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): June 4, 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 7.01 Regulation FD Disclosure.

1. MAIA Biotechnology, Inc. (the "Company") has made available a presentation (the "Presentation") about the Company's business which was posted to the Company's website on June 4, 2024, a copy of which is filed as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") and is hereby incorporated by reference.

2. The Company has made available a summary ("Summary") highlighting certain aspects of the Company's business, clinical programs and partnership with Regeneron which was posted to the Company's website on June 4, 2024, a copy of which is filed as Exhibit 99.2 to this Current Report on Form 8-K (this "Report") and is hereby incorporated by reference.

The information contained in each of the Presentation and the Summary is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements the Company may make by press release or otherwise from time to time. Each of the poster and the summary speaks as of the date of this Report. While the Company may elect to update the Presentation and/or the Summary in the future to reflect events and circumstances occurring or existing after the date of this Report, the Company specifically disclaims any obligation to do so.

Each of the Presentation and the Summary contains forward-looking statements, and as a result, investors should not place undue reliance on these forward-looking statements.

The information set forth in this Report, including, without limitation, the Presentation and the Summary, is 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, nor shall it be incorporated by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such a filing. This Report (including the exhibits hereto) will not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Item 8.01 Other Events.

On June 4, 2024, the Company issued a press release announcing New Clinical Data Showing THIO's Strong Efficacy in Non-Small Cell Lung Cancer.

A copy of the press release is attached hereto as Exhibit 99.3 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	Presentation
99.2	Summary
99.3	Press Release dated June 4, 2024
104	Cover Page Interactive Data File (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: June 4, 2024

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1

MAIA BIOTECHNOLOGY

TELOMERE TARGETING IMMUNOTHERAPIES FOR CANCER

NYSE AMERICAN: MAIA

June 2024

FORWARD-LOOKING STATEMENTS

MAIA BIOTECHNOLOGY
NYSE American: MAIA

All statements in this presentation, other than those relating to historical facts, are "forward-looking statements." These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans, and strategies; statements that contain projections of results of operations or of financial condition; statements relating to the industry and government policies and regulations relating to our industry; and all statements (other than statements of historical facts) that address activities, events, or developments that we intend, expect, project, believe, or anticipate will or may occur in the future. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments, and other factors they believe to be appropriate. Important factors that could cause actual results, developments, and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things: the overall global economic environment; general market, political, and economic conditions in the countries in which we operate: projected capital expenditures and liquidity; changes in our strategy; government regulations and approvals; the application of certain service license; and litigation and regulatory proceedings. Factors that may cause such differences also include, but are not limited to, those discussed under Risk Factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2023 and other periodic reports filed by the Company from time to time with the Securities and Exchange Commission. You may get these documents for free by visiting EDGAR on the Commission's website at www.sec.gov. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation as a result of, among other factors, the factors referenced in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods. This presentation shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any of our securities nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. Any offering of securities can only be made in compliance with applicable securities laws. You should read carefully the factors described in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023 to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. These statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from those anticipated by the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this prospectus. These forward-looking statements speak only as of the date of this presentation, and we assume no obligation to update or revise these forward-looking statements for any reason.

INVESTMENT PROFILE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

New science for cancer therapy: dual MOA telomere targeting and immunogenicity.

- Lead molecule THIO in clinic; 2nd generation compounds in R&D

Phase 2 trial THIO-101 nearing completion: THIO sequenced with CPI in NSCLC.

- Unprecedented disease control, response, post-therapy patient benefit
- Clinical supply agreement with Regeneron (Libtayo®)

Key targeted clinical milestones within reach.

- THIO-101 topline data in mid-2024; long-term data in 2nd half of 2024
- Multiple potential pathways to FDA commercial approval

Significant market opportunity in hard-to-treat cancers with unmet need.

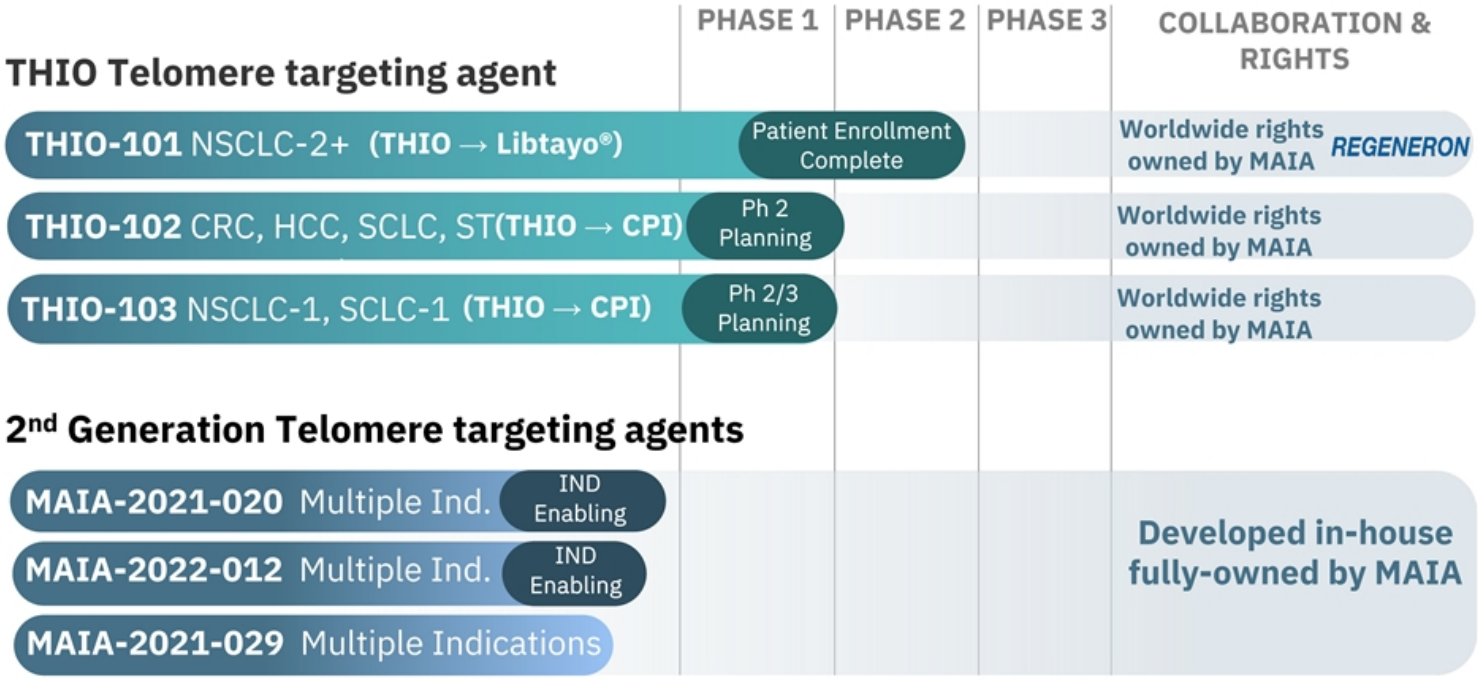
- NSCLC: largest tumor type globally, $34B annual sales
- 3 FDA Orphan Drug Designations: liver (HCC), lung (SCLC) and brain (malignant gliomas)

THIO trials planned for additional cancer indications.

- THIO-102 — colorectal cancer (CRC), HCC, SCLC, solid tumors
- THIO-103 — SCLC, NSCLC

ROBUST PIPELINE

MAIA BIOTECHNOLOGY
NYSE American: MAIA



MAIA BIOTECHNOLOGY

NYSE American: MAIA

MISSION AND APPROACH

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Cancer is the most dominant age-related disease

Population aged >80 expected to triple by 2050

142 million

2020

426 million

2050

At age 90:
40% will be diagnosed
20% will die of it


MAIA
BIOTECHNOLOGY
NYSE American: MAIA
THIO is the only direct telomere targeting anticancer agent in clinical development
7

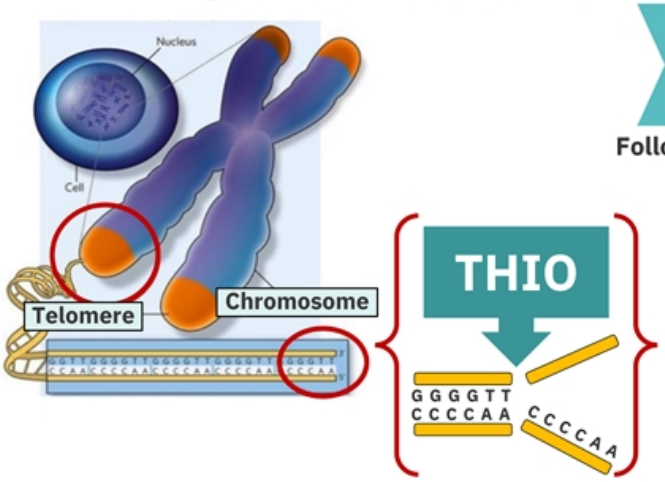
THIO – NOVEL MECHANISMS OF ACTION

MAIA BIOTECHNOLOGY
NYSE American: MAIA

THIO

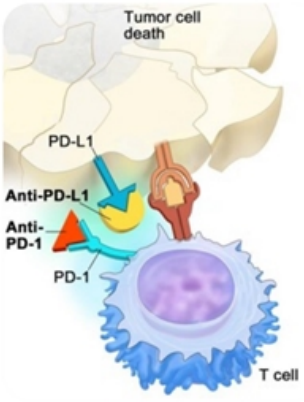
THIO has a dual MoA:

1. Telomere targeting
2. Immunogenic effect



Followed by

Immune Checkpoint Inhibitor



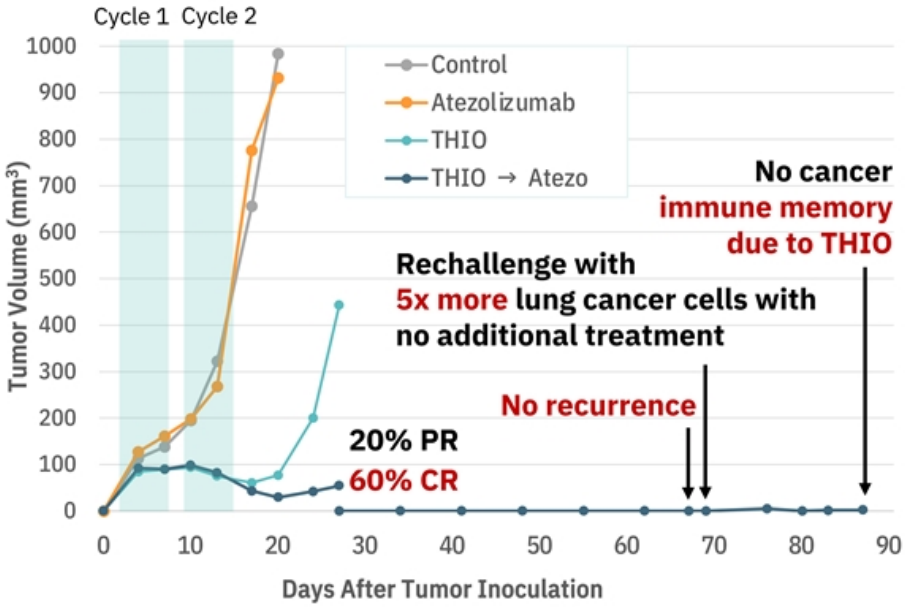
- ★ LIBTAYO® (cemiplimab) REGENERON
- IMFINZI® (durvalumab) AstraZeneca
- KEYTRUDA® (pembrolizumab) MERCK
- TEVIMBRA® (tislelizumab) BeiGene
- TECENTRIQ® (atezolizumab) Genentech
- Jemperli® (dostarlimab-gxly) GSK
- OPDIVO® (nivolumab) Bristol Myers Squibb
- BAVENCIO® (avelumab) EMD SERONO

★ Partnership with REGENERON for NSCLC

THIO-101 NSCLC TRIALS - RATIONALE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- THIO followed by CPI results in 60% complete response
- Only 2 cycles of therapy were administered on weeks 1 and 2; no further therapy throughout the study
- No recurrence after long-term follow-up
- Anticancer immune memory has been induced: no cancer after rechallenge with 5x more lung cancer (LLC) cells with no additional therapy



Mender et al, Cancer Cell, 2020; THIO followed by Tecentriq (atezolizumab; Roche/Genentech) tested first; repeated later with THIO followed by Keytruda (pembrolizumab; Merck); and Libtayo (cemiplimab; Regeneron)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

THIO-101 TRIAL

NON-SMALL CELL LUNG CANCER

REGENERON AGREEMENT

MAIA BIOTECHNOLOGY
NYSE American: MAIA

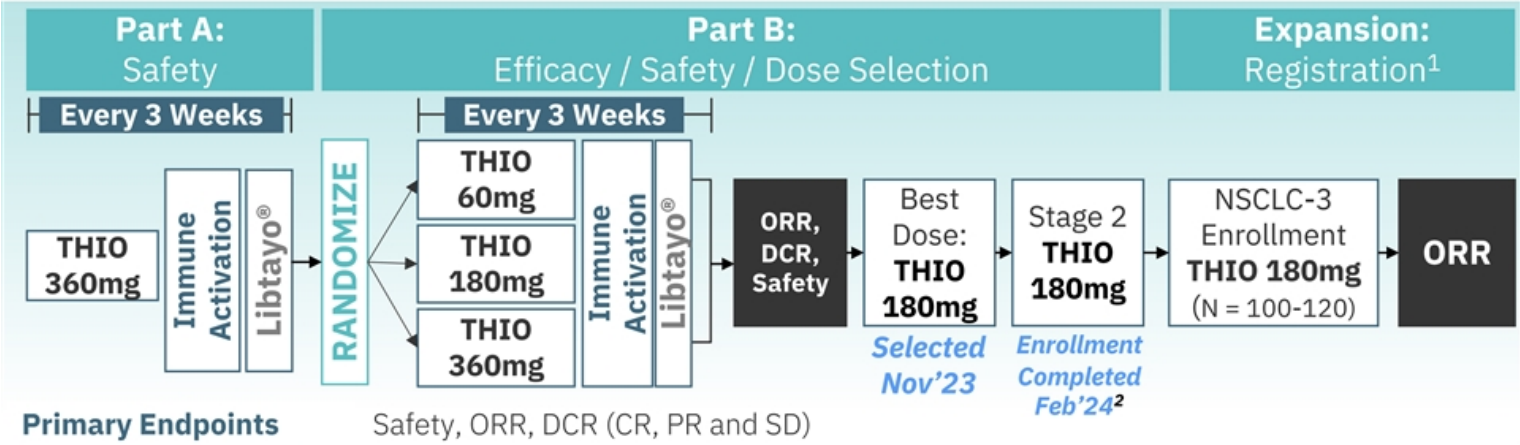
MAIA BIOTECHNOLOGY & REGENERON

MAIA Biotechnology, Inc. Announces Clinical Supply Agreement with Regeneron for Phase 1/2 Clinical Trial Evaluating THIO in Sequential Administration with Libtayo® (cemiplimab) in Advanced Non-Small Cell Lung Cancer

THIO-101 - TRIAL DESIGN

MAIA BIOTECHNOLOGY
NYSE American: MAIA

A Multicenter, Open-Label, Dose-Finding Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with LIBTAYO® (*cemiplimab*) in NSCLC patients RESISTANT TO CHECKPOINT INHIBITORS



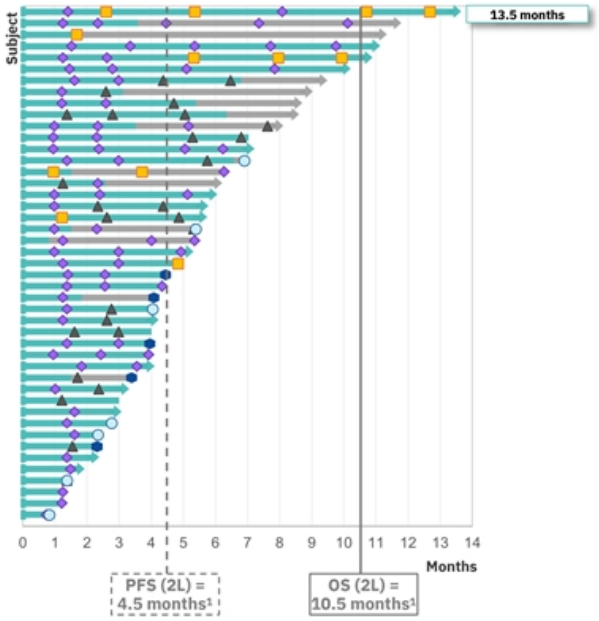
Primary Endpoints	Safety, ORR, DCR (CR, PR and SD)
Secondary Endpoints	DoR; PFS; OS
Exploratory Endpoints	PK and PD (activity of THIO in circulating tumor cells measured by specific biomarkers)

ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT05208944?term=05208944&draw=2&rank=1
1. Would require FDA agreement.
2. https://ir.maiabiotech.com/news-events/press-releases/detail/91/maia-biotechnology-completes-enrollment-in-thio-101-phase-2

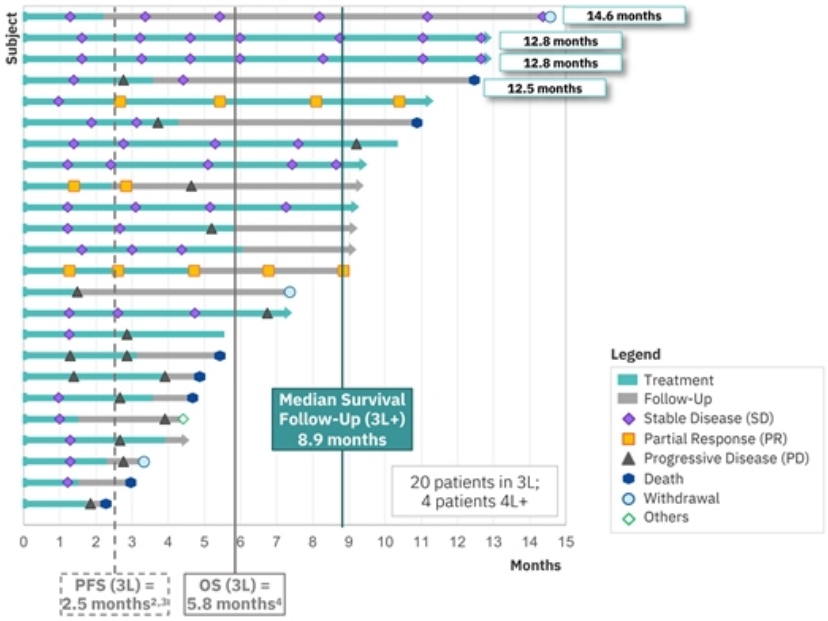
PATIENTS' SURVIVAL BY LINE OF THERAPY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Second Line (All Doses): 45 patients



Third Line+ (All Doses): 24 patients



Note: This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data subject to change. Clinical data presented from 30Apr2024 data cut. Includes all patients with ≥1 post-baseline response assessment.

1. https://clinicaltrials.gov/study/NCT01168973?tab=results
2. Shepherd F, et al. N Engl J Med 2005;353:123-132.
3. Fossella F, et al. J Clin Oncol 2000;18(12):2354-62.
4. Girard N, et al. J Thorac Onc 2009;12:1544-1549.

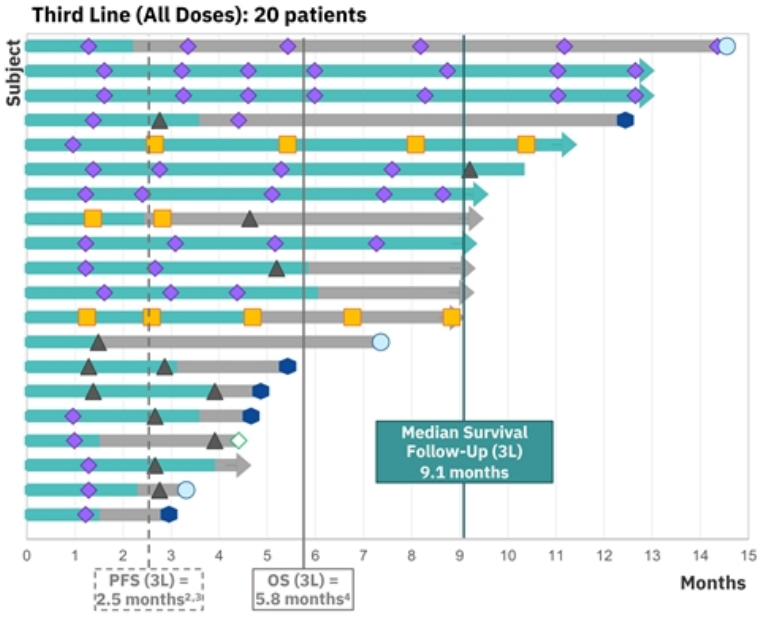
TREATMENT IN THIRD-LINE

Extended Survival

- 20 subjects in 3L completed at least 1 post baseline assessment at time of cut-off
- 13/20 (65%) patients crossed 5.8 months OS threshold
- 17/20 (85%) crossed 2.5 months PFS threshold

Unprecedented Efficacy

- DCR 85% vs 25-35% chemotherapy
- ORR (180mg dose) 38% vs 6-10% chemotherapy[5]



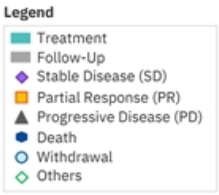
Note: This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data subject to change.
Clinical data presented from 30Apr2024 data cut. Includes all patients with ≥1 post-baseline response assessment.

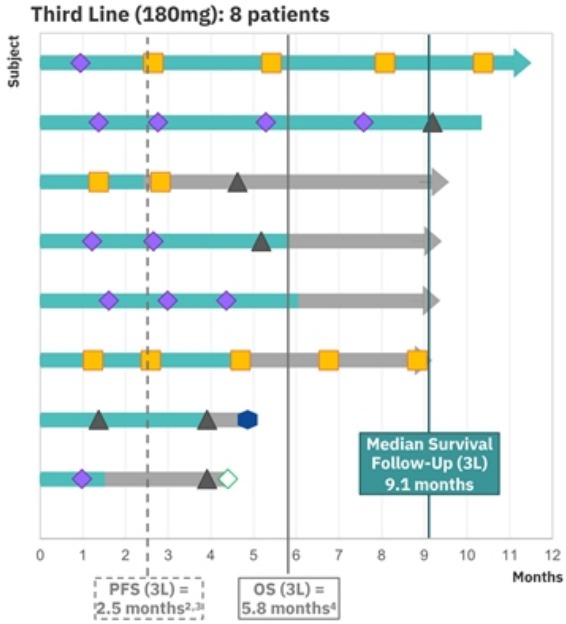
2. Shepherd F, et al. N Engl J Med 2005;353:123-132.
3. Fossella F, et al. J Clin Oncol 2000;18(12):2354-62.
4. Girard N, et al. J Thorac Onc 2009;12:1544-1549.
5. https://ir.maiabiotech.com/news-events/press-releases/detail/94/maia-biotechnology-announces-strong-efficacy-of-thio-as

BEST 3L RESULTS IN THE 180MG DOSE

NSCLC-3 – 180mg:

- 6/8 (75%) patients crossed 5.8 months OS threshold
- 7/8 (88%) crossed 2.5 months PFS threshold





Note: This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data subject to change. Clinical data presented from 30Apr2024 data cut. Includes all patients with ≥1 post-baseline response assessment.

1. https://clinicaltrials.gov/study/NCT01168973?tab=results
2. Shepherd F, et al. N Engl J Med 2005;353:123-132.
3. Fossella F, et al. J Clin Oncol 2000;18(12):2354-62.
4. Girard N, et al. J Thorac Onc 2009;12:1544-1549.

EXPECTED EFFICACY VS. CURRENT TREATMENTS

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Third-Line NSCLC	THIO (180mg) + Libtayo® (cemiplimab)	Chemotherapy	Tarceva® (erlotinib)	Taxotere® (docetaxel)
Population	CPI Resistant (3L)	CPI Naïve (3L)	CPI Naïve (2L+)	CPI Naïve (2L)
DCR	88%	36%	45%	54%
ORR	38%	6%	9%	5.7%
PFS	**5.5 - 6 months (projected)**		2.2 months	1.9 months (8.3 weeks Time to Progression)
OS	**> 10 months (projected)**	5.8 months	6.7 months	5.7 months
Trial / Study	THIO-101	Third-Line Chemotherapy in Advanced NSCLC (Girard et al, JTO)	BR.21	TAX320
Source	https://clinicaltrials.gov/study/NCT05208944	https://www.jto.org/article/S1556-0864(15)31281-8/pdf	https://www.nejm.org/doi/full/10.1056/NEJMoa050753	https://pubmed.ncbi.nlm.nih.gov/10856094/

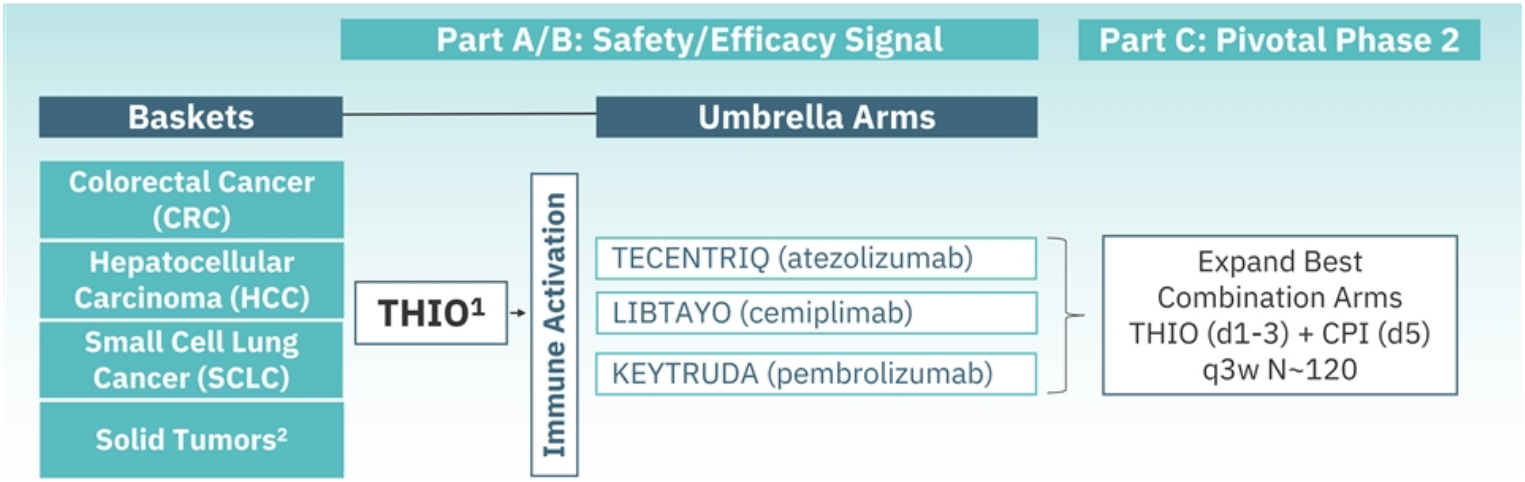
MAIA BIOTECHNOLOGY
NYSE American: MAIA

PLANNED UPCOMING TRIALS

THIO-102 TRIAL (PLANNED)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with Anti-PD-1 or Anti-PD-L1

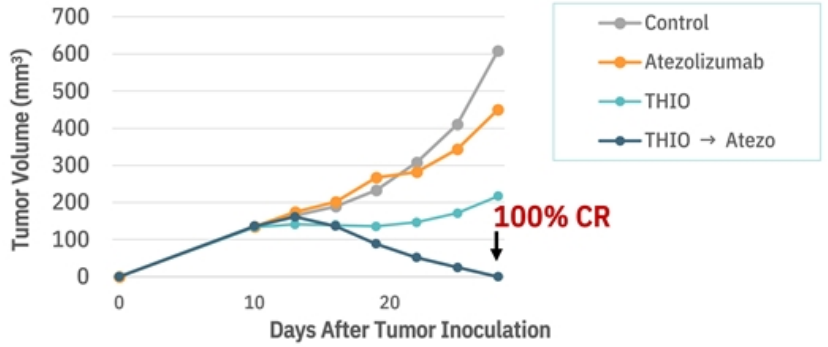


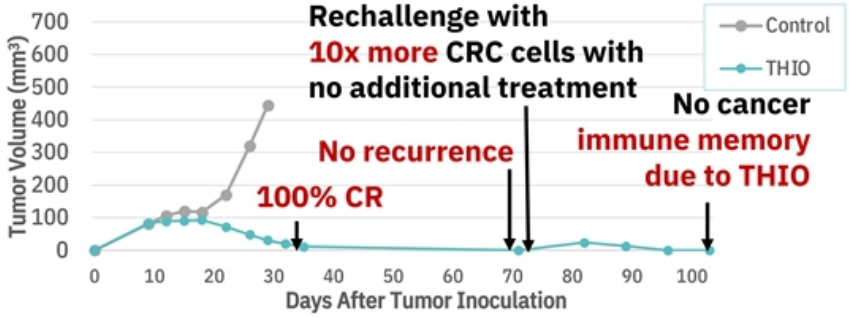
[1] Dose to be selected from THIO-101 study results
[2] E.g. Breast, Prostate, Gastric, Pancreatic, Ovarian, etc

THIO-102 – COLORECTAL RATIONALE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- THIO followed by CPI results in 100% complete response
- Only 2 cycles of therapy were administered on weeks 1 and 2; no further therapy throughout the study
- No recurrence after long-term follow-up
- Anticancer immune memory has been induced: no cancer after rechallenge with 10x more CRC cells with no additional therapy

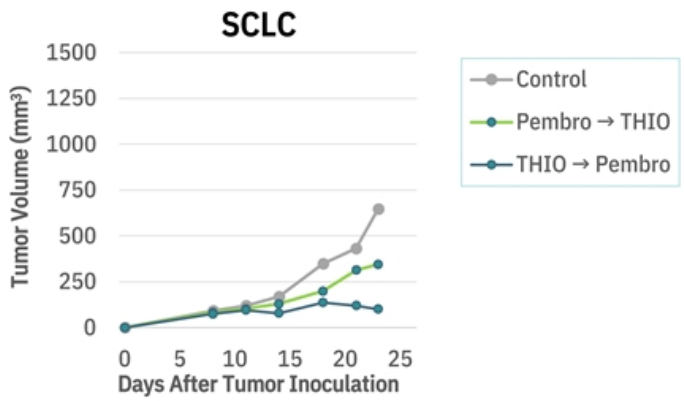


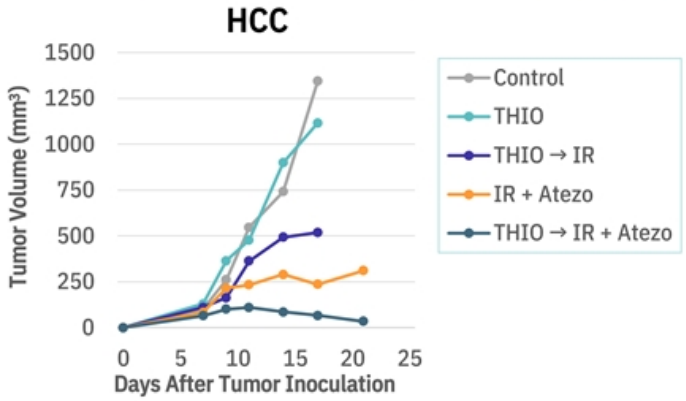


Mender et al, Cancer Cell, 2020

SCLC & HCC – ORPHAN DRUG DESIGNATION

MAIA BIOTECHNOLOGY
NYSE American: MAIA





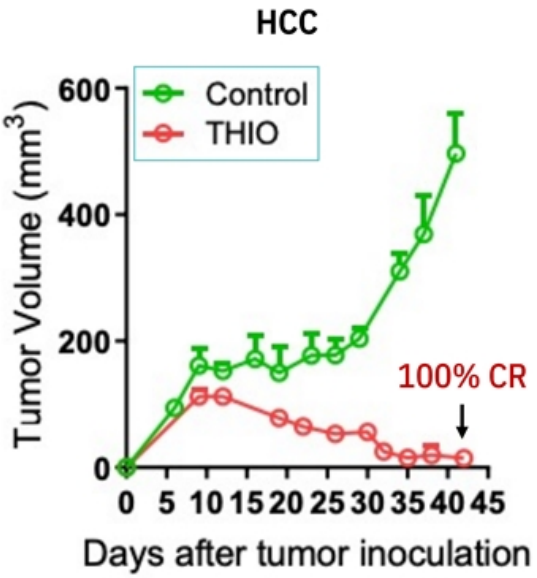
- THIO is synergistic with anti-PD-1 agent Pembrolizumab in Small Cell Lung Carcinoma (H2081) *in vivo* in humanized murine cancer model
- Treatment with THIO followed by Pembrolizumab results in highly potent anticancer effect, as compared to Pembrolizumab alone
- THIO converts immunologically "cold non-responsive" SCLC tumor into "hot and responsive" to Pembrolizumab

- THIO is highly synergistic and effective in combination with anti-PD-L1 agent Atezolizumab and Ionizing Radiation (IR 10Gy) in HCC53N Hepatocellular Carcinoma
- Treatment with THIO in combination with IR and Atezolizumab results in a complete regression of aggressive HCC tumors. The combination of IR and Atezolizumab is just partially efficacious

EXCELLENT EFFICACY IN HCC MODELS

MAIA BIOTECHNOLOGY
NYSE American: MAIA

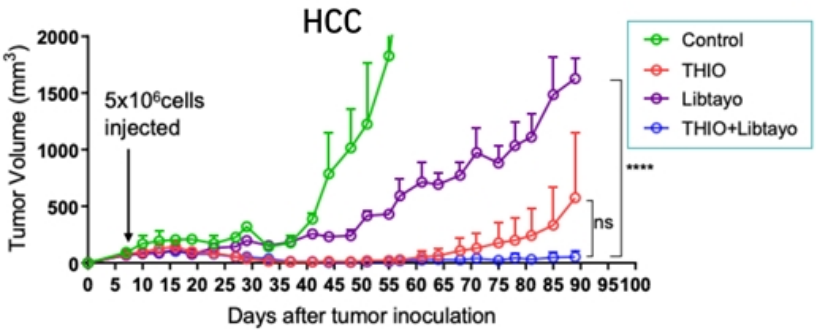
- THIO achieved complete and durable responses in Hepatocellular Carcinoma (HCC), the dominant histology in primary liver cancer (90%), in *in vivo* models

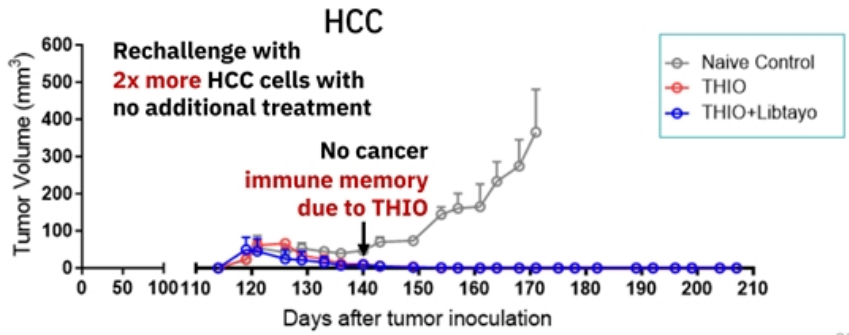


HCC ANTI-CANCER IMMUNE MEMORY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- When combined with immunotherapy checkpoint inhibitor Libtayo®, duration of response was further potentiated
- Upon rechallenge with two times more cancer cells and no additional treatment, tumor growth was completely prevented
- Administration of THIO alone and in combination with Libtayo® generated anti-cancer immune memory

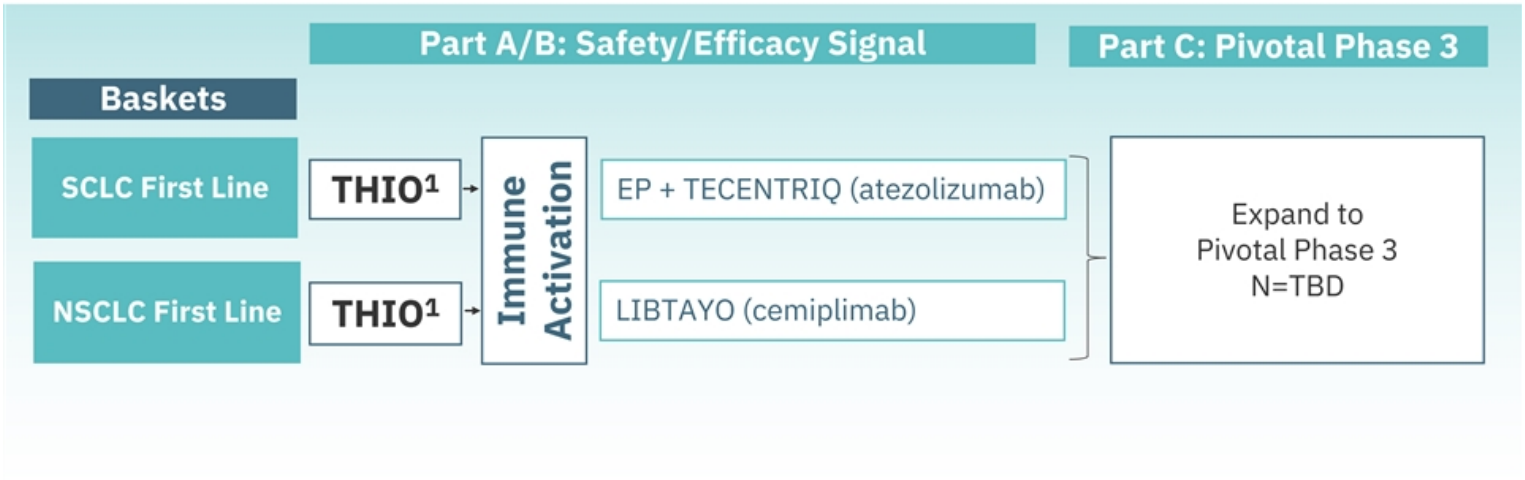




THIO-103 TRIAL (PLANNED)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with Anti-PD-1 or Anti-PD-L1



[1] Dose to be selected from THIO-101 study results

INVESTMENT OPPORTUNITY

EXCLUSIVITY AND INTELLECTUAL PROPERTY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Goal: New Chemical Entity (NCE) Marketing Exclusivity

- THIO has never been previously approved by the FDA for commercialization
- Robust exclusivity
- US: 7 years; EU, Japan, other markets: 10 years

Robust and Growing Patent Portfolio for THIO

- 5 issued patents
- 29 pending patent applications

Current patents/provisional applications broadly cover the following key areas:

- Telomere targeting compounds (2034+)
- THIO's immunogenic treatment strategy: sequential combination with CPIs (2041)

EXPERIENCED MANAGEMENT TEAM

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Vlad Vitoc, MD, MBA

Founder and CEO

- 24+ years in Oncology Pharma/ Biotech: Commercial, Medical
- 12 compounds launched across 20+ tumor types
- Leadership roles at Bayer (Nexavar), Astellas (Tarceva, Xtandi), Cephalon (Treanda), Novartis (Zometa), Incyte (Jakafi)

Sergei Gryaznov, PhD

Chief Scientific Officer

- 25+ years as Scientist
- Expert Drug Discovery and Development, Oncology with 120+ publications
- Head of the J&J Oligonucleotide Center of Excellence Worldwide
- Expert of telomeres and telomerase in cancer, co-inventor of THIO

Jeffrey Himmelreich, MBA

Head of Finance

- 20+ years of financial expertise
- CFO for privately held and publicly traded companies in the healthcare and manufacturing industries
- Active CPA licensed in the state of Pennsylvania and is a Chartered Global Management Accountant

NOVARTIS astellas Pfizer BAYER janssen Incyte Cephalon Oncology geron PHARMACIA exicure

SIGNIFICANT MARKET OPPORTUNITY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Developing agents for the top tumor types markets globally

NSCLC (#1 WW) **Mortality:** 1.7M / **Sales:** $34B	**HCC** **Mortality:** 0.8M / **Sales:** $3B
CRC (#2 WW) **Mortality:** 1.0M / **Sales:** $20B	**SCLC** **Mortality:** 0.3M / **Sales:** $2B

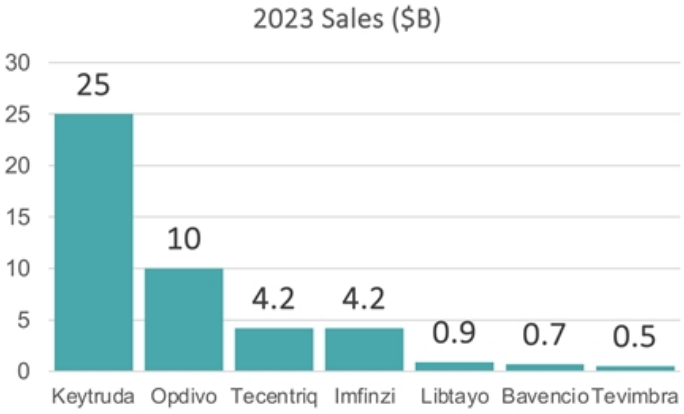
$46B CPIs Group (2023 Sales)

- 5 CPIs approved for NSCLC:
  - > 30% of NSCLC drug sales
  - > 40% of total CPI sales
- Keytruda®: $9B in NSCLC of $25B total

Partnership with Regeneron (Libtayo®)

- Profile similar to Keytruda®
- Libtayo® is entrant #5 in CPIs
- Needs superior efficacy to Keytruda®
- Sequential combination with THIO is key

Checkpoint Inhibitors Market



- Keytruda® expected to hit $30B in 2026, biosimilars expected by 2028
- Libtayo® trending towards $2.2B in 2026

COMPARABLE COMPANIES

MAIA BIOTECHNOLOGY
NYSE American: MAIA

MAIA BIOTECHNOLOGY	MIRATI THERAPEUTICS	zentalis	IOVANCE BIOTHERAPEUTICS	KURA ONCOLOGY	Turning Point Therapeutics
$95M	**$4.1B**	**$0.8B**	**$2.5B**	**$1.5B**	**$4.1B**
Market Cap	Market Cap	Market Cap	Market Cap	Market Cap	Market Cap
$4.36/share	$58/share	$12/share	$9/share	$21/share	$76/share

- On June 3, 2022, Bristol Myers Squibb (BMS) announced the acquisition of Turning Point Therapeutics in an all-cash transaction for **$4.1B** in equity value
- On October 9, 2023, BMS acquired Mirati for **$4.8B** in cash, plus up to $1B in contingent value right
- Commercial stage companies: Mirati (on acquisition), Iovance
- Phase 2 companies: Zentalis, Kura and Turning Point (on acquisition)

Note: Market Caps as of May 29, 2024 (source: S&P CapitalIQ)

MULTIPLE VALUE-DRIVING MILESTONES

MAIA BIOTECHNOLOGY
NYSE American: MAIA

★ **Major inflection points**

	2024			2025			2026	
THIO-101 Ph2 NSCLC-2+	**Early Efficacy Update** (Biotech Showcase)	**Part B Efficacy** (ASCO) ★	**Part B Long-term Efficacy** (ESMO) ★	**Part B Full Efficacy** (ASCO) ★	**Part C Efficacy Update** (ESMO)	**Part C Enrollment Complete**	Filing for US approval	**Potential Accelerated Approval in US** ★
THIO-102 Ph2 CRC, SCLC, HCC, ST				**Enrollment** First Patient In ★		**Early Safety Report** ★		**Early Efficacy Report** (ASCO)
THIO-103 Ph2/3 SCLC-1, NSCLC-1				**Enrollment** First Patient In ★				**Early Safety Report** ★

Note: Estimated timelines. Trial names, targeted indications and projected dates may be subject to changes.

MAIA BIOTECHNOLOGY

THANK YOU

Investor Relations Contact
+1 (872) 270-3518
ir@maiabiotech.com

MAIA Biotechnology, Inc.
444 West Lake Street, Suite 1700
Chicago, IL 60606

APPENDIX

U.S. FDA GRANTED 3 ORPHAN DRUG DESIGNATIONS TO THIO

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- The FDA's Orphan Drug Act of 1983 is designed to <u>incentivize the development of therapies that demonstrate promise for the treatment of rare (orphan) diseases or conditions</u>
- **Rare disease -** affects fewer than 200,000 people total in the U.S, or if the cost of developing a drug and making it available in the U.S. will exceed any potential profits from its sale due to the small target population size
- **Multiple incentives -** to make development more financially possible for companies to pursue:
  - ✓ up to 7 years of market exclusivity
  - ✓ up to 20 years of 25% federal tax credit for expenses the U.S.
  - ✓ waiver of Prescription Drug User Fee Act (PDUFA) fees, a value of ~$2.9 million in 2021
- **Only highest quality data is considered for ODD -** a testament to the potential of THIO in the treatment of multiple indications
- **THIO has been granted 3 ODDs:**
  - ✓ Hepatocellular Carcinoma (HCC, 90% of primary liver cancers)
  - ✓ Small Cell Lung Cancer (SCLC, deadliest lung cancer)
  - ✓ Glioblastoma (brain cancer)

MAIA Biotechnology, Inc. Announces FDA Orphan Drug Designation for THIO for the Treatment of Hepatocellular Carcinoma (HCC)

April 26, 2022 08:37 AM Eastern Daylight Time

https://ir.maiabiotech.com/news-events/press-releases/detail/35/maia-biotechnology-inc-announces-fda-orphan-drug

MAIA Biotechnology Receives FDA Orphan Drug Designation for THIO for the Treatment of Small-Cell Lung Cancer (SCLC)

August 02, 2022 08:00 AM Eastern Daylight Time

https://ir.maiabiotech.com/news-events/press-releases/detail/41/maia-biotechnology-receives-fda-orphan-drug-designation-for

FDA Grants Orphan Drug Designation to MAIA Biotechnology for THIO as a Treatment for Glioblastoma

- Third orphan drug designation (ODD) granted to THIO by the FDA; drug also holds ODDs for hepatocellular carcinoma and small cell lung cancer
- Benefits include 7 years of U.S. market exclusivity after drug approval and tax credits for qualified clinical testing
- Expected glioblastoma market growth from $2.2 billion to $3.2 billion globally in the next three years

November 10, 2023 07:01 AM Eastern Standard Time

https://ir.maiabiotech.com/news-events/press-releases/detail/91/fda-grants-orphan-drug-designation-to-maia-biotechnology

Exhibit 99.2

MAIA BIOTECHNOLOGY

Telomere Targeting Immunotherapies for Cancer

Vlad Vitoc, MD, MBA
Chief Executive Officer
444 West Lake Street, Suite 1700 - Chicago, IL 60606
(312) 416-8592 vvitoc@maiabiotech.com
(215) 971-5488 maiabiotech.com

MAIA is an immuno-oncology company focused on the development and commercialization of first-in-class drugs intended to meaningfully improve and extend the lives of people with hard-to-treat cancers. We are exploring new science for cancer therapy utilizing a novel dual mechanism of action: telomere targeting and immunogenicity. Our lead program is THIO, a first-in-class anticancer agent in clinical development for the treatment of Non-Small Cell Lung Cancer (NSCLC) in patients.

Company Highlights

Clinical Programs

THIO-101

Ph 2 trial of THIO + Libtayo® (cemiplimab)

- Go-to-market trial in second-line+ NSCLC
- Objectives: select most efficacious dose and expand into pivotal trial; file for accelerated approval in 2025
- Enrollment completed earlier than expected in Feb 2024; trial nearing completion
- Topline data expected mid-2024; long-term data on second half of 2024
- Preliminary Overall Response Rate for best dose 180mg:
  - ✓ 38% ORR in third-line vs. 6-10% with SoC
  - ✓ 75% of patients crossed 5.8 months OS threshold in third-line
- Preliminary Disease Control Rate (DCR), best predictor for overall survival benefit (meta-analysis of 74 trials worldwide):
  - ✓ 85% DCR in third-line vs. 25-35% with Soc

THIO-102 (planning)

Ph 2 trial of THIO + checkpoint inhibitors

- Go-to-market trial in late line of therapy in multiple tumor types: Colorectal Cancer (CRC), Hepatocellular Carcinoma (HCC, 90% of primary type of liver cancers), Small Cell Lung Cancer (SCLC) and Solid Tumors of any type (ST)
- Objectives: select most efficacious combination by tumor type and expand into pivotal trials (12+ possible market entry indications)
- File for accelerated approvals in 2026 and beyond

THIO-103 (planning)

Ph 2/3 trial of THIO + checkpoint inhibitors

- First-line NSCLC and SCLC
- Expand to Breast, Prostate, Pancreatic, Ovarian, Gastric Cancer, etc.
- Objectives: confirmatory for accelerated approvals from THIO-101 and THIO-102

THIO is a Unique Direct Telomere Targeting Agent

- Potential to be used in combination with other anticancer and immune therapies
- Novel dual mechanism of action: telomere targeting + immunogenic
- 3 FDA Orphan Drug Designations: HCC, SCLC, and Glioblastoma
- Excellent efficacy: achieved complete and durable responses in HCC *in vivo* models (peer-reviewed published study)
- Featured in multiple renowned scientific publications including Cancer Cell and Nature

Partnership with Regeneron

- Clinical supply agreement: Regeneron provides Libtayo® for THIO-101
- Equivalent to $32M non-dilutive participation (largest financing move to date)
- Potential to expand existing relationship and target new companies

Cap Table

NYSE American: MAIA

Share Price[1]	$4.36	Float[2]	14M
Market Cap[1]	$95M	Insider Holdings[2]	27%
FD Shares Outstanding[2]	35M	Cash[2]	$8M

1. As of May 30, 2024
2. As of Apr 25, 2024

MAIA Biotechnology's goal is to bring revolutionary cancer treatments to the market, with the only direct telomere targeting agent in clinical development. MAIA is developing agents for the top tumor types markets globally.

Significant Market Opportunity

- Cancer is the most dominant of the age-related disease categories and has life altering impacts in the lives of patients and their close ones
- The number of people aged 80 years or older is expected to triple between 2020 and 2050 to reach 426 million
- Approximately 40% of people alive today are projected to be diagnosed with a cancer type in their lifetime, and 20% will die of it
- NSCLC is the leading tumor type: Mortality 1.7M / Sales $32B (2022)
- CRC is second: Mortality 1M / Sales $20B (2022)

Strong and Growing IP Portfolio

- Potential for receiving NCE marketing exclusivity
- 5 patents issued, 29 patent applications pending

Next Generation Potential Telomere Targeting Therapeutics in R&D

- 84 new molecules engineered; same mechanism of action as THIO
- Following THIO to commercial stage within 4-5 years

Robust Pipeline

	PHASE 1	PHASE 2	PHASE 3	COLLABORATION & RIGHTS
THIO Telomere targeting agent				
THIO-101 NSCLC-2+ (THIO → Libtayo®)	Patient Enrollment Complete			Worldwide rights owned by MAIA REGENERON
THIO-102 CRC, HCC, SCLC, ST (THIO → CPI)	Ph 2 Planning			Worldwide rights owned by MAIA
THIO-103 NSCLC-1, SCLC-1 (THIO → CPI)	Ph 2/3 Planning			Worldwide rights owned by MAIA
2nd Generation Telomere targeting agents				
MAIA-2021-020 Multiple Ind.	IND Enabling			Developed in-house fully-owned by MAIA
MAIA-2022-012 Multiple Ind.	IND Enabling			
MAIA-2021-029 Multiple Indications				

Vlad Vitoc, MD, MBA

Founder, Chairman, and Chief Executive Officer

- 24+ years in Pharma/Biotech: Commercial, Medical,
- 12 compounds launched across 20+ tumor types
- Leadership roles at Bayer (Nexavar), Astellas (Tarceva, Xtandi), Cephalon (Treanda), Novartis (Zometa), and Incyte (Jakafi)

Scan QR Code to access our investor presentation

Exhibit 99.3

MAIA Biotechnology Reveals New Clinical Data Showing THIO's Strong Efficacy in Non-Small Cell Lung Cancer

THIO's favorable disease control and overall response rates exceed reported standard-of-care data in third line treatment

CHICAGO, IL – June 04, 2024 - MAIA Biotechnology, Inc., (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announced new efficacy data from its Phase 2 THIO-101 clinical trial evaluating THIO sequenced with the immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced non-small cell lung cancer (NSCLC) who failed 2 or more standard-of-care therapy regimens. Updated results show a favorable overall response rate (ORR) of 38% and a disease control rate (DCR) of 85% from THIO + CPI in third-line treatment. The new data was presented in a poster session at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting on June 3, 2024.

The primary objectives of THIO-101 Phase 2 trial are to examine the safety and tolerability of THIO as an anticancer drug and as an immune system primer, and to examine the clinical efficacy of THIO in the form of ORR. At the time of the most recent data cut-off (April 30, 2024), all evaluable patients had completed ≥1 post-baseline assessment.

Results from third-line treatment:

- Disease control rate (DCR) was 85% for THIO vs. standard of care DCR of 25–35% for chemotherapy[1]
- 65% of patients crossed the 5.8-month overall survival (OS) threshold[2]
- 85% of patients crossed the 2.5-month progression-free survival (PFS) threshold[3-4]
- Median survival follow-up time is currently 9.1 months (n=20)

Results from third-line treatment with THIO 180mg (optimal dose selection)

- Median PFS of 5.5 months (24.1 weeks)
- 78% OS rate at 6 months
- 38% ORR vs. standard of care 6–10% for chemotherapy[5]
- 75% of patients crossed the 5.8-month OS threshold[5]
- 88% of patients crossed the 2.5-month PFS threshold[6-7]
- Median survival follow-up time is currently 9.1 months (n=8)

---

1 Matsumoto H, et al. Transl Lung Cancer Res 2021;10:2278–89.
2 Girard N, et al. J Thorac Onc 2009;12:1544-1549.
3 Shepherd F, et al. N Engl J Med 2005;353:123-132.
4 Fossella F, et al. J Clin Oncol 2000;18(12):2354-62.

“All exceptional measures of efficacy in our trial to date have exceeded our own expectations and outperformed standard of care treatments,” said Vlad Vitoc, M.D., MAIA’s Chairman and Chief Executive Officer. “The data presented at ASCO advances THIO’s excellent clinical profile as a strong, safe, and highly effective alternative for patients who progressed following chemotherapy and other available treatments. We eagerly anticipate full efficacy data from THIO-101 in the second half of this year.”

To date, treatment with THIO + cemiplimab has been generally well tolerated in a heavily pre-treated patient population. Full enrollment in THIO-101 was completed on February 19, 2024, earlier than expected as per trial design. The Company expects that THIO-101 will be the first completed clinical study of a telomere targeting agent in the field of cancer drug discovery and treatment.

The poster and updated Company presentations can be accessed on the company’s website.

About THIO

THIO (6-thio-dG or 6-thio-2’-deoxyguanosine) is a first-in-class 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. The modified nucleotide 6-thio-2’-deoxyguanosine (THIO) induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. THIO-damaged telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment with THIO followed by PD-(L)1 inhibitors resulted in profound and persistent tumor regression in advanced, in vivo cancer models by induction of cancer type–specific immune memory. THIO is presently 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 anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of THIO administered prior to cemiplimab (Libtayo®) 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 compound and a priming immune activator (2) to assess the clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. Treatment with cemiplimab (Libtayo®) followed by THIO has been generally well-tolerated to date in a heavily pre-treated population. 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 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.

Investor Relations Contact
+1 (872) 270-3518
ir@maiabiotech.com