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 21, 2025

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.

The Company has made available a presentation about the Company's business and was posted to the Company's website on March 21 2025, a copy of which is filed as Exhibit 99.1 to this Current Report on Form 8-K (the "Report") and is hereby incorporated by reference.

The information contained in the presentation 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. The presentation speaks as of the date of this Report. While the Company may elect to update the presentation 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.

The presentation contains forward-looking statements, and as a result, investors should not place undue reliance on these forward-looking statements.

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 Materials
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: March 21, 2025

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
March 2025

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, 2024 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, 2024. 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, 2024 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
- Ateganosine approved as nonproprietary (generic) name for THIO

Phase 2 trial THIO-101 expansion in 2025: THIO sequenced with CPI in NSCLC.

- Unprecedented disease control, response, post-therapy patient benefit
- Continued clinical supply agreement with Regeneron (Libtayo®)
- Potential filing for accelerated approval in 2026

Phase 3 trial THIO-104: THIO + CPI vs. Investigator's Choice in NSCLC.

- Interim analysis can lead to potential filing for early full commercial approval in 2026
- Final analysis for potential filing for commercial approval in 2027

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)
- 1 FDA Rare Pediatric Disease Designation for pediatric diffuse high-grade gliomas

Multiple THIO trials planned for additional cancer indications.

- Colorectal cancer (CRC), Liver (HCC), and SCLC to start enrollment in 2026

ROBUST PIPELINE

THIO Telomere Targeting Agent – Clinical Trials Pipeline

Clinical Trial	Indication	Treatment	Status	Preclinical	Phase 1	Phase 2	Phase 3	Rights
THIO-104	NSCLC 3L	THIO → CPI	Planned Phase 3					Worldwide rights owned by MAIA
THIO-101	NSCLC 2L+	THIO → Libtayo®	Ongoing Phase 2			Clinical supply agreement with REGENERON		
THIO-102	CRC, HCC, SCLC, ST	THIO → CPI	Planned Phase 2					
THIO-103	NSCLC-1, SCLC-1	THIO → CPI	Planned Phase 2/3					

2nd Generation Telomere Targeting Agents

Agent	Indication	Status	Preclinical	Phase 1	Phase 2	Phase 3	Rights
MAIA-2021-020	Multiple Tumor Types	IND Enabling					Developed in-house fully-owned by MAIA
MAIA-2022-012	Multiple Tumor Types	IND Enabling					
MAIA-2021-029	Multiple Tumor Types	IND Enabling					

MISSION AND APPROACH

ONCOLOGY LANDSCAPE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Cancer is the most dominant age-related disease

Sources: UN (World Social Report, 2023); Worldometer (Life Expectancy of the World Population, 2024).

THIO (ateganosine) is the only direct telomere targeting anticancer agent in clinical development

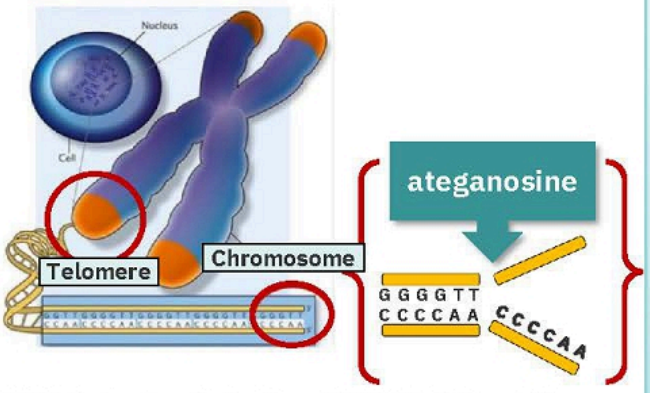
NOVEL MECHANISM OF ACTION

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Ateganosine (6-thio-2'-deoxyguanosine, THIO)

Ateganosine has a dual Mechanism of Action:

1. Telomere targeting
2. Immunogenic effect

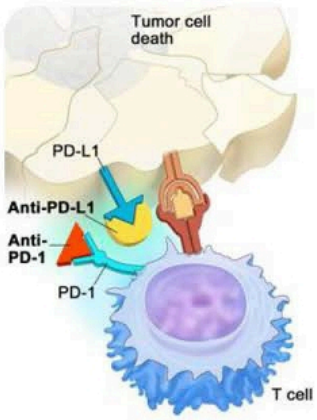


- 3 FDA Orphan Drug Designations: HCC, SCLC, Malignant Gliomas
- 1 Rare Pediatric Disease Designation (RPDD): Pediatric Gliomas

Followed by Immune Checkpoint Inhibitor (CPI)

- Examples of commercially available CPIs:

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

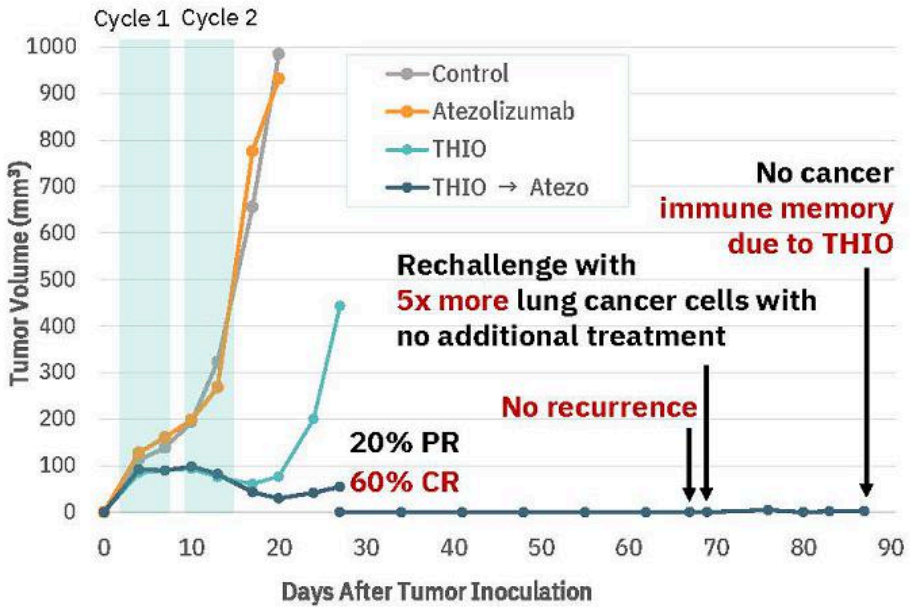


- MAIA has a clinical supply agreement with REGENERON for NSCLC on THIO-101

THIO-101 NSCLC TRIAL - 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



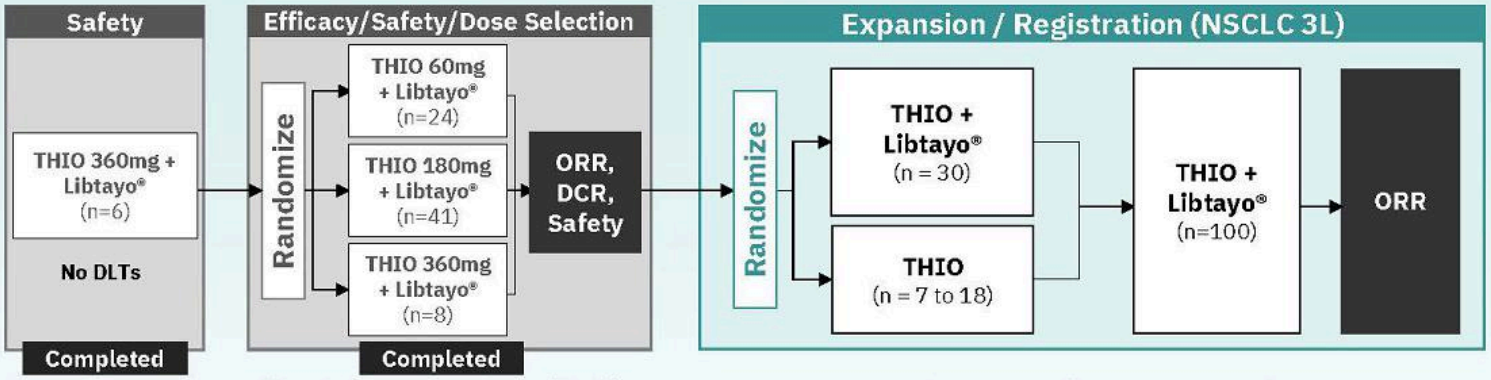
Note: Mender et al, Cancer Cell, 2020; THIO followed by Tecentriq (atezolizumab; Roche/Genentech) tested first; repeated later with THIO followed by Keytruda (pembrolizumab; Merck); and Libtayo (cemiplimab; Regeneron). Data from preclinical results.

NSCLC CLINICAL TRIALS

THIO-101 PHASE 2 PIVOTAL TRIAL DESIGN (ONGOING)

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 Who Are Resistant to Checkpoint Inhibitors



- Modified 3+3 design
- Completed

- Simon's 2-stage in each arm (N=41):
  - ✓ Stage 1 (n=19)
  - ✓ Stage 2 (n=22)
- Best dose THIO 180mg - selected on Nov'23
- Enrollment completed Feb'24

- Up to 148 patients – Enrollment to start Q1'25
- Patient population:
  - CPI Resistance (SITC)
  - Chemotherapy Resistance

Treatment with THIO + Libtayo®

THIO
Cycles every 3 weeks

Day 1	Day 2	Day 3	Day 4	Day 5
THIO 60mg	THIO 60mg	THIO 60mg	Immune Activation	Libtayo® 350mg

Scans every 6 weeks

ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT05208944

THIO-104 PHASE 3 PIVOTAL TRIAL DESIGN (PLANNED)

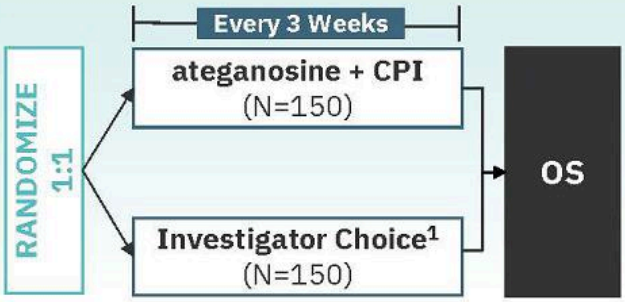
MAIA BIOTECHNOLOGY
NYSE American: MAIA

A Multicenter, Open-label, Pivotal Phase 3 Trial Evaluating the Efficacy of THIO (ateganosine) Administered in Sequence with a Checkpoint Inhibitor in NSCLC Patients Who Are Resistant to Checkpoint Inhibitors and Chemotherapy

NSCLC 3L

- CPI Resistance (SITC criteria)
- Prior Platinum Therapy
- 2 prior lines of systemic therapy
- Excluding Driver Mutations
- Exclude untreated or symptomatic CNS mets
- PS 0-1

- Stratified by:
  - prior docetaxel vs. no prior docetaxel



[1] Investigator Choice options: gemcitabine, vinorelbine, docetaxel

Primary Endpoints	**Target OS:** 9.3m v. 5.8m (HR 0.62); **Minimum OS:** 7.8m v. 5.8m (HR 0.74)
Secondary Endpoints	DCR; ORR; DoR; PFS; Safety
Exploratory Endpoints	PK and PD (activity of THIO in circulating tumor cells measured by specific biomarkers)

BEST RESULTS IN THIRD-LINE WITH THE 180MG DOSE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

THIO-101 (Pivotal Phase 2, ongoing):

- Current data in third-line indicates that as of 15-Jan-2025, estimated Median Overall Survival (OS) is at 16.9 months with a 95% CI lower bound of 12.5 months and 99% CI lower bound of 10.8 months
- The treatment has been generally well-tolerated to date in this heavily pre-treated population[1]

3L NSCLC is an excellent market entry segment for THIO:

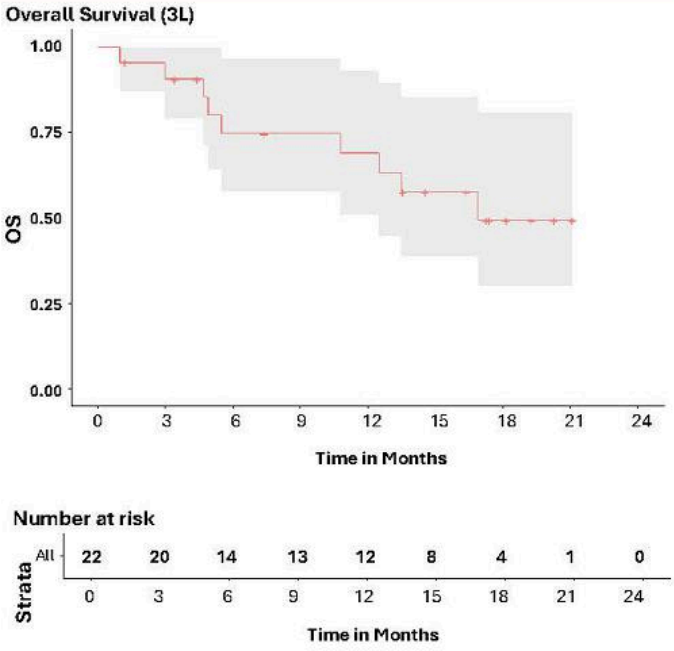
- Best results observed in THIO-101
- Highly unmet medical need in this CPI and chemo-resistant population
- Large population
- No current standard of care for this setting
- Limited competition for clinical trials patients

THIO-104 (Phase 3, planned):

- Full approval trial planned to start in H1 2025

Focus on execution:

- Probability of OS to be > 7.8 months (HR 0.74 vs. chemo) is >99%



Note: Clinical data presented from **15Jan2025** data cut and includes all patients who received at least one dose of THIO (intent to treat population). This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data is subject to change.

1. Details on safety can be found on the previously announced SITC 2024 presentation available on MAIA's website.

EXPECTED EFFICACY IN PIVOTAL TRIALS IN NSCLC 3L

MAIA BIOTECHNOLOGY
NYSE American: MAIA

	THIO-101 Pivotal Phase 2	THIO-104 Pivotal Phase 3	
	THIO + Libtayo® (n = 137-148)	**THIO + CPI** (n = 150)	**Chemotherapy** (n = 150)
Target Population	• CPI + Platinum Resistant • Prior treatment with docetaxel	• CPI + Platinum Resistant • Stratified: prior docetaxel vs. no prior docetaxel	
DCR	88%	>80%	30%
ORR	38%	>30%	6%
PFS	5.5 months	5.5 months	2 months
OS	Not reached at 12.2 months median follow-up[1]	Projected: >12 months Needed: 7.8 months	5.8 months

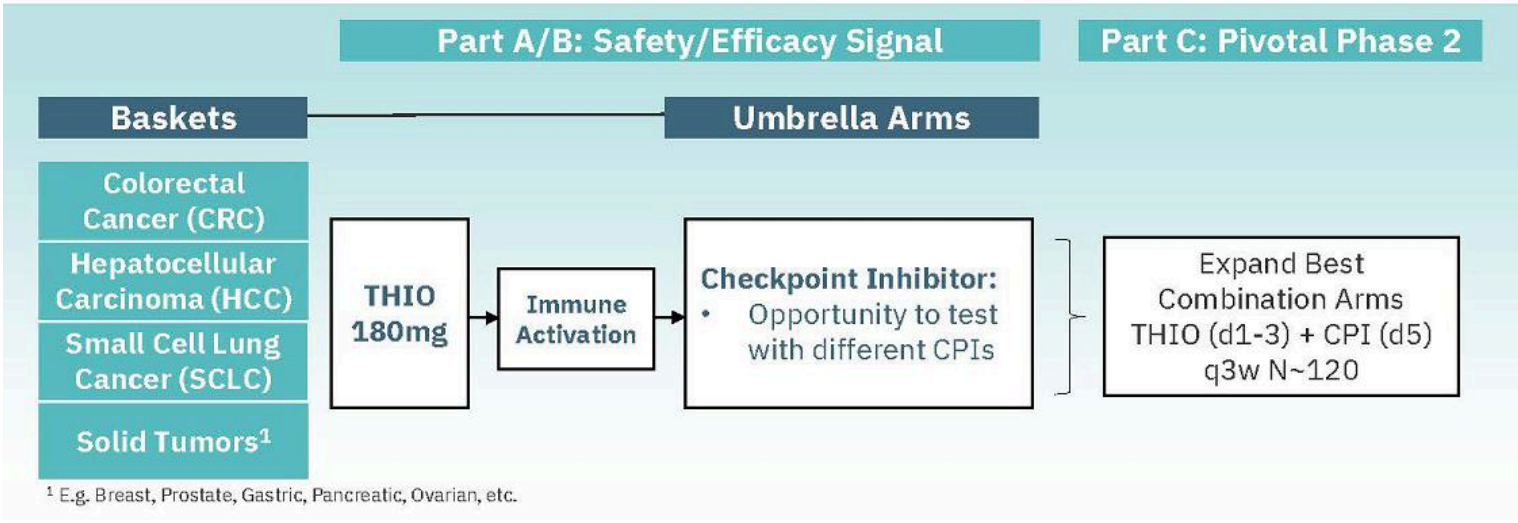
1. Based on the lower bound of the 95% confidence interval of the median OS (November 15 data cut off). Final estimates may differ as follow-up continues.

OTHER TUMOR TYPES PLANNED 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 a Checkpoint Inhibitor (CPI)

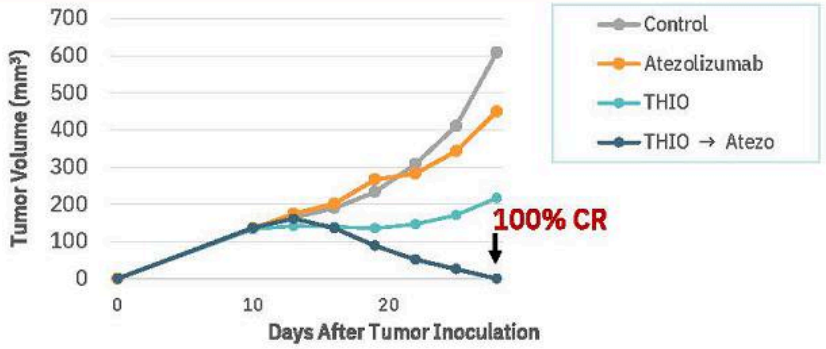


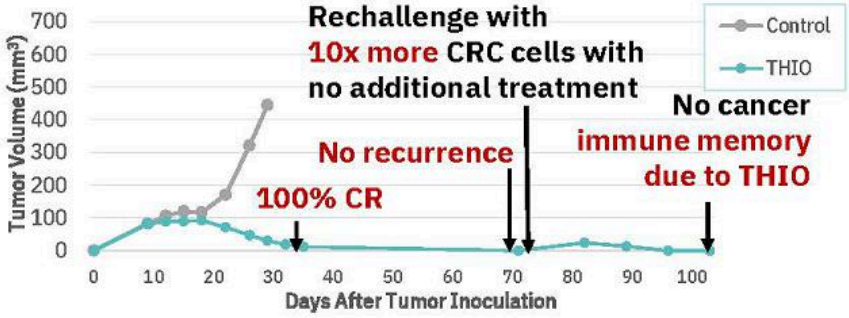
[1] E.g. Breast, Prostate, Gastric, Pancreatic, Ovarian, etc.

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

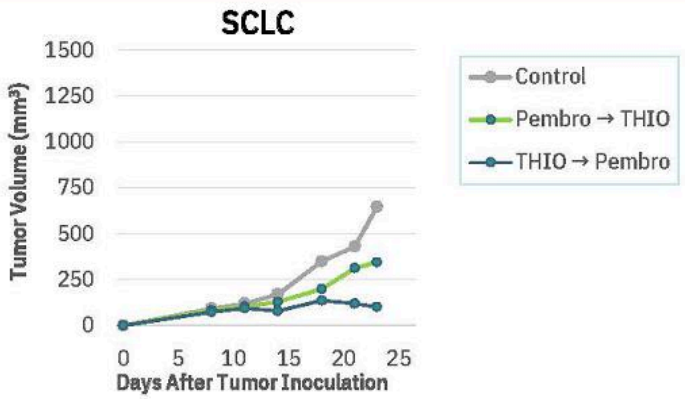


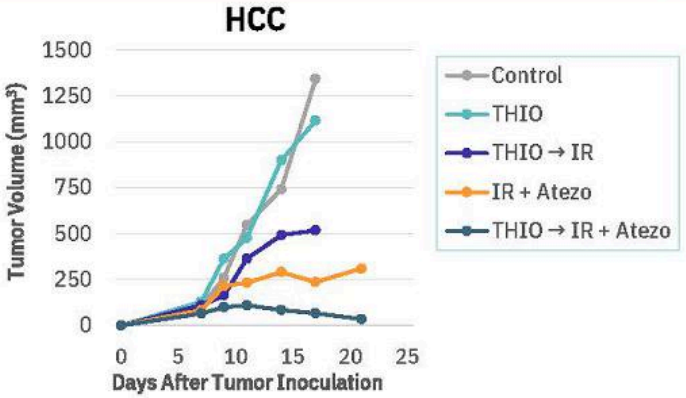


Note: Mender et al, Cancer Cell, 2020.

SCLC & HCC – ORPHAN DRUG DESIGNATION

MAIA BIOTECHNOLOGY
NYSE American: MAIA





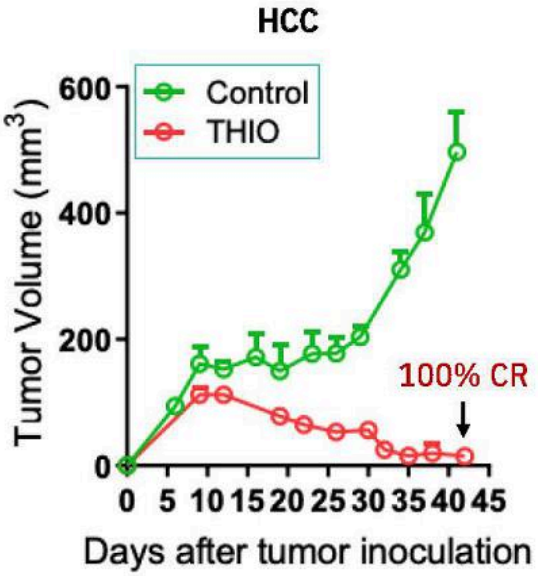
- THIO is synergistic with anti-PD-1 agent Pembrolizumab in Small Cell Lung Carcinoma (H2081) *in vivo* in humanized murine cancer model
- Treatment with THIO followed by Pembrolizumab results in highly potent anticancer effect, as compared to Pembrolizumab alone
- THIO converts immunologically "cold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

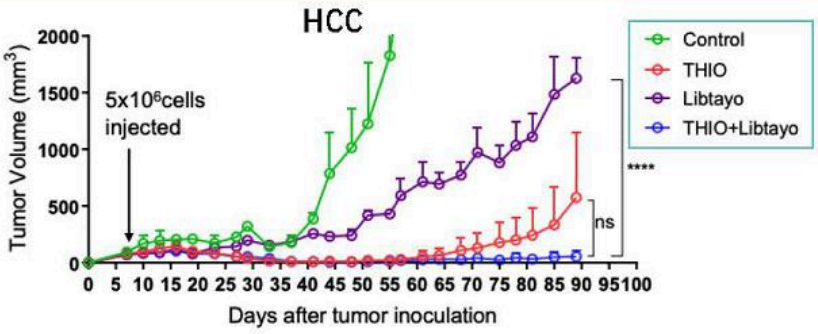
- THIO achieved complete and durable responses in Hepatocellular Carcinoma (HCC), the dominant histology in primary liver cancer (90%), in *in vivo* models

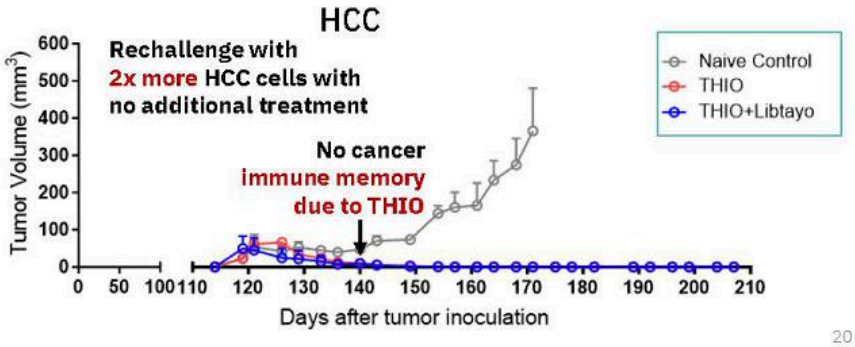


HCC ANTI-CANCER IMMUNE MEMORY

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

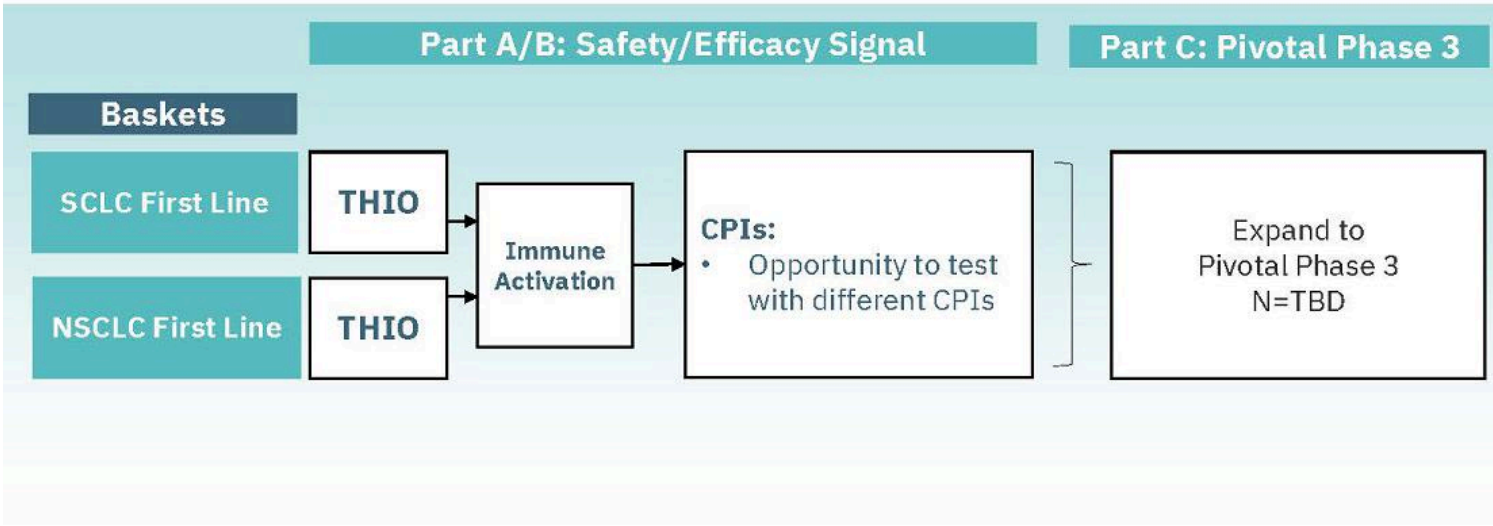




THIO-103 TRIAL (PLANNED)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with a Checkpoint Inhibitor (CPI)



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

- 9 issued patents
- 22 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

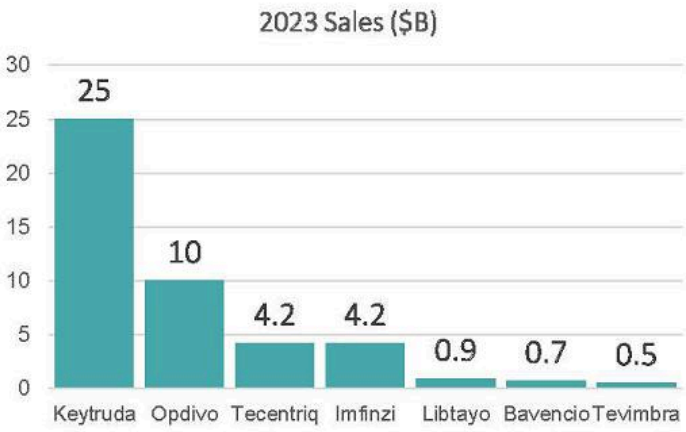
Developing agents for the top tumor types markets globally

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

Checkpoint Inhibitors Market



- Keytruda® expected to hit $30B in 2026, biosimilars expected by 2028

COMPARABLE COMPANIES

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- **August 2022** - Bristol Myers Squibb (BMS) completed **$4.1B** acquisition of Turning Point Therapeutics
- **January 2024** - BMS completed **$5.8B** acquisition of Mirati Therapeutics

MAIA BIOTECHNOLOGY	Bicycle	ARRIVENT	ARCUS	Turning Point Therapeutics	MIRATI THERAPEUTICS
$50.6M	**$0.66B**	**$0.67B**	**$0.9B**	**$3.8B**	**$4.1B**
Market Cap[1]	Market Cap[1]	Market Cap[1]	Market Cap[1]	Market Cap[2]	Market Cap[2]
$1.75/share	$9.5/share	$19.6/share	$9.1/share	$76/share	$58/share
NYSE:MAIA	NASDAQ:BCYC	NASDAQ:AVBP	NYSE:RCUS	Acquired by BMS	Acquired by BMS
Clinical Development Stage	Clinical Development Stage	Clinical Development Stage	Clinical Development Stage	Clinical Development Stage	Clinical Development Stage
Phase II	**Phase II**	**Phase III**	**Phase III**	**Phase II**	**Commercial**

1. Market cap and share price (close) as of March 19, 2025 (Source: Yahoo! Finance)
2. Last known market cap and share price before acquisition (Source: companiesmarketcap.com)

MULTIPLE VALUE-DRIVING MILESTONES

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	2025				2026		
THIO-104 Ph3 NSCLC 3L		**Enrollment** First Patient In ★				**Potential Filing for Early Full Approval in US (from interim analysis)** ★	
THIO-101 Ph2 NSCLC 2L+	**Part C** First Patient In ★	**Part B Full Efficacy** ★	**Part C Efficacy Update**	**Enrollment Complete**	**Filing for US approval**	**Potential Filing for Accelerated Approval in US** ★	
THIO-102 Ph2 CRC, SCLC, HCC, ST				**Enrollment** First Patient In ★		**Early Safety Report** ★	**Early Efficacy Report**
THIO-103 Ph2/3 SCLC 1L, NSCLC 1L					**Enrollment** First Patient In ★		**Early Safety Report** ★

★ **Major inflection points**

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 AND 1 RARE PEDIATRIC DISEASE DESIGNATION TO THIO

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THIO has been granted 3 Orphan Drug Designations (ODD):

- ✓ Hepatocellular Carcinoma (HCC, 90% of primary liver cancers)
- ✓ Small Cell Lung Cancer (SCLC, deadliest lung cancer)
- ✓ Glioblastoma (brain cancer)

- The FDA's Orphan Drug Act of 1983 is designed to incentivize the development of therapies that demonstrate promise for the treatment of rare (orphan) diseases or conditions
- **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 1 Rare Pediatric Disease Designation (RPDD):

- ✓ Pediatric-type diffuse high-grade gliomas

- The rare pediatric disease program aims to incentivize drug development for rare pediatric diseases. A sponsor who receives an approval for a drug or biological product for a rare pediatric disease may qualify for a voucher that can be redeemed to receive priority review for a different product.