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 20, 2023
Date of Report (Date of earliest event reported)

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)

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 20, 2023, MAIA Biotechnology, Inc. (the "Company") issued a press release announcing preliminary survival data in the Part A safety lead-in of its ongoing phase 2 trial, THIO-101 evaluating THIO in patients with advanced Non-Small Cell Lung Cancer (NSCLC). 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:

Exhibit No.	Description
99.1	Press release, dated as of April 20, 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 20, 2023

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Biotechnology Reports Preliminary Survival Data in Part A of THIO-101 Phase 2 Trial for Non-Small Cell Lung Cancer

CHICAGO – April 20, 2023 – MAIA Biotechnology, Inc. (NYSE American: MAIA) today announced preliminary survival data in the Part A safety lead-in of its ongoing phase 2 trial, THIO-101 evaluating THIO in patients with advanced Non-Small Cell Lung Cancer (NSCLC).

The first 2 patients enrolled in Part A of the study continue to be alive, approximately 10 and 9 months respectively, from treatment initiation. Both patients have advanced Stage IV metastatic disease and are heavily pretreated, receiving third and fourth line of therapy respectively after previously failing treatment with an immune checkpoint inhibitor.

As previously reported, the first 6 evaluable patients in Part A of THIO-101 cleared the THIO high dose (THIO 360 mg per cycle (120 mg on Days 1-3 Q3W) followed by the standard 350 mg dose of cemiplimab on Day 5) with no dose limiting toxicities. Treatment has been generally well tolerated and enrollment is underway in Part B. As of now, the first 2 patients continue to be progression free following their last dose, 7 and 6 months respectively, with no new treatment.

“The current treatment options in patients with advanced relapsed or refractory NSCLC who failed two or more therapy regimens are limited and show minimal benefit. Furthermore, discontinuation of treatment is rapidly followed by physical decline and death, therefore seeing patients with such survival and no disease progression in this clinical setting, is noteworthy” says MAIA’s Chief Medical Officer Mihail Obrocea.

“This observation may correlate well with the evidence of induction of innate and adaptive immune responses seen in the preclinical models of lung cancer, where only three doses of THIO followed by an immune checkpoint inhibitor resulted in long-lasting complete tumor regression with no recurrence,” says MAIA’s Chief Scientific Officer, Sergei Gryaznov.

“In real-world clinical practice, observed survival in such heavily pretreated patients is 3-4 months. These preliminary survival results are very encouraging for patients with lung cancer,” added Vlad Vitoc, MAIA’s Chief Executive Officer.

About THIO-101, a Phase 2 Clinical Trial
THIO-101 is a multicenter, open-label, dosing finding Phase 2 clinical trial. It is the first trial designed to evaluate THIO's potential immune system activation effects in NSCLC patients by administering THIO in advance of administration of an immune checkpoint inhibitor allowing for immune activation and PD-1 sensitivity to take effect. The trial will test the hypothesis that low doses of THIO administered prior to a checkpoint inhibitor will enhance and prolong immune response in patients with advanced NSCLC who previously did not respond or developed resistance and progressed after first-line treatment regimen containing another checkpoint inhibitor. The trial design has two primary objectives: (1) to evaluate the safety and tolerability of THIO administered as an anticancer agent and a priming immune system agent (2) to assess the clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. For more information on this Phase II trial, please visit ClinicalTrials.gov using the identifier NCT05208944.

About THIO
THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a telomere-targeting agent currently in clinical development to evaluate its activity in non-small cell lung cancer (NSCLC), in sequential administration with Regeneron's anti-PD1 therapy, Libtayo® (cemiplimab). Telomeres play a fundamental role in the survival of cancer cells and their resistance to current therapies. THIO is being 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. 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 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.

Contacts
Investor Inquiries
MAIA Biotechnology
Joseph McGuire
Chief Financial Officer
jmcguire@maiabiotech.com
904-228-2603
ICR Westwicke
Stephanie Carrington
Stephanie.carrington@westwicke.com
646-277-1282