UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-41455

MAIA BIOTECHNOLOGY, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-1495913**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
444 West Lake Street, Suite 1700 Chicago, IL	**06060**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (312) 416-8592

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, $0.0001 par value per share	MAIA	NYSE American

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b) ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No☒

As of June 30, 2022, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $0. The registrant's shares of common stock commenced trading on NYSE American on July 28, 2022.

The number of shares of Registrant’s Common Stock outstanding as of March 22, 2023 was 10,996,404

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement for the annual stockholder meeting to be held in 2023 are incorporated by reference into Part III of this Annual Report on Form 10-K as noted herein. The registrant intends to file its proxy statement within 120 days after its fiscal year end.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, forward-looking statements may be identified by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "expect," "objective," "plan," "potential," "seek," "grow," "target," "if," and similar expressions intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, including risks described in the section titled “Risk Factors” set forth in Part I, Item 1A of this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission (the "SEC"). It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Annual Report on Form 10-K may not occur, and actual results may differ materially and adversely from those anticipated or implied in the forward-looking statements. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our financial performance;
- there is substantial doubt regarding our ability to continue as a going concern. We will need substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our drug candidates;
- the ability to receive FDA clearance for clinical trials;
- the ability to secure clinical sites, enroll patients, and initiate clinical trials;
- the ability of our clinical trials to demonstrate safety and efficacy of our drug candidates, and other positive results;
- the success, cost and timing of our development activities, preclinical studies and clinical trials;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- our plans relating to commercializing our drug candidates, if approved;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any drug candidates for which we obtain approval;
- our ability to attract and retain key scientific and clinical personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our reliance on third parties to conduct clinical trials of our drug candidates, and for the manufacture of our drug candidates for preclinical studies and clinical trials;
- our ability to establish our own manufacturing facilities domestically;
- our ability to expand our drug candidates into additional indications and patient populations;
- the success of competing therapies that are or may become available;
- the beneficial characteristics, safety and efficacy of our drug candidates;
- regulatory developments in the United States and other jurisdictions;
- our ability to obtain and maintain regulatory approval of our drug candidates, and any related restrictions, limitations and/or warnings in the label of any approved drug candidate;
- our plans relating to the further development and manufacturing of our drug candidates, including additional indications for which we may pursue;
- our plans and ability to obtain or protect intellectual property rights;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology; and
- potential claims relating to our intellectual property.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K. You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. 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 do not intend to update any of these forward-looking statements after the date of this Annual Report on Form 10-K or to conform these statements to actual results or revised expectations.

Because some of these risks and uncertainties cannot be predicted or quantified and may be beyond our control, you should read this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

This Annual Report on Form 10-K contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. We obtained the industry, market and similar data set forth in this report from our own internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe that the data we use from third parties are reliable, we have not separately verified these data. Further, while we believe our internal research is reliable, such research has not been verified by any third party. You are cautioned not to give undue weight to any such information, projections and estimates.

PART I

Item 1. Business.

Our Company

We were incorporated in Delaware in August 2018 as a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer. THIO, our lead asset, is an investigational dual mechanism of action drug candidate incorporating telomere targeting and immunogenicity. We completed our selection process for the clinical sites for our Phase 2 study in Australia and Europe and our application to start the Phase 2 study in Australia has been approved on March 1, 2022, by the Australian Regulatory Agency - Bellberry Human Research Ethics Committee. In July 2022, the first patient was administered with THIO in our Phase 2 human trial (THIO-101) in Australia. In December 2022, regulatory authorities in three European countries, Hungary, Poland, and Bulgaria, approved the implementation of THIO-101, Phase 2 clinical trial evaluating THIO in patients with NSCLC. Patients with advanced Non-Small Cell Lung Cancer (NSCLC) will be treated first with THIO followed a few days later by the immune checkpoint inhibitor Libtayo® (cemiplimab) manufactured and commercialized by Regeneron. Cemiplimab is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 on T-cells. Cemiplimab has been approved in the United States and the rest of the world for multiple cancer indications, including NSCLC. In February 2021, we signed a clinical supply agreement with Regeneron to receive cemiplimab at no cost, which represents a significant cost-savings for the study. In return, we have granted Regeneron exclusive development rights in combination with PD-1 inhibitors for NSCLC for the study period. Based on the clinical data we aim to generate by the THIO-101 trial, in late 2024 we plan to seek an accelerated approval of THIO in the United States for the treatment of patients with advanced NSCLC. Even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA. In addition, in the Fourth Quarter of 2023, we plan to initiate a Phase 2 clinical trial in multiple solid tumor indications of THIO administered in sequence with Anti-PD-1 or Anti-PD-L1.

We completed an initial public offering on August 1, 2022 and our shares of common stock commenced trading on NYSE American under the ticker symbol "MAIA" on July 28, 2022. We sold 2,000,000 shares of common stock at $5 per share for gross proceeds of $10,000,000 in the initial public offering. On August 3, 2022, we sold an additional 300,000 shares of common stock at $5 per share for gross proceeds of $1,500,000 upon the full exercise of the underwriter's overallotment option. After deducting $2,406,170 for cash issuance costs, net proceeds from the initial public offering, including the overallotment, were $9,093,830.

Our Lead Product Candidate

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a telomere-targeting agent currently in clinical development to evaluate its activity in NSCLC. Telomeres, along with the enzyme telomerase, play a fundamental role in the survival of cancer cells and their resistance to current therapies. THIO is being 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.

In 2019, our research team discovered that THIO produced telomere modifications and disruption, which ultimately induced cancer-specific innate and adaptive immune responses against immunologically "cold" tumors or tumor types that were unresponsive to immune checkpoint inhibitors. This hypothesis was tested and demonstrated in syngeneic and humanized mouse models. THIO administered to mice in low doses and followed by an immune-checkpoint inhibiting agent, such as an anti-PD-1 or anti-PD-L1 compound, induced complete tumor regression with no tumor recurrence during the 14 weeks of observation. Further, no toxicities were reported in the tumor-free mice. These new findings were published in the highly reputable, peer-reviewed research scientific journal, Cancer Cell in July 2020. Based on these recent discoveries, a new therapeutic approach has been designed to advance THIO into a Phase 2 clinical trial (THIO-101) in patients with advanced NSCLC.

Our regulatory strategy includes a planned filing of an Investigational New Drug application (IND) with the U.S. FDA in the near future. This would allow U.S. sites to participate in the THIO-101 NSCLC trial. The human safety data generated in Australia and Europe would constitute the basis of the IND application. Although we plan to rely solely on the safety and efficacy data we generate in our own clinical trials in support of our planned NDA filing, we take added confidence in the potential tolerability of THIO in light of the fact that the THIO doses we plan to test represent a range of 4 to 40 times lower than the maximum tolerated dose tested in the earlier clinical trials sponsored by the National Cancer Institute in the 1970s. The planned THIO-101 phase 2 trial is intended to be a proof-of-concept study that may be modified depending on interim results to include both primary and secondary endpoints and be consistent with previously approved cancer treatments. In September 2022, we submitted a pre-IND meeting request to FDA to discuss, among other elements, the existing non-clinical and clinical data to support the conduct of our planned THIO-101 phase 2 trial under an IND to include patients from the United States. MAIA received feedback in-line with the proposed plans from the FDA regarding its manufacturing, preclinical and clinical development plan. MAIA also obtained guidance from the FDA on the assessment of its safety and efficacy in the THIO-101 Phase 2 trial that will be incorporated in the U.S. IND application. MAIA plans to file its U.S. IND in the first half of 2023 and commence enrolling patients in the U.S. in the second half of 2023. Based on the clinical data we aim to generate in the THIO-101 study and assuming THIO achieves its intended clinical effect with a manageable

safety profile at one of the doses tested in the study, we expect to seek early FDA guidance and agreement for using this clinical trial as basis for requesting an accelerated approval. The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval.

MAIA Biotechnology will still be required to conduct studies to confirm the anticipated clinical benefit. These studies are known as confirmatory trials. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market. The FDA's accelerated approval pathway, even if initially granted, does not guarantee an accelerated review or marketing approval by the FDA. The THIO-101 study protocol may need to be amended to increase the number of patients enrolled, undergo modification of the statistical analysis or change in the trial design and/or primary endpoints.

Our Science--Driven Telomere Targeting Approach

Telomeres are regions of repetitive DNA nucleotide sequences that are associated with specialized proteins at the ends of linear chromosomes in cells. THIO's mechanism of action comprises telomere targeting and induction of anti-cancer immunogenicity. The enzyme telomerase recognizes THIO's metabolite formed *in situ* and incorporates it into the structure of the cancer cell's telomeres, creating a faulty structure, which breaks apart the telomere spatial structure. As a result, the THIO-modified telomeric structure unwinds, recognized as DNA damage, and the cancer cells die. We believe THIO transforms "cold" tumors into "hot" tumors rendering them responsive to immunotherapy (checkpoint inhibitors) and this process takes place promptly within 24 to 72 hours. We also believe we can improve the immunotherapy efficacy and we can restore the immunotherapy efficacy in patients who have progressed or developed resistance to prior immunotherapy.

Telomere maintenance is a fundamental biologic process for cell proliferation and resilience in cancer cells, and thus represents one of the key therapeutic targets for cancer treatment. Telomerase is an enzyme that is present in a majority of human cancer cells (over 85% in the aggregate), across various tumor types. In contrast, its activity is detected in less than 1% of normal cells. THIO has only been shown to be active in cancer cells that are telomerase positive (TERT+) and actively dividing. Cancer cells are constantly telomerase positive due to an uncontrolled division process, while a relatively small number of normal cells are telomerase positive only transiently. Therefore, THIO activity is expected to be highly specific to cancer cells versus normal cells. Cancer-specific disturbance of telomeric structure, mediated by telomerase, is likely to lead to disruption in the cell cycle, followed by a very rapid and telomere-length independent cell death. THIO was observed in preliminary in vitro and in vivo studies to induce cancer-specific telomere disruption, by using the enzyme telomerase which differentiates THIO from all other available cancer therapies currently in clinical use. We are also currently developing potential next-generation small molecule telomere modifying agents with the goal of identifying additional proprietary drug candidates, across multiple cancer types.

Our Second Generation Molecule Candidates

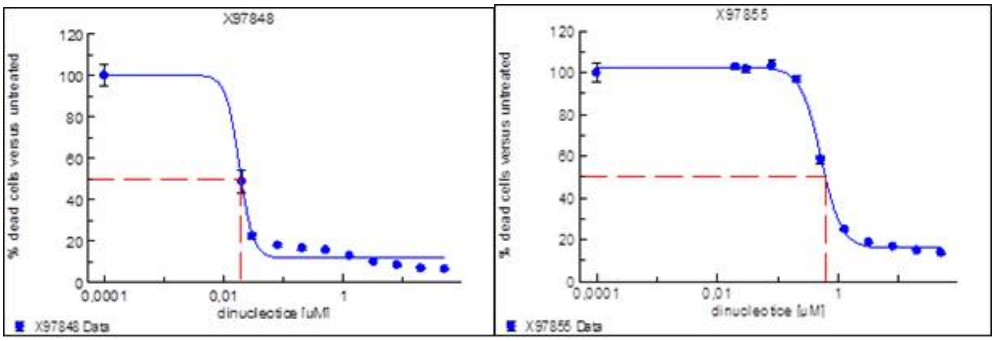
Our THIO program drives our development pipeline of second-generation telomere targeting agents. We have initiated an early-stage research and discovery program aimed at identifying new compounds capable of acting through similar mechanisms of activity as THIO, such as the targeting and modifying telomeric structures of cancer cells through cancer-cell intrinsic telomerase activity. The main objective for this program is to discover new compounds with potentially improved specificity towards cancer cells relative to normal cells and with increased anticancer activity. This program may also allow us to strengthen our patent portfolio. Our current 2nd-generation pipeline of potential telomere-targeting agents includes seven compounds that have successfully undergone *in vitro*inhibitory testing in five cancer models. The data from those studies showed a significantly lower 50% inhibitory concentration (IC50) for those compounds compared to THIO, as reflected in the following figure:

	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

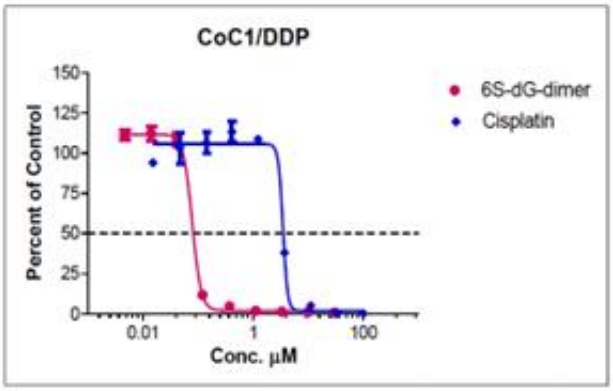
IC50 is the half maximal inhibitory concentration, and it is a measure of the potency of a substance in inhibiting a specific biological or biochemical function, such as cell proliferation. Cell lines: MC38, LLC, Hep55-1C, H2081,

and HEK293 are Non-Small Cell Lung Carcinoma, Colorectal, Hepatocellular carcinoma, Small Cell Lung Carcinoma, and Immortalized Human Kidney cell line, respectively. *- Data unavailable

The figures below represent dose-response curves from which IC50 values were derived for second generation compounds #5 (X97848), and #12 (X97855) in HEK293 cells:



The graph below demonstrates the dose response curves for our number five next generation compound, designated as 6S-dG-dimer, in ovarian cancer-derived cell line CoC1/DDP, in comparison with cisplatin (current standard of care in this setting). The corresponding IC50 values are shown next to the plot.



IC50 (µM)

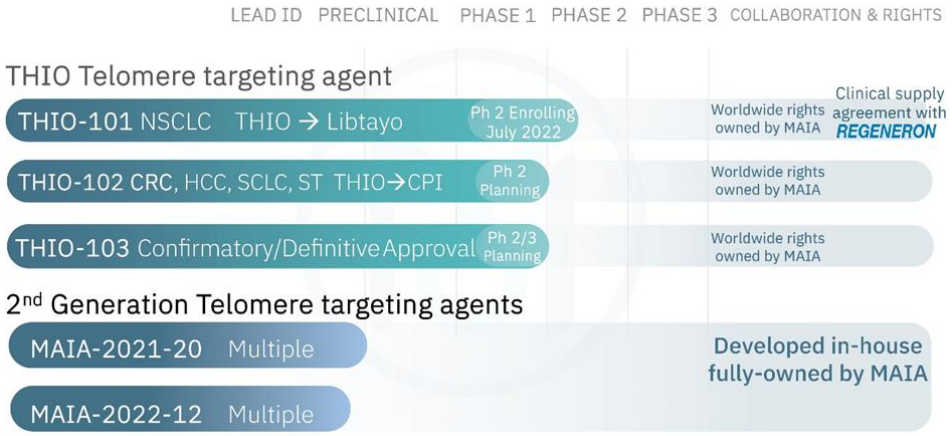
Compound	CoC1/DDP
6S-dG-dimer	0.08
Cisplatin	3.54

In mid-January 2023, MAIA nominated one lead new molecular entity candidate (designated as MAIA-2021-20) and one back-up new molecular entity candidate (MAIA-2022-12) for further advancement into preclinical GLP-toxicity and other studies, and may advance one of these candidates into human clinical trials upon completion of the required preclinical evaluations. MAIA also has filed a broad provisional patent application covering the composition of matter for the new telomere-targeting molecules in the fourth quarter of 2022.

Although the program is in early stages and we may not be able to identify suitable compounds, we believe we will be able to create a second generation of THIO-like compounds.

OUR PIPELINE

Our pipeline includes several potential targeted immuno-oncology candidates for relapsed and refractory cancers.



Pipeline products are under investigation and have not been proven to be safe or effective. There is no guarantee any product will be approved in the sought-after indication or will meet the developmental milestones set forth above.

Our Strategy

Our goal is to be the leader in the discovery, development and commercialization of cancer telomere targeting agents and other similar small molecules. Our initial focus is to efficiently advance our Phase 2 clinical program with THIO in sequential combination with cemiplimab. Ultimately, our goal would be to position THIO as a patient anticancer immunity priming treatment for all immune-activating agents used in the treatment of cancer. To date, THIO has never been tested in clinical trials in combination with any check-point inhibitor. The key elements of our strategy are to:

- Advance our existing clinical programs, including seeking accelerated approval for THIO in NSCLC as a tumor mass-reducing and simultaneously immune system priming agent administered in advance of the immune-activating agent, cemiplimab for treatment of advanced NSCLC, and ultimately, as a cancer treatment foundation in multiple indications and geographies. Even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA.
- Broaden the clinical development of THIO by exploring synergistic administration prior to other standard-of care immune-therapies including cell therapy.
- Develop a franchise of telomere-targeting cancer treatments.
- Leverage our regulatory strategy to acquire additional human data faster outside U.S. for other cancer indications.
- Selectively enter into strategic collaborations with pharmaceutical and biotechnology companies that have immune activating therapies.
- Expand our existing intellectual property portfolio.

We will face certain challenges in implementing our business strategy including, among others, the fact that earlier development of THIO was not commercially pursued. Even if THIO successfully advances through clinical studies and towards approval for use, we may face early competition from generic alternatives to THIO after expiration of any applicable regulatory exclusivities.

THIO Market Opportunity and Unmet Medical Need

Most cancer cells are telomerase positive (TERT+), including 73% to 100% of primary human cancers dependent upon tumor type, indicating a significant potential therapeutic utilization for THIO across most of the tumor types. We believe successful targeting of telomeres in TERT+ cancers may represent a significant potential for broad therapeutic utilization.

Tumor Type	TERT(+)	Tumor Type	TERT(+)
Non-Small Cell Lung Cancer (NSCLC)	78%	Pancreatic Cancer	95%
Colorectal (CRC)	82-89%	Small Cell Lung Cancer (SCLC)	100%
Hepatocellular Carcinoma (HCC)	79-86%	Ovarian Cancer	91%
Breast Cancer	88%	Renal Cell Carcinoma (RCC)	83%
Prostate Cancer	90%	Glioblastoma Multiforme (GBM)	75%
Bladder Cancer	92%	Neuroblastoma	94%
head & Neck Squamous Cell Carcinoma (HNSCC)	`86%	Lymphoma (high grade)	100%
Gastric Cancer	85%	Chronic Myeloid Leukemia (CML)	71%
Melanoma	83-86%	Chronic Lymphocytic Leukemia (CLL)	`57%
Cervical Cancer	100%	Acute Myeloid Leukemia (AML)	73%

Sources: A Survey of Telomerase Activity in Human Cancer – JW Shay, S Bacchetti – European Journal of Cancer, 33,5,787-791, 1997. Telomerase Active in Human Liver Tissues; H Tahara, et al; Cancer Research 55, 2734-2736 1995; Highly /aggressive Metastatic Melanoma Cell Unable to Maintain Telomere Length; N Viceconte et al; Cell Reports 2017; and Clinical Relevance of Telomerase Status and Telomerase Activity in Colorectal Cancer; T Femandez et al; PLOS one 2016

Our initial development program will focus on Non-Small Cell Lung Cancer (NSCLC), Colorectal Cancer (CRC), Hepatocellular Carcinoma (HCC) and Small Cell Lung Cancer (SCLC) in areas of clear unmet need and/or areas with deficient immunotherapy effect within each tumor type. Each tumor type and area of unmet or undermet needs represent significant clinical and commercial opportunity. We believe that THIO offers a desirable profile with significant commercial potential.

Tumor Type	Incidence 2020 (M)	Prevalence 2020 (M)	Mortality 2020 (M)	Annual Sales 2020 ($B)	Annual Sales 2028 ($B)
Non-Small Cell Lung Cancer	1.9	2.3	1.5	21.0	32.7
Breast	2.3	7.8	0.7	12.0	15.0
Prostate	1.4	5.0	0.4	8.5	12.8
Colorectal	1.9	5.2	0.9	8.0	10.7
Liver	0.9	1.0	0.8	1.0	5.0
Small Cell Lung Cancer	0.3	0.3	0.3	0.9	2.3

Sources: WHO; Global Data

The table below reflects the current market for check-point inhibitors because there is no current market for THIO-like molecules. The years in the indication columns on the table below signify the timing of FDA approval in the US for the clinical indications of interest. Because the key element of our strategy is to develop THIO to work in combination with check-point inhibitors, if THIO is eventually approved by the FDA for use in conjunction with check-point inhibitors, this table provides a high-level understanding of the potential market for THIO in that combination. There is no assurance, however, that any potential market for THIO would follow the current landscape for checkpoint inhibitor franchises.

Current Landscape of Checkpoint Inhibitor Franchises

Drug	Company	2021 Sales ($B)	Indications (tumor types)	NSCLC	SCLC	CRC	HCC
				Year of FDA Approval			

KEYTRUDA*(pembrolizumab)*	Merck	17.2	18	2015	2019	2017	2018
OPDIVO*(nivolumab)*	BMS / Ono	8.6	10	2015	2018	2017	2017
TECENTRIQ*(atezolizumab)*	Genentech / Roche	3.5	5	2016	2019		2020
IMFINZI*(durvalumab)*	AstraZeneca	2.5	2	2018	2020		
TYVYT*(sintilimab)*	Eli Lilly / Innovent	0.9	4				
LIBTAYO*(cemiplimab)*	Regeneron	0.5	3	2021			
BAVENCIO*(avelumab)*	Pfizer / Merck AG	0.4	3				
TBD *(tislelizumab)*	Novartis / BeiGene	0.3	2				
JEMPERLI *(dostarlimab)*	GSK	0.1	1				
TOTAL		33.9					

Source: BioMed Tracker 2022

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection wherever appropriate for our product candidates, formulations, processes, methods and any other proprietary technologies, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our practice is to actively seek to obtain, where appropriate, intellectual property protection for our current product candidates and any future product candidates, proprietary information, and proprietary technology through a combination of patents, protection of proprietary know-how and trade secrets, and contractual arrangements, both in the United States and abroad. However, full patent protection may not provide us with complete protection against competitors who may seek to circumvent our intellectual property. Our success will depend on the skills, knowledge, experience and know-how of our management research and development personnel, as well as that of our advisors, consultants, and other contractors. To help protect our proprietary know-how that is not patentable, we seek to put in place appropriate internal policies for the management of confidential information requiring all our employees, consultants, advisors, and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information, and which will require disclosure and assignment to us of the ideas, developments, discoveries, and inventions important to our business. See "*Risk Factors – Risks Related to our Intellectual Property*" for additional information.

We file for patents, both directly and in collaboration with our licensing partners, in the United States with counterparts in certain countries in Europe and certain key market countries in the rest of the world, thereby covering the major pharmaceutical markets.
On December 8, 2020, we entered into an amended and restated agreement (of our prior November 29, 2018 agreement) with The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center (collectively, UTSW). Pursuant to the amended and restated agreement, which we refer to as the UTSW1 Agreement, we obtained (1) an exclusive, worldwide license to develop and commercialize the following patent families, which are generally directed to methods of using THIO and are owned and/or controlled by UTSW:

Title / PCT Application Number
Telomerase Mediated Telomere Altering Compounds / PCT/US2014/33330 (WO2014/168947), issued in the US, MX, NZ and RU (all method of use) pending in BR, CA, CN, EP, HK and SG.
6-Thio-2'-Deoxyguanosine (6-Thio-dG) Results in Telomerase Dependent Telomere Dysfunction and Cell Death in Various Models of Therapy-Resistant Cancer Cells / PCT/US2017/34706 (WO2017/205756), pending in the US (method of use)
Use of 6-thio-dG to Treat Therapy-Resistant Telomerase positive Pediatric Brain Tumors / PCT/US2019/023596 (WO2019/183482), pending in the US (method of use)
Treatment of Drug Resistant Proliferative Diseases with Telomerase Mediated Telomere Altering Compounds / PCT/US2017/023858 (WO/2017/165675), pending in the US (method of use)

and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW1 Agreement includes an exclusive license to US patent no. 10,463,685 (expires April 8, 2034), and pending US patent application nos. 16/450,430 (having an earliest expiration of March 23, 2037, if a patent is granted), 16/304,538 (having an earliest expiration of May 26, 2037, if a patent is granted), and 16/982,979 (having an earliest expiration of March 22, 2039, if a patent is granted). All patents are method of use.

On December 23, 2020, we entered into a second agreement with UTSW, which set forth the agreement between the parties pursuant to the Company exercising its option rights in the UTSW1 Agreement and obtaining additional license rights. Pursuant this second

license with UTSW, which we refer to as the UTSW2 Agreement, we obtained (1) an exclusive, worldwide license to develop and commercialize the following UTSW patent family:

Title / PCT Application Number
Sequential Treatment of Cancers Using 6-Thio-dG and Checkpoint Inhibitors / PCT/US2021/022090, pending in the US and PCT (method of use)

and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW2 Agreement includes an exclusive license to pending US patent application no. 17/200,539 (having an earliest expiration of March 12, 2041, if a patent is granted). This patent is generally directed to methods of using THIO in combination with immune checkpoint inhibitors.

We continually assess and refine our intellectual property strategy as we develop new technologies and therapeutic candidates. As our business evolves, we may, among other activities, file additional patent applications in pursuit of our intellectual property acquisition and protection strategy, to adapt to competition or to seize potential opportunities.

Our Team

We have assembled an experienced management team with deep research, development, and commercialization experience in the areas of telomere-related science, immunotherapy, and across a vast array of oncology indications.

Key Team highlights:

- Our team is led by our Co-founder, Chief Executive Officer and President Vlad Vitoc. He is an M.D. and M.B.A. with over 22 years of experience in the Pharmaceuticals and Biotechnology industries. He has served on leadership teams in various oncology companies and business units and has a track record of success at Bayer Pharmaceuticals, Astellas Pharma Inc., Cephalon Inc. and Incyte Corporation, including development and commercialization of major oncology brands, organizational capability building, talent recruiting and development, and functional leadership.
- Our Chief Medical Officer and Head of Development, Mihail Obrocea, M.D., is a former practicing academic medical hematologist/oncologist and experienced pharmaceutical physician executive that brings over 20 years of successful cancer drug development track record from Juno Therapeutics Inc. (acquired by Celgene/BMS), Pharmacyclics Inc., AbbVie Bio Corp., Mannkind Corp., MedImmune, Inc. and Pfizer, Inc., among others. His experience includes clinical development of cell therapies (CAR-T), cancer vaccines, antibodies, and antibody drug conjugates (ADCs) and small molecules across a wide range of tumor types and clinical indications.
- Our Chief Scientific Officer, Sergei M. Gryaznov, is a Ph.D. who is an internationally recognized scientist and expert in the areas of modern drug discovery and development, oncology, telomerase, immune-regulatory therapeutics, nucleosides, nucleotides, DNA and RNA analogues, lipid and other conjugates, small molecules and nucleic acid based therapeutic agents. He is the co-inventor of a novel telomere-by-telomerase-targeting therapeutic approach to potential cancer treatment and responsible for leading the research team that characterized THIO's telomere targeting activity.
- Our Chief Financial Officer, Joseph F. McGuire has served as Chief Financial Officer for several privately held and publicly traded companies in the health care, 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. Most recently, Mr. McGuire was the chief financial officer at Avadim Health, Inc. ("Avadim"). 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.

We have engaged the following advisors, who are leading, internationally recognized experts in oncology, telomeres and telomerase research, to be a part of our Scientific Advisory Board ("SAB"), which provides independent non-binding scientific advice to our management team in the roles detailed below under each member's name:

1. Tom Gajewski, M.D., Ph.D. – Professor of Cancer Immunotherapy (University of Chicago)
    - One of the key pioneers in cancer immunotherapies and accomplished in the field
    - Key investigator on all phase 2 and phase 3 trials in Melanoma (with Keytruda®, Opdivo®, etc.)
    - Past president of the Society for Immunotherapy of Cancer (SITC)
    - Served on the program committees for the American Society for Clinical Oncology (ASCO) and the American Association for Cancer Research (AACR)
    - Serves as an editor for Cancer Research and Journal for Immunotherapy of Cancer

- On our SAB, will cover translational research for all cancers, for clinical development

2. Tudor Ciuleanu, M.D., Ph.D. – Professor of Oncology (University of Medicine and Pharmacy, Cluj-Napoca, Romania)

- Top Key Opinion Leader (KOL) in NSCLC and CRC in Europe
- Key investigator in more than 90 phase 3 and phase 2 clinical trials, including most immune therapy agents
- One of the best published clinical investigators (appears in most references in the National Comprehensive Cancer Network (NCCN) guidelines)
- President of Romanian Federation of Cancer Societies
- Editor for the Journal of Clinical Oncology (JCO), Romanian edition
- On our SAB, will lead clinical activities in Europe across tumor types – NSCLC, CRC, Gastric, HCC, Head and Neck, Urological cancers, and Lymphomas

3. Jerry Shay, Ph.D. – Professor and Vice Chairman of the Department of Cell Biology (University of Texas Southwestern)

- One of the world leaders in the study of telomeres and telomerase
- Scientific co-founder of the research supporting our lead program THIO and an integral advisor to the program
- Highly influential biomedical researcher with over 30 issued patents and more than 500 peer reviewed publications
- Southland Financial Corporation Distinguished Chair in Geriatric Research and a Distinguish Professor at University of Texas Southwestern, having received the University of Texas Regent's Outstanding Teaching Award and the Minnie Steven Piper Foundation Professor Award
- Awarded the Eunice Kennedy Shriver NIH Alliance Pioneer Award in 2017
- On our SAB, Dr. Shay will provide scientific leadership as the THIO co-inventor and a worldwide recognized expert in the science of telomeres and telomerase in cancer. Dr. Shay serves as the Chairman of the SAB.

4. David Ashley, M.D., Ph.D. – Professor of Neuro-Oncology (Duke University)

- Top KOL in pediatric and adult neuro-oncology
- Expert in translational research and clinical development
- Expert in immuno-oncology, having developed and clinically tested dendritic cell vaccines and other immuno-therapeutics
- Principal investigator of a number of important national and international studies, both clinical and pre-clinical
- Former Director of two major cancer centers, The Royal Children's Hospital Melbourne and Andrew Love Cancer Centre – Barwon Health
- On our SAB, will assist in translational research in Brain Cancers for clinical development

5. Gunnur Dikmen, M.D., Ph.D. – Professor at Hacettepe University Medical Faculty, Department of Medical Biochemistry, as well as the director of the Hacettepe University hospital's emergency laboratory.

- Broad range of experimental and clinical experience in molecular & cell biology and clinical biochemistry, translating research results from bench to bedside and from academia to clinical laboratory to mentor the next generation of multidisciplinary research projects by providing new therapeutic approaches for cancer and telomere related diseases.
- Expert in the biology of telomeres and telomerase in the treatment of cancer.
- Under her capacity as Secretary-General of the Turkish Biochemical Society, organized various important national and international courses and congresses.
- On our SAB, will assist in preclinical and translational research, across tumor types.

6. Adam Yopp, M.D. –Associate Professor and Division Chief of Surgical Oncology and Colorectal Surgery, at Harold C. Simmons NCI-designated Comprehensive Cancer Center at UT Southwestern Medical Center in Dallas.

   - Completed a fellowship in surgical oncology at Memorial Sloan-Kettering Cancer Center focusing on upper GI and hepatopancreatobiliary malignancy and joined UT Southwestern in 2009.
   - Director of the Liver Tumor Program at UTSW and both his research and clinical interests are focused on the delivery of care in patients with primary liver cancer.
   - Much-recognized key opinion leader in liver cancer.
   - On our SAB, will assist with developing THIO for the treatment of liver cancer.

Our SAB is primarily compensated by way of the grant of stock options as determined by the Company as appropriate in recognition of the specific services or areas of expertise of each member.

We are also supported by a seasoned board of directors, whose members have significant entrepreneurial skills in company building and corporate financing as well as decades of collective leadership and board experience.

Our Programs

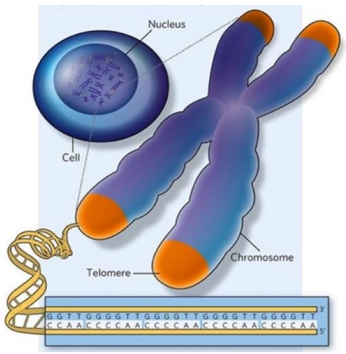
Telomere Targeting Program

Targeting Telomeres via Telomerase Leads to Cancer Cell Death

Telomeres are regions of repetitive nucleotide sequences that are associated with specialized proteins at the ends of linear chromosomes, that represent a critical key therapeutic target for cancer. Telomeres are often depicted in imagery like the end of a shoelace.

- Maintenance of telomeres is essential for unlimited cellular proliferation and confers immortality in cancer cells. Telomeres in human cells consist of double-stranded and single-stranded repeats of the sequence TTAGGG, which terminate in a single-stranded 3´- extension overhang of the G-rich strand. Their major function is to cap and protect the ends of chromosomes and thus to provide genetic stability. This capping function is mediated by a special architecture in which the 3´-overhang participates with telomere-binding proteins in a large loop structure called T-loop. The image on the right reflects the general location of telomeres as the end-cap of the chromosomes, which are located in the nucleus of the cell.

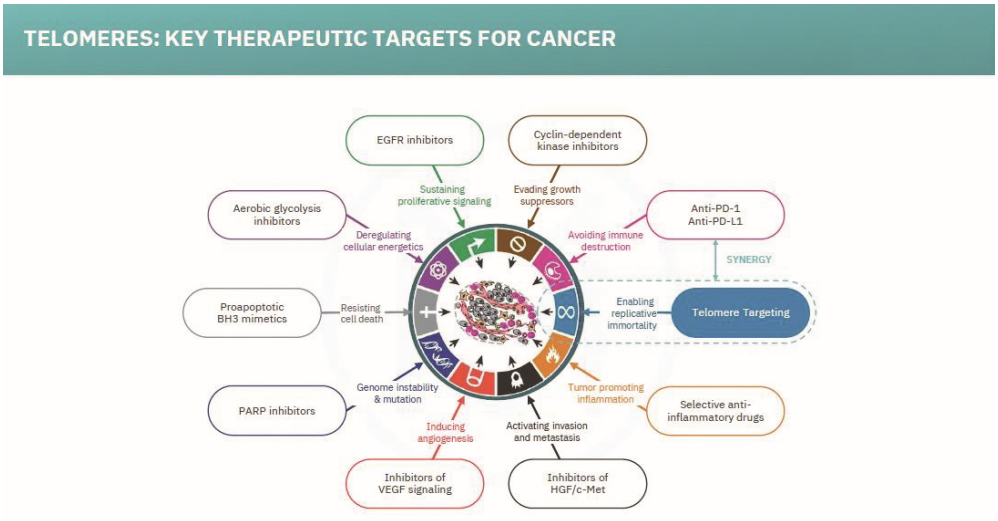
Adapted from *Transcendental Meditation and lifestyle modification increase telomerase*, December 6, 2015.



The most successful anti-cancer drugs in the market today typically interfere with only one of the specific capabilities or “hallmarks” cancer cells use for tumor growth and progression. In contrast, our lead drug candidate, THIO, targets two major hallmark pathways:

- Targeting cancer cell *telomeric* DNA structure and functional integrity; and
- Activating the immune system that turns immunologically “cold” tumors into “hot” tumors that are responsive to therapy. THIO synergizes with immune activating agents, like checkpoint inhibitors, for the potential to attack and destroy tumors.

The chart below reflects the many different methods by which successful anti-cancer drugs might prevent tumor growth and where THIO stands in relation to the other approaches.



Adapted from Cell 2011, Volume 144, Issue 5, Pages 646-674 (DOI:10.1016/j.cell.2011.02.013)

Role of the Enzyme Telomerase

Telomerase is a ribonucleoprotein enzyme (reverse transcriptase) that synthesizes telomere repeats from the beginning, or *de novo*. In human cells, the telomerase holoenzyme consists of a high-molecular-weight complex with a template region-containing RNA subunit, hTR, and a protein component, the catalytic subunit human telomerase reverse transcriptase (hTERT). In most normal somatic cells, telomerase activity is absent and telomere repeats are lost with cell division and with aging. Telomerase is especially important in fetal tissues, reproductive cells and other tissues where extensive cell proliferation is necessary. However, most adult normal tissues are telomerase silent. Telomere attrition, beyond a certain threshold, results in the uncapping of chromosome ends, which subsequently induces DNA damage and onset of replicative senescence. In contrast, about 73% to 100% of all cancer cells in most tumor types have detectable telomerase activity, which leads to the stabilization of telomeres and allows for unlimited growth potential along with disease progression. Successful targeting of telomerase positive (TERT+) cancers represents a significant potential for therapeutic utilization in almost all tumor types.

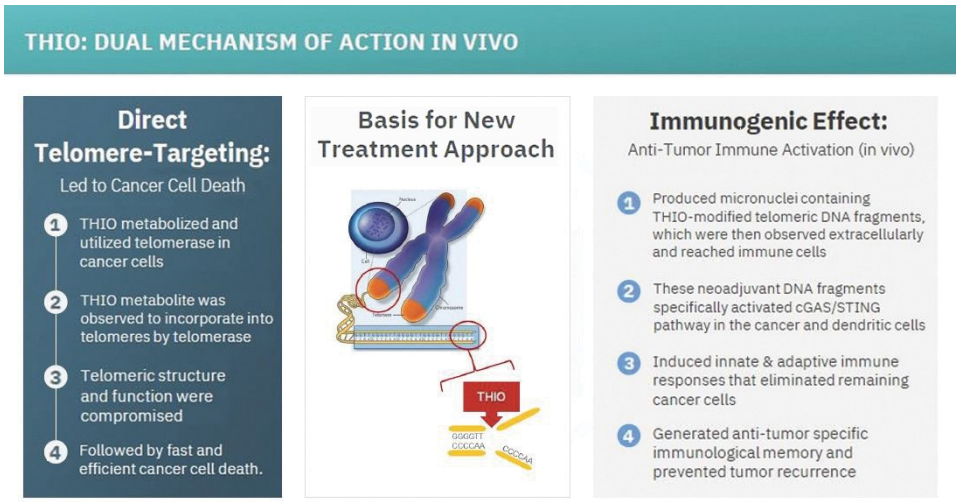
Since most cancer cells are reliant on telomerase for their survival, and telomerase is undetectable or only transiently present at low levels in normal cells, telomeres of cancer cells and telomerase are attractive targets for the development of new cancer therapeutics. “Proof of Principle” for validation of telomere structural integrity-targeting as a therapeutic concept was demonstrated *in vitro* in human tumor cells using dominant negative mutant forms of hTERT. In these experiments, telomerase activity was abolished, which was associated with continuous telomere shortening, subsequently leading to the cancer cells death. Research has also indicated that cancer cell specific anti-telomeres and anti-telomerase therapies may have fewer side effects than more traditional treatments, such as chemotherapy or radiotherapy. This has made anti-cancer therapies based on telomerase inhibition an area of interest in medicine. However, attempts to directly target telomerase in clinical trials have not yet produced an approved drug, as these efforts have encountered material limitations primarily due to increased toxicities that may result from the long lag period between initiation of anti-telomerase treatment and its therapeutic effects.

Differentiated Activity of THIO, a Telomere-Targeting Agent

THIO (6-thio-2’-deoxyguanosine or 6-thio-dG) is a small molecule telomere targeting agent that uses the enzyme telomerase for DNA integration predominantly in the telomeric structure. Based on pre-clinical studies, THIO’s telomere targeting activity is believed to be primarily cancer-specific in tumor cells with active telomerase, but not in normal cells. Based on our extensive review of publicly-available information, to our knowledge THIO’s direct telomere targeting action utilizing telomerase is different from other commercially available cancer therapies and those currently in publicly disclosed clinical trials. Telomeres, along with the enzyme

telomerase, play a fundamental role in the survival of cancer cells and their resistance to current therapies. The statements above are not intended to give any indication that THIO has been proven effective or that it will receive regulatory approval.

In non-clinical studies, published initially in 2014 along with subsequent studies, THIO was found to be converted, in cells, into the substrate recognized by telomerase, and then incorporated into telomeres of the cancer cells. Once incorporated, THIO compromised the cancer cell's telomere structure and function, leading to "uncapping" of the telomeres, induction of DNA damage responses, and rapid cancer cell death. These profound structural modifications of cancer cell telomeres were irreparable. In both *in vitro* and *in vivo* studies, THIO showed a very prompt effect, causing telomere uncapping and leading to cancer cell death*, independent* of the initial tumor telomere length.



The above graphic represents an established method of action from previously conducted research in rodents that forms the scientific rationale for further clinical studies, but has not yet been tested in humans.

In 2019, further non-clinical research in syngeneic and humanized mouse models of telomerase-expressing cancers uncovered previously unknown telomere targeting activity of THIO specifically resulting from its breakdown of cancer cells. The THIO-containing DNA fragments, resulting from THIO telomere disruption, are packed into micronuclei and are released from the treated cancer cell into the blood stream, which enhances immune responses. An immune response was observed, attributed to stimulation of the cGAS/STING pathways in the host APCs (Dendritic Cells, pDCs), as well as activation of NK cells and CD 8+ and CD 4+ lymphocytes *in vivo*. At the same time as the T-cells activation, THIO treatment reduced levels of myeloid-derived suppressor cells (MDSCs) in the tumor micro-environment (TME), which is considered important for an anticancer immune response. While THIO activated CD8+ T cells, it also increased the total number of CD8+ T cells and upregulated PD-1 expression in the CD8+ T cells on per cell basis in the mouse model. This research demonstrated how the THIO-produced telomere stress may have the potential to increase innate sensing and adaptive anti-tumor immunity. In short, this immune system stimulation and TME remodeling proceeded in a specific antigen-dependent manner and induced adaptive immune responses that eradicated remaining cancer cells *in vivo*.

The above noted recent studies in a humanized mouse model also supported the hypothesis that sequential administration of THIO followed by an anti-PD-L1type of checkpoint inhibitor may overcome resistance to checkpoint blockade in advanced cancer models, suggesting that the combination therapy could benefit PD-L1-resistant patients.

Administration of low doses of THIO, aimed to activate the immune system via THIO-induced telomeric DNA modification, followed by checkpoint inhibitor therapy (anti-PD-L1 or anti-PD1), eliminated advanced tumors in preclinical models with confirmation of cancer cell type specific immune memory. This potential for THIO to induce immune memory, if confirmed in human clinical trials, would be a distinct feature of THIO's mechanism of action, offering the possibility that the immune system may continue to be active against the cancer cells over extended periods of time, potentially reducing the need for additional treatment.

These pre-clinical results provided the basis for our new clinical therapeutic strategy for sequentially administering THIO as a telomere-targeted agent first, to activate the immune system against the specific cancer, followed by immunotherapy or other immune-activating therapy.

Limitations of Other Therapeutic Approaches

In contrast to THIO, which targets telomeres, a challenge for the potential clinical application of pharmaceutically useful telomerase inhibitors (e.g., Imetelstat), is the therapeutic window (the range of dosage of a drug or of its concentration in a bodily system that provides safe effective therapy) and the often-observed delay between initiation of treatment and phenotypic response (called the "lag period"). Since the antiproliferative effect of any direct telomerase inhibitor is dependent on the telomere length of any given tumor cell, clinical response will be delayed until the telomeres become critically short, and thus can no longer protect the chromosomes, and as a result, the cancer cell dies. This requires a significant number of cell divisions to become apparent, and treatment may have to be given continuously for weeks to months, potentially in conjunction with other treatment modalities, to achieve an appropriate level of efficacy.

THIO: A Telomere Targeting Agent

Background

THIO (6-thio-2'-deoxyguanosine) is a synthetically-modified small molecule nucleoside that was originally designed to be an improved chemotherapy drug developed to work around purine analog resistance, which was standard-of-care therapy in the 1970s. Sponsored by the National Cancer Institute, THIO was extensively investigated in at least 19 clinical trials with over 600 cancer patient subjects (adult and pediatric) treated, both as monotherapy or in combination with other commonly used standard agents of the time. See "THIO Clinical Trials" below for more information about these trials. A traditional treatment strategy was used where patients were treated to maximum tolerated dose (MTD), a common approach for cancer therapy drug development. Although study results were promising, development was abandoned in favor of other therapies.

The previous human experience presents significant limitations as it dates to the 1970s and early 1980s when the implementation of ICH Good Clinical Practices was not yet in effect. The published studies did not disclose certain data points in line with the current ICH Good Clinical Practices, such as efficacy endpoints and serious adverse events, whether those endpoints were reached, whether the data was found to be statistically significant and serious adverse events. Further, we do not know whether those prior studies were powered for statistical significance in the way our planned studies will be powered, based generally on the results of these prior human studies, we believe that THIO has a well-established safety profile, which we intend to independently demonstrate through our own clinical studies. Moreover, all prior studies were conducted primarily in heavily pre-treated, refractory patients.

Further detailed analysis of the body of prior THIO research indicates researchers were not aware of three key factors, which if they had been known at the time, may have impacted the decision to cease development. These factors have only been discovered since 2014 (with the most recent in 2019), as illustrated in the following graphic:

1. THIO's detailed telomere targeting mechanism and resulting immune activation.
2. At high drug exposure (MTD), THIO can be immunosuppressive.
3. Proper administration of THIO to activate the immune system followed by immunotherapy to achieve best response.

Telomeres are vital DNA-structures discovered by Jack Szostak's laboratory, for which he received the Nobel Prize in 2009, which are present at the ends of each chromosome which protect the genome from degradation, unnecessary recombination, repair, and interchromosomal fusion. Telomeres, along with the enzyme telomerase, are both crucial for the survival of cancer cells. Telomerase was discovered by Elizabeth Blackburn and Carol Greider, who shared the Nobel Prize with Jack Szostak in 2009.

THIO is believed to selectively target telomerase positive (TERT+) cancer cells, where the enzyme is activated, versus normal cells. 73% to 100% of primary human cancers are TERT+ dependent upon tumor type, indicating a significant potential therapeutic utilization for THIO in almost all tumor types. THIO's cancer-specific disturbance of telomeric structure by telomerase leads to disruption in the cell cycle, followed by rapid cell death. Based on extensive review of publicly-available information, THIO's direct telomere targeting action utilizing telomerase is different from other commercially available cancer therapies and those currently in publicly disclosed clinical trials.

In 2019, the MAIA research team showed that in mouse models THIO-produced telomere modification and disruption induced cancer-specific innate and adaptive immune response against immunologically "cold" or unresponsive tumor types. When THIO was administered at low doses, in syngeneic and humanized mouse models of telomerase-expressing cancers, followed by a break to allow for the activation of the immune system against the specific cancer, then followed by a standard-of-care immunotherapy agent like a check point inhibitor (CPI), either PD-1 or PD-L1, complete tumor regression was observed, with no observed toxicities. These effects have been replicated in multiple preclinical models, utilizing all leading checkpoint inhibitors or radiation therapy.

Based on these studies, we hypothesized that THIO, administered in advance of immune-activating therapies (e.g., checkpoint inhibitors, radiation therapy, etc.), at dose levels significantly lower than the levels evaluated in previous clinical trials, will "*prime"*

the tumor environment and initiate an overall anti-tumor immune response. This represents an entirely new therapeutic approach for THIO and forms the basis for the new clinical strategy for planned future trials.

THIO Preclinical Development

The following summarizes the relevant preclinical studies. Extensive preclinical studies have been performed to validate THIO's primary mechanism of action: targeting telomeres directly and causing cancer cell death via telomerase-mediated DNA damage.

To our knowledge, THIO alone has shown significant telomere targeting activity in numerous non-small cell lung cancer (NSCLC) and multiple other cancer-based cell lines *in vitro* and *in vivo*, including but not limited to small cell lung cancer (SCLC), melanoma, colorectal cancer (CRC), glioblastoma multiforme (GBM), diffuse intrinsic pontine glioma (DIPG), neuroblastoma, pancreatic, hepatocellular carcinoma (HCC), as well as head and neck cancer, breast cancer and prostate cancer.

In vitro: in summary, EC_{50} values (the concentrations at which half of the total number of cancer cells are dead) were approximately 0.4 μM to 1.5 μM. THIO was not cytotoxic in normal, untransformed telomerase-negative cells at concentrations up to 100 μM.

In vivo: in summary, the doses that resulted in cancer cell death were in the range of 2.5 - 5.0 mg/kg, depending on the tumor type and the schedule of the drug administration ranging from 1 to 3 days per cycle.

In March 2022, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) to THIO for the treatment of hepatocellular carcinoma, and in May 2022, the FDA granted ODD to THIO for the treatment of small cell lung cancer. The FDA's Office of Orphan Products Development may grant orphan designation status to drugs and biologics that are intended for the treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain benefits, including financial incentives, to support clinical development and the potential for up to seven years of market exclusivity for the drug for the designated orphan indication in the U.S. if the drug is ultimately approved for its designated indication.

THIO in Sequential Administration in Advance of Checkpoint Inhibitors (CPIs) Therapy

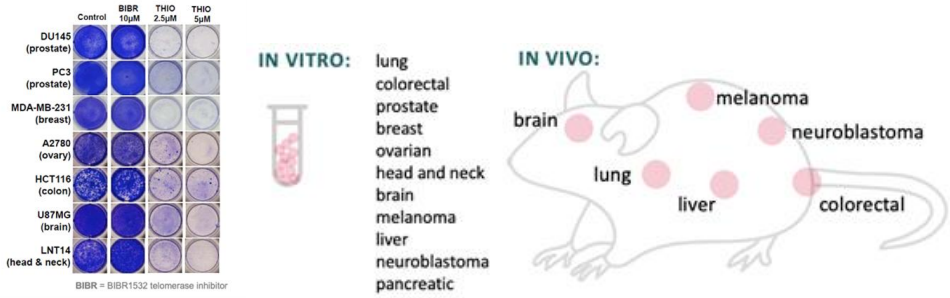
In vivo, THIO, at 3 mg/kg/dose, (which corresponds to a 20 mg/patient/day low-dose), administered followed by a one-day break, followed by an immune checkpoint inhibitor (either anti-programmed cell death protein 1 (PD-1) or anti-programmed death ligand 1 (PD-L1) products), resulted in complete tumor regression in NSCLC and CRC syngeneic mouse tumor models.

At this low dose, THIO was able to transform immunologically "cold' tumors, (tumors that do not respond to the CPI treatment), into immunologically "hot" tumors, which then responded well to the following sequential treatment with a CPI. These potent anti-tumor phenotypic effects were also accompanied by the efficient induction of the tumor-specific CD8+ cells, as well as CD4+, and natural killer (NK)-cells (Mender, 2020b).

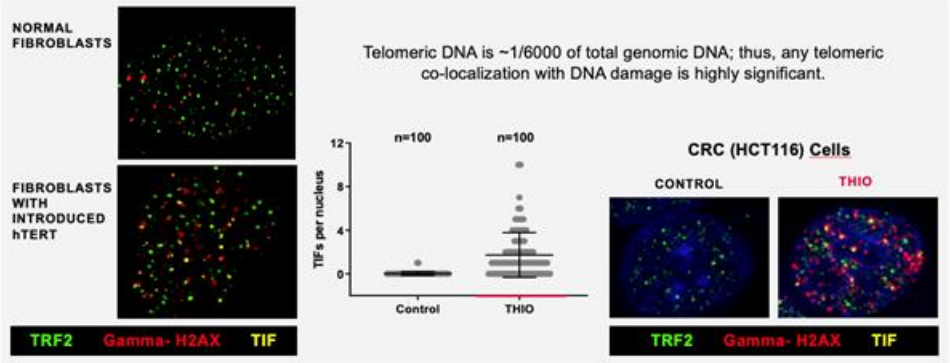
These responses were achieved through telomerase-dependent and cancer cell specific activation of a) DNA damage responses, and b) cGAS/STING pathways by THIO. This body of research represents the basis for the new immune-activation treatment strategy.

The following represents key highlights from THIO preclinical research:

- THIO has been tested in multiple preclinical studies evaluating various tumor types *in vitro* including in lung, colorectal, prostate, breast, ovarian, head and neck, brain, melanoma, and liver cancer. THIO has also been tested in *in vivo* mouse models of lung, colorectal, brain, melanoma, liver and brain cancers. In the below graphic, the left panel depicts cancer cell colony formation *in vitro* assay results conducted with various types of telomerase positive cancers, namely prostate, breast, ovarian, colon, brain, head and neck. In the control column, cancer cells grew. In the second column, with the telomerase inhibitor BIBR, the cancer cells also grew. In the third column, in which the telomere targeting agent THIO was administered at a concentration of 2.5μM, cancer cell growth was visibly inhibited. In the fourth column, in which THIO was administered at a concentration of 5μM, cancer cells were also visibly inhibited. The same concentrations of THIO were also administered *in vivo* in rodent models (mice), caring tumors, derived from either brain, or liver, or melanoma, or neuroblastoma, or colorectal cancer cells were treated with THIO (at 2 mg/kg to 5 mg/kg doses), significant reduction in tumor masses resulting from the treatment with THIO was observed. Note that THIO's activity seen in preclinical models has yet to be demonstrated in humans.



- THIO demonstrated potential to *selectively* cause cancer cell death with active enzyme telomerase versus normal cells *in vitro*. The below graphic illustrates formation of telomeric damage foci (TIFs) in telomerase activity-positive cancer cells, but not in normal non-cancerous cells, resulting from application of THIO. These data indicate molecular mechanism of THIO that targets telomeric DNA of cancer cells through their telomerase enzymatic activity. At the same time, normal cells, that are devoid of telomerase activity, are not affected by THIO.



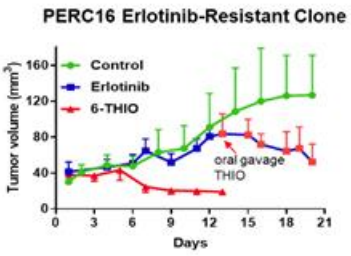
Mender I. et al., Cancer Discovery (2015)

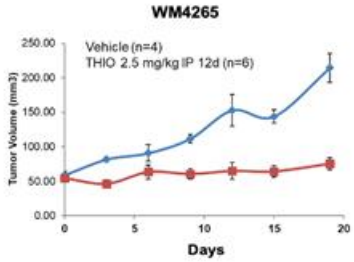
*TIF – telomere damages induced foci
*TRF2 – protein associated with telomeres
* Gamma-H2AX – protein associated with induction of DNA damage
*CRC – colorectal cancer
*hTERT – protein components of telomerase enzyme

- THIO, as a single agent, showed *in vitro* telomere targeting activity in cancer cells that are resistant to tyrosine kinase inhibitors (TKIs), checkpoint inhibitors, IL-2, IFNα, YERVOY®(ipilimumab) and a host of chemotherapies. The below graphic, in NSCLC and Melanoma models respectively, demonstrates in vivo telomere targeting activity of THIO in mice models of lung cancer, derived from PERC16 cells, and melanoma derived from WM4265 cells. Both cell lines are resistant to multiple standard-of-care drug compounds, as listed in the Figure legends.

- **PERC16** human lung cancer cells (TKI-resistant)
- 5 mg/kg THIO once-daily i.p. injection
- 15 mg/kg erlotinib once-daily oral gavage

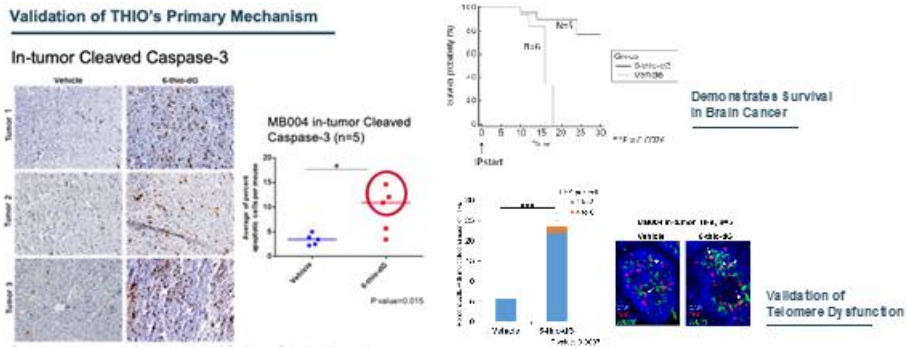
- **WM4265:** Derived from a melanoma patient resistant to cisplatin, vinblastine, temozolomide, IL-2, IFN-α, ipilimumab and pembrolizumab (Checkpoint Inhibitors)





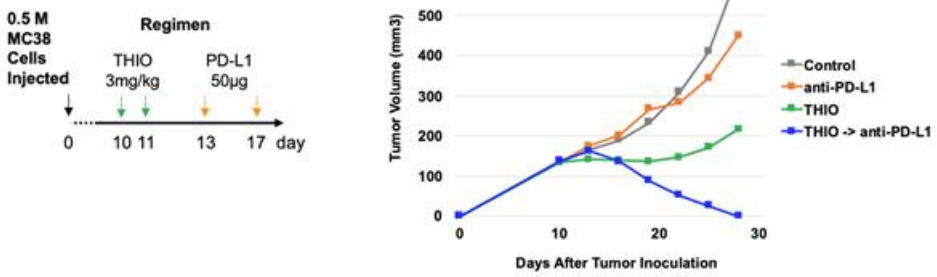
*i.p. – intraperitoneal injection
*IL-2 – cytokine interleukin 2
*IFN-a – interferon alfa

- THIO was observed to penetrate the blood-brain barrier and inhibits tumor growth, inducing in-tumor telomere dysfunction and cancer cell death, in *in vitro* models of difficult to treat pediatric brain cancer, where no therapy exists. In the below graphic, this is shown through presence of Caspase-3 enzyme which is associated with cell death. Sengupta, S. et al. Induced telomere damage to treat telomerase expressing therapy-resistant pediatric brain tumors. Mol Cancer Therapeutics, 17(7): 1504-1514, 2018.

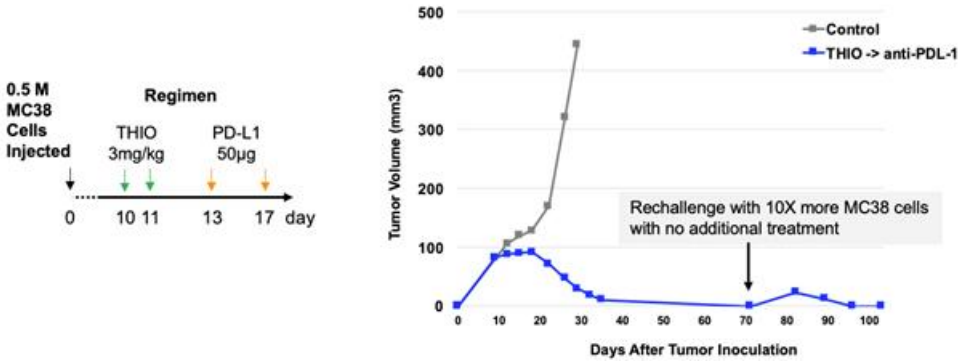


*TIF – telomere damage induced foci
*MB004 – brain cancer cell line

- THIO transformed "cold" tumors into "hot" tumors that were responsive to immunotherapy. THIO utilized a telomere targeting pathway that synergized with checkpoint inhibitors and other immune-activating therapies. The tumor-specific immune activation, resulting from THIO's primary mode of action, overcame resistance to current check point inhibitor (CPI) standard-of-care therapy, as illustrated in the following Colorectal Cancer model. The below graphic demonstrates telomere targeting activity of THIO alone, and in sequential combination with immune checkpoint inhibitor (anti-PD-L1 compound, atezolizumab), in mice model of colorectal cancer, derived from MC-38 cells. Two doses of THIO are shown to control tumor growth while anti-PD-L1 agent. Sequential administration of THIO (2 days), followed by administration of the anti-PD-L1 agent, demonstrates disappearance of tumor cells.



- Immunological memory was observed in mouse models, where the immune system continued to be active against the specific treated tumor cell type for 100 days post-tumor inoculation. The below graphic demonstrates that the tumor-free animals that were treated with the sequential combination of THIO and anti-PD-L1 compound were followed for 70 days, with no observed tumor recurrence. Subsequently, animals were re-challenged with 10 times more MC38 cancer cells. Cancer growth was not observed in these animals, demonstrating induction of anti-tumor-protecting memory after sequential administration of THIO and anti-PD-L1 agent; ref: Mender, I., et al. Telomere stress potentiates STING-dependent anti-tumor immunity. Cancer Cell, 38,3, 400-411.E6, September 14, 2020.



Moreover, due to the cGAS/STING activation caused by THIO, telomere targeting activity was observed in numerous preclinical tumor models when THIO was administered followed by immune activating therapy such as immune checkpoint inhibitors (anti-PD-L1 or anti-PD-1 antibody). *A summary of the pharmacological aspects of the investigational product and, where appropriate, its significant metabolites studied in animals, should be included. Such a summary should incorporate studies that assess potential therapeutic activity (e.g. efficacy models, receptor binding, and specificity) as well as those that assess safety (e.g., special studies to assess pharmacological actions other than the intended therapeutic effect(s)). The results of all relevant nonclinical pharmacology, toxicology, pharmacokinetic, and investigational product metabolism studies should be provided in summary form. This summary should address the methodology used, the results, and a discussion of the relevance of the findings to the investigated therapeutic and the possible unfavourable and unintended effects in humans.*

It is therefore hypothesized that THIO, administered in advance of immune-activating therapies (e.g., checkpoint inhibitors, radiation therapy, etc.), at dose levels significantly lower than the levels evaluated in previous clinical trials, will "*prime"* the tumor

environment and initiate an overall anti-tumor immune response. If confirmed through additional clinical studies, this could represent an entirely new therapeutic approach for THIO and form the basis for the new clinical strategy for planned future trials.

THIO Clinical Trials

We plan to rely solely upon our self-generated clinical safety and efficacy data, if favorable, in support of our anticipated NDA filing for THIO. However, THIO, as a compound, was the subject of investigation in numerous clinical trials in the 1970s to the early-80s in a variety of solid tumors and hematological malignancies. The compound was evaluated in at least nineteen (19) Phase 1 to Phase 3 clinical trials with over 600 patients treated by major cancer institutions and cancer cooperative groups. THIO was studied in combination with common agents in use at the time, including methyl-CCNU or mitomycin, two widely used alkylating agents to treat a variety of cancers and leukemias. Studies utilizing THIO as a single agent have been published in peer-reviewed journals. As part of the existing data base of clinical experience with the drug, we expect to reference the older NCI studies in the public domain as well as reference NCI's original IND filing in support of an IND filing, pursuant to FDA regulations.

The following tables summarize the THIO single agent peer-reviewed published data available from the previous clinical trials.

Phase 1

Study	Tumor Type	Regimen/Dose Schedule	Evaluable Subjects	Description of Observed Adverse Events	Responses
C76-92	Pediatric Acute Leukemia who received prior 6-mercaptopurine (6-MP) or 6-thioguanine	THIO 200 to 2,250 mg/m^2 given every 12 hours for 3 doses every 2 weeks Maximum tolerated dose (MTD) was determined to be 1,750 mg/m^{2}given every 12 hours for 3 doses every 2 weeks	31	Reversible urate nephropathy, elevations of liver enzymes, nausea and vomiting, alopecia, and skin reactions	Therapeutic Responses observed in 6/23 (26%) patients comprised of 2 complete responses and 4 partial responses

Source: Higgins, G. R., Jamin, D. C., Shore, N. A., Momparler, R., Hartman, G. and Siegel, S. E. (1985). "Phase I evaluation of beta-2'-deoxythioguanosine in pediatric patients with leukemia." Cancer Treat Rep 69(6): 699-701t

Phase 2 – Single Agent Studies

Protocol	Tumor Type	Regimen/Dose Schedule	Evaluable Subjects	ORR (Overall Response)	PR (Partial Response)	CR (Complete Response)	Observed Adverse Events
SEG-248	**Total Patients**		**117**	**27 (23%)**	**11 (9%)**	**16 (14%)**	Leukopenia Thrombocytopenia Skin rash Alopecia (reversible) Nausea and vomiting
	Acute Myelocytic Leukemia (AML)	300 mg/m^2 daily for 5 days	17	4 (24%)	1 (6%)	3 (18%)	
		400 mg/m^2 daily for 5 days	49	10 (20%)	6 (12%)	4 (8%)	
	Blastic transformation of chronic myelogenous leukemai (BTL)	300 mg/m^2 daily for 5 days	11	3 (27%)	-	3 (27%)	
		400 mg/m^2 daily for 5 days	26	6 (23%)	3 (12%)	3 (12%)	
	Acute Lymphocytic Leukemia (ALL)	300 mg/m^2 daily for 5 days	4	2 (50%)	-	2 (50%)	
		400 mg/m^2 daily for 5 days	10	2 (20%)	1 (10%)	1 (10%)	
EST 4273 (ECOG)	Colorectal (prior 5-FU chemotherapy)	THIO 100 mg/m^2 daily for 5 days every 3 weeks vs	61	3 (5%)	3 (5%)	-	Leukopenia, thrombocytopenia, nausea and vomiting
		MeCCNU 175 mg/m^2 every 8 weeks	55	5 (9%)	5 (9%)	-	

Omura, G. A., Vogler, W. R., Smalley, R. V., Maldonado, N., Broun, G. O., Knospe, W. H., et al. (1977b). "Phase II Study of beta-2'-deoxythioguanosine in adult acute leukemia. (Study SEG-248)" Cancer Treat Rep 61(7): 1379-1381 Douglass, H. O., Jr., Lavin, P. T., Woll, J., Conroy, J. F. and Carbone, P. (1978). "Chemotherapy of advanced measurable colon and rectal carcinoma with oral 5-fluorouracil, alone or in combination with cyclophosphamide or 6-thioguanine, with intravenous 5-fluorouracil or beta-2'-deoxythioguanosine or with oral 3(4-methyl-cyclohexyl)-1(2-chlorethyl)-1-nitrosourea: A Phase II-III study of the Eastern Cooperative Oncology Group (EST 4273)." Cancer 42(6): 2538-2545

The previous human experience presents significant limitations as it dates to the 1970s and early 1980s when the implementation of ICH Good Clinical Practices was not yet in effect. The published studies did not disclose certain data points in line with the current ICH Good Clinical Practices, such as efficacy endpoints and serious adverse events. , whether those endpoints were reached, whether the data was found to be statistically significant and serious adverse events. Further, we do not know whether those prior studies were powered for statistical significance in the way our planned studies will be powered. Based generally on the results of these prior

human studies, we believe that THIO has a well-established safety profile, which we intend to independently demonstrate through our own clinical studies. Moreover, all prior studies were conducted primarily in heavily pre-treated, refractory patients.

Notwithstanding these limitations, the available data provides substantial information on the clinical experience with and clinical profile of THIO with an exposure exceeding 600 subjects (adult and pediatric) at doses significantly higher than those intended for investigation in the current program and new treatment strategy. All studies were conducted in heavily pre-treated/refractory patients, most of whom were pre-treated with other standards of care including chemotherapy.

To date, THIO has not received marketing approval in any country; therefore, there is no marketing experience to be reported.
The planned clinical trials will assess a novel THIO therapeutic strategy: - evaluate the safety and efficacy of low potentially immunogenic doses of THIO administered to activate the immune system against the tumor to be treated, followed by standard-of-care immunotherapy (checkpoint inhibitor) or other immune activating therapies.

THIO Developmental Initiatives and Objectives

Based on the existing data regarding pre-clinical information on THIO, we believe it is possible to enter the next human clinical study in the near term with the new low dose immunogenic approach with THIO. We plan to approach the FDA to request a modified toxicity requirement to allow us a reduced time and expenditure to IND in the United States, however, the FDA may not grant such request. We are currently working with experts to evaluate the extent and quality of the existing data supporting THIO and had a pre-IND meeting with the FDA for guidance in 2022.

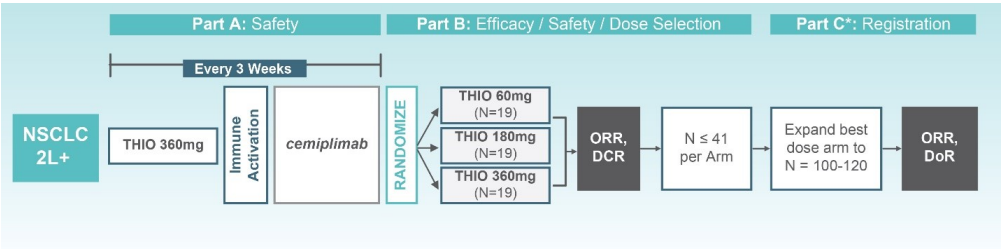
Phase 2 and 3 Programs

Our primary short-term objective is to assess this approach in a Proof-of-Concept study outlined below.

This first study is a dose-finding, Phase 2 clinical trial evaluating both safety and efficacy of THIO sequenced with cemiplimab in patients with advanced non-small lung cancer (NSCLC) who progressed or showed no clinical benefit to first line treatment containing an immune checkpoint inhibitor. This trial, designated as THIO-101 study is our first human clinical trial to test the immune system activation demonstrated in preclinical animal models: lower doses of THIO administered prior to a checkpoint inhibitor treatment reverses drug resistance, enhance and prolong immune responses in patients with advanced lung cancer who did not respond or progressed after a prior cancer treatment which contained another immune checkpoint inhibitor.

The trial design has two primary objectives: (1) safety of THIO administered as a priming immune system agent prior to cemiplimab administration and (2) clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. The study is ongoing in Australia and Europe and we expect will be followed by the United States.

The following chart sets forth the design of the THIO-101 trial:



This “dose-finding” trial will assess the safety, mechanism of activity, and immune system activation of four THIO doses tested out in separate arms administered in parallel. Each dosing arm will be further evaluated for efficacy based on Overall Response Rate (ORR), Duration of Response (DoR) and Progression Free Survival (PFS) to determine to optimal (safe and effective) dose of THIO administered in sequence with cemiplimab. Additional patients may be recruited for further clinical evaluation in any of the THIO arms based on safety and clinical benefit. Each arm of the trial will enroll a minimum of 22 and up to 41 evaluable patients. Subsequently, we expect to target earlier lines of therapy (1st line) in pivotal Phase 3 confirmatory studies in NSCLC.

In September 2022, we submitted a pre-IND meeting request to FDA to discuss, among other elements, the existing non-clinical and clinical data to support the conduct of our planned THIO-101 phase 2 trial under an IND to include patients from the United States. FDA’s November 2022 feedback indicated that our protocol generally sounds reasonable, subject to certain modifications to the

protocol and requests for additional information. We intend to incorporate FDA's feedback and provide the requested information as part of our IND submission to FDA, which we anticipate filing in the near future.

In an effort to obtain FDA and/or EMEA approval of THIO in combination with other standard of care approved cancer immunotherapies, we will have to conduct head-to-head studies which will compare standard of care treatment alone to standard of care treatment combined with THIO. In such studies, we would have to show that THIO added to standard of care therapies adds a significant treatment benefit by slowing down tumor progression and increasing the overall survival of the cancer patients.

In addition, we are actively evaluating other regulatory strategies and pathways that have the potential to accelerate and/or expand the study of THIO administered in sequence with an immune-checkpoint inhibitor in other solid tumor indications.

In the event THIO demonstrates early clinical efficacy, we plan to expand our clinical development program in multiple tumor types and assess several regulatory approval pathways utilizing our other development programs. The clinical development plan includes the initiation of an additional "basket trial" in multiple cancer types. This study uses a special design which allows different cancer indications to be studied under the same single trial umbrella. Some of the indications considered are:

- hepatocellular carcinomas (HCC)
- small-cell lung cancer (SCLC)
- melanoma
- breast cancer
- pancreatic cancer
- glioblastoma multiforme (GBM)
- ovarian cancer
- prostate cancer

Ultimately, we envision positioning THIO as the foundational priming treatment for all immune-activating agents over time based upon THIO's tumor-specific immune-activation approach that enables key clinical strategies that could dramatically expand the immunotherapy market.

Second Generation of Telomere Targeting Agents

We have initiated an early-stage research and discovery program aimed at identifying new compounds capable of acting through the same mechanism of action as THIO, such as targeting and modifying telomeric structures of cancer cells through cancer-cell intrinsic telomerase activity. The main objective for this program is to discover compositionally new compounds with potentially improved specificity towards cancer cells relative to normal cells, and to assess telomere targeting activity in comparison with THIO. This program may also allow us to strengthen our patent portfolio. Although the program is in early stages and we may not be able to identify suitable compounds, we believe we will be able to create or discover a second generation of THIO-like compounds.

Strategic Collaborations and Key Agreements

Through our licensing agreements with The University of Texas Southwestern Medical Center ("UTSW"), we have commercial rights to certain U.S. patents, as well as their foreign counterparts, for the use of THIO in treating telomerase-expressing lung and colon cancer cells. We are currently using this technology to study a treatment regimen comprising the use of THIO treatment followed by cemiplimab (Regeneron) treatment in NSCLC. In addition, we have licensed a number of pending U.S. and foreign patent applications from UTSW directed to other indications, and we are continuing to pursue discussions with several companies to develop other treatment regimens using THIO for additional cancer indications.

Clinical Supply Agreement with Regeneron Pharmaceuticals, Inc.

In 2021, we entered into a Clinical Supply Agreement with Regeneron Pharmaceuticals, Inc. (REGN) to supply cemiplimab for the THIO-101 study. Regeneron will contribute the drug supply without cost, which represents a significant direct cost savings for our program. In exchange, Regeneron will receive development exclusivity for NSCLC indication during the study period, which means that MAIA cannot study THIO in NSCLC with any other PD-1 antagonist (a product sub-class of immune checkpoint inhibitors). All other tumor types remain open, and we are in discussions with other pharmaceutical companies to evaluate additional agreements that may be appropriate to support the expanded development of THIO. The supply agreement will remain in force until all of the obligations of the parties' related to the studies contemplated by the agreement are completed, or until terminated by either party. The agreement may be terminated in the event of unsafe use of cemiplimab, material breach, regulatory action or corruption.

In addition, our management believes that strong partnership interest will develop from other pharmaceutical companies who have checkpoint inhibitor franchises or those with cancer immunotherapy interest. We expect to continue discussions with several

companies that have expressed interest and plan to expand discussions to capitalize on these opportunities. The checkpoint inhibitor market is large, and our goal is to ultimately position THIO as the foundational priming treatment to be used prior to all checkpoint inhibitors.

The University of Texas Southwestern Medical Center License Agreement 1

On December 8, 2020, we entered into an amended and restated agreement (of our prior November 29, 2018 agreement) with The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center (collectively, UTSW). Pursuant to the amended and restated agreement, which we refer to as the UTSW1 Agreement, we obtained (1) an exclusive, worldwide license to develop and commercialize the following UTSW patent families generally directed to methods of using THIO (below) and (2) a non-exclusive worldwide license to develop and commercialize related technology rights.

Title / PCT Application Number
Telomerase Mediated Telomere Altering Compounds / PCT/US2014/33330 (WO2014/168947)
6-Thio-2'-Deoxyguanosine (6-Thio-dG) Results in Telomerase Dependent Telomere Dysfunction and Cell Death in Various Models of Therapy-Resistant Cancer Cells / PCT/US2017/34706 (WO2017/205756)
Use of 6-thio-dG to Treat Therapy-Resistant Telomerase positive Pediatric Brain Tumors / PCT/US2019/023596 (WO2019/183482)
Treatment of Drug Resistant Proliferative Diseases with Telomerase Mediated Telomere Altering Compounds / PCT/US2017/023858 (WO/2017/165675)

Under the UTSW1 Agreement, we agreed to pay UTSW a minimal license fee, deferred license fees, milestone fees, and running royalties beginning on the first net sale (among others). For additional details regarding our relationship with UTSW, see the section entitled "*Business — Intellectual Property —License Agreement 1 with The Board of Regents of The University of Texas System/The University of Texas Southwestern Medical Center*." The UTSW1 Agreement includes an exclusive license to US patent no. 10,463,685 (expires April 8, 2034), and pending US patent application nos. 16/450,430 (having an earliest expiration of March 23, 2037, if a patent is granted), 16/304,538 (having an earliest expiration of May 26, 2037, if a patent is granted), and 16/982,979 (having an earliest expiration of March 22, 2039, if a patent is granted).

The University of Texas Southwestern Medical Center License Agreement 2

On December 23, 2020, we entered into a second agreement with The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center, which set forth the agreement between the parties pursuant to the Company exercising its option rights in the UTSW1 Agreement and obtaining additional license rights. Pursuant this second license with UTSW, which we refer to as the UTSW2 Agreement, we obtained (1) an exclusive, worldwide license to develop and commercialize the following UTSW patent family (below) and (2) a non-exclusive worldwide license to develop and commercialize related technology rights.

Title / PCT Application Number
Sequential Treatment of Cancers Using 6-Thio-dG and Checkpoint Inhibitors / PCT/US2021/022090

Under the UTSW2 Agreement, we agreed to pay UTSW a minimal license fee, deferred license fees, milestone fees, and running royalties beginning on the first net sale (among others). For additional details regarding our relationship with UTSW, see the section entitled "*Business — Intellectual Property —License Agreement 2 with The Board of Regents of The University of Texas System /The University of Texas Southwestern Medical Center*." The UTSW2 Agreement includes an exclusive license to pending US patent application no. 17/200,539 (having an earliest expiration of March 12, 2041, if a patent is granted).

THIO Program

License Agreement 1 with The Board of Regents of The University of Texas System /The University of Texas Southwestern Medical Center

On December 8, 2020 (the "Effective Date"), we entered into an amended and restated agreement (of our prior November 29, 2018 agreement) with The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center, (collectively, UTSW) to develop and commercialize certain UTSW owned and/or controlled patents and related technology directed to methods of using THIO ("the UTSW1 Agreement"). The license is exclusive as to worldwide Patent Rights for all uses in the Field, which is defined as all therapeutic, prophylactic and diagnostic fields of use for all indications, including

discovery and development uses. The license is sublicensable with prior UTSW written approval consistent with the terms of UTSW1 Agreement.

The UTSW1 Agreement includes an exclusive license to the "Patent Rights" of the worldwide patent families including all provisional applications and any divisionals, continuations, continuations-in-part and foreign counterpart applications that are entitled to claim priority thereto, and any patents resulting therefrom, of the following:

Title / PCT Application Number
Telomerase Mediated Telomere Altering Compounds / PCT/US2014/33330 (WO2014/168947)
6-Thio-2'-Deoxyguanosine (6-Thio-dG) Results in Telomerase Dependent Telomere Dysfunction and Cell Death in Various Models of Therapy-Resistant Cancer Cells /PCT/US2017/34706 (WO2017/205756)
Use of 6-thio-dG to Treat Therapy-Resistant Telomerase positive Pediatric Brain Tumors /PCT/US2019/023596 (WO2019/183482)
Treatment of Drug Resistant Proliferative Diseases with Telomerase Mediated Telomere Altering Compounds / PCT/US2017/023858 (WO/2017/165675)

The UTSW1 Agreement also grants the Company a non-exclusive worldwide license under the Technology Rights to develop, manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Field, wherein Technology Rights means Licensor's rights in technical information, know-how, processes, procedures, compositions, devices, methods, formulas, protocols, techniques, designs, drawings or data created before the Effective Date by Inventors at UTSW which are necessary or reasonably useful for practicing Patent Rights.

The UTSW1 Agreement also grants the Company the first right to negotiate an exclusive license under any patent rights covering or claiming any improvement, which is any patentable invention and is conceived or reduced to practice solely by Dr. Jerry Shay or those under his direct supervision at UTSW within 3 years of the Effective Date, under certain conditions.

The term of the UTSW1 Agreement begins on the Effective Date and continue until the earliest of: (i) termination pursuant to the UTSW1 Agreement, (ii) the last date of expiration or termination of the Patent Rights; or (iii) if Technology Rights are licensed and no Patent Rights are applicable, twenty (20) years after the Effective Date. The Company may terminate the UTSW1 Agreement for convenience, at any time prior by providing ninety (90) days' written notice to UTSW. UTSW may terminate the UTSW1 Agreement if the Company (i) becomes in arrears in any payments due, and fails to make the required payment within 30 days after delivery of written notice from UTSW, (ii) is in breach of any material non-payment provision, and does not cure such breach within 60 days after delivery of written notice, (iii) UTSW delivers notice to the Company of three or more actual breaches in any 12-month period, even in the event that the Company cures such breaches in the allowed period, (iv) becomes insolvent or bankrupt, then termination is immediate.

UTSW and/or the co-owners of certain patents have reserved the right to publish the scientific findings related to the Patent Rights and use and to permit other academic institutions to use the licensed subject matter for teaching, research, education, and other education-related, non-commercial purposes. The Patent Rights are also subject to any rights of the United States federal, state and/or local Government(s), as well as nonprofit entities, if certain patents or technologies were created in the course of Government-funded or non-profit entity-funded research.

Pursuant to the UTSW1 Agreement, the Company paid to UTSW a nominal one-time upfront license fee. The Company is also obligated to pay all accrued patent expenses as well as ongoing patent expenses on a scheduled basis tied to Company fund-raising through Series A funding until Company has reimbursed all patent expenses. In the event that the Company assigns the agreement to a third party, the Company is obligated to pay UTSW an assignment fee in the mid-six figures within 15 days of such assignment. The agreement cannot be assigned without UTSW's consent.

Under the UTSW1 Agreement, the Company is obligated to use diligent efforts to bring licensed products to market through a funded, ongoing and active research and development, manufacturing, regulatory, marketing or sales program (all as commercially reasonable) and provide semi-annual reports to UTSW on its progress. The Company is also obligated to pay agreed upon milestone payments to UTSW. Failure of the Company to fulfill these obligations may be treated as a material breach by UTSW.

The only milestones that require payments under the UTSW1 Agreement include: (i) first commercial sale in the U.S. of licensed product for treating an oncology indications ; (ii) first commercial sale in the U.S. of licensed product for treating a non-oncology indications; (iii) first time aggregate Net Sales (as defined in the UTSW1 Agreement) of licensed product for treating an oncology indications exceeds low-nine figure sales in a contract year; (iv) first time aggregate Net Sales of licensed product for treating a non-oncology indications exceeds low nine-figure sales in a contract year; (v) first time aggregate Net Sales of licensed product for treating

an oncology indications exceeds low ten-figure sales in a contract year; (vi) first time aggregate Net Sales of licensed product for treating a non-oncology indications exceeds low ten-figure sales in a contract year. There are no milestone payments required on any development or regulatory milestones. The only required milestone payments under the UTSW1 Agreement related to commercial sales milestones, and the aggregate amount of milestone fees payable pursuant to the UTSW1 Agreement will not exceed $112 million.

The Company will also pay UTSW running royalties on a yearly basis as a percentage of Net Sales of the Company or its sublicensee. There are single digit royalty rates for licensed products and licensed services covered by a Valid Claim (as defined in UTSW1 Agreement) and dependent on whether Net Sales are greater than or less than/equal to low ten figures of sales, with Net Sales above that amount commanding a slightly higher percentage. In each case, the royalty percentage is lower before patent issuance in each jurisdiction. In the event that the licensed product or licensed service is not covered by a Valid Claim, the running royalty rates are reduced by a certain percentage. The royalty obligations continue on a country-by-country basis until the later of expiration of the last Valid Claim in each country or ten (10) years after the First Commercial Sale (as defined in UTSW1 Agreement) in each country. In the event that the Company or its sublicensee challenges the Patent Rights, then the Company will be obligated to pay multiples of the applicable royalty rate of the Net Sales and, should the outcome of such challenge determine that any claim of the Patent Rights challenged is both valid and infringed then the Company will pay royalties at the rate of multiples of the applicable royalty rate of the Net Sales sold thereafter and reimburse UTSW for all fees and costs associated with defending such challenge, including attorney's fees and expert fees.

The UTSW1 Agreement also contains an anti-stacking provision pursuant to which in the event the Company or its sublicensee pays royalties or other payments to a third party who owns or controls intellectual property deemed necessary to develop, manufacture, have manufactured, distribute, have distributed, use, lease, loan, import, offer for sale and/or sell any licensed products and licensed services, the Company may reduce payments to UTSW by a certain percentage of the royalty, milestone or other payments paid to such third party. However, such adjustment in royalty payments to UTSW may not be reduced by more than a certain percentage of the royalty obligation in any contract year. In the event that the payment to the third party who owns or controls intellectual property deemed necessary to extend or expand the franchise or exclusivity of a previously launched licensed product (e.g., such as a new formulation as a second generation product containing the same compound as the previously launched Licensed Product), then the Company may reduce payments to UTSW by a certain percentage of the royalty, milestone or other payments paid to such third party. However, such adjustment in royalty payments to UTSW may not be reduced below a certain percentage of the royalty obligation in any contract year.

UTSW maintains direct control over the prosecution and maintenance activities of the Patent Rights, and the Company is obligated to reimburse past and ongoing patent expenses as noted above. UTSW will permit the Company to comment on submissions to government patent agencies, during prosecution and will consider the Company's comments, but UTSW retained control over all final decisions.

The UTSW1 Agreement contains a representation that UTSW has the rights and authority to grant to Company the licensed rights and is to its knowledge unaware of any third-party infringer or any infringement of third-party intellectual property rights. The UTSW1 Agreement also requires the Company to indemnify UTSW and other related parties against any liabilities, damages, causes of action, suits, judgments, liens, penalties, fines, losses, costs and expenses arising out of any product the Company produces under the UTSW1 Agreement, and requires the Company, beginning with the earlier of the first clinical trial or commercial sale or other commercialization, to obtain liability insurance.

The Company will have the first and sole right but not the obligation, at its own expense, to initiate an infringement suit or other appropriate actions against third party infringers and monetary recovery received therefrom, after the Company is reimbursed for expenses in enforcing the Patent Rights, is shared between the Company and UTSW pursuant to a good faith negotiation between the parties at that time. If the Company does not file suit within six months after a written request by UTSW, then UTSW may bring suit to enforce any Patent Right and retain all recoveries from such enforcement. If UTSW pursues such infringement action, it may, as part of the resolution of such efforts, grant nonexclusive license rights to the alleged infringer notwithstanding Licensee's exclusive license rights.

In accordance with the terms of the UTSW1 Agreement, on April 24, 2020 Company sublicensed all Company rights and obligations under the UTSW1 Agreement to Company affiliate THIO Therapeutics, Inc.

License Agreement 2 with The Board of Regents of The University of Texas System /The University of Texas Southwestern Medical Center

On December 23, 2020 (the "Effective Date"), we entered into a second agreement with The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center, (collectively, UTSW), which set forth the agreement between the parties pursuant to the Company exercising its option rights in the UTSW1 Agreement and obtaining additional license rights ("the UTSW2 Agreement"). The license is exclusive as to worldwide Patent Rights for all uses in the Field,

which is defined as all therapeutic, prophylactic and diagnostic fields of use for all indications, including discovery and development uses. The license is sublicensable with prior UTSW written approval consistent with the terms of UTSW2 Agreement.

The UTSW2 Agreement includes an exclusive license to the "Patent Rights" of the worldwide patent family including all provisional applications and any divisionals, continuations, continuations-in-part and foreign counterpart applications that are entitled to claim priority thereto, and any patents resulting therefrom, of the following

Title / PCT Application Number
Sequential Treatment of Cancers Using 6-Thio-dG and Checkpoint Inhibitors / PCT/US2021/022090

The UTSW2 Agreement also grants the Company a non-exclusive worldwide license under the Technology Rights to develop, manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Field, wherein Technology Rights means UTSW's rights in technical information, know-how, processes, procedures, compositions, devices, methods, formulas, protocols, techniques, designs, drawings or data created before the Effective Date by inventors at UTSW which are necessary or reasonably useful for practicing Patent Rights.

The terms of the UTSW2 Agreement are similar in many respects to those set forth in the UTSW1 Agreement. Pursuant to the UTSW2 Agreement, the Company paid to UTSW a nominal one-time upfront license fee. The UTSW2 Agreement recognizes the accrual of low five-figures in patent expenses relative to the Patent Rights of this agreement and provides for deferral of this fee and related ongoing patent expense fees on a schedule connected to the Company's fundraising through Series A funding. Once the Company has raised mid seven-figures, the patent expense fees are be paid in full for all patent expenses incurred by UTSW for the Company's licensed technologies which accrued between December 12, 2019, and the date at which the mid seven-figures has been raised. Until the Company has reimbursed all patent expenses it is obligated to report its fundraising progress to UTSW on a quarterly basis.

The milestone payments are the same as in the UTSW1 Agreement wherein the milestone fees are based solely on commercial sales milestones and are payable one time only, regardless of the number of licensed products or licensed services developed and regardless of the number of indications or patient sub-populations treated with a licensed product(s) and regardless of whether the licensed products or licensed services developed are within the rights granted by the UTSW1 Agreement or the UTSW2 Agreement. In other words, there are no milestone payments required on any development, or regulatory milestones under the UTSW1 Agreement or the UTSW2 Agreement. The only required milestone payment under the UTSW1 Agreement or the UTSW2 Agreement relate to commercial sales milestones and the aggregate amount of milestone fees payable pursuant to the UTSW1 Agreement or the UTSW2 Agreement will not exceed $112 million. In the event the Company assigns the UTSW2 Agreement to a third party, the Company is obligated to pay UTSW low six-figures within 15 days of such assignment, which is cumulative of the UTSW1 Agreement assignment fee, such that if both agreements are assigned to a third party, a total of high six-figures would be owed to UTSW. The agreement cannot be assigned without UTSW's consent.

The Company will also pay UTSW running royalties on a yearly basis as a percentage of Net Sales of the Company or its sublicensee. There are mid-single digit royalty rates for licensed products and licensed services covered by a Valid Claim (as defined in UTSW2 Agreement) and dependent on whether Net Sales are greater than or less than/equal to low ten-figures in sales, with Net Sales above that amount commanding a slightly higher percentage. In each case, the royalty percentage is lower before patent issuance in each jurisdiction. In the event that the licensed product or licensed service is not covered by a Valid Claim, the running royalty rates are reduced by a certain percentage. The royalty obligations continue on a country-by-country basis until the later of expiration of the last Valid Claim in each country or ten (10) years after the First Commercial Sale (as defined in UTSW2 Agreement) in each country. In the event that the Company or its sublicensee challenges the Patent Rights, then the Company will be obligated to pay multiple times the applicable royalty rate of the Net Sales and, should the outcome of such challenge determine that any claim of the Patent Rights challenged is both valid and infringed then the Company will pay royalties at the rate of multiple times the applicable royalty rate of the Net Sales sold thereafter and reimburse UTSW for all fees and costs associated with defending such challenge, including attorney's fees and expert fees.

The UTSW2 Agreement also contains an anti-stacking provision pursuant to which in the event the Company or its sublicensee pays royalties or other payments to a third party who owns or controls intellectual property deemed necessary to develop, manufacture, have manufactured, distribute, have distributed, use, lease, loan, import, offer for sale and/or sell any licensed products and licensed services, the Company may reduce payments to UTSW by a certain percentage of the royalty, milestone or other payments paid to such third party. However, such adjustment in royalty payments to UTSW may not be reduced by more than a minimum percentage of the royalty obligation in any contract year. In the event that the payment to the third party who owns or controls intellectual property deemed necessary to extend or expand the franchise or exclusivity of a previously launched licensed product (e.g., such as a new formulation as a second-generation product containing the same compound as the previously launched Licensed Product), then the Company may reduce payments to UTSW by a certain percentage of the royalty, milestone or other payments paid to such third party.

However, such adjustment in royalty payments to UTSW may not be reduced by more than a certain percentage obligation in any contract year.

The Company has the development and reporting obligations as the UTSW1 Agreement and as with the UTSW1 Agreement, UTSW has reserved the right to publish the scientific findings related to the Patent Rights and use and to permit other academic institutions to use the licensed subject matter for teaching, research, education, and other educationally related, non-commercial purposes. The Patent Rights are also subject to any rights of the United States federal, state and/or local Government(s), as well as nonprofit entities, if certain patents or technologies were created in the course of Government-funded or non-profit entity-funded research.

The obligations and rights as to patent prosecution and defense of the Patent Rights are the same as those for the UTSW1 Agreement. The term and termination provisions of the UTSW2 Agreement is the same as the UTSW1 Agreement, however in the event that the UTSW1 Agreement is terminated for any reason, or expires, then the UTSW2 Agreement likewise is terminated or deemed to have expired.

The above description of UTSW1 Agreement and UTSW2 Agreement is just a summary and readers are referred to UTSW1 Agreement and UTSW2 Agreement, which are attached hereto as Exhibits 10.2 and 10.3 respectively, for a full and complete description of the patent expenses, milestone payments, fees and royalties payable by MAIA.

Some of our intellectual property, including the intellectual property licensed under UTSW1 and UTSW2, has been conceived or developed through government-funded research and thus may be subject to federal regulations providing for certain rights for the U.S. government or imposing certain obligations on us, such as a license to the U.S. government under such intellectual property, "march-in" rights, certain reporting requirements and a preference for U.S.-based companies, and compliance with such regulations may limit our exclusive rights and our ability to contract with non-U.S. manufacturers. See Risks Relating to Our Intellectual Property - Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Competition

The biotechnology industry is characterized by a rapid evolution of technologies, significant competition and strong defense of intellectual property. While we believe that our platforms, technology, knowledge, experience, and scientific resources provide us with unique competitive advantages, we expect to face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions, among others.

Any therapeutic candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future. For example, current competitors in the non-small lung cancer indication are Merck, Regeneron, Eli Lilly and Roche. There are also many other large and small companies developing products for this indication. Key product features that, if approved, would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our therapeutics, the ease of use and effectiveness of any complementary diagnostics and/or companion diagnostics, and price and levels of reimbursement.

Our competitors also include large pharmaceutical and biotechnology companies, which may be developing therapeutic candidates with mechanisms similar to our compounds or targeting the same clinical indications as our therapeutic candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our therapeutic candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These early stage and more established competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as

those we are developing. Any pharmaceutical candidate that we develop must be approved by the United States Food and Drug Administration, or FDA, before it may be legally marketed in the United States and by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

United States Government Regulation

In the United States, the FDA regulates biopharmaceutical products under the Federal Food, Drug, and Cosmetic Act and the Public Health Services Act, or PHSA, and implementing regulations.

Approval Processes

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- Submission to the FDA of an Investigational New Drug Application, or an IND, which must become effective before human clinical trials may begin;
- Performance of several phases of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug or biologic for its intended use;
- Submission to the FDA of a New Drug Application, or an NDA, for a new drug product, or a Biologics License Application, or a BLA, for a new biological product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug or biologic is to be produced to assess compliance with the FDA's current good manufacturing practice standards, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity;
- Potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA.

Failure to comply with the applicable U.S. requirements at any time during the product development or approval process, or after approval, may subject an applicant to administrative or judicial sanctions brought by the FDA and the Department of Justice, or DOJ, or other governmental entities, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning or untitled letters;
- seizures or administrative detention of product;
- total or partial suspension of production or distribution; or
- injunctions, fines, disgorgement, or civil or criminal penalties.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. There can be no certainty that approvals will be granted.

Once a biopharmaceutical candidate is identified for development, it enters the preclinical or nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some nonclinical testing may continue even after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND.

Clinical trials involve the administration of the drug or biological candidate to healthy volunteers or patients having the disease being studied under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements.

Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed.
Human clinical trials prior to approval are typically conducted in three sequential Phases that may overlap or be combined:

- Phase 1. The drug or biologic is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients having the specific disease.
- Phase 2. The drug or biologic is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule for patients having the specific disease.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials, which usually involve more subjects than earlier trials, are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA or BLA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA by the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug or biological candidate and, among other things, must include methods for testing the identity, strength, quality and purity of the final drug or biologic. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug or biological candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug or biologic, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

The FDA reviews for completeness all NDAs and BLAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA or BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA.

After the NDA or BLA submission is accepted for filing, the FDA reviews the application to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. In addition to its own review, the FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an

advisory committee, but it considers such recommendations carefully when making decisions. During the approval process, the FDA also will determine whether special marketing conditions or restrictions under a risk evaluation and mitigation strategy, or REMS, are necessary to assure the safe use of the drug or biologic. If the FDA concludes that a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is to be manufactured, and may also inspect facilities that provide raw materials for use in the product. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical trial sites to assure their compliance with cGCP during the conduct of studies of the subject drug. If during the review of the application the FDA identifies questions or concerns regarding the application, data, manufacturing process or manufacturing facilities, it may issue a deficiency letter which the sponsor must adequately address to the FDA's satisfaction.

The NDA or BLA review and approval process is lengthy and difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not, in its submitted form, satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA will issue a "complete response letter" (CRL) if the agency decides not to approve the NDA or BLA. The complete response letter usually describes the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter will typically include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be for more limited conditions of use than the sponsor had proposed, such as limitations to specific diseases or subsets of a disease, limited patient populations, second-line or third-line use limitations, limited dosages or other limitations which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which may involve clinical trials designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Companion Diagnostics

Many drugs for cancer indications involving patient-specific genetic mutations or biomarkers are approved by FDA with limitations that the specific genetic mutation must be confirmed in each patient by use of an FDA-approved diagnostic test, commonly referred to as a "companion diagnostic." The FDA issued a final guidance document in July 2014 addressing agency policy in relation to *in vitro* companion diagnostic tests. The guidance explains that for some drugs and therapeutic biologics, the use of a companion diagnostic test is essential for the safe and effective use of the product, such as when the use of a product is limited to a specific patient subpopulation that can be identified by using the test. According to the guidance, the FDA generally will not approve such a product if the companion diagnostic is not also approved or cleared for the appropriate indication, and accordingly the therapeutic product and the companion diagnostic should be developed and approved or cleared contemporaneously. The FDA has also issued a Guidance, *Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product* (2016), which is "is intended to be a practical guide to assist therapeutic product sponsors and IVD sponsors in developing a therapeutic product and an accompanying IVD companion diagnostic," and a Guidance, *Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products*(2020), which "describes considerations for the development and labeling of in vitro companion diagnostic devices (referred to as "companion diagnostics" herein) to support the indicated uses of multiple drug or biological oncology products, when appropriate."

As stated in its Guidance, the FDA may decide that it is appropriate to approve such a product without an approved or cleared *in vitro* companion diagnostic device when the drug or therapeutic biologic is intended to treat a serious or life-threatening condition for which no satisfactory alternative treatment exists and the FDA determines that the benefits from the use of a product with an unapproved or uncleared *in vitro* companion diagnostic device are so pronounced as to outweigh the risks from the lack of an approved or cleared *in vitro* companion diagnostic device. The FDA encourages sponsors considering developing a therapeutic product that requires a companion diagnostic to request a meeting with both relevant device and therapeutic product review divisions to ensure that the product development plan will produce sufficient data to establish the safety and effectiveness of both the therapeutic product and the companion diagnostic. To date, no product targeting TERT+ cancer patients has been approved by FDA, and the applicability to THIO of FDA's Companion Diagnostics Guidance and policy is yet to be determined. If a companion diagnostic is required to be developed and approved in order to receive approval of THIO, the cost and length of time to fully develop and receive approval (if at all) of THIO may both be increased, as described in more detail in the section *Risk Factors – Risks Relating*

to Government Regulation. Because the FDA's policy on companion diagnostics is set forth only in guidance, this policy is subject to change and is not legally binding.

Expedited Development and Review Programs

The FDA has a Fast-Track program that is intended to expedite or facilitate the process for reviewing new drug and biological products that meet certain criteria. Specifically, new drug and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Under a Fast Track designation, the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if (i) the sponsor provides a schedule for the submission of the sections of the NDA or BLA, (ii) the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and (iii) the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

Any product submitted to the FDA for marketing approval, including those submitted under a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or the new product has the potential to offer a significant improvement in the treatment, diagnosis or prevention of a disease compared with marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of accelerated approval, the FDA generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies to confirm the safety and efficacy for the approved indication. Failure to conduct such studies or conducting such studies that do not establish the required safety and efficacy may result in revocation of the original accelerated approval. In addition, the FDA currently requires as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch or subsequent marketing of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process, and even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA.

The Hatch-Waxman Amendments and Generic Competition

Orange Book Listing

Once a drug product is approved under an NDA, the product is listed in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. An NDA-approved drug product will be designated in the Orange Book as a Reference Listed Drug (RLD). Sponsors of approved NDA's are required to list with the FDA patents whose claims cover the product's active ingredient, formulation, or an approved method of using the drug.

Patent Term Extensions

Depending upon the timing, duration and specifics of FDA approval of the use of our therapeutic candidates, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product or therapeutic candidate's approval date. The patent term restoration period is generally one half of the time between the effective date of an IND and the submission date of a NDA, plus the time between the submission date of a NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product or therapeutic candidate is eligible for the extension and the application for extension must be made prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

ANDA Approval Process

The Hatch-Waxman Amendments established an abbreviated FDA approval process for generic drugs that are shown to be pharmaceutically equivalent and bioequivalent to drugs previously approved by the FDA through the NDA process. Approval to market and distribute these drugs is obtained by filing an abbreviated new drug application, or ANDA, with the FDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

Section 505(b)(2) NDA Approval Process

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments to the FDCA and enables the applicant to rely, in part, on the FDA's previous approval of a similar product, and/or published literature, in support of its application. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved or for any new indication sought by the Section 505(b)(2) applicant.

ANDA and 505(b)(2) products may be significantly less costly to bring to market than the reference listed drug, and companies that produce generic products are generally able to offer them at lower prices. Moreover, generic versions of RLDs are often automatically substituted for the RLD by pharmacies when dispensing a prescription written for the RLD. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

ANDA and 505(b)(2) NDA Patent Certification Requirements

Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a Section 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA, as applicable, that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. If an ANDA is submitted to FDA with a Paragraph IV Certification, the generic applicant must also provide a "Paragraph IV Notification" to the holder of the NDA for the RLD and to the owner of the listed patent(s) being challenged by the ANDA applicant, providing a detailed written statement of the bases for the ANDA applicant's position that the relevant patent(s) is invalid or would not be infringed. If the patent owner brings a patent infringement lawsuit against the ANDA applicant within 45 days of the Paragraph IV Notification, FDA approval of the ANDA will be automatically stayed for 30 months, or until 7-1/2 years after the NDA approval if the generic application was filed between 4 years and 5 years after the NDA approval. Any such stay will be terminated earlier if the court rules that the patent is invalid or would not be infringed. The applicant may, in certain circumstances, elect to submit a "section viii" statement with respect to a listed method of use patent, certifying that the proposed generic labeling does not contain (or carves out) any language that would infringe a method of use patented listed in the Orange Book for the RLD.

The ANDA or Section 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the reference drug has expired as described in further detail below.

Regulatory Exclusivities

New Chemical Entity (NCE) Exclusivity

The Hatch-Waxman amendments provides a period of five years of non-patent marketing exclusivity for the first approved drug containing a new chemical entity ("NCE") as an active ingredient. An NCE is an active moiety that has not been approved by the FDA in any other NDA. A fixed combination drug product may receive NCE exclusivity if one of its active ingredients is an NCE, but not if all of its active ingredients have previously been approved. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA or 505(b)(2) NDA seeking approval of a product that contains the same active moiety, except that the FDA may accept such

an application for filing after four years if the application includes a paragraph IV certification to a listed patent. In the case of such applications accepted for filing between four and five years after approval of the reference drug, the 30-Month Stay of approval triggered by a timely patent infringement lawsuit is extended by the amount of time necessary to extend the stay until 7-1/2 years after the approval of the reference drug NDA.

New Clinical Trial (3-Year) Exclusivity

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular indication or condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability studies) was essential to the approval of the application or supplemental application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or Section 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Orphan Drug Designation and Orphan Exclusivity

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to a therapeutic candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects either (i) fewer than 200,000 individuals in the United States, or (ii) more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a product or therapeutic candidate for this type of disease or condition will be recovered from sales in the United States for that product or therapeutic candidate. Orphan Drug Designation must be requested before submitting a BLA. After the FDA grants Orphan Drug Designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product or therapeutic candidate that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the approved product is entitled to orphan product exclusivity, which means that the FDA may not approve any other marketing applications for the same drug for the same indication, except under limited circumstances, for seven years. Orphan product exclusivity, however, could also block the approval of one of our therapeutic candidates for seven years if a competitor obtains approval of the same drug as defined by the FDA, or if our therapeutic candidate is determined to be contained within a competitor's approved drug for the same indication or disease.

In addition, an orphan drug credit is available for qualifying costs incurred between the date the FDA designates a drug as an orphan drug and the date the FDA approves the drug.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. Under the Best Pharmaceuticals for Children Act, or BPCA, certain therapeutic candidates may obtain an additional six months of exclusivity if the sponsor conducts pediatric research and submits new clinical information requested in writing by the FDA, referred to as a Written Request, relating to the use of the active moiety of the product or therapeutic candidate in children. The data do not need to support a label change for pediatric use; rather, the additional protection is granted if the pediatric clinical trial is deemed to have fairly responded to the FDA's Written Request. Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product or therapeutic candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population. The issuance of a Written Request does not require the sponsor to undertake the described trials. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Post-Approval Requirements

Following approval of a new drug or biologic product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, continuing cGMP compliance, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a

new NDA or a NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials.

Once an NDA or BLA approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product or therapeutic reaches the market. Later discovery of previously unknown problems with a product or therapeutic candidate, including adverse events of unanticipated severity or frequency, may result in in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved application, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or
- mandated modification of promotional materials and labeling and the issuance of corrective information.

Accordingly, a therapeutic candidate manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- cGMP compliance requirements;
- record-keeping requirements;
- reporting of adverse experiences with the therapeutic candidate;
- providing the FDA with updated safety and efficacy information;
- therapeutic sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes; and complying with FDA promotion and advertising requirements, which include, among other things, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in-patient populations that are not described in the product's approved labeling, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Therapeutic manufacturers and other entities involved in the manufacture and distribution of approved therapeutic products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA, foreign regulatory agencies, and some state agencies for compliance with cGMPs and other laws. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations also require investigation and correction of any noncompliance with cGMP requirements. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the NDA or BLA applicant and any third-party manufacturers involved in producing the approved product. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of quality control and quality assurance.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or the PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act, or the DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10‑year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further

legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to regulations of other jurisdictions governing any clinical trials and commercial sales and distribution of our therapeutic candidates. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. It also is not yet clear how the United Kingdom's recent withdrawal from the European Union will affect the approval of medicinal products in the United Kingdom. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company can consider applying for marketing authorization in several European Union member states by submitting its marketing authorization application(s) under a centralized, decentralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines derived from biotechnology, orphan medicinal products, or those medicines with an active substance not authorized in the European Union on or before May 20, 2004 intended to treat acquired immune deficiency syndrome, cancer, neurodegenerative disorders or diabetes and optional for those medicines containing a new active substance not authorized in the European Union on or before May 20, 2004, medicines which are highly innovative, or medicines to which the granting of a marketing authorization under the centralized procedure would be in the interest of patients at the European Union-level. The decentralized procedure provides for recognition by European Union national authorities of a first assessment performed by one of the member states. Under this procedure, an identical application for marketing authorization is submitted simultaneously to the national authorities of several European Union member states, one of them being chosen as the "Reference Member State," and the remaining being the "Concerned Member States." The Reference Member State must prepare and send drafts of an assessment report, summary of product characteristics and the labeling and package leaflet within 120 days after receipt of a valid marketing authorization application to the Concerned Member States, which must decide within 90 days whether to recognize approval. If any Concerned Member State does not recognize the marketing authorization on the grounds of potential serious risk to public health, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states. The mutual recognition procedure is similar to the decentralized procedure except that a medicine must have already received a marketing authorization in at least one of the member states, and that member state acts as the Reference Member State.

As in the United States, we may apply for designation of a therapeutic candidate as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made.

Orphan drugs in the European Union enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product, the marketing authorization holder is unable to supply sufficient quantity of the medicinal product, or the marketing authorization holder has given its consent.

Coverage, Pricing and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There may be significant delays in obtaining coverage and reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. It is time consuming and expensive to seek reimbursement from third-party payors. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. In the U.S., third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of therapeutics have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic and biosimilar products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement for the pharmaceutical or biological products apply to companion diagnostics.

Moreover, in some foreign countries, the proposed pricing for a product and therapeutic candidate must be approved before it may be lawfully marketed. The requirements governing therapeutic pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our therapeutic candidates. Historically, therapeutic candidates launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product and therapeutic candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product and therapeutic candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product and therapeutic candidates. For example, in the United States, the system for FDA to collect and expend user fees paid by manufacturers of drugs, biologics, and medical devices must be reauthorized by statute every five years, and since 1992, each reauthorization legislation has included, to greater or lesser degrees, various other changes to the FDA's regulatory systems and procedures. The current legislative authority for FDA user fees expires in September 2022, and by that time, new legislation will be required for FDA to continue collecting prescription drug user fees in future fiscal years. The expected 2022 reauthorization may include new legal provisions that could significantly impact our business in ways that cannot be predicted at this time. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of reducing drug prices, containing healthcare costs more generally, improving quality and/or expanding access.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted in March 2010 and has had a significant impact on the health care industry in the U.S. The ACA expanded coverage for the uninsured while at the same time containing overall healthcare costs. It also included the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. With regard to biopharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA and we expect there may be additional challenges and amendments to the ACA in the future.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA that affect health care expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which was signed into law on March 27, 2020, and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation.

Additionally, on December 20, 2019, the Further Consolidated Appropriations Act for 2020 became law (P.L. 116-94), which includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the "CREATES Act." The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. While the Trump administration put forward various proposals and executive orders aimed at reducing drug prices, the Biden administration is likely to pursue its own proposals going forward. In August 2021, President Biden announced his support for legislative proposals to grant Medicare the power to negotiate lower drug prices, for pharmaceutical companies to face penalties if they raise prices faster than inflation, and to impose a new cap on how much Medicare recipients have to spend on medications. Such proposals may be included in upcoming legislation in Congress, but the outcome of such proposals remains uncertain.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Other Healthcare Laws

Our current and future business operations are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we research, and, if approved, market, sell and distribute our therapeutic candidates. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, physician sunshine and drug pricing transparency laws and regulations such as:

- The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, prohibit, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Actions under these laws may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices;

- The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, includes federal, civil and criminal provisions that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- The Physician Payments Sunshine Act, among other things, imposes requirements on manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to HHS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors and, beginning in 2022 for payments and other transfers of value provided in the previous year, certain advanced non-physician health care practitioners), teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations impose specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, health plans, and healthcare clearinghouses, that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions; and
- Analogous state laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws which require the registration of pharmaceutical sales representatives; and state laws and non-United States laws and regulations (particularly European Union laws regarding personal data relating to individuals based in Europe) that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.
- Ensuring that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant civil, criminal and administrative penalties, including monetary damages, fines, disgorgement, imprisonment, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, reputational harm, diminished profits and future earnings, additional reporting requirements if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and the curtailment or restructuring of our operations.

Manufacturing

We do not own or operate manufacturing facilities to produce any of our therapeutic candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all our required raw materials, Active Pharmaceutical Ingredient (API), and finished products for our preclinical and clinical trials and if and when applicable, commercialization. We currently employ internal resources to manage our manufacturing relationships with these third parties.

Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's current good manufacturing practices, or cGMP, regulations. cGMP regulations require, among other things, quality control and quality assurance as well as corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after

approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented.

Regulations - Environmental

We are subject to various environmental laws of federal, state and local governments and foreign governments at various levels. Compliance with existing laws has not had a material adverse effect on our capital expenditures, competitive position, financial condition or results of operations, and management does not believe it will have such an impact in the current fiscal year. However, we cannot predict the impact of unforeseen environmental contingencies or new or changed laws or regulations on our business.

Employees

As of December 31, 2022, we had a total of 18 full-time employees which includes one employee employed by our Romanian subsidiary. We believe that we maintain a satisfactory working relationship with our employees, and we have not experienced any significant labor disputes or any difficulty in recruiting staff for our operations. None of our employees is represented by a labor union.

Human Capital Resources

Employee Engagement, Talent Development & Benefits. We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, and opportunities for equity ownership.

Diversity, Inclusion, and Culture. Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values.

Our Corporate Information

We were incorporated in Delaware in August 2018, and we have operations in Chicago, Illinois, with some of our team members setup virtually and working remotely in California, Nevada and Florida, among others. Our principal executive office is located at 444 West Lake Street, Suite 1700, Chicago, IL 60606, and our phone number is (312) 416-8592. In July 2021, we established a wholly owned Australian subsidiary, MAIA Biotechnology Australia Pty Ltd, to conduct various preclinical and clinical activities for the development of our product candidates. In April 2022, we established a wholly owned Romanian subsidiary, MAIA BIOTECHNOLOGY ROMANIA S.R.L. to conduct various preclinical and clinical activities for the development of our product candidates. Our website address is *www.MAIABiotech.com*. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider any information contained on, or that can be accessed through, our website as part of this Annual Report on Form 10-K or in deciding whether to purchase our common stock.

Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements, and registration statements; and
- exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

If some investors find our common stock less attractive as a result of these exemptions, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933 (the "Securities Act") for complying with new or revised

accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We intend to take advantage of the benefits of this extended transition period.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. References herein to emerging growth company will have the meaning associated with it in the JOBS Act.

Implications of Being a Smaller Reporting Company

Additionally, we are a "smaller reporting company" as defined in Rule 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common stock held by non-affiliates equals or exceeds $250 million as of the end of that year's second fiscal quarter, or (2) our annual revenues equaled or exceeded $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates equals or exceeds $700 million as of the end of that year's second fiscal quarter.

Item 1A. Risk Factors.

Any investment in our common stock involves a high degree of risk. You should carefully consider the risks described below, which we believe represent certain of the material risks to our business, together with the information contained elsewhere in this Annual Report on Form 10-K, before you make a decision to invest in our common stock. Please note that the risks highlighted here are not the only ones that we may face. For example, additional risks presently unknown to us or that we currently consider immaterial or unlikely to occur could also impair our operations. If any of the following events occur or any additional risks presently unknown to us actually occur, our business, financial condition and operating results may be materially adversely affected.

Summary Risk Factors

- We have incurred losses since our inception and anticipate that we will continue to incur increasing losses for the foreseeable future.
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of THIO.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.
- We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.
- We are heavily dependent on the success of THIO, our most advanced candidate, which is still under clinical development, and if this drug does not receive regulatory approval or is not successfully commercialized, our business may be harmed.
- Clinical trials are expensive, time consuming, difficult to design and implement, and involve uncertain outcomes.
- Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.
- We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being studied which could delay or prevent the start of clinical trials for our product candidates.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for THIO or any other candidates, our business will be substantially harmed.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.
- Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.
- The market opportunities for THIO, if approved, may be smaller than we anticipate.
- Development of THIO could take longer, be more expensive, or become impractical if the FDA requires the use of an FDA-approved companion diagnostic test in conjunction with treatment with THIO.
- If we are unable to obtain FDA approval for our IND application for the planned THIO phase 2 trial, our clinical development of THIO may be significantly delayed and our business may be substantially harmed.
- Even if we obtain FDA approval for THIO or any other candidates in the United States, we may never obtain approval for or commercialize THIO or any other development candidate in any other jurisdiction, which would limit our ability to realize their full global market potential.
- The successful commercialization of THIO and any other candidate we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies.
- Even if THIO or any candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.
- If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing THIO, if approved.

- A variety of risks associated with operating internationally could materially adversely affect our business.
- Our employees and independent contractors, including principal investigators, clinical trial sites, contract research organizations ("CROs"), consultants, vendors, and any third parties we may engage in connection with development and commercialization, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.
- We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of THIO and intend to rely on CMOs for the production of commercial supply of THIO, if approved. Our dependence on CMOs may impair the development and commercialization of the drug, which would adversely impact our business and financial position.
- We intend to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.
- We depend on license agreements with the University of Texas Southwestern, or UTSW, to permit us to use patents and patent applications, as well as to exploit specific technological know-how. Termination of these rights or the failure to comply with obligations under these agreements could materially harm our business and prevent us from developing or commercializing our product candidates.
- We have been granted licenses of use to patent applications. There can be no assurance that any of the patent applications that we have licenses to will result in issued patents. As a result, our ability to protect our proprietary technology in the marketplace may be limited.
- Our patents may be challenged in courts or in patent offices which could result in the invalidation, narrowing or unenforceability of our patents and our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.
- Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Intellectual property rights do not address all potential threats to our competitive advantage.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.
- If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.
- We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.
- We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- The price of our common stock may be volatile and you could lose all or part of your investment.
- We do not intend to pay dividends for the foreseeable future, and our ability to pay dividends to our stockholders is restricted by applicable laws and regulations.
- We may, in the future, issue additional capital stock, which would reduce investors' percent of ownership and may dilute our share value.
- Our failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, financial condition, and results of operations.
- We identified material weaknesses in our internal control over financial reporting, and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain

effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

- The lack of public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U.S. securities laws, which could have a materially adverse effect on our business.
- Our shares of common stock are currently listed on NYSE American. If we are unable to maintain listing of our securities on NYSE American or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history and have incurred losses since our formation. We incurred net losses of $15,769,279 and $12,578,211 for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $44,207,272. We have not commercialized any products and have never generated revenue from the commercialization of any product. To date, we have devoted most of our financial resources to research and development, including our preclinical and clinical work, and to intellectual property.

We expect to incur significant additional operating losses for the next several years, at least, as we advance THIO and any other candidates through clinical development, complete clinical trials, seek regulatory approval and commercialize the drug or any other candidates, if approved. The costs of advancing candidates into each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any of our candidates to marketing approval in even a single jurisdiction will be substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of any products or achieve or maintain profitability. Our expenses will also increase substantially if and as we:

- enroll our Phase 2 trial, or conduct clinical trials for any other indications or other candidates;
- establish sales, marketing, distribution, and compliance infrastructures to commercialize our drug, if approved, and for any other candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our development and planned future commercialization efforts, as well as to support our transition to a public reporting company; and
- acquire or in-license or invent other candidates or technologies.

Furthermore, our ability to successfully develop, commercialize and license any candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described under "— *Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval*" and "— *Risks Related to Commercialization*." As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the value of our common stock will be materially and adversely affected.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of THIO.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of THIO and launch and commercialize THIO, if we receive regulatory approval. We will require additional capital for the further development and potential commercialization of THIO and may also need to raise additional funds

sooner to pursue a more accelerated development of THIO. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Based on our cash reserves as December 31, 2022 of $10.95 million and current financial condition as of the date of this Annual Report on Form 10-K, there is substantial doubt about our ability to continue as a going concern. (*See — Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Capital Resources — Our Ability to Continue as a Going Concern"* for further information.) Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the:

- initiation, progress, timing, costs and results of preclinical studies and clinical trials, including patient enrollment in such trials, for THIO or any other future candidates;
- clinical development plans we establish for THIO and any other future candidates;
- obligation to make royalty and non-royalty sublicense receipt payments to third-party licensors, if any, under our licensing agreements;
- number and characteristics of candidates that we discover or in-license and develop;
- outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- effects of competing technological and market developments;
- costs and timing of the implementation of commercial-scale manufacturing activities; and
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, to fund our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate candidate development or future commercialization efforts.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We were incorporated in Delaware and began our operations in August 2018. Our operations to date have been limited to financing and staffing our company, licensing candidates, conducting preclinical studies, manufacturing clinical supply, and preparing for clinical studies of THIO. We have not yet demonstrated the ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval

We are heavily dependent on the success of THIO, our most advanced candidate, which is still under clinical development, and if this drug does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

We do not have any products that have gained regulatory approval. Currently, our lead clinical stage candidate is THIO. As a result, our business is dependent on our ability to successfully complete clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize THIO in a timely manner. We cannot commercialize THIO in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize THIO outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of THIO for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, generally including two adequate and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that THIO is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Even if we were to successfully obtain approval of THIO from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for THIO in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other candidate that we may in-license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for THIO, we will still need to develop a commercial organization, establish commercially viable pricing and obtain approval for adequate reimbursement from third-party and government payors. If we are unable to successfully commercialize THIO, we may not be able to earn sufficient revenue to continue our business.

We may face future business disruption and related risks resulting from the outbreak of the coronavirus (COVID-19) or from another pandemic, epidemic or outbreak of an infectious disease, any of which could have a material adverse effect on our business.

The development of our drug candidates could be disrupted and materially adversely affected in the future by a pandemic, epidemic or outbreak of an infectious disease like the outbreak of COVID-19. For example, as a result of measures imposed by the governments in regions affected by COVID-19 businesses and schools have been suspended due to quarantines or “stay at home” orders intended to contain this outbreak. The spread of COVID-19 from China to other countries has resulted in the Director General of the World Health Organization declaring the outbreak of COVID-19 as a Public Health Emergency of International Concern (PHEIC), based on the advice of the Emergency Committee under the International Health Regulations (2005). In March 2020, and subsequently, various international travel restrictions were imposed and modified between the US and foreign countries and such restrictions may continue, be reimposed, or be expanded or otherwise further modified for the foreseeable future. COVID-19 continues to spread globally, including with the advent of the new “Delta” variant throughout 2021. The COVID-19 outbreak has impacted international stock markets, which continue to reflect the uncertainty associated with the slow-down in global economies and the reduced levels of international travel experienced since the beginning of January 2020. We continue to assess our business plans and the impact COVID-19 may have on our ability to advance the development of our drug candidates, including delays in starting or completing clinical trials, or to raise financing to support the development of our drug candidates, but no assurances can be given that this analysis will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular. One of our initial clinical studies is taking place in Australia, which previously imposed one of the strictest COVID-19-related measures, including lock-downs, and may do so again in the future. While we have not currently experienced any potential delays or increased costs as a result of these measures, we may do so in the future.

The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or materially and adversely affect our collaborators and out-license partners’ ability to perform preclinical studies and clinical trials. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Clinical trials are expensive, time-consuming and difficult to design and implement, and involve an uncertain outcome.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, THIO and our other compounds may not have favorable results in later preclinical and clinical studies or receive regulatory approval. We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence and continue to conduct a trial;
- reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining Institutional Review Board, or IRB, approval at each site, or Independent Ethics Committee, or IEC, approval at sites outside the United States;
- recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers;
- having patients complete a trial or return for post-treatment follow-up;
- imposition of a clinical hold by regulatory authorities, or IRBs, including as a result of unforeseen safety issues or side effects or failure of trial sites to adhere to regulatory requirements or follow trial protocols;
- clinical sites deviating from trial protocol, failing to adequately enroll study subjects, committing fraud or other violations of regulatory requirements, or dropping out of a trial, which can render data from that site unusable in support of regulatory approval;
- addressing patient safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of THIO for use in clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in "— *Risks Related to Our Dependence on Third Parties*."

Treatment of cancer patients with our oncology product candidates may be used in combination with other cancer drugs, such as other immuno-oncology agents, monoclonal antibodies or other protein-based drugs or small molecule anti-cancer agent such as targeted agents or chemotherapy, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. Additionally, our product candidates could potentially cause adverse events. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from obtaining regulatory approval or achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products. Because all of our product candidates are derived from our platform technologies, a clinical failure of one of our product candidates may also increase the actual or perceived likelihood that our other product candidates will experience similar failures.

Of the large number of products in development, only a small percentage successfully complete the FDA or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of a biologics license application (BLA) or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.

We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter and use of our platform technologies may not ever result in marketable products. We may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process or transferring that process to commercial partners or establishing our own commercial manufacturing capabilities, which may prevent us from completing our clinical trials or commercializing any products on a timely or profitable basis, if at all.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

As we develop our product candidates and initiate clinical trials of our additional product candidates, serious adverse events, or SAEs, undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. Should we observe SAEs in our clinical trials or identify other undesirable side effects or other unexpected findings depending on their severity, our trials could be delayed or even stopped and our development programs may be halted entirely.

Even if our product candidates initially show promise in early clinical trials, the side effects of biological products are frequently only detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development or after approval and are determined to be attributed to our product candidate, we may be required to develop a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or ADA caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is administered or conduct additional clinical trials;
- the product may become less competitive, and our reputation may suffer;
- we may decide to remove the product from the marketplace; and
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties.

Interim, topline and preliminary data from our clinical trials may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as patient enrollment and treatment continues and more patient data become available. Adverse differences between previous preliminary

or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the properties that we desire; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable additional candidates for preclinical and clinical development, our opportunities to successfully develop and commercialize therapeutic products will be limited.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for THIO or any other candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for THIO or any other candidates. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval of a NDA from the FDA. Our ability to obtain approval by the FDA or other regulatory authorities can be adversely impacted for various reasons including:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our candidates, or other products containing the active ingredient in our candidates;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our development candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA or comparable foreign authorities may disagree regarding the formulation, labeling and/or the specifications of our candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may inspect and find deficiencies at the clinical trial sites we use to conduct our clinical studies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Prior to obtaining approval to commercialize a candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The planned THIO-101 phase 2 trial is intended to be a proof-of-concept trial that may be expanded depending on interim results and includes both primary and secondary endpoints consistent with previously approved medicines. If THIO achieves its intended effects and does not exhibit unacceptable safety risks, we plan to seek accelerated approval of THIO based on positive results of the expanded phase 2 THIO-101 trial, followed by full approval based on the results of a single phase 3 clinical study, as opposed to the traditional approach of conducting two or more phase 3 studies. Even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA. A single-study approach is permissible in

certain circumstances, particularly in oncology, but such circumstances are exceptional and FDA may not agree with that proposed approach, and thus we may be required to conduct two phase 3 trials.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the adequacy of the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with our safety interpretation of our drug;
- the FDA or comparable foreign regulatory authorities may disagree with our efficacy interpretation of our drug; or
- the FDA or comparable foreign regulatory authorities may regard our CMC package as inadequate, and more particularly:
- if our NDA does not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;
- if the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;
- if the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;
- if the FDA determines that it has insufficient information to determine whether such drug is safe for use under such conditions;
- if based on information we submit and any other information before the FDA, the FDA determines there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or
- if the FDA determines that our labeling is false or misleading in any particular way.

Of the large number of drugs that enter clinical development, only a small percentage successfully complete the regulatory approval processes and are approved and commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market THIO or any other candidates, which would significantly harm our business, results of operations and prospects.

In addition, the FDA or an applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, the FDA or foreign regulatory agency may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, or may require warnings, other safety-related labeling information, or impose post-market safety requirements, including distribution restrictions, that negatively impact the commercial potential of the drug. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the nature of the trial protocol;
- the existing body of safety and efficacy data with respect to the product candidate;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- competing clinical trials being conducted by other companies or institutions;
- our ability to maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- delays or difficulties in enrollment and completion of studies due to the COVID 19 pandemic.

Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.

The results of preclinical studies, early clinical trials or analyses of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our clinical trials for THIO are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval.

Serious adverse events or undesirable side effects caused by THIO or any other candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. THIO has been previously evaluated in at least 19 clinical studies both as monotherapy and in combination with other therapies in multiple solid tumors and hematologic malignancies. A classic treatment strategy was used where patients were treated to maximum tolerated dose (MTD). Dose-limiting reversible toxicities were mainly hematologic (leukopenia, thrombocytopenia), gastrointestinal (nausea, vomiting) and generalized skin rashes; increases in blood urea nitrogen, creatinine, aspartate aminotransferase, alanine transaminase, and bilirubin were also recorded (Douglass, 1979; Gagliano, 1981; Higgins, 1985). The available data provides substantial information on the safety profile of THIO in over 600 subjects (adult and pediatric) at doses significantly higher than those intended for investigation in the current program.

If unacceptable side effects arise in the development of our candidates, we, the FDA or the IRBs at the institutions in which our studies are conducted, or the DSMB, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our development candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or contraindication;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

The market opportunities for THIO, if approved, may be smaller than we anticipate.

We expect to initially seek approval for THIO for use as a priming treatment in combination with the immune check point inhibitor cemiplimab in non-small cell lung cancer (“NSCLC”) in the United States. Our estimates of market potential have been derived from a variety of sources, including scientific literature, patient foundations and primary and secondary market research, and may prove to be incorrect. Even if we obtain significant market share for any product candidate, if approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications.

We have never obtained marketing approval for a development candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our development candidates.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our development candidates or may conclude after review of our data that our application is

insufficient to obtain marketing approval of our development candidates. If the FDA does not accept or approve our NDAs for our development candidates, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our development candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Development of THIO could take longer, be more expensive, or become impractical if the FDA requires the use of an FDA-approved companion diagnostic test in conjunction with treatment with THIO.

THIO is active in cells that are telomerase positive (TERT+). The status of a tumor as being TERT+ can only be established by use of an in vitro test of the tumor cells. While experimental versions of such tests currently exist, none to date have received FDA approval. Under current FDA Guidances, for drugs and therapeutic biologics where the use of a specific diagnostic test is essential for the safe and effective use of the therapeutic product, such as when the use of a product is limited to a specific patient subpopulation that can be identified by using the test, the FDA generally will not approve the therapeutic product if a relevant "companion diagnostic" test is not also approved or cleared for the appropriate indication. As stated in its Guidances, the FDA may decide that it is appropriate to approve such a therapeutic product without an approved or cleared *in vitro* companion diagnostic device when the drug or therapeutic biologic is intended to treat a serious or life-threatening condition for which no satisfactory alternative treatment exists and the FDA determines that the benefits from the use of a product with an unapproved or uncleared *in vitro* companion diagnostic device are so pronounced as to outweigh the risks from the lack of an approved or cleared *in vitro* companion diagnostic device. Although the vast majority of cancers are TERT+, the FDA may determine that THIO can only be approved (if at all) for patients whose cancer has been confirmed to be TERT+ through use of an FDA-approved companion diagnostic. If the FDA were to take such a position, the development and potential approval and commercialization of THIO would take longer, be more expensive, and could become impractical.

Even if we obtain FDA approval for THIO or any other candidates in the United States, we may never obtain approval for or commercialize THIO or any other development candidate in any other jurisdiction, which would limit our ability to realize their full global market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for THIO or any development candidate, we will still face extensive and ongoing regulatory requirements and obligations and any development candidates, if approved, may face future development and regulatory difficulties.

Any candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and Good Clinical Practice, or GCP, requirements for any clinical trials that we conduct post-approval.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If any of our product candidates receive marketing approval, the accompanying label may limit the approved indicated use of the product candidate, which could limit sales of the product candidate. The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Further, the FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

We may seek a Breakthrough Therapy designation for THIO from the FDA. However, we might not seek such designation or be granted the designation by the FDA if sought, and even if we are granted the designation, it may not lead to a faster development or regulatory review or approval process.

We may seek a Breakthrough Therapy designation for THIO or one or more of our other candidates. Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). For purposes of Breakthrough Therapy designation, clinically significant endpoint generally refers to an endpoint that measures an effect on irreversible morbidity or mortality (IMM) or on symptoms that represent serious consequences of the disease. A clinically significant endpoint can also refer to findings that suggest an effect on IMM or serious symptoms. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for fast track designation (under a separate request), priority review, or accelerated approval, if supported by clinical data at the time the NDA is submitted to the FDA. FDA encourages a Breakthrough Therapy designation request to be submitted, and received by FDA, no later than the end-of-phase-2 meetings. Even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA.

Designation as a Breakthrough Therapy is within the discretion of the FDA both at the time of the submission of such a request, and during FDA's review of the drug and supporting data. Even if we believe that one of our candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation or may grant such a designation and subsequently rescind the designation prior to approval. Even if we receive and maintain Breakthrough Therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate

approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of THIO or any other candidates we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize THIO or any other product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased market demand for any product; and
- loss of revenue.

The product liability insurance coverage we plan to acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. We intend to acquire insurance coverage to include larger clinical studies, different countries and the potential sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect the results of our operations and business, including preventing or limiting the commercialization of any product candidates we develop.

Risks Related to Commercialization

We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost-effective basis and to market them successfully. If THIO is approved, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies in the United States and other jurisdictions. These organizations may have significantly greater resources than we do and may conduct similar research; seek patent protection; and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with us.

Our competitors may, among other things:

- have significantly greater name recognition, financial, manufacturing, marketing, drug development, technical, and human resources than we do, and future mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors;
- develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe effects;
- obtain quicker regulatory approval;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel; establishing clinical trial sites and patient registration; and in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, or are more convenient or are less expensive than THIO. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may

obtain approval for THIO, which could result in our competitors establishing or strengthening their market position before we are able to enter the market.

We may face early generic competition for THIO or our other products.

Pharmaceutical companies developing novel products face intense competition from generic drug manufacturers who aggressively seek to challenge patents and non-patent exclusivities for branded products, and who are able to use much less-onerous product development and FDA approval pathways for their generic products. The active ingredient of THIO was extensively tested as early as the 1970s and we intend to rely in part on the clinical data previously developed for the drug in support of an NDA for THIO. Generic drug applicants and other competitors may be able to similarly rely upon the prior clinical data in support of efforts to gain approval of competing products using the same active ingredient as THIO. If one or more such competitors complete development and seek and obtain regulatory approval before we do, our ability to obtain approval of and market THIO may be delayed.

Under the FDA's generic drug approval processes, described in more detail in the section titled "Hatch-Waxman and Generic Competition," we believe that THIO, if approved before any other application for a drug containing the same active ingredient, may be eligible for a five-year regulatory exclusivity period known as new chemical entity, or NCE Exclusivity, which would delay FDA review and approval of a competing product application that relies in whole or in part upon the FDA's approval of THIO, but such exclusivity is only determined by the FDA after a drug is approved and the FDA may determine that THIO is not eligible for NCE Exclusivity, or that approval of THIO must be delayed due to another applicant's relevant exclusivity. A new drug may, upon approval of its initial NDA or approval of supplemental NDAs, qualify for a three-year exclusivity period during which no generic version could be approved for the specific conditions of use covered by such exclusivity. Three-year exclusivity does not prevent FDA approval of another drug with the same active ingredient for a different indication or other conditions of use not protected by the exclusivity. Even if a competing version of THIO was approved with a different indication or condition of use, physicians would be free to prescribe such drug for uses that are covered by our regulatory exclusivity, if any.

The successful commercialization of THIO and any other candidate we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as THIO, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our drug and any other product candidates we develop. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when a comparable alternative drug, an equivalent generic drug, a biosimilar, or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as alternatives to less expensive drugs and offer to reimburse patients only for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return

on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

We may also be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost-containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits.

Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if THIO or any candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If THIO or any candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing THIO, if approved.

We do not have any infrastructure for the sales, marketing or distribution of THIO, or compliance functions related to such activities, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market and successfully commercialize our drug or any product candidate we develop, if approved, we must build our sales, distribution, marketing, managerial, compliance, and other non-technical capabilities or make arrangements with third parties to perform these services. We expect to build a focused sales, distribution and marketing infrastructure to market THIO, if approved, in the United States, with expected licenses in other countries and regions, including large markets such as Japan and Europe. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, oversee the compliance of sales and marketing functions, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, distribution and compliance capabilities could delay any product launch, which would adversely impact the commercialization of that product. For example, if the commercial launch of THIO for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for

any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include, but are not limited to:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates, if approved, in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in a product and such collaborator's ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of THIO, if approved, for certain markets overseas; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of THIO, we may be forced to delay the potential commercialization of the drug or reduce the scope of our sales or marketing activities. If we need to increase our expenditures to fund commercialization activities for THIO we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We may also have to enter into collaborative arrangements for THIO at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to it or otherwise agree to terms unfavorable to us. Any of these occurrences may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may never become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

A variety of risks associated with operating internationally could materially adversely affect our business.

In July 2021, we established a wholly owned Australian subsidiary, MAIA Biotechnology Australia Pty Ltd, to conduct various pre-clinical and clinical activities for the development of our product candidates and in April 2022, we established a wholly owned Romanian subsidiary, MAIA BIOTECHNOLOGY ROMANIA S.R.L. to conduct various preclinical and clinical activities for the development of our product candidates. Additionally, our business strategy includes potentially expanding further internationally if any of our product candidates receive regulatory approval. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- the expansion of the Russian military invasion of Ukraine;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm any future international expansion and operations and, consequently, our results of operations.

Risks Related to Our Dependence on Third Parties

Our employees and independent contractors, including principal investigators, clinical trial sites, contract research organizations ("CROs"), consultants, vendors, and any third parties we may engage in connection with development and commercialization, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Our employees and independent contractors, including principal investigators, clinical trial sites, consultants, vendors and any third parties we may engage in connection with development and commercialization of our product candidates, could engage in misconduct, including intentional, reckless or negligent conduct or unauthorized activities that violate: the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse and other healthcare laws and regulations; or laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of THIO and intend to rely on CMOs for the production of commercial supply of THIO, if approved. Our dependence on CMOs may impair the development and commercialization of the drug, which would adversely impact our business and financial position.

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials and commercial quantities of THIO and any candidates we develop, if approved. Reliance on CMOs may expose us to more risk than if we were to manufacture our product candidates ourselves. We intend to have manufactured a sufficient clinical supply of THIO drug substance to enable us to complete our clinical trials, and we have also engaged a CMO to provide clinical and commercial supply of the drug product.

The facilities used to manufacture our product candidates must be inspected by the FDA and comparable foreign authorities. While we provide oversight of manufacturing activities, we do not and will not control the execution of manufacturing activities by, and are or will be essentially dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates. As a result, we are subject to the risk that our product candidates may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacture of our product candidates or that obtained approvals could be revoked. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

We rely on and will continue to rely on CMOs to purchase from third-party suppliers the raw materials necessary to produce our product candidates. We do not and will not have control over the process or timing of the acquisition of these raw materials by our

CMOs. Moreover, we currently do not have any agreements for the production of these raw materials. Supplies of raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternative suppliers to prevent a possible disruption of the manufacture of our product candidates.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

We intend to continue to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We rely, and will continue to rely, on CROs, CRO-contracted vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including our Phase 2 trials of THIO. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards.

We and our CROs will be required to comply with the good laboratory practice requirements for our preclinical studies and GCP requirements for our clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Accordingly, if our CROs fail to comply with these requirements, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our clinical trials. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with any CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

The number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers and the loss of, or a disruption in our relationship with, any one or more collaborators could harm our business.

If any collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our continued development of our

product candidates could be delayed, and we may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of any collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all.

In addition, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of our product candidates. If a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of our business and our stock price could be adversely affected.

We may in the future collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our programs, and our business may be materially and adversely affected.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our development candidates, if approved, and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, has substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted, or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- expansion of the entities eligible for discounts under the Public Health Service program; and

- a licensure framework for follow on biologic products.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. It is uncertain the extent to which any such changes may impact our business or financial condition.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The

U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, or FCA, which, among other things, impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. A claim includes "any request or demand" for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with physicians and other healthcare providers, some of whom receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary

fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Any clinical trial programs we conduct or research collaborations we enter into in the European Economic Area may subject us to the General Data Protection Regulation.

If we conduct clinical trial programs or enter into research collaborations in the European Economic Area, or EEA, we may be subject to the General Data Protection regulation, or GDPR. The GDPR applies extraterritorially and implements stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data, robust disclosures to individuals, a comprehensive individual data rights regime, data export restrictions governing transfers of data from the EEA/European Union, or EU, to other jurisdictions, short timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data, other special categories of personal data and coded data and additional obligations if we contract third-party processors in connection with the processing of personal data. The United Kingdom has implemented its own version of the GDPR, which contains similar requirements. The GDPR provides that EU member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

Recent legislation may materially adversely affect our financial condition, results of operations and cash flows.

Recently enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, and revising the rules governing NOLs. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, or the IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

The reduction of the corporate tax rate under the legislation may cause a reduction in the economic benefit of deferred tax assets available to us. Furthermore, under the legislation, although the treatment of tax losses generated before December 31, 2017, has generally not changed, tax losses generated in calendar year 2018 and beyond will only be able to offset 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going-forward basis. We intend to work with our tax advisors and auditors to determine the full

impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation.

Risks Related to Our Intellectual Property

We depend on license agreements with the University of Texas Southwestern, or UTSW, to permit us to use patents and patent applications, as well as to exploit specific technological know-how. Termination of these rights or the failure to comply with obligations under these agreements could materially harm our business and prevent us from developing or commercializing our product candidates.

We are a party to license agreements with UTSW under which we were granted rights to patents and patent applications, as well as proprietary technologies, that are important and necessary to our business. Our rights to use these patents and patent applications and employ the inventions claimed in these licensed patents, as well as the exploitation of proprietary technology, are subject to the continuation of, and our compliance with, the terms of our license agreements.

Our license agreements impose upon us various diligence, payment and other obligations, including the following:

- our obligation to pay UTSW various milestone payments;
- our obligation to pay UTSW royalties based on net sales; and
- our obligation to pay UTSW fees associated with the prosecution, maintenance, or filing of the patents and patent applications we have licensed.

If we fail to comply with any of our obligations under the license agreements, or we are subject to a bankruptcy or dissolution, UTSW may have the right to terminate their respective license agreements, in which event we would not be able to market any product candidates covered by the licenses.

We do not currently own any patents, and we are heavily reliant upon licenses from UTSW to certain patent rights that are important or necessary to the development of our technology and product candidates. As a result, we may be limited in our ability to prevent competitors from developing and commercializing competitive products.

We do not control the prosecution, maintenance, or filing of the patents and patent applications that are licensed to us under the license agreements. Thus, these patents and patent applications were not drafted by us or our attorneys, and we do not directly control the prosecution of these patents and patent applications. We cannot be certain that drafting or prosecution of the patents and patent applications licensed to us has been conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. UTSW directly controls the preparation, filing and prosecution of patent applications, and is responsible for maintaining the patents, covering technology that we license.

If we fail to comply with the obligations under our license agreement, including as a result of COVID-19 impacting our operations or due to lack of funds, or if we use the licensed intellectual property in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreement is terminated, we may not be able to develop, manufacture, market or sell the product candidates covered by our agreement. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement.

Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate the intellectual property of the licensor that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over

intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's rights.

In addition, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to seek alternative options, such as developing new product candidates with design-around technologies, which may require more time and investment, or abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

We have been granted licenses of use to patent applications. There can be no assurance that any of the patent applications that we have licenses to will result in issued patents. As a result, our ability to protect our proprietary technology in the marketplace may be limited.

We have been granted licenses of use to patent applications in many countries worldwide. These applications cover a range of treatment methods. Unless and until the pending patent applications are issued, their protective scope is impossible to determine. It is also impossible to predict whether or how many of the patent applications will result in issued patents. Even if pending applications are issued, they may be issued with coverage significantly narrower than what is currently sought.

Our proprietary position for our product candidates currently depends in part upon licenses to patents protecting methods of use, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition of matter patent claims on the active pharmaceutical ingredient, or API, in pharmaceutical drug products are generally considered to be the favored form of intellectual property protection for pharmaceutical products, as such patents generally provide protection without regard to any particular method of use, manufacture or formulation of the API used. Method of use patent claims protect the use of a product for the specified method. These types of patent claims do not prevent a competitor or other third party from making and marketing an identical API for an indication that is outside the scope of the method claims. Moreover, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Our patents may be challenged in courts or in patent offices which could result in the invalidation, narrowing or unenforceability of our patents and our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

There is no assurance that all the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents further cover THIO or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to any patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period during which we could market a product candidate under patent protection could be reduced.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. However, in certain instances, the laws of the United States are more restrictive than those of foreign countries. For example, a recent series of Supreme Court Cases has narrowed the types of subject matter considered eligible for patenting. Accordingly, certain diagnostic methods are considered ineligible for patenting because they are directed to a "law of nature." Further, publications of discoveries in scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated, held unenforceable, in whole or in part, or reduced in term. Such a result could limit our ability to stop others from using or commercializing similar or identical technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become subject to third parties' claims alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to protect or enforce our patents, which could be costly and/or time consuming, delay or prevent the development and commercialization of our product candidates or put our patents and other proprietary rights at risk.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, *inter partes* review, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors.

Numerous U.S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We may be subject to third-party claims including infringement, interference, or derivation proceedings before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if we believe third party infringement claims are without merit, a court of competent jurisdiction could hold that the third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable.

Proceedings challenging our patents or those that we license may also result in our patent claims being invalidated or narrowed in scope. Similarly, if our patents or patent applications are challenged during interference or derivation proceedings, a court may hold that a third-party is entitled to certain patent ownership rights instead of us. Further, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, methods of manufacture, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable.

Defending such claims would cause us to incur substantial expenses and, if unsuccessful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights. If we are found to have infringed such rights willfully, the damages may be enhanced and may include attorneys' fees. Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated.

As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require us to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which could give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. Modifying our product candidates to design around third-party intellectual property rights may result in significant cost or delay to us and could prove to be technically infeasible.

Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of eligibility, lack of novelty, obviousness or non-enablement. Third parties might allege unenforceability of our patents because someone connected with prosecution of the patent withheld relevant information, or made a misleading statement, during prosecution.

The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Furthermore, our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing on our patents or other intellectual property rights.

Additionally, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected.

Finally, even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop, manufacture and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our future product candidates, or their manufacture or use may currently be unpublished. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

From time to time we may identify patents or applications in the same general area as our products and product candidates. We may determine these third-party patents are irrelevant to our business based on various factors including our interpretation of the scope of the patent claims and our interpretation of when the patent expires. If the patents are asserted against us, however, a court may disagree with our determinations. Further, while we may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, our determination may be incorrect, and the issuing patent may be asserted against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates so that we no longer infringe on the third-party intellectual property rights.

Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical and pharmaceutical industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical and pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act (AIA) which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent with the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. In addition, the USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and the EU, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us.

We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries having similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of a patent covering each product candidate under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a non-expired patent which claims a human drug product, a method of using the product, or a method of manufacturing the product, as compensation for effective patent term lost during product development and the FDA

regulatory review process. Moreover, only one patent may be extended covering the drug product and the total patent term including the extension cannot exceed 14 years following regulatory approval. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

Further, under certain circumstances, patent terms covering our products or product candidates may be extended for time spent during the pendency of the patent application in the USPTO (referred to as Patent Term Adjustment, or PTA). The laws and regulations underlying how the USPTO calculates the PTA is subject to change and any such PTA granted by the USPTO could be challenged by a third-party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, resulting in a shorter patent term, which may negatively impact our ability to exclude competitors. Because PTA added to the term of patents covering pharmaceutical products has particular value, our business may be adversely affected if the PTA is successfully challenged by a third party and our ability to exclude competitors is reduced or eliminated.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We may develop, acquire, or license intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

For example, some of our intellectual property, including the intellectual property licensed from the University of Texas Southwestern Medical Center was funded in whole or in part by the United States government, the United States government has certain rights to such patent rights and technology, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes and march-in rights, and impose certain reporting and domestic manufacturing requirements. These rights may permit the United States government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to United States industry. In addition, our rights in such inventions are and may be subject to certain requirements to manufacture products embodying such inventions in the United States. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

Intellectual property rights do not address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to THIO or our future product candidates but that are not covered by the claims of the patents that we own or license from others;
- others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights;
- we or any of our collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership of our patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. Because we expect to rely on third parties to manufacture THIO and any future product candidates, and we expect to collaborate with third parties on the development of THIO and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. However, trade secrets or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for any other of our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our clinical-stage product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. The EMA may also object to our proposed proprietary product name that infringes the existing rights of third parties.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development or commercialization of THIO or our future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize THIO or our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, which could materially harm our business. At this time, we are unaware of any intellectual property that interferes with ours or is complementary and needed to commercialize THIO.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership or right to use. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Our proprietary information may be lost, or we may suffer security breaches.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, disruption of our operations, damage to our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

Risks Related to Our Employees, Managing Our Growth and Our Operations

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

We are highly dependent on the development, regulatory, commercialization and business development expertise of Vlad Vitoc and Mihail Obrocea, as well as the other principal members of our management, scientific and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop product candidates, gain regulatory approval, and commercialize new products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize product candidates will be limited.

We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or acquire new facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of THIO or any other product candidate could be delayed.

Risks Relating to Our Common Stock

An active, liquid trading market for our common stock may not develop.

Our common stock was listed and began trading on the NYSE American on July 28, 2022 under the symbol "MAIA." Prior to the listing, there was no public market for our common stock. An active trading market for shares of our common stock may never develop or be sustained. If an active trading market does not develop, you may have difficulty selling any of our shares that you purchase.

The price of our common stock may be volatile.

Securities markets worldwide have experienced in the past, and are likely to experience in the future, significant price and volume fluctuations. This market volatility, as well as general economic, market, or political conditions could reduce the market price of our common stock regardless of our results of operations. The trading price of our common stock has been and is likely to continue to be volatile and could be subject to wide price fluctuations in response to various factors including, among other things, the risk factors described herein and other factors beyond our control. Factors affecting the trading price of our common stock could include, but are not limited to:

- market conditions in the broader stock market;
- actual or anticipated variations in our quarterly results of operations;
- developments in our industry in general;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- adverse results or delays in clinical trials;
- failure to commercialize our product candidates;
- unanticipated serious safety concerns related to the use of our product candidates;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- issuance of new, negative or changed securities analysts' reports or recommendations or estimates;
- sales, or anticipated sales, of our stock, including sales by our officers, directors and significant stockholders;
- additions or departures of key personnel;
- regulatory or political developments;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC;
- announcements, media reports or other public forum comments related to litigation, claims or reputational charges against us;
- guidance, if any, that we provide to the public, any changes in this guidance, or our failure to meet this guidance;
- the development and sustainability of an active trading market for our common stock;
- investor perceptions of the investment opportunity associated with our common stock relative to other investment alternatives;
- other events or factors, including those resulting from system failures and disruptions, earthquakes, hurricanes, war, acts of terrorism, global outbreaks or pandemic, other natural disasters or responses to these events;
- changes in accounting principles;
- litigation and governmental investigations; and
- changing economic conditions.

These and other factors may cause the market price and demand for shares of our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

We could be subject to securities class action litigation.

In the past, when the market price of a stock has been volatile, holders of that stock sometimes have instituted securities class action litigation against the company that issued the stock following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. Securities litigation against us, regardless of the merits or outcome, could result in substantial costs and divert the time and attention of our management from our business, which could have a material adverse effect on our business, financial condition, and results of operations.

Future sales of our common stock, or the perception in the public markets that these sales may occur, could cause the market price for our common stock to decline.

At the time of this date of this Annual Report on Form 10-K, 632,703 shares of common stock are reserved for issuance under our 2021 Equity Incentive Plan. We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Sales of substantial amounts of shares of our common stock in the public market, or the perception that those sales will occur, could cause the market price of our common stock to decline. Of the shares of common stock outstanding, 8,350,367 are restricted securities within the meaning of Rule 144 under the Securities Act and subject to certain restrictions on resale. Restricted securities may be sold in the public market only if they are registered under the Securities Act, or are sold pursuant to an exemption from registration such as Rule 144 or Rule 701.

We, each of our officers, directors, and certain of our stockholders agreed in connection with our initial public offering, which was consummated on August 1, 2022, subject to certain exceptions, not to offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, for a period of 12 months after the date of the prospectus in our initial public offering, without the prior written consent of the representative. Certain of our other stockholders, who are not insiders, have agreed, subject to certain exceptions, not offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, for a period of 12 months after the date of the prospectus, without the prior written consent of the representative. Following the expiration of the applicable lock-up period, all of the issued and outstanding shares of our common stock will be eligible for future sale, subject to the applicable volume, manner of sale, holding period, and other limitations of Rule 144. Following the expiration of the applicable lock-up period, all of the issued and outstanding shares of our common stock will be eligible for future sale, subject to the applicable volume, manner of sale, holding period, and other limitations of Rule 144.

We do not intend to pay dividends for the foreseeable future, and our ability to pay dividends to our stockholders is restricted by applicable laws and regulations.

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. As a result of our current dividend policy, you may not receive any return on an investment in our common stock unless you sell our common stock for a price greater than that which you paid for it. Any future determination to declare and pay cash dividends will be at the discretion of our board of directors and will depend on, among other things, our financial condition, results of operations, cash requirements, contractual restrictions and such other factors as our board of directors deems relevant. Our ability to declare and pay dividends to our stockholders is subject to certain laws, regulations, and policies, including minimum capital requirements and, as a Delaware corporation, we are subject to certain restrictions on dividends under the Delaware General Corporation Law (the "DGCL"). Under the DGCL, our board of directors may not authorize payment of a dividend unless it is either paid out of our surplus, as calculated in accordance with the DGCL, or if we do not have a surplus, it is paid out of our net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. Our ability to pay dividends depends on our receipt of cash dividends from our operating subsidiaries, which may further restrict our ability to pay dividends as a result of the laws of their jurisdiction of organization or agreements of our subsidiaries, including agreements governing our indebtedness. For more information, see "*Dividend Policy*."

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law. Pursuant to our amended and restated bylaws and the DGCL, our directors will not be liable to the Company or any stockholders for damages for any breach of fiduciary duty, except (i) acts that breach his or her duty of loyalty to the Company or its stockholders; (ii) acts or omissions without good faith or involving intentional misconduct or knowing violation of the law; (iii) pursuant to Section 174 of the DGCL regarding director liability for

unlawful payment of a dividend or unlawful stock purchase or redemption; or (iv) for any transaction from which the director derived an improper personal benefit. In addition, we have entered into indemnification agreements with each of our executive officers and directors. The indemnification agreements provide the executive officers and directors with contractual rights to indemnification, expense advancement and reimbursement, to the fullest extent permitted under the DGCL. The bylaws also require us, if so requested, to advance expenses that such director or officer incurred in defending or investigating a threatened or pending action, suit or proceeding, provided that such person will return any such advance if it is ultimately determined that such person is not entitled to indemnification by us. Any claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

We may, in the future, issue additional capital stock, which would reduce investors' percent of ownership and may dilute our share value.

We have the right to raise additional capital or incur borrowings from third parties to finance our business. We may also implement public or private mergers, business combinations, business acquisitions and similar transactions pursuant to which it would issue substantial additional capital stock to outside parties, causing substantial dilution in the ownership of the Company by our existing stockholders. Our Board of Directors has the authority, without the consent of any of the stockholders, to cause us to issue more shares of common stock and/or preferred stock at such price and on such terms and conditions as are determined by the Board of Directors in its sole discretion. The issuance of additional shares of capital stock by us will dilute your ownership percentage in the Company and could impair our ability to raise capital in the future through the sale of equity securities.

Certain stockholders who are also officers and directors of the Company may have significant control over our management.

Our directors and executive officers own as of March 22, 2022, an aggregate of 3,581,804 shares of our common stock, which constitutes 32.5% of our issued and outstanding common stock. As a result, our directors and executive officers may have a significant influence on our affairs and management, as well as on all matters requiring stockholder approval, including electing and removing members of our Board of Directors, causing us to engage in transactions with affiliated entities, causing or restricting our sale or merger, and certain other matters. Such concentration of ownership and control could have the effect of delaying, deferring or preventing a change in control of us even when such a change of control would be in the best interests of our stockholders.

Anti-takeover protections in our amended and restated certificate of incorporation and our amended and restated bylaws, or our contractual obligations may discourage or prevent a takeover of our Company, even if an acquisition would be beneficial to our stockholders.

Provisions contained in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of the DGCL, could delay or make it more difficult to remove incumbent directors or could impede a merger, takeover or other business combination involving us or the replacement of our management, or discourage a potential investor from making a tender offer for our common stock, which, under certain circumstances, could reduce the market value of our common stock, even if it would benefit our stockholders. Among other things, these provisions:

- do not permit cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;
- delegate the sole power of a majority of the board of directors to fix the number of directors;
- provide the power to our board of directors to fill any vacancy on our board of directors, whether such vacancy occurs as a result of an increase in the number of directors or otherwise;
- generally limit stockholders ability to call special meetings of stockholders and generally prohibit stockholder action to be taken by written consent; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, agents or other stockholders.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for any (i) derivative action or proceeding brought on our behalf, (ii) action asserting a claim of breach of a fiduciary duty or other wrongdoing by any current or former director, officer, employee, agent or stockholder to us or our stockholders, (iii) any action or proceeding asserting a claim against us or any current or former director, officer or other employee of the company, arising out of or pursuant to arising under any provision of the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) action asserting a claim governed by the internal affairs doctrine of the law of the State of Delaware, except for, as to each of (i) through (iv) above, any action as to which the Court of

Chancery of the State of Delaware determines that there is an indispensable party not subject to the personal jurisdiction of the Court of Chancery of the State of Delaware (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery of the State of Delaware within ten (10) days following such determination), in which case the United States District Court for the District of Delaware or other state courts of the State of Delaware, as applicable, shall, to the fullest extent permitted by law, be the sole and exclusive forum for any such claims. However, the exclusive forum provisions shall not apply to suits brought to enforce a duty or liability created by the Securities Act, the Securities Exchange Act of 1934, as amended (the "Exchange Act") or any other claim for which the federal courts have exclusive jurisdiction, for which the federal district courts of the District of Delaware shall be the sole and exclusive forum unless the Company consents in writing to the selection of an alternative forum. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. To the fullest extent permitted by law, any person or entity purchasing or otherwise acquiring or holding any interest in any shares of our capital stock shall be deemed to have notice of and consented to the forum provision in our amended and restated bylaws. This choice of forum provision may limit a stockholder's ability to bring a claim in a different judicial forum, including one that it may find favorable or convenient for a specified class of disputes with us or our directors, officers, other stockholders, or employees, which may discourage such lawsuits, make them more difficult or expensive to pursue, and result in outcomes that are less favorable to such stockholders than outcomes that may have been attainable in other jurisdictions. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition and results of operations.

We are considered a "smaller reporting company" and are exempt from certain disclosure requirements, which could make our stock less attractive to potential investors.

Rule 12b-2 of the Exchange Act defines a "smaller reporting company" as an issuer that is not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent that is not a smaller reporting company and that:

- Had a public float of less than $250 million as of the last business day of its most recently completed fiscal quarter, computed by multiplying the aggregate number of worldwide number of shares of its voting and non-voting common equity held by non-affiliates by the price at which the common equity was last sold, or the average of the bid and asked prices of common equity, in the principal market for the common equity; or
- In the case of an initial registration statement under the Securities Act or the Exchange Act for shares of its common equity, had a public float of less than $250 million as of a date within 30 days of the date of the filing of the registration statement, computed by multiplying the aggregate worldwide number of such shares held by non-affiliates before the registration plus, in the case of a Securities Act registration statement, the number of such shares included in the registration statement by the estimated offering price of the shares; or
- In the case of an issuer who had annual revenue of less than $100 million during the most recently completed fiscal year for which audit financial statements are available, had a public float as calculated under paragraph (1) or (2) of this definition that was either zero or less than $700 million.

As a "smaller reporting company" we are not required and may not include a Compensation Discussion and Analysis section in our proxy statements; we provide only 3 years of business development information; provide fewer years of selected data; and have other "scaled" disclosure requirements that are less comprehensive than issuers that are not "smaller reporting companies" which could make our stock less attractive to potential investors, which could make it more difficult for you to sell your shares.

We are considered an "emerging growth company," and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non-affiliates exceeds $700 million as of the end of our prior second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or

revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

General Risk Factors

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters may materially impact reporting of our financial condition and results of operations.

Accounting principles generally accepted in the United States and related accounting pronouncements, implementation guidelines, and interpretations we apply to a wide range of matters that are relevant to our business, such as accounting for long-lived asset impairment and share-based compensation, are complex and involve subjective assumptions, estimates and judgments by our management. Changes in these rules or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change or add significant volatility to our reported or expected financial performance.

Our failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, financial condition, and results of operations.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles ("GAAP"). Under standards established by the Public Company Accounting Oversight Board ("PCAOB") and the Exchange Act, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB and Rule 12b-2 of the Exchange Act define a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented, or detected and corrected, on a timely basis.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of our IPO and in each year thereafter. Our auditors will also need to attest to the effectiveness of our internal control over financial reporting upon losing our Emerging Growth Company status and becoming an accelerated filer or a large accelerated filer. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected, and we could become subject to litigation or investigations by the stock exchange on which our common stock are listed, the SEC or other regulatory authorities, which could require additional financial and management resources and could have a material adverse effect on our business, financial condition, and results of operations.

The lack of public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U.S. securities laws, which could have a materially adverse effect on our business.

Our officers have limited public company experience, which could impair our ability to comply with legal and regulatory requirements such as those imposed by Sarbanes-Oxley Act. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Any such deficiencies, weaknesses or lack of compliance could have a materially adverse effect on our ability to comply with the reporting requirements of the Exchange Act, which is necessary to maintain our public company status. If we were to fail to fulfill those obligations, our ability to continue as a U.S. public company would be in jeopardy in which event you could lose your entire investment in our Company.

We identified material weaknesses in our internal control over financial reporting, and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Upon becoming a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our controls over financial reporting. Although we are required to disclose changes made in our internal controls and procedures on a quarterly basis, we will not be required to make our first annual assessment of our internal controls over financial reporting pursuant to Section 404 until the year following our first annual report

required to be filed with the SEC. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on the effectiveness of our internal control over financial reporting, provided that our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the Securities and Exchange Commission, or SEC, following the later of the date we are deemed to be an "accelerated filer" or a "large accelerated filer," each as defined in the Exchange Act, or the date we are no longer an emerging growth company, as defined in the JOBS Act. We could be an emerging growth company for up to five years.

We identified deficiencies in our internal control that we consider to be material weaknesses in our internal control over financial reporting which existed as of December 31, 2022. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

The Company did not maintain an effective control environment as there was an insufficient complement of personnel within the finance and accounting function with appropriate degree of knowledge, experience and training in the application of U.S. generally accepted accounting principles ("U.S. GAAP). These factors contributed to the following additional material weaknesses.

We failed to design, implement and maintain effective controls regarding:

- risks associated with segregation of duties.
- risks associated with accounting for non-recurring complex transactions.

As we work towards remediating these material weaknesses, we will design and implement controls to properly account for non-recurring complex transactions in accordance with U.S. generally accepted accounting principles. In addition, we will design, document, and consistently perform control activities in the identified areas which are currently lacking. To assist us in the remediation and performance of remediated controls we hired a Corporate Controller, and we will continue to utilize an accounting and financial reporting advisory firm with significant experience with publicly held companies to assist our management in evaluating the accounting treatment for complex transactions.

We may identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley, and we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. We cannot assure that our existing material weakness will be remediated or that additional material weaknesses will not exist or otherwise be discovered, any of which could adversely affect our reputation, financial condition and results of operations.

Unanticipated changes in the insurance market or factors affecting self-insurance reserve estimates could have a material adverse effect on our business, financial condition and results of operations.

We use a combination of insurance and self-insurance coverage to provide for potential liabilities for workers' compensation, general liability, property losses, auto liability, directors and officers liability, pharmacy liability and employee health care benefits. However, there are types of losses we may incur but against which we cannot be insured or which we believe are not economically reasonable to insure, such as losses due to acts of war, employee and certain other crime, certain wage and hour and other employment-related claims, including class actions, actions based on certain customer protection laws, certain cyber events and some natural and other disasters or similar events. If we incur these losses and they are material, our business could suffer. Liabilities associated with the risks that are retained by us are determined, based in part, by considering historical claims experience, severity factors, inflation, and other actuarial assumptions. Our determination of the risk we retain is subject to a high degree of variability related to, among other things, future interest and inflation rates, future economic conditions, litigation trends and benefit-level changes. Any deviation of actual claims and other expenses related to these and other risks in excess of our assumptions, estimates, and historical trends, may have a material adverse effect on our business, financial condition and results of operations.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. In February 2022, Russia launched a full-scale military invasion of Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets. Additionally, Russia's prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic, including agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial

Telecommunication (SWIFT) payment system. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 10-K.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past led and may in the future lead to market-wide liquidity problems. On March 10 and March 12, 2023, the Federal Deposit Insurance Corporation ("FDIC") took control and was appointed receiver of Silicon Valley Bank ("SVB") and Signature Bank, respectively, after each bank was unable to continue its operations. We are unable to predict the extent or nature of the impacts of the failures of SVB and Signature Bank and related circumstances at this time. Similarly, we cannot predict the impact that the high market volatility and instability of the banking sector more broadly could have on economic activity and our business in particular. The failure of other banks and financial institutions and measures taken, or not taken, by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations.

Although we do not hold any of our funds at SVB or Signature Bank, if the financial institutions with which we do business enter receivership or become insolvent in the future, there is no guarantee that the Department of the Treasury, the Federal Reserve and the FDIC will intercede to provide us and other depositors with access to balances in excess of the $250,000 FDIC insurance limit, that we would be able to access our existing cash, cash equivalents and investments, that we would be able to maintain any required letters of credit or other credit support arrangements, or that we would be able to adequately fund our business for a prolonged period of time or at all, any of which could have a material adverse effect on our business, financial condition and results of operations. In addition, if any parties with which we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to continue to fund their business and perform their obligations to us could be adversely affected, which, in turn, could have a material adverse effect on our business, financial condition and results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our headquarters is in Chicago, Illinois where we currently lease office space with approximately 124 square feet under a six month lease starting in October 2022, under which we currently pay $3,000 per month. We believe that this space is sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms. Additionally, we intend to maintain our business model designed to leverage virtual technology to minimize brick and mortar facilities while optimizing our ability to attract top talented employees that may reside in any geography.

Item 3. Legal Proceedings.

At the date of the Annual Report on Form 10-K, we are not party to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 4. Mine Safety Disclosures.

Not applicable

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information and Holders

Our common stock is traded on NYSE American under the symbol "MAIA". As of March 22, 2023, 10,996,404 shares of the Company's common stock were issued and outstanding and were owned by approximately 136 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, future debt instruments may materially restrict our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of the board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of current or then-existing debt instruments and other factors the board of directors deems relevant

Recent Sales of Unregistered Securities

During January and February 2022, we issued and sold 263,729 shares of our common stock with an aggregate principal amount of approximately $2.4 million.

Between April 22, 2022 and May 3, 2022, warrant holders exercised warrants, resulting in the issuance of 153,000 shares of common stock for proceeds of approximately $275,400.

In May 2022, we issued and sold 11,111 shares of our common stock with an aggregate principal amount of approximately $0.1 million.

On December 18, 2022, we entered into an agreement with FORCE Family Office, LLC ("Force") for the provision of investor relations services from January 16, 2023 through July 16, 2023, pursuant to which we issued 18,000 shares of common stock on January 16, 2023. Pursuant to the agreement, we also agreed to issue an additional 18,000 shares of common stock on April 16, 2023 unless the agreement is terminated beforehand.

On March 8, 2023, we entered into an agreement with The Money Channel NYC Inc. for media services, pursuant to which we agreed to issue 22,500 shares of common stock on March 8, 2023 and an additional 22,500 shares of common stock every ninety days after the execution date of the contract until termination of the agreement. The term of the agreement extends for 180 days, and renews automatically until we provide written notice prior to the end of the term.

Between January 1, 2021 and August 1, 2022, we granted to our employees, officers, directors and other persons who provide services to us options to purchase up to 2,634,513 shares of common stock under the 2018 Stock Option Plan and the Amended and Restated 2020 Stock Option Plan, at a weighted average exercise price of $3.21 per share. In addition, we issued to certain persons who provided services to us and in conjunction with convertible notes, warrants to purchase up to 769,865 shares of our common stock at a weighted average exercise price of $6.04 per share, which expire at various dates through September 2028 and vested upon issuance.

No underwriters were involved in the foregoing issuances of securities. The securities described above were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The recipient of securities in the transactions described above represented that it was an accredited investor and was acquiring the securities for their own account for investment purposes only, and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time and appropriate legends were affixed to the instruments representing such securities issued in such transactions.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion together with our financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that are based on our current expectations, estimates and projections about our business and operations. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors, including those which we discuss under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. See "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a clinical stage biotechnology company engaged in the discovery, development and commercialization of therapies targeting cancer. Our initial disease target is lung cancer, a serious medical condition with an incidence of over 235,000 new cases in the US in 2021, representing 12.4% of all cancers, and over 131,000 deaths, or 21.7% of all cancers. Worldwide, lung cancer incidence is over 2,200,000 per year (ranking second only after breast cancer), and mortality over 1,800,000 (ranking first). Specifically, we are targeting Non-Small Cell Lung Cancer (NSCLC), which represents 85% of all lung cancers.

We accomplished the following key milestones:

- In November 2018, we in-licensed THIO from University of Texas Southwestern, in Dallas. The patent license is global and exclusive for the duration of the patients' lives.
- In 2019, we completed a common stock seed round in the amount of $2 million.
- In 2019, we generated the first data for THIO demonstrating complete regression with no recurrence when administered in advance of atezolizumab (TecentriQ®; Genentech), in colorectal and lung cancer preclinical models.
- In the First Quarter 2020, we filed a provisional patent application for THIO in sequential combination with checkpoint inhibitors, covering all tumor types. The patent was allowed in the US in the First Quarter 2021 and expires in 2041.
- In the First Quarter 2021, we entered into a Drug Supply Agreement with Regeneron Pharmaceuticals, Inc. Under this agreement, Regeneron will provide cemiplimab (LIBTAYO; anti-PD-1 checkpoint inhibitor) at no charge for the THIO-101 trials, testing THIO administration for immune activation followed by cemiplimab in NSCLC. This drug supply agreement replaces direct drug purchase expense that we would be otherwise required to incur. In exchange, Regeneron received development exclusivity in NSCLC for the duration of the trial which is expected to be two years, meaning we cannot conduct trials in NSCLC with another checkpoint inhibitor during the time of the trial. All other areas of study and development in any other tumor types remain open.
- In the First Quarter 2021, we initiated our clinical supply manufacturing (CMC) under Good Manufacturing Practices (GMP) conditions to provide clinical supply for THIO-101 and other development needs.
- In the Second Quarter 2021, we completed a convertible note funding round in the amount of approximately $8 million.
- In the Third Quarter 2021 and Fourth Quarter 2021, we sold common shares of MAIA for total proceeds of approximately $6.2 million.
- In the First Quarter 2022, we completed the Crossover Round for total proceeds of approximately $2.4 million.
- In the First Quarter 2022, THIO received approval by the Bellberry Human Research Ethics Committee (HREC) in Australia to initiate the THIO-101 Phase 2 clinical study.
- In March 2022, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) to THIO for the treatment of hepatocellular carcinoma, and in May 2022, the FDA granted ODD to THIO for the treatment of small-cell lung cancer. The FDA's Office of Orphan Products Development may grant orphan designation status to drugs and biologics that are intended for the treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain benefits, including financial incentives, to support clinical development and the potential for up to seven years of market exclusivity for the drug for the designated orphan indication in the U.S. if the drug is ultimately approved for its designated indication.

- In May 2022, we completed the Additional Round for total proceeds of approximately $99,999.
- In May 2022, we entered into a research and collaboration agreement with the Nationwide Children's Hospital to evaluate the potential of THIO in combination with current standard-of-care therapies for brain cancer. The organizations is conducting preclinical studies to assess the efficacy and safety of THIO in combination with radiotherapy and immune checkpoint inhibitors in vitro and in vivo models.
- In July 2022, we completed our selection process for the clinical sites for our Phase 2 study in Australia and Europe and our application to start the Phase 2 study in Australia has been approved. In July 2022, the first patient was administered with THIO in our Phase 2 human trial (THIO-101) in Australia. We have also submitted a similar application to conduct the same Phase 2 study in Europe.
- On July 28, 2022, the Company's shares of common stock began trading on the NYSE American under the symbol MAIA. On August 1, 2022, the Company sold 2,000,000 shares of common stock at $5.00 per share for net proceeds of $10,000,000 in an initial public offering prior to deducting underwriting discounts, commissions, and other offering expenses. On August 3, 2022, the Company sold an additional 300,000 shares of common stock at $5.00 per share when the underwriter exercised the overallotment for net proceeds of $1,500,000 prior to deducting underwriting discounts, commissions, and other offering expenses. We believe we have raised sufficient capital to fund the THIO-101 lead-in and preliminary efficacy of the phase 2 THIO-101 trial.
- In December 2022, regulatory authorities in three European countries, Hungary, Poland, and Bulgaria, approved the implementation of THIO-101, MAIA's Phase 2 clinical trial. THIO-101 is a critical component of THIO's clinical development process and it is of the utmost importance that we collaborate with leading cancer institutes in Australia and now in Europe, for a target total of 30 clinical trial sites in six countries.
- In December 2022, we completed a pre-Investigational New Drug (pre-IND) meeting with the U.S. Food and Drug Administration (FDA) for the planned U.S. expansion of the THIO-101 Phase 2 trial evaluating THIO, an investigational telomere-targeting agent, in patients with advanced non-small cell lung cancer (NSCLC).
- In the first week of March 2023, the first two patients were dosed in Europe in MAIA's Phase 2 clinical trial, THIO-101 evaluating THIO in patients with advanced Non-Small Cell Lung Cancer (NSCLC). Following regulatory clearances in Hungary, Poland, and Bulgaria, five clinical sites have been activated in these three European countries.

Impact of the COVID-19 Pandemic on Our Operations

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 Outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 Outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 Outbreak continues to evolve as of the date of this report. As a result, we cannot estimate the full magnitude that the pandemic will have on our business. If the COVID-19 Outbreak continues, it may have a material adverse effect on our financial condition, liquidity, and future results of operations for the future. We are actively monitoring the impact of the global pandemic on our financial condition, liquidity, operations, industry, and workforce. Given the daily evolution of the COVID-19 Outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 Outbreak on our results of operations, financial condition, or liquidity for the future. One of our initial clinical studies is taking place in Australia, which initially imposed one of the strictest COVID-19-related measures, including lock-downs. While we are not currently experiencing any delays or increased costs as a result of these measures, we may do so in the future.

Impact of the War in Ukraine on Our Operations

The short and long-term implications of Russia's invasion of Ukraine are difficult to predict at this time. The imposition of sanctions and counter sanctions may have an adverse effect on the economic markets generally and could impact our business, financial condition, and results of operations. Because of the highly uncertain and dynamic nature of these events, the Company terminated any planned research activities in Russia.

Financial Operations Overview and Analysis For the Years Ended December 31, 2022 and 2021

Comparison of the Years Ended December 31, 2022 and 2021

	Year Ended December 31,		Change	
	2022	2021	Dollars	Percentage
Operating expenses:				
Research and development expenses	$ 8,933,314	$ 3,496,796	$ 5,436,518	155%
General and administrative expenses	6,143,527	4,289,831	1,853,696	43%
Ratchet share expense	1,099,360	—	1,099,360	100%
Total operating costs and expenses	16,176,201	7,786,627	8,389,574	108%
Loss from operations	(16,176,201)	(7,786,627)	(8,389,574)	108%
Other income (expense):				
Interest expense	(6,967)	(827,539)	820,572	(99)%
Interest income	1,870	2,012	(142)	(7)%
Australian research and development incentives	313,625	43,666	269,959	618%
Paycheck protection program loan forgiveness	—	62,500	(62,500)	(100)%
Change in fair value of embedded features	—	(203,000)	203,000	(100)%
Change in fair value of warrant liability	98,394	(1,546,280)	1,644,674	(106)%
Loss on extinguishment of convertible notes and convertible notes, related parties	—	(2,322,943)	2,322,943	(100)%
Other income (expense), net	406,922	(4,791,584)	5,198,506	(108)%
Net loss	(15,769,279)	(12,578,211)	(3,191,068)	25%
Net loss attributable to noncontrolling interests	—	(74,331)	74,331	(100)%
Deemed dividend on warrant modifications	(450,578)	—	(450,578)	100%
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (16,219,857)	$ (12,503,880)	$ (3,715,977)	30%

Operating Expenses

Research and development expenses

Research and development expenses increased by approximately $5,437,000 or 155%, from approximately $3,497,000 for the year ended December 31, 2021 to approximately $8,933,000 for the year ended December 31, 2022. The increase was primarily related to an increase in payroll and bonus expense of approximately $2,244,000 related to increased headcount of nine additional employees during the fiscal year 2022, the increase in clinical expenses related to the clinical trial startup of THIO of approximately $1,979,000, an increase in Scientific pre-clinical research of approximately $1,127,000, an increase in professional fees of approximately $18,000, and an increase in other expenses related to research and development of approximately $116,000 offset by a decrease in stock based compensation costs of approximately $47,000 related to employee options granted during fiscal year 2022.

General and administrative expenses

General and administrative expenses increased by approximately $1,854,000 or 43% from approximately $4,290,000 for the year ended December 31, 2021 to approximately $6,144,000 for the year ended December 31, 2022. The increase was primarily attributable to the increased costs to create additional infrastructure to support our operations as a public company. Increases included an increases in payroll and bonus expense of approximately $929,000 related to the increase in head count over the same period last

year, the approximate increase in other expenses of $896,000 and an increase of approximately $358,000 in professional fees offset by decrease in stock based compensation expense of approximately $329,000 primarily due to the 2021 expense related to founder's stock-based compensation expense.

Ratchet Expense

Ratchet expense increased by approximately $1,099,000 or 100% for the year ended December 31, 2022 due to the issuance of ratchet shares to certain private investors that purchased shares of our common stock prior to our initial public offering.

Other income (expense), net

Other income (expense), net increased approximately $5,199,000 from other expense of approximately $4,792,000 for the year ended December 31, 2021 to other income of approximately $407,000 for the year ended December 31, 2022. The increase in other income (expense), net was primarily the result of a loss on extinguishment of convertible notes and convertible notes of approximately $2,323,000 in 2021, approximately $1,645,000 of expense for the change in fair value of the warrant liability, the change in the fair value of bifurcated embedded feature of $203,000, expense related to approximately $828,000 of interest for convertible notes for the year ended December 31, 2021, and other income increased by approximately $270,000 of income related to the Australian research and development incentives for the year ended December 31, 2022 offset by a decrease in other income of approximated $63,000 for the paycheck protection loan forgiveness for the year ended December 31, 2021 and offset by the approximate $7,000 of interest expense for the year ended December 31, 2022.

Liquidity and Capital Resources

The following table presents selected financial information and statistics as of and for the years ended December 31, 2022 and 2021:

Years Ended December 31, 2022 and 2021

	As of December 31,	
	2022	**2021**
Balance Sheet Data:		
Cash	10,950,927	$ 10,574,592
Working capital [(1)]	8,539,131	8,526,499
Total assets	12,022,040	11,327,199
Accrued bonus	1,094,582	384,750
Deferred compensation	—	111,271
Total stockholders' equity	8,507,793	9,181,203

[(1)] We define working capital as current assets less current liabilities.

Capital Resources

Our Ability to Continue as a Going Concern

As of December 31, 2022, our available cash totaled approximately $10,951,000 which represented an increase of approximately $376,000 compared to December 31, 2021. As of December 31, 2022, we had working capital of approximately $8,539,000 which represents an increase of approximately $13,000 compared to December 31, 2021. We have generated no revenues as of December 31, 2022. The Company’s current operating plan indicates that it will continue to incur losses from operations and generate negative cash flows from operating activities given ongoing expenditures related to the completion of its ongoing clinical trials and the Company’s lack of revenue generating activities. Based on the Company’s cash reserves as December 31, 2022 of $10.95 million and current financial condition as of the date of the Annual Report on Form 10-K, the accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

To meet the Company’s future working capital needs, the Company will need to raise additional equity or enter into debt financing. While the Company has historically been able to raise additional capital through issuance of equity and/or debt financing, and while the Company has implemented a plan to control its expenses in order to satisfy its obligations due within one year from the date of issuance of these financial statements, the Company cannot guarantee that it will be able to raise additional equity, raise debt, or contain expenses. Accordingly, there is substantial doubt about the Company’s ability to continue as a going concern within one year after these financial statements are issued.

Sale of Common Stock

During January and February 2022, the Company sold 263,729 shares of common stock at $9 per share for gross proceeds of $2,373,561 before transaction costs and expenses.

Between April 22, 2022 and May 3, 2022, warrant holders exercised warrants, resulting in the issuance of 153,000 shares of common stock for proceeds of approximately $275,400.

On May 19, 2022, the Company sold 11,111 shares of common stock at $9.00 per share for gross proceeds of $99,999 with no transaction costs. On August 1, 2022, the Company sold 2,000,000 shares of common stock at $5 per share for gross proceeds of $10,000,000 in an initial public offering. On August 3, 2022, the Company sold an additional 300,000 shares of common stock at $5 per share for gross proceeds of $1,500,000 per the overallotment option for the underwriter.

We will need to raise additional capital to fund our operations, to develop and commercialize THIO, and to develop, acquire or in-license other products. We may seek to fund our operations through public equity, private equity, or debt financings, as well as other sources. We cannot make any assurances that additional financings will be available to us and, if available, on acceptable terms or at all. This could negatively impact our business and operations and could also lead to the reduction of our operations.

Cash Flows

Cash Flows years ***ended December 31, 2022 and 2021***

	Years Ended December 31,	
	2022	**2021**
Net cash flows used in operating activities	$ (11,655,725)	$ (4,122,896)
Net cash flows provided by financing activities	12,036,790	14,033,731
Effect of foreign currency exchange rate changes on cash	(4,430)	—
Net increase in cash and cash equivalents	$ 376,635	$ 9,910,835

Operating Activities

For the year ended December 31, 2022, net cash used in operating activities was approximately $11,657,000, which consisted of a consolidated net loss of approximately $15,769,000 offset by non-cash charges of approximately $3,320,000 which primarily includes approximately $2,319,000 in stock-based compensation, approximately $1,099,000 of expense related to the ratchet share issuance, offset by a gain of approximately $98,000 related to the changes in fair value of the warrant liability. Total changes in operating assets and liabilities of approximately $793,000 were primarily driven by an approximate $211,000 increase in accounts payable, and an approximate $1,027,000 increase in accrued expenses and an approximate $440,000 decrease in deferred offering costs offset by an approximate $111,000 decrease in deferred compensation, an approximate increase of $269,000 in Australian research and development incentives receivable and an approximate $505,000 increase in prepaid expenses and other current assets.

For the year ended December 31, 2021, net cash used in operating activities was approximately $4,123,000, which consisted of a consolidated net loss of approximately $12,578,000 offset by non-cash charges of approximately $7,330,000 which primarily includes approximately $2,723,000 in stock-based compensation, a loss of approximately $203,000 related to the change in fair value of embedded features related to convertible notes, a loss of approximately $1,546,000 related to the changes in the fair value of the warrant liability, and amortization of debt discount on convertible notes of approximately $597,000, offset by a gain from forgiveness of Payroll Protection Plan loan of approximately $63,000. Total changes in operating assets and liabilities of approximately $1,126,000 were primarily driven by an approximate $806,000 increase in accounts payable, and an approximate $1,261,000 increase in accrued expenses, offset by an approximate $7,000 decrease in related party payables, an approximate $15,000 increase in prepaid expenses and other current assets, an approximate $264,000 increase in deferred compensation, and an approximate $652,000 increase in deferred offering costs.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2022 was approximately 12,037,000 consisted primarily of gross proceeds from the sale of common stock in the initial public offering of approximately $11,500,000, net proceeds from issuance of common stock of approximately of $2,474,000 in a crossover round, and proceeds from issuance of common stock upon exercise of warrants of approximately $385,000 and stock options of approximately $84,000 offset by approximately $2,406,000 of the offering costs paid in the year ended December 31, 2022.

Net cash provided by financing activities for the year ended December 31, 2021 was approximately $14,034,000 which consisted primarily of proceeds from issuance of convertible notes totaling approximately $7,369,000, collections of subscriptions receivable of approximately $322,000 for MAIA, proceeds from issuance of common stock (net of transaction costs) of approximately $5,742,000, proceeds from the paycheck protection program loan totaling $63,000, proceeds from exercise of warrants of approximately $529,000 for MAIA, and proceeds from exercise of stock options of approximately $9,000 for MAIA.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of our operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to the valuation of stock options and warrants and accruals for outsourced research and development activities. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected. We define our critical accounting policies as those accounting principles that require it to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 1 to our financial statements, we believe the following are the critical accounting policies used in the preparation of its financial statements that require significant estimates and judgments.

Stock-based compensation

Our stock-based awards are classified as equity (restricted stock awards, and stock options, and warrants). We recognize related stock-based compensation expense based on the grant date fair value of the awards. The fair value of restricted stock awards is based on the trading value of the Company's common stock. We estimate the fair value of stock options and warrants using the Black-Scholes-Merton valuation model which requires the use of subjective assumptions that could materially impact the estimation of fair value and related compensation expense to be recognized. One of these assumptions include the expected volatility of our stock price. Developing this assumption requires the use of judgment. The Company lacks company-specific historical and implied volatility information. Therefore, we estimate our expected stock volatility based on the historical volatility of a publicly traded set of peer companies.

Two of the assumptions used in the Black-Scholes-Merton valuation model are historical volatility and fair value of common stock. Historical volatility is subject to uncertainty due to changes in the market over time. The fair value of our common stock is subject to uncertainty due to the possibility of changes in the results of our clinical trials, which could impact the fair value of our common stock. The total expense related to stock options is material to our financial statements on an annual basis, and significant fluctuations in the volatility assumption or the fair value of our common stock could result in material changes in related compensation expense to be recognized.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our prepaid and accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our prepaid and accrued research and development expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at the time. We confirm the accuracy of estimates with the service providers and make adjustments if necessary. Examples of estimated prepaid and accrued research and development expenses include expenses for:

- Clinical Research Organizations (CROs) in connection with clinical studies;
- Investigative sites in connection with clinical studies;
- Vendors in connection with preclinical development activities; and
- Vendors related to product manufacturing, development and distribution of clinical materials.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. The scope of services under these contracts can be modified and some of the agreements may be canceled by either party upon written notice. There may be instances in which

payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed we may report amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates and the amount actually incurred.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

Beginning on page F-2 are the consolidated financial statements with applicable notes and the related Report of Independent Registered Public Accounting Firm.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Under the supervision of and with the participation of our management, including our Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2022, the end of the period covered by this Annual Report. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level due to material weaknesses in internal control over financial reporting.

The Company noted 1) insufficient segregation of duties within the Company's control activities and procedures throughout the year, and 2) an insufficient level of detail to identify all relevant risks of material misstatement including the risks associated with the accounting treatment and financial reporting of non-recurring complex transactions. These factors contributed to a material weaknesses in the application U.S. GAAP to effectively evaluate the accounting treatment for certain non-recurring complex transactions during the quarter ended September 30, 2022.

Although the material weaknesses described above have not yet been fully remediated as of December 31, 2022, our management is committed to remediating identified control deficiencies, fostering continuous improvement in our internal controls and enhancing our overall internal controls environment. Our management believes that these actions, when fully implemented, will remediate the material weaknesses we have identified and strengthen our internal control over financial reporting. Our remediation efforts are ongoing and additional initiatives may be necessary.

As we work towards remediating these material weaknesses, we will design and implement controls to properly address the risks associated with segregation of duties and to account for non-recurring complex transactions in accordance with U.S. GAAP. To assist us in the remediation and performance of remediated controls we hired a Corporate Controller, and we will expand the nature and extent of our review of technical accounting treatment internally and continue to utilize an accounting and financial reporting advisory firm with significant experience with publicly held companies to assist our management in evaluating the accounting treatment for complex transactions.

We may identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley, and we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. We cannot assure that our existing material weakness will be remediated or that additional material weaknesses will not exist or otherwise be discovered, any of which could adversely affect our reputation, financial condition and results of operations.

Changes in Internal Control over Financial Reporting

We monitor our internal control over financial reporting on a continuous basis. During the year ended December 31, 2021, we identified a material weakness in our internal control over financial reporting related valuation of our common stock, the calculation of earnings per share in accordance with U.S. GAAP, the reconciliation of significant account balances, and authorization over cash disbursements.

- We have refined our entity-level controls to ensure that they adequately address above material weaknesses and the focal points of the COSO framework as they relate to our business and organization, the precision, sufficiency, review and approval of the reconciliation and review of significant account balances, authorization over cash disbursements, and Stock-based compensation or valuation of common stock calculations to address these material weaknesses. We have determined these material weaknesses have been remediated.

In addition to the measures taken in response to the material weakness defined above, there were no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, during the period ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Controls Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on the investor relations section of our website. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website or in a Current Report on Form 8-K.

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2023 annual meeting of stockholders to be filed not later than 120 days after the end of the 2022 fiscal year, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2023 annual meeting of stockholders to be filed not later than 120 days after the end of the 2022 fiscal year, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2023 annual meeting of stockholders to be filed not later than 120 days after the end of the 2022 fiscal year, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2023 annual meeting of stockholders to be filed not later than 120 days after the end of the 2022 fiscal year, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2023 annual meeting of stockholders to be filed not later than 120 days after the end of the 2022 fiscal year, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements.

The consolidated financial statements required by this item are submitted in a separate section beginning on page F2 of this Annual Report on Form10-K.

(a)(2) Exhibits.

The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Description
3.1[(1)]	Amended and Restated Certificate of Incorporation of MAIA Biotechnology, Inc
3.2[(1)]	Amended and Restated Bylaws of MAIA Biotechnology, Inc.
4.1*	Description of Registrant's Securities.
4.2[(1)]	Form of Representative's Warrant (Included in Exhibit 10.19)
4.3[(4)]	Form of Warrant
4.4[(4)]	Specimen certificate representing shares of common stock
10.1[(1)]	Form of Indemnification Agreement.
10.2[(2)]	Employment Agreement, dated as of September 16, 2022, between the Company and Vlad Vitoc.
10.3[(2)]	Employment Agreement, dated as of September 16, 2022, between the Company and Mihail Obrocea.
10.4[(2)]	Employment Agreement, dated as of September 16, 2022, between the Company and Sergei Gryaznov.
10.5[(2)]	Employment Agreement, dated as of September 16, 2022, between the Company and Joseph McGuire.
10.6†[(3)]	Supply and Non-Exclusive License Agreement between the Company and Regeneron Pharmaceuticals, Inc. dated February 1, 2021.
10.7†[(3]	Patent & Technology License Agreement between the Company and The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center dated December 8, 2020.
10.8†[(3)]	Patent & Technology License Agreement between the Company and The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center dated December 23, 2020.
10.9+[(4)]	MAIA Biotechnology, Inc. 2018 Stock Option Plan.
10.10+[(4)]	MAIA Biotechnology, Inc. Amended & Restated 2020 Equity Incentive Plan.
10.11+[(5)]	MAIA Biotechnology, Inc. 2021 Equity Incentive Plan.
10.12+[(6)]	Form of Director Stock Option Award under Amended & Restated 2020 Equity Incentive Plan.
10.13+[(6)]	Form of Compensatory Management Stock Option Award Agreement under Amended & Restated 2020 Equity Incentive Plan.
10.14+[(6)]	Form of Consulting Stock Option Award Agreement under Amended & Restated 2020 Equity Incentive Plan.
10.15+[(6)]	Form of Employee Stock Option Award Agreement under Amended & Restated 2020 Equity Incentive Plan.
10.16+[(7)]	Form of Incentive Stock Option Award under 2021 Equity Incentive Plan.
10.17+[(7)]	Form of Non-qualified Stock Option Award under 2021 Equity Incentive Plan.
10.18+[(7)]	Form of Director and Consultant Non-qualified Stock Option Award under 2021 Equity Incentive Plan.
10.19[(1)]	Underwriting Agreement dated as of July 27, 2022 between the Company and ThinkEquity, LLC
16.1[(8)]	Letter from EisnerAmper LLP regarding the change in the Registrant's certifying accountant, dated November 21, 2022.
21.1[(4)]	List of Subsidiaries of the Registrant.
23.1*	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

(1) Filed as an exhibit to the registrant's Current Report on Form 8-K filed with the SEC on August 1, 2022.

(2) Filed as an exhibit to the registrant's Current Report on Form 8-K filed with the SEC on September 21, 2022.
(3) Filed as an exhibit to the registrant's Registration Statement on Form S-1 filed with the SEC on May 31, 2022.
(4) Filed as an exhibit to the registrant's Registration Statement on Form S-1 filed with the SEC on April 11, 2022.
(5) Filed as an exhibit to the registrant's Registration Statement on Form S-8 filed with the SEC on August 1, 2022.
(6) Filed as an exhibit to the registrant's Registration Statement on Form S-1 filed with the SEC on June 29, 2022.
(7) Filed as an exhibit to the registrant's Quarterly Report on Form 10-Q filed with the SEC on August 22, 2022.
(8) Filed as an exhibit to the registrant's Current Report on Form 8-K filed with the SEC on November 22, 2022.

+ Indicates management contract or compensatory plan.
† Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]") because the Registrant has determined that the information is not material and is the type that the Registrant treats as private or confidential.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 24, 2023.

MAIA BIOTECHNOLOGY, INC.

By: /s/ Vlad Vitoc
Name: Vlad Vitoc
Title: Chief Executive Officer and Chairman

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Vlad Vitoc Vlad Vitoc	Chairman and Chief Executive Officer (Principal Executive Officer)	March 24, 2023
/s/ Joseph F. McGuire Joseph F. McGuire	Chief Financial Officer (Principal Financial Officer)	March 24, 2023
/s/ Steven Chaouki Steven Chaouki	Director	March 24, 2023
/s/ Ramiro Guerrero Ramiro Guerrero	Director	March 24, 2023
/s/ Louie Ngar Yee Louie Ngar Yee	Director	March 24, 2023
/s/ Cristian Luput Cristian Luput	Director	March 24, 2023
/s/ Stan V. Smith Stan V. Smith	Director	March 24, 2023
/s/ Jean-Manassé Theagène Jean-Manassé Theagène	Director	March 24, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
MAIA Biotechnology, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheet of MAIA Biotechnology, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2022, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses, has negative cash flows from operations, and has an accumulated deficit of $44,207,272 as of December 31, 2022. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2022.

Charlotte, North Carolina
March 24, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
MAIA Biotechnology, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of MAIA Biotechnology, Inc. and Subsidiaries (the "Company") as of December 31, 2021, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor from 2021 to 2022.

EISNERAMPER LLP
Iselin, New Jersey
April 8, 2022

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 10,950,927	$ 10,574,292
Prepaid expenses and other current assets	554,321	54,537
Australia research and development incentives receivable	302,789	43,666
Total current assets	11,808,037	10,672,495
Deferred offering costs	211,203	651,582
Other assets	2,800	3,122
Total assets	$ 12,022,040	$ 11,327,199
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,165,505	$ 960,401
Accrued expenses	2,103,401	1,185,595
Total current liabilities	3,268,906	2,145,996
Long term liabilities:		
Warrant liability	245,341	—
Total liabilities	3,514,247	2,145,996
Commitments and contingencies (Note 5)		
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value, 30,000,000 and 70,000,000 shares authorized at December 31, 2022 and December 31, 2021 respectively, 0 shares issued and outstanding	—	—
Common stock, $0.0001 par value, 70,000,000 and 30,000,000 shares authorized at December 31, 2022 and December 31, 2021 respectively, 10,955,904 and 7,584,980 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	1,096	758
Additional paid-in capital	52,729,942	37,618,438
Accumulated deficit	(44,207,272)	(28,437,993)
Accumulated other comprehensive loss	(15,973)	—
Total stockholders' equity	8,507,793	9,181,203
Total liabilities and stockholders' equity	$ 12,022,040	$ 11,327,199

See the accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Statements of Operations

	Years Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development expenses	$ 8,933,314	$ 3,496,796
General and administrative expenses	6,143,527	4,289,831
Ratchet share expense	1,099,360	—
Total operating expenses	16,176,201	7,786,627
Loss from operations	(16,176,201)	(7,786,627)
Other income (expense):		
Interest expense	(6,967)	(827,539)
Interest income	1,870	2,012
Australian research and development incentives	313,625	43,666
Paycheck protection program loan forgiveness	—	62,500
Change in fair value of embedded features	—	(203,000)
Change in fair value of warrant liability	98,394	(1,546,280)
Loss on extinguishment of convertible notes and convertible notes, related parties	—	(2,322,943)
Other income (expense), net	406,922	(4,791,584)
Net loss	(15,769,279)	(12,578,211)
Net loss attributable to noncontrolling interests	—	(74,331)
Deemed dividend on warrant modification	(450,578)	—
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (16,219,857)	$ (12,503,880)
Net loss per share		
Basic and diluted	$ (1.75)	$ (2.37)
Weighted average common shares outstanding basic and diluted	9,276,761	5,278,435

See accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Statements of Comprehensive Loss

	Years Ended December 31,	
	2022	**2021**
Net loss	$ (16,219,857)	$ (12,503,880)
Foreign currency translation adjustment	(15,973)	—
Comprehensive loss	$ (16,235,830)	$ (12,503,880)

See accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc.
Consolidated Statements of Changes in Stockholders' Equity
for the Year ended December 31, 2022

	Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2021	—	$ —	7,584,980	$ 758	$ 37,618,438	$ (28,437,993)	$ —	$ 9,181,203
Issuance of common shares upon exercise of stock options	—	—	46,500	5	83,995	—	—	84,000
Issuance of common shares upon exercise of warrants	—	—	529,712	53	385,347	—	—	385,400
Stock-based compensation	—	—	—	—	2,319,427		—	2,319,427
Issuance of common shares in connection with equity financing	—	—	274,840	28	2,473,532	—	—	2,473,560
Issuance of common shares in connection with initial public offering, net of $2,749,905 issuance cost	—	—	2,300,000	230	8,749,865	—	—	8,750,095
Issuance of ratchet shares	—	—	219,872	22	1,099,338	—	—	1,099,360
Modification of warrant in equity	—	—	—	—	450,578	—	—	450,578
Deemed dividend on modification of warrant	—	—	—	—	(450,578)	—	—	(450,578)
Foreign currency translation adjustment	—	—	—	—	—	—	(15,973)	(15,973)
Net loss	—	—	—	—	—	(15,769,279)	—	(15,769,279)
Balance at December 31, 2022	—	$ —	10,955,904	$ 1,096	$ 52,729,942	$ (44,207,272)	$ (15,973)	$ 8,507,793

See accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc.
Consolidated Statements of Changes in Stockholders' Equity
for the Year ended December 31, 2021

	Preferred Stock		Common Stock							
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Subscription Receivable	Total MAIA Equity (Deficit)	Noncontrolling Interest	Total Stockholders' (Deficit) Equity
Balance at December 31, 2020	—	$ —	4,433,644	$ 443	$ 12,599,585	$ (15,934,113)	$ (2,002)	$ (3,336,087)	$ 1,719,787	$ (1,616,300)
Issuance of common shares upon exercise of stock options	—	—	5,000	1	8,999	—	—	9,000	—	9,000
Issuance of common shares upon exercise of warrants	—	—	283,616	28	529,397	—	—	529,425	—	529,425
Issuance of restricted common shares	—	—	15,278	2	27,498	—	—	27,500	—	27,500
Cancellation of restricted common shares	—	—	(5,557)	(1)	—	—	—	(1)	—	(1)
Stock-based compensation expense - MAIA	—	—	—	—	2,428,935	—	—	2,428,935	—	2,428,935
Stock-based compensation expense - DGD	—	—	—	—	—	—	—	—	161,460	161,460
Stock-based compensation expense - THIO	—	—	—	—	—	—	—	—	104,999	104,999
Issuance of stock options to satisfy accrued bonus	—	—	—	—	786,531	—	—	786,531	—	786,531
Issuance of stock options to satisfy deferred compensation	—	—	—	—	285,418	—	—	285,418	—	285,418
Issuance of common shares upon conversion of convertible notes	—	—	1,375,228	138	11,001,136	—	—	11,001,274	—	11,001,274
Issuance of common shares upon conversion of SAFE	—	—	5,208	—	25,000	—	—	25,000	—	25,000
Issuance of common shares in connection with Equity Financing	—	—	772,563	77	6,180,426	—	(320,000)	5,860,503	—	5,860,503
Receipt of stock subscription receivable	—	—	—	—	—	—	322,002	322,002	—	322,002
Transaction costs incurred in connection with Equity Financing	—	—	—	—	(118,332)	—	—	(118,332)	—	(118,332)
Reclassification of warrant liability to equity	—	—	—	—	1,952,000	—	—	1,952,000	—	1,952,000
Issuance of restricted common shares to founder pursuant to THIO Merger Agreement	—	—	700,000	70	(70)	—	—	—	—	—
Dissolution of DGD	—	—	—	—	1,098,110	—	—	1,098,110	(1,098,110)	—
Dissolution of THIO pursuant to Merger Agreement	—	—	—	—	813,805	—	—	813,805	(813,805)	—
Net loss	—	—	—	—	—	(12,503,880)	—	(12,503,880)	(74,331)	(12,578,211)
Balance at December 31, 2021	—	$ —	7,584,980	$ 758	$ 37,618,438	$ (28,437,993)	$ —	$ 9,181,203	$ —	$ 9,181,203

See accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss, including noncontrolling interests	$ (15,769,279)	$ (12,578,211)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,319,427	2,722,893
Loss on extinguishment of convertible notes	—	2,322,943
Gain from forgiveness of Paycheck Protection Program loan	—	(62,500)
Change in fair value of embedded features	—	203,000
Issuance of ratchet shares	1,099,360	
Change in fair value of warrant liability	(98,394)	1,546,280
Amortization of debt discount	—	596,953
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(505,233)	(15,155)
Deferred offering costs	440,379	(651,582)
Australia research and development incentives receivable	(269,395)	—
Other assets	322	(3,122)
Accounts payable	211,346	805,516
Accrued expenses	915,742	997,126
Due to related parties	—	(7,037)
Net cash used in operating activities	(11,655,725)	(4,122,896)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, warrants, and embedded conversion features	—	7,369,000
Proceeds from Paycheck Protection Program loan	—	62,500
Collections of subscriptions receivable	—	322,002
Proceeds from issuance of common stock, net of transaction costs	2,473,560	5,742,171
Proceeds from exercise of stock options	84,000	9,000
Proceeds from exercise of warrants	385,400	529,425
Proceeds from sale of common stock in initial public offering	11,500,000	—
Payment of initial public offering transaction costs	(2,406,170)	—
Payment on loan payable to officer	—	(367)
Net cash provided by financing activities	12,036,790	14,033,731
Net effect of foreign currency exchange on cash	(4,430)	—
Net increase in cash	376,635	9,910,835
Cash at beginning of period	10,574,292	663,457
Cash at end of period	$ 10,950,927	$ 10,574,292
Supplemental disclosure of cash flow information:		
Conversion of convertible notes and accrued interest into MAIA common stock	$ —	$ 8,249,587
Conversion of SAFE into MAIA common stock	$ —	$ 25,000
Options issued for accrued bonus	$ —	$ 786,531
Options issued for deferred compensation	$ —	$ 285,418
Reclassification of warrant liability to equity	$ —	$ 1,952,000
Issuance of convertible note for payment on loan to officer	$ —	$ (21,000)
Previously paid issuance costs in connection with the initial public offering	$ 651,582	$ —
Warrants issued to underwriters in connection with the initial public offering	$ 343,735	$ —

See accompanying notes to the consolidated financial statements.

1. NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business, Organization, and Principles of Consolidation

MAIA Biotechnology, Inc. and Subsidiaries (collectively, "the Company") is a biopharmaceutical company that develops oncology drug candidates to improve and extend the lives of people with cancer. MAIA Biotechnology, Inc. ("MAIA") was incorporated in the state of Delaware on August 3, 2018. These consolidated financial statements include the accounts of MAIA and its subsidiaries, as follows:

- THIO Therapeutics, Inc. ("THIO"), incorporated in the state of Delaware on November 26, 2018. On August 13, 2021, MAIA and THIO completed a plan of reorganization in which THIO merged with and into MAIA. Prior to the merger, MAIA owned 93.3% of the outstanding shares of THIO common stock, which were canceled in connection with the merger. The remaining 6.7% minority stockholder of THIO received one share of MAIA common stock for each share of THIO common stock owned prior to the merger.
- DGD Pharmaceuticals Corporation ("DGD"), incorporated in the state of Delaware of April 1, 2019. In July 2020, the board of directors approved the dissolution of DGD, and shortly thereafter also approved a special dividend/return of capital to its stockholders. On August 13, 2021, DGD was officially dissolved via a filing of a Certificate of Dissolution with the state of Delaware.
- MAIA Drug Development Corporation ("MAIA DD") incorporated in the state of Texas on September 10, 2018, and was 100% owned by MAIA, until MAIA DD was legally dissolved in July 2021. The operations of MAIA DD were nominal.
- In July 2021, the Company established a wholly owned Australian subsidiary, MAIA Biotechnology Australia Pty Ltd, to conduct various pre-clinical and clinical activities for the development of the Company's product candidates.
- In April 2022, the Company established a wholly owned Romanian subsidiary, MAIA Biotechnology Romania S.R.L., to conduct various pre-clinical and clinical activities for the development of the Company's product candidates.

Liquidity

At December 31, 2022, the Company had working capital of $8,539,131, an accumulated deficit of $44,207,272, cash of $10,950,927 and current liabilities of $3,268,906. Since inception the Company has experienced net losses and negative cash flows from operations each fiscal year. The Company has no revenues and expects to continue to incur operating losses for the foreseeable future, and may never become profitable. The Company is dependent on its ability to continue to raise equity and/or debt financing to continue operations, and the attainment of profitable operations.

During January and February 2022, the Company sold 263,729 shares of common stock at $9 per share for gross proceeds of $2,373,561 before transaction costs and expenses. During May 2022, the company sold 11,111 shares of common stock at $9 per share for gross proceeds of $99,999. The Company commenced trading on July 28, 2022on the NYSE American under the ticker symbol "MAIA." The Company sold 2,000,000 shares of common stock at $5 per share for gross proceeds of $10,000,000 in the initial public offering. On August 3, 2022, the Company sold an additional 300,000 shares of common stock at $5 per share for gross proceeds of $1,500,000 per the overallotment option for the underwriter. After deducting $2,406,170 for cash issuance costs, net proceeds from the offering and overallotment were $9,093,830.

Going Concern Considerations

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

To date the Company has incurred recurring losses, negative cash flow from operations and has accumulated a deficit of $44,207,272 from the Company's inception through December 31, 2022. As of December 31, 2022, the Company had approximately $10,951,000 million in cash and cash equivalents.

To meet the Company's future working capital needs, the Company will need to raise additional equity or enter into debt financing. While the Company has historically been able to raise additional capital through issuance of equity and/or debt financing, and while the Company has implemented a plan to control its expenses in order to satisfy its obligations due within one year from the date of

issuance of these financial statements, the Company cannot guarantee that it will be able to raise additional equity, raise debt, or contain expenses. Accordingly, there is substantial doubt about the Company's ability to continue as a going concern within one year after these financial statements are issued.

Impact of the COVID-19 Pandemic on our Operations

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 Outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 Outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 Outbreak continues to evolve as of the date of this report. As a result, we cannot estimate the full magnitude that the pandemic will have on our business. If the COVID-19 Outbreak continues, it may have a material adverse effect on our financial condition, liquidity, and future results of operations for the future. We are actively monitoring the impact of the global pandemic on our financial condition, liquidity, operations, industry, and workforce. Given the daily evolution of the COVID-19 Outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 Outbreak on our results of operations, financial condition, or liquidity for the future. One of our clinical studies is taking place in Australia, which initially imposed one of the strictest COVID-19-related measures, including lock-downs. While we are not currently experiencing any delays or increased costs as a result of these measures, we may do so in the future.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP" or "GAAP"). You should read the discussion and analysis together with such consolidated financial statements and the related notes thereto.

The consolidated financial statements include the accounts of the Company's wholly owned subsidiaries. All transactions and accounts between and among its subsidiaries have been eliminated. All adjustments and disclosures necessary for a fair presentation of these audited consolidated financial statements have been included.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's Chief Executive Officer, views the Company's operations and manages its business as a single operating segment, which is the business of discovering and developing products for the treatment of immunotherapies for cancer.

Use of Estimates

The preparation of the Company's audited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to the valuation of common stock, stock options and warrants, accruals for outsourced research and development activities, and the valuation allowance of deferred tax assets. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Certain Risks and Uncertainties

The Company's activities are subject to significant risks and uncertainties including the risk of failure to secure additional funding to properly execute the Company's business plan. The Company is subject to risks that are common to companies in the pharmaceutical industry, including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, reliance on third party manufacturers, protection of proprietary technology, and compliance with regulatory requirements.

Foreign Currency Translation

The financial statements of the Company's foreign subsidiaries, where the local currency is the functional currency, are translated using exchange rates in effect as of the applicable balance sheet dates for assets and liabilities and average exchange rates during the

period for results of operations. The resulting foreign currency translation adjustment, is included in shareholders' equity as accumulated other comprehensive loss.

Off-Balance Sheet Risk and Concentrations of Credit Risk

The Company has no significant off-balance sheet risks, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Cash accounts are maintained at financial institutions that potentially subject the Company to concentrations of credit risk. At December 31, 2022 and 2021, substantially all of the Company's cash was deposited in accounts at one financial institution. The Company maintains its cash deposits, which at times may exceed the federally insured limits, with a reputable financial institution and, accordingly, the Company believes such funds are subject to minimal credit risk.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of three months or less to be cash equivalents. As of December 31, 2022 and 2021, cash includes cash in a depository bank account; the Company has no cash equivalents as of December 31, 2022 and 2021.

Fair Value Measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. "Accounting Standards Codification (ASC) Topic 820", Fair Value Measurements and Disclosures ("ASC 820") establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value:

- Level 1 - Valuations based on quoted prices for identical assets and liabilities in active markets.
- Level 2 - Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Valuations based on unobservable inputs reflecting our own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of and during the years ended December 31, 2022 and 2021. The carrying amount of accounts payable approximated fair value as they are short term in nature. The fair value of warrants issued for services is estimated based on the Black-Scholes model during the years ended December 31, 2022 and 2021. The estimated fair value of the warrants issued with the convertible notes, warrants issued to underwriters and embedded features, represented Level 3 measurements.

General and Administrative

General and administrative expenses primarily consist of costs for corporate functions, including payroll and related expenses, depreciation and amortization, rent, outside legal expenses, insurance costs, and other general and administrative costs.

Research and Development

The Company's research and development expenses consist primarily of costs associated with the Company's clinical trials, salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in ongoing research and development efforts. Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received.

As part of the process of preparing the consolidated financial statements, the Company is required to estimate its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice the Company monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses as of each balance

sheet date in our consolidated financial statements based on facts and circumstances known to the Company at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. The significant estimates in the Company's accrued research and development expenses are related to expenses incurred with respect to CROs, CMOs and other vendors in connection with research and development and manufacturing activities.

The Company bases its expense related to CROs and CMOs on its estimates of the services received and efforts expended pursuant to quotations and contracts with such vendors that conduct research and development and manufacturing activities on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the applicable research and development or manufacturing expense. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or prepaid expense accordingly. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented.

Research and Development Incentive

The Company recognizes other income from Australian research and development incentives when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The research and development incentive is one of the key elements of the Australian Government's support for Australia's innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997, as long as eligibility criteria are met. Under the program, a percentage of eligible research and development expenses incurred by the Company through its subsidiary in Australia are reimbursed.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive regime described above. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time and it is included in Australian research and development incentives in the consolidated statements of operations.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates all of its financial instruments, to determine if such instruments contain features that qualify as embedded derivatives.

Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the statement of operations each period.

Stock-Based Compensation

The Company records share-based compensation for awards granted to employees, non-employees, and to members of the board of directors based on the grant date fair value of awards issued, and the expense is recorded on a straight-line basis over the requisite service period. Forfeitures are recognized when they occur.

The Company uses the Black-Scholes-Merton option pricing model to determine the fair value of stock options and warrants. The use of the Black-Scholes-Merton option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. The Company has concluded that its historical share option exercise experience does not provide a reasonable basis upon which to estimate expected term. Therefore, the expected term was determined according to the simplified method, which is the average of the vesting tranche dates and the contractual term. Due to the lack of company specific historical and implied volatility data, the estimate of expected volatility is primarily based on the historical volatility of a group of similar companies that are publicly traded. For these analyses, companies with comparable characteristics are selected, including enterprise value and position within the industry, and with historical share price information sufficient to meet the expected life of the share-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its share-based awards. The risk-free interest rate is determined by reference to U.S. Treasury zero-coupon issues with remaining maturities similar to the expected term of the options. The Company has not paid, and does not anticipate paying, cash dividends on shares of its common stock.

Prior to the offering, in order to estimate the fair value of shares of the common stock, the Company's board of directors considered, among other things, sales of common stock to third party investors and valuations of common stock, business, financial condition and results of operations, including related industry trends affecting operations; the likelihood of achieving a liquidity event, such as an offering, or sale, given prevailing market conditions; the lack of marketability of our common stock; the market performance of comparable publicly traded companies; and U.S. and global economic and capital market conditions.

All stock-based compensation costs are recorded in general and administrative or research and development costs in the consolidated statements of operations based upon the underlying individual's role at the Company.

Common Stock Warrants

The Company accounts for common stock warrants as either equity instruments or liabilities in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480"), depending on the specific terms of the warrant agreement.

When warrants are issued for services to non-employees, under ASC 718, Compensation – Stock Compensation ("ASC 718"), the warrants shall be classified as a liability if 1) the underlying shares are classified as liabilities or 2) the entity can be required under any circumstances to settle the warrant by transferring cash or other assets. The measurement of equity-classified non-employee share-based payments is generally fixed on the grant date and are considered compensatory, as defined by ASC 718.

Income Taxes

Income taxes are recorded in accordance with ASC 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Deferred Offering Costs

Deferred offering costs were included in other assets and consisted of legal, accounting, underwriting fees and other costs incurred through the December 31, 2021 balance sheet date that are directly related to the initial public offering and were charged to additional paid-in capital upon the completion of the initial public offering on August 1, 2022.

Deferred offering costs were included in other assets and consisted of legal, accounting, underwriting fees and other costs incurred through the December 31, 2022 balance sheet date that are directly related to a planned follow on offering and will be charged to additional paid-in capital upon the completion of the follow on offering.

Net Loss Per Share

Basic loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. Diluted loss per share excludes, when applicable, the potential impact of stock options, unvested shares of restricted stock awards, and common stock warrants because their effect would be anti-dilutive due to our net loss. Gains on warrant liabilities are only considered dilutive when the average market price of the common stock during the period exceeds the exercise price of the warrants. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per common share are the same.

The following table summarizes the Company's potentially dilutive securities, in common share equivalents, which have been excluded from the calculation of dilutive loss per share as their effect would be anti-dilutive:

	Years Ended December 31,	
	2022	2021
Shares issuable upon exercise of stock options	6,545,628	5,797,185
Shares issuable upon exercise of warrants	796,985	1,311,117
Unvested restricted stock awards	—	58,333

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Leases

In February 2016, the FASB issued ASU No. 2016-02, as amended, Leases ("Topic 842"), which applies to all leases. Under Topic 842, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing leases, while the statement of operations will reflect lease expense for operating leases and amortization and interest expense for financing leases. Topic 842 is effective for public entities for fiscal years beginning after December 15, 2018 and periods beginning after December 15, 2021 for all other entities. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. The Company adopted this new standard as of January 1, 2022. At the inception of an arrangement the Company determines whether the arrangement is or contains a lease based on the circumstances present. All leases with a term greater than one year are recognized on the condensed consolidated balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the consolidated balance sheet leases with terms of one-year or less if entered into. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. At the inception of an arrangement the Company determines whether the arrangement is or contains a lease based on the circumstances present. Currently none of the Company's operating lease commitments are subject to the new standard as its leases are short-term in nature (i.e., less than twelve months).

2. RELATED PARTY TRANSACTIONS

Consulting Services

Leigh-Ann Durant, a former member of the Company's board of directors prior to her stepping down in November 2021, provided consulting services to the Company for which the Company incurred $88,994 for consulting services provided by Ms. Durant during the year ended December 31, 2021. The Company paid Ms. Durant $34,560 in cash and issued her options to purchase 23,964 shares of common stock with a total fair value of $54,434 during the year ended December 31, 2021. Ms. Durant was no longer considered a related party in 2022.

Radu Vitoc, a shareholder and brother of the CEO, provides consulting services to the Company for which the Company incurred $4,700 for services provided during the year ended December 31, 2021. The Company paid Mr. Vitoc $2,350 in cash and issued him options to purchase 184 shares of common stock with a total fair value of $1,100. The remaining $1,250 for services provided in fiscal 2021 were settled in March, 2022 for 226 options issued to Mr. Vitoc. The Company also issued him a convertible note in the amount of $50,000 during April 2021, which was converted into 8,557 shares of common stock on September 30, 2021 at a conversion price of $6.00 per share, and also received 4,278 warrants to purchase shares of common stock at an exercise price of $6.00 per share. In 2022, Mr. Vitoc provided consulting services to the Company through July 2022 for which the Company incurred $36,900 for services provided during the year ended December 31, 2022. The Company paid Mr. Vitoc $19,950 in cash and issued him options to purchase 4,690 shares of common stock with a total fair value of $19.950. In August 2022, Mr. Vitoc became an employee of the Company.

CEO Loan Agreement

The Company's chief executive officer lent the Company a total of $25,000 in August and September of 2018. These amounts, were unsecured, had no stated interest rate, and no stated repayment terms. The Company repaid $3,633 of the loan to the CEO during 2020 and $367 during 2021. The Company paid these loans in full in March 2021, by issuing the CEO a convertible note in the amount of $21,000. The convertible note issued to the CEO was converted into 3,621 shares of common stock on September 30, 2021 at a conversion price of $6.00 per share. No further notes to the CEO were incurred in the year ended December 31, 2022.

3. ACCRUED EXPENSES

As of December 31, 2022 and 2021, accrued expenses consisted of the following:

	December 31, 2022	December 31, 2021
Bonus	$ 1,094,582	$ 384,750
Professional fees	332,589	380,277
Research and development costs	516,961	268,140
Deferred compensation to former officers	—	111,271
Other	159,269	41,157
Total accrued expenses	$ 2,103,401	$ 1,185,595

Deferred Compensation Agreements

As of December 31, 2022 and December 31, 2021, the Company had $0 and $111,271, respectively, of deferred compensation due to certain employees and officers of the Company pursuant to deferred compensation agreements executed during fiscal 2020 and 2019 as part of a non-qualified deferred compensation plan. Pursuant to the deferred compensation agreements, the employees had deferred a portion of their annual base salary to be paid upon a Qualified Fund Raising. The Qualified Fund Raising was achieved during July 2021. Upon this event, the employees' salaries were increased up to the market rates set forth in their respective agreements, and all amounts were paid to the employees. The remaining deferred compensation balance as of December 31, 202l relates to amounts incurred for employees who were no longer with the Company as of the payout date. During the year ended December 31, 2021, the Company accrued $193,379 in deferred compensation. The Company paid $457,749 in cash and issued 268,769 options with a total fair value of $296,264 during the year ended December 31, 2021, to settle a portion of the deferred compensation balance totaling $743,167. The fair value of the options issued in excess of the deferred compensation balance settled totaling $10,846 was recorded as stock-based compensation expense which is presented within general and administrative expenses on the statement of operations for the year ended December 31, 2021.

Accrued Bonus

During the year ended December 31, 2022 and 2021, the Company accrued $1,094,582 and $384,750, respectively, in bonus expense relating to employees and officers of the Company. On April 16, 2021, the 2020 accrued bonus balance was settled by issuance of 713,536 stock options with a total fair value of $786,531. The fair value of the options issued in excess of the accrued bonus balance totaled $6,531 and was recorded as stock-based compensation expense which is presented within general and administrative expenses on the statement of operations for the year ended December 31, 2021. The 2021 accrued bonus was paid in cash in August of 2022.

4. PAYCHECK PROTECTION PROGRAM

On January 31, 2021, the Company received a second PPP Loan in the amount of $62,500. Under the terms of PPP Loan, interest accrues on the outstanding principal at the rate of 0.98% per annum. The term of the PPP Loan is two years. To the extent that the loan amount is not forgiven by the SBA, the Company is obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the PPP Loan, until the maturity date. The loan amount may be eligible for forgiveness if used for qualifying expenses and other qualifying criteria are met. The Company used the entire PPP Loan for qualifying expenses.

The Company received full forgiveness of all outstanding principal and accrued and unpaid interest on the PPP Loan in November 2021. The forgiveness of the PPP Loan qualified for debt extinguishment in accordance with ASC 470-50, Debt Modifications and Extinguishments, and as a result, the outstanding principal and interest was written off in the amount of $62,500, and the Company recorded a gain on extinguishment totaling $62,500 for the year ended December 31, 2021.

5. CONVERTIBLE NOTES PAYABLE

Convertible Notes Payable issued in 2019

In July 2019, the Company issued a Convertible Promissory Note totaling $10,000 to one individual (the "2019 Convertible Note"). The 2019 Convertible Note bore interest at 8% per annum, was unsecured, with a scheduled maturity date of December 31, 2021. The 2019 Convertible Note contained an automatic conversion feature, such that in the event the Company consummated an Equity Financing, as defined in the agreement, prior to the 2019 Convertible Note's scheduled maturity, the outstanding principal and interest would automatically converted into Preferred Stock (the shares of a class or series of preferred stock of the Company issued in connection with an Equity Financing) of the Company issued in connection with the Equity Financing. The Equity Financing is defined as a bona fide transaction or series of transactions with the principal purpose of raising capital, pursuant to which the Company receives gross aggregate proceeds of not less than $5,000,000 (before any transaction related expenses and costs). The conversion price will be set at 65% of the price of the preferred stock issued in the aforementioned Equity Financing.

Embedded Put Feature

The Company determined that the terms related to the Equity Financing conversion, (the “Embedded Put Feature”) were not clearly and closely related to the 2019 Convertible Note host instrument and meets the definition of a derivative. Therefore, the Embedded Put Feature was bifurcated from the 2019 Convertible Note and separately measured at fair value. The derivative liability has been subsequently marked-to-market each reporting period with changes in fair value recognized in the statement of operations.

The Embedded Put Feature was initially recorded as a debt discount and a related derivative liability at fair value. The debt discount is amortized using the effective interest rate over the original term of the 2019 Convertible Note.

Interest expense on the 2019 Convertible Note totaled $0 and $607 for the year ended December 31, 2022 and 2021, respectively.

The debt discount and value of the Embedded Put Feature in the 2019 Convertible Note totaled $1,000 at issuance. The balance of the debt discount was $0 as of December 31, 2022 and 2021. During the year ended December 31, 2022 and 2021, amortization of debt discount amounted to $0 and $310, respectively.

Convertible Notes Payable issued in 2020

During 2020, the Company issued Convertible Promissory Notes totaling $610,000 to various investors or holders, including $110,000 of Convertible Promissory Notes to related parties (collectively, the "2020 Convertible Notes") throughout fiscal 2020. The 2020 Convertible Notes bore interest at 6% per annum, was unsecured, with a scheduled maturity date of May 31, 2022.

The 2020 Convertible Notes are automatically convertible into shares of the Company's Equity Financing Shares (shall mean the shares of any class or series of preferred stock of the Company issued in connection with an Equity Financing), upon the closing of an Equity Financing yielding gross proceeds of in excess of $5,000,000 (before any transaction related expenses and costs). The 2020 Convertible Notes also are convertible into common shares of the Company at the holders' election upon (i) a Change in Control whereby any person or group becomes a beneficial owner of more than 50% of the Company's outstanding voting securities in connection with a merger or reorganization, or (ii) at the time of maturity.

Common stock issued on conversion shall be shares of the Company’s stock that have substantially the same rights and preferences as the shares issued in such Equity Financing.

Conversion Prices

The conversion price is set at 75% of the price of the preferred stock issued in the aforementioned Equity Financing. The 2020 Convertible Notes also contain a clause that accelerates their maturity upon a change in control of the Company, as defined above.

Embedded Put Features

The Company has determined that the terms related to the Equity Financing conversion, Change in Control, and maturity conversion features (collectively, the "Embedded Put Features") included within the 2020 Convertible Notes were not clearly and closely related to the 2020 Convertible Note host instrument and meet the definition of a derivative. Therefore, the Embedded Put Features were bifurcated from the 2020 Convertible Notes and measured at fair value. The derivative liability has been subsequently marked-to-market each reporting period with changes in fair value recognized in the statement of operations.

The Embedded Put Features were initially recorded as a debt discount and a related derivative liability at fair value in the amount of $131,000 at issuance of the 2020 Convertible Notes (see Note 8). The debt discount is amortized using the effective interest rate over the original term of the 2020 Convertible Notes.

Maturity Date

The maturity date on the 2020 Convertible Notes is the earliest occurrence of (i) the closing of a Qualified Equity Financing, or (ii) the date upon which the Convertible Notes are otherwise converted into equity securities, or (iii) May 31, 2022.

Interest expense on the 2020 Convertible Notes totaled $27,375 and $11,523 for the year ended December 31, 2021 and 2020, respectively.

Debt discounts on the 2020 Convertible Notes totaled $0 and $0 as of December 31, 2022 and 2021, respectively. During the year ended December 31, 2021 amortization of debt discounts amounted to $83,608. There was no amortization of debt discounts for the year ended December 31, 2022.

Warrants

In connection with each of the 2020 Convertible Notes, the Company issued each holder warrants (the 2020 Warrants) to acquire additional shares of common stock of the Company. Each holder of a 2020 Convertible Note received a warrant to purchase that number of shares of common stock as determined by multiplying the number of Equity Financing Shares which are issuable upon conversion of the holder's Convertible Note by 50%, at an exercise price equal to the conversion price per share used in the conversion of the Convertible Note.

The 2020 Warrants were initially recorded as a debt discount and a related warrant liability at fair value in the amount of $65,660 (see Note 8) at issuance of the 2020 Convertible Notes. Subsequent to issuance, the 2020 Warrants have been marked-to-market each reporting period with changes in fair value recognized in the statement of operations. The debt discount is amortized using the effective interest rate over the original term of the 2020 Convertible Notes.

Convertible Notes Payable issued in 2021

During the year ended December 31, 2021, the Company issued Convertible Promissory Notes totaling $7,390,000 to various investors or holders, including $1,863,300 of Convertible Promissory Notes to related parties (collectively, the "2021 Convertible Notes") which included a $21,000 Convertible Promissory Note to settle a loan to the Company's CEO (see Note 2) . The 2021 Convertible Notes bear interest at 6% per annum, are unsecured, and have scheduled maturity dates ranging from February 15, 2023 through June 28, 2023.

The 2021 Convertible Notes are automatically convertible into shares of the Company's Equity Financing Shares (shall mean the shares of any class or series of preferred stock of the Company issued in connection with an Equity Financing), upon the closing of an Equity Financing yielding gross proceeds of in excess of $5,000,000 (before any transaction related expenses and costs). The 2021 Convertible Notes also are convertible into common shares of the Company at the holders' election upon (i) a Change in Control whereby any person or group becomes a beneficial owner of more than 50% of the Company's outstanding voting securities in connection with a merger or reorganization, or (ii) at the time of maturity.

Common stock issued on conversion shall be shares of the Company's stock that have substantially the same rights and preferences as the shares issued in such Equity Financing.

Conversion Prices

The conversion price was set at 75% of the price of the common stock issued in the aforementioned Equity Financing. The 2021 Convertible Notes also contain a clause that accelerates their maturity upon a change in control of the Company, as defined above.

Embedded Put Features

The Company has determined that the terms related to the Equity Financing conversion, Change in Control, and maturity conversion features (collectively, the "Embedded Put Features") included within the 2021 Convertible Notes were not clearly and closely related to the 2021 Convertible Note host instrument and meet the definition of a derivative. Therefore, the Embedded Put Features were bifurcated from the 2021 Convertible Notes and measured at fair value. The derivative liability has been subsequently marked-to-market each reporting period with changes in fair value recognized in the statement of operations.

The Embedded Put Features were initially recorded as a debt discount and a related derivative liability at fair value in the amount of $2,821,000 at issuance of the 2021 Convertible Notes (see Note 6). The debt discount is amortized using the effective interest rate over the original term of the 2021 Convertible Notes.

Maturity Date

The maturity date on the 2021 Convertible Notes is the earliest occurrence of (i) the closing of a Qualified Equity Financing, or (ii) the date upon which the Convertible Notes are otherwise converted into equity securities, or (iii) maturity dates ranging from February 15, 2023 through June 28, 2023.

Interest expense on the 2021 Convertible Notes totaled $199,049 and $0 for the year ended December 31, 2021 and 2020, respectively.

During the year ended December 31, 2022 and 2021, amortization of debt discounts amounted to $0 and $513,035, respectively.

Warrants

In connection with each of the 2021 Convertible Notes, the Company issued each holder warrants (the 2021 Warrants) to acquire additional shares of common stock of the Company. Each holder of a 2021 Convertible Note received a warrant to purchase that number of shares of common stock as determined by multiplying the number of Equity Financing Shares which are issuable upon conversion of the holder's Convertible Note by 50%, at an exercise price equal to the conversion price per share used in the conversion of the Convertible Note.

The 2021 Warrants were initially recorded as a debt discount and a related warrant liability at fair value in the amount of $320,460 (see Note 6) at issuance of the 2021 Convertible Notes. Subsequent to issuance, the 2021 Warrants have been marked-to-market each reporting period with changes in fair value recognized in the statement of operations. The debt discount is amortized using the effective interest rate over the original term of the 2021 Convertible Notes.

Conversion of Convertible Notes Upon Equity Financing

Convertible Notes

In connection with the sale of common stock in fiscal 2021, an Equity Financing of gross proceeds in excess of $5 million, the Company converted all $8,010,000 of its outstanding principal and all accrued and unpaid interest of approximately $240,000 related to the Company's 2019 Convertible Note, 2020 Convertible Notes, and 2021 Convertible Notes into 1,375,228 shares of the Company's common stock on September 30, 2021 at a conversion price of $6.00 per share.

The Company accounted for the conversion of the Convertible Notes as an extinguishment. The Company recorded an approximate $2.3 million loss on extinguishment, upon conversion, year ended December 31, 2021. The loss on extinguishment of the Convertible Notes included a write-off of the unamortized debt discount of approximately $3.3 million.

As of December 31, 2021 there were no Convertible Notes outstanding.

Warrants

On September 30, 2021, in connection with conversion of the 2020 and 2021 Convertible Notes, the terms of the warrants issued with the 2020 and 2021 Convertible notes became fixed such that the warrants are exercisable for a fixed number of shares of common stock at a fixed exercise price per share based on the amount of shares issuable upon conversion of the Convertible Notes and an exercise price equal to the conversion price per share used in the conversion of the Convertible Notes. The warrants are exercisable for 686,489 shares of common stock with an exercise price of $6.00 and expire at various dates throughout fiscal 2028.

As of December 31, 2021, 4,504 of these warrants have been exercised.

6. SIMPLE AGREEMENT FOR FUTURE EQUITY

In October 2019, the Company issued a simple agreement for future equity ("SAFE Agreement") for $25,000. 'The SAFE Agreement requires automatic conversion to preferred stock in the event of an equity financing. If the Company experiences a liquidity event, as defined, the holder may opt for either conversion or repayment in cash, with repayment based upon a valuation at the time of such event. Upon a dissolution event, as defined, the SAFE Agreement requires repayment in cash. The conversion price will be set at 60% of the price of the preferred stock issued in the aforementioned equity financing. The SAFE Agreement shall terminate upon either the issuance of shares or repayment in cash as per the agreement's terms. Due to the contingencies associated with the potential conversion and conversion price as well as the valuation upon a future liquidity event should one occur, no discount associated with these features has been recorded in the accompanying consolidated financial statements.

In connection with the sale of common stock in 2021, an Equity Financing, the SAFE in the amount of $25,000 was converted into 5,208 shares of the Company's common stock on September 30, 2021. The price of the common shares issued in the equity financing was $8.00. 'The conversion price was equal to 60% of $8.00 per share, or $4.80 per share.

7. FAIR VALUE OF FINANCIAL LIABILITIES

Derivative Liability

The table below provides a summary of the changes in fair value of the derivative liabilities related to Convertible notes using significant unobservable inputs (level 3):

	Year Ended December 31,	
Derivative liabilities:	**2022**	**2021**
Balance, beginning of period	$ —	$ 127,000
Derivative liability on convertible notes payable	—	2,821,000
Loss (Gain) on fair value of embedded features	—	203,000
Extinguishment of derivative liability in connection with debt conversion	—	(3,151,000)
Balance, end of period	$ —	$ —

The Embedded Put Features were separately measured at fair value, with changes in fair value recognized in current operations. The scenario-based analysis estimates the fair value of the Convertible Notes based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the holders, including various settlement, equity financing, and corporate transaction and dissolution scenarios. Estimating fair values of Embedded Put Features required the development of significant and subjective estimates that changed over the duration of the instrument with related changes in internal and external market factors. Because the Embedded Put Features are initially and subsequently carried at fair values, the Company’s income reflected the volatility in these estimate and assumption changes.

Immediately prior to the conversion of the convertible notes, the derivative liability was marked to fair value resulting in a loss of $203,000 for the year ended December 31, 2021. The recurring Level 3 fair value measurements of the embedded derivative liability included the following significant unobservable inputs as of the conversion. The probability of the Convertible Notes outstanding at maturity was estimated to be approximately 0%; the probability of an equity financing was estimated to be approximately 100%; and the probability of default, change in control or dissolution was estimated to be approximately 0%. On September 30, 2021 the embedded derivative liability was extinguished in connection with the conversion of the convertible notes.

Financial liabilities consisting of warrant liabilities measured at fair value on a recurring basis are summarized below. The fair value of the warrant liabilities recorded are as follows:

	Fair value at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	245,341	—	—	245,341
Total liabilities	$ 245,341	$ —	$ —	$ 245,341

There was no warrant liabilities measured at fair value on a recurring basis at December 31, 2021. The table below provides a summary of the changes in fair value of the warrant liabilities measured on a recurring basis using significant unobservable inputs (Level 3):

	Years Ended December 31,	
Warrant liabilities:	2022	2021
Balance, beginning of period	$ —	$ 85,260
Warrant liability	343,735	320,460
(Gain) loss on fair value of warrant liability	(98,394)	1,546,280
Reclassification of warrant liability to equity	—	(1,952,000)
Balance, end of period	$ 245,341	$ —

8. STOCKHOLDERS' EQUITY

Upon the closing of the Company's initial public offering, the Company's shareholders agreement terminated pursuant to its terms. In connection with the closing of the Company's initial public offering, the Company amended and restated its Amended and Restated Certificate of Incorporation (the "Amended and Restated Certificate of Incorporation") and amended and restated its Bylaws (the "Amended and Restated Bylaws"). The Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on August 1, 2022 and became effective on that date, and among other things, increased the authorized number of common stock to 70,000,000 shares and decreased the authorized number of preferred stock to 30,000,000 shares.

Sales of MAIA Common Stock

During January and February 2022, the Company sold 263,729 shares of common stock at $9.00 per share for gross proceeds of $2,373,561 with no transaction costs. During May 2022, the Company sold 11,111 shares of common stock at $9 per share for gross proceeds of $99,999 with no transaction costs. The Company issued these shareholders additional shares upon the closing of the Company's initial public offering such that the $9.00 price per share they paid was equal to the price per share in the Company's initial public offering of $5.00. The number of Ratchet Shares were calculated using the $5.00 per share price in the Company's initial public offering and 219,872 shares of common stock were issued on August 1, 2022 to the investors in the Recent Private Rounds. The Ratchet shares were determined to be a freestanding instrument that was classified as a liability when the right was granted and subsequently reclassified to equity when shares were issued. The Ratchet Shares were valued at $1,099,360, based on the $5 price of the initial public offering and were recorded as expense included in operating expense.

Initial Public Offering

On July 28, 2022 the Company's shares of common stock began trading on the NYSE American under the symbol MAIA. On August 1, 2022, the Company sold 2,000,000 shares of common stock at $5.00 per share for gross proceeds of $10,000,000 in an initial public offering prior to deducting underwriting discounts, commissions, and other offering expenses. On August 3, 2022, the Company sold an additional 300,000 shares of common stock at $5.00 per share when the underwriter exercised the overallotment for gross proceeds of $1,500,000 prior to deducting underwriting discounts, commissions, and other offering expenses. After deducting the underwriting discount and other offering expenses payable by the Company, the total net proceeds for the initial public offering and the overallotment were approximately $9,100,000.

MAIA Biotechnology, Inc. Restricted Stock Awards

During the year ended December 31, 2021, MAIA recognized $202,500 of stock compensation expense related to 112,500 of MAIA's restricted shares granted to the founders. On August 13, 2021, upon the dissolution of THIO and merger into MAIA (see Note 1), a founder's 612,500 fully vested THIO restricted shares were canceled and the founder was issued 612,500 MAIA restricted shares.

Additionally, in accordance with the founder's original award, the founder was also issued 87,500 MAIA restricted shares which vested ratably each quarter through April 1, 2022 to replace the equivalent number of unvested THIO restricted shares. There are no unvested shares as of December 31, 2022 related to the founder's restricted shares. During the 12 months ended December 31, 2022, MAIA recognized $52,500 of expense related to restricted stock for the year ended 2022.

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at January 1, 2022	58,333	$ 1.80
Vested	(58,333)	1.80
Unvested balance at December 31, 2022	—	$ —

MAIA Stock Warrants

In January 2022, the Company and certain warrant holders executed waivers related to the acceptance and approval of an amendment to the holders' warrant agreements originally issued between May 6, 2020 and February 26, 2021 in connection with the Company's issuance of convertible notes. The amendment removed the IPO expiration provision from the warrant agreements, and the warrants are now only to be exercisable, in whole or in part, during the exercise period ending on the earliest to occur of: (a) various dates in 2028 as stated within the warrant agreements; or (b) immediately prior to the closing of a change of control. The value of the warrant modification to the 144,497 warrants was calculated using the Black-Scholes-Merton option pricing model. The incremental fair value attributable to the modified awards compared to the original awards immediately prior to the modification was calculated at $450,578 and was treated as a deemed dividend and is reflected as "Deemed dividend on warrant modification" in the accompanying statement of operations.

During January 2022, warrants were exercised, resulting in the issuance of 61,111 shares of MAIA common stock for proceeds of $110,000. During May 2022, warrants were exercised, resulting in the issuance of 153,000 shares of common stock for proceeds of approximately $275,400. Another 394,501 warrants were exercised with a cashless exercise assuming the fair market value of $9.00 per share resulting in the issuance of 315,601 shares of common stock.

At the closing of the initial public offering, 20,520 warrants with an exercise price of $5.00 per share expired.

Concurrently with the closing of the Company's initial public offering, the Company issued warrants to purchase an aggregate of up to 100,000 shares of its common stock to the Representative or its designees, at an exercise price of $6.25 per share (the "Representative's Warrants"). The Representative's Warrants are exercisable beginning on January 23, 2023, and expire on July 27, 2027, pursuant to the terms and conditions of the Representative's Warrants. On August 3, concurrently with the full exercise of the Underwriter's over-allotment option, the Company issued additional warrants to purchase an aggregate of up to 15,000 shares of its common stock to the Representative or its designees on the same terms. The warrants are not indexed to the Company's own stock and therefore meet the definition of a derivative liability. The warrants are liability classified instruments and were initially recorded as $343,735, which was the value determined using the Black-Scholes method using a term of five years, risk free interest rate of 2.82% and volatility of 77.5%. As of December 31, 2022 the Company remeasured the warrant liability resulting in a value of $245,341. The gain on remeasurement of the warrant liability in the amount of $98,394 was included in other income. Only the 115,000 warrants issued in 2022 are classified as a liability, all other outstanding warrants are equity classified.

	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Balance at January 1, 2022	1,311,117	$ 4.03	7.30
Issued	115,000	6.25	
Exercised	(608,612)	1.80	
Expired	(20,520)	5.00	
Balance at December 31, 2022	796,985	$ 6.04	5.16

The value of the warrants are calculated using the Black-Scholes-Merton option pricing model with the following assumptions for warrants granted during the years ended December 31, 2022 and 2021:

	2022	2021
Risk-free interest rate	2.8% - 4.1%	0.6% - 1.3%
Expected term (in years)	4.6 - 5	5 - 7
Expected volatility	78% - 92%	81% - 106%
Expected dividend yield	—%	—%

MAIA Biotechnology, Inc. Stock Award Plans

In 2018, the Company adopted the MAIA Biotechnology, Inc. 2018 Stock Option Plan (the "MAIA 2018 Plan"). MAIA's board of directors administers the MAIA Plan for the purposes of attracting, retaining, and motivating key employees, directors, and consultants of MAIA. The terms of the MAIA 2018 Plan continue to govern the 1,924,500 options outstanding in the plan of December 31, 2022.

In 2020, the Company adopted the MAIA Biotechnology, Inc. Amended and Restated 2020 Equity Incentive Plan (the "MAIA 2020 Plan"), also administered by the board of directors. The MAIA 2020 Plan permitted awards to take the form of stock options, restricted stock and restricted stock units. The terms of the MAIA 2020 Plan continue to govern the 3,983,023 options outstanding in the plan as of December 31, 2022. There are no shares reserved for future issuance in the MAIA 2018 Plan or the MAIA 2020 Plan .

On August 1, 2022 the Company approved the MAIA Biotechnology, Inc. 2021 Equity Incentive Plan (the "MAIA 2021 Plan") with 1,909,518 shares of common stock reserved for issuance. As of December 31, 2022 there were 1,271,413 shares of common stock available for future issuance under the MAIA 2021 Plan and 638,105 options outstanding in the MAIA 2021 Plan.

Stock options are to be granted with an exercise price which is at least equal to the stock's estimated fair value at the date of grant, and with a contractual term of no more than ten years from the date of grant. In the case of an option granted to a 10% stockholder, the exercise price shall be generally no less than 110% of the fair market value per share on the date of grant, and the contractual term shall be seven years. Outstanding options awarded under the MAIA 2021 Plan may, but need not, vest and therefore become exercisable in periodic installments that may, but need not, be equal. The option may be subject to other terms and conditions as to the time or times when it may be exercised (which may be based on performance or other criteria) as the board of directors may deem appropriate. Unexercised options are canceled ninety days after termination of an employee, director, founder, or consultant. Unexercised options are canceled immediately if an employee, director, founder, or consultant is terminated for cause; under certain other circumstances, the period to cancellation may differ as described in the respective plan documents. Certain clauses in the Plans also govern the Company's exercise repurchase rights and various other features of awards granted under the plans.

As of December 31, 2022, only stock options have been awarded pursuant to the MAIA stock award plans.

The following table summarizes the activity and information regarding MAIA's outstanding and exercisable options classified as equity awards as of December 31, 2022:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance at January 1, 2022	5,797,185	$ 2.22	8.59	—
Granted	811,831	4.77		
Exercised	(46,500)	1.81		
Cancelled/forfeited	(16,888)	1.82		
Balance at December 31, 2022	6,545,628	$ 2.55	7.85	$ 9,773,706
Options exercisable at December 31, 2022	5,449,715	$ 2.24	7.59	$ 8,804,841

During the year ended December 31, 2022, the fair value of the Company's common stock was estimated for financial reporting purposes from January 1 to January 26, 2022 based on valuations of $8.87 per share as of December 31, 2021. For our valuations of common stock performed, we used a hybrid method of the Option Pricing Method ("OPM") and the Probability-Weighted Expected Return Method ("PWERM"). PWERM considers various potential liquidity outcomes. Our approach included the use of an initial public offering scenario, a scenario assuming continued operation as a private entity, and a dissolution scenario. Under the hybrid OPM and PWERM, the per share values calculated under the OPM and PWERM are weighted based on expected exit outcomes and the quality of the information specific to each allocation methodology to arrive at a final estimated fair value per share
of the common stock before a discount for lack of marketability is applied. From January 27 to May 31, 2022 the fair value of the Company's common stock was estimated for financial reporting purposes at $9 per share based on the sale of common stock from

January 27, 2022 to May 19, 2022. From June 1, 2022 to August 1, 2022 the fair value of the Company's common stock was estimated for financial reporting purpose at $5 per share based on the price paid in the initial public offering. Following the initial public offering, the fair value of common stock, is based on the closing price of the common stock in the public market.

During the year ended December 31, 2021, the fair value of the Company's common stock was estimated for financial reporting purposes based on valuations. From January 1, 2021 to February 28, 2021 a valuation of $1.80 was used. During the period of March 1, 2021 to June 6, 2021, the fair value of the Company's common stock was estimated for financial reporting purposes based on valuations of $1.83 per share in February and April 2021 due to the lack of any single specific event that would have indicated a definitive change in the value of the Company. The February and April 2021 valuations used the income approach and the market approach in estimating the fair value of our common stock. The market approach utilized guideline public companies in estimating fair
value of our stock. The income approach estimates enterprise value based on the estimated present value of future cash flows the business is expected to generate over its remaining life. The estimated present value is calculated using a discount rate reflective of the risks associated with an investment in a similar company in a similar industry or having a similar history of revenue growth. The market approach measures the value of a business through an analysis of recent sales or offerings of comparable investments or assets, and in our case, focused on comparing us to a group of our peer companies. In applying this method, valuation multiples are derived from historical and projected operating data of the peer company group. We then apply the selected multiples to our operating data to
arrive at a range of indicated enterprise values of the Company. We then subtracted the net debt to determine equity value not be necessary to determine the fair value of our common stock.

The value of option grants are calculated using the Black-Scholes-Merton option pricing model with the following assumptions for options granted during the years ended December 31, 2022 and 2021.

	2022	2021
Risk-free interest rate	2.14% - 4.45%	0.36% - 1.27%
Expected term (in years)	5 - 6.25	5 - 6.50
Expected volatility	71.9% - 87.9%	71.4% - 81.5%
Expected dividend yield	—	—

The weighted-average grant date fair values of stock options issued during the years ended December 31, 2022 and 2021 were $3.75 and $3.55, respectively. At December 31, 2022, the total unrecognized compensation related to unvested employee and non-employee stock option awards granted was $3,447,367 which the Company expects to recognize over a weighted average period of approximately 3.26 years.

Stock based compensation related to the Company's stock plans are as follows:

	Years Ended December 31,	
	2022	2021
General and administrative	$ 1,422,799	$ 1,779,185
Research and development	896,628	943,708
Total stock-based compensation	$ 2,319,427	$ 2,722,893

9. EMPLOYEE RETIREMENT PLAN

Our eligible employees have been permitted to participate in our 401(k) beginning October 1, 2022. Participation in the 401(k) plan is offered for the benefit of our employees, including our named executive officers, who remain employed with us, and who satisfy certain eligibility requirements. We match employee contributions using a benchmark to industry standards. The Company will make a safe harbor matching contribution equal to 100% of employee salary deferrals that do not exceed 1% of their compensation plus 50% of their salary deferrals between 1% and 6% of their compensation. The 2022 Company match is immaterial. The Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax or after-tax (Roth) basis, through contributions to the 401(k) plan. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) plan.

10. COMMITMENTS AND CONTINGENCIES

Legal

From time to time, the Company is involved in legal actions and claims arising in the normal course of business. Management believes there are no matters which will have a material adverse effect on the Company's financial position, operations or cash flows.

Patent Licensing, Sponsored Research, and Patent & Technology Agreements

THIO - In November 2018 and as amended in December 2020, the Company entered into a Global Patent Licensing Agreement ("PLA") titled "Patent and Technology License Agreement AGT. NO. L2264 - MAIA Biotechnology" with the University of Texas Southwestern ("UTSW") to license patent families for a specific compound ("THIO") from UTSW to MAIA. The agreement, as amended, has a term of 20 years. The agreement requires MAIA to reimburse UTSW for agreed-upon expenses related to THIO. The agreement requires certain payments upon assignment of the license to a third party as well as upon reaching specific milestones, ranging between $1,000,000 and $50,000,000, not to exceed a combined milestone payment total of $112,000,000. As of December 31, 2022, no assignment has occurred and none of the defined milestones have been completed and therefore no payments are due to UTSW related to the milestones. The agreement requires royalties of 2-4% (depending on THIO reaching specified sales levels in the respective jurisdictions) royalty payments on net sales up to $1,000,000,000, and 2.5-5% on net sales above $1,000,000,000.

Also in December 2020, the Company entered into a second license agreement with UTSW titled "Patent and Technology License Agreement AGT. NO. L3648 — MAIA Biotechnology" pursuant to which UTSW is licensing an additional compound to MAIA. The agreement has a term of 20 years and requires the Company to reimburse UTSW for certain agreed-upon expenses. The agreement requires certain payments upon assignment of the license to a third party as well as upon reaching specific milestones, ranging between $1,000,000 and $50,000,000, not to exceed a combined milestone payment total of $112,000,000. As of December 31, 2022, no assignment has occurred and none of the defined milestones have been completed and therefore no payments are due to UTSW related to the milestones.

The agreement requires royalties of 2-4% (depending on THIO reaching specified sales levels in the respective jurisdictions) royalty payments on net sales up to $1,000,000, and 2.5-5% on net sales above $1,000,000,000.

The Company will also pay UTSW running royalties on a yearly basis as a percentage of Net Sales of the Company or its sublicensee. There are single digit royalty rates for licensed products and licensed services covered by a Valid Claim (as defined in the agreement) and dependent on whether Net Sales are greater than or less than/equal to $1,000,000,000, with Net Sales above that amount commanding a slightly higher percentage. In each case, the royalty percentage is lower before patent issuance in each jurisdiction. In the event that the licensed product or licensed service is not covered by a Valid Claim, the running royalty rates are reduced by fifty percent (50%). The royalty obligations continue on a country-by-country basis until the later of expiration of the last Valid Claim in each country or ten (10) years after the First Commercial Sale (as defined in UTSW2 Agreement) in each country.

Regeneron - In February 2021, the Company reached an agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron") to perform one clinical trial for the treatment of patients with Non-Small Cell Lung Cancer (NSCLC) involving a Regeneron drug candidate that utilizes one of the Company's compounds/agents. The Company is responsible for all costs of the study with Regeneron supplying their drug cemiplimab representing a cost savings for the Company, the first phase of which is expected to take approximately two years. The overall term of the agreement is for five years unless earlier terminated for certain reasons as defined in the agreement. Either party may terminate a study plan in the event that patient screening for the clinical study does not commence within twelve (12) months after (a) the Effective Date, with respect to the initial study, or (b) the execution of the applicable study plan, with respect to each other study. If either party terminates a study plan, the Company shall reimburse Regeneron for the Regeneron product it received in connection with such study plan based on the actual out-of-pocket cost to Regeneron of such Regeneron product. As of December 31, 2022 neither party has terminated the agreement.

11. INCOME TAXES

The Company's net deferred tax assets consist of the following components:

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 3,294,955	$ 3,013,721
Stock-based compensation	1,183,941	1,800,935
Research and development	1,499,300	—
Accrued compensation	244,848	109,673
Other	6,724	102,825
Total net deferred tax assets before valuation allowance	6,229,768	5,027,154
Valuation allowance	(6,229,768)	(5,027,154)
Net deferred tax asset	$ —	$ —

At December 31, 2022, the Company has unused U.S. federal and state net operating loss ("NOL") carryforwards of $15.4 million that may be applied against future taxable income. The state NOL carryforwards begin to expire in 2030. The U.S. federal NOL carryforwards may be carried forward indefinitely, however are limited to 80 percent of taxable income. The Company has unused Australian NOL carryforwards of $0.1 million that may be carried forward indefinitely. The Company has unused U.S. federal research and experimentation ("R & E") tax credits of $0.1 million that begin to expire in 2041.

The use of the Company's NOL and R & E credit carryforwards may, however, be subject to limitations as a result of an ownership change. A corporation undergoes an "ownership change," in general, if a greater than 50% change (by value) in its equity ownership by one or more five-percent stockholders (or certain groups of non-five-percent stockholders) over a three-year period occurs. After such an ownership change, the corporation's use of its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income is subject to an annual limitation determined by the equity value of the corporation on the date the ownership change occurs multiplied by a rate determined monthly by the Internal Revenue Service.

If an ownership change occurs and if the Company earns net taxable income, the Company's ability to use its pre-change NOLs to offset U.S. federal and taxable income would be subject to these limitations, which could potentially result in increased future tax liability compared to the tax liability the Company would incur if its use of NOL carryforwards were not so limited. In addition, for state income, franchise and similar tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase the Company's state income, franchise, or similar taxes.

In accordance with ASC 740, "Income Taxes," the Company recorded a valuation allowance to fully offset its deferred tax assets, because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets at December 31, 2022 and 2021.The valuation allowance increased by approximately $1.2 million and $2.1 million during the years ended December 31, 2022 and 2021, respectively, mainly due to increases in the NOL carryforward and other deferred tax assets. The Company will continue to assess the realizability of the deferred tax assets at each interim and annual balance sheet date based upon actual and forecasted operating results.

The Company incurred a pretax book loss of approximately $15.8 million for the year ended December 31, 2022, which consisted of a U.S. loss of approximately $15.3 million and a foreign loss of approximately $0.5 million. The Company incurred a pretax book loss of approximately $12.6 million for the year ended December 31, 2021, which consisted of a U.S. loss of approximately $12.5 million and a foreign loss of approximately $0.1 million.

No provision or benefit for U.S. federal, state, or foreign income taxes has been recorded for the years ended December 31, 2022 and 2021, mainly due to net losses incurred by the Company in all jurisdictions other than Romania, which provides for a tax exemption.

The income tax benefit differs from the benefit that would result from applying federal statutory rates to loss before income taxes as follows:

	December 31,	
	2022	2021
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal tax benefit	(7.7)%	4.4%
Stock-based compensation	(1.2)%	(1.9)%
Loss on extinguishment of debt	(1.5)%	(3.9)%
Other nondeductible expenses/(nontaxable income)	(3.0)%	(2.8)%
Change in valuation allowance	(7.6)%	(16.8)%
Income tax benefit	—%	—%

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes any interest and penalties accrued related to unrecognized tax benefits as income tax expense. The Company did not have any significant unrecognized tax benefits during the years ended December 31, 2022 and 2021. The Company files income tax returns in the U.S. federal jurisdiction, several U.S. States, Australia, and Romania. The Company's tax returns since inception remain open to examination by the taxing authorities.

12. SUBSEQUENT EVENTS

Issuance of Common Stock

On January 16, 2023, we issued 18,000 shares of common stock for investor relations services from January 16, 2023 through July 16, 2023. Per the agreement an additional 18,000 shares of common stock will be issued on April 16, 2023 if their services are still in place per the contract.

On March 8, 2023, we entered into an agreement with The Money Channel NYC Inc. for media services, pursuant to which we agreed to issue 22,500 shares of common stock on March 8, 2023 and an additional 22,500 shares of common stock every ninety days after the execution date of the contract until termination of the agreement. The term of the agreement extends for 180 days, and renews automatically until we provide written notice prior to the end of the term.

Issuance of Options

From January 1 to March 20, 2023 we issued 638,710 options at a weighted exercise price of $4.10 to employees and consultants.

Exhibit 4.1

DESCRIPTION OF REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

The following is a description of the securities of MAIA Biotechnology, Inc. that are registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), certain provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws. The description is a summary, does not purport to be complete and is subject to and qualified in its entirety by reference to Delaware law and to our amended and restated certificate of incorporation and amended and restated bylaws, copies of which are filed as exhibits to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and are incorporated by reference herein.

As used herein, the terms "Company," "we," "our" and "us" refer to MAIA Biotechnology, Inc., a Delaware corporation.

Authorized Capitalization

Our authorized capital stock consists of 70,000,000 shares of common stock, par value $0.0001 per share and 30,000,000 shares of preferred stock, par value $0.0001 per share of which 10,996,404 shares of common stock and no shares of preferred stock were issued and outstanding as of March 24, 2023.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote in the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive on a pro rata basis our net assets available for distribution to stockholders after the payment of all debts and other liabilities, subject to the prior rights of any holders of outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our amended and restated certificate of incorporation our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that delay, defer, or discourage transactions involving an actual or potential change in control of us or change in our management. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares. These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

No Stockholder by Written Consent

Any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law (DGCL), which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

The Court of Chancery of the State of Delaware is the exclusive forum in which we and our directors may be sued by our stockholders, to the fullest extent permitted by law, for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation, or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our bylaws will not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act, or any other claim for which federal courts have exclusive jurisdiction. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find either choice of forum provision contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

Advance Notice Requirements for Stockholder Nominations and Proposals

Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although our amended and restated bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Classified Board.

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws, our board of directors is divided into three staggered classes of directors of the same or nearly the same number and each are assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors are elected for a three-year term to succeed the directors of the same class whose terms are then expiring.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class shall consist of one third of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

National Securities Exchange Listing

Our common stock is listed on NYSE American, or the "NYSE American", under the symbol "MAIA.".

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 24, 2023, with respect to the consolidated financial statements included in the Annual Report of MAIA Biotechnology, Inc. on Form 10-K for the year ended December 31, 2022. We consent to the incorporation by reference of said report in the Registration Statements of MAIA Biotechnology, Inc. on Form S-8 (File No. 333-266453).

/s/ Grant Thornton LLP

Charlotte, North Carolina
March 24, 2023

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of MAIA Biotechnology, Inc. on Form S-8 (No. 333-266453) of our report dated April 8, 2022, on our audit of the financial statements as of December 31, 2021 and for the year then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 24, 2023.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
March 24, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vlad Vitoc, certify that:

1. I have reviewed this Annual Report on Form 10-K of MAIA Biotechnology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 24, 2023

By: /s/ *Vlad Vitoc*

Vlad Vitoc
Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph F. McGuire, certify that:

1. I have reviewed this Annual Report on Form 10-K of MAIA Biotechnology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 24, 2023

By: /s/ *Joseph F. McGuire*

Joseph F. McGuire
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of MAIA Biotechnology, Inc. (the "Company") on Form 10-K for the period ending December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 24, 2023

By: /s/ *Vlad Vitoc*

Vlad Vitoc
Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of MAIA Biotechnology, Inc. (the "Company") on Form 10-K for the period ending December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 24, 2023

By: /s/ *Joseph F. McGuire*

Joseph F. McGuire
Chief Financial Officer
(Principal Financial Officer)