Initiation Report

MAIA BIOTECHNOLOGY, INC.

MAIA Biotechnology, Inc. – Combining Telomere Targeting and Checkpoint Inhibitor, Targeting Effective Cancer Killing and Immune System Priming Treatment

MAIA Biotechnology, Inc. (NYSE: MAIA)

Share Price: $3.50

Valuation: $11.25

Key Statistics

52 Week Range	$3.10-$9.64
Avg. Volume (3 months)	121,012
Shares Outstanding	10.95M
Market Capitalization	$38.31M
EV/Revenue	N/A
Cash Balance*	$14.06M
Analyst Coverage	2

***Cash balance as of September 2022**

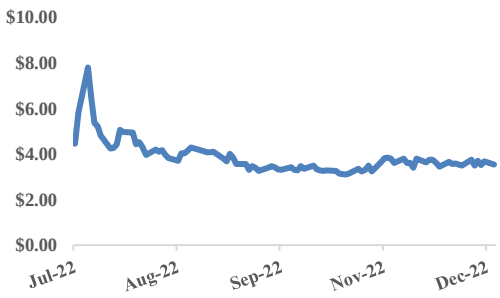
Revenue (in $mm)

Dec - FY	2021A	2022E	2023E
1Q	0.00	0.00	0.00
2Q	0.00	0.00	0.00
3Q	0.00	0.00	0.00
4Q	0.00	0.00	0.00
FY	0.00	0.00	0.00

EPS (in $)

Dec – FY	2021A	2022E	2023E
1Q	(0.23)	(0.50)	(0.53)
2Q	(0.78)	(0.40)	(0.48)
3Q	(1.02)	(0.49)	(0.47)
4Q	(0.10)	(0.41)	(0.45)
FY	(2.37)	(1.80)	(1.93)

Stock Price Chart



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Investment Highlights

- **Pan-cancer Therapeutic Applications with Potential to Overcome Therapeutic Resistance** - The company's lead small molecule telomere targeting agent, 6-thio-dG or THIO has the potential to be an effective therapeutic alternative to almost all forms of major cancer types. The presence of telomerase activity in over 85% of malignancies and in less than 1% of normal cells allows THIO to target multiple forms of solid and hematological malignancies with a high level of specificity. Furthermore, THIO has a differentiated dual mechanism of action, targeting telomere via telomerase and also inducing anti-cancer immunogenicity. With the potential to convert immunologically "cold" tumors into "hot" tumors, THIO can significantly improve the immunotherapy efficacy while overcoming the prior developed or intrinsic resistance.

- **Historical Trials and Robust Pre-clinical Trials Providing Initial Insights into THIO's Potential Efficacy and Safety -** THIO has been evaluated in multiple in vivo and in vitro models and in human clinical trials (under NCI IND in the 1970's) in multiple cancer types providing crucial insights into the drug's potential efficacy, safety, and immune stimulatory role. THIO treatment was found to induce telomeric DNA damage in cancer cells with high specificity vis-à-vis normal counterparts leading to inhibition of cancer cell proliferation, senescence, and apoptosis. In in vivo models, upregulation of CD8+ T cell proliferation was also observed with the induction of antigen-specific immune memory. THIO appears to be more effective and safer than telomerase inhibitors due to the noticeably lower comparative lag period between initiation and phenotypic and expected clinical responses. Being evaluated in multiple clinical trials during the 1970s and early 1980s, THIO demonstrated a well-established safety profile at the maximum tolerated dose levels, approximately four to forty times higher than those being evaluated in the current clinical trial. In addition, those early trials provided an understanding of the clinical experience and clinical profile of THIO administered in more than 600 subjects.

- **Large Market Opportunity -** The company has begun a phase 2 clinical trial evaluating THIO in sequential combination with Libtayo® (cemiplimab; Regeneron) in patients with advanced non-small cell lung cancer (NSCLC), which is the company's first indication. NSCLC is the second most diagnosed cancer and a leading cause of cancer mortality across the globe. Even after the approval of multiple immunotherapies as a first-line treatment, the disease is still characterized by high unmet medical needs. Of the total $23 billion of NSCLC drug sales in 2021, approximately 52% or $12 billion is contributed by immune checkpoint inhibitors. THIO is being evaluated with one such PD-1 checkpoint inhibitor, Libtayo® (cemiplimab). Based on multiple pre-clinical trials, we believe THIO has the potential to complement Libtayo® (cemiplimab) and significantly improve the efficacy if administered as a sequential combined therapy compared to monotherapy. Based on our estimates and assumptions, THIO's NSCLC indication global market opportunity is approximately $20 billion. The company has also planned to commence THIO phase 2 clinical trial in patients with SCLC, HCC, and CRC, further expanding its market opportunity.

- **Valuation -** We have valued the company using risk-adjusted DCF as our preferred methodology. We have discounted the cash flows at 15.0% and assumed the probability of success at 25.0% for our lead indication, yielding a value of $123.24 million or $11.25 per share.

Company Description

Founded in 2018 and headquartered in Chicago, Illinois, MAIA is a biotechnology company engaged in discovering, developing, and commercializing novel cancer therapies with high unmet medical needs. The company's lead therapeutic candidate is currently being evaluated in a phase 2 clinical trial for the treatment of non-small-cell lung cancer.

Please see last page for important disclosures

Company Overview

MAIA Biotechnology Inc. (NYSE: MAIA) is a clinical-stage biotechnology company working in the discovery, development, and commercialization of cancer-targeting therapies. Their major offering is THIO (aka 6-thio-dG, 6-thio-2'-deoxyguanosine), a small molecule drug with the potential first-in-class, being the sole direct telomere targeting agent in cancer cells, and is currently in clinical development. Lung cancer is the company's primary indication which has a global incidence of more than 2,200,000 patients per annum (second to breast cancer) and is also a leading cause of cancer death with a mortality count of more than 1,800,000. MAIA is also in the process of developing second-generation telomere targeting agents potentially with improved anti-cancer activity compared to THIO.

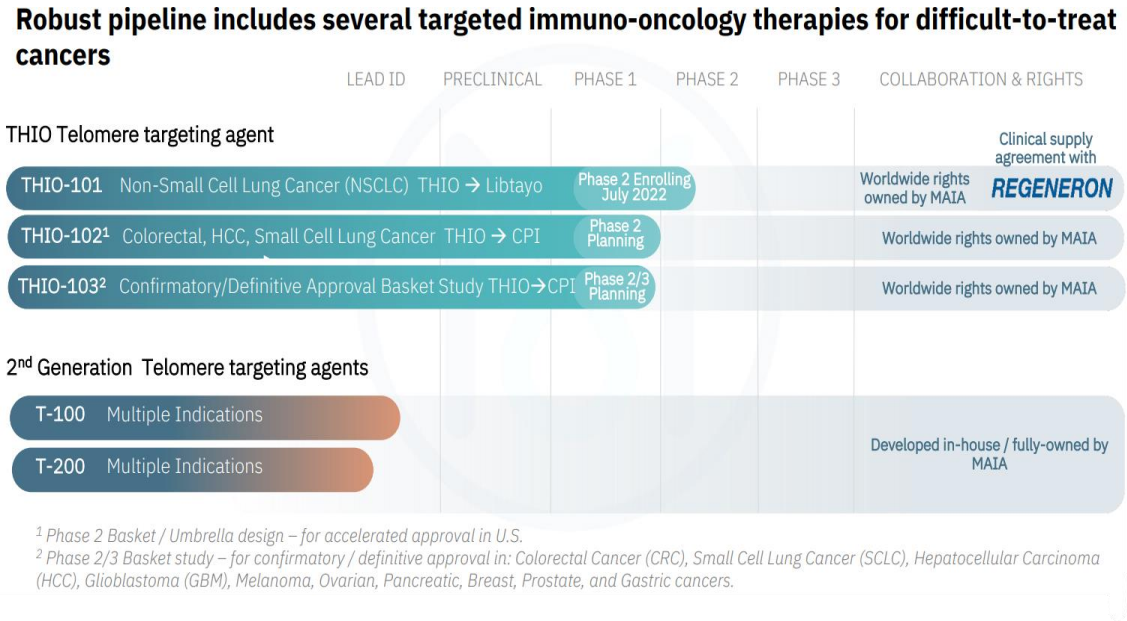

Exhibit 1: MAIA Product Pipeline. Source: Company Presentation

MAIA Biotechnology is developing potentially safe and effective therapies for multiple forms of difficult-to-treat solid tumors with high unmet medical needs, poor prognosis, and developed therapeutic resistance

Telomeres, repetitive d-(TTAGGG) DNA–protein complexes located at the chromosomes' ends and are integral for cancer cell survival. These telomeres are maintained by an enzyme called telomerase in most tumors. Telomerase activity is found in the majority of human cancers, and it significantly contributes to the proliferation and reproductive immortality of cancer cells. THIO targets telomere via telomerase, thus compromising the structure of the telomere and causing the uncapping of chromosome ends which brings about rapid tumor cell death. THIO, along with anti-PD-L1 or anti-PD1 therapy, fully eliminated advanced tumor growth *in vivo* preclinical models and produced cancer cell type-specific memory in the immune system to keep it active against cancer cells for a longer period of time. Currently, MAIA is advancing THIO into Phase 2 clinical study in Non-Small Cell Lung Cancer (NSCLC), which is the first study testing the THIO immune system activation and safety accompanied by the sequential administration of cemiplimab. The first patient in the trial was dosed in July 2022, with initial trial results expected in Q4 2022. The company has plans to evaluate multiple other cancer indications that, include small-cell lung cancer, hepatocellular carcinoma, and advanced colorectal cancer.

Understanding Telomere Targeting and The Role of Telomerase Enzymes in Promoting Therapy-resistant Tumors

Therapeutic resistance or drug resistance is a highly common phenomenon in cancer research and treatment, wherein tumor cells become tolerant or resistant to different anticancer agents. Intrinsic resistance (pre-existing) and acquired resistance (induced after therapy) have been responsible for the failure of cancer treatment options, including chemotherapies and targeted therapies. Cancer cells employ various mechanisms contributing to drug resistance. Tumor heterogeneity, tumor microenvironment (TME), target gene alteration, and increased efflux of drugs are a few of the common mechanisms playing an important role in tumorigenesis and drug resistance. Currently, 90% of failures in chemotherapy are during the invasion and metastasis of cancers related to drug resistance.[1] Furthermore, it is found that resistance to anti-PD1 therapy affects up to 60% of the patients treated.[2]

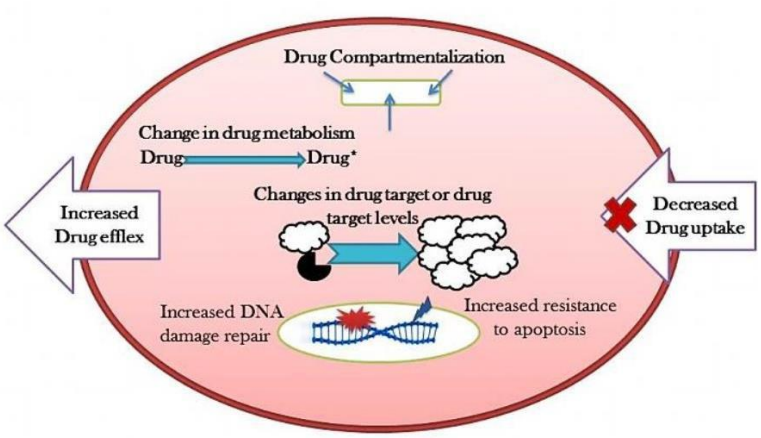

Exhibit 2: Mechanism of Drug Resistance in Cancer Cells. Source: Mansoori et al., 2017

Drug resistance has raised the need for developing newer treatment modalities for various types of cancers with high unmet medical needs

Drug resistance has raised the need for developing newer treatment modalities for various types of cancers with high unmet medical needs. The most frequent form of acquired resistance in NSCLC (the leading cause of cancer death) is secondary mutations in EGFR (e.g., T790M "gatekeeper") occurring in 60% of patients treated with second-generation TKIs [3]. Precisely targeting factors that drive cancer growth and proliferation have had remarkable initial success, but as the treatment proceeds, a large majority of patients (30% - 55%) with NSCLC develop drug resistance, relapse, and die due to the disease progression.[4] Combinational and personalized therapies currently represent the optimal treatment option over monotherapies due to their ability to target several cancer traits, inhibit more clones in tumors and make new cancer mutations resistant to a combination therapy much more complex and difficult.[4]

One such treatment modality that has the potential to overcome the drug resistance mechanism is the inhibition of telomerase activity or targeting telomeres functioning in cancer cells. Telomere-Telomerase functioning is highly correlated with cancer cell proliferation and is a hallmark of poor prognosis. Telomeres are a chain of a repetitive sequence of DNA found at both ends of

[1] Mansoori et al., Adv Pharm Bull., 2017
[2] Jake et al., Cancer Treatment Reviews, 2017
[3] Sosa et al., Front Oncol., 2018
[4] Wang et al., Cancer Drug Resist, 2019

chromosomes. Telomeres protect chromosomes from enzymatic end-degradation and ensure the correct replication of cells in a way that preserves genetic information. Telomeres are analogues to plastic ends of shoelaces that protect them from fraying or unravelling. Each time the cell divides, the protective caps shorten and reach the point of inactivation or replicative senescence. Scientific evidence and research indicate that telomere functioning holds the key to biological aging and cancer proliferation.

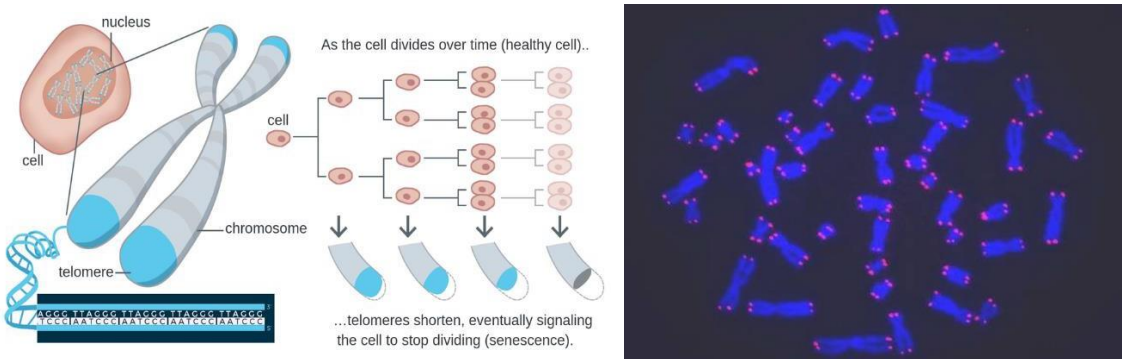

Exhibit 3: Human Cell, Chromosome, Telomere (Left) Visualization of Telomeres Using Digital Fluorescence Microscopy. Source: Labster.com, Sugarman, et al., 2019

The company's lead therapeutic candidate, 6-thio-dg, or THIO, is a direct telomere targeting agent with the potential to overcome therapeutic resistance and induce an immune response

Telomerase, a ribonucleoprotein complex, counteracts the telomere-shortening mechanism, which can lead to unlimited cell proliferation and immortality. The protective mechanism of telomerase is absent in human somatic cells, while cancer cells, including over 85% of malignancies, have detectable telomerase enzymic activity.[5] This represents a major mechanism of cancer cell growth and disease progression.

The telomerase holoenzyme consists of two major components, functional RNA, hTR, and the other is catalytic protein reverse Transcriptase activity (hTERT). Telomeres and the enzyme Telomerase alterations play an important role in drug resistance and sensitivity to current cancer therapies. Inhibiting Telomerase activity, or more importantly, specific modification and alteration of structural integrity of telomeres in cancer cells, represents a key pathway to creating successful cancer therapy for multiple types of drug-sensitive and drug-resistant cancers.[6]

THIO - Telomere Targeting Agent with Dual Mechanism of Action

The company's lead therapeutic candidate THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a purine nucleoside analog that is incorporated into telomeres positive cells via telomerase and targets telomeres to achieve the desired therapeutic effect. Targeting telomerase directly is ineffective due to high toxicities and the long lag period between initiation and effect of the therapeutic treatment. THIO has been found to decrease the lag period experienced by previous direct telomerase inhibitors and demonstrated independence of telomere length in its ability to affect cancer in a timely manner with a reduced toxicity profile.[7]

[5] Cong et al., Microbiol Mol Biol Rev., 2002
[6] Ryan et al., Molecular Pharmacology, 2005
[7] Sugarman et al., Mol Carcinog., 2019

Exhibit 4: THIO Dual Mechanism of Action (MoA). Source: MAIA Corporate Presentation

THIO has been evaluated in multiple pre-clinical and clinical trials providing insights into its ability to successfully inhibit tumour growth and cause cancer cell death. Data from these trials indicated THIO's robust cancer killing ability and well-established safety profile

THIO utilizes a dual mechanism of action that not only directly targets telomere DNA structure and functional integrity, but also yields immunogenic effects converting immunologically cold tumors into hot tumors that are refractory to checkpoint inhibitors. The company is currently evaluating the drug in a phase 2 clinical trial in combination with immune checkpoint inhibitor Libtayo® (cemiplimab) for the potential treatment of non-small cell lung cancer (NSCLC). Telomerase activity is detected in almost all forms of malignancies and thus represents almost a universal oncological target. In line with the underlying findings, THIO has also been evaluated in multiple forms of malignancies in multiple pre-clinical models, with the company planning to further evaluate it in clinical settings in patients with advanced colorectal cancer, hepatocellular carcinoma, and small-cell lung cancer.

THIO Clinical Trials - An Overview of Clinical Research

THIO as a pharmacological agent has been assessed in different forms of cancer in nineteen phases 1 to phase 3 clinical trials enrolling over 600 patients from the 1970s to the early 1980s. Even though the historical clinical trial had significant limitations, including a lack of information regarding the way the statistical significance was set and data points in line with the current ICH Good Clinical Practices, it still provided reasonable insights into the clinical profile of the drug. Given the sample population of over 600 subjects with doses significantly higher than currently being tested, past trials provided important information regarding potential efficacy and, most importantly, the safety profile.

Observed adverse events relating to the combination and single-agent historical clinical studies included leukopenia, thrombocytopenia, skin rash, alopecia (reversible), nausea, and vomiting. The past clinical trial results indicated THIO's favorable safety and toxicity profile, which is still a concern in many of the telomerase inhibitor compounds. Further analysis of historical clinical trial results indicate that researchers were unaware of THIO's targeting mechanism, immune system activating ability, and immunosuppressive nature at higher doses.

THIO - Preclinical Trial Design and Results

Multiple preclinical studies were undertaken to evaluate THIO in all major types of malignancies. The *in vitro* cell line assays included telomerase-positive lung, colorectal, liver, prostate, head and neck, melanoma, and brain tumor. THIO has also been evaluated in syngeneic and genetic-deficient mouse models of telomerase-positive lung, colorectal, liver, melanoma, and brain cancers.

In vitro studies, HCT116 (colon cancer), A549 (lung cancer), and a panel of non-small cell lung cancer cell lines (H2882, HCC2429, HCC15, among others) were administered with 0.5 to 10 μmol/L THIO and 6-thioguanine. Similar treatment was administered in BJ human cell lines, colonic epithelial, and cell lines (HCEC1) to understand the effect of THIO-induced telomere dysfunction in normal cells.

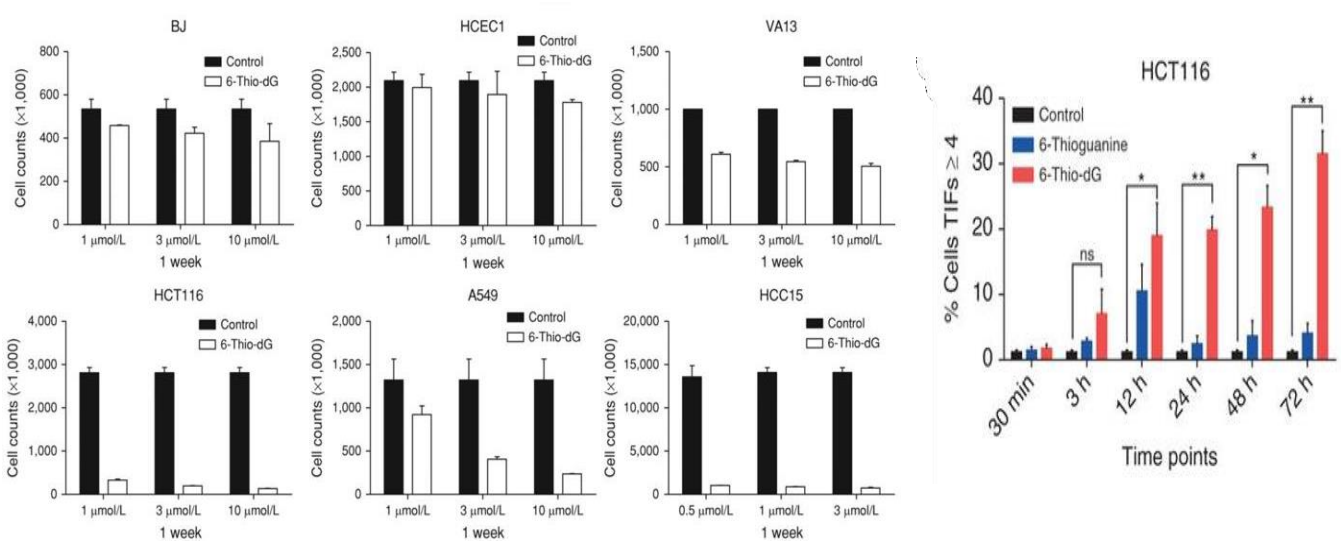

Exhibit 5: Cell Count after One Week of Treatment and TIF Index. Source: Mender et al., 2015

As represented by Exhibit 5, the cancer cells (HCT116, A549, and HCC15) at different dosage levels saw a considerable reduction post one week of administration compared to the control arm. The normal untransformed cells (BJ, HCEC1, and VA13) were comparatively much less affected, providing an indication of THIO's ability to target and induce cancer cell death while not harming or destroying normal healthy cells. Furthermore, telomeric and genomic DNA damage in cancer cells was assessed using TIF Index and genomic DNA damage foci per cell. Telomere dysfunction-Induced Foci (TIFs) is an established biomarker of efficacy indicating telomere-associated DNA damage. TIFs can be identified as the colocalization of telomeres with DNA damage response factors such as γ-H2AX.

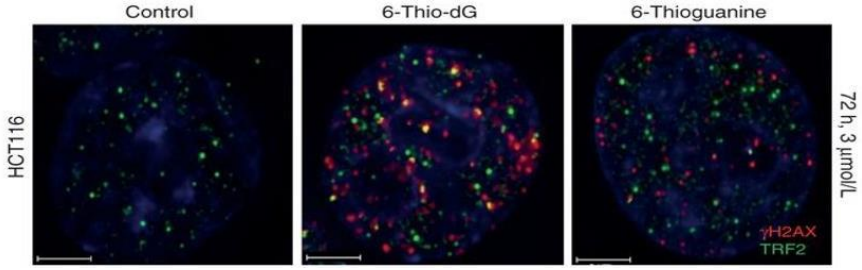

Exhibit 6: Microscopy Image of HCT116 after Treatment with THIO and 6-thioguanine. Source: Mender et al., 2015

The 6-thio-dG treatment induced a 7.8-fold increase in telomeric DNA damage and overall modes increase in genomic damage as compared with 6-thioguanine after 72 hours.[8] Expected contrasting results were observed in non-cancerous normal cells, which lack telomerase, with no detectable telomeric DNA damage. In Exhibit 6, the red dots show DNA damaging response factor, yH2AX, the green dots show TRF2, and the yellow dots indicate the presence of TIFs. The increased presence of yellow and red dots in the 6-thio-dG arm indicates the presence of TIFs and yH2AX as a result of telomere dysfunction cascades.

Telomeres-telomerase activity has also been found to be a potentially attractive therapeutic target in different deadly brain tumors. An analysis of 18,430 samples across 31 cancer types identified TERT promoter mutations in 89% of glioblastoma (GBM) and 45% of low-grade glioma (LGG).[9] Multiple pre-clinical trials have been conducted evaluating THIO's anti-tumor activity in brain tumor cell lines.

Multiple preclinical studies were undertaken to evaluate THIO in all major types of malignancies. The cancer cells (HCT116, A549, and HCC15) at different dosage levels saw a considerable reduction post one week of administration compared to the control arm

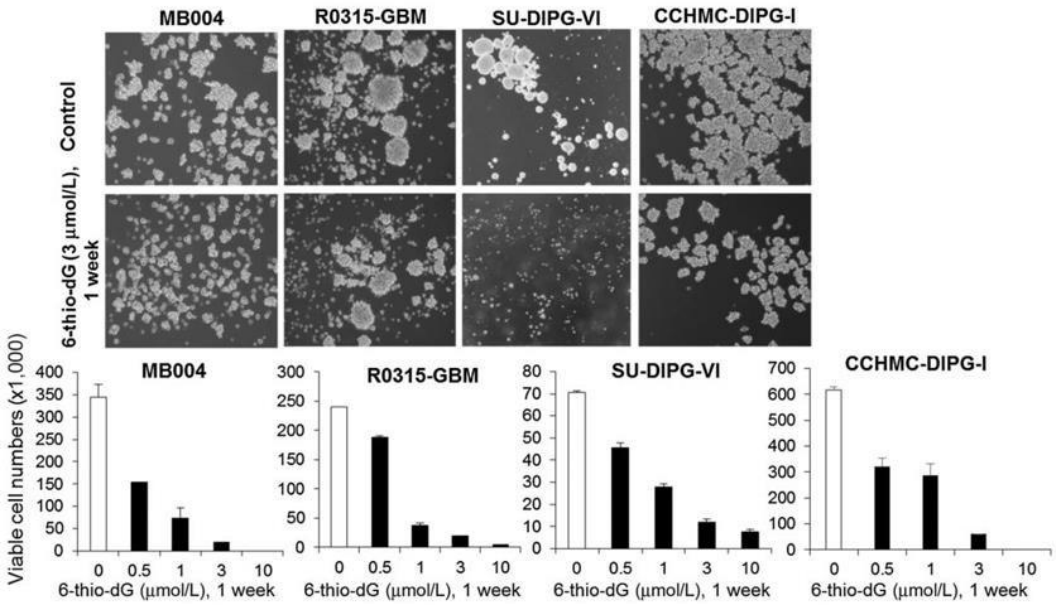

Exhibit 7: TER2+ Pediatric Brain Tumor Cells. Source: Sengupta, S. et al., 2018

As observed previously in NSCLC and colon cancer models, treatment with THIO was able to inhibit growth in TERT(+) medulloblastoma, GBM, and DIPG cancer cells. THIO caused an acute increase in the number of cells with TIFs (~25%) in telomerase-positive cells after 2 days, with the effect being amplified, reaching the TIF-positive cell count of approximately 34% at day 5.[10] Another *in vitro* study of 3 different mouse glioma cell lines and 17 human glioma cell lines exhibited similar results, inhibiting cancer cell proliferation, and inducing senescence and apoptosis. THIO treatment in vitro brain tumor studies were able to impair cancer cell viability and cell division by inducing telomeric DNA damage.

[8] Mender et al., Cancer Discover, 2015
[9] Yu et al., Clin Cancer Res., 2021
[10] Sengupta., Mol Cancer Therapeutics, 2018

Further *in vivo* studies were not only directed to confirm the results observed in multiple cell line models but also to understand THIO's safety profile and interaction between cancer cells and the innate adaptive immune system. These underlying studies also provided crucial insights into THIO's effectiveness in a combinational therapeutic setting as compared to monotherapy.

To determine general toxicity levels, 129S2 wild-type female mice were administered daily for 25 days with 1.67 mg/kg and 5mg/kg dose levels of both THIO and 6-thioguanine. 5 mg/kg treatment of THIO did not result in any deaths, with the weight of the mouse remaining stable over the course of the treatment period. In contrast, treatment with 5mg/kg of 6-thioguanine resulted in three deaths, and dosage levels above 3 mg/kg were found to be toxic in mice. Further analysis indicated THIO, when compared to control, did not cause any toxic effects when evaluating the histopathology of the liver, kidney spleen, and colon.

Additional *in vivo* studies included the evaluation of 3 mg/kg THIO in immunocompetent mice inoculated with TERT+ murine colon cancer cells (MC38). The results were similar to as observed in *in vitro* models with treatment-inducing tumor growth inhibition and decreased tumor volume (exhibit 8, left). To understand the stimulatory role of the immune system, similar studies were conducted in Rag-1 knockout immunodeficient mice lacking T- and B- cells. Notably, THIO treatment was not able to yield any therapeutic effect when compared to the control. The tumor volume increased as the treatment progressed, indicating an important role in the immune response to inhibit tumor growth when treated with THIO. Upregulation of CD8+ T cell proliferation was observed (in immunocompetent mice), as indicated by elevated Ki67 expression confirming the dependence of THIO's therapeutic effect on T cells.

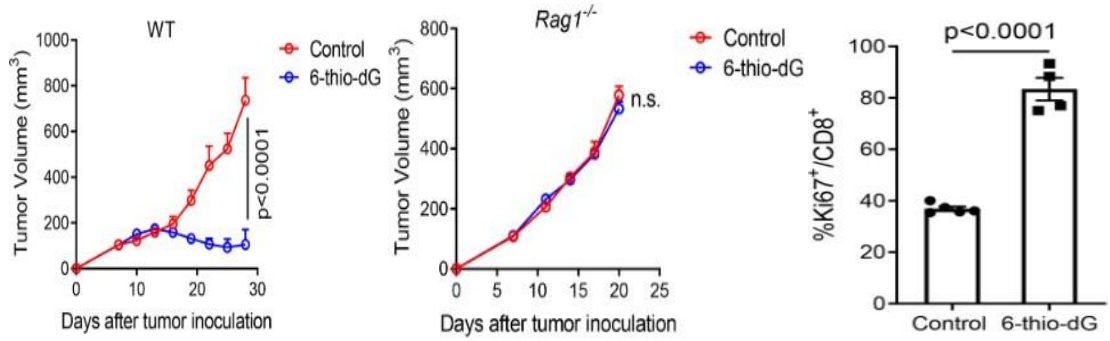

Exhibit 8: Tumor Volume after Treatment with THIO in Immunocompetent Mice (Left) and Mmmunodeficient Mice (Middle). Frequency of Ki67+CD8+ T Cells (Left). Source: Mender et al., 2020

In addition to T-cell proliferation, THIO treatment also induced the upregulation of PD-1 expression. PD-1 is an immune checkpoint receptor found on T cells that inhibits immune cells' effecter function and blocks T cell activity during the immune response. The elevated PD-1 expression might eventually inhibit the cytotoxic $CD8^+$ T cell function after 6-thio-dG treatment.[11] Based on this reasoning, THIO has been evaluated in a combinational setting with anti-PD-1/PD-L1 agents, which is expected to show a sustained anti-tumor response while overcoming the PD-L1 blockade resistance mechanism.

[11] Mender et al., Cancer Cell., 2020

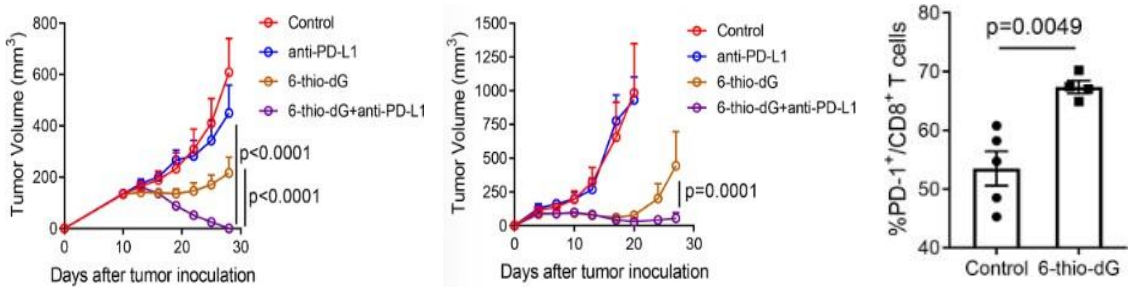

Exhibit 9: Tumor Volume in Mice Bearing TERT+ MC38 tumor (Left) and TERT+ LLC (Middle). Frequency of PD-$1^{+}CD8^{+}$T cells (Right) Source: Mender et al., 2020

In C57BL/6, mice inoculated with MC38 tumor cells were administered, twice, with THIO and anti-PD-L1 alone as a monotherapy. In another arm, both the therapies, THIO, and anti-PD-L1 agent were sequentially administered. Tumors in only the combination treatment group were completely inhibited achieving a 100% survival rate. Anti-PD-L1 or THIO as monotherapies were not able to induce sustained tumor growth inhibition (exhibit 9, left). This combination therapy was further tested in a comparatively less immunogenic Lewis lung carcinoma (LLC) tumor model. The results were consistent with the MC38 tumor model, with combination therapy achieving essentially complete tumor inhibition, while anti-PD-L1 monotherapy exhibited no therapeutic effect (exhibit 9, middle). Notably, 40% of mice eventually completed rejected tumors in a combinational setting.[11] Treatment with 6-thio-dG also led to the development of a tumor-specific immune memory which stimulates an anti-tumor response when the animals with the observed complete responses to the treatment were reinjected with LLC cells. This tumor-protecting effect was also observed when the agent's combination-treated mice with MC38 tumors were followed for 5 weeks and re-challenged with MC38 tumor cells. The results indicated the development of *antigen-specific immune memory* that rejected the re-challenged MC38 tumor cells.

In multiple in-vivo and in-vitro preclinical trials, 6-thio-dg has shown to successfully induce telomere dysfunction via telomerase that successfully led to DNA damage and cancer cell apoptosis

In multiple in vivo and in vitro preclinical studies (Mender et al., 2015, Sengupta. et al., 2018, Mender et al., 2018, Mender et al., 2020, Yu et al., 2021) 6-thio-dG has shown to successfully induce telomere dysfunction via telomerase activity that not only successfully leads to DNA damage and cancer cell apoptosis, but also accomplishes it with the shorter lag period between treatment and expected effect that results in prolonged treatment and hematological toxicities. Further, the combination sequential treatment of THIO and anti-PD-L1 demonstrated a robust anti-tumor response overcoming immunological resistances in advanced tumor models in vivo. The ability of 6-thio-dG treatment to develop tumor-specific immune memory protection further accentuates the positive preclinical efficacy data. The combination sequential treatment with THIO and immune check point inhibitors is believed to yield optimal safety and efficacy data, particularly in therapy-resistant tumors, which is currently being evaluated in human clinical trials.

THIO-101: Phase 2 Clinical Trial For NSCLC

Based on the robust data from preclinical studies and extensive historical clinical experience with 6-thio-dG, the company has initiated an open-label, multicenter, dose-finding, phase 2 clinical trial evaluating THIO sequenced with FDA-approved anti-PD-1 therapy, Libtayo® (cemiplimab) in patients with advanced NSCLC. The trial seeks to enroll up to 182 participants, who have already been treated with immune checkpoint inhibitors and displayed disease progression or no therapeutic benefit.

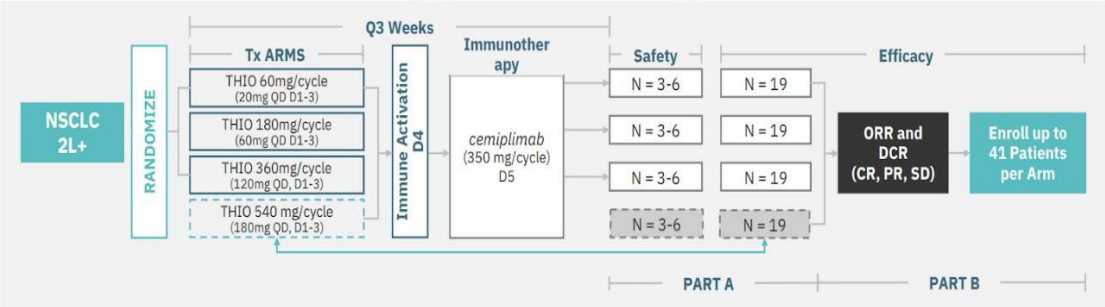

Exhibit 10: THIO-101 Phase 2 Clinical Trial Design Source: Company Presentation

THIO sequenced with cemiplimab will be administered to NSCLC patients divided into three parallel separate arms with different THIO dosage levels (the fourth arm, at 540 mg/cycle is optional). The objective of the underlying trial is to assess the safety, dosage tolerance, and immune system activation of THIO as an anti-cancer agent before the administration of cemiplimab and the efficacy of the treatment with sequential administering cemiplimab. The current trials are being conducted in Australia and Eastern Europe. The planned filings of IND with the U.S. FDA is expected to take place in the near future.

The company has entered into a licensing agreement with The University of Texas Southwestern Medical Centre (UTSW), obtaining global and exclusive rights to develop and commercialize THIO for TERT+ cancer indications

The lowest and highest dosage arms include administration of 60 mg/cycle to 360 mg/cycle of THIO, respectively, which represent 40 times lower dosage than the maximum tolerated dosage (MTD) determined in the historical clinical trials. Based on the dosage levels and historical trial data, we expect satisfactory safety data to allow the company to file an Investigational New Drug application (IND) with the U.S. FDA. The initial safety data based on the lead-in group (n/arm = 3-6) is expected to be announced by Q2 2023, and preliminary efficacy data in the second half of 2023.

The primary endpoints and secondary endpoints of the trial include the determination of overall response rate (ORR), dose-limiting toxicities (DLTs), treatment-emergent adverse events (TEAEs), Overall Survival (OS), progression-free survival (PFS), and duration of response (DoR). Additional outcome measures include the assessment of PK and exploratory pharmacodynamic biomarkers through gamma-H2AX induction assay and TIFs formation assays.

Strategic Collaborations and Intellectual Property

The company has entered into a licensing agreement with The University of Texas Southwestern Medical Center (UTSW), obtaining global and exclusive rights to develop and commercialize THIO for hTERT(+) cancer indications. As per the agreement, MAIA is required to fulfill certain obligations, including licensing fees, milestone payments, and royalty payments. The company has also entered into a clinical supply agreement with Regeneron Pharmaceuticals, Inc (REGN) to supply Libtayo® (cemiplimab) for its THIO-101 clinical trial. Libtayo®, a PD-1 inhibitor has been approved for has been approved by the U.S FDA for multiple cancer indications, including non-small cell lung cancer (NSCLC), cutaneous squamous cell carcinoma (CSCC), and basal cell carcinoma (BCC). MAIA will receive the drug free of costs from Regeneron. In return, MAIA will provide development exclusivity for its NSCLC indication, which means the cemiplimab will remain the only PD-1 antagonists that the company will be pursuing with THIO for NSCLC.

The company's patent portfolio covers several areas of THIO's treatment strategy, including telomerase-mediated telomere-altering compounds, treatment of drug-resistant cancers, and sequential treatment using THIO and checkpoint inhibitors. The portfolio includes four issued patents and 16 pending patent applications. The growing robust patent portfolio and the goal to obtain NCE exclusivity are expected to provide the necessary protection upon approval and commercialization.

Goal: **NCE Marketing Exclusivity**

- THIO (6-thio-2'-deoxyguanosine) has never been previously approved by the FDA
- NCE exclusivity if granted blocks submission of competing ANDAs and 505(b)(2) NDAs for 5 years

Robust and Growing Patent Portfolio for THIO

1 issued US patent
3 issued foreign patents
5 pending US patent applications
8 pending foreign patent applications

Current patents/provisionals broadly cover the following key areas:

Telomerase mediated telomere altering compounds
THIO's immunogenic treatment strategy: sequential combination with checkpoint inhibitors
Treatment of therapy-resistant cancers

Jurisdiction	Status	Number	Title	Expected Expiry	Type of Patent Protection
US	Issued	10,463,685	Telomerase Mediated Telomere Altering Compounds	April 8, 2034	Use of 6-Thio-dG to treat lung cancer or colon cancer
MX	Issued	387008	Telomerase Mediated Telomere Altering Compounds	April 8, 2034	Use of 6-Thio-dG to treat lung cancer or colon cancer
NZ	Issued	73228	Telomerase Mediated Telomere Altering Compounds	April 8, 2034	Use of 6-Thio-dG to reduce the size or a tumor or the growth rate of the tumor
Russia	Issued	2713555	Telomerase Mediated Telomere Altering Compounds	April 8, 2034	Use of 6-Thio-dG to treat lung cancer or colon cancer
US	Pending	16/450,430	Treatment of Drug Resistant Proliferative Diseases with Telomerase Mediated Telomere Altering Compounds	March 23, 2037	A method of treating NSCLC using a 6-mercaptopurine deoxyribonucleoside analogue
US	Pending	16/304,538	6-thio-2'deoxyguanosine (6-thio-dG) results in telomerase dependent telomere dysfunction and cell death in various models of therapy-resistant cancer cells	May 26, 2037	A method of treating a subject with cancer comprising 6-thio-dG) wherein cells of said cancer are telomerase-positive and exhibit enriched telomere transcriptional signature(s), wherein said subject has had disease progression during or after platinum-based therapy, radiotherapy, or immunotherapy
US	Pending	16/982,979	Use of 6-thio-dG to Treat Therapy-Resistant Telomerase Positive Pediatric Brain Tumors	March 22, 2039	A method of treating a brain cancer in a pediatric subject, comprising administering a telomerase substrate precursor analog to a subject in need thereof, thereby treating pediatric brain cancer.
US	Pending	17/200,539	Sequential Treatment of Cancers Using 6-Thio-dG, Checkpoint Inhibitors and Radiation Therapy	March 12, 2041	A method of treating a cancer, in a subject comprising administering to said subject 6-thio-2'-deoxyguanosine (6-thio-dG) followed by treatment with an immune checkpoint inhibitor, wherein the cancer is selected from the group consisting of pancreatic, lung, mesothelioma, stomach, esophagus, liver, biliary tract, bladder, head & neck, oral, nasopharyngeal, adult brain, colon, rectum, colorectal, prostate, ovarian, cervical, uterine, testicular, lymphoma, leukemia, skin, breast, kidney, neuroblastoma, Merkel cell carcinoma, myelodysplastic syndrome, myelofibrosis, and multiple myeloma.
US	Pending	63/388,688	Dinucleotides and Their Use in Treating Cancer	July 13, 2043	New dinucleotide compounds for treating cancer by targeting telomeres in cancer cells

Exhibit 11: Patent Portfolio Source: Company Presentation

THIO-102: Phase 2 Clinical Trial for Multiple Cancer Indications

The company is in the process of preparing another open-label, multicenter, and phase 2 clinical to evaluate THIO in combination with FDA-approved Anti-PD-1 or Anti-PD-L1 (Keytruda® (pembrolizumab), Libtayo® (cemiplimab) Tecentriq® (atezolizumab)) in multiple TERT(+) cancer indications. The basket/umbrella trial is expected to be initiated by the end of 2023, and the dosage levels for different cohorts for the trial will be selected post the trial results from the THIO-101 clinical study. The three cancer indications that the company plans to target are advanced colorectal cancer, hepatocellular carcinoma, and small-cell lung cancer. Of these three, the company has already received an orphan drug designation for THIO for the treatment of two of the above-stated three cancer indications - small cell lung cancer and hepatocellular carcinoma.

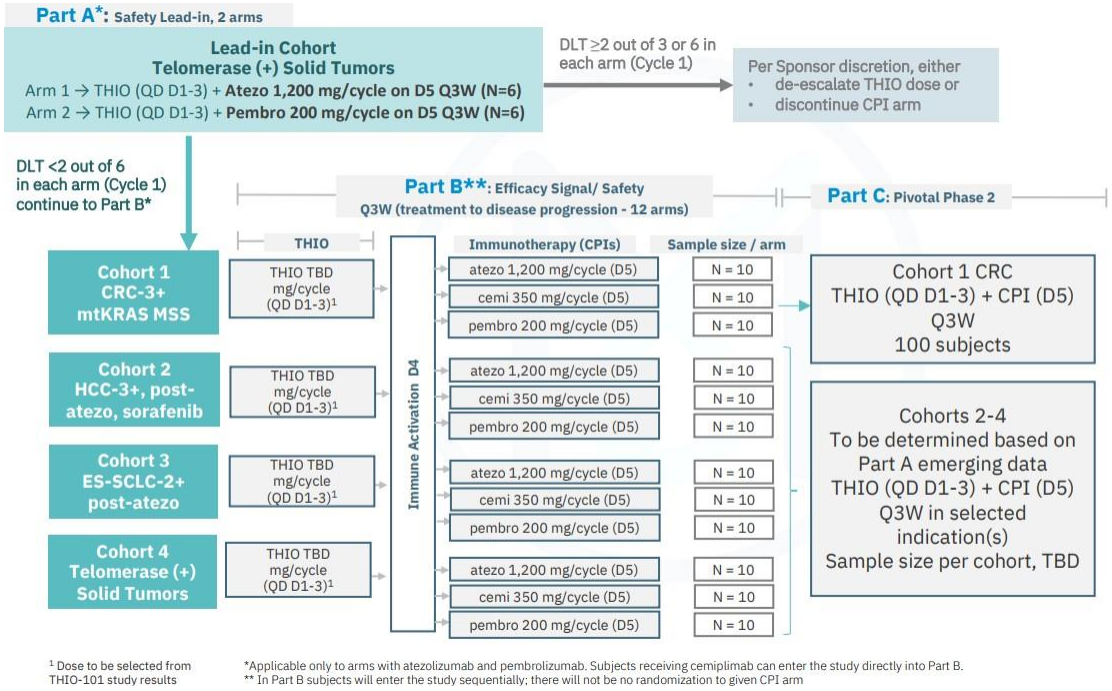

Exhibit 12: THIO-101 Phase 2 Preliminary Clinical Trial Design Source: Company Presentation

Second-Generation Telomere Targeting Agents

MAIA started a program for the early-stage research and discovery, which aims to discover new compounds with the capability to act via a similar mechanism of activity as THIO. This involves targeting and modifying the telomeric structures of the cancer cells through telomerase activity intrinsic to the cancer cells. The program is aimed to identify potential pharmacological agents with a higher degree of specificity to cancer cells in comparison to normal cells and with the potential for increased antitumor activity. This will strengthen the MAIA product pipeline and patent portfolio. The second-generation pipeline of telomere-targeting agents encompasses five compounds that have been successfully evaluated in *in vitro* inhibitory testing in five cancer models in vitro.

MAIA started a program for early-stage research and discovery, which aims to determine new compounds with the capability to act via a similar mechanism of activity as THIO

	IC50, µM				
	Cell Lines				
Compound ID	**MC38**	**LLC**	**Hep55-1C**	**H2081**	**HEK293**
THIO(6-thio-dG)	1.5	1.6	5.0	0.92	-*
Compound #5	0.35	0.34	0.35	0.34	0.02
Compound #6	0.35	0.35	0.34	0.34	0.01
Compound #11	0.36	0.80	0.44	0.35	0.63
Compound #12	0.84	0.50	0.77	0.35	0.61

Exhibit 13: IC50 data of Second-generation Compounds in Comparison to THIO in Multiple Cell Line Models. Source: Company Filings

The *in vitro* studies showed significantly lower IC50 for the second-generation compounds when compared to THIO, indicating relatively higher potency of the evaluated compounds when compared to THIO. The positive data has allowed the company to progress the five second-generation compounds to *in vivo* testing, which is expected to be followed by pre-IND evaluation of two of those compounds with a goal of advancing at least one of them to clinical trials by the end of 2024.

THIO's primary target, non-small-cell lung cancer is the second leading cause of cancer death worldwide. The majority of the NSCLC cases diagnosed are in advanced stages which also leads to poor prognosis

Market Opportunity

Lung Cancer is the second most diagnosed form of malignancy across the globe and remains the leading cause of death due to cancer, accounting for 18% of global cancer deaths. Non-small cell lung cancer (NSCLC) represents approximately 84% of all lung cancer cases diagnosed. [12] Furthermore, In the United States, NSCLC carries a 5-year survival rate of 26%, while for small-cell lung cancer (SCLC), the 5-year survival rate is just 7%. An estimated 236,740 adults are estimated to be diagnosed with lung cancer in the United States in 2022.[13] A majority of NSCLC cases are diagnosed in later stages, which often results in poor treatment outcomes. Considerable progress has been made in the treatment of advanced NSCLC with the introduction of multiple immune checkpoint inhibitors (ICIs) as first-line therapy. Of the $23 billion NSCLC drug sales in 2021, ICIs sales accounted for $12 billion, which is estimated to reach $18.2 billion in sales by 2028.[14] Keytruda® (pembrolizumab) continues to maintain its dominance within the NSCLC setting, generating $7.5 billion in sales in 2021.

Drug	Company	Year of Approval	Sales
Keytruda® (pembrolizumab)	Merck & Co.	2015	$17.18
Opdivo® (nivolumab)	BMS	2015	$7.52
Tecentriq® (atezolizumab)	Genentech/ Roche	2016	$3.42
Imfinzi® (durvalumab)	AstraZeneca	2018	$2.41
Libtayo® (cemiplimab)	Regeneron	2021	$0.46

Exhibit 14: FDA-approved ICIs Approved for NSCLC and their Approval Year. Source: Diamond Equity Research Company Filings. *sales value in $bn and is for multiple FDA-approved cancer indications.

The company believes it can position THIO as an anti-cancer immunity priming treatment for multiple immune-activating agents used in the treatment of cancer

THIO in sequential combination with Libtayo® (cemiplimab) is being evaluated as a second-line treatment for NSCLC, which remains the primary pipeline indication. Even though Libtayo® was already approved for NSCLC patients with PD-L1 expression levels ≥50%, the company recently received another FDA approval for advanced NSCLC as a first-line treatment along with chemo irrespective of PD-L1 expression levels or cancer histology. Libtayo® is the second Immune checkpoint inhibitor after Keytruda® that has gained such approval. Both the drugs have similar clinical profiles, and given the recent FDA approval, we might see a much faster growth in sales for Libtayo®. This is likely beneficial for THIO as well, as it expands the eligible patient population for the Libtayo-chemo regimen.

[12] Cancer.org
[13] cancer.net/cancer-types/lung-cancer-non-small-cell/statistics
[14] Company Presentation, clinicaltrialsarena.com/

Libtayo® is the fifth FDA-approved immune checkpoint inhibitor (ICI) for NSCLC and has been fiercely competing with other approved ICIs with a peak sales forecast in the range of $1.5 - $2 billion. We believe that THIO, in sequential combination with Libtayo® has the potential to be more efficacious, strengthening the competitive positioning of Libtayo® and possibly contributing to much higher peak sales than currently being forecasted.

Market Opportunity Estimation	2020	2021	2022
Lung Cancer Prevalence	1,608,555	1,640,726	1,673,541
% Growth rate		*2.0%*	*2.0%*
% Of cases that are advanced	70.0%	70.0%	70.0%
% Of cases with NSCLC	85.0%	85.0%	85.0%
% Of NSCLC cases that are TERT+	78.0%	78.0%	78.0%
Total Number of Cases	**746,530**	**761,461**	**776,690**
% Patients Treated with SoC Regimen of ICIs	42.0%	42.0%	42.0%
Total Eligible Patients for THIO + Libtayo®	**313,543**	**319,814**	**326,210**
Estimated Annual Treatment Cost for THIO	$60,000.0	$60,000.0	$60,000.0
Market Opportunity in Dollar Terms (in $mm)	**$18,813**	**$19,189**	**$19,573**

Exhibit 15: Global Market Opportunity Estimation. Source: Diamond Equity Research

Our research indicates that approximately 320,000 global NSCLC patients targeted by the company are eligible to be treated with THIO and Libtayo® as a sequential combination treatment. We have assumed an annual treatment cost of $60,000. Based on our estimates and assumptions, we believe the total serviceable available global market opportunity for THIO as a second-line treatment is $20 billion. THIO, in combination with Libtayo®, has the potential to capture a large portion of the growing $20 billion market. Additionally, the company is also pursuing THIO for other multiple cancer indications and for NSCLC's earlier lines of treatment, vastly expanding its total addressable market. The broad therapeutic utilization of THIO adds valuable optionality for the drug to be pursued even for hard-to-treat brain cancers.

Competitive Overview

The company's competition involves numerous biotechnology and pharmaceutical companies that have developed or are developing therapies for the treatment of non-small cell lung cancer (NSCLC). Even though they do not have the same mechanism, these therapies might have the potential to compete and potentially capture the estimated eligible patients targeted by THIO. Exploration into the specific mechanisms of telomere maintenance in cancer has led to the development of drugs such as Imetelstat (GRN163L), BIBR1532, VE-822, and NVP-BEZ235 being investigated as therapeutic approaches for treating telomerase and alternative lengthening of telomeres (ALT) tumors.[7] GRN 163L and BIBR1532 are telomerase inhibitors, while VE-822 and NVP-BEZ235 are ATR (ataxia telangiectasia mutated and Rad3-related) inhibitors. All of the above-stated drugs share a similar mechanism of treating cancer, i.e., by targeting the telomere but using different pathways. Multiple studies and research papers (Mender et al., 2015, Sugarman et al., 2019) have concluded that telomerase inhibitors have a long lag period between the

treatment and its desired effect, which results in a longer treatment period and, thus, significant chances for increased toxicity.

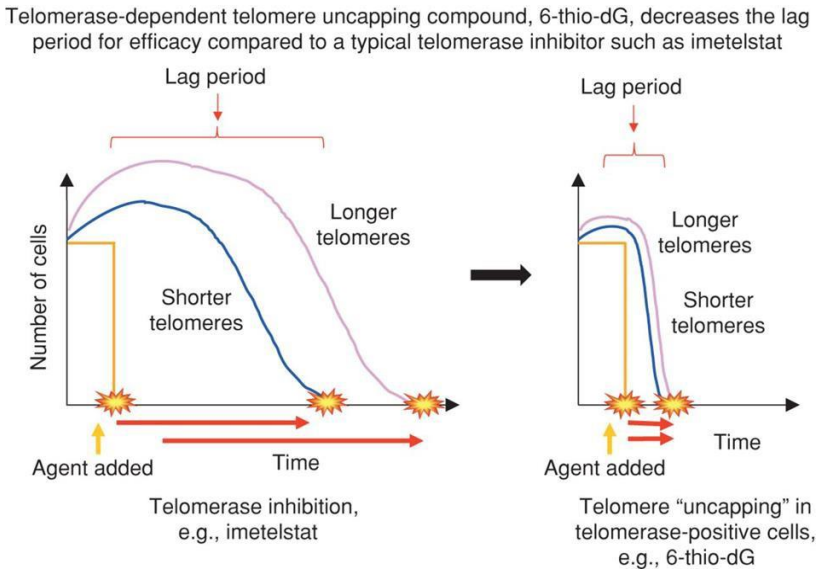

Exhibit 16: Treatment with 6-thio-dG vs. Telomerase Inhibition. Source: Mender et al., 2015

Imetelstat (GRN163L) is currently being clinically evaluated by Geron Corporation in multiple hematologic malignancies, which include Myelodysplastic Syndromes (MDS), Myelofibrosis (MF), Acute Myeloid Leukemia (AML) and Essential thrombocythemia (ET).

Management Overview

MAIA Biotechnology is led by an experienced team with deep expertise and extensive experience in biotech, life sciences, healthcare, and related fields. The management strives to develop first-in-class drugs with novel mechanisms of action intended to meaningfully improve and extend the lives of people with cancer.

Dr. Vlad Vitoc, MD, MBA - Chief Executive Officer

Dr. Vitoc is the Chairman of the Board and holds the position of Chief Executive Officer and President at MAIA Biotechnology. Dr. Vitoc has a broad array of experience across commercial strategic analysis and planning and medical affairs, of which he has 20 years of experience. Dr. Vitoc has managed and supported over 20 early, launch, and mature-stage compounds, which have included targeted therapies and immune therapies across more than 25 tumor types, including colorectal cancer, hepatocellular carcinoma, lung cancer, breast cancer, prostate cancer, and renal cell carcinoma. Dr. Vitoc received an M.D. from the Iuliu Hațieganu University of Medicine and Pharmacy, Romania, and his MBA from the University of South Carolina.

Dr. Sergei M. Gryaznov, Ph.D. - Chief Scientific Officer

Dr. Gryaznov holds the position of Chief Scientific Officer at MAIA Biotechnology. Dr. Gryaznov is an internationally recognized scientist and expert in the areas of modern drug discovery and development, oncology, telomerase, immune-regulatory therapeutics, small molecules, and nucleic acid-based therapeutic agents. Dr. Gryaznov is the co-inventor of a novel telomere-by-telomerase-targeting therapeutic approach to potential cancer treatment and is responsible for leading the research team that characterized THIO's telomere-targeting activity. Dr. Gryaznov obtained an M.S. with Honors in Organic Chemistry and a Ph.D. in Chemistry of Natural Products from M.V. Lomonosov Moscow State University. Dr. Gryaznov also completed a post-doctoral fellowship program in Chemistry at Northwestern University in Evanston, IL.

Joseph F. McGuire - Chief Financial Officer

Mr. Joseph McGuire holds the position of Chief Financial Officer at MAIA Biotechnology. He brings over 30 years of experience to MAIA, having served as Chief Financial Officer for several privately held and publicly traded companies in the healthcare, financial services, investment, and manufacturing industries. In these roles, his responsibilities included SEC financial reporting, investor relations, corporate governance, legal and audit liaison, and team building. Previously, Mr. McGuire was the Chief Financial Officer at Avadim Health, Inc. ("Avadim"), an advanced immune and neuromuscular care company. Mr. McGuire began his career with Price Waterhouse, where he was a certified public accountant, and later held management positions with Dean Witter Reynolds and Paine Webber, Inc. Joe received a Bachelor of Science in accounting from the University of Notre Dame.

Dr. Mihail Obrocea, MD - Chief Medical Officer

Dr. Obrocea holds the position of Chief Medical Officer at MAIA Biotechnology. Dr. Obrocea is a hematologist/oncologist with over 20 years of experience in drug development. He has deep domain expertise in developing cell therapy, cancer vaccines, monoclonal antibodies, and small molecules. Dr. Obrocea's research has been published in numerous oncology peer-reviewed literature; he has co-authored and published several books related to cancer vaccines and immunology; he holds several patents in the biotechnology field. Dr. Obrocea received an M.D. from the Carol Davila University of Medicine & Pharmacy in Bucharest, Romania and completed a residency in Internal Medicine at Yale University affiliated hospitals in Connecticut and a Hematology/Oncology fellowship at Norris Cotton Cancer Center at Dartmouth-Hitchcock Medical Center in New Hampshire

Financial Positioning

MAIA is a pre-revenue biotechnology company and is dependent on external sources of financing to support its research and operational activities. As of September 30, 2022, the company reported a cash balance of $14.06 million with zero-debt. The average operating cash burn contributed by research and development expenses and administrative expenses based on the past four quarters amounted to $2.69 million. The recent quarter (Q3 2022) operating cash burn was reported at $4.32 million. We have estimated an annual operating cash burn of $12.73 million and $20.08 million for 2022 and 2023. Based on our estimates and current cash balance, we believe the $14.06 million cash balance will be able to support the company's research and operating activities for 3-4 quarters. The company may have to raise capital by the end of 2023 either through equity issuance or through other means of financing.

Year-end 31 Dec. (in $mm)	2020A	2021A	2022E	2023E	2024E
INCOME STATEMENT					
Revenue	$0.00	$0.00	$0.00	$0.00	$0.00
Gross Profit	$0.00	$0.00	$0.00	$0.00	$0.00
EBITDA	($6.98)	($7.79)	($15.11)	($24.27)	($34.14)
Depreciation & Amortization	$0.00	$0.00	$0.00	$0.00	$0.00
EBIT	($6.98)	($7.74)	($14.65)	($24.27)	($34.14)
Interest Income/Expense	($0.03)	($0.83)	$0.01	$0.01	$0.03
Profit Before Tax (PBT)	($6.96)	($12.58)	($16.19)	($24.26)	($34.10)
Profit After Tax (PAT)	($6.64)	($12.50)	($16.19)	($24.26)	($34.10)
Basic Shares Outstanding	4.43	5.28	8.97	12.56	22.61
EPS - basic	($1.50)	($2.37)	($1.80)	($1.93)	($1.51)
EPS - diluted	($1.50)	($2.37)	($1.80)	($1.93)	($1.51)
BALANCE SHEET					
Cash and cash equivalents	$0.66	$10.57	$12.24	$32.15	$2.68
Other current assets	$0.08	$0.10	$0.69	$0.81	$0.93
Total current assets	$0.75	$10.67	$12.93	$32.96	$3.61
Non-current assets	$0.00	$0.65	$1.34	$1.46	$1.58
Total Assets	**$0.75**	**$11.33**	**$14.27**	**$34.42**	**$5.20**
Short-term borrowing	$0.04	$0.00	$0.00	$0.00	$0.00
Other current liabilities	$1.65	$2.15	$4.12	$5.29	$6.45
Total current liabilities	$1.69	$2.15	$4.12	$5.29	$6.45
Long-term borrowing	$0.43	$0.00	$0.00	$0.00	$0.00
Other non-current liabilities	$0.24	$0.00	$0.00	$0.00	$0.00
Total liabilities	$2.36	$2.15	$4.12	$5.29	$6.45
Total Equity	($1.62)	$9.18	$10.15	$29.13	($1.25)
Total Liabilities & Equity	**$0.75**	**$11.33**	**$14.27**	**$34.42**	**$5.20**

Exhibit 17: Income Statement Snapshot. Source: Diamond Equity Research

Valuation

We have valued the company using risk-adjusted DCF as our preferred methodology. Our valuation approach incorporates THIO's primary indication, non-small-cell lung cancer (NSCLC). We have forecasted THIO's sales for NSCLC starting 2025e as a second-line treatment and adjusting the forecast by accounting for a 25% probability of success. We have modelled to market the therapy as a first-line treatment as well, and have accounted for the delayed commercialization of THIO + Libtayo® for earlier lines of treatment. Based on robust and detailed results in multiple in vivo and in vitro trials and clinical experience based on historical human trials, we believe a 25% probability of success is an ideal assumption. We have estimated the sales for the US, EU5, and the Rest of the World (RoW) up until 2035 assuming the annual treatment cost of THIO at $60,000. Furthermore, the company is actively evaluating pathways with the potential to accelerate and/or expand the study of the sequential combination of THIO with ICIs in colorectal cancer (CRC) indication. We have incorporated TERT+ KRASmt advanced CRC as our secondary indication in our valuation model with a lower probability of success.

To value the company, we have discounted our risk-adjusted cash flow estimates by 15.0%, yielding a value of $123.24 million or $11.25 per share contingent on successful execution by the company.

Therapy	Targeted Disease	Probability of Success	Status	Commercialization Year
THIO + Libtayo®	**NSCLC**	**25%**	**Phase 2**	**2025e**
THIO + ICIs	**CRC**	**10%**	**-**	**2027e**

Calculated Equity Value ($mm)	
Enterprise Value	$118.12
- Debt and Preferred Stock	$0.00
+ Cash	$14.06
Net Debt	$14.06
Equity Value	$132.18

Approaches (in $ mm)	Value	Weight	Wtd. Value
DCF	$133.18	90%	$118.96
GPCM	$42.82	10%	$4.23
GTM	-	0%	$0.00
Wtd Avg. Equity Value (USD)			**$123.19**
No of Diluted Shares Outstanding			**10.95**
Intrinsic Value Per Share			**$11.25**

Company Name	Ticker	Price	Currency	Country	Mkt Cap.	P/B	P/R&D
Mirati Therapeutics	MRTX	76.75	USD	USA	3,260	3.90x	5.99x
Arcus Biosciences	RCUS	27.31	USD	USA	1,980	2.80x	7.68x
Iovance Biotherapeutics	IOVA	6.62	USD	USA	1,040	2.70x	3.59x
Zentalis Pharmaceuticals	ZNTL	22.20	USD	USA	1,270	3.00x	7.45x
Nuvalent, Inc.	NUVL	30.85	USD	USA	1,741	7.40x	32.20x
Geron Corporation	GERN	2.26	USD	USA	862	8.00x	9.42x
Gritstone bio, Inc.	GRTS	2.65	USD	USA	221	1.60x	1.70x
Spectrum Pharmaceuticals	SPPI	0.44	USD	USA	87	2.40x	1.69x
Median						**2.90x**	**6.72x**
Mean						**3.98x**	**8.72x**

Exhibit 18: Valuation Snapshot. Source: Diamond Equity Research
*Market Cap in $mm

Risks Profile

- **Clinical Development Risks:** The success of the company heavily relies on the success of the THIO clinical trial. They may face risks with the emergence of pandemics, epidemics, or outbreaks. It is also important to note that clinical trials are expensive, time-consuming, and difficult to plan and implement, all with the risk of an uncertain outcome. MAIA products are based on novel technologies, which make it difficult to predict the cost, timing, and results of product candidates. Other parts of the trial process, such as patient retention, are also complicated and could be disrupted by negative externalities.

- **Financial/Dilution Risks:** MAIA has a limited operating history, is not profitable yet, and might never achieve or sustain profitability. Even if THIO is successful, it will need further financing to develop new products. This runs the risk of dilution. There is also the risk of concentrating scarce resources on a product candidate that fails to yield returns and fails to capitalize on a profitable drug.

- **Regulatory Risks:** Any disruptions in the FDA or other authorities, domestic or foreign, could impact development and commercialization. FDA and other regulatory processes are lengthy, costly, uncertain, and time-consuming. Serious side effects or other adverse findings might emerge after final approval leading to discontinuation of the product, losing approval on all products, or if discovered after marketing approval, it could lead to the loss of marketing authorizations on their other product candidates. Besides regulatory approvals for product candidates, there are the regulatory requirements required for continued marketing.

- **Commercialization Risks:** MAIA has never commercialized a product, so it is difficult to determine the viability of a new product. The market opportunity for THIO might also be smaller than anticipated. The company faces major competition from other biotechnology and pharma companies. They may also face early generic drug competition for THIO or other products.

- **Counterparty Risks:** Counterparties such as employees and independent contractors such as clinical trial sites, principal investigators, contract research organizations (CROs), consultants, contract manufacturing organizations (CMOs), and other third parties could engage in malpractices, renege on the terms of their contract, etc. and lead to a major operational loss and hindrances to development. Furthermore, the number and nature of collaborations could harm potential partnerships, and any loss of relationships would significantly damage the business.

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