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): January 20, 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** **(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 January 20, 2026, MAIA Biotechnology, Inc. (the "Company") issued a press release entitled "MAIA Biotechnology Advances Ateganosine Cancer Treatment Program, Outlines 2026 Clinical Milestones and Growth Momentum" 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, 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 January 20, 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: January 20, 2026

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Biotechnology Advances Ateganosine Cancer Treatment Program, Outlines Targeted 2026 Clinical Milestones and Growth Momentum

High probability of technical success in pivotal Phase 3 trial based on unmatched efficacy data for third-line non-small cell lung cancer (NSCLC) treatment

FDA's Fast Track designation for ateganosine in NSCLC advances concurrent Phase 2 expansion and Phase 3 trials along strategic regulatory pathways

Strong momentum toward goal of early commercial approval

Potential breakthrough therapeutic for estimated $50+ billion global immunotherapy market;
first and only telomere-targeting anticancer agent in clinical development anywhere

CHICAGO – January 20, 2026 – MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today provided a corporate update on 2025 achievements and highlighted key targeted milestones and growth catalysts for 2026.

"MAIA's strong clinical execution in 2025 delivered exceptional efficacy data for ateganosine sequenced with a checkpoint inhibitor, including disease control, response rates, and survival data well above standard of care benchmarks," said MAIA founder and CEO Vlad Vitoc, M.D. "The results clearly differentiate our novel telomere-targeting science and support the U.S. FDA's Fast Track designation granted in 2025, positioning ateganosine for potential eligibility under the Accelerated Approval and Priority Review regulatory pathways.

"Our statistical assessments of ateganosine imply a high probability of technical success in our concurrent Phase 3 and Phase 2 trials. As our first-in-class small molecule advances toward potential early commercial approval—possibly within 18 to 24 months—we believe our strong execution is driving a clear value-creation inflection point, with meaningful long-term benefits for stockholders."

2025 Achievements

- **Secured FDA Fast Track designation for ateganosine as a treatment for NSCLC**. Fast Track *expedites the review of investigational drugs that treat serious conditions and fill an unmet* medical need.

- **Marked a major clinical milestone by initiating a full approval THIO-104 Phase 3 trial** in third-line (3L) NSCLC patients resistant to immunotherapy and chemotherapy.

- **Advanced the *THIO-101 Phase 2 clinical trial to the Part C expansion phase****, substantially increasing the patient pool to include countries in Asia and Europe. The expansion trial p*ositions the ateganosine program for broader regulatory and commercial relevance.

- **Awarded $2.3 million grant from the National Institutes of Health (NIH)** for the expansion of Phase 2 trial. The grant is intended to support expenses related to the enrollment of U.S. patients who are resistant to chemo and immunotherapy.

- **Validated telomere-targeting as a differentiated therapeutic approach** with applicability to multiple high mortality cancers. To our knowledge, ateganosine remains the only direct telomere-targeting anticancer agent in clinical development anywhere.

- **Established checkpoint inhibitor combination partnerships** through a master agreement with Roche for atezolizumab and a clinical supply agreement with BeOne Medicines for tislelizumab, enabling multiple future combination trials.

- **Raised approximately $17.6 million from capital raises throughout 2025,** with participation by members of the Board in nearly all transactions. This signals strong conviction and confidence in the long-term value creation potential of the ateganosine platform. As of December 31,2025, MAIA's directors and officers hold more than 5 million shares or approximately 13% of the Company.

Targeted 2026 Milestones

- **Initial measures of efficacy from Phase 3 study. Interim disease control rates (DCR), overall response rates (ORR) and progression free survival (PFS) analysis of ateganosine compared to the control arm will support regulatory discussions. Strong interim data could lead to early full commercial approval.**

- **Conclusion of Part C of Phase 2 study.** Expansion of the trial provides additional clinical efficacy data to support regulatory review for commercial approval.

- **Engage in regulatory interactions with the FDA**. Expand ongoing FDA dialogue under the Fast Track designation, including discussions around trial enhancements and prospects for Accelerated Approval and Priority Review.

- **Clinical development of second-generation molecules to start in Phase 1 trials. Additional small molecules fully developed in-house with better expected efficacy compared to ateganosine.**

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

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