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): December 11, 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	**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.

1. On December 11, 2025, MAIA Biotechnology, Inc. (the "Company") issued a press release entitled "MAIA Leadership Continues Insider Buying in 2025 and Trial Data Signals Breakout Potential" A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

2. On December 11, 2025, the Company issued a press release entitled "MAIA Biotechnology Announces First Patient Dosed in THIO-104 Phase 3 Pivotal Trial Evaluating Ateganosine as Third-Line Treatment for Advanced Non-Small Cell Lung Cancer" A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

3 On December 11, 2025, the Company issued a press release entitled "MAIA's Ateganosine Surges Ahead with Breakthrough Momentum as Pivotal Phase 3 Trial Initiates" 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 December 11, 2025 (Insider buying)
99.2	Press Release dated December 11, 2025 (First Patient Dosed in THIO-104 Phase 3 Pivotal Trial)
99.3	Press Release dated December 11, 2025 (MAIA's Ateganosine Surges Ahead)
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: December 11, 2025

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Leadership Continues Insider Buying in 2025 and Trial Data Signals Breakout Potential

CHICAGO – December 11, 2025 – A recent round of open-market purchases marks another display of confidence as the small molecule telomere-targeting cancer therapy by MAIA Biotechnology, Inc. (NYSE American: MAIA) advances through mid- to late-stage clinical development. Newly filed disclosures show that CEO **Dr. Vlad Vitoc** and other board members acquired approximately **182,445 shares** between November 21 and 28, 2025. Insiders' participation has been viewed by the market as a strong signal of alignment, conviction, and belief in the long-term value creation potential of the ateganosine platform.

The latest insider buying arrives as ateganosine continues to deliver encouraging results. These outcomes have strengthened internal and external confidence that MAIA's novel telomere-targeting approach may represent a meaningful new therapeutic pathway for patients with advanced non-small cell lung cancer (NSCLC).

Taken together—material insider buying at market prices, sustained insider participation across 2025 financings, and strengthening clinical signals—MAIA's leadership continues to demonstrate a unified stance: confidence in the company's strategy, confidence in ateganosine's growing body of clinical evidence, and confidence in the opportunity ahead as the program advances toward later-stage development. To date, Directors and Officers hold 4,480,120 shares or 12.95% of the company.

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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Exhibit 99.2

MAIA Biotechnology Announces First Patient Dosed in THIO-104 Phase 3 Pivotal Trial Evaluating Ateganosine as Third-Line Treatment for Advanced Non-Small Cell Lung Cancer

Key milestone achieved as Company advances clinical program to full approval trial of ateganosine sequenced with a checkpoint inhibitor in comparison to chemotherapy

CHICAGO – December 11, 2025 – MAIA Biotechnology, Inc. (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today announced that the first patient has been dosed in the Company's THIO-104 Phase 3 pivotal trial evaluating the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) as a third-line treatment for advanced non-small cell lung cancer (NSCLC).

The multicenter, open-label trial of patients who are resistant to CPI and chemotherapy treatments, is designed to assess overall survival for ateganosine sequenced with a CPI compared to investigator's choice of chemotherapy in a 1:1 randomization of up to 300 patients. MAIA has received regulatory approval to screen patients in Taiwan, Turkey, select European Medicines Agency (EMA) countries, and Georgia. Screening and enrollment are now underway.

"Our strategy to bring our telomere-targeting treatment to market is proceeding according to plan as we advance our ateganosine program to a Phase 3 trial. This larger trial will provide us a robust dataset to support our case for commercial approval by the U.S. FDA," said Vlad Vitoc, M.D., CEO of MAIA. "We have many sites in several countries already screening patients, and with our first patient dosed, we have achieved a key milestone along our path to potential FDA commercial approval. We expect to see Phase 3 results consistent with Phase 2 trial data showing median survival of 17.8 months compared to approximately six months of survival from chemotherapy. We are confident that ateganosine could become the new treatment standard for patients suffering from this devastating disease."

Ateganosine sequenced with a CPI has shown exceptional efficacy in third-line NSCLC patients. As of September 17, 2025, the observed progression free survival (PFS) in THIO-101 was 5.6 months, more than double the standard of care PFS of 2.5 months. One patient that began therapy in March 2023 has shown survival of 30 months, or 912 days.

The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ateganosine for the treatment of NSCLC.

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-104 Phase 3 Clinical Trial

THIO-104 is a multicenter, open-label, randomized Phase 3 clinical trial, designed to evaluate ateganosine's telomere-targeting anti-tumor activity when followed by PD-(L)1 inhibition in patients with advanced third-line NSCLC who previously did not respond or developed resistance to treatment regimens containing checkpoint inhibitor and/or chemotherapy and have progressed. The trial has two primary objectives: (1) to assess the clinical efficacy of ateganosine compared to investigator's choice of chemotherapy, using median Overall Survival (OS) as the primary clinical endpoint (2) to evaluate the safety and tolerability of ateganosine in sequential combination with a checkpoint inhibitor. For more information on this Phase 3 trial, please visit ClinicalTrials.gov using the identifier NCT06908304.

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.

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Exhibit 99.3

MAIA's Ateganosine Surges Ahead with Breakthrough Momentum as Pivotal Phase 3 Trial Initiates

CHICAGO – December 11, 2025 – Ateganosine (THIO, 6-thio-2'-deoxyguanosine), a first-in-class telomere-targeting therapy under development by **MAIA Biotechnology (NYSE American: MAIA),** appears to be gaining increasing attention in the oncology community as emerging clinical results continue to surpass expectations in advanced non-small cell lung cancer (NSCLC). With the therapy's Phase 2 trial ongoing and a pivotal Phase 3 program initiated this week, ateganosine is being closely watched as one of the most distinctive investigational approaches in solid-tumor treatment today.

We believe that MAIA has positioned itself at the forefront of a new scientific category in oncology. To our knowledge, Ateganosine remains the only direct telomere-targeting anticancer agent currently in clinical development anywhere—a key distinction in a treatment landscape where most therapeutic advances build upon established mechanisms rather than introduce entirely new ones.

According to management, statistical assessments of the Phase 3 trial points to a very high probability of technical success for regulatory approval of ateganosine.

The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ateganosine for the treatment of NSCLC.

A Dual Mechanism Unlike Existing Therapies

Ateganosine works through a dual mechanism of action that we believe differentiates it from existing chemotherapies, targeted agents, and immunotherapies.

First, the molecule is selectively incorporated into cancer-cell telomeres by telomerase, an enzyme active in more than 80% of human cancers. This incorporation disrupts telomeric structure and function, driving selective cancer-cell death.

Simultaneously, this disruption generates micronuclei carrying ateganosine-modified telomeric DNA fragments. These fragments interact with immune cells and trigger a potent immunogenic response involving both the cGAS/STING innate pathway and adaptive T-cell activation, further promoting tumor regression.

This integrated telomere-targeting–plus–immune-activation model represents a mechanism that to our knowledge is not seen in current NSCLC treatments and may hold implications for broader solid-tumor indications.

Phase 3 Outcomes are the Next Step

The launch of a Phase 3 trial reflects growing confidence in the maturing clinical profile. With NSCLC remaining one of the largest and most challenging oncology markets globally, in our opinion, the commercial opportunity for a first-in-class therapy with this level of early performance is substantial.

As the only telomere-targeting agent in clinical development that we are aware of, ateganosine could mark the start of a new therapeutic category. Should its results to date translate into later-stage confirmation, we believe the therapy could emerge as a major entrant in next-generation cancer treatment.

About MAIA Biotechnology, Inc.

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