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

May 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 May 8, 2023, MAIA Biotechnology, Inc. (the "Company") issued a press release announcing its results of operations for the quarter ended March 31, 2023, attached hereto as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure.

Press Release

As disclosed in Item 2.02 above, on May 8, 2023, the Company issued a press release announcing its results of operations for the quarter ended March 31, 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 May 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: May 8, 2023

MAIA BIOTECHNOLOGY, INC.

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

MAIA Biotechnology Reports First Quarter 2023 Financial Results and Provides Corporate Update

- Reported positive topline data from the completed Part A safety lead-in of the THIO-101 Phase 2 go-to-market trial in advanced Non-Small Cell Lung Cancer (NSCLC) and commenced recruitment in Part B randomized efficacy/dose selection
- Outlined preliminary safety data from Part A survival safety data from THIO-101 with first two enrolled patients alive after approximately 10 and 9 months post treatment initiation, respectively
- Reported strong efficacy of THIO in liver in vivo cancer models; study showed THIO with complete and durable responses in Hepatocellular Carcinoma (HCC), the dominant histology of primary liver cancer (90%),
- Raised approximately $5.75 million in gross proceeds from public offering of 2,555,500 shares of common stock at a public offering price of $2.25 per share

CHICAGO – May 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 first quarter ended March 31, 2023, and provided a corporate update.

“We are thrilled with the advancement of the THIO-101 trial, inclusive of reporting the positive topline data and preliminary survival data from the completed Part A safety lead-in of our ongoing phase 2 trial,” said Vlad Vitoc, M.D., MAIA’s Chairman and Chief Executive Officer. “The clinical activity seen with THIO thus far, in addition to its favorable safety and efficacy profiles, puts us one step closer to our goal of treating NSCLC and liver cancer. Additionally, we are proud to have strengthened our balance sheet by completing the follow-on offering. As we progress through the year, we look forward to our plan to share the safety data from Part B randomized efficacy/dose selection and receive IND clearance in the U.S.”

Corporate Highlights

Reported positive topline data from the completed Part A safety lead-in of the THIO-101 Phase 2 go-to-market trial in advanced Non-Small Cell Lung Cancer (NSCLC) and commenced recruitment in Part B randomized efficacy/dose selection: Topline data from Part A demonstrated that MAIA’s telomere-targeting agent, THIO, administered in sequential combination with Regeneron’s anti-PD-1 therapy, Libtayo® (cemiplimab), were generally well-tolerated.

Reported preliminary survival data in Part A of THIO-101 Phase 2 trial for Non-Small Cell Lung Cancer: As of April 2023, the first two patients enrolled in Part A continued 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.

Reported strong efficacy of THIO in liver in vivo cancer models: Study showed THIO with complete and durable responses in Hepatocellular Carcinoma (HCC), which is the dominant histology in primary liver cancer (90%). When combined with immunotherapy checkpoint inhibitor (CPI), the 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.

Closed common stock public offering: Raised gross proceeds of approximately $5.75 million, before deducting underwriting discounts and offering expenses, in a public offering of 2,555,500 shares of common stock at a public offering price of $2.25 per share.

First Quarter 2023 Financial Results

Cash Position: The Company had cash totaling approximately $7.6 million as of March 31, 2023, compared to $10.9 million in cash as of March 31, 2022. The amount as of March 31, 2023 does not include the net proceeds from the public offering of shares of common stock received subsequent to quarter end.

Research and Development (R&D) Expenses: R&D expenses were approximately $2.2 million for the quarter ended March 31, 2023, compared to approximately $2.1 million for quarter ended March 31, 2022. The increase was primarily related to an increase in payroll and bonus expenses of approximately $0.46 million related to the increased headcount of additional research and development employees offset by a decrease in Clinical and Scientific research fees of approximately $0.23 million due less THIO-101 trial start-up fees, and a decrease in consulting and other fees of approximately $0.12 million. R&D expenses included approximately $0.3 million and $0.3 million of non-cash stock compensation expense in the first quarter of 2023 and 2022, respectively.

General and Administrative (G&A) Expenses: G&A expenses were approximately $2.0 million for the quarter ended March 31, 2023, compared to approximately $1.4 million for the quarter ended March 31, 2022. The increase for the quarter was primarily due to approximate increases in payroll and bonus expenses of $0.3 million, an increase of approximately $0.6 million of other expenses related to the costs of operating as a public company, offset by a decrease in stock-based compensation of approximately $0.2 million and professional fees of approximately $0.1 million. G&A expenses included approximately $0.3 million and $0.4 million of non-cash stock compensation expense in the quarters ended March 31, 2023, and 2022, respectively.

Other Income (Expense): Other income was approximately $0.07 million for the quarter ended March 31, 2023, and other expense for the quarter ended March 31, 2022 was approximately $0.03 million. The increase was primarily related to increases in the Australia research and development incentives of approximately $0.02 million and a gain on the change in the fair value of the warrant liability of approximately $0.02 million, offset by increases to interest expense of approximately $0.005 million.

Net Income (Loss): Net loss was approximately $4.1 million for the quarter ended March 31, 2023, as compared to net loss of approximately $3.9 million for the quarter ended March 31, 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 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 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.

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