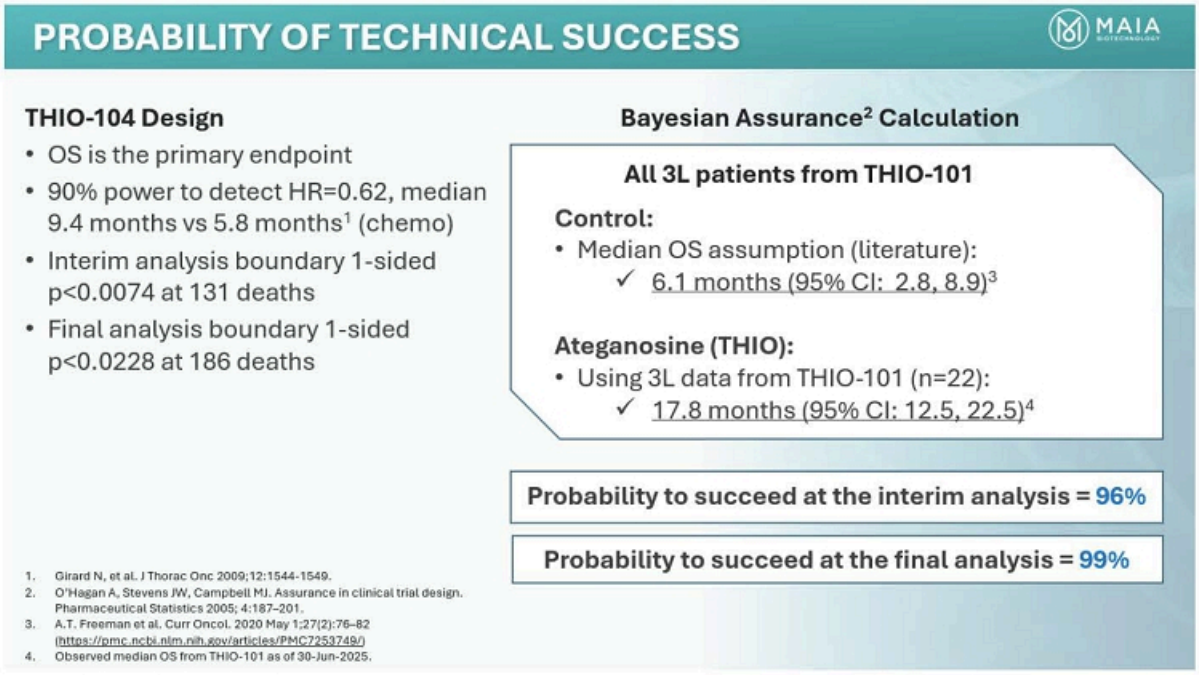
There are currently no other treatments in development for this patient setting that we're aware of, and we believe ateganosine has the potential to establish the standard of care in late-stage NSCLC to meaningfully improve outcomes for this much needed patient population.

[1] Immune Checkpoint Inhibitors Market Analysis by Mordor Intelligence, July 2025

Robust Clinical Pipeline

Pivotal Phase 3 Clinical Trial (THIO-104): High Probability of Technical Success

Initiated in 2025, the THIO-104 Phase 3 trial is designed to directly compare the treatment of ateganosine sequenced with CPI and investigator's choice of chemotherapy, the current utilized treatment for third-line NSCLC patients. THIO-104 is expected to enroll up to 300 patients globally, and statistical assessments point to a very high probability of technical success if the results are consistent with Phase 2 data. An interim analysis of overall survival (OS) is expected to give us a good basis for topline results. This data, expected next year, may support a discussion with the FDA where we plan to present our case for an early full commercial approval of ateganosine in third-line NSCLC.



Phase 2 Clinical Trial (THIO-101): Potential for Accelerated Approval

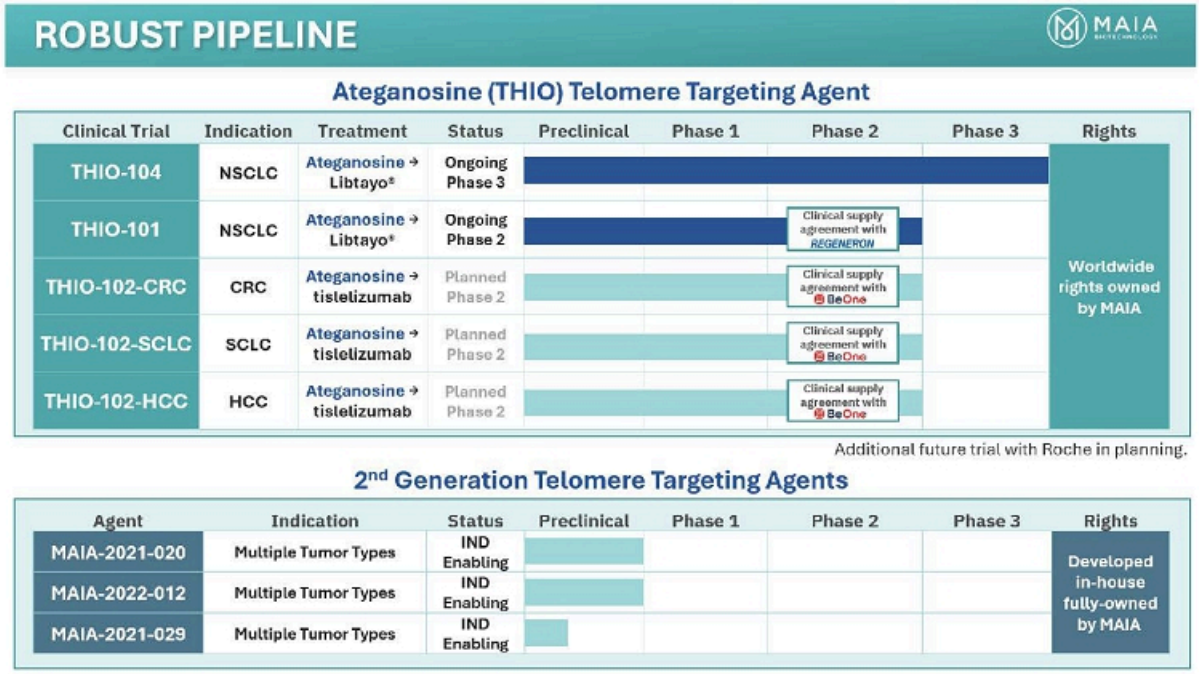
Our THIO-101 Phase 2 trial began in 2022, and parts A and B provided key inputs for our market strategy: optimal dosing for a well-defined patient population. In 2025, we initiated the expansion stage of the trial, Part C, to further confirm the efficacy observed to date and to clinically evaluate the contribution of components between ateganosine and CPI. The additional data from the expansion may further support an accelerated approval filing with the FDA. The launch of Part C was a key milestone that expands the patient pool to Asia and other countries in Europe.

Other Cancer Indications

The combination of ateganosine sequenced with any CPI has vast applicability for care. In addition to NSCLC, we plan to initiate multiple Phase 2 studies for other high-risk cancer indications: colorectal cancer (CRC), the third most common cancer; small cell lung cancer (SCLC), the deadliest lung cancer; and hepatocellular carcinoma (HCC), which represents 90% of primary liver cancers. To support these future trials, MAIA has secured a clinical supply agreement with BeOne Medicines for tislelizumab (Tevimbra®) and a master agreement with Roche for atezolizumab (Tecentriq®).

Second Generation Anticancer Agents

R&D continues for our 2nd-generation pipeline of potential telomere-targeting agents, with better efficacy compared to ateganosine observed in vitro models.



Regulatory Achievements, NIH Support

In July 2025, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for ateganosine for the treatment of NSCLC. This designation allows for more frequent FDA communication, potential rolling review, and eligibility for Accelerated Approval and Priority Review.

If approved, ateganosine will hold FDA New Chemical Entity (NCE) five-year marketing exclusivity. An NCE is a small molecule drug with a novel active ingredient that hasn't been previously approved or marketed.

We continue to hold three U.S. FDA Orphan Drug Designations for ateganosine in HCC, SCLC and malignant gliomas. We also hold the FDA's U.S. FDA Rare Pediatric Disease Designation for pediatric-type diffuse high-grade gliomas (pHGGs), which are aggressive brain tumors in children distinct from adult types.

In September 2025, the National Institutes of Health (NIH) awarded a $2.3 million grant to MAIA for the expansion of THIO-101. The grant is intended to support expenses related to the enrollment of U.S. patients who are resistant to chemo and immunotherapy in third-line NSCLC. This is another great recognition of the ateganosine's efficacy as a promising candidate for treatments in an underserved patient population.

Looking Ahead

As we move forward, we are optimistic about the progress and potential outcomes of our advanced trials and the broader promise of ateganosine. We are grateful to our stockholders, employees, partners and investigators, for their continued support and commitment. With strong momentum and a clear path ahead, we believe MAIA Biotechnology's future is bright and rich with opportunity.

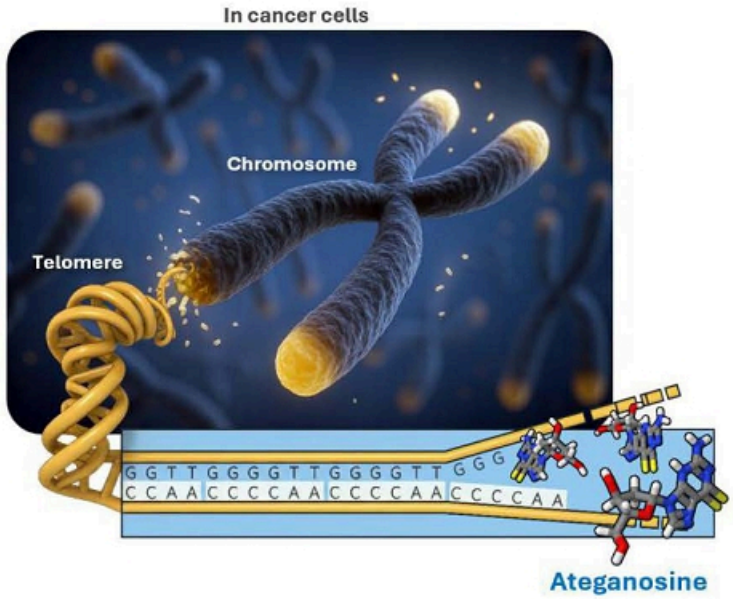
Sincerely,

Vlad Vitoc, M.D.
Chairman and Chief Executive Officer

Small Molecule Design

Ateganosine (THIO, 6-thio-2'-deoxyguanosine) offers an all-new science for cancer therapy based on a novel dual mechanism of action involving telomere-targeting and immunogenic effect. First, the small molecule is incorporated into telomeres by the enzyme telomerase (present in over 80% of human cancers). Telomeric structure and function are compromised, leading to selective cancer cell death. At the same time, micronuclei are produced containing ateganosine-modified telomeric DNA fragments. These activate both innate and adaptive immune responses, further promoting cancer cell death.

Clinical data has shown that the sequential treatment of ateganosine followed by immune checkpoint inhibitors (CPI) results in profound and persistent tumor regression in advanced cancer models.



Forward Looking Statements

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Investor Relations Contact

+1 (872) 270-3518
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Exhibit 99.2

MAIA Biotechnology's Phase 3 Momentum Demonstrates Potential Breakthrough Anticancer Opportunity in $50 Billion Immunotherapy Market

Ongoing Phase 3 full approval clinical trial of ateganosine holds high probability of technical success for interim and full analysis

FDA Fast Track designation offers clear pathway for ateganosine as third-line therapy for non-small cell lung cancer (NSCLC)

First and only direct telomere-targeting anticancer agent in clinical development anywhere

MAIA CEO details development pipeline in letter to shareholders

CHICAGO – February 24, 2026 – MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today published a 2026 Letter to Shareholders by Founder and CEO Vlad Vitoc, M.D. featuring the Company's strong momentum in clinical trials of its lead molecule, ateganosine, as a treatment for non-small cell lung cancer (NSCLC). As a potential breakthrough therapy, ateganosine holds substantial commercial opportunity in a $50 billion global immunotherapy market.[1]

As stated in the Letter, Dr. Vitoc wrote, "Our development strategy intentionally targets the third-line (3L) NSCLC population, where the unmet need is urgent. No established standard of care exists in 3L treatment, with most oncologists currently treating 3L patients with chemotherapy, leading to particularly poor clinical outcomes. In clinical studies, ateganosine sequenced with an immune checkpoint inhibitor (CPI) has demonstrated outcomes that exceed those historically achieved with either CPI-based therapy or chemotherapy alone. These findings position ateganosine not as a competitor to CPIs, but as the foundation of a new treatment category designed specifically for advanced NSCLC following CPI and chemotherapy failure. By focusing on a third-line population with no defined standard of care, we are addressing an underserved group of approximately 50,000 patients annually in the United States and creating a differentiated, incremental revenue opportunity outside of the CPI market.

"Ateganosine could mark the start of a new therapeutic category in cancer treatment and could become the standard of care for multiple cancer indications," Dr. Vitoc added. "The commercial opportunity for ateganosine could be immense."

Dr. Vitoc concluded his Letter with the following statement: "As we move forward, we are optimistic about the progress and potential outcomes of our advanced trials and the broader promise of ateganosine. We are grateful to our stockholders, employees, partners and investigators, for their continued support and commitment. With strong momentum and a clear path ahead, we believe MAIA Biotechnology's future is bright and rich with opportunity."

[1] Immune Checkpoint Inhibitors Market Analysis by Mordor Intelligence, July 2025

MAIA's 2026 Letter to Shareholders is available in its entirety at ir.maiabiotech.com.

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 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

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