

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 1, 2025

MAIA Biotechnology, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41455
(Commission
File Number)

83-1495913
(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 April 1, 2025, MAIA Biotechnology, Inc. (the “Company”) issued a 2025 Letter to Shareholders detailing the Company’s anticipated clinical milestones for its cancer treatment candidates.

A copy of the 2025 Letter to Shareholders is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On April 1, 2025, the Company issued a press release announcing the release of the 2025 Letter to Shareholders detailing Company’s anticipated clinical milestones for its cancer treatment candidates.

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, 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	2025 Letter to Shareholders
99.2	Press Release dated April 1, 2025
104	Cover Page Interactive Data File - the cover page XBRL tags are 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 1, 2024

MAIA BIOTECHNOLOGY, INC.

By: /s/ Vlad Vitoc

Name: Vlad Vitoc

Title: Chief Executive Officer



MAIA
BIOTECHNOLOGY

Letter to Shareholders 2025 NYSE American: MAIA

- ✓ Phase 2 trial THIO-101 expansion underway; potential filing in 2026 for accelerated approval
- ✓ Phase 3 THIO-104 set to begin in mid-2025; potential filing in 2026 for early full approval
- ✓ Lead asset THIO shows exceptional efficacy in advanced non-small cell lung cancer (NSCLC)
- ✓ Multiple THIO trials planned in additional cancer indications
- ✓ Significant market opportunity in hard-to-treat cancers with unmet medical needs

MAIA Letter to Shareholders

March 2025

Dear fellow shareholders,

MAIA continues to bring innovation to the biotech industry as one of the earliest pioneers of telomere targeting as a strategy for cancer treatment. Our lead candidate is THIO (ateganosine), the only clinical-stage telomere-targeting anticancer agent throughout the field of cancer discovery.

Last year we shared a consistent sequence of clinical updates demonstrating THIO's efficacy in advanced non-small cell lung cancer (NSCLC). We are working on multiple potential regulatory pathways that could provide accelerated approval and robust exclusivity for THIO in this indication. Multiple milestones this year are expected to pave the path toward a potential FDA decision as early as next year.

We believe that the commercial opportunity for THIO is vast, not only in the \$34 billion NSCLC therapy market¹, but also in many of the top tumor markets globally. THIO's orphan drug and rare pediatric disease designations by the U.S. Food and Drug Administration (FDA) offer additional routes for clinical development, and we are working to advance two of our most promising next generation THIO-derived telomere-targeting molecules to clinical trials.

MAIA's multiple key milestones for 2025 will begin with first patient dosing in a THIO-101 Phase 2 expansion trial (part C) in NSCLC third line (3L) therapy. Full long-term efficacy data for THIO-101 parts A and B is expected by mid-year 2025. In the latter half of 2025, we plan to initiate enrollment in our Phase 3 trial THIO-104 in NSCLC, also in 3L therapy. The THIO-104 trial plays a key role in our commercial strategy for THIO because it will serve as a conditional confirmatory trial if THIO-101 obtains accelerated approval status, or as a full approval trial otherwise.

By the end of this year, we expect to have all required approvals to start enrolling patients in our THIO-102 Phase 2 clinical trials in three other tumor types: hepatocellular carcinoma (HCC, 90% of liver cancers), colorectal cancer (CRC, the second leading cause of cancer death in the US), and small cell lung cancer (SCLC, the deadliest type of lung cancer). These trials will leverage our recently announced clinical supply agreement with global oncology company BeiGene to evaluate the efficacy of treatment with THIO in combination with BeiGene's immune checkpoint inhibitor.

THIO Telomere Targeting Agent – Clinical Trials Pipeline

Clinical Trial	Indication	Treatment	Status	Preclinical	Phase 1	Phase 2	Phase 3	Rights
THIO-104	NSCLC 3L	THIO → CPI	Planned Phase 3					Worldwide rights owned by MAIA
THIO-101	NSCLC 2L+	THIO → Libtayo®	Ongoing Phase 2			Clinical supply agreement with REGENERON		
THIO-102	CRC, HCC, SCLC, ST	THIO → CPI	Planned Phase 2					
THIO-103	NSCLC-1, SCLC-1	THIO → CPI	Planned Phase 2/3					

2nd Generation Telomere Targeting Agents

Agent	Indication	Status	Preclinical	Phase 1	Phase 2	Phase 3	Rights
MAIA-2021-020	Multiple Tumor Types	IND Enabling					Developed in-house fully-owned by MAIA
MAIA-2022-012	Multiple Tumor Types	IND Enabling					
MAIA-2021-029	Multiple Tumor Types	IND Enabling					

Recently, the United States Adopted Names (USAN) Council approved "ateganosine" as the nonproprietary (generic) name for THIO. This marked a key step along our development and regulatory pathway. We will adopt "ateganosine" for our molecule going forward, but will retain the name "THIO" in our clinical trial designations.

¹ Custom Market Insights, "Global Non-Small-Cell Lung Cancer Drug Market Size/Share Worth USD 68,888.6 Million by 2033..." May 2024

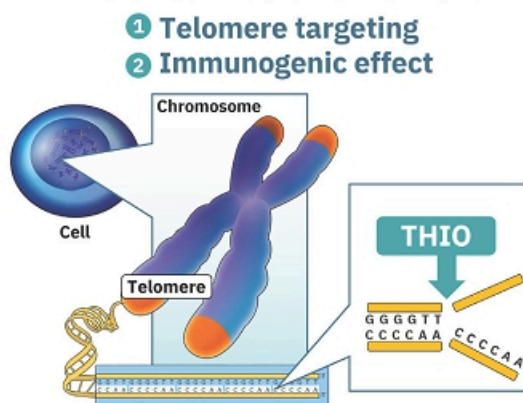
THIO Efficacy

We reported THIO's latest efficacy data in January 2025. Third line data showed median overall survival (OS) of 16.9 months for the 22 NSCLC patients who received at least one dose of THIO (the intent-to-treat population) in parts A and B of THIO-101. The overall survival data can improve as some patients continue treatment and follow-up scans. As of today, there is a 99% probability that OS for NSCLC patients treated with THIO will extend past OS for chemotherapy treatment by a wide margin.

Studies of standard-of-care chemotherapy treatments for NSCLC in similar settings have shown OS of 5 to 6 months.²

We look forward to further evaluating THIO's efficacy in the upcoming clinical trials and continuing to demonstrate THIO's unique dual mechanism of action as a potent anticancer treatment.

THIO's Dual Mechanism of Action



Clinical Trials

Phase 2 THIO-101 (ongoing)

THIO-101 studies hard-to-treat NSCLC patients who failed two or more standard-of-care therapy regimens including checkpoint inhibitor (CPI) treatment (dosed alone) and chemotherapy. THIO sequenced with a CPI has shown durable activity and exceptional efficacy along with unprecedented disease control, response, and survival results to date. THIO has been generally well-tolerated in this heavily pre-treated population³.

Phase 2 THIO-101 (expansion)

As we progressed through THIO-101, we found that THIO is most effective in third line NSCLC therapy. The expansion trial is a larger study of THIO in NSCLC, in 3L treatment only. We expect to enroll up to 148 additional patients in the U.S. and select countries in Europe and Asia. Compelling evidence of efficacy and safety, if determined, could support an FDA New Drug Application (NDA) seeking filing for accelerated approval in 2026.

Phase 3 THIO-104

We recently announced the trial design for a Phase 3 pivotal trial called THIO-104. The primary endpoint is overall survival for THIO sequenced with a CPI compared to investigator's choice of chemotherapy in a 3L setting. The secondary endpoints include disease control rate, overall response rate, duration of response, progression-free survival and safety. Interim analysis, if positive, could lead to filing for early full commercial approval in 2026, and final analysis could lead to filing for full commercial approval in 2027.

Phase 2 THIO-102 Studies

Three planned Phase 2 trials will test THIO sequenced with a checkpoint inhibitor for safety and efficacy in colorectal cancer (CRC), hepatocellular carcinoma (HCC), and small cell lung cancer (SCLC). We are planning to begin enrollment for these trials in early 2026.

Markets for Hard-to-Treat Cancers

NSCLC is the largest tumor type globally with \$34 billion in annual drug sales. Within that market there are only six CPIs approved for NSCLC, and there are zero approved telomere-targeting agents.

Statistics for THIO's three ODD indications also provide a significant market opportunity:

- HCC represents 90% of primary liver cancers,
- SCLC is the deadliest lung cancer, and
- Malignant gliomas, including glioblastoma, which is the most aggressive and prevalent type of brain cancer.

² Girard N, et al. J Thorac Onc 2009;12:1544-1549

³ Details on safety can be found on the previously announced SITC 2024 presentation available on MAIA's website.

THIO also holds FDA Rare Pediatric Disease Designation for pediatric diffuse high-grade gliomas. Under the incentive program, designated developers of drugs in this category receive priority review vouchers can be redeemed for FDA priority review of a different product or sold to another sponsor. Since 2015, FDA priority review vouchers have sold for \$100 million on average.⁴

Market Exclusivity

Exclusivity is the pillar of our development, regulatory and commercial strategies. Since THIO has never been approved for commercialization previously, we will pursue the FDA's 5-year New Chemical Entity (NCE) exclusivity. THIO's three FDA ODDs provide up to seven years of market exclusivity each, and THIO would have 10-year exclusivity in certain international markets, if approved. As the only anticancer treatment of its kind that we are aware of in clinical development, we believe that THIO has a significant head start and a strong competitive position.

Next Horizons

THIO's clinical performance has shown great potential. We think THIO's science could eventually become standard of care for several high-mortality cancer types.

We believe the value of our THIO franchise is more than the sum of its parts, with potential upside comparable to NSCLC oncology companies.

COMPARABLE COMPANIES

- **August 2022** - Bristol Myers Squibb (BMS) completed **\$4.1B** acquisition of Turning Point Therapeutics
- **January 2024** - BMS completed **\$5.8B** acquisition of Mirati Therapeutics

MAIA BIOTECHNOLOGY	Bicycle	ARRIVENT	ARCUS	Turning Point Therapeutics	MIRATI THERAPEUTICS
\$50.6M Market Cap ¹	\$0.66B Market Cap ¹	\$0.67B Market Cap ¹	\$0.9B Market Cap ¹	\$3.8B Market Cap ²	\$4.1B Market Cap ²
\$1.75/share	\$9.5/share	\$19.6/share	\$9.1/share	\$76/share	\$58/share
NYSE:MAIA	NASDAQ:BCYC	NASDAQ:AVBP	NYSE:RCUS	Acquired by BMS	Acquired by BMS
Clinical Development Stage Phase II	Clinical Development Stage Phase II	Clinical Development Stage Phase III	Clinical Development Stage Phase III	Clinical Development Stage Phase II	Clinical Development Stage Commercial

1. Market cap and share price (close) as of March 15, 2025 (Source: Yahoo! Finance)
2. Last known market cap and share price before acquisition (Source: companiesmarketcap.com)

We believe that MAIA has exciting opportunities ahead, and we are grateful for your ongoing support and contributions to our progress.

Sincerely,

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

Forward Looking Statements

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Investor Relations Contact

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ir@maiabiotech.com

⁴ Pharmaceutical Technology, GlobalData Pharma Intelligence Centre, January 2024

MAIA Biotechnology CEO Details Anticipated Clinical Milestones for Novel Cancer Immunotherapy in 2025 Letter to Shareholders

- Lead compound THIO (ateganosine) is the only clinical-stage telomere-targeting anticancer agent throughout the field of cancer discovery
- Potential FDA filings in 2026 for accelerated approval from THIO-101 and early full approval from THIO-104
- Full Shareholder Letter available in Investors section of MAIA's corporate website

CHICAGO, IL – April 1, 2025 – MAIA Biotechnology, Inc., (NYSE American: MAIA) (“MAIA” or the “Company”), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today published a 2025 Shareholder Letter by CEO Vlad Vitoc, M.D. detailing the Company's key milestones for 2025 including several clinical trials and regulatory pathways.

“MAIA continues to bring innovation to the biotech industry as one of the earliest pioneers of telomere targeting as a strategy for cancer treatment. Our lead candidate is THIO (ateganosine), the only clinical-stage telomere-targeting anticancer agent throughout the field of cancer discovery,” states Dr. Vitoc at the opening of his shareholder letter. “We are working on multiple potential regulatory pathways that could provide accelerated approval and robust exclusivity for THIO in non-small cell lung cancer (NSCLC). Multiple milestones this year are expected to pave the path toward a potential FDA decision as early as next year.”

Letter Highlights

- Phase 2 trial THIO-101 expansion underway; potential filing in 2026 for accelerated approval.
- Phase 3 THIO-104 set to begin in mid-2025; potential filing in 2026 for early full approval.
- Lead asset THIO shows exceptional efficacy in advanced NSCLC.
- Multiple THIO trials planned in additional cancer indications.
- Significant market opportunity in hard-to-treat cancers with unmet medical needs.

MAIA's letter to shareholders is available at ir.maiabiotech.com.

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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