UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K/A
(Amendment No. 1)

Current Report
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

February 13, 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. □

Explanatory Note

On February 13, 2023, MAIA Biotechnology, Inc. (the "Company") filed a Current Report on Form 8-K to furnish a copy of the Company's press release announcing its intention to initiate its second Phase 2 clinical trial evaluating THIO. On the same day, the Company updated the press release to include an additional model with pre-clinical data. This amended Current Report on Form 8-K is being filed solely to furnish the updated press release.

Item 7.01. Regulation FD Disclosure.

On February 13, 2023, MAIA Biotechnology, Inc. (the "Company") issued a press release announcing its intention to initiate its second Phase 2 clinical trial evaluating THIO. 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 February 13, 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: February 13, 2023

MAIA BIOTECHNOLOGY, INC.

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

444 West Lake Street, Suite 1700 | Chicago, IL 60606, USA
www.maiabiotech.com | +1 (312) 416-8592 main

MAIA BIOTECHNOLOGY'S TELOMERE-TARGETING AGENT THIO, IN COMBINATION WITH CHECKPOINT INHIBITOR IMMUNE THERAPIES ATEZOLIZUMAB (ANTI-PD-L1) OR PEMBROLIZUMAB (ANTI-PD-1), DEMONSTRATED SIGNIFICANTLY GREATER TUMOR INHIBITION

- **MAIA Intends to initiate its second Phase 2 go-to-market trial – THIO-102 - evaluating THIO with atezolizumab, pembrolizumab and other checkpoint inhibitors in multiple tumor types, including small cell lung cancer, liver cancer and colorectal cancer**

February 13, 2023, CHICAGO-- MAIA Biotechnology, Inc. (NYSE American: MAIA) announced today it intends to initiate its second Phase 2 go-to-market trial evaluating THIO, the world's first telomere-targeting agent, in patients with four cancer indications. The FDA has awarded MAIA's lead anti-cancer agent THIO two Orphan Drug Designations, based on the preclinical efficacy data, for liver (hepatocellular carcinoma) and small cell lung cancer models. The trial is designed to evaluate THIO in sequential combination with the immunotherapies pembrolizumab or atezolizumab, which are the most used checkpoint inhibitors in Oncology. A third immunotherapy checkpoint inhibitor could be added later such as nivolumab, durvalumab, dostarlimab, etc.

The trial previously demonstrated positive and encouraging preclinical results in colorectal, liver, and small cell lung cancer models.

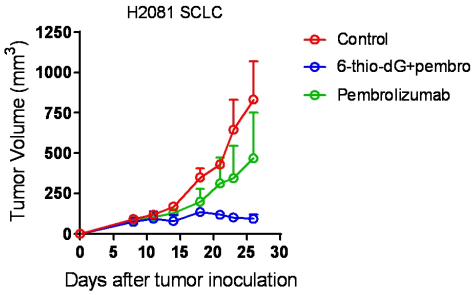

Figure Legend:
THIO (6-thio-dG) is synergistic with anti-PD-1 agent pembrolizumab in Small Cell Lung Carcinoma (SCLC) *in vivo* in humanized murine cancer model. Treatment with THIO sequentially followed by pembrolizumab results in highly potent anticancer effect, as compared to the effects of pembrolizumab alone.

THIO converts immunologically “cold” non-responsive SCLC tumor into “hot” and responsive to pembrolizumab.

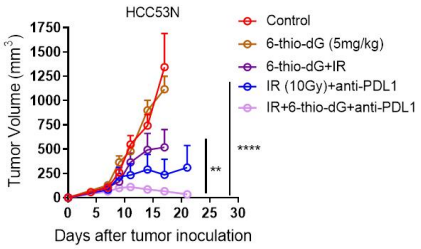

Figure Legend:
THIO is highly synergistic and effective in combination with anti-PD-L1 agent atezolizumab and Ionizing Radiation (IR) in HCC53N cell-based model of Hepatocellular Carcinoma (HCC).

THIO in Colorectal Cancer (CRC) model

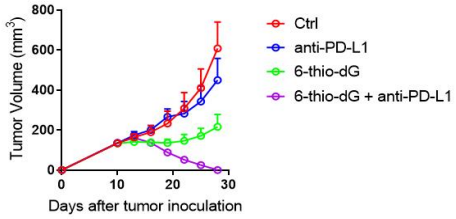

Figure Legend:
THIO (6-thio-dG) is highly synergistic and curative with anti-PD-L1 agent atezolizumab in MC 38 cell-based syngeneic model of Colorectal Cancer (CRC). Treatment with THIO sequentially followed by atezolizumab results in highly potent anticancer effect, as compared to the effects of atezolizumab alone. THIO administration converts immunologically “cold non-responsive” CRC tumor into “hot and responsive to anti-PD-L1 agent atezolizumab”.

Treatment with THIO in combination with IR and atezolizumab has shown results of complete regression of aggressive HCC tumors. At the same time, the combination of IR and atezolizumab is just partially efficacious.

“The THIO-102 trial is operationally on track to begin enrolling patients later this year,” said Mihail Obrocea, MD, MAIA’s Chief Medical Officer. “Based on the data generated on these indications, we are targeting accelerated approvals in these tumor types; in addition, we have now added a fourth arm which includes solid tumors of all types, that will serve as a signal generation arm; we will include telomerase positive breast, prostate, gastric, pancreatic, ovarian, along with potentially other tumor types.”

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“These are patients that are facing very limited treatment options, usually chemotherapy with minimal efficacy and high toxicity,” said MAIA Chairman and Chief Executive Officer Vlad Vitoc, M.D. “THIO sequenced with an immune checkpoint inhibitor has demonstrated complete tumor regression in several cancer preclinical models. We believe that THIO can substantially improve on the limited clinical efficacy shown so far by atezolizumab, pembrolizumab and others. This go-to-market trial - THIO 102 - may provide THIO with more than 9 additional indications. Our existing trial with non-small cell lung cancer is another indication, potentially giving THIO more than 10 indications in total. Most oncology compounds at this stage of development have only one. We have 10 shots on goal!”

About THIO-102

THIO-102 is an upcoming multicenter, open-label, go-to-market Phase 2 trial designed to evaluate the safety and efficacy of THIO administered in sequence with anti-PD-1 or anti-PD-L1 in patients with telomerase (+) tumors. Following an innovative basket/umbrella design, the trial is comprised of four baskets: small cell lung cancer, liver, colorectal, and solid tumors all types. The first basket is in first line treatment of small cell lung cancer, where MAIA plans to evaluate THIO added to the current standard of care, EP + atezolizumab. In the remaining arms, MAIA plans to evaluate THIO in sequential combination with atezolizumab or pembrolizumab; the objective is to select the best combination by tumor type in Part A and expand into Part B that will include multiple Phase 2 pivotal arms seeking accelerated approvals.

About THIO
THIO is a telomere-targeting agent currently in clinical development to evaluate its activity in non-small cell lung cancer (NSCLC). 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 higher 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 clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer. The Company's lead program is THIO, a potential first-in-class cancer telomere targeting agent in clinical development for the treatment of patients with telomerase-positive cancers. For more information, please visit www.maiabiotech.com.

Forward Looking Statements
This press release includes forward-looking statements including, but not limited to, statements related to the closing of the offering and the expected use of proceeds, development of drug candidates, our operations and business strategy, our expected financial results, and corporate updates. The forward-looking statements contained in this press release are based on management's current expectations and are subject to substantial risks, uncertainty and changes in circumstances. Actual results may differ materially from those expressed by these expectations due to risks and uncertainties, including, among others, those related to our ability to obtain additional capital on favorable terms to us, or at all, including, without limitation, to fund our current and future preclinical studies and clinical trials and the success, timing and cost of our drug development program and our ongoing or future preclinical studies and clinical trials, including, without limitation, the possibility of unfavorable new clinical and preclinical data and additional analyses of existing data, that the risks that prior clinical and preclinical results may not be replicated, and risks associated with the current coronavirus pandemic. Forward-looking statements speak only as of the date of this press release, and we undertake no obligation to review or update any forward-looking statement except as may be required by applicable law.

Investor Inquiries

MAIA Biotechnology
Joe McGuire
Chief Financial Officer
jmcguire@maiabiotech.com
904-228-2603

ICR Westwicke
Stephanie Carrington
Stephanie.carrington@westwicke.com
646-277-1282
Source: MAIA Biotechnology, Inc.