

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

April 18, 2023

Date of Report (Date of earliest event reported)

MAIA Biotechnology, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

444 West Lake Street, Suite 1700
Chicago, IL

(Address of principal executive offices)

001-41455

(Commission File Number)

83-1495913

(IRS Employer
Identification No.)

60606

(Zip Code)

Registrant's telephone number, including area code: (312) 416-8592

N/A

(Former name or former address, if changed since last report)

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.

On April 18, 2023, MAIA Biotechnology, Inc. (the “Company”) issued a press release announcing positive preclinical study findings on THIO in hepatocellular carcinoma liver cancer models. Pursuant to Regulation FD, the press release is furnished with this Current Report as Exhibit 99.1.

The information set forth in Item 7.01 of this Current Report on Form 8-K and in the attached Exhibit 99.1 is deemed to be “furnished” and shall 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. The information set forth in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated as of April 18, 2023.
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 18, 2023

MAIA BIOTECHNOLOGY, INC.

By: /s/ Vlad Vitoc

Name: Vlad Vitoc

Title: Chief Executive Officer



MAIA Biotechnology Announces Excellent Efficacy of THIO in Liver Cancer Models

- Study showed THIO with complete and durable responses in Hepatocellular Carcinoma (HCC), the dominant histology in primary liver cancer (90%), in *in vivo* models
- When combined with immunotherapy checkpoint inhibitor (CPI), duration of response was further potentiated
- Administration of THIO alone and in combination with CPI generated anti-cancer immune memory
- Upon rechallenge with two times more cancer cells and no additional treatment, tumor growth was completely prevented

CHICAGO, IL – April 18, 2023 – MAIA Biotechnology, Inc. (NYSE American: MAIA) today announced the peer-reviewed publication of an original research article in this month’s issue of *Molecular Cancer Therapeutics* (volume 22, issue 4), the renowned American Association of Cancer Research (AACR) journal that publishes translational research studies focused on the discovery and preclinical development of therapeutic agents for oncology. The preclinical study, entitled “Activating an Adaptive Immune Response with a Telomerase-Mediated Telomere Targeting Therapeutic in Hepatocellular Carcinoma,” showed highly potent anticancer activity of THIO in multiple HCC preclinical models.

The study revealed the anti-tumor immune response role of THIO as a telomere targeting therapeutic in HCC models. THIO induces telomere damage and activates the cGAS-STING pathway, which is a major intracellular signaling pathway that plays a role in innate immune responses. THIO enhances the cross-priming capacity of dendritic cells (DCs), which are antigen presenting cells of the adaptive immune system, and activates tumor specific T cells. Observed potent anticancer activity is taking place in CD8-positive T cell dependent manner. Moreover, the study showed a potential role of immunogenic protein molecule HMGB1 (high-mobility group box 1, which are released during cancer cell death), in THIO induced T cell activation. In addition, the study demonstrated enhanced efficacy and durability of complete tumor regression when THIO is followed by administration of immunotherapies (an



anti-PD-1 or anti-PD-L1) and anti-VEGF (anti-vascular endothelial growth factor, one of the major anti-angiogenic drug target) in advanced, resistant HCC tumors providing a strong scientific rationale for a clinical trial in HCC.

“The knowledge gained from this study will help support our understanding of the compound’s mechanism of action and its broad therapeutic utility. Moreover, this publication strengthens our scientific rationale already included in our current clinical development plan for THIO-102, a Phase 2 clinical study in multiple solid tumor indications, including HCC,” said MAIA’s Chief Scientific Officer Sergei Gryaznov, Ph.D.

“The findings from our study provides solid rationale for THIO to be evaluated as a treatment of liver cancer, as our Company already holds the US FDA Orphan Drug Designation for this clinical indication. This published evidence supports our strong belief that THIO, especially in combination with immune checkpoint inhibitors and other standard of care agents, may be clinically studied for treatment of various forms of cancer,” added Vlad Vitoc, M.D., MAIA’s Chief Executive Officer.

The full results are available in *Molecular Cancer Therapeutics* and online [here](#).

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. Its lead program is 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 of 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 Inquiries

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