
**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): June 24, 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 June 24, 2025, the Company issued a press release announcing the appointment of additional members to its scientific advisory board. 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 June 24, 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: June 24, 2025

MAIA BIOTECHNOLOGY, INC.

By: /s/ Vlad Vitoc

Name: Vlad Vitoc

Title: Chief Executive Officer

MAIA Biotechnology Welcomes Leading Hepatocellular Carcinoma Clinician-Scientists to Scientific Advisory Board
Planning for Phase 2 clinical trial in hepatocellular carcinoma (HCC) underway

CHICAGO – June 24, 2025 – MAIA Biotechnology, Inc. (NYSE American: MAIA) (“MAIA”, the “Company”), a clinical-stage biopharmaceutical company focused on developing targeted immunotherapies for cancer, today announced the appointment of two prominent oncologists to its Scientific Advisory Board (SAB), Claudia Fulgenzi, MD, and David J. Pinato, MD, MRCP (UK), PhD. Both are specialists in hepatocellular carcinoma (HCC), a tumor type to be studied in future clinical trials of MAIA’s lead candidate ateganosine (THIO) sequenced with a checkpoint inhibitor.

As SAB members they will advise MAIA on designs and protocols for its company sponsored trial (CST) in HCC and may participate in future investigator sponsored trials (IST).

“Drs. Pinato and Fulgenzi are scientific experts on inflammation as a pathogenic and prognostic mechanism in primary liver cancers. Together, their research has focused on improving the treatment of HCC, particularly with the use of anti-cancer immunotherapy,” said MAIA Chairman and CEO Vlad Vitoc, M.D. “They will bring a wealth of knowledge to our SAB, with specialized expertise that will inform our plans and preparations for our upcoming clinical program in HCC.

“By the end of this year, we expect to have all required approvals to begin enrolling patients in a HCC trial,” Dr. Vitoc added.

MAIA was granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) for ateganosine as a treatment for HCC in 2022. ODDs can provide up to seven years of market exclusivity.

Dr. David Pinato is a clinician scientist in the Department of Surgery and Cancer at Imperial College London and a consultant oncologist at Imperial College Healthcare NHS Trust. As Director of Developmental Cancer Therapeutics at Imperial College, he leads a translational research program focused on the early clinical implementation of novel experimental anticancer therapies with particular emphasis on anti-cancer immunotherapy.

Dr. Pinato’s research efforts in liver cancer have been recognized by the American Society of Clinical Oncology (ASCO) and the Society for Immunotherapy of Cancer (SITC). He has received awards by the British Society of Pharmacology and the Royal Society of Medicine, and fellowships by the European School of Oncology and Fulbright Program.

Dr. Pinato completed his core medical training across some of the busiest acute hospitals in London and was elected to the Royal College of Physicians (MRCP). His research has been published in leading journals in the field including the Journal of Clinical Oncology, Annals of Oncology, Hepatology and many others. Dr. Pinato lectures internationally in the field of molecular oncology with a specific interest in HCC and acts as a reviewer for several peer-reviewed journals including The Lancet, Cancer Discovery, Hepatology and Journal of Hepatology.

Dr. Claudia Fulgenzi is a specialist in medical oncology at Imperial College London, with dedicated professional interest in the field of immune-oncology and gastro-intestinal cancers, particularly hepatic-biliary malignancies. Dr. Fulgenzi graduated in medicine from the University of Rome Tor Vergata and subsequently specialized in medical oncology at the University Campus Bio Medico of Rome, Italy. Her contributions to the field have been recognized with prestigious awards including the ASCO Merit Award, the Young Investigator award by the International Liver Cancer Association (ILCA) and the American Society of Clinical Oncology.

Dr. Fulgenzi is actively engaged in clinical practice in London, serving as an honorary consultant in oncology at Chelsea and Westminster Hospital and as a specialty doctor in the early phase clinical trial unit at Hammersmith Hospital. In these capacities, she conducts clinical and translational research, contributes to clinical trial design, and provides expert medical guidance to cancer patients.

Hepatocellular carcinoma is the most frequently occurring primary liver tumor representing approximately 90% of all liver cancers. HCC currently ranks 5th by incidence and 3rd by mortality on a global scale.

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 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.maiaibiotech.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.

Investor Relations Contact

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