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): March 28, 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" and originally presented and displayed at the European Lung Cancer Congress 2025 on March 28, 2025. The Poster will also be posted to the Company's website on March 28, 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 information contained in the Poster is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements the Company may make by press release or otherwise from time to time. The Poster speaks as of the date of this Report. While the Company may elect to update the Poster in the future to reflect events and circumstances occurring or existing after the date of this Report, the Company specifically disclaims any obligation to do so.

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

The information set forth in this Report, including, without limitation, the Poster, is not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be incorporated by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such a filing. This Report (including the exhibits hereto) will not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

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	Poster
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

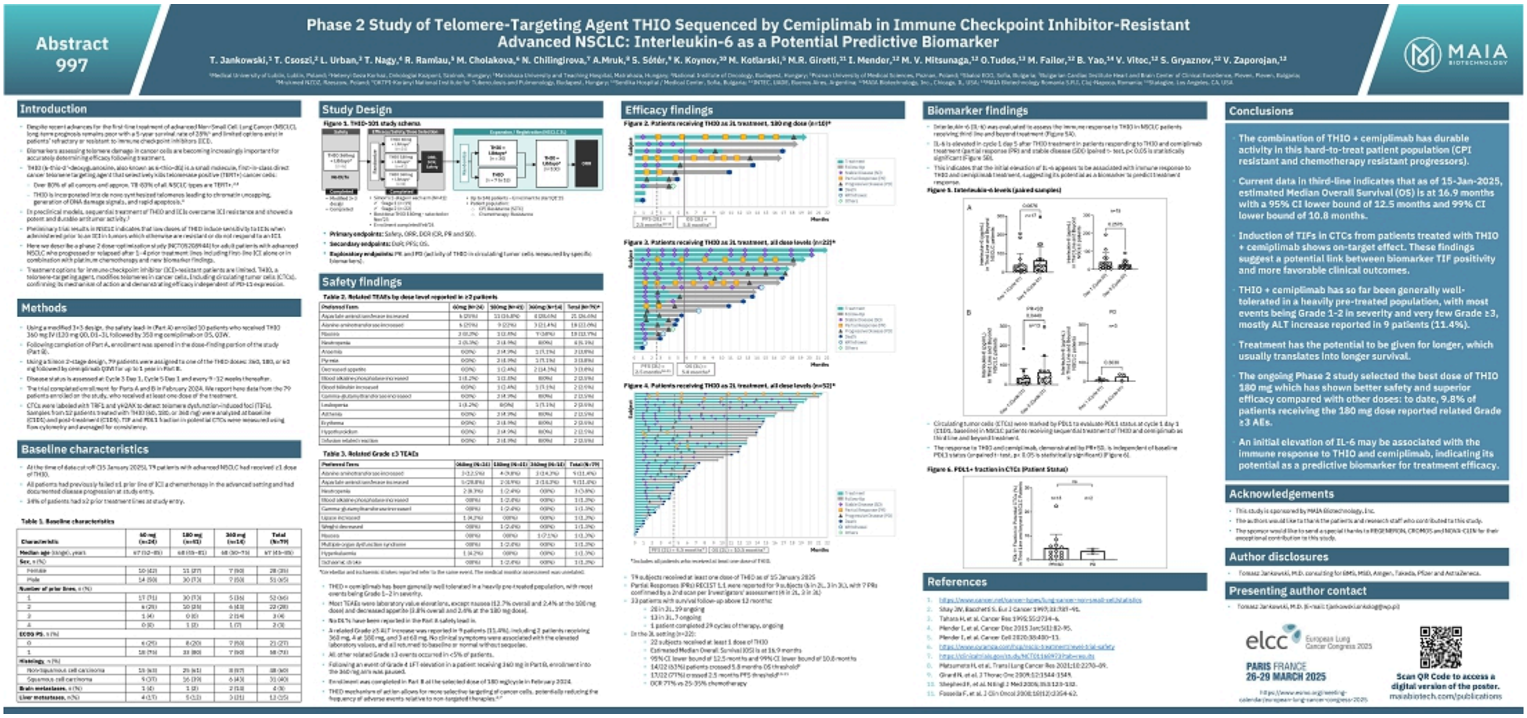
SIGNATURES

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: March 28, 2025

MAIA BIOTECHNOLOGY, INC.

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


Abstract 997
Phase 2 Study of Telomere-Targeting Agent THIO Sequenced by Cemiplimab in Immune Checkpoint Inhibitor-Resistant Advanced NSCLC: Interleukin-6 as a Potential Predictive Biomarker
T. Jankowski,1 T. Csoszi,2 L. Urban,3 T. Nagy,4 R. Ramlau,5 M. Cholakova,6 N. Chilingirova,7 A.Mruk,8 S. Sótér,9 K. Koynov,10 M. Kotlarski,5 M.R. Girotti,11 I. Mender,12 M. V. Mitsunaga,12 O.Tudos,13 M. Failor,12 B. Yao,14 V. Vitoc,12 S. Gryaznov,12 V. Zaporojan,12
MAIA BIOTECHNOLOGY
Introduction
Study Design
Figure 1. THIO-101 study schema
Primary endpoints: Safety, ORR, DCR (CR, PR and SD).
Secondary endpoints: DoR; PFS; OS.
Methods
Safety findings
Table 2. Related TEAEs by dose level reported in ≥2 patients
Table 3. Related Grade ≥3 TEAEs
Baseline characteristics
Table 1. Baseline characteristics
Efficacy findings
Figure 2. Patients receiving THIO as 3L treatment, 180 mg dose (n=10)*
Figure 3. Patients receiving THIO as 3L treatment, all dose levels (n=22)*
Figure 4. Patients receiving THIO as 3L treatment, all dose levels (n=53)*
Biomarker findings
Figure 5. Interleukin-6 levels (paired samples)
Figure 6. PDL1+ fraction in CTCs (Patient Status)
References
Conclusions
The combination of THIO + cemiplimab has durable activity in this hard-to-treat patient population (CPI resistant and chemotherapy resistant progressors).
Current data in third-line indicates that as of 15-Jan-2025, estimated Median Overall Survival (OS) is at 16.9 months with a 95% CI lower bound of 12.5 months and 99% CI lower bound of 10.8 months.
Induction of TIFs in CTCs from patients treated with THIO + cemiplimab shows on-target effect. These findings suggest a potential link between biomarker TIF positivity and more favorable clinical outcomes.
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%).
Treatment has the potential to be given for longer, which usually translates into longer survival.
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.
An initial elevation of IL-6 may be associated with the immune response to THIO and cemiplimab, indicating its potential as a predictive biomarker for treatment efficacy.
Acknowledgements
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The authors would like to thank the patients and research staff who contributed to this study.
Author disclosures
Presenting author contact
elcc European Lung Cancer Congress 2025
PARIS FRANCE
26-29 MARCH 2025
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