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

Date of Report (Date of earliest event reported): March 5, 2024

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)**

(312) 416-8592
(Registrant's telephone number, including area code)

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 8.01 Other Events.

On March 5, 2024, MAIA Biotechnology, Inc. (the "Company") issued a 2024 Letter to Shareholders detailing the Company's immuno-oncology cancer treatment candidates and development pipeline.

A copy of the 2024 Letter to Shareholders is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On March 5, 2024, the Company issued a press release announcing the release of the 2024 Letter to Shareholders detailing the Company's immuno-oncology cancer treatment candidates and development pipeline

A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

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. 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, including, but not limited to: (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. 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	2024 Letter to Shareholders
99.2	Press Release dated March 5, 2024
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 6, 2024

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

March 2024

Dear fellow shareholders,

At MAIA Biotechnology, our tenacious pursuit of innovative medicines to improve and extend people's lives with cancer has led us to the forefront of cancer research. As we wrap up the Phase 2 clinical trial of our lead molecule THIO in non-small cell lung cancer (NSCLC) and pursue additional indications and a pipeline of next-generation THIO-like molecules, we are creating a robust and transformational cancer treatment franchise.

Our groundbreaking work explores a new science for cancer therapy utilizing a novel dual mechanism of action: telomere targeting and immunogenicity. We are developing THIO as a second line or later treatment for NSCLC patients who have progressed beyond standard-of-care regimens. The telomere-centric action of THIO is being evaluated in THIO-101, a Phase 2 go-to-market clinical trial of THIO sequenced with the immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in advanced NSCLC patients. Throughout the trial, the pace of enrollment has exceeded the average pace in similar NSCLC trials, and we completed our target enrollment earlier than expected on February 19, 2024.

Preliminary THIO-101 data reported to date has shown unprecedented disease control rates in second-line and third-line treatment that outperform the standard of care. We are expecting updated third-line data during the current quarter of 2024 and anticipate topline data in the second half of this year. We expect that THIO-101 will be the first completed clinical study of a telomere targeting agent in the field of cancer drug discovery and treatment.

Investigational THIO

Telomerase is present in 85% to 90% of human cancers and contributes significantly to the proliferation and reproductive immortality of cancer cells. THIO is a small molecule telomere targeting anticancer agent that acts by producing direct telomeric DNA damage and inducing cancer-specific immune responses. THIO's action in cancer treatment has been featured in multiple renowned scientific publications, such as Cancer Cell and Nature.

Our preclinical findings show that THIO works against difficult-to-treat tumor types that are generally unresponsive to CPI immunotherapy alone. In preclinical testing, THIO was proven curative in combination with immunotherapy checkpoint inhibitors, such as Libtayo® (Regeneron), Keytruda® (Merck), and Tecentriq® (Roche/Genentech) in multiple tumor types: lung, colorectal, liver, and brain cancers. These results were achieved at doses approximately 40 times under the maximum tolerated dose. Such an efficacy/safety profile is unprecedented in oncology. The U.S. Food and Drug Administration (FDA) has reviewed and endorsed the data, awarding THIO three Orphan Drug Designations (ODD): hepatocellular carcinoma (the dominant histology of primary liver cancers, ~90%), small cell lung cancer (the deadliest type of lung cancer), and malignant gliomas (the deadliest group of brain cancers, including glioblastomas). With each ODD we can benefit from seven years of U.S. market exclusivity after drug approval and tax credits for qualified clinical testing.

The leading checkpoint inhibitors in the market currently account for over $37 billion in global annual sales combined[1]. As a whole, the checkpoint inhibitor class is forecasted to reach $148 billion globally by 2030[2]. THIO would work very well with any of the CPIs.

[1] Company research

[2] BioSpace**,** Immune Checkpoint Inhibitors Market Size

THIO-101 Phase 2 Clinical Trial

The THIO-101 trial has two primary objectives: *1)* to evaluate the safety and tolerability of THIO administered as an anticancer compound and an activator of the human immune system, and *2)* to assess the clinical efficacy of THIO. As part of the trial design, we tested three different doses, and we selected the most efficacious dose of THIO 180mg in November 2023.

Since THIO-101's beginning in 2022, we are strongly encouraged that patients in our study are receiving benefit long after discontinuing therapy, with no new anti-cancer treatments initiated. The safety profile of THIO has shown to be far better than the standard of care, chemotherapy[3].

Long-term survival for the first two subjects dosed in the trial (both receiving third-line treatment) is 14.6 and 12.5 months as of our latest published data. In real-world clinical practice, similarly heavily pretreated patients expected survival without treatment is only 3 to 4 months.

THIO Indications

Non-small cell lung cancer is the largest tumor type globally by mortality (1.7 million deaths annually) and dollar sales ($34 billion annually). It is an insidious disease that evolves with no recognizable symptoms until the cancer is well advanced.

Along with NSCLC, our pipeline of immuno-oncology therapies includes multiple hard-to-treat cancers.

Our most recent orphan drug designation for THIO, granted in 2023, is for malignant gliomas, which include glioblastoma, the most aggressive and most common type of brain cancer with only limited treatment options. THIO's potent anticancer activity has been observed in diffuse intrinsic pontine glioma (DIPG), one of the most aggressive and treatment-resistant brain tumors affecting the central nervous system in children.

Multiple tumor types including small cell lung cancer, liver cancer, and colorectal cancer will be studied in a second Phase 2 go-to-market trial, THIO-102, to evaluate THIO with checkpoint inhibitors in these indications.

[3] Cyramza® + docetaxel; REVEL Study: https://cyramza.lilly.com/hcp/nsclc-treatment/revel-trial-safety

Second Generation Telomere Targeting Agents

Our second-generation telomere targeting program is engaged in research and development for new drugs derived from THIO. We have developed more than 80 THIO-like compounds to date, with three U.S. patent applications. Preclinical studies of several of these agents have shown highly significant anti-cancer efficacy at low dose levels in multiple in vivo and in vitro models, warranting further investigation as our next generation of telomere targeting candidates.

Next Horizons

Our key targeted milestones for THIO this year are THIO-101 progression-free survival (PFS) and THIO-101 duration of response (DoR), both of which represent major clinical inflection points.

We will soon engage with the FDA to align on the optimal trajectory to obtain commercial approval, with multiple paths under consideration. We anticipate a final decision on THIO from the FDA in 2026.

In closing, we deeply appreciate your interest and support of our clinical research and trials.

As we move forward, we plan to pursue the FDA's accelerated approval program for THIO, saving significant time and costs in our research, and most importantly, bringing advanced NSCLC patients earlier access to our novel new anticancer therapy. We couldn't be more enthusiastic about the future for MAIA and look forward to sharing our continuing progress in 2024 and beyond.

Sincerely,

Vlad Vitoc, M.D.
Chairman and Chief Executive Officer

Forward Looking Statements

MAIA cautions that all statements, other than statements of historical facts contained in this letter to shareholders, 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.

Exhibit 99.2

MAIA Biotechnology CEO Details Immuno-Oncology Cancer Treatment Candidates and Development Pipeline in Letter to Shareholders

- THIO-101 Phase 2 trial nears completion with survival and response data forthcoming; exploration of multiple cancer indications and next-generation molecules continues
- Shareholder Letter available in Investor Relations section of MAIA's corporate website.

CHICAGO, IL – March 05, 2024 – MAIA Biotechnology, Inc., (NYSE American: MAIA) ("MAIA" or the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today published a 2024 Letter to Shareholders by Chairman and Chief Executive Officer Vlad Vitoc, M.D., detailing the Company's immuno-oncology cancer treatment candidates and development pipeline.

"At MAIA Biotechnology, our tenacious pursuit of innovative medicines to improve and extend people's lives has led us to the forefront of cancer research. As we wrap up the Phase 2 clinical trial of our lead molecule THIO in non-small cell lung cancer (NSCLC) and pursue additional indications and a pipeline of next-generation THIO-like molecules, we are creating a robust and transformational cancer treatment franchise," states Dr. Vitoc at the opening of his shareholder letter.

Letter Highlights

- THIO-101 Phase 2 clinical trial nears completion; survival and response data updates forthcoming.
- Along with NSCLC, MAIA's pipeline of immuno-oncology therapies includes multiple hard-to-treat cancers.
- More than 80 THIO-like compounds have been developed for the Company's second-generation telomere targeting program.
- Company's pipeline includes THIO-102 Phase 2 and THIO-103 Phase 2/3 clinical trials (planning stage), and Investigational New Drug (IND)-enabling studies for second-generation telomere targeting agents.

MAIA's letter to shareholders is available at ir.maiabiotech.com.

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

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Investor Relations Contact

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