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 22, 2022
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 22, 2022, MAIA Biotechnology, Inc. (the "Company") issued a press release announcing its results of operations for the quarter ended June 30, 2022, attached hereto as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure.

Press Release and Supplemental Information

As disclosed in Item 2.02 above, on August 22, 2022, the Company issued a press release announcing its results of operations for the quarter ended June 30, 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 August 22, 2022.
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 22, 2022

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA Biotechnology Reports Second Quarter 2022 Financial Results and Provides Corporate Update

CHICAGO – August 22, 2022 -- **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, 2022, and provided a corporate update.

"We continue to make significant progress with advancing the clinical development of THIO. We recently dosed the first patient in our Phase 2 clinical trial for NSCLC, THIO-101, for Non-Small Cell Lung Cancer. We have received orphan drug designation from the FDA for two other oncology indications - SCLC and HCC," said Vlad Vitoc, M.D., MAIA's Chairman and Chief Executive Officer.

"We are thrilled to have recently strengthened our balance sheet with the completion of our July IPO and continue to maintain no long-term debt," stated Joe McGuire, MAIA's Chief Financial Officer.

Corporate Highlights

FDA Orphan Drug Designation for THIO for SCLC: The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to THIO, a telomere-targeting agent currently in development to evaluate its activity in NSCLC cancer indications, for the treatment of small-cell lung cancer (SCLC).

First patient dosed in Phase 2 trial in NSCLC: The first patient has been dosed in MAIA's Phase 2 clinical trial, THIO-101, evaluating the administration of THIO in sequence with cemiplimab in patients with advanced Non-Small Cell Lung Cancer (NSCLC). The trial designed to evaluate THIO's anticancer activity and potential immune system activation effects in NSCLC patients by administering THIO in advance of the checkpoint inhibitor cemiplimab (developed by Regeneron), allowing for patient immune system activation and PD-1 sensitivity to take effect.

Research collaboration with Nationwide Children's Hospital: MAIA has entered into a research and collaboration agreement with the Nationwide Children's Hospital to evaluate the potential of THIO in combination with current standard-of-care therapies for brain cancer. The organizations will conduct preclinical studies to assess the efficacy and safety of THIO in combination with radiotherapy and immune checkpoint inhibitors in vitro and in vivo models.

FDA Orphan Drug Designation for THIO for HCC: The FDA has granted ODD to THIO for the treatment of hepatocellular carcinoma (HCC).

Wholly owned subsidiaries established to support global development of THIO: MAIA established two wholly owned subsidiaries in Romania and Australia to broaden and accelerate its global development plan for THIO.

Initial public offering (IPO): MAIA completed its IPO on August 1st and has commenced trading on the NYSE American under the ticker symbol "MAIA." The gross proceeds from the initial public offering and the exercise of the overallotment option were $11.5 million prior to deducting underwriting discounts, commissions, and other offering expenses.

Second Quarter 2022 Financial Results

Cash Position: The Company had cash totaling $8.2 million as of June 30, 2022, compared to $10.6 million in cash as of December 31, 2021. Current cash with proceeds from the initial public offering is anticipated to be sufficient to fund operations for the next 24 months.

Research and Development (R&D) Expenses: R&D expenses were approximately $2.1 million for the quarter ended June 30, 2022, compared to approximately $0.6 million for the same quarter of 2021. The increase for the quarter was primarily due to the increase in clinical expenses related to clinical preparation and the startup of the THIO trials of approximately $1.0 million, an increase in payroll and bonus expenses of approximately $0.6 million, offset by a decrease in stock-based compensation of approximately $0.1 million. R&D expenses included approximately $0.2 million and $0.3 million of non-cash stock compensation expense in the second quarter 2022 and 2021, respectively.

General and Administrative (G&A) Expenses: G&A expenses were approximately $1.3 million for the quarter ended June 30, 2022, compared to approximately $0.9 million for the same quarter of 2021. The increase for the quarter was primarily due to approximate increases in payroll and bonus expenses of $0.2 million, professional fees of $0.2 million, and other general fees of $0.1 million, offset by a decrease in stock-based compensation of approximately $0.1 million. G&A expenses included approximately $0.4 million and $0.4 million of non-cash stock compensation expense in the quarters ended June 30, 2022, and 2021, respectively.

Other Income (Expense): Other income was approximately $0.1 million for the quarter ended June 30, 2022, and other expense for the quarter ended June 30, 2021, was approximately $2.0 million. Other income in the quarter ended June 30, 2022, consisted primarily of approximately $0.1 million in Australian research and development incentives. Other expense for the quarter ended June 30, 2021, primarily consisted of interest expense of approximately $0.3 million, the change in the fair values of the warrant liability of approximately $1.6 million, and the change in the fair value of the bifurcated embedded features of approximately $0.1 million.

Net Income (Loss): Net loss was approximately $3.3 million for the quarter ended June 30, 2022, as compared to net loss of approximately $3.5 million for the same quarter of 2021.

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). 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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