
**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): May 31, 2025

MAIA Biotechnology, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41455
(Commission
File Number)

83-1495913
(IRS Employer
Identification No.)

444 West Lake Street, Suite 1700
Chicago, IL
(Address of principal executive offices)

60606
(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.

MAIA Biotechnology, Inc. (the “Company”) has prepared a poster (the “Poster”) showing the 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. The Poster was selected as an “abstract” and originally presented and displayed at the 2025 ASCO (American Society of Clinical Oncology) Annual Meeting on May 31, 2025. The Poster will also be posted to the Company’s website on June 2, 2025, 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.

The information contained in the Poster 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 Poster speaks as of the date of this Report. While the Company may elect to update the Poster 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 Poster contains forward-looking statements, and as a result, investors should not place undue reliance on these forward-looking statements.

The information set forth in under Item 7.01 of this Report, including, without limitation, the Poster, 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

The Company has made available a presentation about the Company’s business and was posted to the Company’s website on June 2, 2025, a copy of which is filed as Exhibit 99.2 to this Current Report on Form 8-K (“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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Poster
99.2	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: June 2, 2025

MAIA BIOTECHNOLOGY, INC.

By: /s/ Vlad Vitoc

Name: Vlad Vitoc

Title: Chief Executive Officer



MAIA
BIOTECHNOLOGY

TELOMERE TARGETING IMMUNOTHERAPIES FOR CANCER
NYSE AMERICAN: MAIA

June 2025

FORWARD-LOOKING STATEMENTS

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 2024, 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 2024, 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.

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

- Lead molecule Ateganosine (THIO) in clinic; 2nd generation compounds in R&D
- Ateganosine approved as non-proprietary (generic) name for THIO by USAN and INN

Phase 2 trial THIO-101 expansion in 2025: Ateganosine (THIO) + Libtayo® in NSCLC.

- Unprecedented disease control, response and survival data
- Continued clinical supply agreement with Regeneron (Libtayo)
- Potential filing for accelerated approval in 2026

Phase 3 trial THIO-104: Ateganosine (THIO) + Libtayo® 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.

- Non-small cell lung cancer (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 children's diffuse high-grade gliomas

Multiple Ateganosine (THIO) + tislelizumab trials planned for 3 additional cancer indications.

- Colorectal cancer (CRC), Liver (HCC), and SCLC to start enrollment in 2026
- Clinical supply agreement with BeOne Medicines (tislelizumab)



Ateganosine (THIO) Telomere Targeting Agent

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



Cancer is the most dominant age-related disease



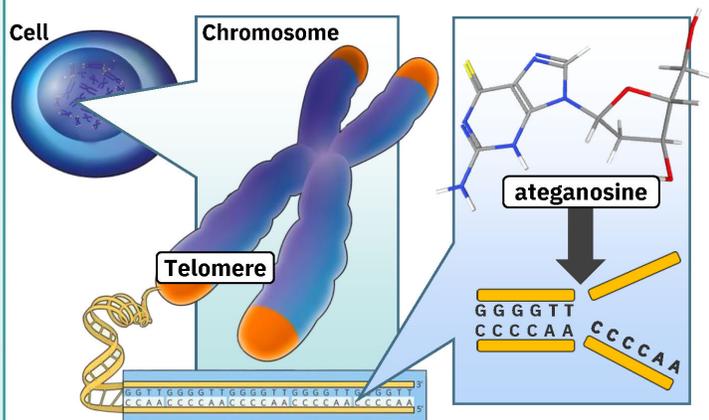
Source: UN (World Social Report, 2023); Worldometer (Life Expectancy of the World Population, 2024).



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

Ateganosine (THIO, 6-thio-2'-deoxyguanosine) has a novel dual mechanism of action

- 1 Telomere targeting
- 2 Immunogenic effect

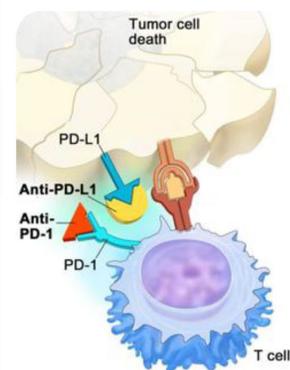


- 3 FDA Orphan Drug Designations: HCC, SCLC, Malignant Gliomas
- 1 Rare Pediatric Disease Designation (RPDD): Pediatric Gliomas

Followed by Immune Checkpoint Inhibitor (CPI)

Examples of commercially available CPIs

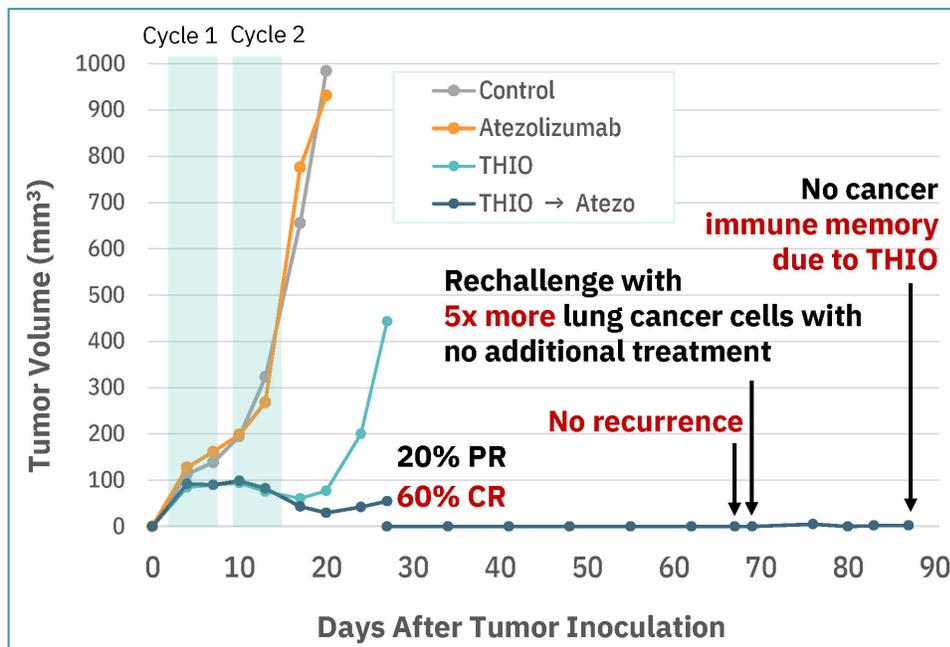
 (cemiplimab) REGENERON	 (tislelizumab) BeOne
 (pembrolizumab) MERCK	 (durvalumab) AstraZeneca
 (atezolizumab) Genentech <small>A Member of the Roche Group</small>	 (dostarlimab-gxly) Injection 500 mg GSK
 (nivolumab) Bristol Myers Squibb	 (avelumab) 20 mg/mL EMD SERONO



- Clinical supply agreement with Regeneron for NSCLC on THIO-101
- Clinical supply agreement with BeOne Medicines for HCC, SCLC and CRC on THIO-102 planned trials

Preclinical Studies in NSCLC

- Ateganosine (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



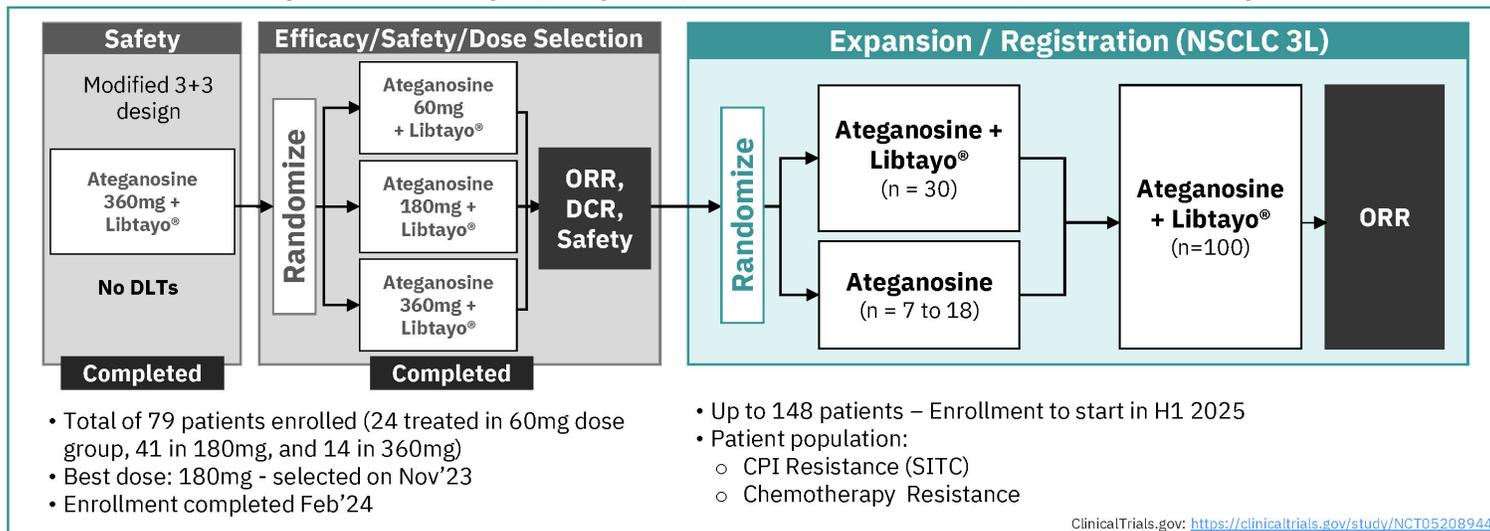
Source: Mender et al, Cancer Cell, 2020; THIO followed by Tecentriq (atezolizumab; Roche/Genentech) tested first; repeated later with THIO followed by Keytruda (pembrolizumab; Merck); and Libtayo (cemiplimab; Regeneron). Data from preclinical results.

NSCLC CLINICAL TRIALS

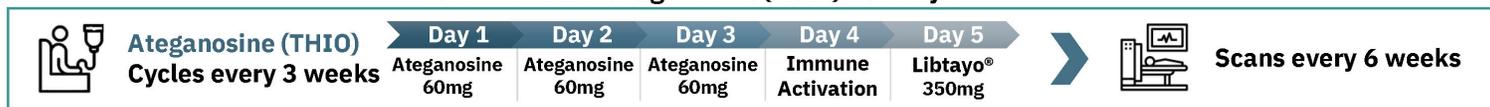


THIO-101 PHASE 2 PIVOTAL TRIAL (ONGOING)

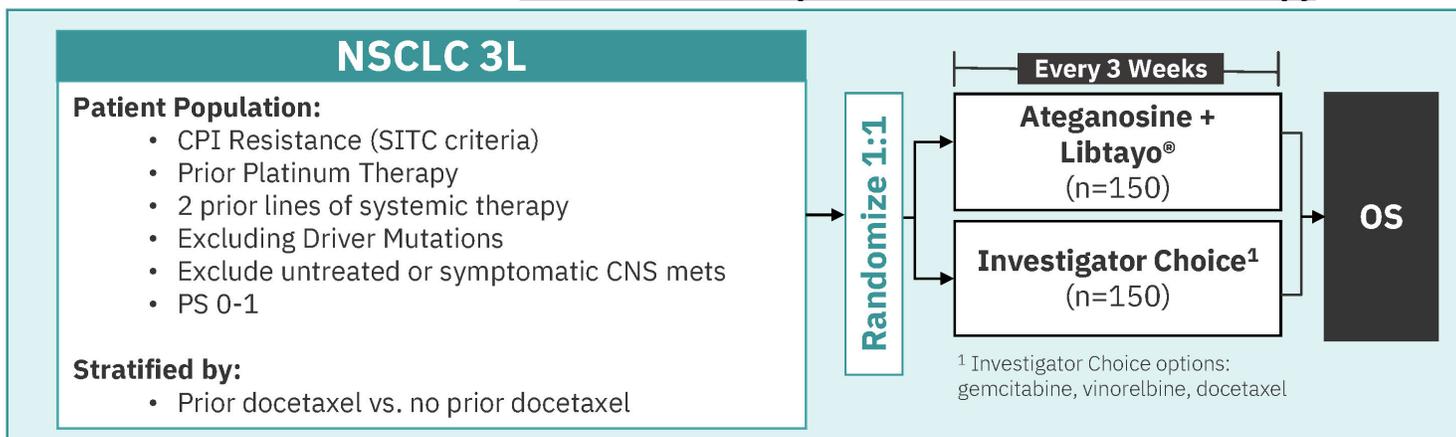
A Multicenter, Open-label, Dose-Finding Phase 2 Trial Evaluating the Safety and Efficacy of Ateganosine (THIO) Administered in Sequence with Libtayo® (cemiplimab) in NSCLC Patients Who Are Resistant to Checkpoint Inhibitors



Treatment with ateganosine (THIO) + Libtayo®



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



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 Ateganosine (THIO) in circulating tumor cells measured by specific biomarkers

THIO-101 (Pivotal Phase 2, ongoing):

- Median Overall Survival (OS) is at **17.8 months**¹
 - 95% CI lower bound: 12.5 months
 - 99% CI lower bound: 10.8 months
- The treatment has been generally well-tolerated to date in this heavily pre-treated population²

3L NSCLC is an excellent market entry segment:

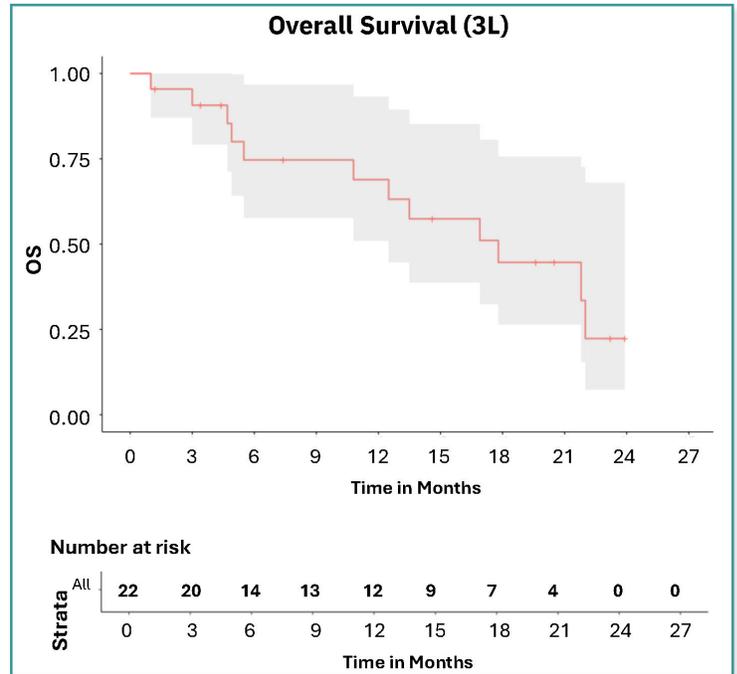
- Best results observed in THIO-101
- Highly unmet medical need in this immunotherapy-resistant and chemotherapy-resistant population
- Large population
- No current standard of care for this setting
- Limited competition for clinical trials patients

THIO-104 (Phase 3, planned):

- Full approval trial planned to start in 2025

Focus on execution:

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



1. Clinical data presented from 15May2025 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.

2. Details on safety can be found on the announced ASCO 2025 poster available on [MAIA's website](#).

THIO-101 Phase 2

	Ateganosine + Libtayo® (n = 137-148)
Target Population	<ul style="list-style-type: none"> • CPI + Platinum Resistant • Prior treatment with docetaxel
ORR	>30% ¹

THIO-104 Pivotal Phase 3

	Ateganosine + Libtayo® (n = 150)	Chemotherapy (n = 150)
Target Population	<ul style="list-style-type: none"> • CPI + Platinum Resistant • Stratified: prior docetaxel vs. no prior docetaxel 	
OS	Expected: >12 months Needed: 7.8 months	5.8 months ²

1. Chemotherapy has overall response rates of ~6-10% (Girard N, et al. J Thorac Onc 2009;12:1544-1549).

2. Girard N, et al. J Thorac Onc 2009;12:1544-1549.

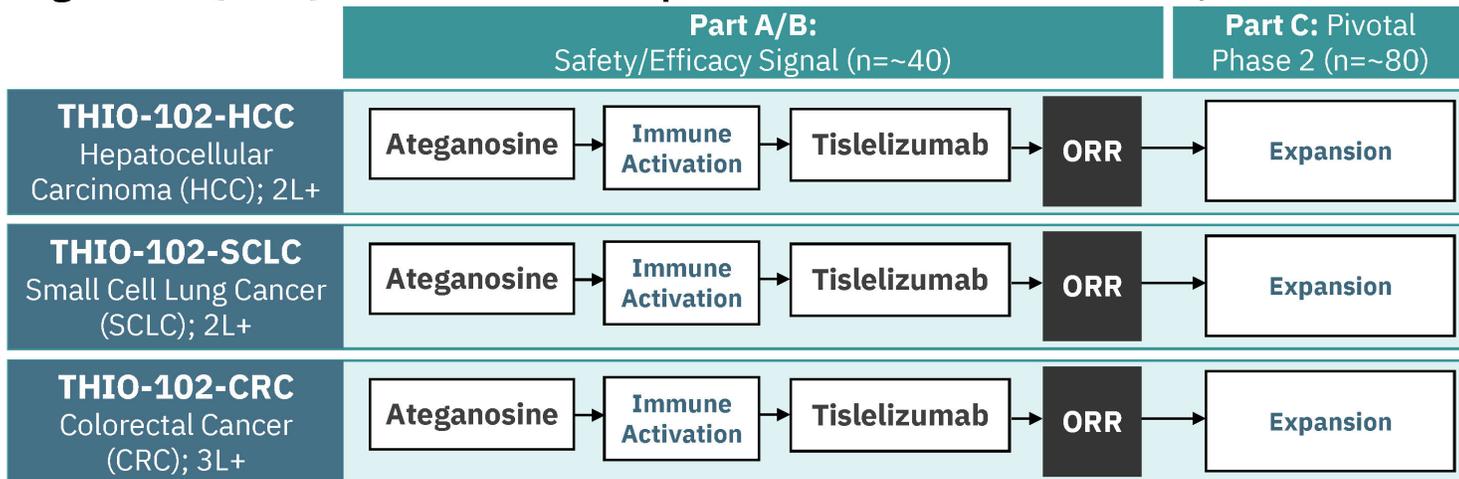
Note: Estimates based on the interim results observed from THIO-101.

PLANNED TRIALS IN OTHER TUMOR TYPES

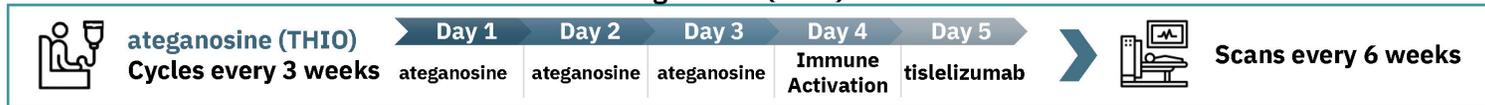


THIO-102 TRIALS (PLANNED)

Multicenter, Open-label, Phase 2 Trials Evaluating the Safety and Efficacy of Ateganosine (THIO) Administered in Sequence with Tislelizumab in HCC, SCLC and CRC



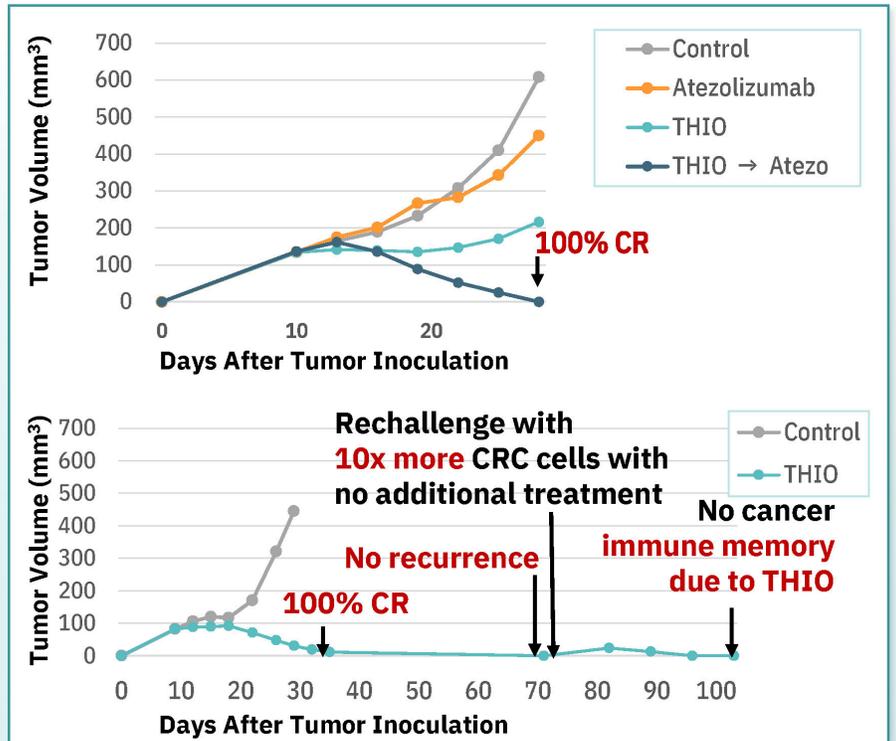
Treatment with Ateganosine (THIO) + tislelizumab



Note: Clinical trials currently in planning stage. Names of trials, indications and number of patients are subject to review and may be updated before trial initiation. Trials in solid tumors, such as Breast, Prostate, Gastric, Pancreatic and Ovarian may be pursued via investigator sponsored trials.

Preclinical Studies in Colorectal Cancer (CRC)

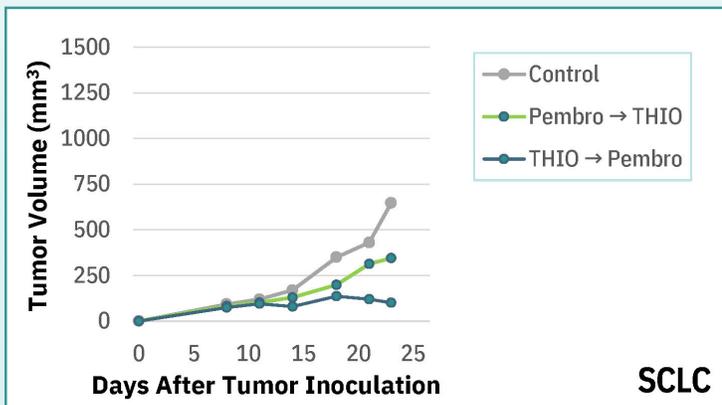
- Ateganosine (THIO) followed by CPI results in 100% complete response
- Only 2 cycles of therapy were administered on weeks 1 and 2; no further therapy throughout the study
- No recurrence after long-term follow-up
- Anticancer immune memory has been induced: no cancer after rechallenge with 10x more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



Source: Mender et al, Cancer Cell, 2020.

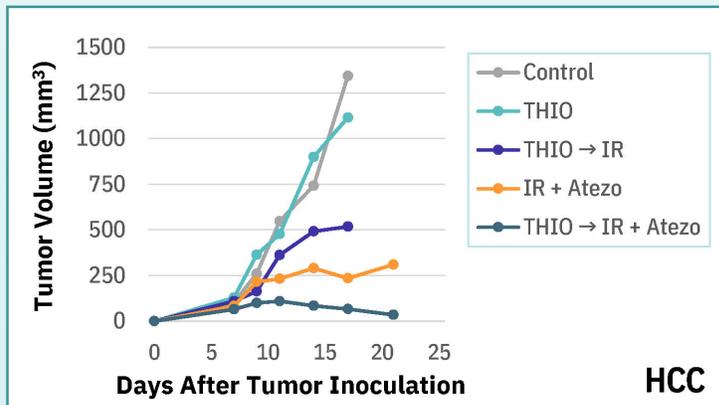
Preclinical Studies in Small Cell Lung Cancer (SCLC)

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

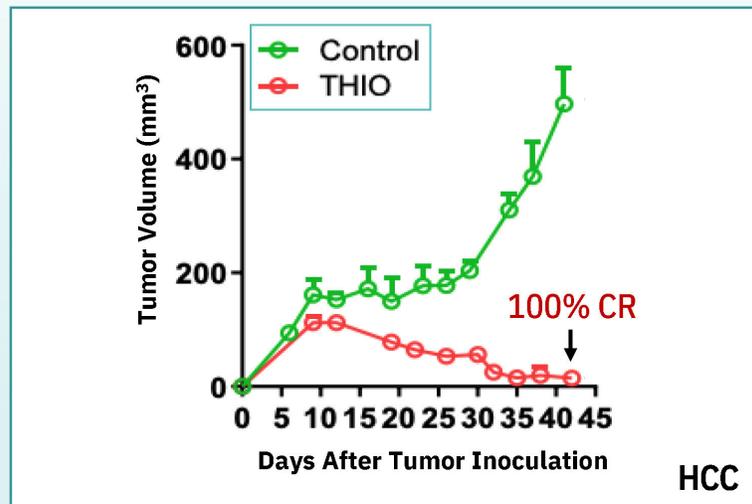


Preclinical Studies in Hepatocellular Carcinoma (HCC)

- Ateganosine (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 ateganosine (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

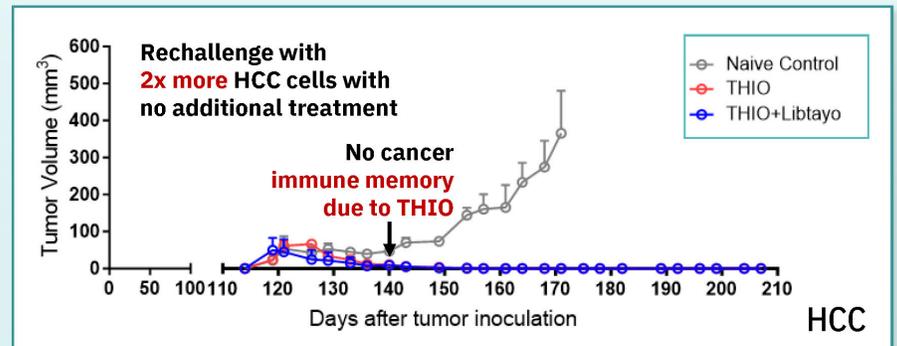
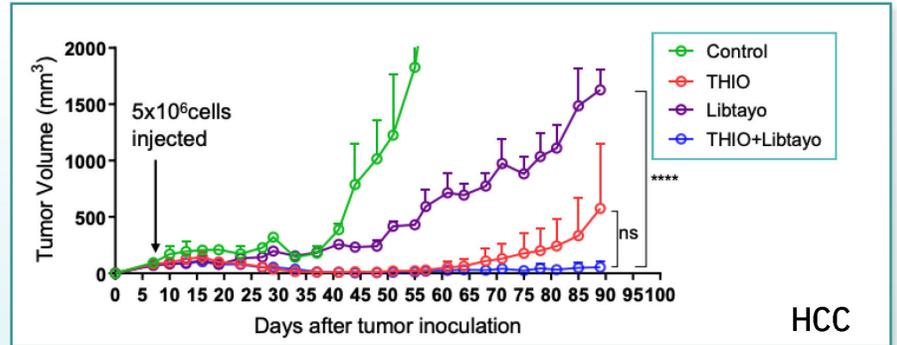


Ateganosine (THIO) achieved **complete and durable responses in Hepatocellular Carcinoma (HCC)**, the dominant histology in primary liver cancer (90%), in *in vivo* models

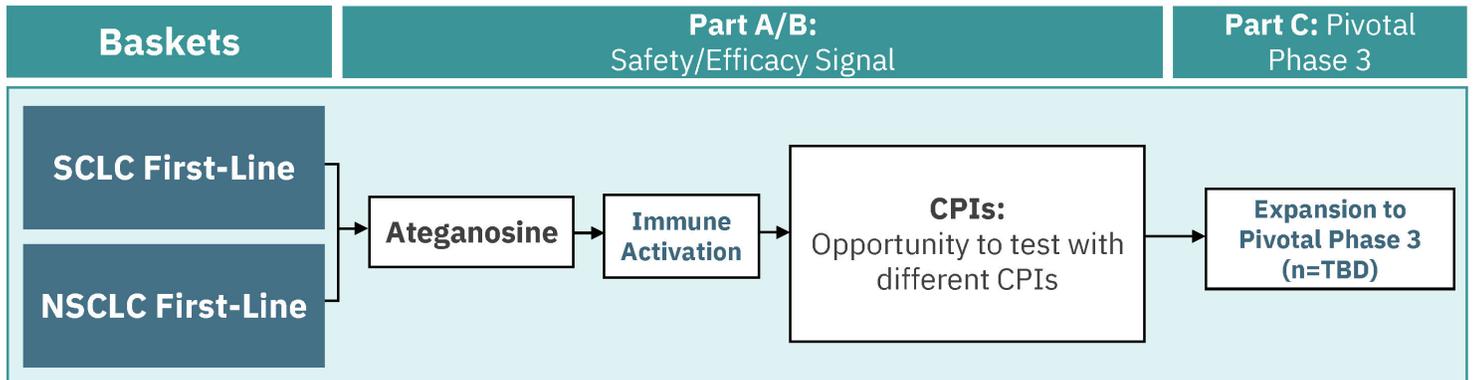


HCC ANTI-CANCER IMMUNE MEMORY

- 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 ateganosine (THIO) alone and in combination with Libtayo® generated anti-cancer immune memory



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



Note: Clinical trial currently in planning stage. Names of trials, indications and number of patients are subject to review and may be updated before trial initiation.

INVESTMENT OPPORTUNITY



Goal: New Chemical Entity (NCE) Marketing Exclusivity

- Ateganosine (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+)
- Ateganosine's (THIO) immunogenic treatment strategy: sequential combination with CPIs (2041)

EXPERIENCED MANAGEMENT TEAM



**Vlad Vitoc,
MD, MBA**
Founder and CEO

- 25+ 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

- 26+ 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





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

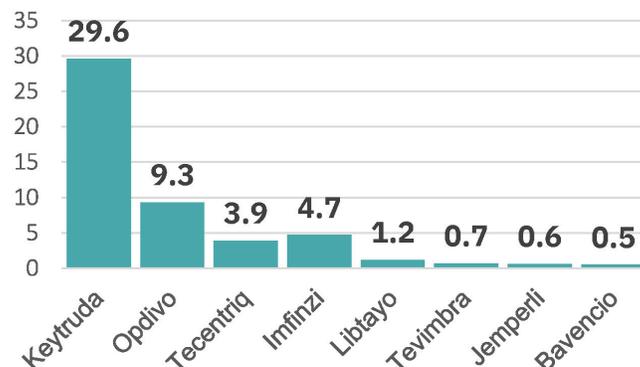


\$50B CPIs Group (2024 Sales)

- 5 CPIs approved for NSCLC:
 - > 30% of NSCLC drug sales
 - > 40% of total CPI sales
- Keytruda®: NSCLC ~30% of \$29.6B total

Checkpoint Inhibitors Market

2024 Sales (\$B)



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

COMPARABLE COMPANIES

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

 <p>\$60.4M Market Cap¹ \$2.04/share NYSE:MAIA Clinical Development Stage Phase II</p>	 <p>\$0.58B Market Cap¹ \$19.6/share NASDAQ:ANAB Clinical Development Stage Phase III</p>	 <p>\$0.69B Market Cap¹ \$20.1/share NASDAQ:AVBP Clinical Development Stage Phase III</p>	 <p>\$0.88B Market Cap¹ \$8.3/share NYSE:RCUS Clinical Development Stage Phase III</p>	 <p>\$3.8B Market Cap² \$76/share Acquired by BMS Clinical Development Stage Phase II</p>	 <p>\$4.1B Market Cap² \$58/share Acquired by BMS Clinical Development Stage Commercial</p>
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1. Market cap and share price (close) as of May 9, 2025 (Source: Yahoo! Finance)
2. Last known market cap and share price before acquisition (Source: companiesmarketcap.com)

MULTIPLE VALUE-DRIVING MILESTONES

Trial (Phase, Indication)	2025	2026	2027
THIO-104 Ph3 NSCLC 3L	 Enrollment First Patient In (FPI)	 Potential Filing for Early Full Approval in US (from interim analysis)	 Potential Filing for Full Approval in US (from final analysis)
THIO-101 Ph2 NSCLC 3L	 Enrollm. Part C FPI	 Efficacy Part B Report	 Enrollm. Part C Completed / Part D FPI
THIO-102-HCC Ph2 HCC 2L+		 Enrollm. FPI	 Safety Early Report
THIO-102-SCLC Ph2 SCLC 2L+		 Enrollment FPI	 Safety Early Report
THIO-102-CRC Ph2 CRC 3L+		 Enrollment FPI	 Safety Early Report
THIO-103 Ph2/3 SCLC 1L, NSCLC 1L			 Enrollm. FPI

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

 **Major inflection points**

THANK YOU

Investor Relations Contact

+1 (872) 270-3518

ir@maiabiotech.com

MAIA Biotechnology, Inc.

444 West Lake Street, Suite 1700

Chicago, IL 60606



MAIA

BIOTECHNOLOGY

NYSE American: MAIA

APPENDIX





U.S. FDA Granted 3 Orphan Drug Designations and 1 Rare Pediatric Disease Designation to ateganosine (THIO)

- **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
- **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.