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): September 7, 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 7.01 Regulation FD Disclosure.

MAIA Biotechnology, Inc. (the "Company") has prepared a poster (the "Poster") showing the efficacy data from its Phase 2 THIO-101 clinical trial evaluating THIO sequenced with the immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced non-small cell lung cancer (NSCLC) who failed 2 or more standard-of-care therapy regimens. The Poster was selected as an abstract titled Study of THIO Sequenced with Cemiplimab in 3rd Line Immune Checkpoint Inhibitor-resistant aNSCLC: Improvement in PFS" and originally presented and displayed at the 2025 IASLC World Conference on Lung Cancer (WCLC) on September 7, 2025. The Poster will also be posted to the Company's website on September 8, 2025, a copy of which is filed as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") and is hereby incorporated by reference.

The Poster contains forward-looking statements, and as a result, investors should not place undue reliance on these forward-looking statements.

Item 8.01 Other Events

Reference is made to the disclosure under Item 7.01 above which is hereby incorporated in this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Poster
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: September 8, 2025

MAIA BIOTECHNOLOGY, INC.

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

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Study of THIO Sequenced with Cemiplimab in 3rd Line Immune Checkpoint Inhibitor-resistant aNSCLC: Improvement in PFS

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Introduction

- Despite recent advances for the first-line treatment of advanced Non-Small Cell Lung Cancer (NSCLC), long-term prognosis remains poor with a 5-year survival rate of 28%[1] and limited options exist in patients' refractory or resistant to immune checkpoint inhibitors (ICI).
- THIO (ateganosine, 6-thio-2'-deoxyguanosine, 6-thio-dG) is a small molecule, first-in-class direct cancer telomere targeting agent that selectively kills telomerase positive (TERT+) cancer cells:
  - Over 80% of all cancers and approx. 78-83% of all NSCLC types are TERT+.[2,3]
  - THIO is incorporated into de novo synthesized telomeres leading to chromatin uncapping, generation of DNA damage signals, and rapid apoptosis.[4]
- In preclinical models, sequential treatment of THIO and ICIs overcame ICI resistance and showed a potent and durable antitumor activity.[5]
- Preliminary trial results in NSCLC indicates that low doses of THIO induce sensitivity to ICIs when administered prior to an ICI in tumors which otherwise are resistant or do not respond to an ICI.
- Treatment options for immune checkpoint inhibitor (ICI)-resistant patients are limited. THIO, a telomere-targeting agent, modifies telomeres in cancer cells, Including circulating tumor cells (CTCs), confirming its mechanism of action and demonstrating potential efficacy in advanced NSCLC, independent of PD-L1 expression.

Methods

- Here we describe a phase 2 dose-optimization study (NCT05208944) for adult patients with advanced NSCLC who progressed or relapsed after 1–4 prior treatment lines including first-line ICI alone or in combination with platinum chemotherapy.
- Using a modified 3+3 design, the safety lead-in (Part A) enrolled 10 patients who received THIO 360 mg IV (120 mg QD, D1–3), followed by 350 mg cemiplimab on D5, Q3W. Following completion of Part A, enrollment was opened in the dose-finding portion of the study (Part B).
- Using a Simon 2-stage design, 79 patients were assigned to one of the THIO doses: 360, 180, or 60 mg followed by cemiplimab Q3W for up to 1 year in Part B.
- Disease status is assessed at Cycle 3 Day 1, Cycle 5 Day 1 and every 9 -12 weeks thereafter.
- The trial completed enrollment for Parts A and B in February 2024. We report here data from the 79 patients enrolled on the study, who received at least one dose of the treatment.
- An expansion cohort based on data from Part B started enrollment in July 2025: up to 48 patients in Part C (one arm with the combination of THIO + cemiplimab, one arm with THIO as monotherapy) and up to 100 patients in Part D.

Baseline characteristics

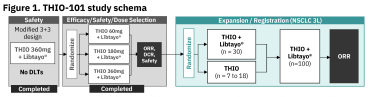
- At the time of data cut-off (June 30, 2025), 79 patients with advanced NSCLC had received ≥1 dose of THIO.
- All patients had previously failed ≥1 prior line of ICI ± chemotherapy in the advanced setting and had documented disease progression at study entry.
- 34% of patients had ≥2 prior treatment lines at study entry.

Table 1. Baseline characteristics

Characteristic	60 mg (n=24)	180 mg (n=41)	360 mg (n=14)	Total (N=79)
Median age (range), years	67 (52–85)	68 (45–81)	68 (50–75)	67 (45–85)
Sex, n (%)				
Female	10 (42)	11 (27)	7 (50)	28 (35)
Male	14 (58)	30 (73)	7 (50)	51 (65)
Number of prior lines, n (%)				
1	17 (71)	30 (73)	5 (36)	52 (66)
2	6 (25)	10 (25)	6 (43)	22 (28)
3	1 (4)	0 (0)	2 (14)	3 (4)
4	0 (0)	1 (2)	1 (7)	2 (3)
ECOG PS, n (%)				
0	6 (25)	8 (20)	7 (50)	21 (27)
1	18 (75)	33 (80)	7 (50)	58 (73)
Histology, n (%)				
Non-Squamous cell carcinoma	15 (63)	25 (61)	8 (57)	48 (60)
Squamous cell carcinoma	9 (37)	16 (39)	6 (43)	31 (40)
Brain metastases, n (%)	1 (4)	1 (2)	2 (14)	4 (5)
Liver metastases, n(%)	4 (17)	5 (12)	3 (21)	12 (15)

Study Design

Figure 1. THIO-101 study schema



- Total of 79 patients enrolled (24 treated in 60mg dose group, 41 in 180mg, and 14 in 360mg)
- Best dose: 180mg - selected on Nov'23
- Enrollment completed Feb'24
- Up to 148 patients – Enrollment started in Jul'2025
- Patient population:
  - CPI Resistance (SITC)
  - Chemotherapy Resistance

- **Primary endpoints:** Safety, ORR, DCR (CR, PR and SD).
- **Secondary endpoints:** DoR; PFS; OS.
- **Exploratory endpoints:** PK and PD (activity of THIO in circulating tumor cells measured by specific biomarkers).

Safety findings

Table 2. Related Grade ≥3 TEAEs

Preferred Term	60mg (N=24)	180mg (N=41)	360mg (N=14)	Total (N=79)
Alanine aminotransferase increased	3 (12.5%)	4 (9.8%)	2 (14.3%)	9 (11.4%)
Aspartate aminotransferase increased	5 (20.8%)	2 (4.9%)	2 (14.3%)	9 (11.4%)
Neutropenia	2 (8.3%)	1 (2.4%)	0(0%)	3 (3.8%)
Blood alkaline phosphatase increased	0(0%)	1 (2.4%)	0(0%)	1 (1.3%)
Gamma-glutamyltransferase increased	0(0%)	1 (2.4%)	0(0%)	1 (1.3%)
Lipase increased	1 (4.2%)	0(0%)	0(0%)	1 (1.3%)
Weight decreased	0(0%)	1 (2.4%)	0(0%)	1 (1.3%)
Nausea	0(0%)	0(0%)	1 (7.1%)	1 (1.3%)
Multiple organ dysfunction syndrome	0(0%)	1 (2.4%)	0(0%)	1 (1.3%)
Hyperkalaemia	1 (4.2%)	0(0%)	0(0%)	1 (1.3%)
Ischaemic stroke	0(0%)	1 (2.4%)	0(0%)	1 (1.3%)

Note: Cerebellar and ischaemic strokes reported refer to the same event. The medical monitor assessment was unrelated.

- THIO + cemiplimab has been generally well tolerated in a heavily pre-treated population, with most events being Grade 1–2 in severity.
- The most commonly reported TEAEs were AST (27%), and ALT increased (23%), followed by nausea (13%), anaemia (11%), hyponatraemia and weight decreased (10% each). At the selected 180 mg dose, nausea occurred in only one patient (2.4%).
- No DLTs have been reported in the Part A safety lead in.
- TEAE related Grade ≥3 were reported in 17 out of 79 (21.5%) patients, with ALT increase reported in 9 patients (11.4%), including 2 patients receiving 360 mg, 4 at 180 mg, and 3 at 60 mg. No clinical symptoms were associated with the elevated laboratory values, and all returned to baseline or normal without sequelae.
- All other related Grade ≥3 events occurred in <5% of patients.
- Following an event of Grade 4 LFT elevation in a patient receiving 360 mg in Part B, enrollment into the 360 mg arm was paused.
- THIO mechanism of action potentially allows for more selective targeting of cancer cells compared to ICI alone, potentially reducing the frequency of adverse events relative to non-targeted therapies.[6,7]

Efficacy findings

- 79 subjects received at least one dose of THIO
- Partial Responses (PRs) RECIST 1.1 were reported for 10 subjects (6 in 2L, 4 in 3L), with 8 PRs confirmed by a 2nd scan per Investigators' assessment (4 in 2L, 4 in 3L)
- 36 patients with survival follow-up above 12 months (22 in 2L, 14 in 3L+)
- 13 patients with treatment or follow-up ongoing (11 in 2L, 2 in 3L)
- 2 patients completed 33 cycles of therapy
- Data presented is focused on 3L (n=22). The trial also enrolled 52 patients in 2L, 4 in 4L and 1 in 5L.
- In the 3L setting (n=22):
  - 22 subjects received at least 1 dose of THIO
  - Estimated Median Overall Survival (OS) is at 17.8 months with a 95% CI lower bound of 12.5 months.
  - DCR 77% vs 25-35% chemotherapy.[8]
- In the 3L setting 180mg (n=10):
  - Estimated Median Progression Free Survival (PFS) in third-line 180 mg, the selected dose, is at 5.6 months. Comparable PFS threshold is 2.5 months. [10-11]

Efficacy findings (continued)

Figure 2. OS for patients receiving THIO as 3L treatment, all dose levels (n=22)*

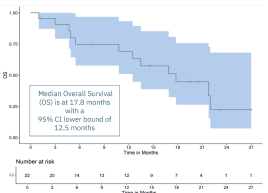


Figure 3. Patients receiving THIO as 3L treatment, all dose levels (n=22)*

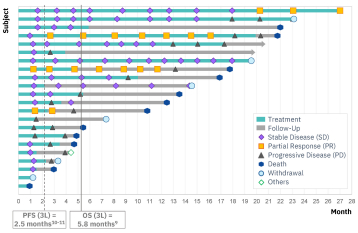


Figure 4. PFS for patients receiving THIO as 3L treatment, 180mg (n=10)*

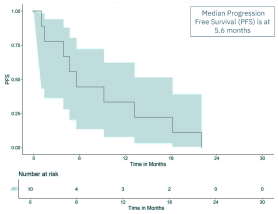
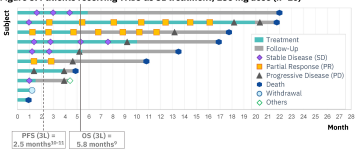


Figure 5. Patients receiving THIO as 3L treatment, 180 mg dose (n=10)*



*Includes all patients who received at least one dose of THIO.

Conclusions

- **Current data in third-line indicates that as of June 30, 2025, estimated Median Overall Survival (OS) is at 17.8 months with a 95% CI lower bound of 12.5 months**
- **Estimated Median Progression Free Survival (PFS) in third-line 180 mg, the selected dose, is at 5.6 months.**
- **Treatment has the potential to be given for longer, which usually translates into longer survival.**
- **The combination of THIO + cemiplimab has durable activity in this hard-to-treat patient population (CPI resistant and chemotherapy resistant progressors).**
- **THIO + cemiplimab has so far been generally well-tolerated in a heavily pre-treated population, with most events being Grade 1-2 in severity and very few Grade ≥3, mostly ALT increase reported in 9 patients (11.4%).**
- **The ongoing Phase 2 study selected the best dose of THIO 180 mg which has shown better safety and superior efficacy compared with other doses: to date, 9.8% of patients receiving the 180 mg dose reported related Grade ≥3 AEs.**

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Author disclosures

- Tomasz Jankowski, M.D. consulting for BMS, MSD, Amgen, Takeda, Pfizer and AstraZeneca.

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