
**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): September 12, 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 8.01 Other Events

On September 12, 2025, MAIA Biotechnology, Inc. (the “Company”) posted an updated presentation about the Company’s business on its website (www.maiabiotech.com), a copy of which is filed as Exhibit 99.1 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	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: September 12, 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

September 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.

INVESTMENT PROFILE

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

- ✓ Lead molecule Ateganosine (THIO) in clinic
- ✓ Second generation compounds in R&D

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

- ✓ Unprecedented disease control, response and survival data
- ✓ Regeneron: continued clinical supply agreement for Libtayo
- ✓ Potential for accelerated approval

Phase 3 trial THIO-104: Ateganosine (THIO) + Libtayo® vs. Investigator's Choice in NSCLC.

- ✓ Interim analysis can lead to potential early full commercial approval
- ✓ Final analysis for potential for commercial approval with very high probability of technical success (based on THIO-101 survival data)

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

- ✓ Colorectal cancer (CRC), liver (HCC), and small cell lung cancer (SCLC)
- ✓ BeOne Medicines: clinical supply agreement for tislelizumab

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

- ✓ Non-small cell lung cancer (NSCLC): largest tumor type globally, \$34B annual sales
- ✓ Roche: master agreement signed in 2025 for a future clinical trial
- ✓ 3 FDA Orphan Drug Designations: liver (HCC), lung (SCLC) and brain (malignant gliomas)
- ✓ 1 FDA Rare Pediatric Disease Designation for children's brain cancers
- ✓ 1 FDA Fast Track Designation: 3L NSCLC patients resistant to chemo and CPI

ROBUST PIPELINE

Ateganosine (THIO) Telomere Targeting Agent

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

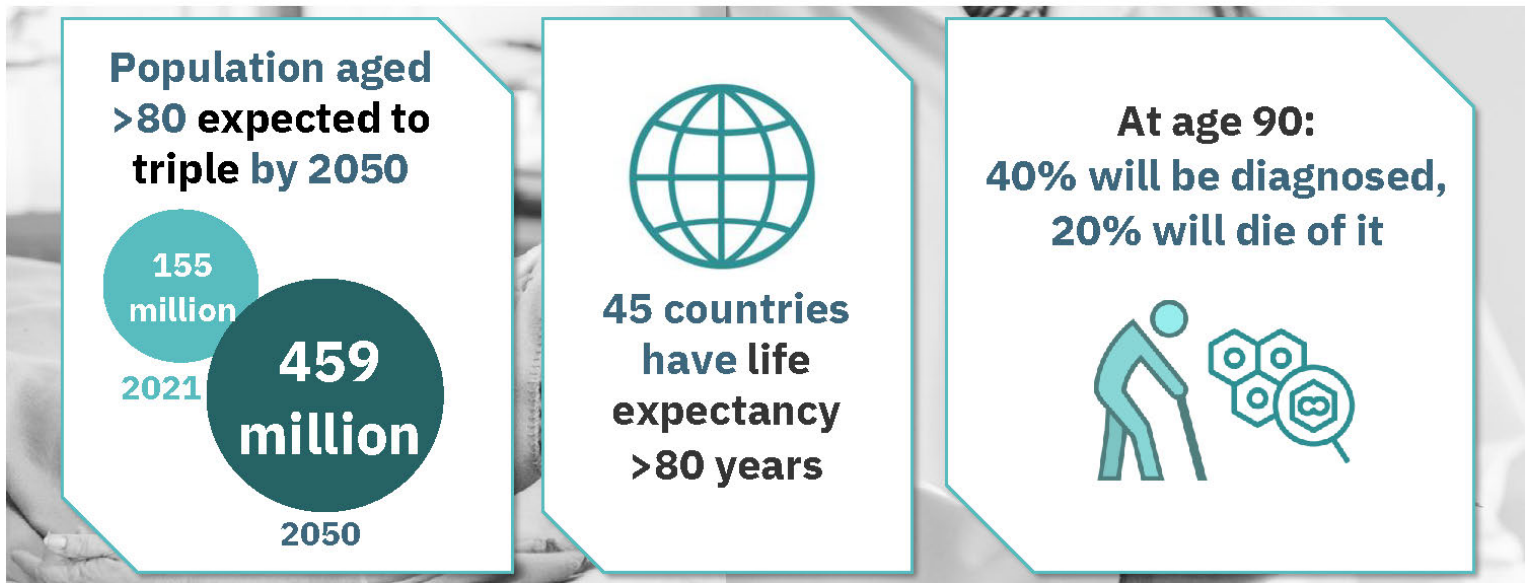
2nd Generation Telomere Targeting Agents

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).

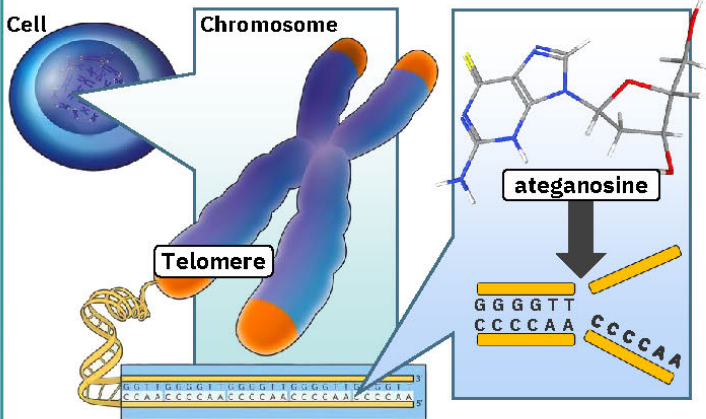


**Ateganosine (THIO)
is the only direct
telomere targeting
anticancer agent
in clinical development**

TREATMENT WITH ATEGANOSINE

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

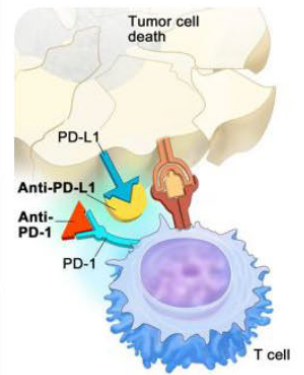
- 1 Telomere targeting
- 2 Immunogenic effect



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

Followed by
Immune Checkpoint Inhibitor (CPI)

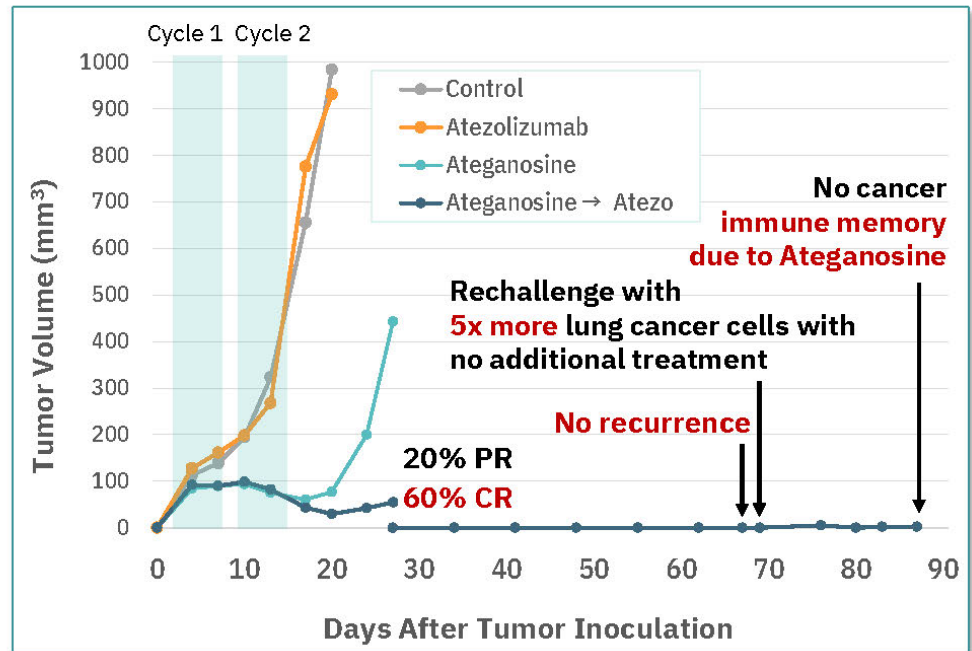
Examples of commercially available CPIs



- Clinical supply agreement with Regeneron for NSCLC on THIO-101
- Clinical supply agreement with BeOne Medicines for CRC, SCLC and HCC on THIO-102 planned trials
- Master agreement with Roche for a future clinical trial

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



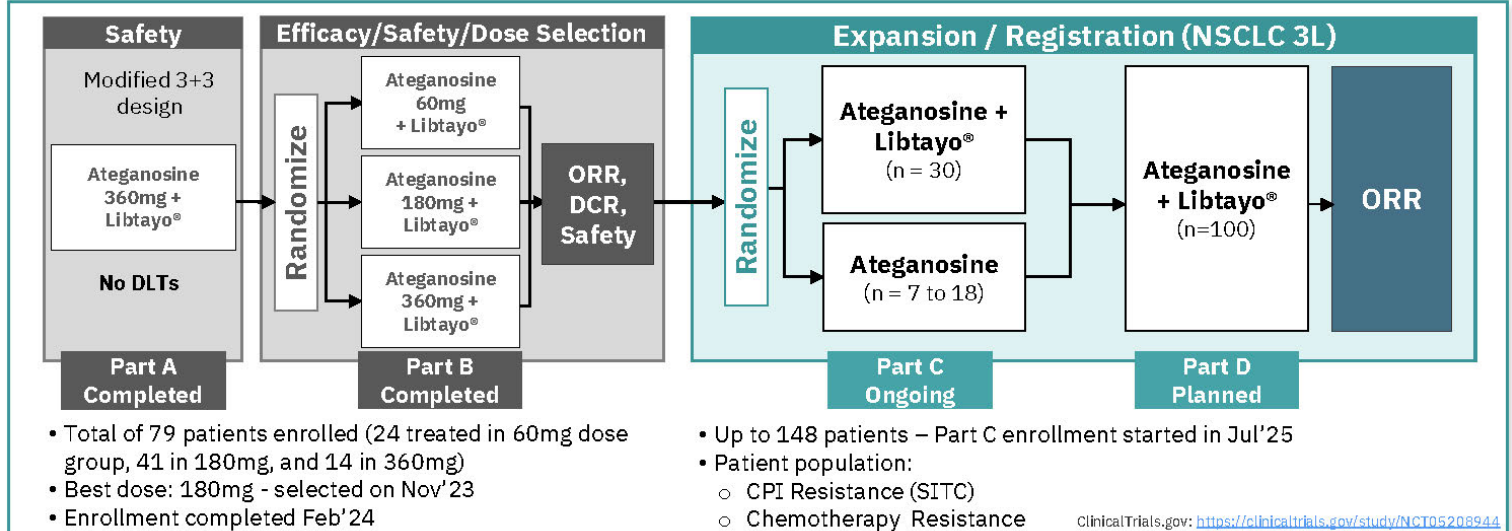
Source: Mender et al, Cancer Cell, 2020; Ateganosine (THIO) followed by Tecentriq (atezolizumab; Roche/Genentech) tested first; repeated later with Ateganosine followed by Keytruda (pembrolizumab; Merck); and Libtayo (cemiplimab; Regeneron). Data from preclinical results.

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®



Ateganosine (THIO)
Cycles every 3 weeks

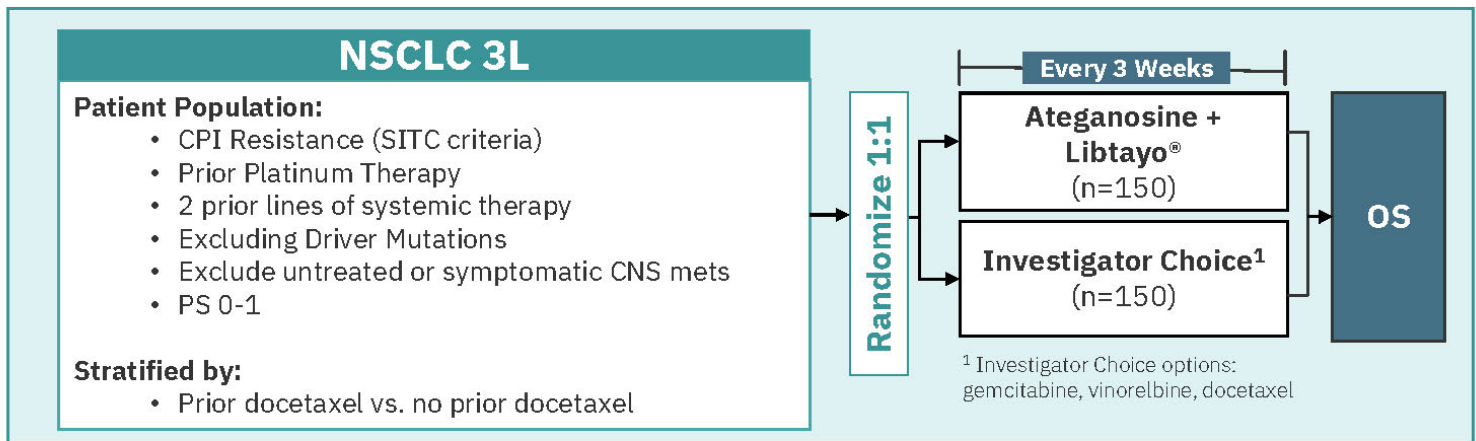
Day 1	Day 2	Day 3	Day 4	Day 5
Ateganosine 60mg	Ateganosine 60mg	Ateganosine 60mg	Immune Activation	Libtayo® 350mg



Scans every 6 weeks

THIO-104 PHASE 3 PIVOTAL TRIAL (INITIATING)

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

BEST RESULTS IN THIRD-LINE NSCLC

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:

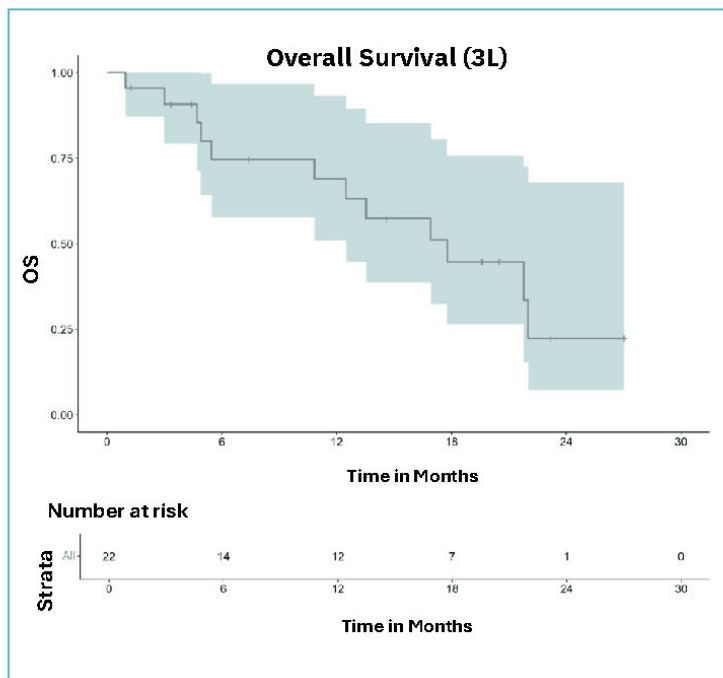
- Best results observed in THIO-101
- Highly unmet medical need in this immunotherapy-resistant and chemotherapy-resistant population
- Large population
- No current standard of care for this setting
- Limited competition for clinical trials patients

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 **30Jun2025** 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](#).

EXPECTED EFFICACY IN TRIALS IN NSCLC 3L

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.

THIO-104 Design

- OS is the primary endpoint
- 90% power to detect HR=0.62, median 9.4 months vs 5.8 months¹ (chemo)
- Interim analysis boundary 1-sided $p < 0.0074$ at 131 deaths
- Final analysis boundary 1-sided $p < 0.0228$ at 186 deaths

Bayesian Assurance² Calculation

All 3L patients from THIO-101

Control:

- Median OS assumption (literature):
✓ 6.1 months (95% CI: 2.8, 8.9)³

Ateganosine (THIO):

- Using 3L data from THIO-101 (n=22):
✓ 17.8 months (95% CI: 12.5, 22.5)⁴

Probability to succeed at the interim analysis = **96%**

Probability to succeed at the final analysis = **99%**

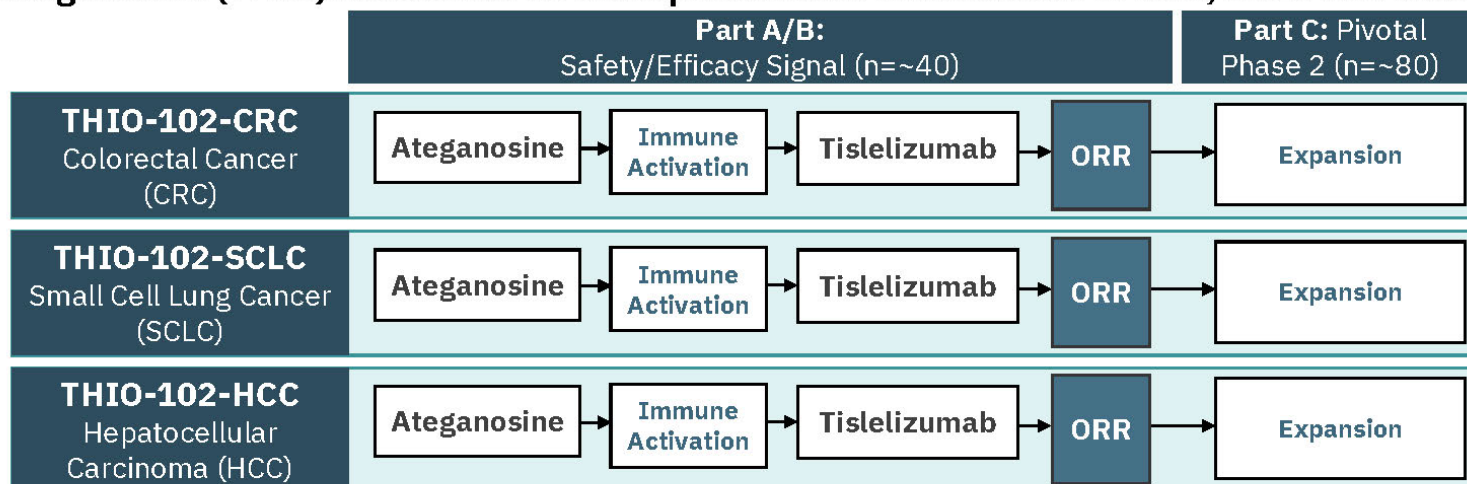
1. Girard N, et al. J Thorac Onc 2009;12:1544-1549.
2. O'Hagan A, Stevens JW, Campbell MJ. Assurance in clinical trial design. Pharmaceutical Statistics 2005; 4:187-201.
3. A.T. Freeman et al. Curr Oncol. 2020 May 1;27(2):76-82
<https://pmc.ncbi.nlm.nih.gov/articles/PMC7253749/>
4. Observed median OS from THIO-101 as of 30-Jun-2025.

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 CRC, SCLC and HCC



Treatment with Ateganosine (THIO) + tislelizumab



ateganosine (THIO)
Cycles every 3 weeks

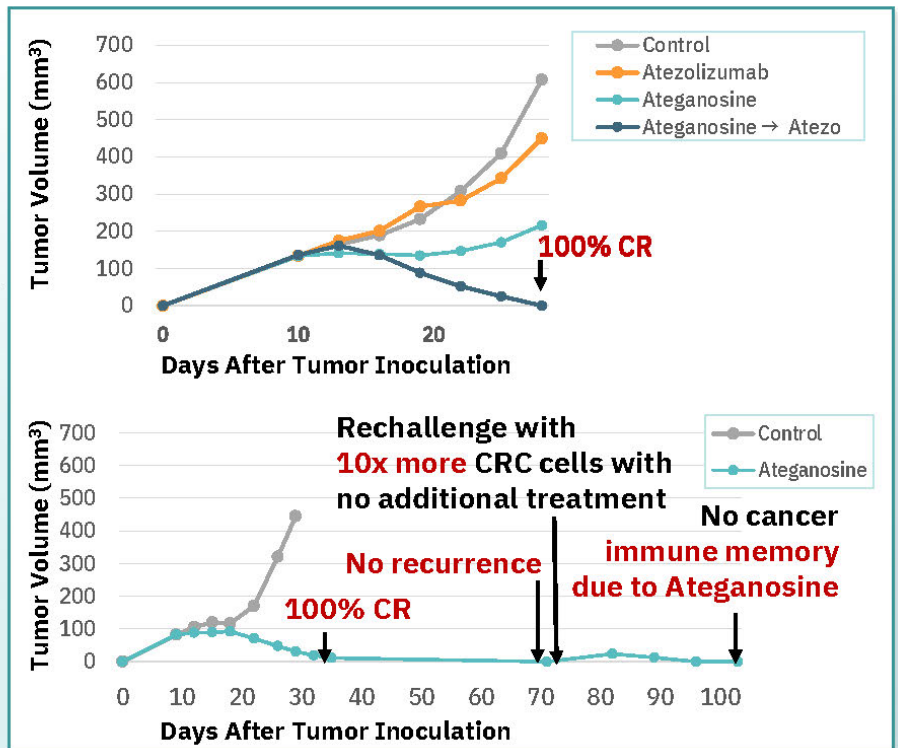


Scans every 6 weeks

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

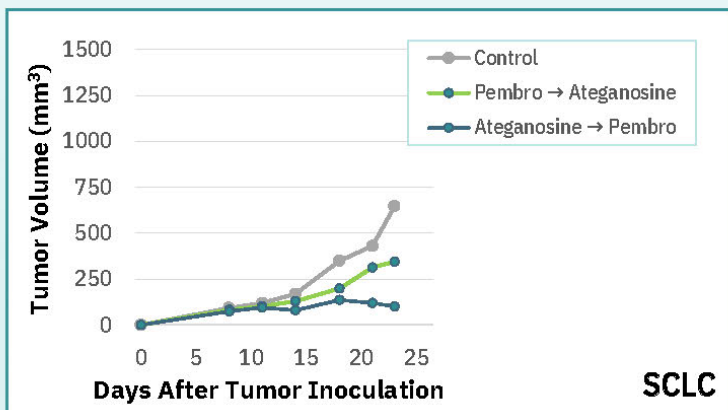


Source: Mender et al, Cancer Cell, 2020.

SCLC & HCC – AWARDED ORPHAN DRUG DESIGNATIONS

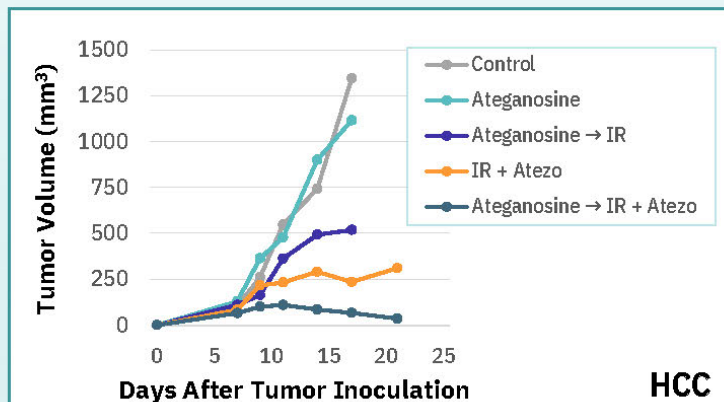
Preclinical Studies in Small Cell Lung Cancer (SCLC)

- 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 converts immunologically “cold non-responsive” SCLC tumor into “hot and responsive” to Pembrolizumab



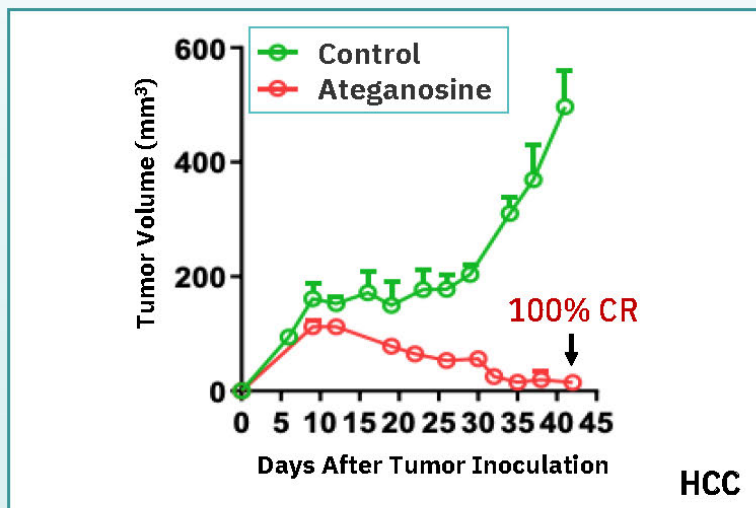
Preclinical Studies in Hepatocellular Carcinoma (HCC)

- 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

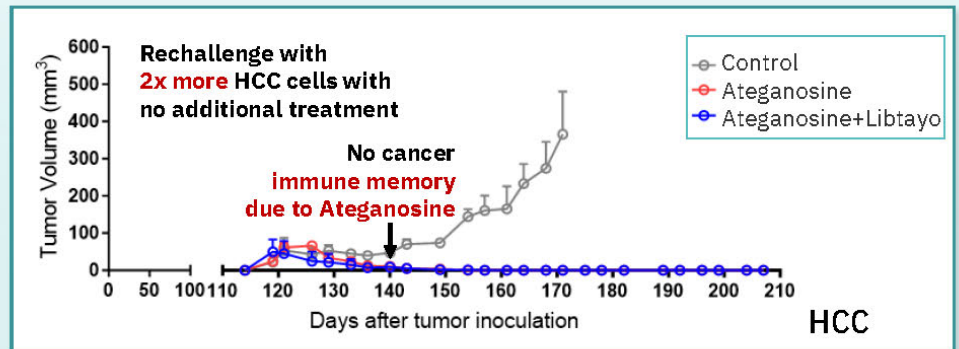
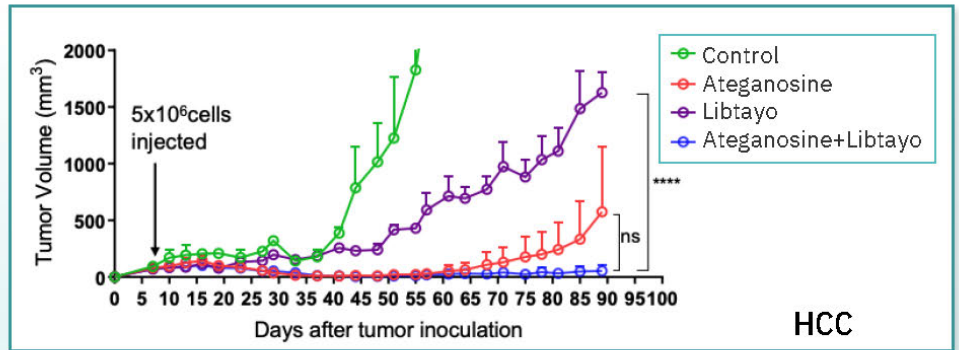


EXCELLENT EFFICACY IN HCC MODELS

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



- 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



INVESTMENT OPPORTUNITY



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



Goal: New Chemical Entity (NCE) Marketing Exclusivity

- Ateganosine (THIO) has never been previously approved by the FDA for commercialization
- Robust exclusivity
 - **US:** Upon FDA approval - 5 years NCE (with additional 2 years based on Hatch Waxman for potential generic challenge), 2 years Rare Pediatric Disease designation, and 7 years Orphan Drug Designation (ODD); MAIA has obtained ODD for HCC, SCLC, Malignant Gliomas (including GBM).
 - **EU, Japan, other markets:** 10 years

Robust and Growing Patent Portfolio for THIO

- 10 issued patents and Europe validated in 19 countries
- 36 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)

Next generation – Composition of matter patents

- MAIA-001, Multiple Tumor Types, exclusivity to 2043
- MAIA-002, Multiple Tumor Types, exclusivity to 2044
- MAIA-003, Multiple Tumor Types, exclusivity to 2044



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

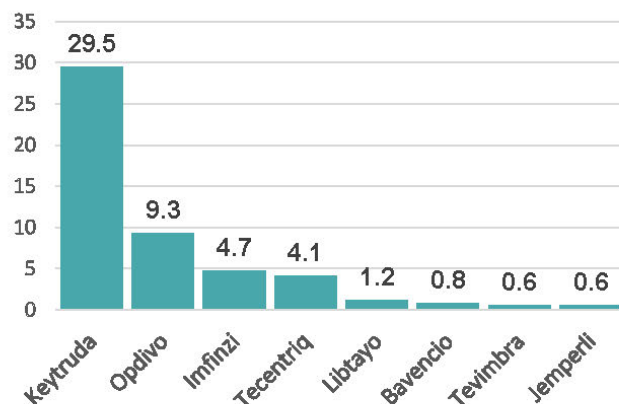


\$50B CPIs Group (2024 Sales)

- 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

Sales (\$ B)



- Keytruda® expected to hit \$35B in 2027, 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

MAIA BIOTECHNOLOGY	AnaptysBio	ARRIVENT	ARCUS	Turning Point Therapeutics	MIRATI THERAPEUTICS
\$56M	\$0.65B	\$0.79B	\$1.2B	\$3.8B	\$4.1B
Market Cap ¹	Market Cap ¹	Market Cap ¹	Market Cap ¹	Market Cap ²	Market Cap ²
\$1.56/share	\$22.8/share	\$18.9/share	\$11.72/share	\$76/share	\$58/share
NYSE:MAIA	NASDAQ:ANAB	NASDAQ:AVBP	NYSE:RCUS	Acquired by BMS	Acquired by BMS
Clinical Development Stage Phase II	Clinical Development Stage Phase III	Clinical Development Stage Phase III	Clinical Development Stage Phase III	Clinical Development Stage Phase II	Clinical Development Stage Commercial

1. Market cap and share price (close) as of September 10, 2025 (Source: Yahoo! Finance)

2. Last known market cap and share price before acquisition (Source: companiesmarketcap.com)

THANK YOU

Investor Relations Contact

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Chicago, IL 60606



MAIA
BIOTECHNOLOGY
NYSE American: MAIA

APPENDIX



MAIA
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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

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.

1 Fast Track Designation (FTD)

☐ Non-Small Cell Lung Cancer

- The FDA Fast Track is a process designed to **facilitate development and expedite the review of drugs** for treating serious conditions and filling an unmet medical need, as in providing a therapy where none exists or which may be potentially better than available therapy. If relevant criteria are met during the Fast Track process, a drug will be eligible for FDA Accelerated Approval and Priority Review (FDA decision within six months).