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 10, 2024

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

Delaware	**001-41455**	**83-1495913**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

444 West Lake Street, Suite 1700 **Chicago, IL** **(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.

1. MAIA Biotechnology, Inc. (the "Company") has made available a presentation (the "Presentation") management intends to use from time to time in presentations about the Company's operations and performance, including at the H.C. Wainwright 26th Annual Global Investment Conference on September 10, 2024 and will also be posted to the Company's website on September 10, 2024. The Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

2. The Company has made available a summary ("Summary") highlighting certain aspects of the Company's business, clinical programs and clinical supply agreement with Regeneron which was posted to the Company's website on September 10, 2024. The Summary is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

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

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

The information set forth in this Report, including, without limitation, the Presentation and the Summary, is not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be incorporated by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such a filing. This Report (including the exhibits hereto) will not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Item 8.01 Other Events.

On September 10, 2024, the Company issued a press release announcing positive survival updates in Phase 2 Study of THIO in Non-Small Cell Lung Cancer.

A copy of the press release is attached hereto as Exhibit 99.3 and is incorporated herein by reference.

Forward-looking Statements

The Company cautions that all statements, other than statements of historical facts, contained in this Current Report on Form 8-K, or furnished herewith, are forward-looking statements. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels or activity, performance or achievements to be materially different from those anticipated by such statements. The use of words such as "may," "might," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward looking statements. However, the absence of these words does not mean that statements are not forward-looking. All forward-looking statements are based on current estimates, assumptions and expectations by our management that, although we believe to be reasonable, are inherently uncertain. Any forward-looking statement expressing an expectation or belief as to future events is expressed in good faith and believed to be reasonable at the time such forward-looking statement is made. However, these statements are not guarantees of future events and are subject to risks and uncertainties and other factors beyond our control that may cause actual results to differ materially from those expressed in any forward-looking statement, including, but not limited to: (i) the initiation, timing, cost, progress and results of our preclinical and clinical studies and our research and development programs, (ii) our ability to advance product candidates into, and successfully complete, clinical studies, (iii) the timing or likelihood of regulatory filings and approvals, (iv) our ability to develop, manufacture and commercialize our product candidates and to improve the manufacturing process, (v) the rate and degree of market acceptance of our product candidates, (vi) the size and growth potential of the markets for our product candidates and our ability to serve those markets, and (vii) our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates. Any forward-looking statement speaks only as of the date on which it was made. The Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Presentation
99.2	Summary
99.3	Press Release dated September 10, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

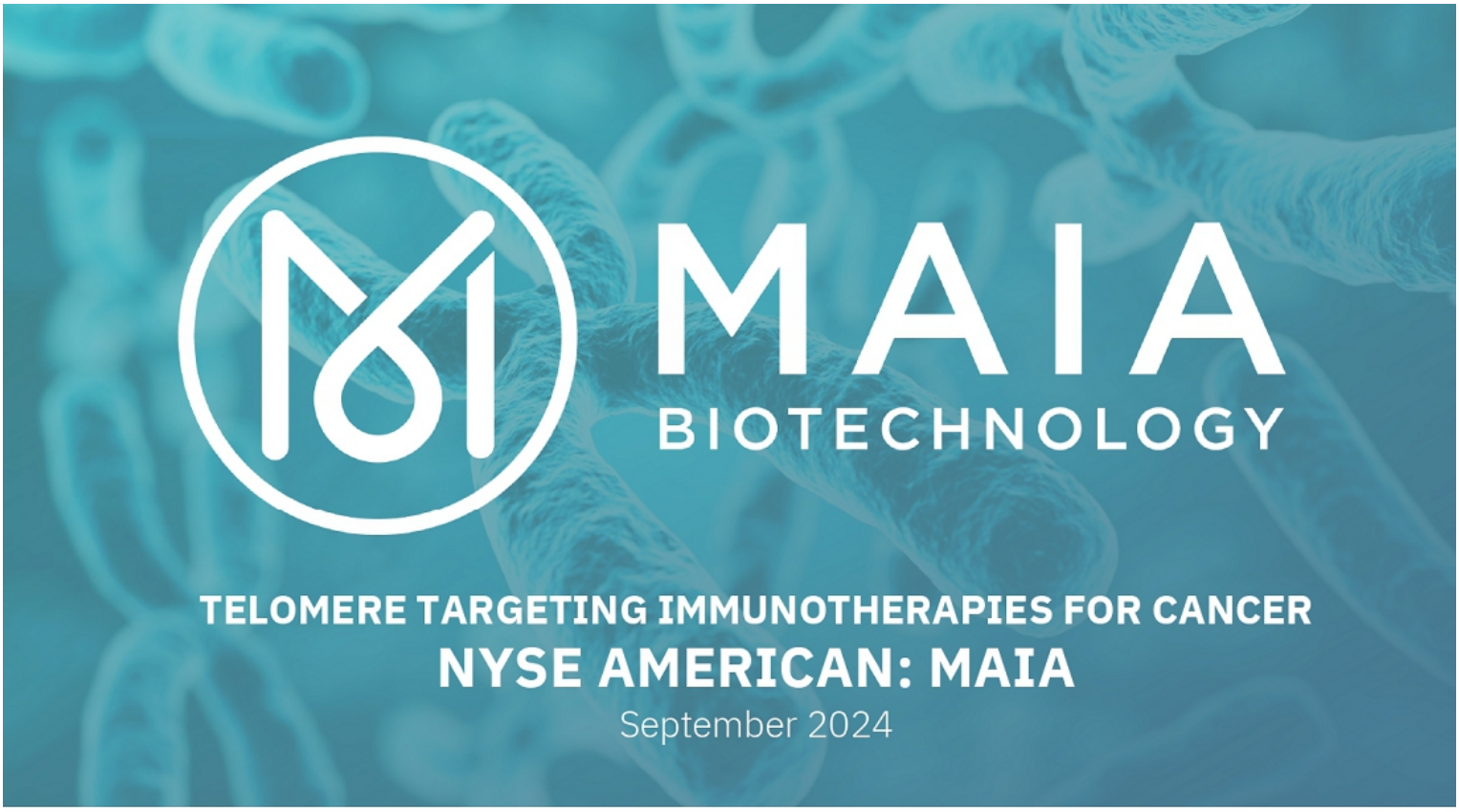
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 10, 2024

MAIA BIOTECHNOLOGY, INC.

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

Exhibit 99.1


MAIA
BIOTECHNOLOGY
TELOMERE TARGETING IMMUNOTHERAPIES FOR CANCER
NYSE AMERICAN: MAIA
September 2024

FORWARD-LOOKING STATEMENTS

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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

INVESTMENT PROFILE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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

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

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

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

Key targeted clinical milestones within reach.

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

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

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

Multiple THIO trials planned for additional cancer indications.

- Expansion for NSCLC
- Colorectal cancer (CRC), Liver (HCC), SCLC, solid tumors

ROBUST PIPELINE

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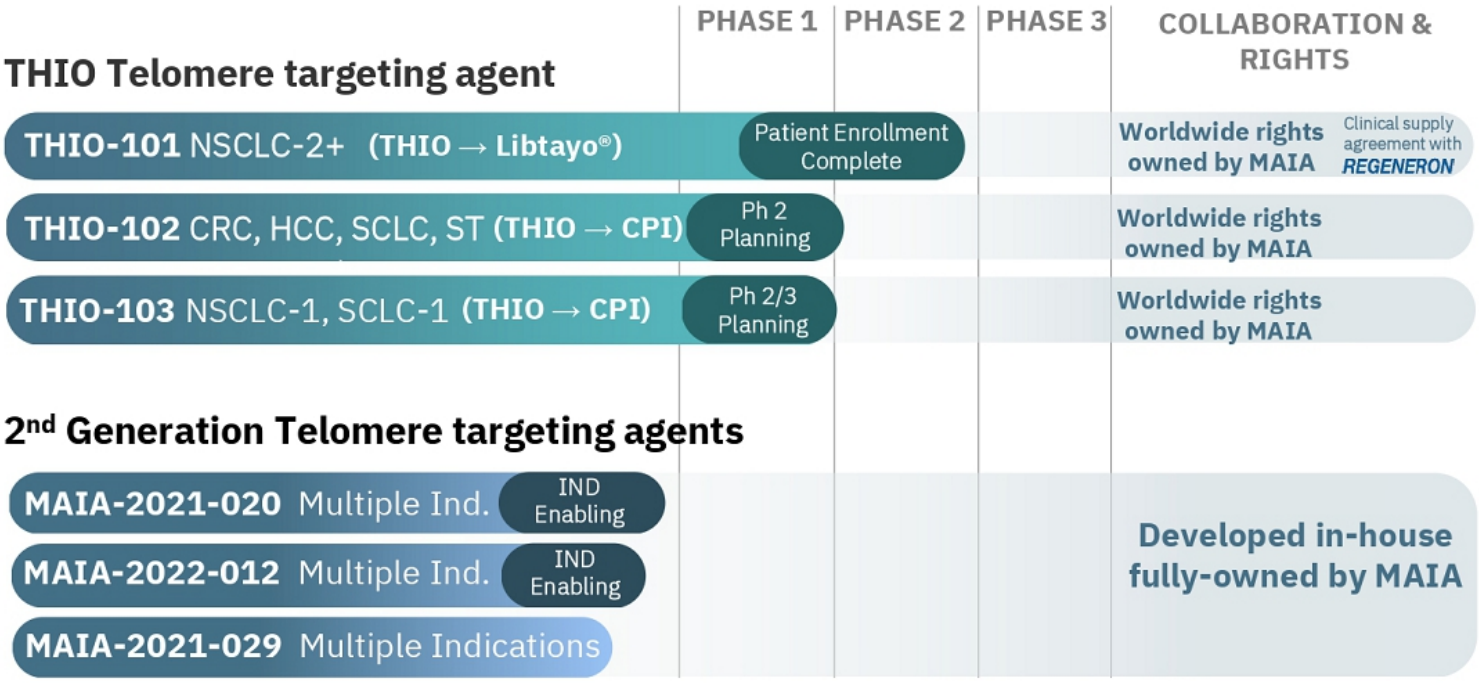


MISSION AND APPROACH

Cancer is the most dominant age-related disease

Population aged >80 expected to triple by 2050

142 million

2020

426 million

2050

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


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

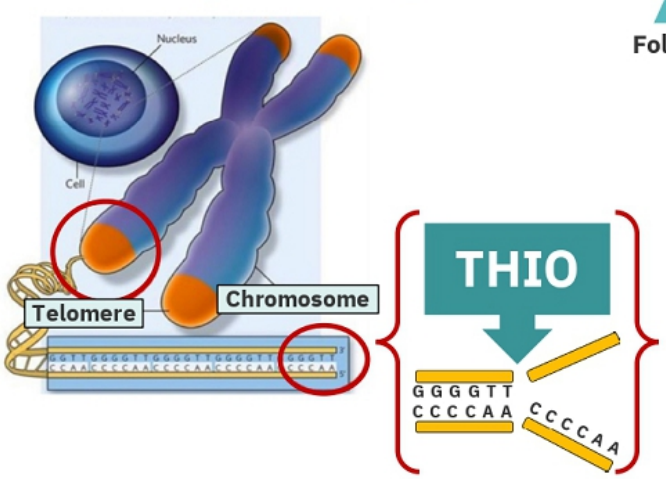
THIO – NOVEL MECHANISMS OF ACTION

MAIA BIOTECHNOLOGY
NYSE American: MAIA

THIO

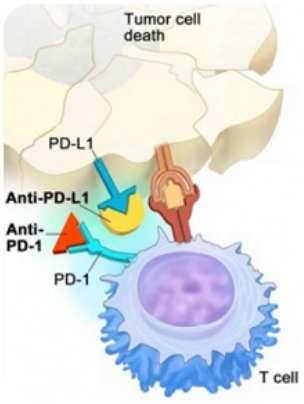
THIO has a dual MoA:

1. Telomere targeting
2. Immunogenic effect



Followed by

Immune Checkpoint Inhibitor



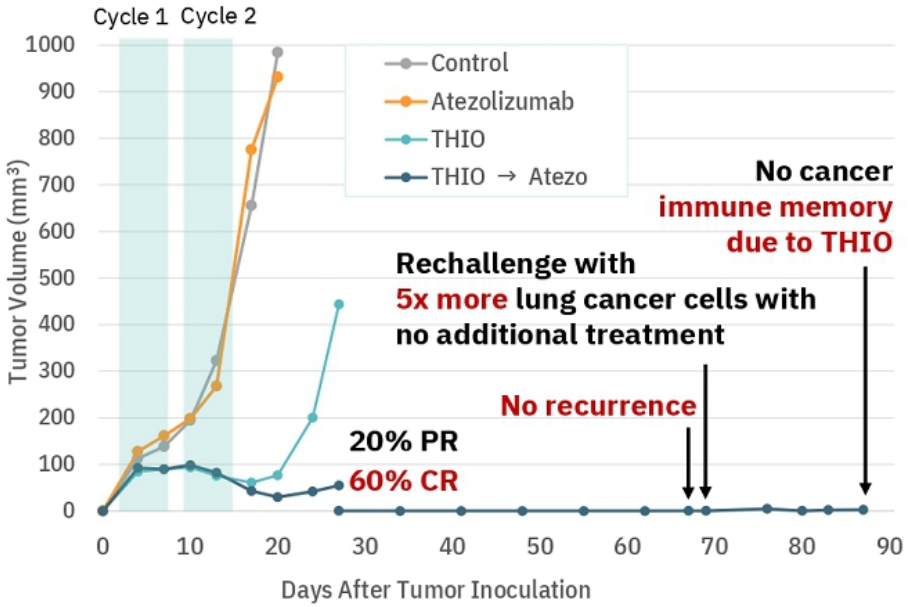
- ★ LIBTAYO® (cemiplimab) REGENERON
- IMFINZI® (durvalumab) AstraZeneca
- KEYTRUDA® (pembrolizumab) MERCK
- TEVIMBRA® (tislelizumab) BeiGene
- TECENTRIQ® (atezolizumab) Genentech
- Jemperli® (dostarlimab-gxly) GSK
- OPDIVO® (nivolumab) Bristol Myers Squibb
- BAVENCIO® (avelumab) EMD SERONO

★ Clinical supply agreement with REGENERON for NSCLC

THIO-101 NSCLC TRIALS - RATIONALE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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



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).

THIO-101 TRIAL

NON-SMALL CELL LUNG CANCER

REGENERON CLINICAL SUPPLY AGREEMENT

MAIA BIOTECHNOLOGY
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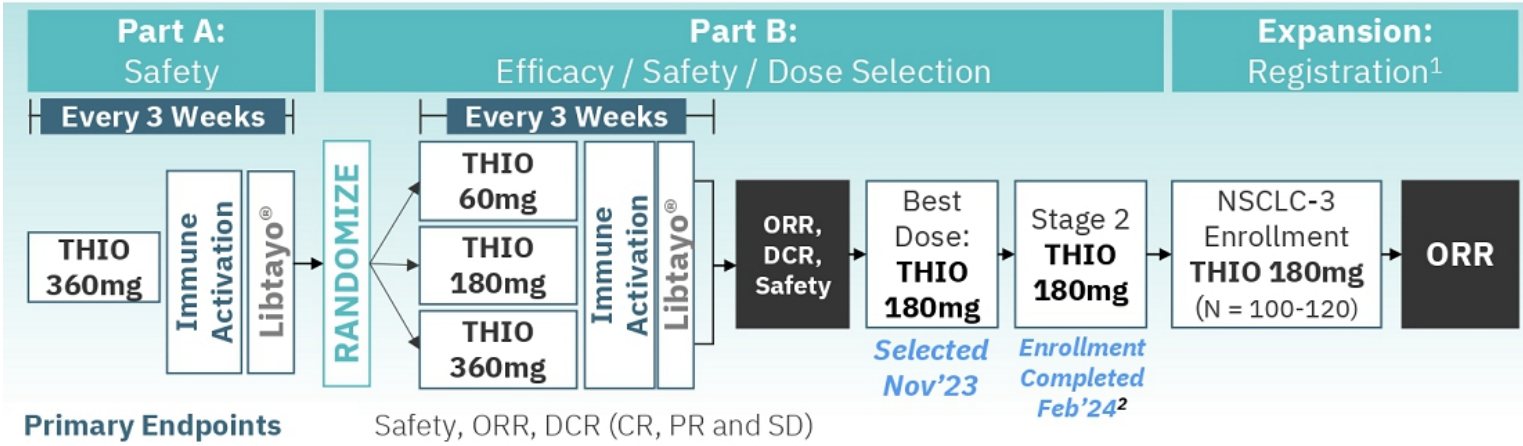
MAIA BIOTECHNOLOGY & REGENERON

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

THIO-101 – TRIAL DESIGN

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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



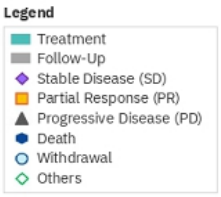
Primary Endpoints	Safety, ORR, DCR (CR, PR and SD)
Secondary Endpoints	DoR; PFS; OS
Exploratory Endpoints	PK and PD (activity of THIO in circulating tumor cells measured by specific biomarkers)

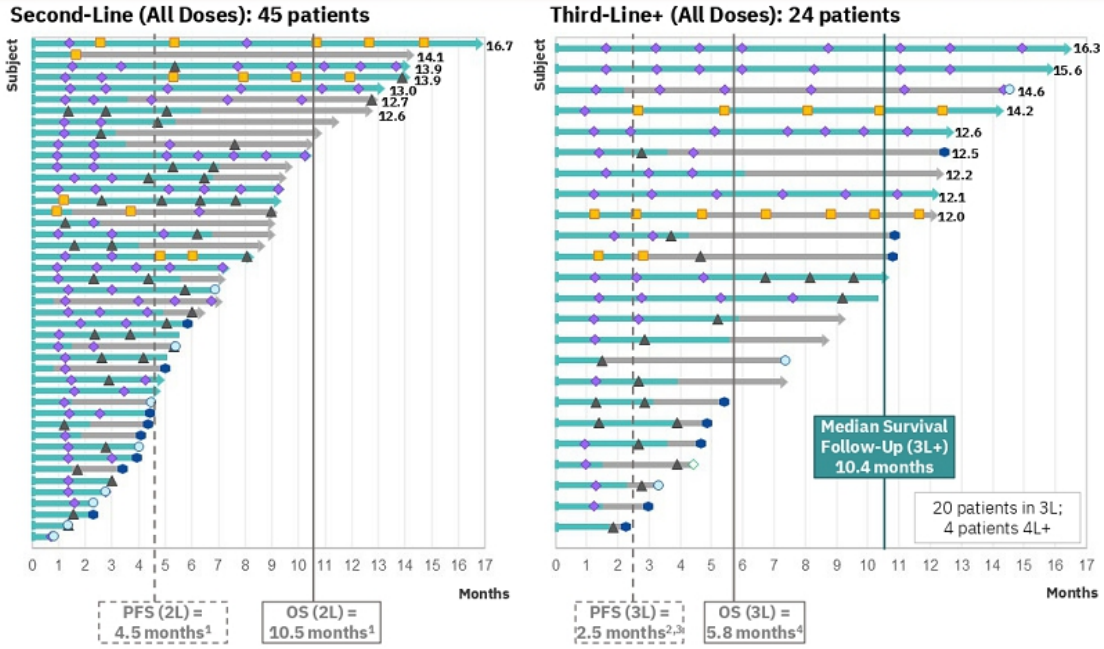
ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT05208944?term=05208944&draw=2&rank=1
1. Would require FDA agreement.
2. https://ir.maiabiotech.com/news-events/press-releases/detail/91/maia-biotechnology-completes-enrollment-in-thio-101-phase-2

PATIENTS' SURVIVAL BY LINE OF THERAPY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- As of 01-Aug-2024, 16 patients had survival follow-up above 12 months:
  - ✓ 7 in 2L, 7 ongoing
  - ✓ 9 in 3L, 7 ongoing
  - ✓ 1 patient with 23 cycles of therapy





Note: This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data subject to change.
Clinical data presented from 01Aug2024 data cut. Includes all patients with ≥1 post-baseline response assessment.

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

TREATMENT IN THIRD-LINE

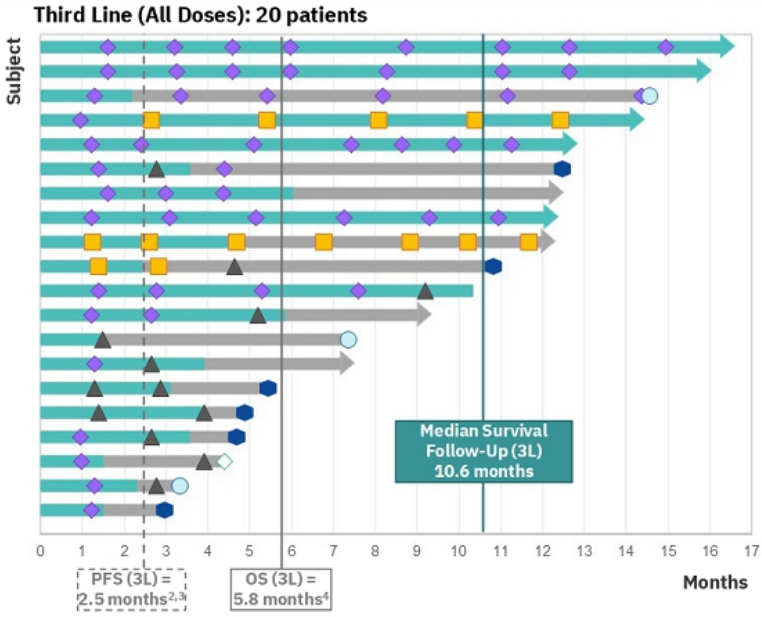
MAIA BIOTECHNOLOGY
NYSE American: MAIA

Extended Survival

- 20 subjects in 3L completed at least 1 post baseline assessment at time of cut-off
- 14/20 (70%) patients crossed 5.8 months OS threshold
- 17/20 (85%) crossed 2.5 months PFS threshold

Unprecedented Efficacy

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



Legend
- Treatment
- Follow-Up
- Stable Disease (SD)
- Partial Response (PR)
- Progressive Disease (PD)
- Death
- Withdrawal
- Others

Note: This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data subject to change.
Clinical data presented from 01Aug2024 data cut. Includes all patients with ≥1 post-baseline response assessment.

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

BEST 3L RESULTS IN THE 180MG DOSE

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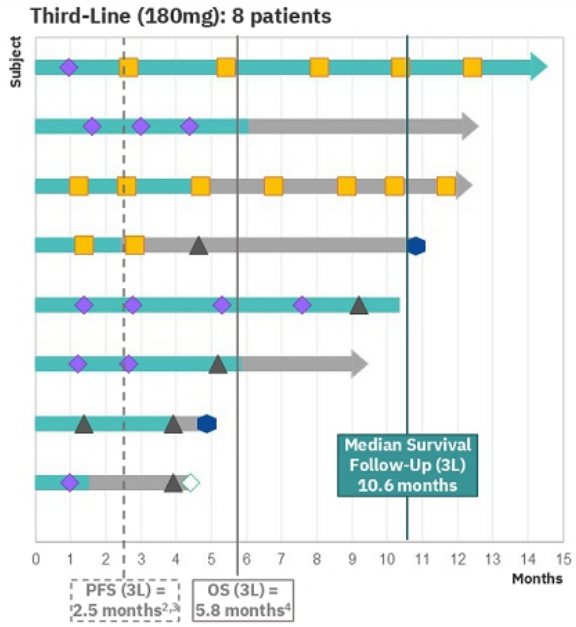
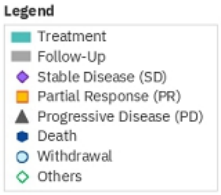
NSCLC-3 – 180mg:

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





Note: This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data subject to change. Clinical data presented from 01Aug2024 data cut. Includes all patients with ≥1 post-baseline response assessment.

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EXPECTED EFFICACY AND CURRENT TREATMENTS

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Third-Line NSCLC	THIO (180mg) + Libtayo® (cemiplimab)	Chemotherapy	Tarceva® (erlotinib)	Taxotere® (docetaxel)
Population	CPI Resistant (3L)	CPI Naïve (3L)	CPI Naïve (2L+)	CPI Naïve (2L)
DCR	88%	36%	45%	54%
ORR	38%	6%	9%	5.7%
PFS	**5.5 months**		2.2 months	1.9 months (8.3 weeks Time to Progression)
OS	**> 10 months (projected[1])**	5.8 months	6.7 months	5.7 months
Trial / Study	THIO-101	Third-Line Chemotherapy in Advanced NSCLC (Girard et al, JTO)	BR.21	TAX320
Source	https://clinicaltrials.gov/study/NCT05208944	https://www.jto.org/article/S1556-0864(15)31281-8/pdf	https://www.nejm.org/doi/full/10.1056/NEJMoa050753	https://pubmed.ncbi.nlm.nih.gov/10856094/

1. Projected efficacy measures of treatment with THIO are indicative and estimated by MAIA Biotechnology exclusively and based on interim observed trends of ongoing Phase 2 clinical trial. Final efficacy measures may differ as follow-up continues.

PLANNED UPCOMING TRIALS

THIO-102 TRIAL (PLANNED)

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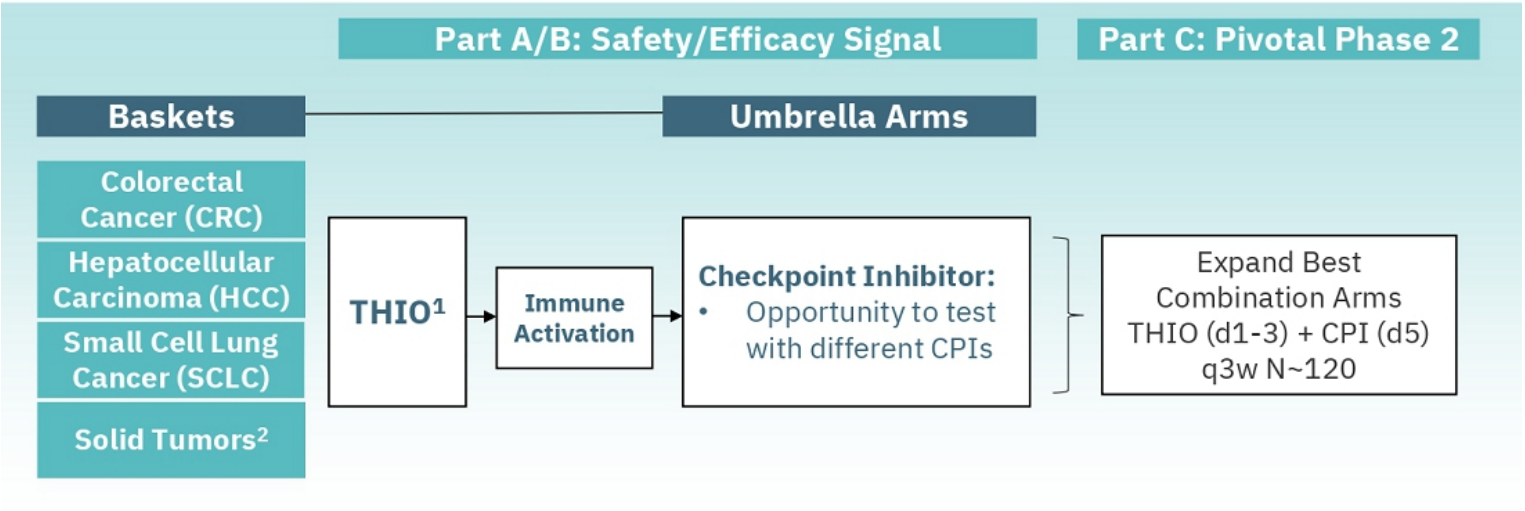
NYSE American: MAIA

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

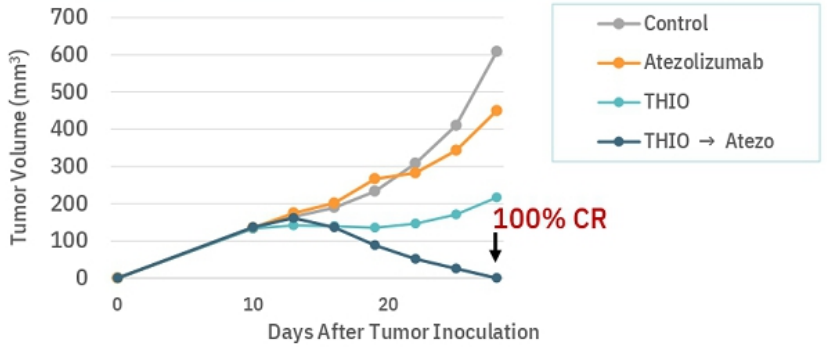


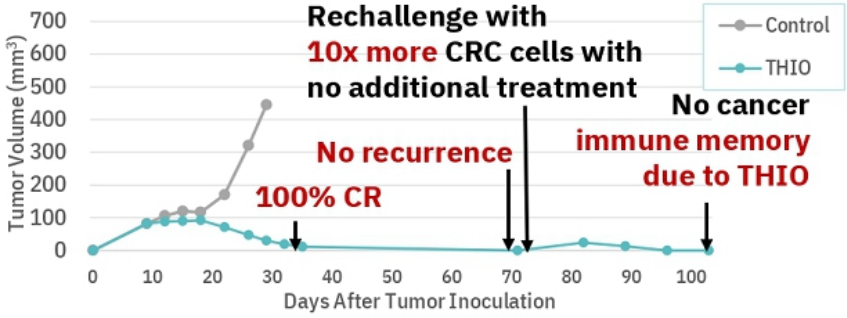
[1] Dose to be selected from THIO-101 study results.
[2] E.g. Breast, Prostate, Gastric, Pancreatic, Ovarian, etc.

THIO-102 – COLORECTAL RATIONALE

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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





Mender et al, Cancer Cell, 2020

SCLC & HCC – ORPHAN DRUG DESIGNATION

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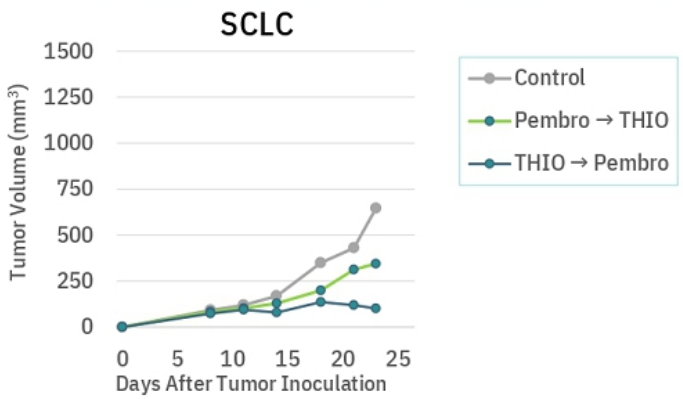
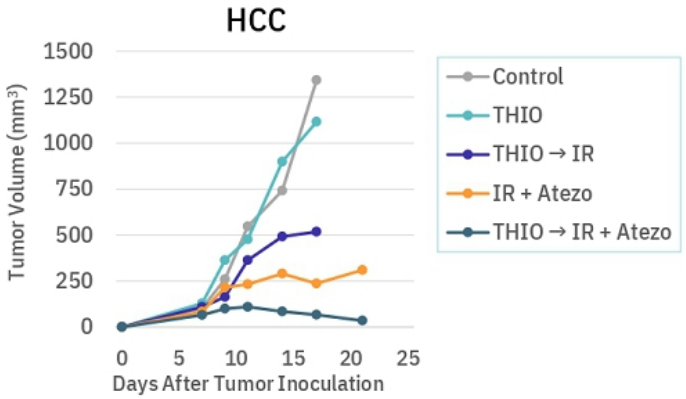
NYSE American: MAIA





- 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

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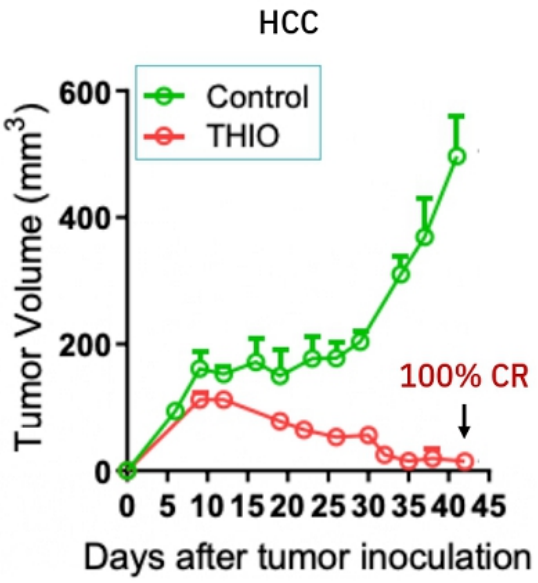
NYSE American: MAIA

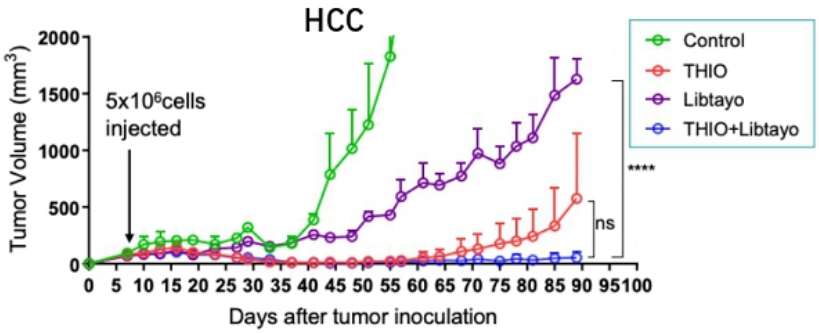
- THIO achieved complete and durable responses in Hepatocellular Carcinoma (HCC), the dominant histology in primary liver cancer (90%), in *in vivo* models

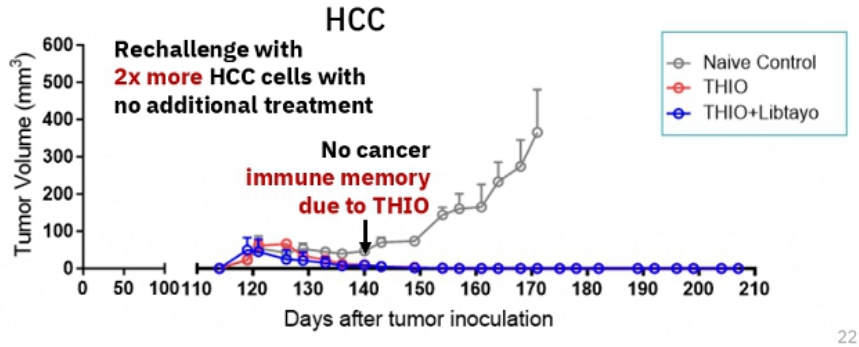


HCC ANTI-CANCER IMMUNE MEMORY

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)

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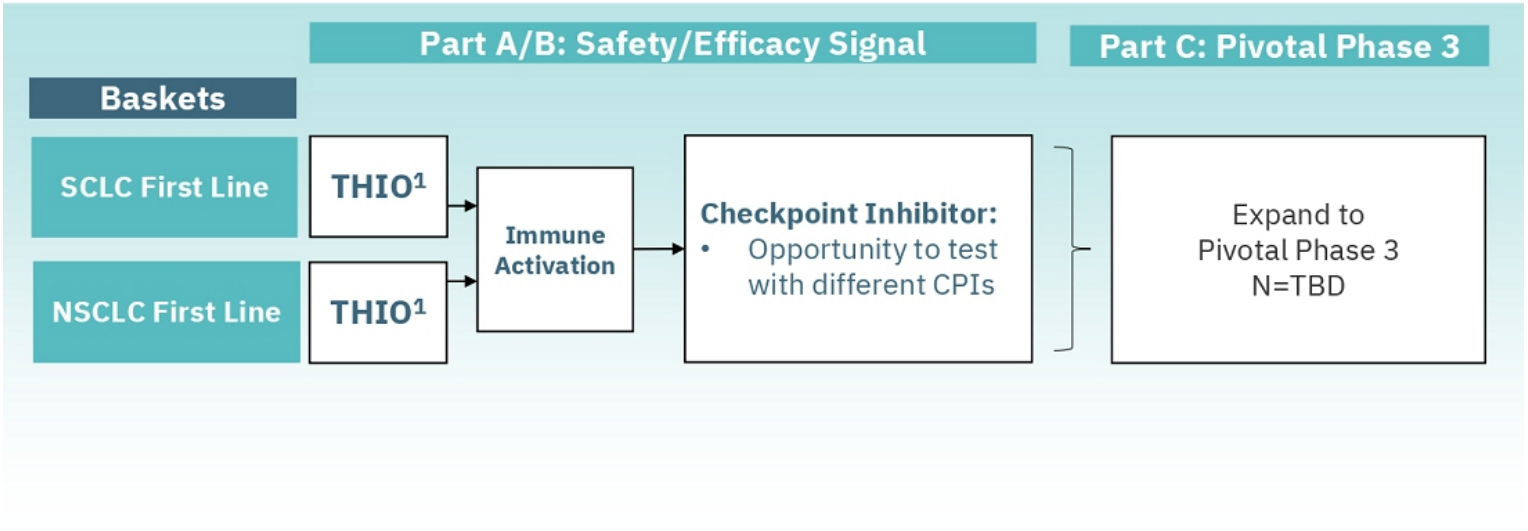
A Multicenter, Open-label, Phase 2 Trial Evaluating the Safety and Efficacy of THIO Administered in Sequence with Anti-PD-1 or Anti-PD-L1



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

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INVESTMENT OPPORTUNITY

EXCLUSIVITY AND INTELLECTUAL PROPERTY

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Goal: New Chemical Entity (NCE) Marketing Exclusivity

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

Robust and Growing Patent Portfolio for THIO

- 5 issued patents
- 29 pending patent applications

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

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

EXPERIENCED MANAGEMENT TEAM

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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

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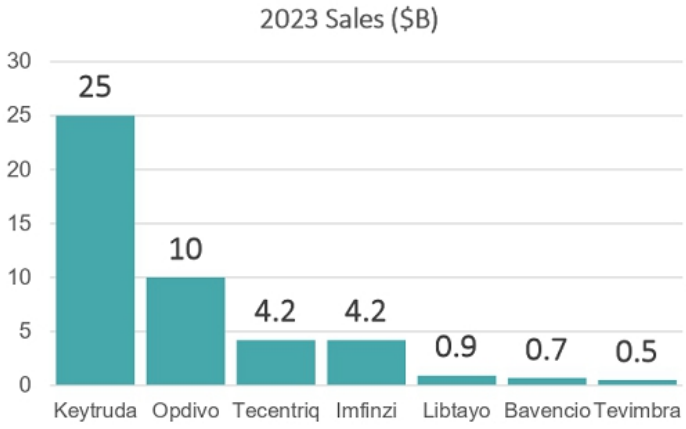
Developing agents for the top tumor types markets globally

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

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MAIA BIOTECHNOLOGY	MIRATI THERAPEUTICS	IOVANCE BIOTHERAPEUTICS	Bicycle	ARCUS	Turning Point Therapeutics
$75.8M	$4.1B	$3.0B	$1.4B	$1.4B	$3.8B
Market Cap[1]	Market Cap[2]	Market Cap[1]	Market Cap[1]	Market Cap[1]	Market Cap[2]
$3.17/share	$58/share	$10/share	$20.5/share	$15.7/share	$76/share

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

1. Market caps as of September 06, 2024 (source: Citadel Securities)
2. Last known market cap before acquisition (source: companiesmarketcap.com)

MULTIPLE VALUE-DRIVING MILESTONES

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★ **Major inflection points**

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

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

MAIA BIOTECHNOLOGY

THANK YOU

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APPENDIX

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

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

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

April 26, 2022 08:37 AM Eastern Daylight Time

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

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

August 02, 2022 08:00 AM Eastern Daylight Time

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

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

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

November 10, 2023 07:01 AM Eastern Standard Time

https://ir.maiabiotech.com/news-events/press-releases/detail/83/fda-grants-orphan-drug-designation-to-maia-biotechnology

MAIA BIOTECHNOLOGY

Telomere Targeting Immunotherapies for Cancer

Vlad Vitoc, MD, MBA
Chief Executive Officer
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(215) 971-5488 maiabiotech.com

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

Company Highlights

Clinical Programs

THIO-101
Ph 2 trial of THIO + Libtayo® (cemiplimab)

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

THIO-102 (planning)
Ph 2 trial of THIO + checkpoint inhibitors

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

THIO-103 (planning)
Ph 2/3 trial of THIO + checkpoint inhibitors

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

THIO is a Unique Direct Telomere Targeting Agent

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

Partnerships and Collaborations

- THIO-101: clinical supply agreement with Regeneron, provides Libtayo® for all patients in the trial
- Broad potential for partnerships with different companies and checkpoint inhibitors in upcoming clinical trials

Cap Table

NYSE American: MAIA

Share Price[1]	$3.17	Float[2]	19.7M
Market Cap[1]	$75.8M	Insider Holdings[2]	17%
FD Shares Outstanding[2]	39M	Cash[2]	$11.6M

1. As of Sep 06, 2024
2. As of Jun 30, 2024

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

Significant Market Opportunity

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

Strong and Growing IP Portfolio

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

Next Generation Potential Telomere Targeting Therapeutics in R&D

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

Robust Pipeline

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

Vlad Vitoc, MD, MBA

Founder, Chairman, and Chief Executive Officer

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

Scan QR Code to access our investor presentation

Exhibit 99.3

MAIA Biotechnology Announces Positive Survival Updates in Phase 2 Study of THIO in Non-Small Cell Lung Cancer

- ***16 patients surpassed 12-month survival follow-up***
- ***THIO's substantial survival benefit in third line surpasses comparable standard-of-care overall survival of 5.8 months***
- ***Median survival follow-up in third line was 10.6 months***
- ***Treatment with THIO followed by Libtayo® has been generally well-tolerated to date***

CHICAGO – September 10, 2024 - MAIA Biotechnology, Inc., (NYSE American: MAIA) ("MAIA", the "Company"), a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer, today announces favorable interim survival benefit from its lead clinical candidate THIO, a telomere-targeting treatment for patients with advanced non-small cell lung cancer (NSCLC). A Phase 2 clinical trial, THIO-101, is evaluating THIO sequenced with Regeneron's immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced NSCLC who failed two or more standard-of-care therapy regimens.

Published available results suggest that overall survival (OS) in third-line patients is 5.8 months.[1]

As of August 01, 2024, 16 patients had survival follow-up surpassing 12 months, including 9 in third line treatment (3L). Interim median survival follow-up in 3L was 10.6 months.

"THIO is showing a survival benefit for patients with advanced NSCLC. As our follow-up continues, we have noted that three of the earliest patients enrolled are approaching 17-month survival. We're on track to achieve our survival goals in third-line therapy," said Vlad Vitoc, M.D., Chairman and Chief Executive Officer of MAIA. "THIO's outperformance to date supports our thesis that our telomere targeting agent could become a treatment option for people suffering from advanced NSCLC."

The 12-month survival data corresponds to the Company's most recent data from THIO-101 demonstrating favorable disease control and overall response rates. As announced in April 2024, THIO 180mg + CPI in third-line treatment showed, in part, overall response rate (ORR) of 38%, disease control rate (DCR) of 88% and median progression-free survival (PFS) of 5.5 months.

MAIA expects to release full efficacy results of THIO-101 this year.

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

About THIO

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a first-in-class investigational telomere-targeting agent currently in clinical development to evaluate its activity in Non-Small Cell Lung Cancer (NSCLC). Telomeres, along with the enzyme telomerase, play a fundamental role in the survival of cancer cells and their resistance to current therapies. The modified nucleotide 6-thio-2'-deoxyguanosine (THIO) induces telomerase-dependent telomeric DNA modification, DNA damage responses, and selective cancer cell death. THIO-damaged telomeric fragments accumulate in cytosolic micronuclei and activates both innate (cGAS/STING) and adaptive (T-cell) immune responses. The sequential treatment with THIO followed by PD-(L)1 inhibitors resulted in profound and persistent tumor regression in advanced, in vivo cancer models by induction of cancer type–specific immune memory. THIO is presently developed as a second or later line of treatment for NSCLC for patients that have progressed beyond the standard-of-care regimen of existing checkpoint inhibitors.

About THIO-101, a Phase 2 Clinical Trial

THIO-101 is a multicenter, open-label, dose finding Phase 2 clinical trial. It is the first trial designed to evaluate THIO's anti-tumor activity when followed by PD-(L)1 inhibition. The trial is testing the hypothesis that low doses of THIO administered prior to cemiplimab (Libtayo®) will enhance and prolong immune response in patients with advanced NSCLC who previously did not respond or developed resistance and progressed after first-line treatment regimen containing another checkpoint inhibitor. The trial design has two primary objectives: (1) to evaluate the safety and tolerability of THIO administered as an anticancer compound and a priming immune activator (2) to assess the clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. Treatment with THIO followed by Regeneron's cemiplimab (Libtayo®) has been generally well-tolerated to date in a heavily pre-treated population. For more information on this Phase II trial, please visit ClinicalTrials.gov using the identifier NCT05208944.

About MAIA Biotechnology, Inc.

MAIA is a targeted therapy, immuno-oncology company focused on the development and commercialization of potential first-in-class drugs with novel mechanisms of action that are intended to meaningfully improve and extend the lives of people with cancer. Our lead program is THIO, a potential first-in-class cancer telomere targeting agent in clinical development for the treatment of NSCLC patients with telomerase-positive cancer cells. For more information, please visit www.maiabiotech.com.

Forward Looking Statements

MAIA cautions that all statements, other than statements of historical facts contained in this press release, are forward-looking statements. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels or activity, performance or achievements to be materially different from those anticipated by such statements. The use of words such as "may," "might," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward looking statements. However, the absence of these words does not mean that statements are not forward-looking. For example, all statements we make regarding (i) the initiation, timing, cost, progress and results of our preclinical and clinical studies and our research and development programs, (ii) our ability to advance product candidates into, and successfully complete, clinical studies, (iii) the timing or likelihood of regulatory filings and approvals, (iv) our ability to develop, manufacture and commercialize our product candidates and to improve the manufacturing process, (v) the rate and degree of market acceptance of our product candidates, (vi) the size and growth potential of the markets for our product candidates and our ability to serve those markets, and (vii) our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates, are forward looking. All forward-looking statements are based on current estimates, assumptions and expectations by our management that, although we believe to be reasonable, are inherently uncertain. Any forward-looking statement expressing an expectation or belief as to future events is expressed in good faith and believed to be reasonable at the time such forward-looking statement is made. However, these statements are not guarantees of future events and are subject to risks and uncertainties and other factors beyond our control that may cause actual results to differ materially from those expressed in any forward-looking statement. Any forward-looking statement speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. In this release, unless the context requires otherwise, "MAIA," "Company," "we," "our," and "us" refers to MAIA Biotechnology, Inc. and its subsidiaries.

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