UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report

Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 7, 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.

MAIA Biotechnology, Inc. (the "Company") has made available a presentation about the Company's business which was posted to the Company's website on May 7, 2024, a copy of which is filed as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") and is hereby incorporated by reference.

The information contained in the 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.

The information set forth in this Report, including, without limitation, the presentation, 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 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

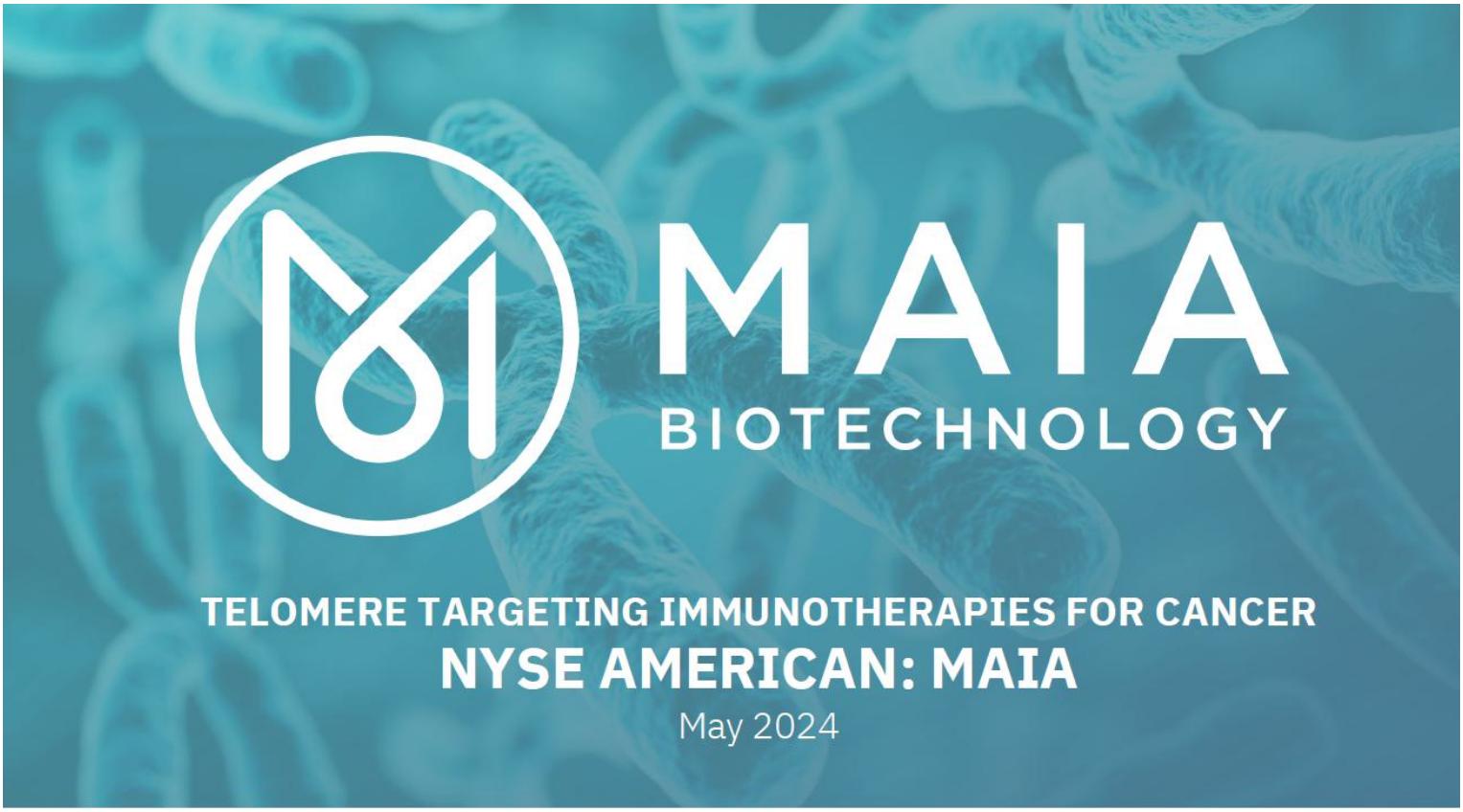
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 7, 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
May 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. The Company has filed a registration statement on Form S-1, as may be amended (Registration No.: 333-269606). Before you invest, you should carefully read the registration statement, including the factors described in the "RISK FACTORS" section of the Registration Statement and other documents that we have filed, and will subsequently file, with the Securities and Exchange Commission to better understand the risks and uncertainties inherent in our business and industry and for more complete information about us and the offering. 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 the Registration Statement. 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 the Registration Statement 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 topline data in mid-2024; 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.

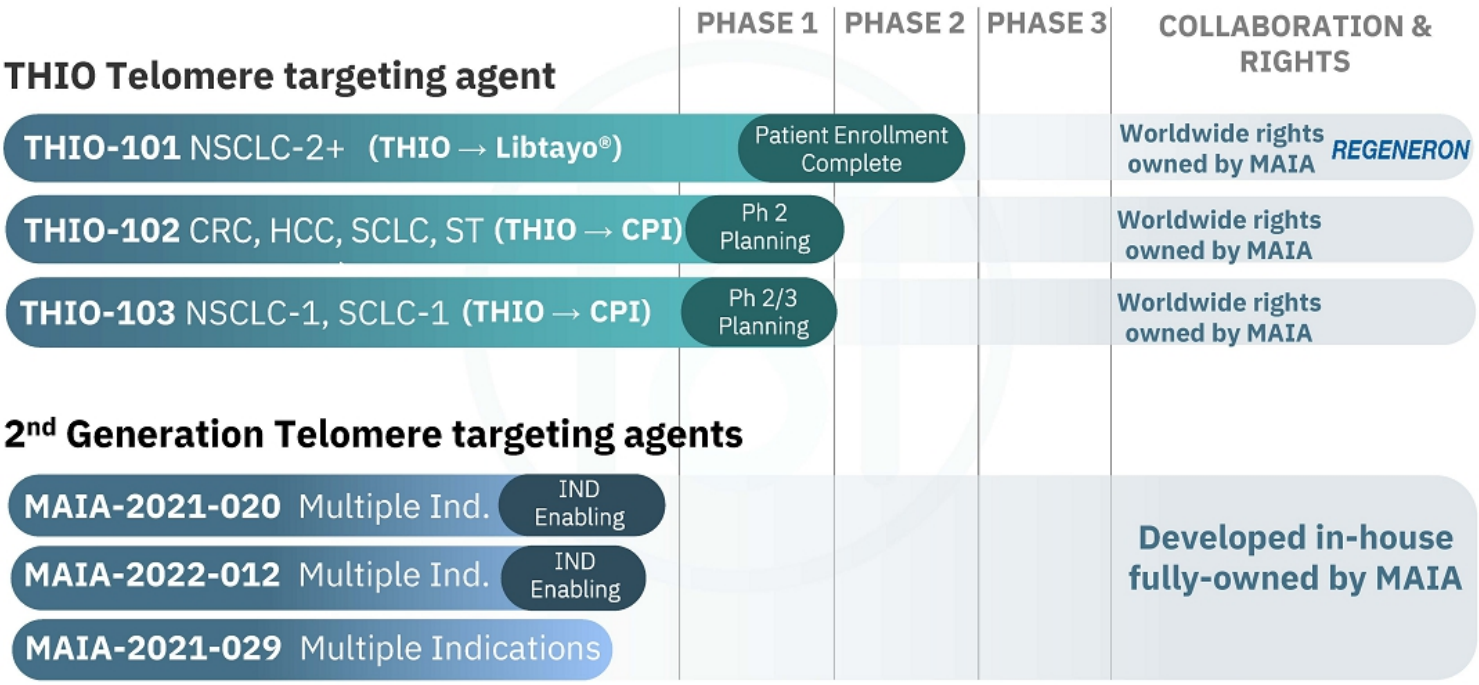
- NSCLC: largest tumor type globally, $34B annual sales
- 3 FDA Orphan Drug Designations: liver (HCC), lung (SCLC) and brain (malignant gliomas)

THIO trials planned for additional cancer indications.

- THIO-102 — colorectal cancer (CRC), HCC, SCLC, solid tumors
- THIO-103 — SCLC, NSCLC

ROBUST PIPELINE

MAIA BIOTECHNOLOGY
NYSE American: MAIA



MISSION AND APPROACH

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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

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

THIO – NOVEL MECHANISMS OF ACTION

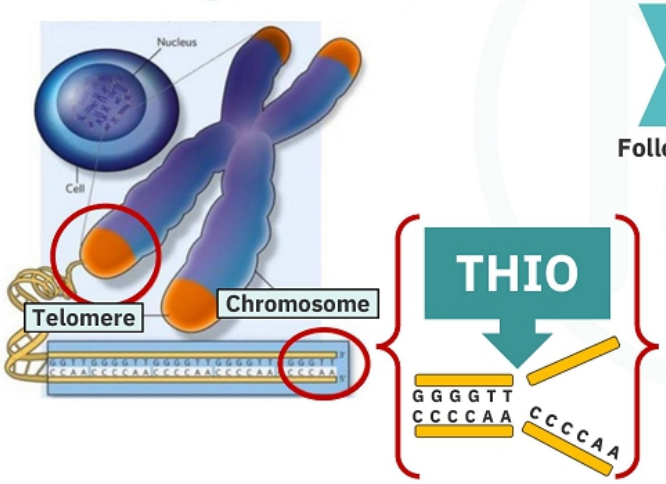
MAIA BIOTECHNOLOGY
NYSE American: MAIA

THIO

Immune Checkpoint Inhibitor

THIO has a dual MoA:

1. Telomere targeting
2. Immunogenic effect



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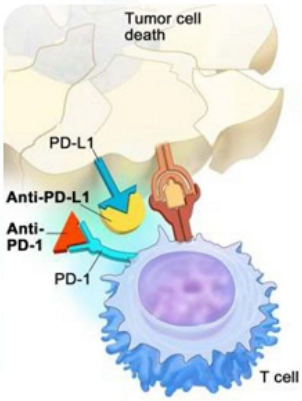


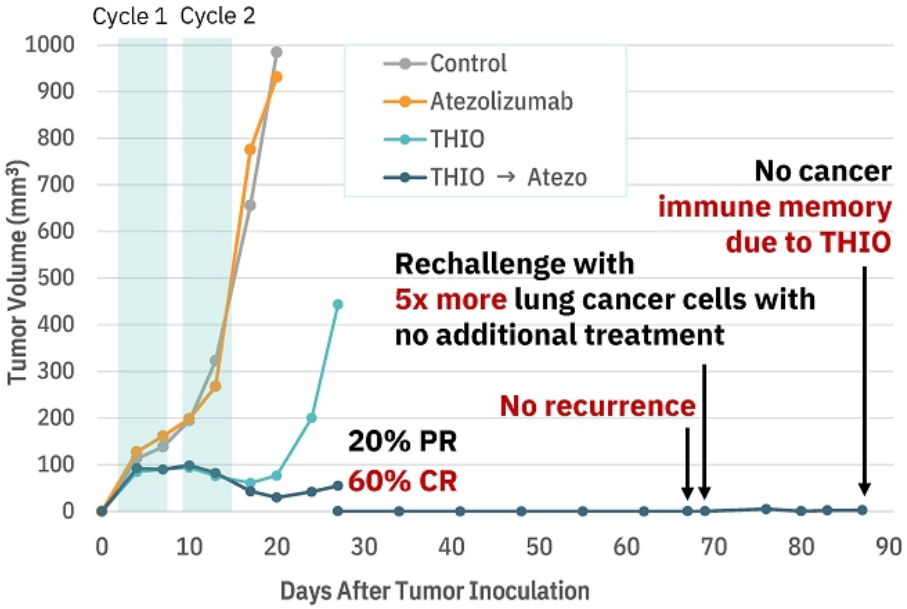
- ★ LIBTAYO® (cemiplimab) REGENERON
- IMFINZI® (durvalumab) AstraZeneca
- KEYTRUDA® (pembrolizumab) MERCK
- TEVIMBRA® (tislelizumab) BeiGene
- TECENTRIQ® (atezolizumab) Genentech
- Jemperli® (dostarlimab-gxly) GSK
- OPDIVO® (nivolumab) Bristol Myers Squibb
- BAVENCIO® (avelumab) EMD SERONO

★ Partnership 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



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)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

THIO-101 TRIAL

NON-SMALL CELL LUNG CANCER

REGENERON AGREEMENT

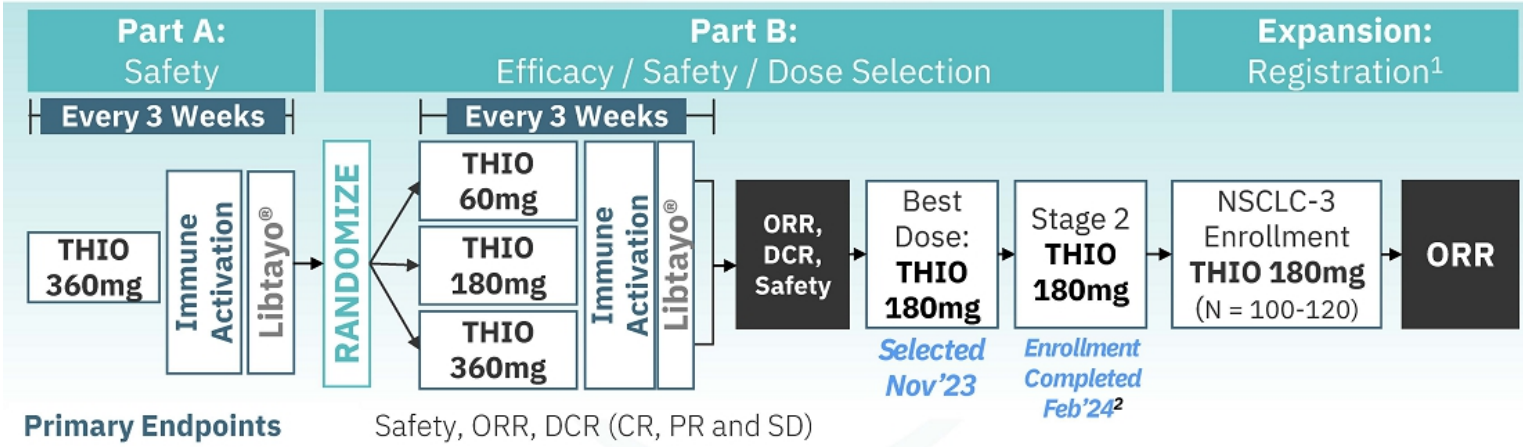
MAIA BIOTECHNOLOGY & REGENERON

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

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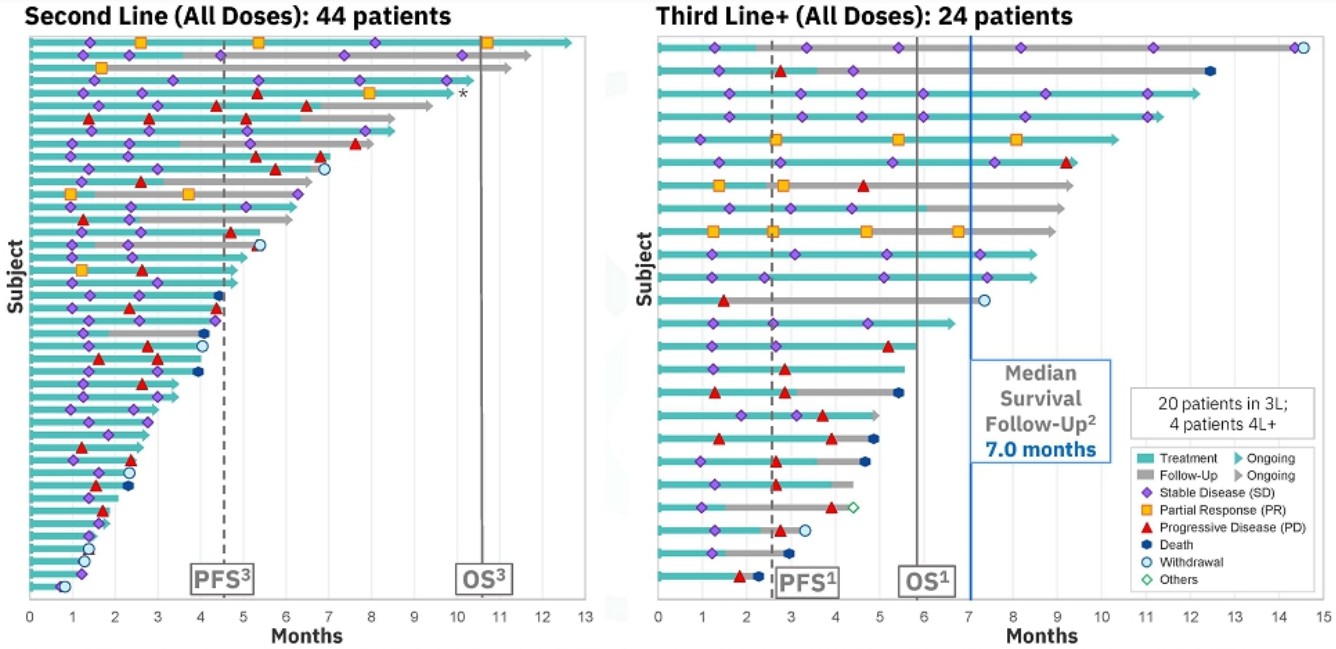

Note: This is a snapshot including ongoing subjects and data pending full verification. Due to short duration of treatment and/or follow up, data subject to change; Clinical data presented from 27Mar2024 data cut.
*Patient had new lesion categorized as PD on scan 3. Additional investigation being conducted as lesion may not be malignant.
[1] PFS and OS lines are projected benchmarks based on literature (detailed in "Expected Efficacy" page)
[2] Median Survival Follow-Up based on 3L+ patients
[3] REVEL Study (https://clinicaltrials.gov/study/NCT01168973?term=NCT01168973&rank=1&tab=results)

TREATMENT IN THIRD-LINE

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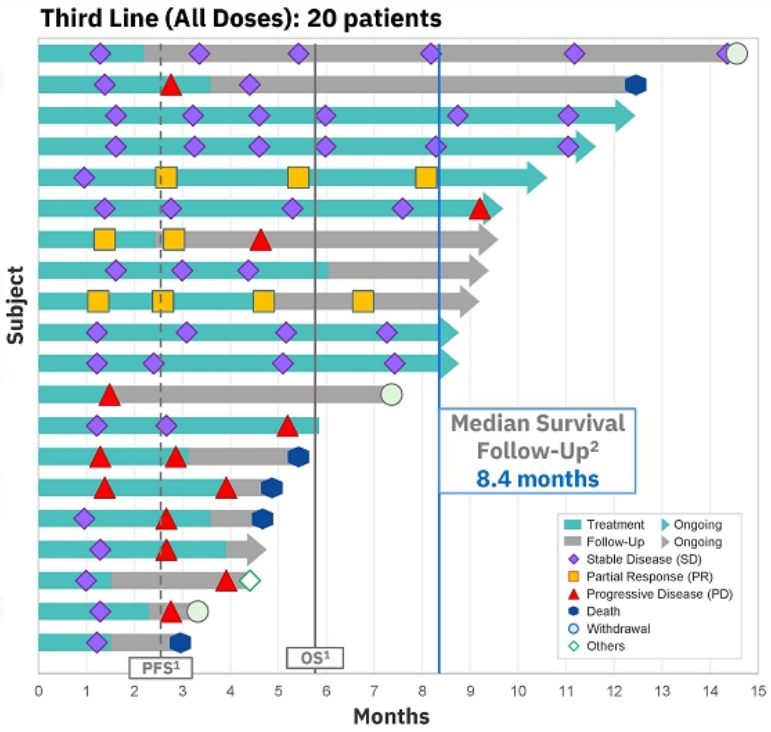
Extended Survival

- 20 subjects in 3L completed at least 1 post baseline assessment at time of cut-off
- 13/20 (65%) 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[3]



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[1] PFS and OS lines are projected benchmarks based on literature (detailed in "Expected Efficacy" page)
[2] Median Survival Follow-Up line based on 3L patients
[3] 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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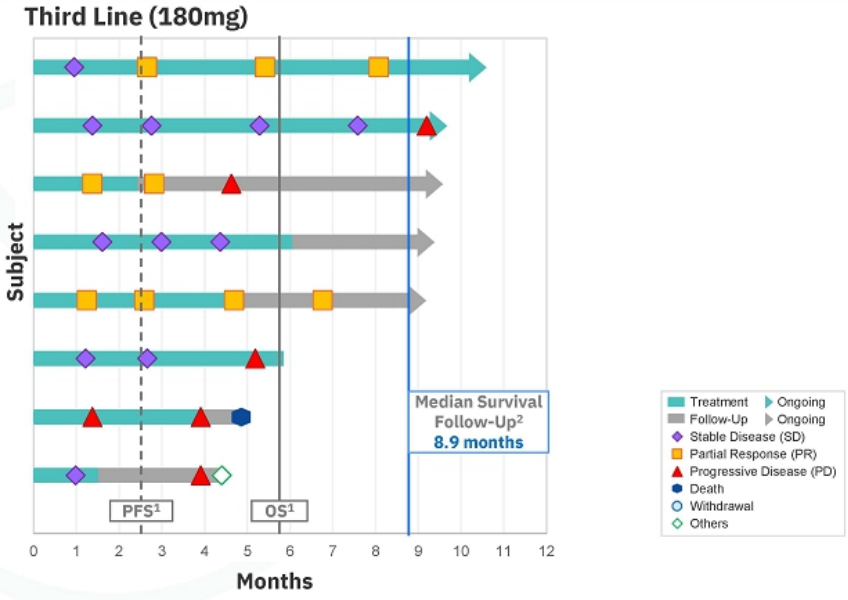
NSCLC-3 – 180mg:

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



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[1] PFS and OS lines are projected benchmarks based on literature (detailed in "Expected Efficacy" page)
[2] Median Survival Follow-Up line based on 3L patients

EXPECTED EFFICACY VS. CURRENT TREATMENTS

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NYSE American: MAIA

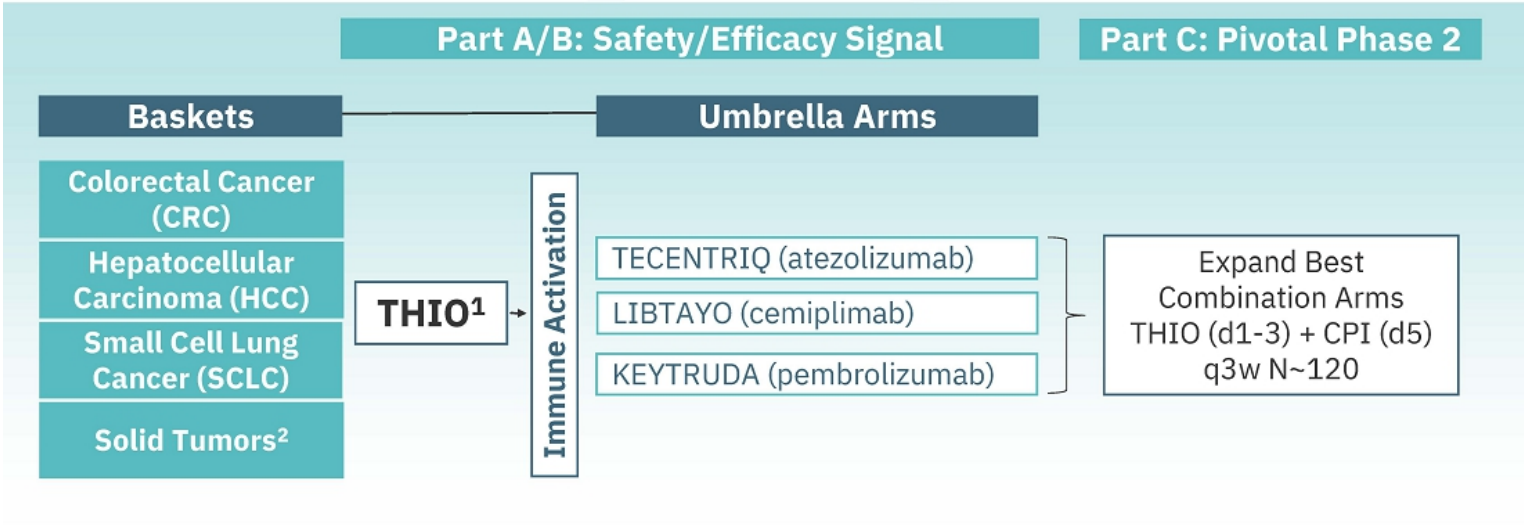
Third-Line NSCLC	THIO (180mg) + Libtayo® (cemiplimab)	Chemotherapy	Tarceva® (erlotinib)	Taxotere® (docetaxel)
Population	CPI Resistant (3L)	CPI Naïve (3L)	CPI Naïve (2L+)	CPI Naïve (2L)
DCR	88%	36%	45%	54%
ORR	38%	6%	9%	5.7%
PFS	**5.5 - 6 months (projected)**		2.2 months	1.9 months (8.3 weeks Time to Progression)
OS	**> 10 months (projected)**	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/

PLANNED UPCOMING TRIALS

THIO-102 TRIAL (PLANNED)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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

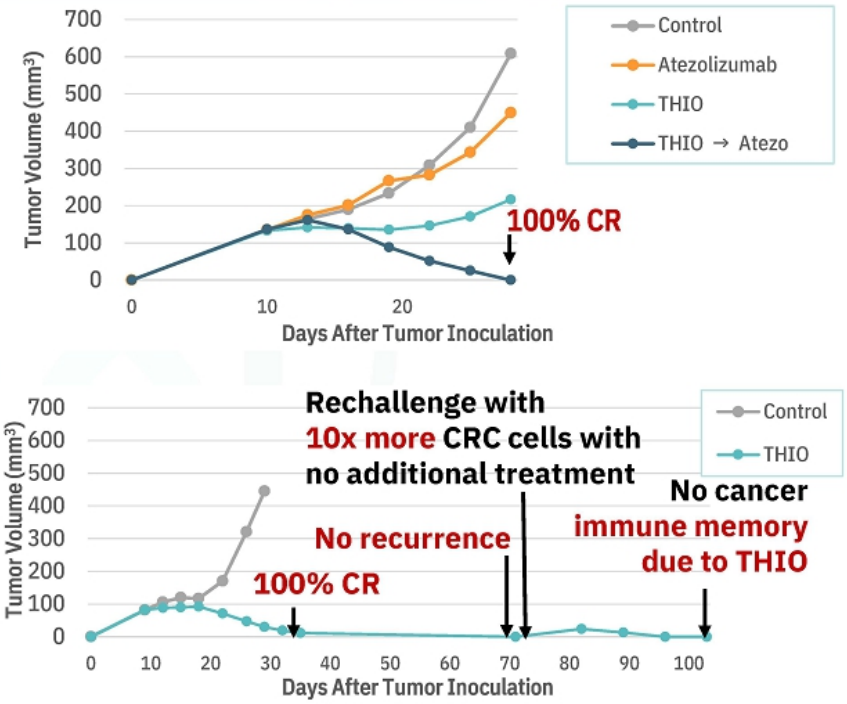


[1] Dose to be selected from THIO-101 study results
[2] E.g. Breast, Prostate, Gastric, Pancreatic, Ovarian, etc

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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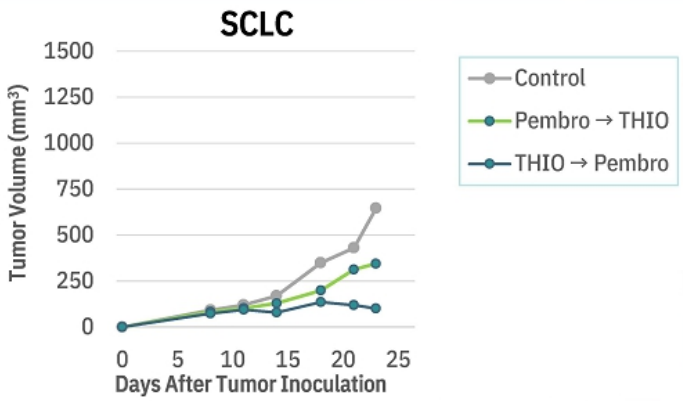
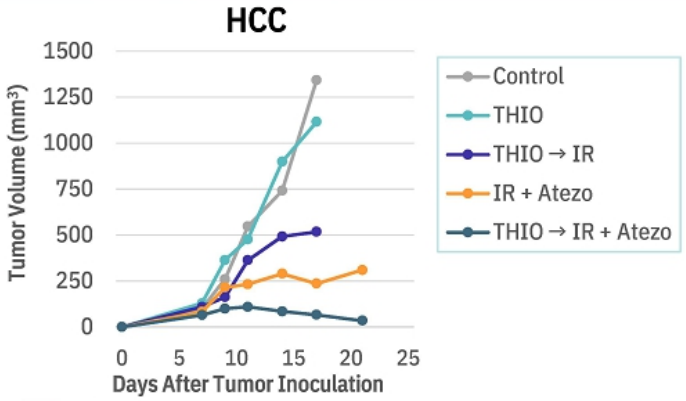




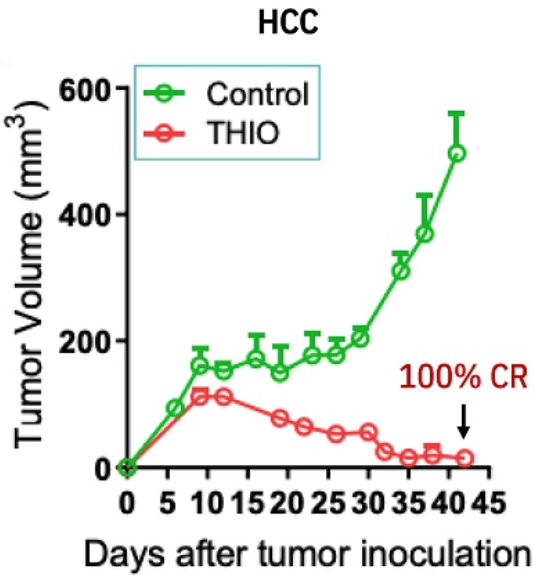
- THIO is synergistic with anti-PD-1 agent Pembrolizumab in Small Cell Lung Carcinoma (H2081) *in vivo* in humanized murine cancer model
- Treatment with THIO followed by Pembrolizumab results in highly potent anticancer effect, as compared to Pembrolizumab alone
- THIO converts immunologically "cold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

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

EXCELLENT EFFICACY IN HCC MODELS

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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



HCC ANTI-CANCER IMMUNE MEMORY

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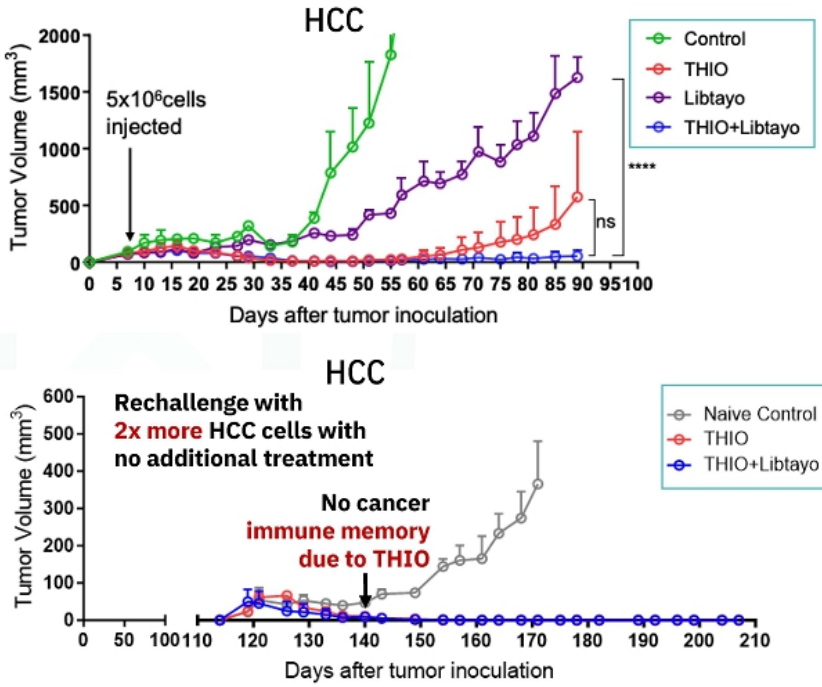
NYSE American: MAIA

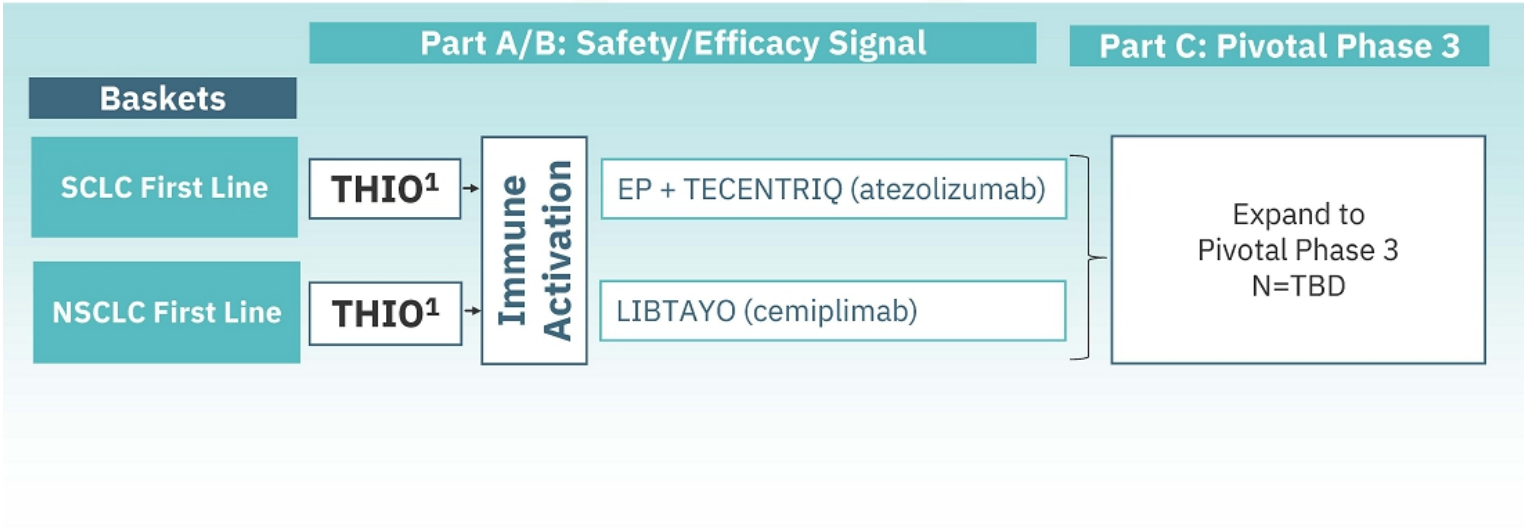
- When combined with immunotherapy checkpoint inhibitor Libtayo®, duration of response was further potentiated
- Upon rechallenge with two times more cancer cells and no additional treatment, tumor growth was completely prevented
- Administration of THIO alone and in combination with Libtayo® generated anti-cancer immune memory



THIO-103 TRIAL (PLANNED)

MAIA BIOTECHNOLOGY
NYSE American: MAIA

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



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

INVESTMENT OPPORTUNITY

EXCLUSIVITY AND INTELLECTUAL PROPERTY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Goal: New Chemical Entity (NCE) Marketing Exclusivity

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

Robust and Growing Patent Portfolio for THIO

- 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

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Vlad Vitoc, MD, MBA

Founder and CEO

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

Sergei Gryaznov, PhD

Chief Scientific Officer

- 25+ years as Scientist
- Expert Drug Discovery and Development, Oncology with 120+ publications
- Head of the J&J Oligonucleotide Center of Excellence Worldwide
- Expert of telomeres and telomerase in cancer, co-inventor of THIO

Jeffrey Himmelreich, MBA

Head of Finance

- 20+ years of financial expertise
- CFO for privately held and publicly traded companies in the healthcare and manufacturing industries
- Active CPA licensed in the state of Pennsylvania and is a Chartered Global Management Accountant

NOVARTIS astellas Pfizer BAYER janssen Incyte Cephalon Oncology geron PHARMACIA exicure

SIGNIFICANT MARKET OPPORTUNITY

MAIA BIOTECHNOLOGY
NYSE American: MAIA

Developing agents for the top tumor types markets globally

NSCLC (#1 WW) **Mortality:** 1.7M / **Sales:** $34B	**HCC** **Mortality:** 0.8M / **Sales:** $3B
CRC (#2 WW) **Mortality:** 1.0M / **Sales:** $20B	**SCLC** **Mortality:** 0.3M / **Sales:** $2B

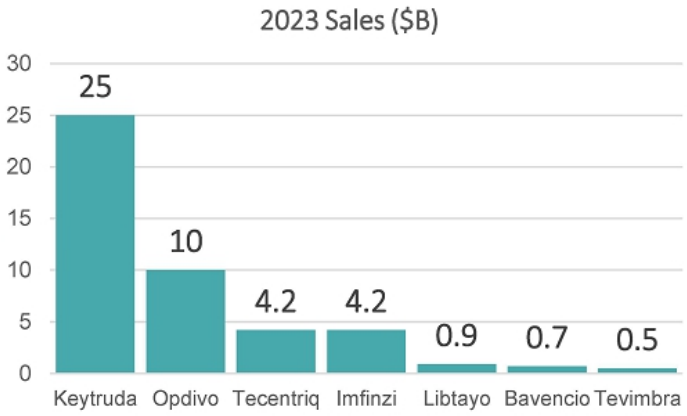
$46B CPIs Group (2023 Sales)

- 5 CPIs approved for NSCLC:
  - > 30% of NSCLC drug sales
  - > 40% of total CPI sales
- Keytruda®: $9B in NSCLC of $25B total

Partnership with Regeneron (Libtayo®)

- Profile similar to Keytruda®
- Libtayo® is entrant #5 in CPIs
- Needs superior efficacy to Keytruda®
- Sequential combination with THIO is key

Checkpoint Inhibitors Market



- Keytruda® expected to hit $30B in 2026, biosimilars expected by 2028
- Libtayo® trending towards $2.2B in 2026

COMPARABLE COMPANIES

MAIA BIOTECHNOLOGY
NYSE American: MAIA

MAIA BIOTECHNOLOGY	MIRATI THERAPEUTICS	zentalis	IOVANCE BIOTHERAPEUTICS	KURA ONCOLOGY	Turning Point Therapeutics
$55M	$4.1B	$0.8B	$3.2B	$1.4B	$4.1B
Market Cap	Market Cap	Market Cap	Market Cap	Market Cap	Market Cap
$2.69/share	$58/share	$11/share	$12/share	$19/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: Zentalis, Kura and Turning Point (on acquisition)

Note: Market Caps as of April 25, 2024 (source: S&P CapitalIQ)

MULTIPLE VALUE-DRIVING MILESTONES

MAIA BIOTECHNOLOGY
NYSE American: MAIA

★ **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** (ESMO) ★	**Part B Full Efficacy** (ASCO) ★	**Part C Efficacy Update** (ESMO)	**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** (ASCO)
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

MAIA BIOTECHNOLOGY
NYSE American: MAIA

- 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)

3x FDA Orphan Drug Designation

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