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

August 8, 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 2.02. Results of Operations and Financial Condition.

On August 8, 2023, MAIA Biotechnology, Inc. (the "Company") issued a press release announcing its results of operations for the quarter ended June 30, 2023, attached hereto as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure.

Press Release

As disclosed in Item 2.02 above, on August 8, 2023, the Company issued a press release announcing its results of operations for the quarter ended June 30, 2023, attached hereto as Exhibit 99.1.

The information set forth in Items 2.02 and 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 Items 2.02 and 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.

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. 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. 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 August 8, 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: August 8, 2023

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Biotechnology Reports Second Quarter 2023 Financial Results and Provides Updates for THIO-101 Phase 2 Trial for Non-Small Cell Lung Cancer

- Filed second provisional new composition of matter patent application for MAIA's third entirely home-grown telomere-targeting molecule
- Reported 35 patients enrolled as of July 2023 in THIO-101 Phase 2 Trial
- First 2 patients dosed with THIO continue to be without documented disease progression for 12.2 and 11.5 months, and remarkably without any new anti-cancer treatment 10.2 and 8.5 months after concluding treatment with THIO, most patients only live for 3-4 months in similar heavily pretreated conditions
- Announced preliminary disease control rate (DCR) of 82%, with 9 of the first 11 patients with post-baseline scans meeting the disease control primary endpoint at first response assessment, typical DCRs are in the 25-35% range for chemotherapy
- Celebrated its 5th anniversary since being founded on August 3rd, 2018

CHICAGO, IL – August 8, 2023—MAIA Biotechnology, Inc., (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today reported financial results for the second quarter ended June 30, 2023, and provided a corporate update.

"We recently reached an important milestone in the THIO-101 phase 2 trial, with our first patients dosed in the trial crossing the 1 year mark since starting therapy with THIO followed by an immune checkpoint inhibitor, without any additional cancer treatment. These positive preliminary results align well with our preclinical data and supported a faster pace of enrollment in the last quarter in Europe as we continue to activate more sites," said Vlad Vitoc, M.D., MAIA's Chairman and Chief Executive Officer. "In addition to THIO, we have 3 proprietary home-grown telomere-targeting molecules patented which further expands our options to treat several cancer indications. For the second half of the year, we look forward to continue evolving in the Part B randomized efficacy/dose selection of THIO-101."

Corporate Highlights

Reported second broad provisional patent application, nominating MAIA-2021-029 as the third new molecular candidate in MAIA's Telomere-Targeting Molecule Program: MAIA is creating and evaluating multiple telomere-targeting compounds designed to modify the telomeric structure through the cancer cell intrinsic telomerase activity and cause the death of these cells. The studies, conducted in vitro in multiple cancer cell lines and in vivo in several pre-clinical cancer models, demonstrated the intended mechanism of action and high-level anti-cancer activity for these new molecules.

Announced updates in enrollment in THIO-101 Phase 2 clinical trial: As of July 2023, announced that 35 patients have been dosed in MAIA's Phase 2 clinical trial, THIO-101, evaluating THIO in patients with advanced Non-Small Cell Lung Cancer (NSCLC). With the addition of sites in Hungary, Poland, and Bulgaria in March 2023, THIO-101 has rapidly increased the number of patients enrolled and dosed with THIO.

Reported positive updates on preliminary survival data for THIO-101: As of July 2023, the first 2 patients dosed with THIO continue to be alive for approximately 12.2 and 11.5 months respectively, from treatment initiation. They have remained free of disease progression for 10.2 and 8.5 months, respectively, without requiring any additional therapy.

Reported updates on disease control rates for THIO-101 Phase 2 trial for advanced Non-Small Cell Lung Cancer: As of July 2023, out of the first 11 patients with post-baseline scans, 82% (9 patients) met the disease control primary endpoint (defined as a complete response, partial response, or stable disease per RECIST 1.1) at first response assessment. In similar heavily treated NSCLC patients, typical disease control rates (DCR) are in the 25-35% range. All patients enrolled had previously failed 2 or more prior lines of treatment including an immune checkpoint inhibitor (CPI) and platinum-based chemotherapy for advanced NSCLC. No new safety analysis was conducted at the time.

Second Quarter 2023 Financial Results

Cash Position: The Company had cash totaling approximately $9.1 million as of June 30, 2023, compared to $8.2 million in cash as of June 30, 2022.

Research and Development (R&D) Expenses: R&D expenses were approximately $2.6 million for the quarter ended June 30, 2023, compared to approximately $2.1 million for quarter ended June 30, 2022. The increase was primarily related to an increase in scientific research expenses of approximately $0.44 million, an increase in payroll and bonus expenses of approximately $0.20 million related to the increased headcount of additional research and development employees, an increase in stock-based compensation costs of approximately $0.06 million and an increase of approximately $0.03 million in other expenses offset by a decrease in Clinical and Scientific research expenses of approximately $0.21 million due to less THIO-101 trial start-up fees, and a decrease in consulting of approximately $0.04 million.

General and Administrative (G&A) Expenses: G&A expenses were approximately $2.0 million for the quarter ended June 30, 2023, compared to approximately $1.3 million for the quarter ended June 30, 2022. The increase for the quarter was primarily due to an increase in other expenses of approximately $0.73 million related to the costs of operating as a public company, and an increase in payroll expense of approximately $0.13 million, offset by a decrease in stock-based compensation of approximately $0.02 million and professional fees of approximately $0.09 million.

Other Income (Expense): Other income was approximately $0.14 million for the quarter ended June 30, 2023, and other income for the quarter ended June 30, 2022 was approximately $0.14 million. The quarterly activity included a gain from the change in the fair value of the warrant liability of approximately $0.10 million offset by a reduction in the Australia research and development incentives of approximately $0.10 million and an increase in interest expense of approximately $0.002 million.

Net Income (Loss): Net loss was approximately $4.5 million for the quarter ended June 30, 2023, as compared to net loss of approximately $3.3 million for the quarter ended June 30, 2022.

About THIO

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is an 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. 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 THIO-101, a Phase 2 Clinical Trial

THIO-101 is a multicenter, open-label, dose 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 sequential combination an anti-PD1 therapy, 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 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 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 factscontained 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 Inquiries

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