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 10, 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.

On December 10, 2025, MAIA Biotechnology, Inc. (the "Company") issued a press release entitled "MAIA Takes Aim at a $50B Immunotherapy Market with Breakthrough Telomere-Targeting Approach" 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 December 10, 2025
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 10, 2025

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Takes Aim at a $50B Immunotherapy Market with Breakthrough Telomere-Targeting Approach

CHICAGO – December 10, 2025 - MAIA Biotechnology (NYSE American: MAIA) – The treatment paradigm for advanced non-small cell lung cancer (NSCLC) is undergoing another shift. After a decade of targeted therapies and checkpoint inhibitors (CPIs) dominating headlines, MAIA believes that a new therapeutic class—telomere-targeting agents—is emerging for the population with substantial unmet medical need: patients without actionable mutations and who no longer respond to CPIs or chemotherapy.

This is a segment that existing therapies leave behind. And it is the segment where we believe that ateganosine, developed by MAIA, may soon become one of the most consequential entrants in years.

A Market Dominated by Checkpoint Inhibitors—But Vulnerable at Its Edges

CPI therapies remain the backbone of NSCLC treatment in patients who don't have an actionable mutation. Collectively, the category generated approximately $50 billion in global sales in 2024, anchored by five major agents approved for NSCLC. The therapeutic concentration in lung cancer is striking:

- >30% of all NSCLC drug sales come from CPIs
- >40% of all CPI global sales originate from NSCLC alone

Merck's Keytruda, the category-defining CPI, reported $29.5 billion in revenue in 2024, with NSCLC representing an estimated 30% of its total sales. Keytruda is expected to approach $35 billion by 2027—just before biosimilars begin entering the market in 2028.

While CPIs have transformed outcomes for some patients, in our opinion their limitations remain clear: patients without actionable mutations, and those who become CPI-refractory, still experience extremely poor prognosis and limited therapeutic benefit. We believe this treatment gap has become one of the industry's largest unmet needs.

Telomere-Targeting: A New Pathway for a Hard-to-Treat Population

We believe that MAIA's ateganosine represents the first drug in a new class. Unlike targeted therapies requiring EGFR, ALK, KRAS, or other mutations—and unlike immunotherapies dependent on PD-1/PD-L1 dynamics—ateganosine has been designed to exploit a universal feature of cancer cells: telomerase activity, present in more than 80% of human tumors.

Its dual mechanism has been designed to disrupt telomeres to trigger direct cancer cell death while simultaneously enabling the immune system to respond to cancer. MAIA was recently awarded Fast Track Designation by the U.S. FDA for the treatment of NSCLC in patients resistant to immunotherapy and chemotherapy, and is initiating a Phase 3 THIO-104 trial.

A Commercial Opportunity That Extends Across Oncology

With the NSCLC market now valued at $34.1 billion—projected to nearly double to $68.8 billion by 2033—the implications of a first-in-class therapy are substantial. In the United States alone, roughly 180,000 patients enter the NSCLC treatment ecosystem every year.

But ateganosine's opportunity does not end with lung cancer. The candidate already carries FDA Orphan Drug Designations (ODDs) for:

- Glioblastoma (market: $2.2B → $3.2B growth expected)
- Hepatocellular carcinoma (HCC) (mortality: 0.8M; sales: $3.8B)
- Small cell lung cancer (SCLC) (mortality: 0.3M; sales: $2.8B)

Each ODD offers seven years of U.S. market exclusivity upon regulatory FDA approval and access to tax credits—advantages that strengthen MAIA's long-term market positioning.

A Strategic Inflection Point for the Entire NSCLC Treatment Landscape

The oncology market is poised for a shift as developers seek to fill in gaps in the treatment landscape. The next decade is expected to reward novel mechanisms, and in our opinioin advanced NSCLC represents the clearest example of that gap.

Telomere-targeting therapeutics may be the next foundation in that evolution. If ateganosine's outcomes are successful, the therapy could become a defining entrant in a space where treatment failure has long been accepted as inevitable. Statistical assessments points to a high probability of technical success for regulatory approval of ateganosine.

In our opinion, MAIA is now positioned at the center of this turning point—scientifically and strategically.

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.

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