

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

March 24, 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)
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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 March 24, 2023, MAIA Biotechnology, Inc. (the “Company”) issued a press release announcing its results of operations for the year ended December 31, 2022, attached hereto as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure.

Press Release

As disclosed in Item 2.02 above, on March 24, 2023, the Company issued a press release announcing its results of operations for the year ended December 31, 2022, 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 March 24, 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: March 24, 2023

MAIA BIOTECHNOLOGY, INC.

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



MAIA Biotechnology Reports Full Year 2022 Financial Results and Provides Corporate Update

- Patient enrollment underway in Europe in ongoing Phase 2 trial in NSCLC (THIO-101)
- Outlined plan to initiate second Phase 2 Go-To-Market trial (THIO-102)
- Presented preclinical data validating efficacy of THIO in hepatocellular carcinoma at SITC Annual Meeting
- Held pre-IND meeting with FDA for planned U.S. expansion of THIO
- Advanced new telomere-targeting molecule program

CHICAGO – March 24, 2023 -- **MAIA Biotechnology, Inc.**, (NYSE: MAIA) (“MAIA”, the “Company”), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today reported financial results for the full year ended December 31, 2022, and provided a corporate update.

“We are very pleased with the progress MAIA has made in recent months, including but not limited to, expanding the THIO-101 trial to Europe and outlining the plan to initiate the Company’s second go-to-market trial for THIO-102,” said Vlad Vitoc, M.D., MAIA’s Chairman and Chief Executive Officer. “As we head into 2023, we remain excited to share the safety data from Part A of the THIO-101 trial, advance patient enrollment at sites in Europe, and seek to receive IND clearance in the U.S.”

Corporate Highlights

Dosed first two patients in Europe in ongoing Phase 2 trial (THIO-101): Dosing has commenced in Europe in MAIA’s Phase 2 clinical trial, THIO-101, evaluating THIO in patients with advanced Non-Small Cell Lung Cancer (NSCLC).

Outlined plan to initiate second Phase 2 go-to-market trial (THIO-102): MAIA is planning to conduct a second Phase 2 trial to evaluate THIO in sequential combination with the immunotherapies pembrolizumab or atezolizumab, which are the most used checkpoint inhibitors in oncology. The Company has demonstrated encouraging preclinical results in colorectal, liver, and small cell lung cancer models.

Presented preclinical data validating efficacy of THIO in hepatocellular carcinoma (HCC) at Society for Immunotherapy of Cancer’s 37th Annual Meeting: Conducted an oral presentation, which indicated that THIO, a first-in-class telomere-targeted agent, may enhance the overall therapeutic efficacy of current immune checkpoint inhibitor-based treatments for HCC.

Expanded Phase 2 THIO-101 trial to Europe: Regulatory authorities in three European countries, Hungary, Poland, and Bulgaria, approved the implementation of THIO-101.

Held Pre-IND meeting with FDA for planned U.S. expansion of THIO-101 Phase 2 Trial for NSCLC: MAIA received positive initial feedback from the FDA regarding its manufacturing, preclinical, and clinical development plan. MAIA also obtained guidance from the FDA on the assessment of its safety and efficacy in THIO-101, which will be incorporated in the U.S. IND application.

Advanced new telomere-targeting molecule program: MAIA is designing and evaluating multiple telomere-targeting compounds designed to modify the telomeric structure through the cancer cell - intrinsic telomerase activity, and thus 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.



Full Year 2022 Financial Results

Cash Position: The Company had cash totaling approximately \$10.9 million as of December 31, 2022, compared to \$10.6 million in cash as of December 31, 2021.

Research and Development (R&D) Expenses: R&D expenses were approximately \$8.9 million for the year ended December 31, 2022, compared to approximately \$3.5 million for year ended December 31, 2021. The increase for the year was primarily due to the increase in clinical expenses related to clinical preparation and the startup of the THIO trials of approximately \$3.1 million, an increase in payroll and bonus expenses of approximately \$2.2 million, an increase in other expenses related to research and development of approximately \$0.1 million and an increase of approximately \$0.02 million in professional fees offset by a decrease in stock-based compensation of approximately \$0.05 million. R&D expenses included approximately \$0.9 million and \$0.9 million of non-cash stock compensation expense in the year 2022 and 2021, respectively.

General and Administrative (G&A) Expenses: G&A expenses were approximately \$6.1 million for the year ended December 31, 2022, compared to approximately \$4.3 million for the year ended December 31, 2021. The increase for the year was primarily due to approximate increases in payroll and bonus expenses of \$0.9 million, an increase of approximately \$0.9 million of other expenses related to the costs of operating as a public company, an increase in professional fees of approximately \$0.3 million offset by a decrease in stock-based compensation of approximately \$0.3 million. G&A expenses included approximately \$1.4 million and \$1.8 million of non-cash stock compensation expense in the years ended December 31, 2022, and 2021, respectively. In addition, ratchet share expense was approximately \$1.1 million for the year ended December 31, 2022, compared to no expense for the year ended December 31, 2021.

Other Income (Expense): Other income was approximately \$0.4 million for the year ended December 31, 2022, and other expense for the year ended December 31, 2021 was approximately \$4.8 million. Other income in the year ended December 31, 2022, consisted primarily of approximately \$0.3 million in Australian research and development incentives and approximately \$0.1 million of the change in the fair values of warrant liability. Other expense for the year ended December 31, 2021 primarily consisted of interest expense for convertible notes of approximately \$0.8 million, expense for the change in the fair values of the warrant liability of approximately \$1.5 million, expense for the change in the fair value of the bifurcated embedded features of approximately \$0.2 million, and the loss on extinguishment of convertible notes of approximately \$2.3 million.

Net Income (Loss): Net loss was approximately \$15.7 million for the year ended December 31, 2022, as compared to net loss of approximately \$12.6 million for the year ended December 31, 2021.

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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