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): April 22. 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** **(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

MAIA Biotechnology, Inc. (the "Company") has made available a presentation about the Company's business and was posted to the Company's website on April 22, 2025, 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

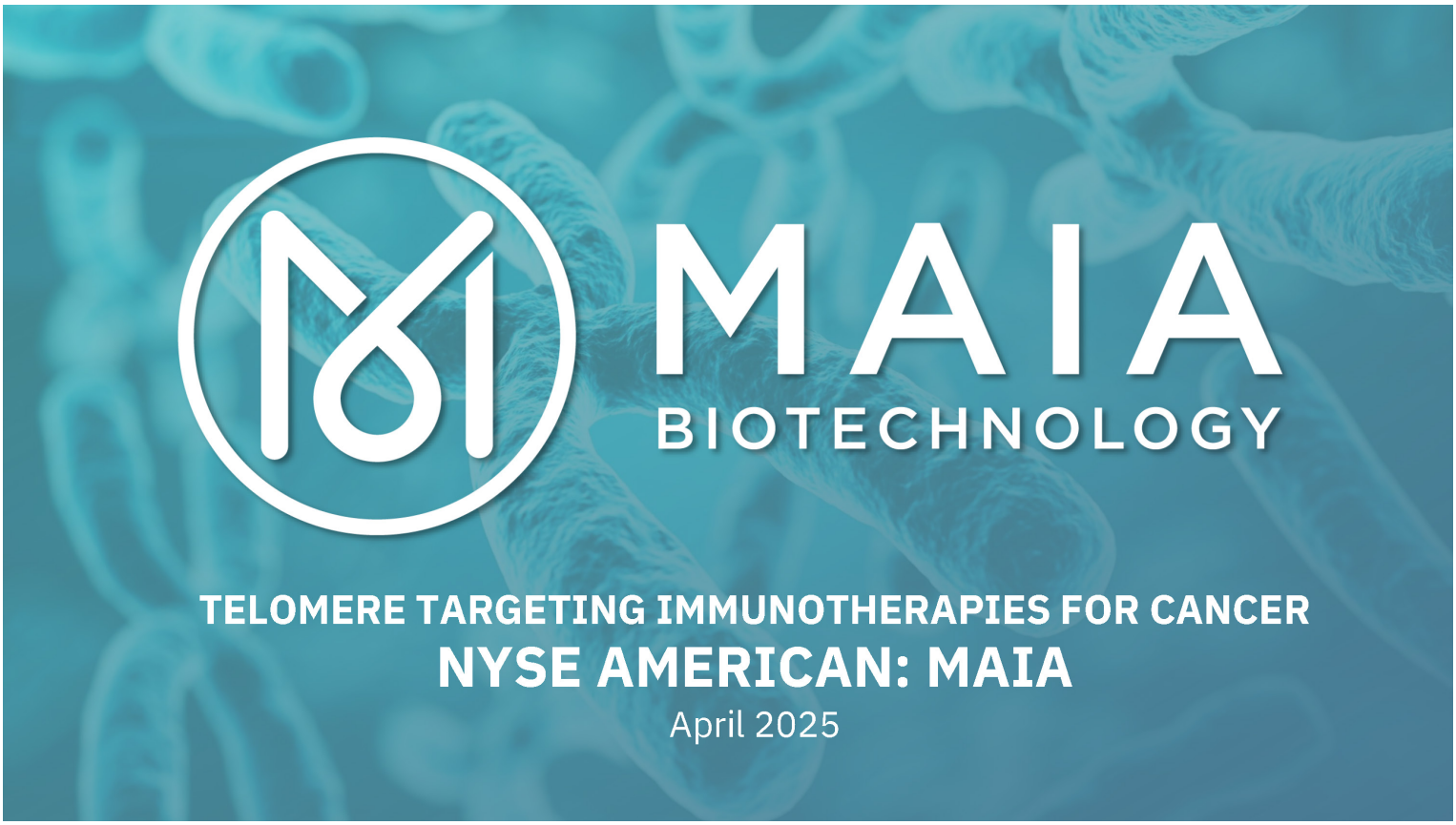
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 22, 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
April 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

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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 BeiGene (tislelizumab)

ROBUST PIPELINE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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 BeiGene		
THIO-102-HCC	HCC 2L+	Ateganosine → tislelizumab	Planned Phase 2			Clinical supply agreement with BeiGene		
THIO-102-SCLC	SCLC 2L+	Ateganosine → tislelizumab	Planned Phase 2			Clinical supply agreement with BeiGene		
THIO-103	NSCLC 1L, SCLC 1L	Ateganosine → tislelizumab	Planned Phase 2/3					

2nd Generation Telomere Targeting Agents

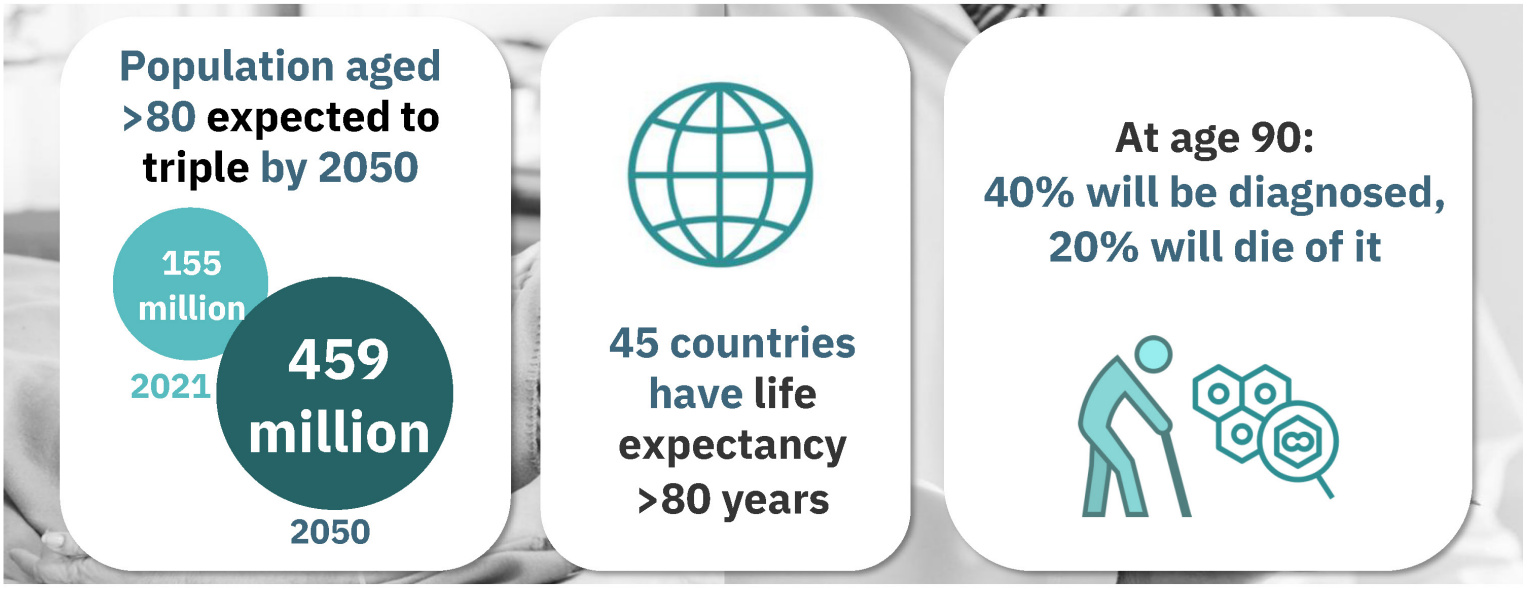
Agent	Indication	Status	Preclinical	Phase 1	Phase 2	Phase 3	Rights
MAIA-2021-020	Multiple Tumor Types	IND Enabling					Developed in-house fully-owned by MAIA
MAIA-2022-012	Multiple Tumor Types	IND Enabling					
MAIA-2021-029	Multiple Tumor Types	IND Enabling					

MISSION AND APPROACH

MAIA BIOTECHNOLOGY

NYSE American: MAIA

Cancer is the most dominant age-related disease



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

NOVEL TREATMENT

MAIA BIOTECHNOLOGY
NYSE American: MAIA

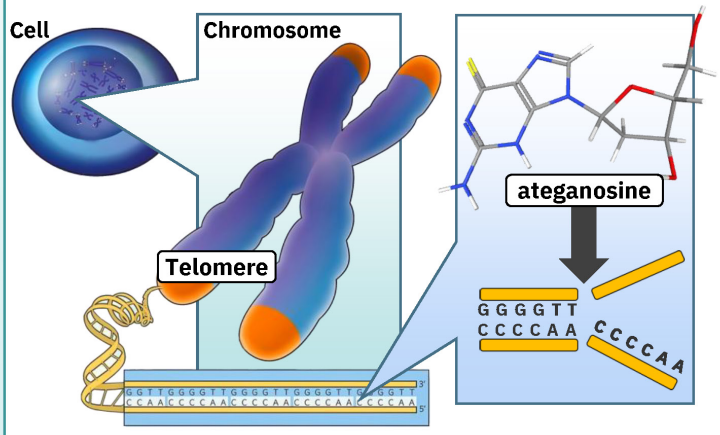
Ateganosine (THIO) is the only direct telomere targeting anticancer agent in clinical development

TREATMENT WITH ATEGANOSINE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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

1 Telomere targeting
2 Immunogenic effect

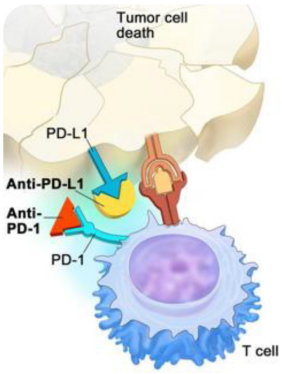


- 3 FDA Orphan Drug Designations: HCC, SCLC, Malignant Gliomas
- 1 Rare Pediatric Disease Designation (RPDD): Pediatric Gliomas

Followed by Immune Checkpoint Inhibitor (CPI)

Examples of commercially available CPIs

- 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



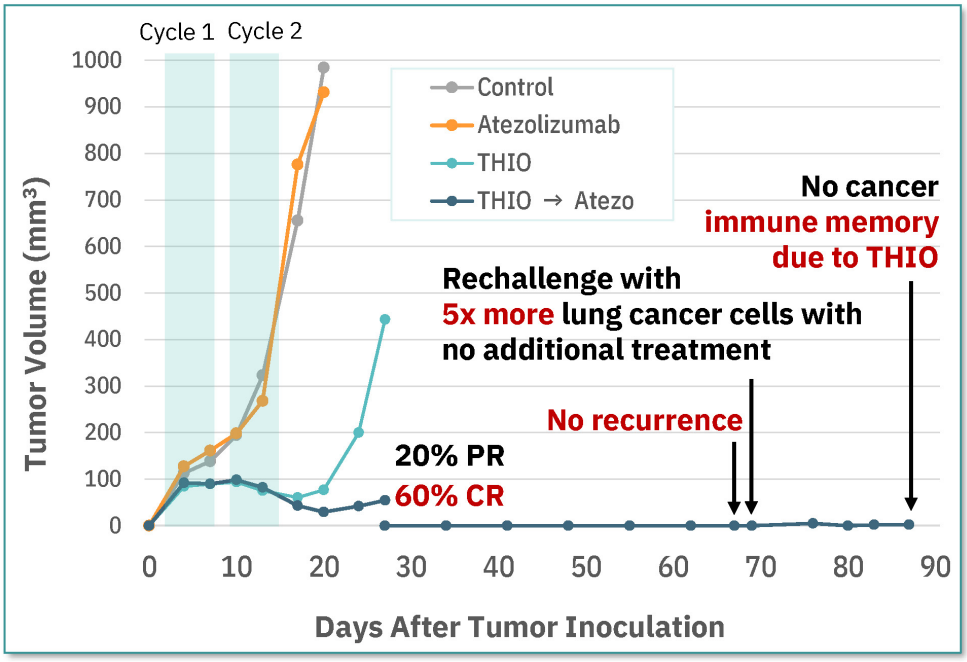
- Clinical supply agreement with Regeneron for NSCLC on THIO-101
- Clinical supply agreement with BeiGene for HCC, SCLC and CRC on THIO-102 planned trials

THIO-101 NSCLC TRIAL - RATIONALE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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.

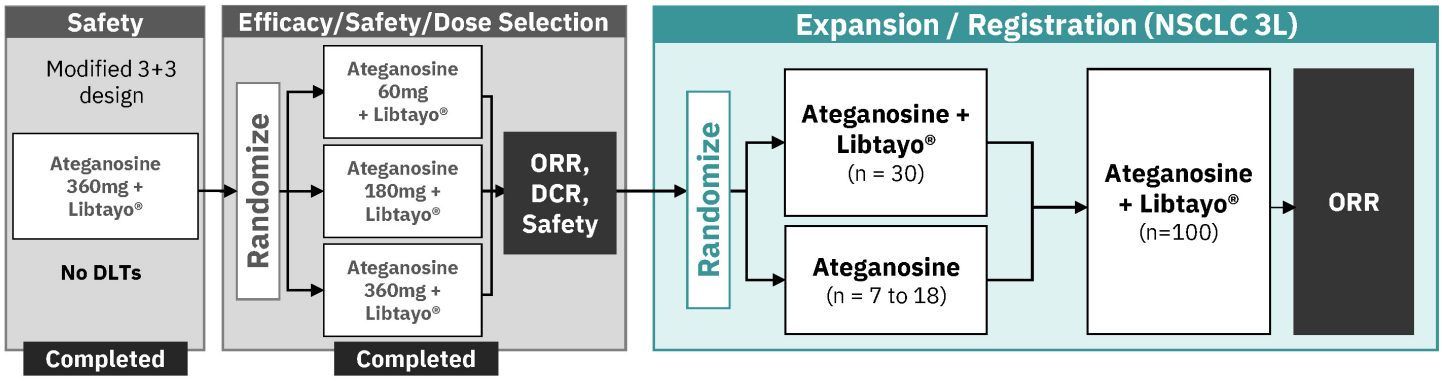
NSCLC CLINICAL TRIALS

MAIA BIOTECHNOLOGY
NYSE American: MAIA

THIO-101 PHASE 2 PIVOTAL TRIAL (ONGOING)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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



- Total of 79 patients enrolled (24 treated in 60mg dose group, 41 in 180mg, and 14 in 360mg)
- Best dose: 180mg - selected on Nov'23
- Enrollment completed Feb'24

- Up to 148 patients – Enrollment to start in H1 2025
- Patient population:
  - CPI Resistance (SITC)
  - Chemotherapy Resistance

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

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)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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

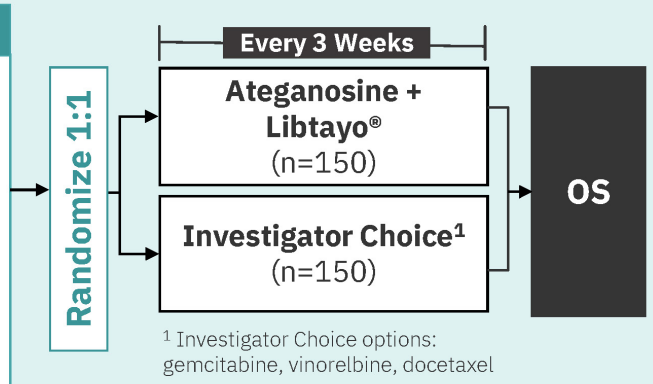
NSCLC 3L

Patient Population:

- 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



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

MAIA BIOTECHNOLOGY
NYSE American: MAIA

THIO-101 (Pivotal Phase 2, ongoing):

- Median Overall Survival (OS) is at **16.9 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 population[2]

3L NSCLC is an excellent market entry segment:

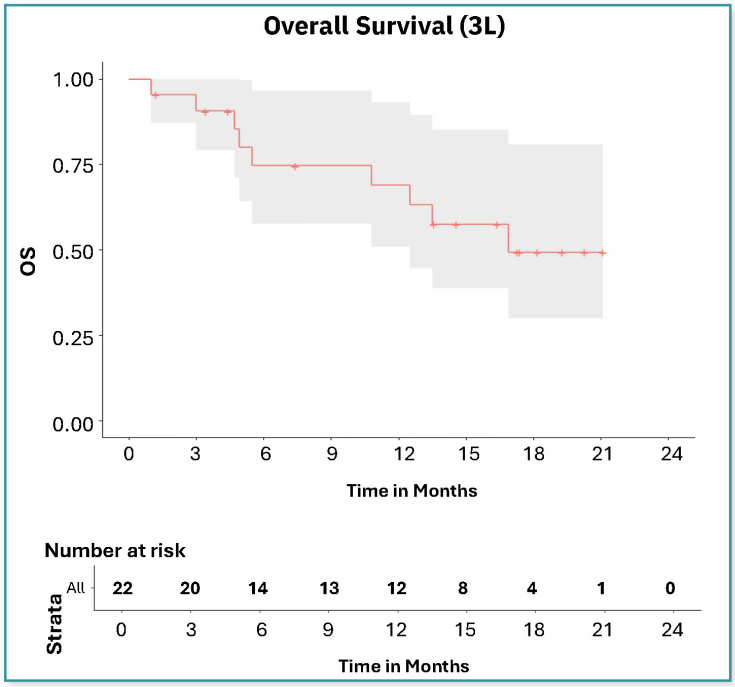
- Best results observed in THIO-101
- Highly unmet medical need in this immunotherapy-resistant and chemotherapy-resistant population
- Large population
- No current standard of care for this setting
- Limited competition for clinical trials patients

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

EXPECTED EFFICACY IN TRIALS IN NSCLC 3L

MAIA BIOTECHNOLOGY
NYSE American: MAIA

THIO-101 Phase 2

	Ateganosine + Libtayo® (n = 137-148)
Target Population	• CPI + Platinum Resistant • Prior treatment with docetaxel
ORR	>30%[1]

THIO-104 Pivotal Phase 3

	Ateganosine + Libtayo® (n = 150)	Chemotherapy (n = 150)
Target Population	• 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.

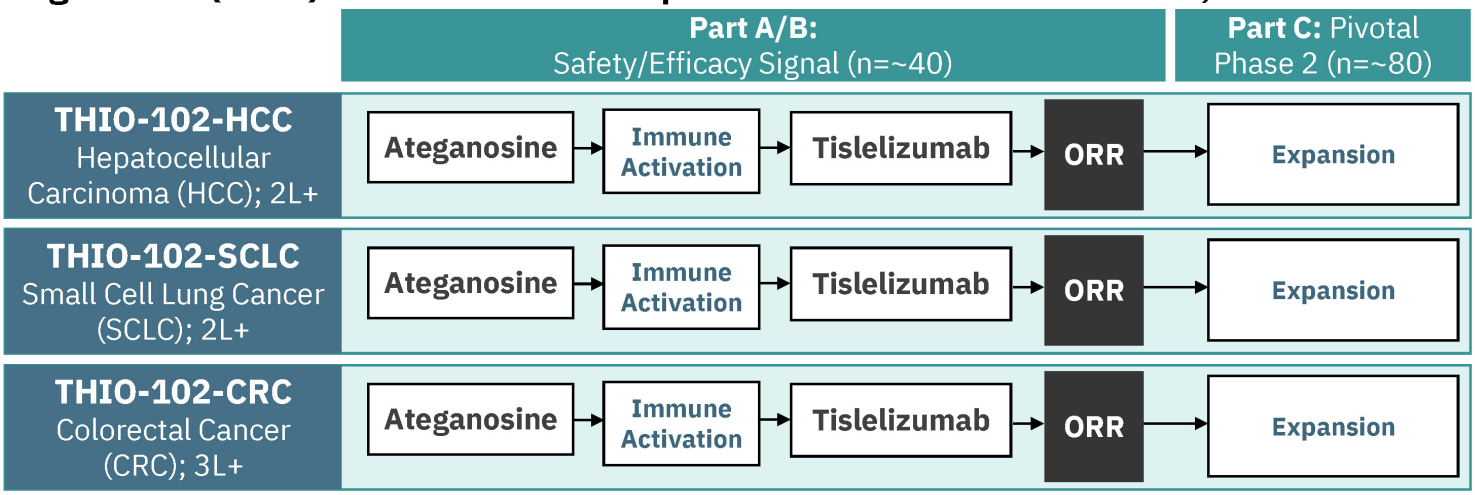
Note: Estimates based on the interim results observed from THIO-101.

PLANNED TRIALS IN OTHER TUMOR TYPES

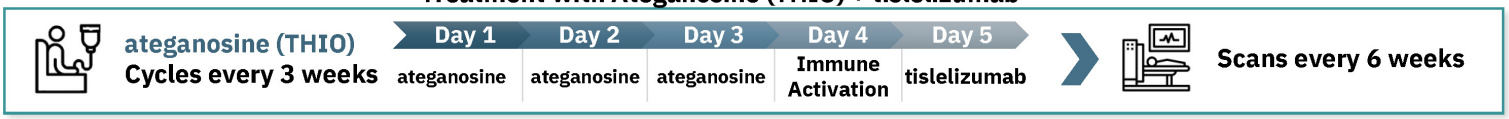
THIO-102 TRIALS (PLANNED)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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



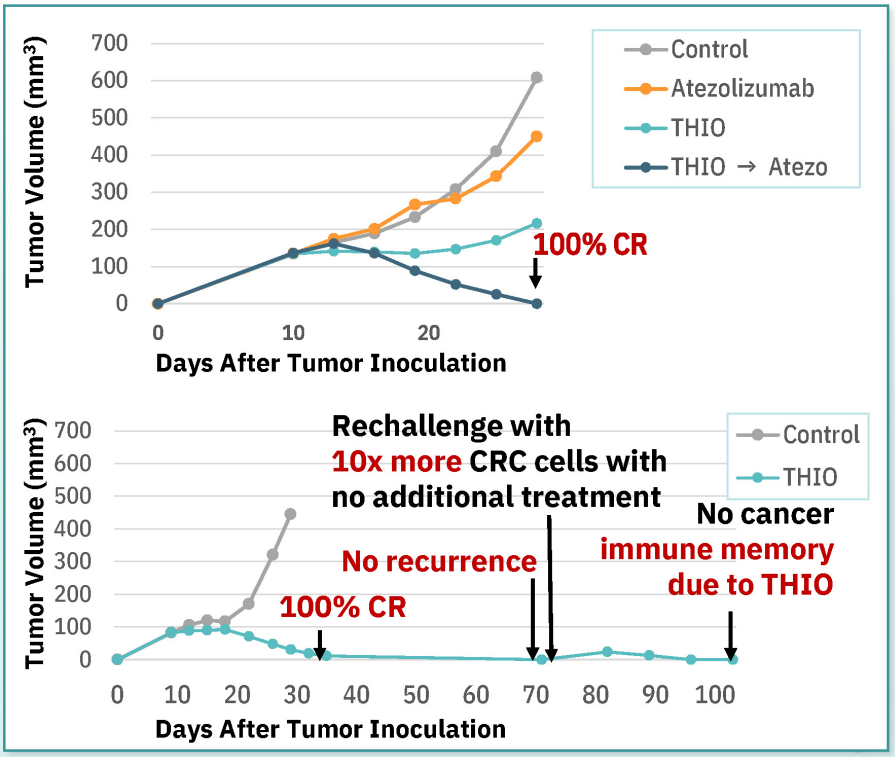
Note: Clinical trials currently in planning stage. Names of trials, indications and number of patients are subject to review and may be updated before trial initiation. Trials in solid tumors, such as Breast, Prostate, Gastric, Pancreatic and Ovarian may be pursued via investigator sponsored trials.

COLORECTAL RATIONALE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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



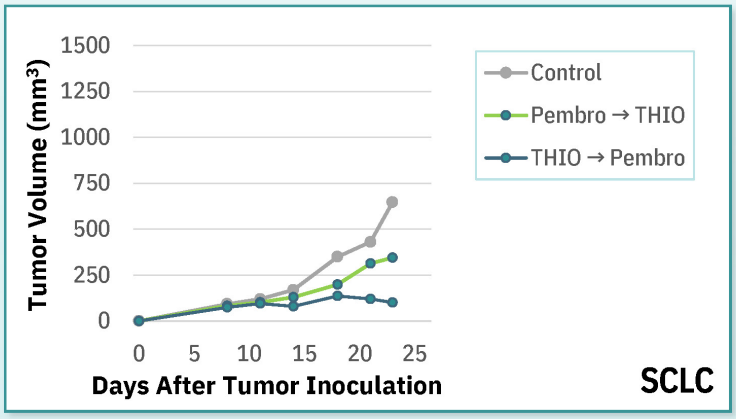
Source: Mender et al, Cancer Cell, 2020.

SCLC & HCC – AWARDED ORPHAN DRUG DESIGNATIONS

MAIA BIOTECHNOLOGY
NYSE American: MAIA

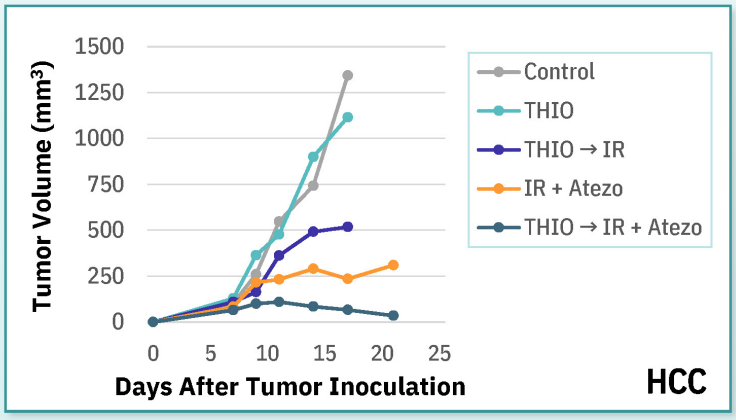
Preclinical Studies in Small Cell Lung Cancer (SCLC)

- 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)

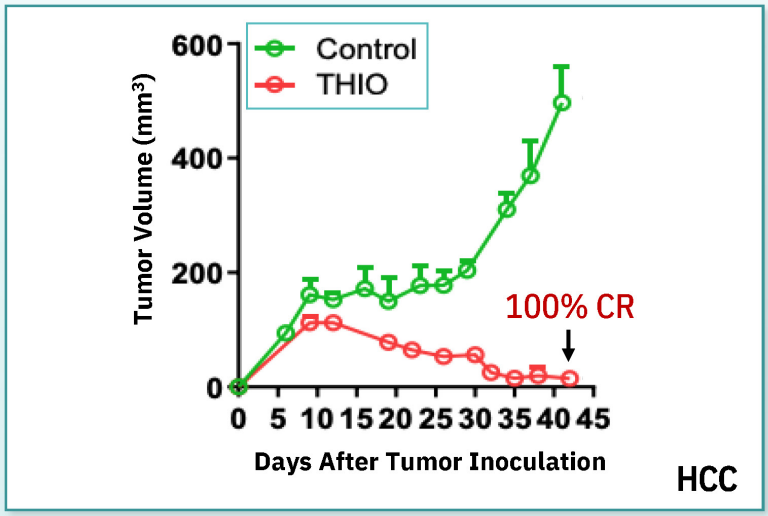
- Ateganosine (THIO) is highly synergistic and effective in combination with anti-PD-L1 agent Atezolizumab and Ionizing Radiation (IR 10Gy) in HCC53N Hepatocellular Carcinoma
- Treatment with ateganosine (THIO) in combination with IR and Atezolizumab results in a complete regression of aggressive HCC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



EXCELLENT EFFICACY IN HCC MODELS

MAIA BIOTECHNOLOGY
NYSE American: MAIA

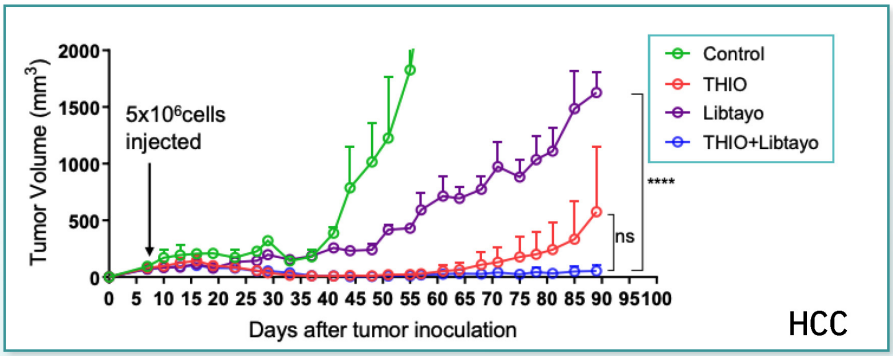
Ateganosine (THIO) achieved **complete and durable responses in Hepatocellular Carcinoma (HCC)**, the dominant histology in primary liver cancer (90%), in *in vivo* models

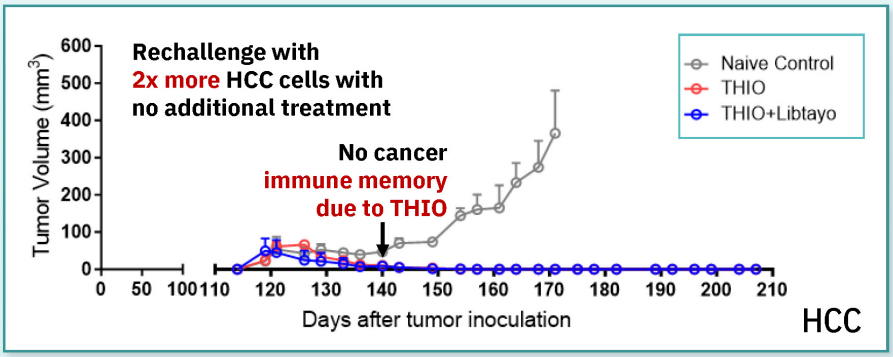


HCC ANTI-CANCER IMMUNE MEMORY

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

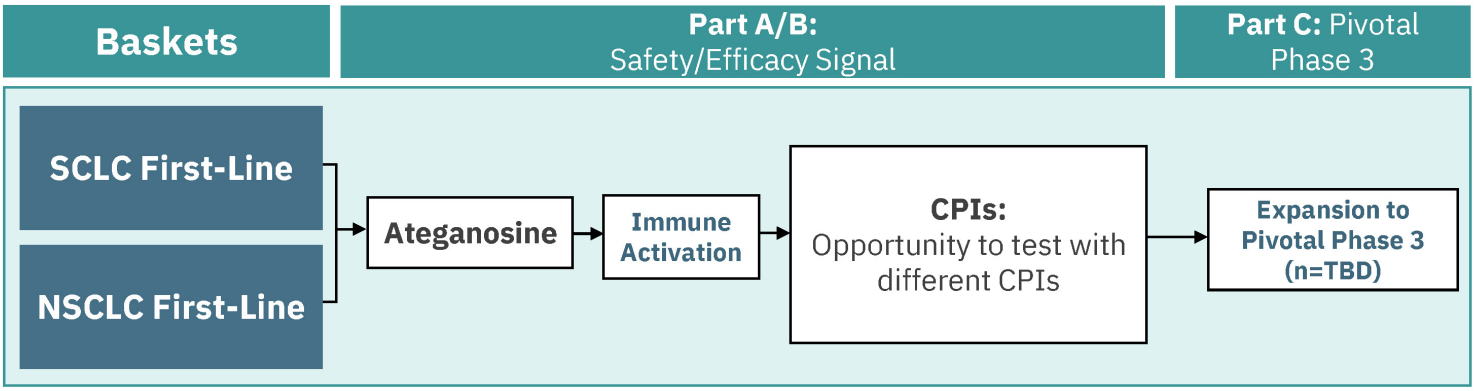




THIO-103 TRIAL (PLANNED)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of 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

MAIA BIOTECHNOLOGY

NYSE American: MAIA

EXCLUSIVITY AND INTELLECTUAL PROPERTY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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

NOVARTIS astellas Pfizer BAYER janssen Incyte Cephalon Oncology geron PHARMACIA exicure

SIGNIFICANT MARKET OPPORTUNITY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

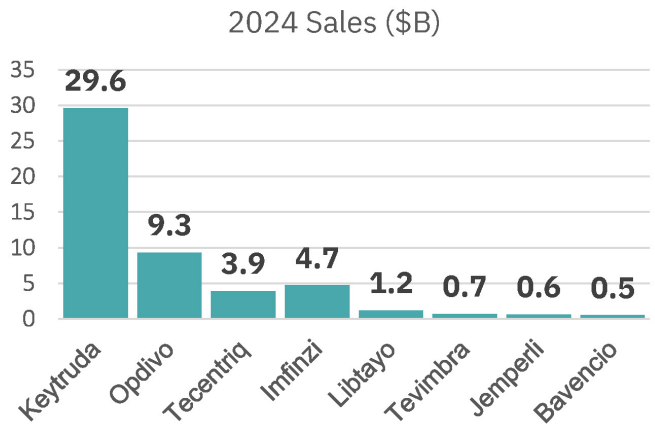
Developing agents for the top tumor types markets globally

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

$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



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

COMPARABLE COMPANIES

MAIA BIOTECHNOLOGY
NYSE American: MAIA

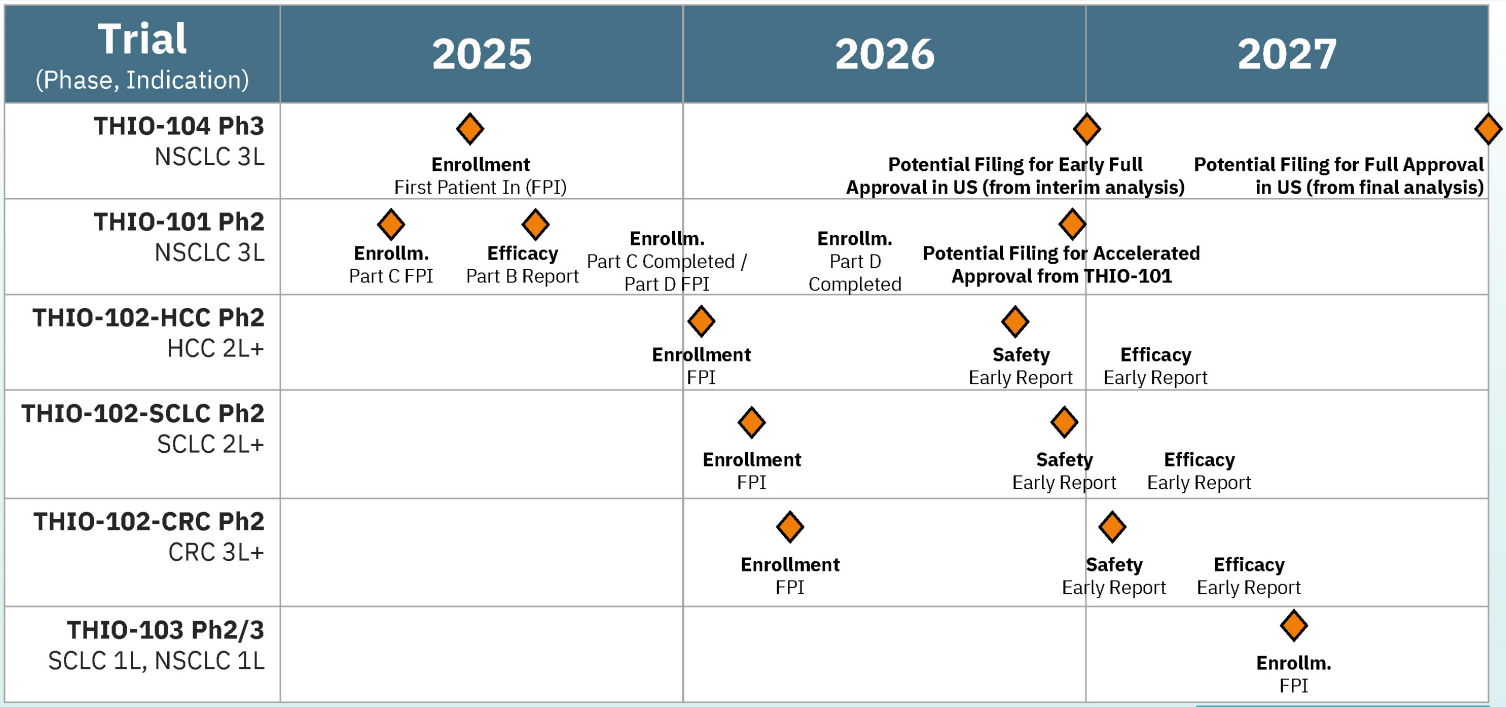
- **August 2022** - Bristol Myers Squibb (BMS) completed **$4.1B** acquisition of Turning Point Therapeutics
- **January 2024** - BMS completed **$5.8B** acquisition of Mirati Therapeutics

MAIA BIOTECHNOLOGY	AnaptysBio	ARRIVENT	ARCUS	Turning Point Therapeutics	MIRATI THERAPEUTICS
$50.6M	**$0.5B**	**$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	$16.4/share	$19.6/share	$9.1/share	$76/share	$58/share
NYSE:MAIA	NASDAQ:ANAB	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 III**	**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

MAIA BIOTECHNOLOGY
NYSE American: MAIA



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

THANK YOU

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APPENDIX

MAIA BIOTECHNOLOGY
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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.