As filed with the U.S. Securities and Exchange Commission on May 31, 2022.

Registration No. 333-264225

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

FORM S-1

(Amendment No. 3)

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Delaware	**2834**	**83-1495913**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

444 West Lake Street, Suite 1700
Chicago, IL 60606
(312) 416-8592
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Vlad Vitoc
Chief Executive Officer
c/o MAIA Biotechnology, Inc.
444 West Lake Street, Suite 1700
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(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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Approximate date of commencement of proposed sale to public: As soon as practicable after the effective date hereof.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. □

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. □

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. □

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. □

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 7(a)(2)(B) of the Securities Act. □

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information contained in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION** **DATED MAY 31, 2022**

Shares
Common Stock

MAIA Biotechnology, Inc.

This is a firm commitment initial public offering of shares of common stock of MAIA Biotechnology, Inc. (the "Company"). Prior to this offering, there has been no public market for our common stock. We anticipate that the initial public offering price of our shares will be between $ and $.

We intend to apply to have our common stock listed on the New York Stock Exchange American, or "NYSE", under the symbol "MAIA."

Investing in our common stock involves a high degree of risk. See "*Risk Factors*" beginning on page 13. Neither the Securities and Exchange Commission (the "SEC") nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to us, before expenses	$	$

(1) Underwriting discounts and commissions do not include a non-accountable expense allowance equal to 1.0% of the initial public offering price payable to the underwriters. We refer you to "Underwriting" beginning on page 146 for additional information regarding underwriters' compensation.

We have granted a 45-day option to the representative of the underwriters to purchase up to additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares to purchasers on or about , 2022.

ThinkEquity

The date of this prospectus is , 2022

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You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with information different from or in addition to that contained in this prospectus, and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

As used in this prospectus, unless the context indicates or otherwise requires, "the Company," "our Company," "we," "us," and "our" refer to MAIA Biotechnology, Inc., a Delaware corporation, and its consolidated subsidiaries.

PROSPECTUS SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. Before you decide to invest in our common stock, you should read the entire prospectus carefully, including "Risk Factors" beginning on page 10 and the financial statements and related notes included in this prospectus.

This prospectus includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this prospectus are the property of their respective owners.

Our Company

We are 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. THIO will enter Phase 2 human trials (THIO-101) in Australia and Europe in the first half of 2022. 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 generated by our 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, but even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA. In addition, in the First Quarter of 2023, we plan to initiate a pivotal Phase 2 clinical trial in patients with advanced colorectal cancer, hepatocellular carcinoma, and small cell lung cancer, of THIO administered in sequence with Anti-PD-1 or Anti-PD-L1 by end of 2023.

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" 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 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. This would allow U.S. sites to participate in the THIO-101 NSCLC trial. The human safety data generated in the first part of 2022 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, and do not plan to rely on clinical data generated by unaffiliated third parties, 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 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. 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, and we are currently working with experts to evaluate the extent and quality of the existing data supporting THIO. We expect to request a pre-IND meeting with the FDA for guidance in 2022. 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. Based on the clinical data generated 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 on the possibility of utilizing one or more of FDA's expedited programs for serious conditions, such as fast track designation, breakthrough therapy designation, priority review and/or accelerated approval designation. Even if granted, accelerated approval status 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

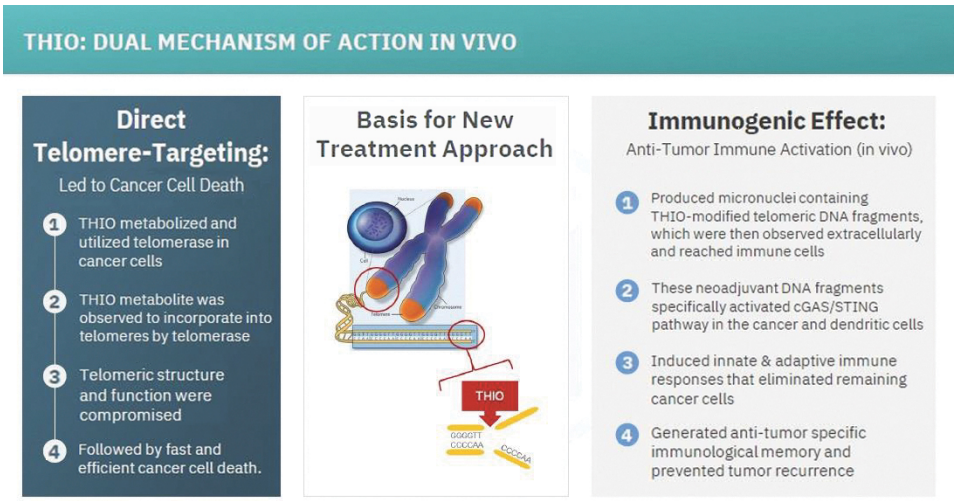
Telomeres are regions of repetitive DNA nucleotide sequences that are associated with specialized proteins at the ends of linear chromosomes in cells. THIO's mechanism of action comprises telomere targeting and induction of anti-cancer immunogenicity. The enzyme telomerase recognizes THIO's metabolite 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 telomeric structure unwinds 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 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 essential 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+). 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 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. We have generated 82 new telomere-targeting compounds of which 60 compounds have been evaluated in vitro. Currently, five molecules have been selected for further evaluation in additional in vitro and in vivo models.

Human clinical trials prior to approval are typically conducted in three sequential Phases that may overlap or be combined. In 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 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. In Phase 3, larger-scale clinical trials are undertaken to evaluate clinical efficacy and safety and the overall risk/benefit ratio of the product. Post-approval studies, or Phase 4 clinical trials, may be conducted voluntarily, or as a condition of FDA's approval of a drug. These studies may be used to confirm preliminary efficacy results, gain additional experience from the treatment of certain patient populations, or to support additional indications or labeling changes.

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. We submitted a similar application to conduct the same Phase 2 study in Europe.

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 the second 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.



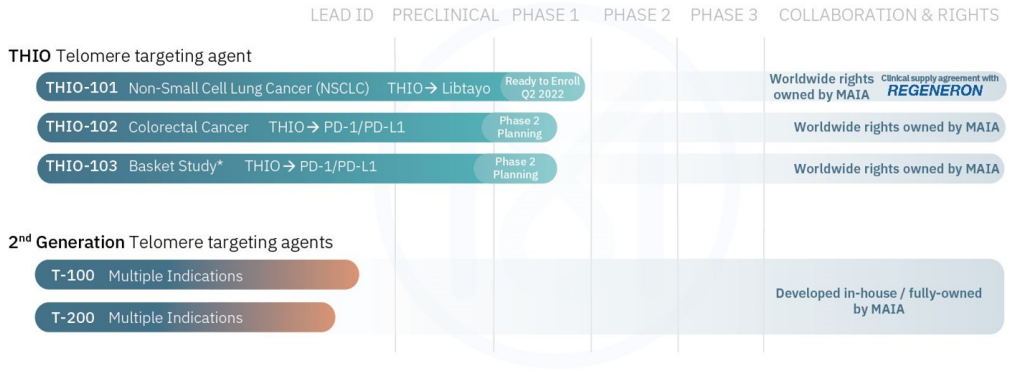
Our Second Generation Target Candidates

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 potentially increased anticancer activity. 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 a second generation of THIO-like compounds.

Our current 2nd-generation pipeline of potential telomere-targeting agents includes five 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. Based on those data, we have progressed those five compounds to *in vivo* testing and with proceeds from the IPO, we plan to initiate pre- clinical testing for at least two of them in mid-2022, with the goal of advancing at least one compound to clinical trials by the end of 2024.

OUR PIPELINE

Our robust pipeline includes several 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 using THIO in sequential combination with cemiplimab. Ultimately, we envision positioning 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 not inclusive of checkpoint inhibitors.
- 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. The FDA's accelerated approval pathway, even if initially granted, does not guarantee an accelerated review or marketing approval by the FDA.

Our Intellectual Property

Our global patent and patent-pending estate covers several areas. Telomerase mediated telomere altering compounds and treatment of therapy-resistant cancers are part of our portfolio. Further, THIO's immunogenic treatment strategy, which focuses on sequential combination with checkpoint inhibitors has been filed. We maintain four issued patents and have 16 pending applications.

Our Leadership Team

We have assembled an experienced management team with deep research, development, and commercialization experience in the areas of cancer treatment, telomere-related science, immunotherapy, and spreading across a vast array of oncology indications. Members of our team bring experiences from multiple biotech and pharmaceutical companies including Pfizer Inc., Bayer Oncology, Novartis Oncology, Astellas Pharma Inc., Janssen - a Johnson & Johnson pharmaceutical company, Incyte Corporation, Pharmacyclics Inc., Juno Therapeutics Inc., Celgene, Cephalon Inc., Geron Corporation, and AbbVie Bio Corp., among others.

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. 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 prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus 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 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 this offering, (b) in which we have total annual gross revenue of at least $1.07 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.

THE OFFERING

Issuer	MAIA Biotechnology, Inc.
Common stock offered	shares of common stock.
Common stock to be outstanding after this offering	shares (or shares if the underwriters' option to purchase additional shares is exercised in full) of common stock.
Offering price	$ per share.
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to an additional shares of our common stock at the initial public offering price, less the underwriting discount, to cover over-allotments, if any.
Use of proceeds	We estimate that we will receive net proceeds of approximately $ million from our sale of common stock in this offering, or approximately $ million if the underwriters exercise their over-allotment option in full. We intend to use the net proceeds from this offering, along with our existing cash and cash equivalents, to fund the planned trials of THIO, pre-clinical development of second-generation of telomere targeting compounds and our other research and development activities, as well as for working capital and other general corporate purposes. See "Use of Proceeds" in this prospectus for a more complete description of the intended use of proceeds from this offering.
Concentration of ownership	Upon completion of this offering, our executive officers and directors will beneficially own, in the aggregate, approximately % of the outstanding shares of our common stock.
Proposed trading market and symbol	We intend to apply to have our common stock listed on the NYSE under the symbol "MAIA." No assurance can be given that our application will be approved.
Risk factors	Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 13 and the other information in this prospectus for a discussion of the factors you should consider carefully before you decide to invest in our common stock.
Lock-Up	We, each of our officers, directors, and certain of our stockholders have agreed, 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 this prospectus, 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 6 months (or in the case of options with a weighted average exercise price of $1.80 or $1.83, for a period of 12 months) after the date of this 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. See the section of this prospectus entitled "Underwriting" for additional information.

The number of shares of our common stock to be outstanding after this offering is based on 7,951,320 shares of our common stock outstanding as of April 26, 2022, and excludes the following:

- 5,880,367 shares of common stock issuable upon exercise of options to purchase shares of common stock outstanding as of April 26, 2022, with a weighted-average exercise price of $2.37 per share;
- 222,133 shares of common stock reserved for future issuance as of April 26, 2022, under our 2020 Plan;
- shares of common stock reserved for issuance under our 2021 Equity Incentive Plan that we intend to adopt in connection with this offering; and
- warrants to purchase 1,235,006 shares of common stock, with a weighted average exercise price of $4.17 per share and of which warrants to purchase 553,021 shares must be exercised or they will expire at the closing of our initial public offering.

Unless we indicate otherwise or unless the context otherwise requires, all information in this prospectus assumes the following:

- no exercise of outstanding options or warrants;
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock from us to cover over-allotments, if any;
- no exercise of the representative's warrants to be issued upon consummation of this offering at an exercise price equal to 125% of the initial offering price of the common stock;
- the filing and effectiveness of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws, each of which will be in effect immediately upon the consummation of this offering; and
- an initial public offering price of $ per share, the midpoint of the estimated initial public offering price range on the cover page of this prospectus.
- an initial public offering price greater than the per share price paid by investors in our Crossover Round and therefore no requirement to issue additional shares of our common stock to the investors in the Crossover Round. See "Description of Capital Stock—Crossover Round."

SUMMARY OF RISK FACTORS

Our business is subject to a number of risks of which you should be aware of before making an investment decision. These risks are discussed more fully in the "*Risk Factors*" section of this prospectus immediately following this prospectus summary. Some of these risks include the following:

- We have incurred losses since our inception and anticipate that we will continue to incur increasing losses for the foreseeable future.
- Even if this offering is successful, 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.
- 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.
- There is no existing market for our common stock and an active, liquid trading market for our common stock may not develop.
- 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.
- A potential 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.
- We will incur increased costs as a result of being a publicly traded company.

SUMMARY FINANCIAL INFORMATION

The following tables present our summary consolidated financial and other data as of and for the periods indicated. The summary consolidated statements of operations data for the fiscal years ended December 31, 2021 and December 31, 2020 and the consolidated balance sheet data as of December 31, 2021 and 2020 are derived from our audited financial statements included elsewhere in this prospectus. The summary consolidated statements of operations data for the three months ended March 31, 2022 and March 31, 2021 and the consolidated balance sheet data as of March 31, 2022 are derived from our unaudited financial statements included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and reflect, in the opinion of management, all adjustments of a normal, recurring nature that are necessary for a fair presentation of the unaudited interim financial statements.

The summarized financial information presented below is derived from and should be read in conjunction with our consolidated financial statements including the notes to those financial statements, which are included elsewhere in this prospectus along with the sections entitled "Selected Financial Data," “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Capitalization.” Our historical results are not necessarily indicative of results that should be expected in any future period, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

	Three Months Ended March 31,		Years Ended December 31,	
	2022	2021	2021	2020
	(Unaudited)			
Total operating expenses	$ 3,443,558	$ 1,050,713	$ 7,786,627	$ 6,975,601
Loss from operations	(3,443,558)	(1,050,713)	(7,786,627)	(6,975,601)
Other income (expense), net	29,713	29,194	(4,791,584)	16,353
Net loss	(3,413,845)	(1,021,519)	(12,578,211)	(6,959,248)
Net loss attributable to MAIA Biotechnology, Inc. shareholders	(3,864,423)	(983,994)	(12,503,880)	(6,636,660)
Net loss per common share - basic and diluted (1)	$ (0.50)	$ (0.23)	$ (2.37)	$ (1.50)
Weighted average common shares outstanding - basic and diluted(1)	7,752,042	4,329,088	5,278,435	4,427,242

(1) See Note 1 to our audited financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per common share.

	March 31, 2022	December 31, 2021	December 31, 2020
	(Unaudited)		
Balance Sheet Data:			
Cash	$ 10,293,460	$ 10,574,292	$ 663,457
Working capital (deficit) (1)	8,097,195	8,526,499	(947,239)
Total assets	11,444,563	11,327,199	746,505
Total liabilities	2,430,893	2,145,996	2,362,805
Total stockholders' equity (deficit)	9,013,670	9,181,203	(1,616,300)

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

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 prospectus, 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. In that event, the trading price of our common stock could decline and you could lose all or part of your investment.

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 $12,578,211 and $6,959,248 for the years ended December 31, 2021 and 2020, respectively. We incurred net losses of $3,413,845 and $1,021,519 for the three months ended March 31, 2022 and March 31, 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $31,851,838. 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:

- commence 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.

Even if this offering is successful, 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.

We believe that the net proceeds from this offering together with our existing cash as of December 31, 2021, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 36 months. We have based this estimate on assumptions that may prove to be wrong, and we could deploy our available capital resources sooner than we currently expect. 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, including purchasers of common stock in this offering, 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, even if we believe that we have sufficient funds for 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, 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 recent outbreak of the novel coronavirus 2019 (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 recent 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 has imposed one of the strictest COVID-19-related measures, including lock-downs. 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 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 prospectus 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 Initial Public Offering and Ownership of Our Common Stock

There is no existing market for our common stock and an active, liquid trading market for our common stock may not develop.

Prior to this offering, there has been a limited market for our common stock. Although we intend to apply to have our common stock listed on the NYSE under the symbol "MAIA," we cannot predict the extent to which investor interest in our Company will lead to the development of an active trading market or how liquid that market may become. If an active trading market does not develop, you may have difficulty selling any of our shares that you purchase. The initial public offering price of our common stock will be determined by negotiation between us and the underwriters, and may not be indicative of prices that will prevail after the completion of this offering. The market price of our common stock may decline below the initial public offering price, and you may not be able to resell your shares at, or above, the initial public offering price.

The price of our common stock may be volatile and you could lose all or part of your investment.

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 is likely to be highly 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.

All shares of common stock sold in this offering will be freely transferable without restriction or further registration under the Securities Act. At the time of this offering, we also will have registered shares of common stock reserved for issuance under our equity incentive plans of which restricted stock units representing shares of common stock are outstanding, which shares may be issued upon issuance and once vested, subject to any applicable lock-up restrictions then in effect. 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, will be restricted securities within the meaning of Rule 144 under the Securities Act and subject to certain restrictions on resale following the consummation of this offering. 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, as described in "Shares Eligible for Future Sale."

We, each of our officers, directors, and certain of our stockholders have agreed, 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 this prospectus, 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 6 months (or in the case of options with a weighted average exercise price of $1.80 or $1.83, for a period of 12 months) after the date of this 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. See the section of this prospectus entitled "Underwriting" for additional information. See "Underwriting" for additional information. 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. See "Shares Eligible for Future Sale" for a discussion of the shares of common stock that may be sold into the public market in the future.

If securities or industry analysts publish unfavorable research about our business, or if our competitors' stock performance decline, the price of our common stock and our trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts may publish about us or our business. We do not have any control over these analysts. Securities and industry analysts do not currently publish research on our Company. Once securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our common stock or publish unfavorable research about our business, the price of our common stock likely would decline. Additionally, if one of our competitor's stock performance declines, the price of our common stock and our trading volume could decline as well. If one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, or if one of our competitor's stock performance declines, demand for our common stock could decrease, which might cause the price of our common stock and trading volume to decline.

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."

We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We will have broad discretion in the application of the net proceeds from this offering and our shareholders will not have the opportunity as part of their investment decision to assess whether the net proceeds are being used appropriately. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our failure to apply the net proceeds of this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. See “Use of Proceeds” for a description of how we intend to use the proceeds of the offering.

If you purchase shares of our common stock in this offering, you will incur immediate dilution in the book value of your shares.

The initial public offering price of our common stock will be substantially higher than the as adjusted net tangible book value per share of our common stock. Therefore, if you purchase our common stock in this offering, you will pay a price per share of our common stock that substantially exceeds the book value of our tangible assets after subtracting our liabilities. Based on an initial public offering price of $ per share, you will experience immediate dilution of $ per share, representing the difference between our net tangible book value per share, after giving effect to this offering, and the initial public offering price. Further, the issuance of any Ratchet Shares to the Crossover Investors, and the future exercise of any outstanding options and/or warrants to purchase shares of our common stock will cause you to experience additional dilution. See “Description of Capital Stock—Crossover Round” and “Dilution.”

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 that will be in effect prior to the completion of this offering 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 intend to enter into indemnification agreements with each of our executive officers and directors that will be in effect upon the completion of this offering. The indemnification agreements will 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 31, 2022, an aggregate of 3,290,577 shares of our common stock, which currently constitutes 41.46 % of our issued and outstanding common stock and, upon closing of this offering, will own an aggregate of shares of our common stock, which will constitute % 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, each of which will be in effect prior to the completion of this offering, 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, each as amended to be in effect upon completion of this offering, 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 will 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 will 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 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 initial public 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 this offering, (b) in which we have total annual gross revenue of at least $1.07 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.

A potential 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"), 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 defines 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. 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 will be 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 will be 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 later of (i) the year following our first annual report required to be filed with the SEC or (ii) the date we are no longer an emerging growth company. 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, 2021. 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). In addition, the Company did not have an effective risk assessment process that defined clear financial reporting objectives and elevated risks, including fraud risks, at a sufficient level of detail to identify all relevant risks of material misstatement including the risks associated with the use of outsourced consultants in the preparation of schedules supporting balances within the consolidated financial statements. These factors contributed to the following additional material weaknesses.

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

- the accounting for stock-based compensation and other stock-based financial instruments in accordance with U.S. GAAP. Specifically, we did not design and maintain controls to timely identify transactions requiring a valuation of our common stock and to review in sufficient detail, the valuation model assumptions used in determining the fair value of our common stock which is used as an input in accounting for stock-based compensation provided to employees and other stock-based financial instruments;
- the calculation of earnings per share in accordance with U.S. GAAP; and
- the reconciliation and review of significant account balances, authorization over cash disbursements, stock-based compensation calculations and related valuation models including inputs, period end financial reporting, risks associated with segregation of duties, and certain other entity level controls.

As we work towards remediating these material weaknesses, we will design and implement controls to properly identify transactions for which a valuation of our common stock is required and to review assumptions used in the valuation models to ensure our equity-based transactions are accounted for in accordance with U.S. generally accepted accounting principles. Additionally, we will design and implement controls to properly calculate basic and diluted weighted-average shares outstanding. Lastly, 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 recently 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 transactions requiring the valuation of our common stock, in retaining and reviewing the work of valuation experts necessary to complete those valuations, and performing the calculation of basic and diluted weighted-average shares outstanding.

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.

We will incur increased costs as a result of being a publicly traded company.

As a company with publicly traded securities, we will incur significant legal, accounting and other expenses not presently incurred as a private company. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules and regulations promulgated by the SEC and the NYSE, will require us to adopt corporate governance practices applicable to U.S. public companies. These rules and regulations will increase our legal and financial compliance costs and may place a strain on our systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. To maintain and improve the effectiveness of our disclosure controls and procedures, we will need to commit significant resources, hire additional staff and provide additional management oversight. We will be implementing additional procedures and processes for the purpose of addressing the standards and requirements applicable to public companies.

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 registration statement on Form S-1.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this prospectus, which reflect our current views with respect to future events and financial performance, and any other statements of a future or forward-looking nature constitute "forward-looking statements" within the meaning of the federal securities laws. We intend the forward-looking statements to be covered by the applicable safe harbor under the federal securities laws. In some cases, you can identify forward-looking statements by terms such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," or the negative of these terms or other similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on the information we have when the statements are made or management's good faith belief as of that time with respect to future events and are subject to significant risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward-looking statements due to a number of factors, including those set forth above under "Risk Factors" and elsewhere in this prospectus. The factors set forth above under "Risk Factors" and other cautionary statements made in this prospectus should be read and understood as being applicable to all related forward-looking statements wherever they appear in this prospectus. The forward-looking statements contained in this prospectus represent our judgment as of the date of this prospectus. We caution readers not to place undue reliance on such statements. We operate in an evolving environment where new risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained above and throughout this prospectus.

INDUSTRY AND OTHER DATA

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Information that is based on estimates, forecasts, 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 based on various factors, including those discussed in "Risk Factors."

TRADEMARKS, SERVICE MARKS AND TRADE NAMES

We own or have rights to use a number of registered and common law trademarks, service marks and/or trade names in connection with our business in the United States and/or in certain foreign jurisdictions.

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the common stock we are offering will be approximately $ million. If the underwriters fully exercise the over-allotment option, the net proceeds of the common stock we sell will be approximately $ million. These assume an initial public offering price of $ per share, the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus. "Net proceeds" is what we expect to receive after deducting the underwriting discount and commission and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, along with our existing cash and cash equivalents, as follows:

- approximately $10-15 million to fund the planned Phase 2 trial of THIO for NSCLC indication (THIO-101);
- approximately $2-4 million to fund the first part of the planned Phase 2 trial of THIO for CRC, HCC, and SCLC (THIO-102)
- approximately $3-5 million to fund pre-clinical to IND development for two second-generation telomere targeting compounds;
- the remaining proceeds to fund our other research and development activities, as well as for working capital and other general corporate purposes.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and commission and estimated offering expenses payable by us in connection with this offering.

The net proceeds from this offering, together with our cash, will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of our product candidates. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources. This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the clinical trials we may commence in the future, as well as any collaborations that we may enter with third parties for our product candidates and any unforeseen cash needs. As a result, our management will have significant discretion in the use of any net proceeds and Investors will be relying on the judgment of our management regarding the application of the proceeds.

Based on our planned use of the net proceeds from this offering and our existing cash, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next 36 months. In particular, we expect that these capital resources will allow us to fund:

- our planned Phase 2 trial of THIO through completion; and
- our planned pre-clinical to IND development for two second-generation telomere targeting compounds.

We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. Our existing cash and cash equivalents as of the date of this prospectus, together with the estimated net proceeds from this offering, may or may not be sufficient to fund development of our product candidates through regulatory approval and commercialization. To obtain the capital necessary to fund our product candidates through regulatory approval and commercialization, we expect to finance our cash needs through public or private equity offerings, debt financings and/or other capital sources which may include strategic collaborations, licensing arrangements or other arrangements with third parties.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends. The payment of dividends, if any, in the future is within the discretion of our Board of Directors and will depend on our earnings, capital requirements and financial condition and other relevant facts. We currently intend to retain all future earnings, if any, to finance the development and growth of our business.

CAPITALIZATION

The following table sets forth our cash and capitalization as of March 31, 2022:

- on an actual basis;
- on a pro forma as adjusted basis to give effect to the sale of common stock in this offering, assuming no exercise of the underwriters' option to purchase additional shares, at an assumed initial public offering price of $ ____ per share, which is the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and the application of the proceeds therefrom as described in "Use of Proceeds."

The information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with our financial statements and accompanying notes appearing at the end of this prospectus and the "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Description of Capital Stock" sections of this prospectus.

	As of March 31, 2022	
	Actual	Pro Forma As Adjusted
	(Unaudited)	(Unaudited)
Cash	$ 10,293,460	$ —
Total debt	—	—
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 70,000,000 shares authorized, 0 shares issued and outstanding, actual; and 0 shares outstanding pro forma as adjusted	—	—
Common stock, $0.0001 par value, 30,000,000 shares authorized, 7,936,320 shares issued and outstanding, actual; and [ ] shares outstanding pro forma as adjusted	794	—
Additional paid-in capital	40,862,993	—
Accumulated deficit	(31,851,838)	
Accumlated other comprehensive income	1,721	—
Total stockholders' equity:	9,013,670	—
Total capitalization:	$ 9,013,670	$ —

The number of shares of common stock issued and outstanding and pro forma in the table above is based on 7,936,320 shares of our common stock outstanding as of March 31, 2022, and excludes the following:

- 5,859,589 shares of common stock issuable upon exercise of options to purchase shares of common stock outstanding as of March 31, 2022, with a weighted-average exercise price of $2.35 per share;
- 242,911 shares of common stock reserved for future issuance as of March 31, 2022, under our 2020 Plan;
- warrants to purchase 1,250,006 shares of common stock with a weighted-average exercise price of $4.14 per share; and
- 29,168 shares of common stock issuable upon the settlement of outstanding restricted common stock awards, inclusive of restricted common stock awards which will vest upon the pricing of this offering.

DILUTION

If you purchase common stock in this offering, your interest will be diluted immediately to the extent of the difference between the assumed initial public offering price of $ per share and the net tangible book value per share of our common stock immediately upon the consummation of this offering.

Our net tangible book value as of March 31, 2022, was $9.01 million, or $1.14 per share. Net tangible book value per share of our common stock represents our total tangible assets (total assets less intangible assets) less total liabilities divided by the number of shares of common stock outstanding as of that date.

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers in this offering and the as adjusted net tangible book value per share of common stock immediately after completion of this offering. After giving effect to our sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus, and after deducting underwriters' commissions and estimated offering expenses, our as adjusted net tangible book value as of December 31, 2021, would have been $ million, or $ per share. This represents an immediate increase in net tangible book value of $ per share to existing stockholders and an immediate dilution in net tangible book value of $ per share to purchasers of securities in this offering, as illustrated in the following table:

Assumed initial public offering price per share		$ —
Net tangible book value per share as of March 31, 2022	$ 1.14	
Increase in net tangible book value per share attributable to new investors	$ —	
As adjusted net tangible book value per share as of March 31, 2022, after giving effect to the offering	$ —	
Dilution per share to new investors in the offering		$ —

A $1.00 increase (or decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus, would increase (or decrease) the as adjusted net tangible book value per share after this offering by approximately $, and dilution in net tangible book value per share to new investors by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option in full to purchase additional shares of common stock in this offering at the assumed offering price of $ per unit, the net tangible book value per share after this offering would be $ per share, the increase in the net tangible book value per share to existing stockholders would be $ per share and the dilution to new investors purchasing common stock in this offering would be $ per share.

To the extent that outstanding exercisable options or warrants are exercised, you may experience further dilution.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be further diluted.

SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the statement of operations data and balance sheet data for the years ended December 31, 2021 and 2020 from our audited financial statements appearing at the end of this prospectus. We have derived the statement of operations data for the three months ended March 31, 2022 and 2021 and the balance sheet data as of March 31, 2022, from our unaudited interim financial statements appearing at the end of this prospectus. The unaudited interim financial statements have been prepared on the same

basis as the audited financial statements and reflect, in the opinion of management, all adjustments of a normal, recurring nature that are necessary for a fair presentation of the unaudited interim financial statements. Our historical results are not necessarily indicative of results that should be expected in any future period, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

	As of March 31, 2022	As of December 31, 2021	As of December 31, 2020
	(Unaudited)		
Balance Sheet Data:			
Cash	$ 10,293,460	$ 10,574,292	$ 663,457
Working capital (deficit) [1]	8,097,195	8,526,499	(947,239)
Total assets	11,444,563	11,327,199	746,505
Accrued Interest	—	—	12,678
Accrued bonus	561,873	384,750	780,000
Deferred compensation	114,333	111,271	661,058
Convertible note payable, current portion	—	—	10,586
Convertible notes payable, net of current portion	—	—	332,841
Derivative liability for embedded conversion features on convertible notes payable and related parties	—	—	127,000
Convertible notes payable, related parties	—	—	98,960
Warrant liability	—	—	85,260
Simple agreement for future equity payable	—	—	25,000
Total stockholders' equity (deficit)	9,013,670	9,181,203	(1,616,300)

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

	Three Months Ended March 31,		Years Ended December 31,	
	2022	2021	2021	2020
	(Unaudited)			
Statement of Operations Data:				
Operating expenses:				
Research and development expenses	$ 2,077,329	$ 262,758	$ 3,496,796	$ 1,412,409
General and administrative expenses	1,366,229	787,955	4,289,831	5,563,192
Total operating expenses	3,443,558	1,050,713	7,786,627	6,975,601
Loss from operations	(3,443,558)	(1,050,713)	(7,786,627)	(6,975,601)
Paycheck protection program loan forgiveness	—	—	62,500	62,500
Australian research and development incentives	29,241	—	43,666	—
Interest expense	—	(62,767)	(827,539)	(32,226)
Interest income	472	141	2,012	679
Change in fair value of embedded features	—	(15,000)	(203,000)	5,000
Change in fair value of warrant liability	—	106,820	(1,546,280)	(19,600)
Loss on extinguishment of convertible notes and convertible notes, related parties	—	—	(2,322,943)	—
Net loss	(3,413,845)	(1,021,519)	(12,578,211)	(6,959,248)
Net loss attributable to noncontrolling interests	—	(37,525)	(74,331)	(322,588)
Deemed dividend on warrant modification	(450,578)	—	—	—
Net loss attributable to MAIA Biotechnology, Inc.	$ (3,864,423)	$ (983,994)	$ (12,503,880)	$ (6,636,660)
Net loss per common share - basic and diluted[1]	$ (0.50)	$ (0.23)	$ (2.37)	$ (1.50)
Weighted average common shares outstanding - basic and diluted[1]	7,752,042	4,329,088	5,278,435	4,427,242

[1] See Note 1 to our audited financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per common share.

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 prospectus. 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 prospectus. 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. After this round, 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 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 the second 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.

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. 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.

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, 2021 and 2020

Comparison of the Years Ended December 31, 2021 and 2020

	Year Ended December 31,		Change	
	2021	2020	Dollars	Percentage
Operating expenses:				
Research and development expenses	$ 3,496,796	$ 1,412,409	$ 2,084,387	148%
General and administrative expenses	4,289,831	5,563,192	(1,273,361)	(23)%
Total operating costs and expenses	7,786,627	6,975,601	811,026	12%
Loss from operations	(7,786,627)	(6,975,601)	(811,026)	(12)%
Other income (expense):				
Paycheck protection program loan forgiveness	62,500	62,500	—	—%
Interest expense	(827,539)	(32,226)	(795,313)	(2468)%
Interest Income	2,012	679	1,333	196%
Australian research and development incentives	43,666	—	43,666	100%
Change in fair value of embedded features	(203,000)	5,000	(208,000)	(4160)%
Change in fair value of warrant liability	(1,546,280)	(19,600)	(1,526,680)	(7789)%
Loss on extinguishment of convertible notes and convertible notes, related parties	(2,322,943)	—	(2,322,943)	(100)%
Other income (expense), net	(4,791,584)	16,353	(4,807,937)	(29401)%
Net loss	(12,578,211)	(6,959,248)	(5,618,963)	(81)%
Net loss attributable to noncontrolling interests	(74,331)	(322,588)	248,257	77%
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (12,503,880)	$ (6,636,660)	$ (5,867,220)	(88)%

Operating Expenses

Research and development expenses

Research and development expenses increased by approximately $2,084,000 or 148%, from approximately $1,412,000 for the year ended December 31, 2020 to approximately $3,497,000 for the year ended December 31, 2021. The increase was primarily related to the increase in clinical expenses related to the clinical preparation of THIO of approximately $802,000, an increase in stock based compensation costs of approximately $518,000 related to employee options granted during fiscal year 2021, an increase in payroll and bonus expenses of approximately $384,000 related to increased headcount of two employees during fiscal year 2021 and bonus accruals for certain executive members of management, an increase in professional fees of approximately $326,000, and an increase in other expenses related to research and development of approximately $56,000.

General and administrative expenses

General and administrative expenses decreased by approximately $1,273,000 or 23% from approximately $5,563,000 for the year ended December 31, 2020 to approximately $4,290,000 for the year ended December 31, 2021. The decrease was primarily related to a decrease in stock based compensation expense of approximately $1,733,000 and a decrease in payroll and bonus expense of approximately $448,000, offset by an increase in professional fess of approximately $636,000, an increase in the state of Delaware business franchise tax of approximately $37,000, and an increase in other general and administrative expenses of approximately $188,000.

Other income (expense), net

Other income (expense), net changed approximately $4,808,000 from other income of approximately $16,000 for the year ended December 31, 2020 to other expense of approximately $4,792,000 for the year ended December 31, 2021. The change 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, an increase in interest expense of approximately $795,000 related to the issuance of additional convertible notes payable issued during the year ended December 31, 2021, and approximately $44,000 related to a research and development incentive. Additionally, other income (expense), net

changed by approximately $208,000 and $1,527,000 for the embedded features and warrants related to the convertible notes payable, respectively, due to the increase of the fair value of the mark-to-market adjustments recorded.

Liquidity and Capital Resources

The following table presents selected financial information and statistics as of and for the years ended December 31, 2021 and 2020:

Years Ended December 31, 2021 and 2020

	Year Ended December 31,	
	2021	**2020**
Balance Sheet Data:		
Cash	$ 10,574,292	$ 663,457
Working Capital (Deficit)	8,526,499	(947,239)
Total assets	11,327,199	746,505
Convertible notes payable - current portion	—	10,586
Loan payable to officer	—	21,367
Convertible notes payable, net of current portion	—	332,841
Convertible notes payable, related parties	—	98,960
Derivative liability for embedded conversion features on convertible notes payable and convertible notes payable, related parties	—	127,000
Warrant liability	—	85,260
Simple agreement for future equity payable	—	25,000
Total stockholders' equity (deficit)	$ 9,181,203	$ (1,616,300)
Statement of Cash Flow Data:		
Net cash flows used in operating activities	$ (4,122,896)	$ (1,844,163)
Net cash flows provided by investing activities	—	—
Net cash flows provided by financing activities	14,033,731	798,055
Net increase (decrease) in cash and cash equivalents	$ 9,910,835	$ (1,046,108)

Capital Resources

As of December 31, 2021, our available cash totaled approximately $10,574,000 which represented an increase of approximately $9,911,000 compared to December 31, 2020. As of December 31, 2021, we had working capital of approximately $8,526,000 which represents an increase of approximately $9,473,000 compared to December 31, 2020. We have generated no revenues as of December 31, 2021, and we expect to continue to incur operating losses for the foreseeable future, and may never become profitable. We are dependent on our ability to continue to raise equity and/or debt financing to continue operations, and the attainment of profitable operations.

Management believes that the Company’s existing cash and cash equivalents will allow the Company to continue its operations at least into the Second Quarter 2023. As a result of recurring losses, the continued viability of the Company beyond the Second Quarter 2023 is dependent on its ability to continue to raise additional capital to finance its operations.

Paycheck Protection Program Loan

On January 31, 2021, we received a second PPP loan with a bank in the amount of $62,500. Under the terms of the PPP loan, interest accrued on the outstanding principal at the rate of 1% per annum. 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 in the amount of $62,500.

Convertible Notes

Between August 2019 and June 2021, we issued unsecured convertible notes payable to investors for a total of $8,010,000. The notes bore simple interest at rates between 6% and 8% per annum and were to mature two years from issuance. The notes also contained an automatic conversion feature, such that in the event we consummate an equity financing, as defined in the agreement, prior to the notes' maturity, the outstanding principal and interest would be converted into shares of the Company which may be issued in connection with such equity financing. These notes were automatically converted into shares of the Company's common stock on September 30, 2021 at $6.00 per share as a result of the sale of common stock which qualified as an equity financing in accordance with the terms of the convertible note agreements. As of December 31, 2021 there were no convertible notes payable outstanding.

Sale of Common Stock

Between July 18, 2021 and December 31, 2021, the Company sold 772,563 shares of common stock at $8.00 per share for gross proceeds of approximately $6.2 million.

In connection with the sale of common stock, 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 Notes, 2020 Convertible Notes, and 2021 Convertible Notes into 1,375,228 shares of the Company's common stock on September 30, 2021.

Additionally, 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.

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. We believe that we currently have sufficient funds to support operations through the next 12 months from the date of this filing.

Cash Flows

Operating Activities

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.

For the year ended December 31, 2020, net cash used in operating activities was approximately $1,844,000, which consisted of a net loss of approximately $6,959,000 offset by non-cash charges of approximately $3,861,000 which primarily includes approximately $3,889,000 in stock-based compensation offset by approximately $63,000 related to gain from forgiveness of Paycheck Protection Program loan and a loss of approximately $5,000 related to the change in fair value of embedded features related to convertible notes offset by changes in the fair value of the warrant liability of approximately $20,000 and amortization of debt discount on convertible notes of approximately $20,000. Total changes in operating assets and liabilities of approximately $1,254,000 were primarily driven by an approximately $824,000 increase in accrued expenses, an approximate $483,000 increase in deferred compensation, an approximate $5,000 increase in related party payables offset by an approximate $58,000 increase in prepaid expenses and other current assets.

Financing Activities

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.

Net cash provided by financing activities for the year ended December 31, 2020 was approximately $798,000 which consisted of proceeds from issuance of convertible notes totaling approximately $610,000, collections of subscriptions receivable of approximately $102,000 and approximately $35,000 for MAIA and DGD, respectively, proceeds from the paycheck protection program loan totaling approximately $63,000, and proceeds from the issuance of common stock of DGD totaling approximately $50,000, offset by return of capital - DGD Pharmaceuticals Corporation totaling approximately $58,000, and payment on loan payable to officer of approximately $4,000.

Financial Operations Overview and Analysis for the Three Months Ended March 31, 2022 and 2021

Comparison of the Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31		Change	
	2022	2021	Dollar	Percentage
Operating expenses:				
Research and development expenses	$ 2,077,329	$ 262,758	1,814,571	690.59%
General and administrative expenses	1,366,229	787,955	578,274	73.39%
Total operating costs and expenses	3,443,558	1,050,713	2,392,845	227.74%
Loss from operations	(3,443,558)	(1,050,713)	2,392,845	-227.74%
Other income (expense):				
Interest expense	—	(62,767)	62,767	-100.00%
Interest income	472	141	331	234.75%
Austrailian research and development incentives	29,241	—		100.00%
Change in fair value of embedded features	—	(15,000)	15,000	-100.00%
Change in fair value of warranty liability	—	106,820	(106,820)	-100.00%
Other income (expense), net	29,713	29,194	519	1.78%
Net loss	(3,413,845)	(1,021,519)	2,392,326	234.19%
Net loss attributable to noncontrolling interests	—	(37,525)	37,525	-100.00%
Deemed dividend on warrant modification	(450,578)	—	(450,578)	100.00%
Net loss attributable shareholder	$ (3,864,423)	$ (983,994)	(2,880,429)	292.73%

Operating Expenses

Research and development expenses

Research and development expenses increased by approximately $1,815,000 or 691%, from approximately $263,000 for the three months ended March 31, 2021 to approximately $2,077,000 for the three months ended March 31, 2022. The increase was primarily related to the increase in clinical expenses related to the clinical preparation and startup of THIO trials of approximately $1,088,000, an increase in payroll and bonus expenses of approximately $330,000 related to increased headcount of four additional research and development employees during the first three months of 2022, an increase in professional fees of approximately $135,000, an increase in stock based compensation costs of approximately $207,000 related to employee options granted during fiscal year 2021, and an increase in other expenses related to research and development of approximately $55,000.

General and administrative expenses

General and administrative expenses increased by approximately $578,000 or 131% from approximately $788,000 for the three months ended March 31, 2021 to approximately $1,366,000 for the three months ended March 31, 2022. The increase was primarily related to an increase in professional fees of approximately $349,000, an increase in payroll of approximately $118,000, and an increase in other general fees of $158,000 offset by a decrease in stock based compensation of approximately $47,000.

Other income (expense), net

Other income (expense), net increased approximately $1,000 from other income of approximately $29,000 for the three months ended March 31, 2021 to other income of approximately $30,000 for the three months ended March 31, 2022. The change in other income (expense), net was primarily the result of a decrease in interest expense of approximately $63,000 related to the issuance of convertible notes payable issued during the three months ended March 31, 2021, a decrease of $15,000 related to a change in fair value of embedded features offset by a net change of approximately $106,000 for change in fair value of warrant liability.

Liquidity and Capital Resources

Capital Resources

As of March 31, 2022, our available cash totalled approximately $10,293,000 which represented a decrease of approximately $281,000 compared to December 31, 2021. As of March 31, 2022, we had working capital of approximately $8,097,000 which represents a decrease of approximately $429,000 compared to December 31, 2021. We have generated no revenues and we expect to continue to incur operating losses for the foreseeable future and may never become profitable. We are dependent on our ability to continue to raise equity and/or debt financing to continue operations, until the attainment of profitable operations.

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. We believe that we currently have sufficient funds to support operations through the next 12 months from the date of this filing. If the Company is unable to raise the necessary funding, management will undertake cost cutting measures, as done in the past, to reduce compensation and reduce the scope of or delay its clinical programs.

Cash Flows Three Months Ended March 31, 2022 and March 31, 2021

	Three Months Ended March 31,	
	2022	2021
Net cash flows used in operating activities	$ (2,545,718)	$ (253,315)
Net cash flows provided by financing activities	2,269,168	2,429,535
Effect of foreign currency exchange on cash	(4,282)	—
Net (decrease) increase in cash and cash equivalents	$ (280,832)	$ 2,176,220

Operating Activities

For the three months ended March 31, 2022, net cash used in operating activities was approximately $2,546,000, which consisted of a consolidated net loss of approximately $3,414,000 offset by non-cash charges of approximately $713,000 in stock-based compensation. Total changes in operating assets and liabilities of approximately $155,000 were driven by an approximate $134,000 increase in prepaid assets, an approximate $67,000 decrease in accounts payable offset by an approximate $353,000 increase in accrued expenses and $3,000 increase in deferred compensation.

For the three months ended March 31, 2021, net cash used in operating activities was approximately $253,000, which consisted of a net loss of approximately $1,021,519 offset by non-cash charges of approximately $507,000 which primarily includes approximately $553,000 in stock-based compensation, $15,000 related to the change in fair value of embedded features, $45,000 amortization of debt discount on convertible notes offset by changes in the fair value of the warrant liability of approximately $107,000. Total changes in operating assets and liabilities of approximately $261,000 were primarily driven by an approximate$120,000 increase in accounts payable, an approximate $48,000 increase in accrued expenses, an approximate increase in deferred compensation of $125,000 and an approximate $44,000 decrease in prepaid expenses offset by an approximate $69,000 increase in other assets and an approximate $7,000 decrease in amounts due to related parties.

For the three months ended March 31, 2022 the effect of foreign currency exchange on cash increased the cash balance as of March 31, 2022 approximately $4,000.

Financing Activities

Net cash provided by financing activities was approximately $2,269,000 and $2,430,000 for the three months ended March 31, 2022 and 2021, respectively. Net cash provided by financing activities for the three months ended March 31, 2022 consisted primarily of proceeds from issuance of common stock with no transaction costs of approximately of $2,374,000 and net proceeds from issuance of common stock upon exercise of warrants of $110,000 and stock options of approximately $48,000 offset by an approximate $262,000 increase in deferred offering costs. Net cash provided by financing activities for the three months ended March 31, 2021 consisted of proceeds from issuance of convertible notes totaling approximately $2,360,000, collections of subscriptions receivable of approximately $2,000, proceeds from the paycheck protection program loan totaling approximately $63,000, and proceeds from exercise of stock options of approximately $5,000.

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, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of expenses during the reporting period. In accordance with U.S. GAAP, we evaluate estimates and judgments on an ongoing basis. The most significant estimates relate to the valuation of common stock, the valuation of stock options and warrants, embedded features in convertible notes, and the valuation allowance of deferred tax assets resulting from net operating losses. We base our estimates and assumptions on current facts, historical experiences, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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.

Fair value of common stock

For all periods prior to this offering, there was no public market for our common stock. The Company sold shares of its common stock to third parties beginning in September 2018 through June 2019 at $1.80 per share. Subsequent to July 2019 the fair value of the shares of common stock underlying our stock-based awards was estimated by our board of directors based in part on valuations until we began selling shares of our common stock to third parties beginning on July 15, 2021 through October 15, 2021 at $8.00 per share and beginning on January 27, 2022 through February 27, 2022 at $9.00 per share. To determine the fair value of our common stock underlying annual option grants to officers and directors, our board of directors considered, among other things, input from management, valuations of our common stock valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant, and factors that may have changed from the date of the most recent valuation through the date of the grant.

These factors included, but were not limited to:

- our results of operations and financial position, including our levels of available capital resources;
- our stage of development and material risks related to our business;
- our business conditions and projections;
- the valuation of publicly traded companies in the life sciences industry sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the likelihood of achieving a liquidity event for our security holders, such as an initial public offering or a sale of our company, given prevailing market conditions;
- the hiring of key personnel and the experience and expertise of management;
- trends and developments in our industry; and
- external market conditions affecting the life sciences industry sectors.

Our valuation as of February 28, 2021 indicated a fair value of our common stock of $1.83 per share. For grants of stock awards and stock option awards during the period February 28, 2021 through July 12, 2021, management set the exercise prices for those awards based on the February 28, 2021 valuation until the Company initiated the sale of common stock at $8.00 per share which was first competed on July 18, 2021 and followed by additional sales through September 26, 2021. The Company set the exercise price of awards granted from July 18, 2021 through October 30, 2021 at $8.00 per share.

In evaluating the fair value of our common stock during the period March 2021 through May 2021, management evaluated events and their potential impact on the estimated fair value per share of the common stock. We considered events during this period which would have an effect on the fair value of our common stock such as milestones related to the clinical development and operations of our drug substances and advances in the production of drug substances and our drug product, however, there were no specific events that would indicate a definitive change in the value of the Company.

Given that there were no specific events that caused the change in fair value of our common stock from the indicated value of $1.83 as of February 28, 2021 to the $8.00 per share realized from the sale of common stock initiated in mid July, we performed a retrospective valuation of our common stock as of April 30, 2021. The retrospective valuation as of April 30, 2021 also indicated a fair value of our common stock of $1.83. In estimating the fair value of stock and stock option awards, we used an estimated fair value of $1.83 for awards granted from February 28, 2021 through May 31, 2021, based on the February 28, 2021 and April 30, 2021 valuations. From June 1, 2021 through October 30, 2021, we used an estimated of fair value of our common stock of $8.00 in valuing our stock and stock option awards. We believe the fair values based on the valuations materially represents the fair value of our common stock during the period February 28, 2021 through May 31, 2021 since no single intervening specific event indicated a definitive change in the value of the Company.

The February 28, 2021 and the April 30, 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.

During November 2021 and December 2021, the fair value of the Company’s common stock was determined to be $8.69 and $8.87, respectively. For our valuations of common stock performed November 2021 and December 2021, 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 value 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.

In the First Quarter of 2022, the Company made further progress in its clinical programs, which included the approval of THIO by the Bellberry Human Research Ethics Committee (HREC) in Australia to initiate the THIO-101 Phase 2 clinical study. Additionally, the Company completed its selection process for the clinical sites for its Phase 2 study in Australia and Europe and its application to start the Phase 2 study in Australia was approved. The Company also plans to submit a similar application in the second quarter of 2022, to conduct the same Phase 2 study in Europe.

The events above resulted in the Company being able to complete sales of its common stock to unrelated third-party investors beginning in January 27, 2022, through February 28, 2022, of 263,729 shares of common stock at a price of $9.00 per share resulting in aggregate proceeds of approximately $2.4 million. Due to the lack of any single specific event that would have indicated a definitive change in the value of the Company, the fair value of the

Company's common stock from January 27, 2022 through March 31, 2022, was determined based on sales of the Company's shares at arm's length to unrelated third parties at $9.00 per share.

Following this offering, it will not be necessary to determine the fair value of our common stock, as our shares will be traded in the public market.

Stock-based compensation

Our stock-based awards are classified as equity (restricted stock awards, 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 our common stock price. 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. These estimates are highly subjective and once this offering is completed these estimates will no longer be necessary since the fair value will be based on the trading value of the Company's common stock.

Two of the assumptions used in the Black-Scholes-Merton valuation model are historical volatility and fair value of common stock, both of which are subject to uncertainty. 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.

BUSINESS

Our Company

We are 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. We submitted a similar application to conduct the same Phase 2 study in Europe. 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 generated 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 First Quarter of 2023, we plan to initiate a pivotal Phase 2 clinical trial of THIO in patients with advanced colorectal cancer administered in sequence with Anti-PD-1 or Anti-PD-L1.

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 the first part of 2022 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. Based on the clinical data generated 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 telomeric structure unwinds 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 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 essential 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+). 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 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.

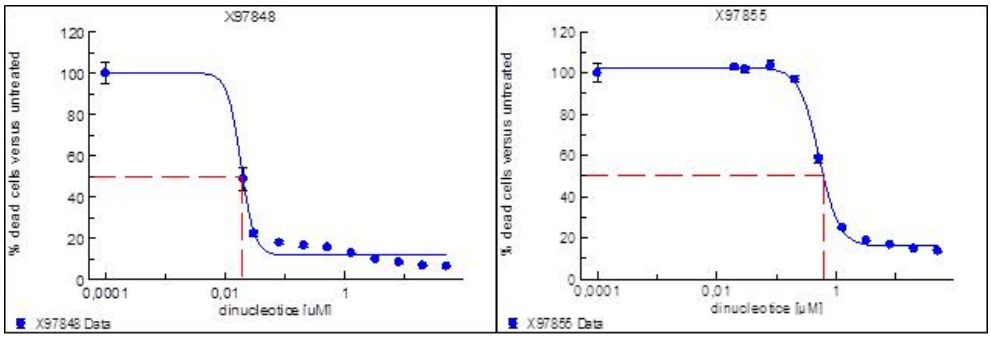
Our Second Generation Target Candidates

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 five 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:

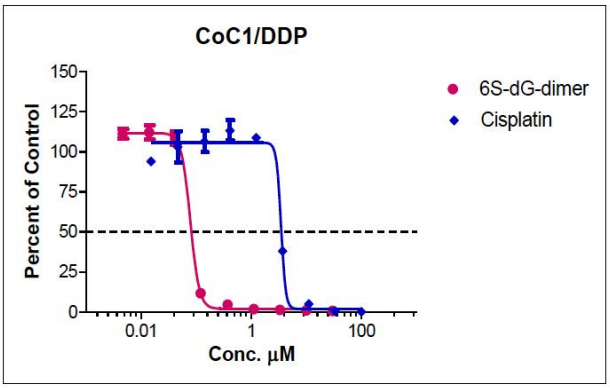
	IC50, μM				
	Cell Lines				
Compound ID	**MC38**	**LLC**	**Hep55-1C**	**H2081**	**HEK293**
THIO(6-thio-dG)	1.5	1.6	5.0	0.92	-*
Compound #5	0.35	0.34	0.35	0.34	0.02
Compound #6	0.35	0.35	0.34	0.34	0.01
Compound #11	0.36	0.80	0.44	0.35	0.63
Compound #12	0.84	0.50	0.77	0.35	0.61

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)

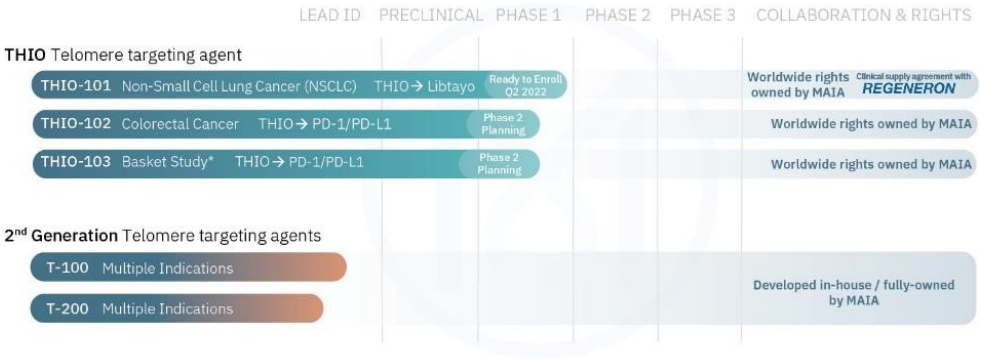
Compound	CoC1/DDP
6S-dG-dimer	0.08
Cisplatin	3.54

Based on the data presented, we have progressed five second-generation compounds to *in vivo* testing, and with proceeds from the IPO, we plan to initiate pre-IND testing for two of them in mid-2022, with the goal of advancing at least one compound to clinical trials by the end of 2024.

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 robust pipeline includes several 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, we envision positioning 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. Successful targeting of telomeres in TERT+ cancers 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.

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 oncologist and experienced pharmaceutical physician executive that brings a 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.)
    - Immediate 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. – Occidental Chemical Chair of Cancer Research and an 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.

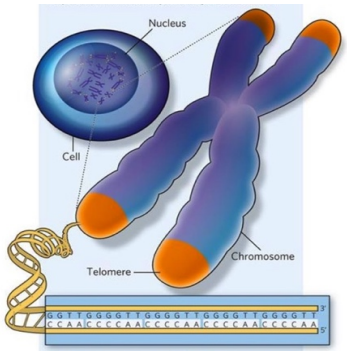
Our Programs

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.

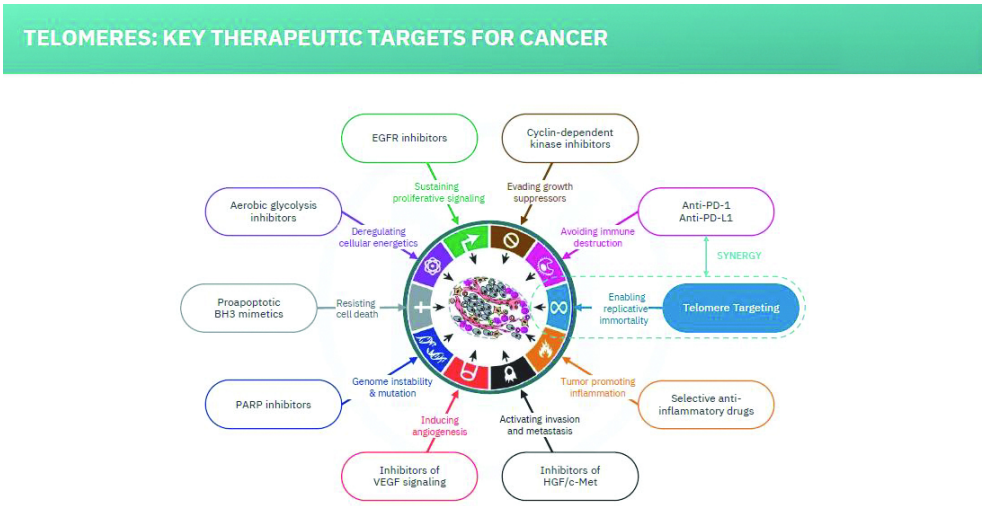


Adapted from *Transcendental Meditation and lifestyle modification increase telomerase*, December 6, 2015.

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

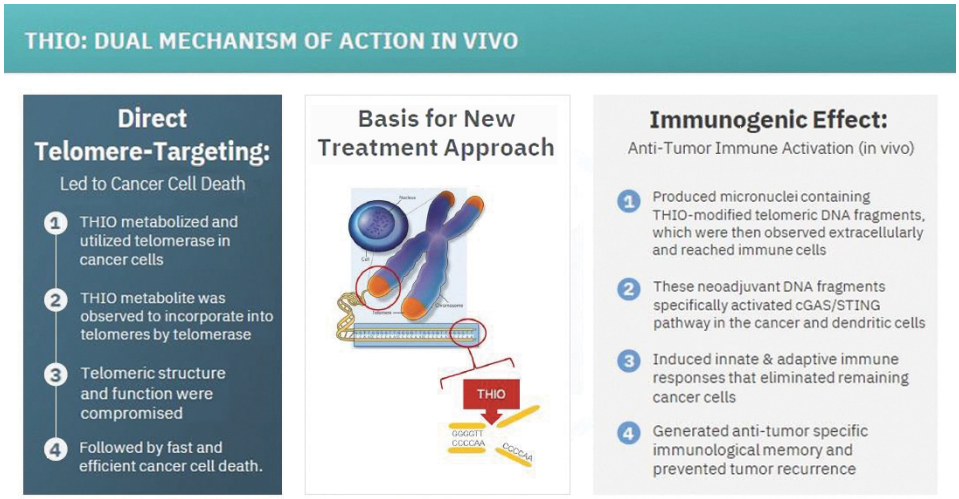
Telomerase is a ribonucleoprotein enzyme (reverse transcriptase) that synthesizes telomere repeats from the beginning, or *de novo*. In human cells, the telomerase holoenzyme consists of a high-molecular-weight complex with a template region-containing RNA subunit, hTR, and a protein component, the catalytic 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

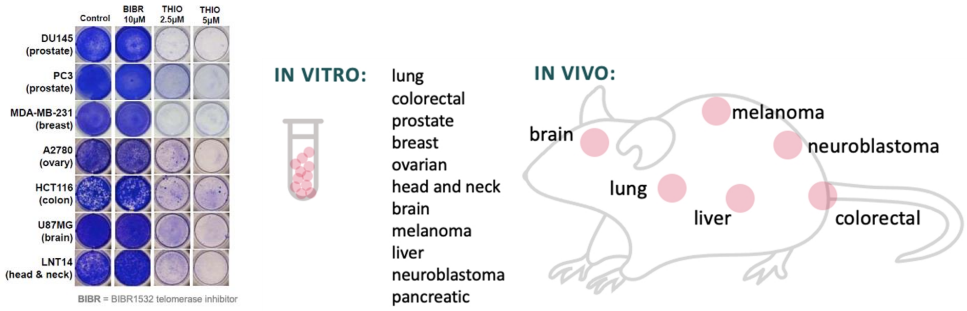
In vivo, THIO, at 3 mg/kg/dose, (which corresponds to a 20 mg/patient/day low-dose), administered followed by a one-day break, followed by an immune checkpoint inhibitor (either anti-programmed cell death protein 1 (PD-1) or anti-programmed death ligand 1 (PD-L1) products), resulted in complete tumor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

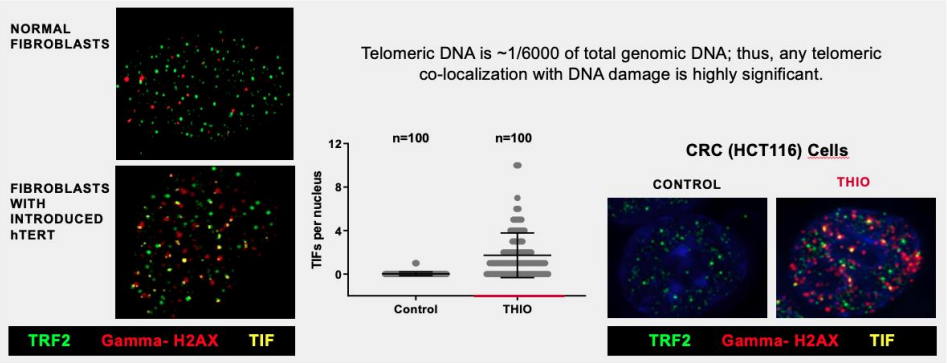
These responses were achieved through telomerase-dependent and cancer cell specific activation of a) DNA damage responses, and b) cGAS/STING pathways by THIO. This body of research represents the basis for the new immune-activation treatment strategy

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.



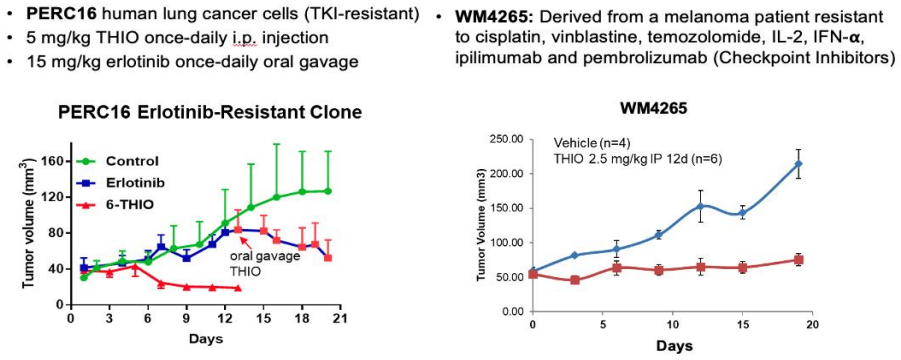
- THIO demonstrated potential to *selectively* cause cancer cell death with active enzyme telomerase versus normal cells *in vitro*. The below graphic illustrates formation of telomeric damage foci (TIFs) in telomerase activity-positive cancer cells, but not in normal non-cancerous cells, resulting from 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

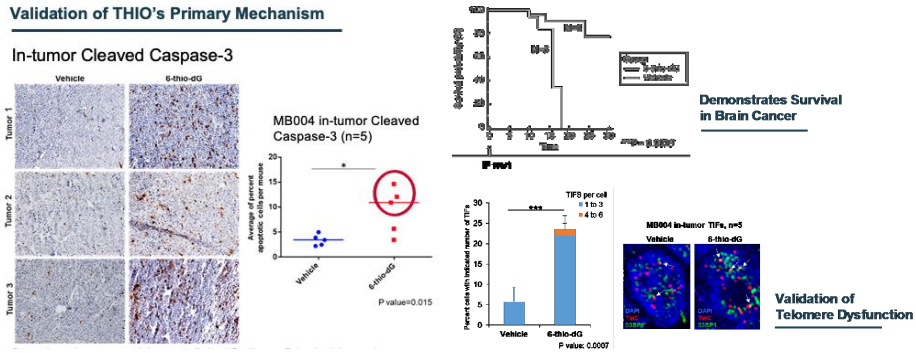
- THIO, as a single agent, showed *in vitro* telomere targeting activity in cancer cells that are resistant to tyrosine kinase inhibitors (TKIs), checkpoint inhibitors, IL-2, IFNα, YERVOY® (ipilimumab) and a host of chemotherapies. The below graphic, in NSCLC and Melanoma models respectively, demonstrates 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.



*i.p. – intraperitoneal injection
*IL-2 – cytokine interleukin 2

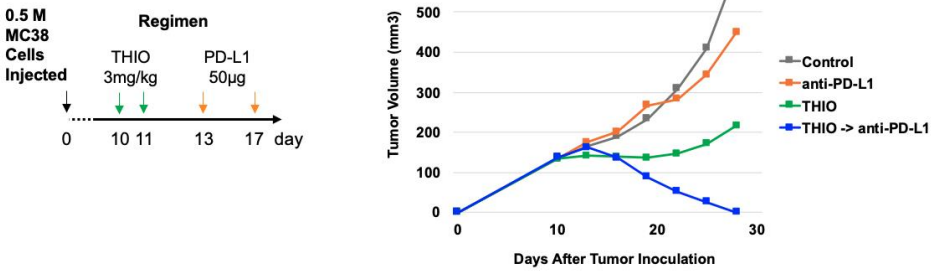
*IFN-a – interferon alfa

- 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.



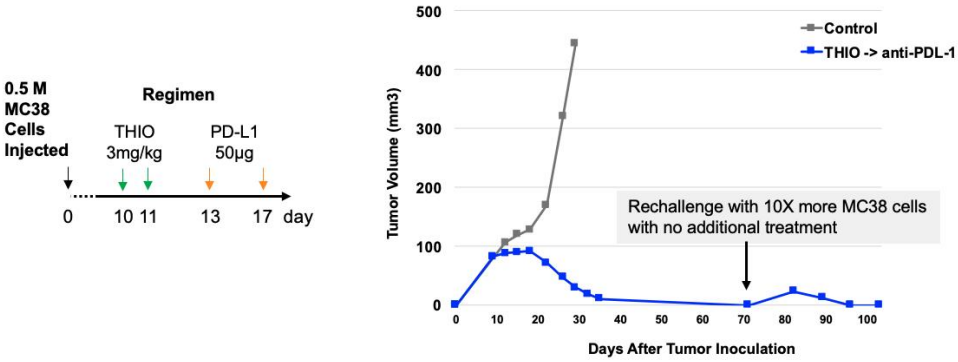
*TIF – telomere damage induced foci
*MB004 – brain cancer cell line

- 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).

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/m2 given every 12 hours for 3 doses every 2 weeks Maximum tolerated dose (MTD) was determined to be 1,750 mg/m2 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
	Total Patients		**117**	**27 (23%)**	**11 (9%)**	**16 (14%)**	
SEG-248	Acute Myelocytic Leukemia (AML)	300 mg/m2 daily for 5 days	17	4 (24%)	1 (6%)	3 (18%)	Leukopenia Thrombocytopenia Skin rash Alopecia (reversible) Nausea and vomiting
		400 mg/m2 daily for 5 days	49	10 (20%)	6 (12%)	4 (8%)	
	Blastic transformation of chronic myelogenous leukemai (BTL)	300 mg/m2 daily for 5 days	11	3 (27%)	-	3 (27%)	
		400 mg/m2 daily for 5 days	26	6 (23%)	3 (12%)	3 (12%)	
	Acute Lymphocytic Leukemia (ALL)	300 mg/m2 daily for 5 days	4	2 (50%)	-	2 (50%)	
		400 mg/m2 daily for 5 days	10	2 (20%)	1 (10%)	1 (10%)	
EST 4273 (ECOG)	Colorectal (prior 5-FU chemotherapy)	THIO 100 mg/m2 daily for 5 days every 3 weeks vs MeCCNU 175 mg/m2 every 8 weeks	61	3 (5%)	3 (5%)	-	Leukopenia, thrombocytopenia, nausea and vomiting
			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 expect to request a pre-IND meeting with the FDA for guidance in 2022.

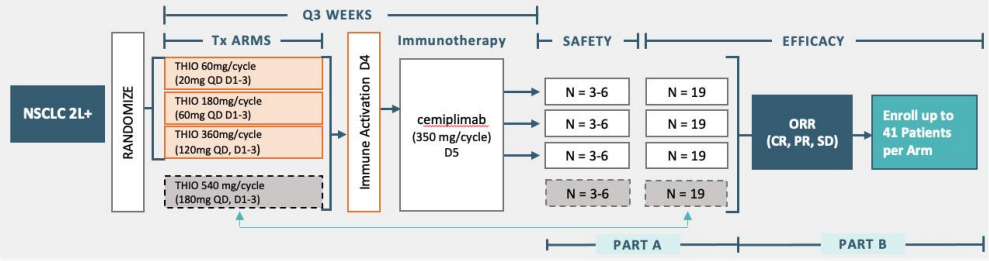
Phase 2 and 3 Programs

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

This first study will be 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 will be 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 an 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. We expect the study to start initially in Australia and Europe 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 order to obtain FDA and 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 colorectal cancer (CRC) indication.

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 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 labelling 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.

Facilities

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 2021, under which we currently pay $2,700 per month. We expect to renew this lease before it expires. 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.

Employees

As of March 28, 2022, we had a total of nine key full-time employees. 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.

Legal Proceedings

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.

Executive Officers and Directors

The following table provides information regarding our executive officers and directors as of the date of this prospectus:

Name	Age	Position
Executive Officers		
Vlad Vitoc	52	Co-Founder President, Chief Executive Officer, Chairman of the Board of Directors
Sergei M. Gryaznov	62	Chief Scientific Officer
Mihail Obrocea	61	Chief Medical Officer
Joseph F. McGuire	63	Chief Financial Officer
Board of Directors (Non-Employee)		
Steven Chaouki	49	Director
Ramiro Guerrero	56	Director
Louie Ngar Yee	55	Director
Cristian Luput	47	Director
Stan Smith	75	Director
Laurentiu Vlad	46	Director

Our Leadership Team

We have assembled a team with deep research, development and commercialization experience in the areas of telomere related science, immunotherapy, and across a vast array of oncology indications. Members of our team bring experience from multiple biotech and pharmaceutical companies including Pfizer Inc., Bayer Pharmaceuticals, Astellas Pharma Inc., Janssen - a Johnson & Johnson pharmaceutical company, Incyte Corporation, Pharmacyclics Inc., Juno Therapeutics Inc., Cephalon Inc., Geron Corporation, Agouron Pharmaceuticals (a Pfizer Company), Novo Nordisk Pharmaceuticals Inc., among others.

Executive Officers

Vlad Vitoc, M.D., MBA

Dr. Vitoc is our Chairman of Board, Chief Executive Officer and President. Dr. Vitoc has a broad array of experience across commercial strategic analysis and planning and medical affairs, in which he has 20 years of experience. During that time, Dr. Vitoc has managed and supported over 20 early, launch, and mature stage compounds, which have included targeted therapies and immune therapies across more than 25 tumor types, including colorectal cancer, hepatocellular carcinoma, lung cancer, breast cancer prostate cancer, and renal cell carcinoma. Vlad received an M.D. from the University of Medicine and Pharmacy “Iuliu Hatieganu”, Cluj-Napoca, Romania, and his M.B.A. from the University of South Carolina.

We believe Dr. Vitoc is qualified to serve on our board of directors because he is a founder of the Company and he has significant knowledge and experience in the pharmaceutical industry and in the management and support of compounds targeting various types of cancers.

Sergei M. Gryaznov, Ph.D.

Dr. Gryaznov is our Chief Scientific Officer. Dr. Gryaznov 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. Dr. Gryaznov 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 lead compound in development. Dr. Gryaznov obtained a M.S., with Honors, in Organic Chemistry and a Ph.D. in Chemistry of Natural Products from M.V. Lomonosov Moscow State University. Dr. Gryaznov also completed a post-doctoral fellowship program in Chemistry at Northwestern University in Evanston, IL.

Mihail Obrocea, M.D.

Dr. Obrocea is our Chief Medical Officer. Dr. Obrocea is a hematologist/oncologist with over 20 years' experience in drug development in both academia and the pharmaceutical/biotechnology industry with expertise in the development of cell therapy, cancer vaccines, monoclonal antibodies, and small molecules. Dr. Obrocea's research has been published in oncology peer-reviewed literature, he has co-authored published books related to cancer vaccines and immunology, and he holds several patents in the field of biotechnology. Dr. Obrocea received an M.D. from the Carol Davila University of Medicine & Pharmacy in Bucharest, Romania.

Joseph F. McGuire

Mr. McGuire is our Chief Financial Officer, and he brings over 30 years of experience to MAIA having served as Chief Financial Officer for several privately held and publicly traded companies in the 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") from October 2014 to May 2021. Avadim subsequently filed a voluntary petition for protection under Chapter 11 of the U.S. Bankruptcy Code and announced on August 17, 2021, the completion of its court-approved sale of substantially all of its assets to a newly created company and emergence from the reorganization proceedings under Chapter 11. Mr. McGuire began his career with Price Waterhouse, where he was a certified public accountant, and later held management positions with Dean Witter Reynolds and Paine Webber, Inc. Joe received a Bachelor of Science in accounting from the University of Notre Dame.

The collective experience of our leadership team includes involvement in the development, approval and/or commercialization of a number of major oncology drugs, including TARCEVA®, NEXAVAR®, IMBRUVICA®, XTANDI®, NERLYNX®, TREANDA®, TRISENOX®, and ZOMETA®, as well as numerous state-of-the-art development programs, including a telomerase inhibitor (IMETELSTAT®), a new immune oncology platform and agent (Cavrolotimod; AST-008), and novel nucleic acid based siRNA and antisense oligonucleotide therapeutics (NP/NPS-oligos). In addition, our team was involved in the development and approval of:

- BREANZY®, an autologous CD19 chimeric antigen receptor (CAR T) treatment for B-cell lymphomas;
- BESPONSA®, a CD22-directed antibody drug conjugate (ADC) for treatment of B-cell acute lymphoblastic leukemia; and
- IMBRUVICA®, or bruton tyrosine kinase inhibitor ibrutinib, for treatment of chronic lymphocytic leukemia and mantle cell lymphomas.

Non-Employee Directors

Louie Ngar Yee; Director

Ms. Louie has 30 years of service with HSBC Group in a variety of functions, principally with businesses of Global Banking and Markets including investment and securities management, asset management, and global research. She also held key leadership positions within Group Internal Audit of HSBC in Latin America, Asia Pacific, and United Kingdom.

Born and educated in Hong Kong, Ms. Louie joined HSBC as an executive trainee in Hong Kong and became an International Manager of HSBC Group in 1996. Since then, she has taken up different roles in Hong Kong, the Philippines, Indonesia, Taiwan, the United States, the United Kingdom, and Latin America, primarily in key management positions to lead, drive and execute a change agenda in a wide range of management situations including business re-engineering, business turnaround, business downsizing, and business set up.

Prior to her current appointment with MAIA Biotechnology in April 2020, Ms. Louie was the Group Chief Operating Officer of Group Internal Audit of HSBC Group.

We believe Ms. Louie is qualified to serve on our board of directors because she has extensive finance, compliance, and audit experience and expertise.

Ramiro Guerrero J.D., LL.M.; Director

Mr. Guerrero is the Founder and CEO of IMPERIO, Inc., a Chicago and Suburban based Real Estate Investment and Brokerage Organization with over 20 years of business experience. He has also been a Venture Capitalist for the past 10 years aiding entrepreneurs and small businesses in their startup ventures. He received his undergraduate B.S. degree in Business/Management from the University of Illinois, his J.D. at the Universidad Metropolitana de Monterrey in Monterrey, Mexico and an LL.M. (Master of Laws) in International Law from St. Mary's University School of Law in San Antonio, Texas and the University of Innsbruck, Austria.

We believe Mr. Guerrero is qualified to serve on our board of directors because he has extensive entrepreneurial start-up experience and expertise.

Cristian Luput; Director

Mr. Luput is the founder and CEO of Optimus Realty Inc, a full-service real estate company specializing in brokering, managing and developing residential properties in Chicago, with over 15 years of extensive expertise in real estate. Mr. Luput has also successfully completed multiple multimillion dollars real estate partnerships, consolidations, mergers and acquisitions.

He is actively involved and serves in the board of directors of several charitable organizations. Mr. Luput is a graduate of Babes-Bolyai, Cluj-Napoca, in Romania with a major in accounting and Business Administration.

We believe Mr. Luput is qualified to serve on our board of directors because has extensive management and entrepreneurial start-up experience and expertise.

Stan V. Smith Ph.D.; Director

Stan V. Smith, Ph.D., is president of Smith Economics Group, Ltd. in Chicago, providing economic and financial consulting nationwide. Trained at the University of Chicago and specializing in litigation economics, Dr. Smith co-authored the first textbook on the subject of economic damages. Dr. Smith has served as an adjunct professor at the University of Chicago and at DePaul University College of Law where he created the first course in the United States in forensic economics.

We believe Dr. Smith is qualified to serve on our board of directors because has extensive economics, financing, and management experience and expertise.

Laurentiu Vlad; Director

Laurentiu Vlad is a highly successful entrepreneur has started and grown two successful companies, in wholesale and retail as well as the lighting industry. His most recent company, Luminii, is the US market leader in linear lighting, having built projects including One World Trade Center, Uber HQ, Space Needle Seattle, and United Polaris Lounges.

We believe Mr. Vlad is qualified to serve on our board of directors because he has extensive management and entrepreneurial start-up experience and expertise.

Steven Chaouki; Director

Steven M. Chaouki is President, U.S. Markets & Consumer Interactive, overseeing two TransUnion business lines. U.S. Markets provides information and insights to business customers across financial services, insurance, public sector, media and diversified markets. Consumer Interactive provides credit, financial and identity protection services to consumers. He previously held the role of Executive Vice President, Financial Services, responsible for the company's financial services business, which provides solutions to banks, credit unions, capital markets, financial services resellers, auto lenders and other customers. Before joining TransUnion, Mr. Chaouki held roles at HSBC in card/retail services and auto finance. Mr. Chaouki earned an M.B.A. from the University of Chicago Booth School of Business and a bachelor's degree from Boston University.

We believe Mr. Chaouki is qualified to serve on our board of directors because he has extensive management and financial experience and expertise.

Family Relationships

There are no family relationships among any of our officers or directors.

Involvement in Certain Legal Proceedings

To the best of our knowledge, except as set forth above regarding Mr. McGuire, none of our directors or executive officers were involved in any legal proceedings described in Item 401(f) of Regulation S-K in the past ten years.

Board Composition

Our board of directors currently consists of seven members, all of whom are members pursuant to the board composition provisions of our current amended and restated certificate of incorporation and agreements with our stockholders, and who will remain members pursuant to the board composition provisions of our amended and restated certificate of incorporation, as amended.

Our nominating and corporate governance committee and our board of directors may consider a broad range of factors relating to the qualifications and background of board nominees, which may include diversity, which is not only limited to race, gender or national origin. We have no formal policy regarding board diversity. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws, each as amended to become effective upon the completion of this offering, also provide that our directors may be removed only for cause by the affirmative vote of the holders of a majority of the votes that all our stockholders would be entitled to cast in an election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office and not by the stockholders, unless the board determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders.

Director Independence. Our board of directors has determined that all members of our board of directors are independent directors, with the exception of Vlad Vitoc, including for purposes of the rules of the NYSE and relevant federal securities laws and regulations.

Staggered 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 will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring.

The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2021 for Class II directors, 2022 for Class III directors and 2023 for Class I directors:

- our Class I directors are Louie Ngar Yee and Steven Chaouki;
- our Class II directors are Vlad Vitoc, Ramiro Guerrero and Cristian Luput; and
- our Class III directors are Laurentiu Vlad and Stan Smith.

Our amended and restated certificate of incorporation and amended and restated bylaws, each as amended to become effective upon the completion of this offering, 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.

Committees of the Board of Directors

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which have the composition and responsibilities described below. Each of the below committees have a written charter approved by our board of directors, effective upon completion of this offering. Each of the committees will report to our board of directors as such committee deems appropriate and as our board of directors may request. Upon completion of this offering, copies of each charter will be posted on the investor relations section of our website. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee

Our audit committee is comprised of Ms. Louie, Mr. Chaouki and Mr. Vlad, with Ms. Louie serving as chair of the committee. Our board of directors has determined that each member of the audit committee meets the independence requirements of Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the applicable NYSE rules, and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Each of Mr. Chaouki and Ms. Louie qualifies as an audit committee financial expert under Item 407 of Regulation S-K. We have adopted an audit committee charter, detailing the principal functions of the audit committee, including:

- assisting board oversight of (1) the integrity of our financial statements, (2) our compliance with legal and regulatory requirements, (3) our independent auditor's qualifications and independence, and (4) the performance of our internal audit function and independent auditors; the appointment, compensation, retention, replacement, and oversight of the work of the independent auditors and any other independent registered public accounting firm engaged by us;
- pre-approving all audit and non-audit services to be provided by the independent auditors or any other registered public accounting firm engaged by us, and establishing pre-approval policies and procedures;
- reviewing and discussing with the independent auditors all relationships the auditors have with us in order to evaluate their continued independence;
- setting clear policies for audit partner rotation in compliance with applicable laws and regulations;
- obtaining and reviewing a report, at least annually, from the independent auditors describing (1) the independent auditor's internal quality-control procedures and (2) any material issues raised by the most recent internal quality-control review, or peer review, of the audit firm, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years respecting one or more independent audits carried out by the firm and any steps taken to deal with such issues;
- meeting to review and discuss our annual audited financial statements and quarterly financial statements with management and the independent auditor, including reviewing our specific disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations"; reviewing and approving any related party transaction required to be disclosed pursuant to Item 404 of Regulation S-K promulgated by the SEC prior to us entering into such transaction; and
- reviewing with management, the independent auditors, and our legal advisors, as appropriate, any legal, regulatory or compliance matters, including any correspondence with regulators or government agencies and any employee complaints or published reports that raise material issues regarding our financial statements or accounting policies and any significant changes in accounting standards or rules promulgated by the Financial Accounting Standards Board, the SEC or other regulatory authorities.

Compensation Committee

Our compensation committee is comprised of Dr. Smith, Mr. Luput and Mr. Guerrero, with Dr. Smith serving as chair of the committee. Each member of this committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act. Our board of directors has determined that each member of the compensation committee is "independent" as defined in the applicable NYSE rules. The composition of our compensation committee meets the requirements for independence under the NYSE listing standards, including the applicable transition rules. We have adopted a compensation committee charter which details the principal functions of the compensation committee, including:

- reviewing and approving on an annual basis the corporate goals and objectives relevant to our Chief Executive Officer's compensation, evaluating our Chief Executive Officer's performance in light of such goals and objectives and determining and approving the remuneration (if any) of our Chief Executive Officer based on such evaluation;
- reviewing and making recommendations to our Board of Directors with respect to the compensation, and any incentive-compensation and equity-based plans that are subject to board approval of all of our other officers;
- reviewing our executive compensation policies and plans;
- implementing and administering our incentive compensation equity-based remuneration plans; assisting management in complying with our proxy statement and annual report disclosure requirements;
- approving all special perquisites, special cash payments and other special compensation and benefit arrangements for our officers and employees; and
- producing a report on executive compensation to be included in our annual proxy statement; and reviewing, evaluating and recommending changes, if appropriate, to the remuneration for directors.

The charter also provides that the compensation committee may, in its sole discretion, retain or obtain the advice of a compensation consultant, independent legal counsel or other adviser and is directly responsible for the appointment, compensation and oversight of the work of any such adviser. However, before engaging or receiving advice from a compensation consultant, external legal counsel or any other adviser, the compensation committee will consider the independence of each such adviser, including the factors required by the NYSE and the SEC.

Nominating and Governance Committee

Our nominating and governance committee is comprised of Ms. Louie, Mr. Luput and Dr. Smith, with Ms. Louie serving as the chair of the committee. We have adopted a nominating and corporate governance committee charter, which details the purpose and responsibilities of the nominating and corporate governance committee, including:

- identifying, screening and reviewing individuals qualified to serve as directors, consistent with criteria approved by the Board of Directors, and recommending to the Board of Directors candidates for nomination for election at the annual meeting of stockholders or to fill vacancies on the Board of Directors;
- developing and recommending to the Board of Directors and overseeing implementation of our corporate governance guidelines;
- coordinating and overseeing the annual self-evaluation of the Board of Directors, its committees, individual directors and management in the governance of the company; and
- reviewing on a regular basis our overall corporate governance and recommending improvements as and when necessary.

The charter also provides that the nominating and corporate governance committee may, in its sole discretion, retain or obtain the advice of, and terminate, any search firm to be used to identify director candidates, and is directly responsible for approving the search firm's fees and other retention terms.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, the Board of Directors considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

Leadership Structure and Risk Oversight

Our board of directors does not have a policy regarding the separation of the roles of Chief Executive Officer and Chairman of the board of directors, as our board of directors believes it is in the best interest of the Company to make that determination based on the position and direction of the Company and the membership of the board of directors. Our board of directors has determined that having an employee director serve as Chairman is in the best interest of our stockholders at this time because of the efficiencies achieved in having the role of Chief Executive Officer and Chairman combined, and because the detailed knowledge of our day-to-day operations and business that the Chief Executive Officer possesses greatly enhances the decision-making processes of our board of directors as a whole. Dr. Stan Smith is the lead independent director.

The Chairman of the board of directors and the other members of the board of directors work in concert to provide oversight of our management and affairs. Our board of directors encourages communication among its members and between management and the board of directors to facilitate productive working relationships. Working with the other members of the board of directors, our Chairman also strives to ensure that there is an appropriate balance and focus among key board responsibilities such as strategic development, review of operations and risk oversight.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee. For a description of transactions between us and members of our compensation committee and affiliates of such members, see the section titled “Certain Relationships and Related Party Transactions”.

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, which will be effective upon completion of this offering. Upon the completion of this offering, our code of business conduct and ethics will be 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.

Summary Compensation Table

The following table shows the total compensation paid or accrued during the fiscal years ended December 31, 2021 and 2020, to our Chief Executive Officer and President and our other two most highly-compensated executive officers that were serving as executive officers as of December 31, 2021 (our "named executive officers").

Name and Principal Position	Year	Salary	Bonus[1]	Option Awards[2]	Non-Qualified Deferred Compensation Earnings	All Other Compensation	Total
Vlad Vitoc, M.D. M.B.A.	2021	$ 264,583	$ 172,000	$ 266,068	—	$ —	$ 702,651
Chief Executive Officer and President	2020	$ 75,000	$ 240,000	$ 970,971	—	$ 125,000	$ 1,410,971
Joseph F. McGuire[3]	2021	$ 112,500	$ 39,519	$ 700,258	—	$ 26,035	$ 878,312
Chief Financial Officer	2020	$ —	$ —	$ —	—	$ —	$ —
Mihail Obrocea[4]	2021	$ 162,500	$ 57,731	$ 1,907,411	—	$ 18,344	$ 2,145,986
Chief Medical Officer	2020	$ —	$ —	$ —	—	$ —	$ —

[1] All of the bonuses earned by our named executive officers in 2021 are expected to be paid in cash in 2022. The bonus earned by Vlad Vitoc in 2020 was paid out by the issuance of 219,550 stock options on April 16, 2021 to Dr. Vitoc in lieu of payment of a cash bonus.
[2] The aggregate grant date fair value of such awards were computed in accordance with Financial Accounting Standards Board ASC Topic 718, Stock Compensation (ASC Topic 718), and do not take into account estimated forfeitures related to service-based vesting conditions, if any. The valuation assumptions used in calculating these values are discussed in Note 7 of the Notes to Consolidated Financial Statements appearing elsewhere herein. These amounts do not represent actual amounts paid or to be realized. Amounts shown are not necessarily indicative of values to be achieved, which may be more or less than the amounts shown as awards may subject to time-based vesting.
[3] Mr. McGuire served as the CFO of the Company since August 16, 2021, and from July 1, 2021 through August 15, 2021, Mr. McGuire served as a consultant to the Company.
[4] Dr. Obrocea served as the Chief Medical Officer of the Company since July 12, 2021, and from December 1, 2020 through July 11, 2021, Dr. Obrocea served as a consultant to the Company.

Employment Agreements

In August 2021, we entered into executive employment agreements with each of senior executive officers in connection with their employment with us, the material terms of which are described below. Except as noted below, these executive employment agreements provide for "at will" employment.

Summary of Employment Agreement with Vlad Vitoc

Under the terms of Dr. Vitoc's employment agreement dated August 2, 2021, Dr. Vitoc is entitled to an initial annual base salary of $430,000. Dr. Vitoc may be eligible to receive an annual cash bonus of up to 40% of his then-current base salary based on the achievement of certain individual and corporate performance metrics and milestones in the previous year, as determined in the sole discretion of our board of directors. Dr. Vitoc may also be eligible for a discretionary annual performance incentive options award based on the previous year's performance, as determined in the discretion of the board of directors. Dr. Vitoc is eligible to participate in regular health insurance and other employee benefit plans as established by the Company.

This agreement also provides for the following severance payments and benefits upon termination by us without Cause (as defined below): (i) all accrued and unpaid base salary payable and accrued and unpaid deferred compensation earned as of the date of termination; (ii) any bonus or other such compensation earned and payable pursuant to any compensation program then in effect; (iii) reimbursement for all incurred but unreimbursed reasonable and necessary business expenses for which he is entitled to reimbursement, for which proper claims are

made within 45 days of termination; (iv) the benefit of any options vested as of the termination date; and (v) a severance payment equal to the base salary and benefits he otherwise would have received for the one year following the termination, payable as salary continuation in accordance with the Company's normal payroll practices.

In addition, in consideration of the payments and benefits provided under his employment agreement, Dr. Vitoc has agreed to certain invention assignment, confidentiality and other restrictive covenants pursuant to an Employee Invention Assignment, Confidentiality and Non-Competition Agreement, including, among other things, non-competition and non-solicitation provisions that apply during the term of Dr. Vitoc's employment and for one year thereafter.

"Cause" means: (i) conviction of or plea of nolo contendere to a felony or a crime involving moral turpitude; (ii) engaging in an act of gross negligence or willful misconduct in the performance of his employment obligations and duties; (iii) committing an act of fraud against, or material misconduct or willful misappropriation of property belonging to the Company or its subsidiaries or affiliates; (iv) engaging in any other misconduct that has had or will have an adverse effect on the Company's or its subsidiaries or affiliates reputation or business; or (v) his material breach of the Employee Invention Assignment, Confidentiality and Non-Competition Agreement or other unauthorized misuse of the Company's or any of or its subsidiaries or other affiliates' trade secrets or proprietary information.

Summary of Employment Agreement with Mihail Obrocea

Under the terms of Dr. Obrocea's employment agreement dated August 2, 2021, Dr. Obrocea is entitled to an initial annual base salary of $380,000. Dr. Obrocea may be eligible to receive an annual bonus of up to 35% of his then-current base salary based on the achievement of certain individual and corporate performance metrics and milestones in the previous year, as determined in the sole discretion of our board of directors. Dr. Obrocea may also be eligible for a discretionary annual performance incentive options award based on the previous year's performance, as determined in the discretion of the board of directors. Dr. Obrocea is eligible to participate in regular health insurance and other employee benefit plans as established by the Company. This agreement also provides for severance payments and benefits upon termination by us without Cause (as defined above) as described above in the summary of Dr. Vitoc's agreement.

In addition, in consideration of the payments and benefits provided under his employment agreement, Dr. Obrocea has agreed to certain invention assignment, confidentiality and other restrictive covenants pursuant to an Employee Invention Assignment, Confidentiality and Non-Competition Agreement, including, among other things, non-competition and non-solicitation provisions that apply during the term of Dr. Obrocea's employment and for one year thereafter.

Summary of Employment Agreement with Joseph F. McGuire

Under the terms of Mr. McGuire's employment agreement dated August 10, 2021, Mr. McGuire is entitled to an initial annual base salary of $300,000. Mr. McGuire also received a sign-on grant of 130,000 stock options, which will vest over a four year period according to the following schedule: 25% of the shares will vest as of the one-year anniversary of the vesting commencement date and 1/48th of the shares will vest monthly thereafter, so long as Mr. McGuire remains in continuous service with the Company through the applicable vesting dates. Mr. McGuire may be eligible to receive an annual bonus of up to 35% of his then-current base salary based on the achievement of certain individual and corporate performance metrics and milestones in the previous year, as determined in the sole discretion of our board of directors. Starting in 2022, Mr. McGuire may also be eligible for a discretionary annual performance incentive options award based on the previous year's performance, as determined in the discretion of the board of directors. Mr. McGuire is eligible to participate in regular health insurance and other employee benefit plans as established by the Company. This agreement also provides for severance payments and benefits upon termination by us without Cause (as defined above) as described above in the summary of Dr. Vitoc's agreement, with the additional requirement that prior to receiving such payments and benefits Mr. McGuire will be required to sign and not revoke a separation agreement and general release of claims in a form reasonably satisfactory to the Company by no later than the sixtieth (60th) day after his employment termination date.

In addition, in consideration of the payments and benefits provided under his employment agreement, Mr. McGuire has agreed to certain invention assignment, confidentiality and other restrictive covenants pursuant to an Employee Invention Assignment, Confidentiality and Non-Competition Agreement, including, among other things, non-competition and non-solicitation provisions that apply during the term of Mr. McGuire's employment and for one year thereafter.

Outstanding Equity Awards as of December 31, 2021

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2021.

	Option Awards(1)					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share ($)(2)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested	Market Value of Shares of Units of Stock that Have Not Vested(3)
Vlad Vitoc	7/1/2021	7,529	—	$ 1.83	6/30/2031	—	—
	4/16/2021	509,906	—	$ 1.83	4/15/2031	—	—
	4/1/2021	23,078	—	$ 1.83	3/31/2031	—	—
	11/3/2020	705,789	—	$ 1.80	11/2/2030	—	—
	4/1/2020	169,500	—	$ 1.80	3/31/2030	—	—
	6/17/2019	20,500	—	$ 1.80	6/16/2029	—	—
	10/1/2018	498,750	145,834	$ 1.80	9/30/2028	—	—
Joseph McGuire	8/31/2021	1,297	—	$ 8.00	8/30/2031	—	—
	8/16/2021	—	130,000	$ 8.00	8/15/2031	—	—
	7/30/2021	656	—	$ 8.00	7/29/2031	—	—
Mihail Obrocea	7/31/2021	772	—	$ 8.00	7/30/2031	—	—
	7/15/2021	—	260,000	$ 1.83	7/14/2031	—	—
	6/7/2021	7,447	—	$ 1.83	6/6/2031	—	—
	6/5/2021	6,476	—	$ 1.83	6/4/2031	—	—
	4/16/2021	10,022	—	$ 1.83	4/15/2031	—	—
	1/31/2021	6,131	—	$ 1.80	1/30/2031	—	—
	1/6/2021	13,269	—	$ 1.80	1/5/2031	—	—

(1) All of the option awards were granted under the 2018 Plan or the 2020 Plan, the terms of which are described below under "—Equity Compensation Plans and Other Benefit Plans—2020 Employee, Director and Consultant Equity Incentive Plan."

Equity Compensation Plans and Other Benefit Plans

2020 Employee, Director and Consultant Equity Incentive Plan

On September 14, 2018, we adopted and approved the 2018 Stock Option Plan (the "2018 Plan"), which provides for the issuance of 3,900,000 shares of our common stock for purposes of attracting, retaining, and motivating key employees, directors, and consultants. On May 29, 2020, we amended the 2018 Plan and approved it as the Amended and Restated 2020 Equity Incentive Plan (the "2020 Plan") and reserved 1,671,000 common stock for issuance. On November 1, 2020, we approved the second amendment of the 2020 Plan to reserve a total of 3,171,000 common stock for issuance. In April and July of 2021 there were amendments to the 2020 Plan to bring the plan to a total of 4,171,000 shares reserved for issuance. The 2020 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock and restricted stock units. As of the date of this prospectus, we have granted an aggregate of options to various key employees, directors, and consultants under the 2020

Plan. As of the date of this prospectus, there are shares available to be granted under the 2020 Plan. On or prior to the consummation of this offering, we intend to cancel the 2020 Plan and convert these stock options to the 2021 Plan, as more fully described below.

2021 Equity Incentive Plan

Our Board of Directors and stockholders have adopted and approved the 2021 Equity Incentive Plan (the "2021 Plan"), which has replaced the 2020 Plan. The 2021 Plan is a comprehensive incentive compensation plan under which we can grant equity-based and other incentive awards to our officers, employees, directors, consultants and advisers. The purpose of the 2021 Plan is to help us attract, retain, and motivate such persons with awards under the 2021 Plan and thereby enhance shareholder value.

Administration. The 2021 Plan is administered by the Board, and upon consummation of this offering will be administered by the compensation committee of the Board, which shall consist of three members of the board, each of whom is a "non-employee director" within the meaning of Rule 16b-3 promulgated under the Exchange Act and "independent" for purposes of any applicable listing requirements. If a member of the compensation committee is eligible to receive an award under the 2021 Plan, such compensation committee member shall have no authority under the plan with respect to his or her own award. Among other things, the compensation committee has complete discretion, subject to the express limits of the 2021 Plan, to determine the directors, employees and nonemployee consultants to be granted an award, the type of award to be granted the terms and conditions of the award, the form of payment to be made and/or the number of shares of common stock subject to each award, the exercise price of each option and base price of each stock appreciation right ("SAR"), the term of each award, the vesting schedule for an award, whether to accelerate vesting, the value of the common stock underlying the award, and the required withholding, if any. The compensation committee may amend, modify or terminate any outstanding award, provided that the participant's consent to such action is required if the action would impair the participant's rights or entitlements with respect to that award. The compensation committee is also authorized to construe the award agreements, and may prescribe rules relating to the 2021 Plan. Notwithstanding the foregoing, the compensation committee does not have any authority to grant or modify an award under the 2021 Plan with terms or conditions that would cause the grant, vesting or exercise thereof to be considered nonqualified "deferred compensation" subject to Code Section 409A, unless such award is structured to be exempt from or comply with all requirements of Code Section 409A.

Grant of Awards; Shares Available for Awards. The 2021 Plan provides for the grant of stock options, SARs, performance share awards, performance unit awards, distribution equivalent right awards, restricted stock awards, restricted stock unit awards and unrestricted stock awards to non-employee directors, officers, employees and nonemployee consultants of MAIA or its affiliates. The aggregate number of shares of common stock reserved and available for grant and issuance under the 2021 Plan is , plus any reserved shares of common stock not issued or subject to outstanding awards granted under the 2020 Plan. The same number of shares of common stock in the aggregate may be issued under the 2021 Plan in connection with incentive stock options. Shares shall be deemed to have been issued under the 2021 Plan solely to the extent actually issued and delivered pursuant to an award. If any award granted under the 2020 Plan or the 2021 Plan expires, is cancelled, or terminates unexercised or is forfeited, the number of shares subject thereto is again available for grant under the 2021 Plan. The 2021 Plan shall continue in effect, unless sooner terminated, until the tenth (10th) anniversary of the date on which it is adopted by the Board. The Board in its discretion may terminate the 2021 Plan at any time with respect to any shares for which awards have not theretofore been granted; provided, however, that the 2021 Plan's termination shall not materially and adversely impair the rights of a holder, without the consent of the holder, with respect to any award previously granted.

Future new hires and additional non-employee directors and/or consultants would be eligible to participate in the 2021 Plan as well. The number of stock options and/or shares of restricted stock to be granted to executives and directors cannot be determined at this time as the grant of stock options and/or shares of restricted stock is dependent upon various factors such as hiring requirements and job performance.

Stock Options. The 2021 Plan provides for either "incentive stock options" ("ISOs"), which are intended to meet the requirements for special federal income tax treatment under Section 422 of the Code, or "nonqualified stock options" ("NQSOs"). Stock options may be granted on such terms and conditions as the compensation committee may determine, which shall be specified in the option agreement; provided, however, that the per share exercise

price under a stock option may not be less than the fair market value of a share of common stock on the date of grant and the term of the stock option may not exceed 10 years (110% of such value and five years in the case of an ISO granted to an employee who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of capital stock of our Company or a parent or subsidiary of our Company). ISOs may only be granted to employees. In addition, the aggregate fair market value of common stock covered by one or more ISOs (determined at the time of grant), which are exercisable for the first time by an employee during any calendar year may not exceed $100,000. Any excess is treated as a NQSO.

Stock Appreciation Rights. A SAR entitles the participant, upon exercise, to receive an amount, in cash or stock or a combination thereof, equal to the increase in the fair market value of the underlying common stock between the date of grant and the date of exercise. The compensation committee shall set forth in the applicable SAR award agreement the terms and conditions of the SAR, including the base value for the SAR (which shall not be less than the fair market value of a share on the date of grant), the number of shares subject to the SAR and the period during which the SAR may be exercised and any other special rules and/or requirements which the compensation committee imposes on the SAR. No SAR shall be exercisable after the expiration of ten (10) years from the date of grant. SARs may be granted in tandem with, or independently of, stock options granted under the 2021 Plan. A SAR granted in tandem with a stock option (i) is exercisable only at such times, and to the extent, that the related stock option is exercisable in accordance with the procedure for exercise of the related stock option; (ii) terminates upon termination or exercise of the related stock option (likewise, the common stock option granted in tandem with a SAR terminates upon exercise of the SAR); (iii) is transferable only with the related stock option; and (iv) if the related stock option is an ISO, may be exercised only when the value of the stock subject to the stock option exceeds the exercise price of the stock option. A SAR that is not granted in tandem with a stock option is exercisable at such times as the compensation committee may specify.

Performance Shares and Performance Unit Awards. Performance share and performance unit awards entitle the participant to receive cash or shares of common stock upon the attainment of specified performance goals. In the case of performance units, the right to acquire the units is denominated in cash values. The compensation committee shall set forth in the applicable award agreement the performance goals and objectives and the period of time to which such goals and objectives shall apply. If such goals and objectives are achieved, such distribution of shares, or payment in cash, as the case may be, shall be made no later than by the fifteenth (15th) day of the third (3rd) calendar month next following the end of the Company's fiscal year to which such performance goals and objectives relate, unless otherwise structured to comply with Code Section 409A.

Distribution Equivalent Right Awards. A distribution equivalent right award entitles the participant to receive bookkeeping credits, cash payments and/or common stock distributions equal in amount to the distributions that would have been made to the participant had the participant held a specified number of shares of common stock during the period the participant held the distribution equivalent right. A distribution equivalent right may be awarded as a component of another award (but not an option or SAR award) under the 2021 Plan, where, if so awarded, such distribution equivalent right will expire or be forfeited by the participant under the same conditions as under such other award. The compensation committee shall set forth in the applicable distribution equivalent rights award agreement the terms and conditions, if any, including whether the holder is to receive credits currently in cash, is to have such credits reinvested (at fair market value determined as of the date of reinvestment) in additional ordinary shares, or is to be entitled to choose among such alternatives.

Restricted Stock Awards. A restricted stock award is a grant or sale of common stock to the holder, subject to such restrictions on transferability, risk of forfeiture and other restrictions, if any, as the compensation committee or the board of directors may impose, which restrictions may lapse separately or in combination at such times, under such circumstances (including based on achievement of performance goals and/or future service requirements), in such instalments or otherwise, as the compensation committee or the board of directors may determine at the date of grant or purchase or thereafter. If provided for under the restricted stock award agreement, a participant who is granted or has purchased restricted stock shall have all of the rights of a shareholder, including the right to vote the restricted stock and the right to receive dividends thereon (subject to any mandatory reinvestment or other requirement imposed by the compensation committee or the board of directors or in the award agreement). During the restricted period applicable to the restricted stock, subject to certain exceptions, the restricted stock may not be sold, transferred, pledged, exchanged, hypothecated, or otherwise disposed of by the participant.

Restricted Stock Unit Awards. A restricted stock unit award provides for a grant of shares or a cash payment to be made to the holder upon the satisfaction of predetermined individual service-related vesting requirements, based on the number of units awarded to the holder. The compensation committee shall set forth in the applicable restricted

stock unit award agreement the individual service-based vesting requirements which the holder would be required to satisfy before the holder would become entitled to payment and the number of units awarded to the holder. The holder of a restricted stock unit shall be entitled to receive either a cash payment equal to the fair market value of a share of common stock or a distribution of one share of common stock, as determined in the sole discretion of the compensation committee and as set forth in the restricted stock unit award agreement, for each restricted stock unit subject to such restricted stock unit award, if and to the extent the holder satisfies the applicable vesting requirements. Such payment or distribution shall be made no later than by the fifteenth (15th) day of the third (3rd) calendar month next following the end of the calendar year in which the restricted stock unit first becomes vested, unless otherwise structured to comply with Code Section 409A. A restricted stock unit shall not constitute an equity interest in the Company and shall not entitle the holder to voting rights, dividends or any other rights associated with ownership of shares of our common stock prior to the time the holder shall receive a distribution of shares, if any.

Unrestricted Stock Awards. An unrestricted stock award is a grant or sale of shares of our common stock to the employees, non-employee directors or non-employee consultants that are not subject to transfer, forfeiture or other restrictions, in consideration for past services rendered to the Company or an affiliate or for other valid consideration.

Change-in-Control Provisions. The compensation committee may, in its sole discretion, at the time an award is granted or at any time prior to, coincident with or after the time of a change in control, cause any award either (i) to be cancelled in consideration of a payment in cash or other consideration in amount per share equal to the excess, if any, of the price or implied price per share of common stock in the change in control over the per share exercise, base or purchase price of such award, which may be paid immediately or over the vesting schedule of the award; (ii) to be assumed, or new rights substituted therefore, by the surviving corporation or a parent or subsidiary of such surviving corporation following such change in control; (iii) accelerate any time periods, or waive any other conditions, relating to the vesting, exercise, payment or distribution of an award so that any award to a holder whose employment has been terminated as a result of a change in control may be vested, exercised, paid or distributed in full on or before a date fixed by the compensation committee; (iv) to be purchased from a holder whose employment has been terminated as a result of a change of control, upon the holder's request, for an amount of cash equal to the amount that could have been obtained upon the exercise, payment or distribution of such rights had such award been currently exercisable or payable; or (v) terminate any then outstanding award or make any other adjustment to the awards then outstanding as the compensation committee deems necessary or appropriate to reflect such transaction or change. The number of shares subject to any award shall be rounded to the nearest whole number.

Amendment and Termination. The compensation committee may adopt, amend and rescind rules relating to the administration of the 2021 Plan, and amend, suspend or terminate the 2021 Plan, but no such amendment or termination will be made that materially and adversely impairs the rights of any participant with respect to any award received thereby under the 2021 Plan without the participant's consent, other than amendments that are necessary to permit the granting of awards in compliance with applicable laws.

Certain U.S. Federal Income Tax Consequences of the 2021 Equity Incentive Plan

The following is a general summary of certain U.S. federal income tax consequences under current tax law to the Company (to the extent it is subject to U.S. federal income taxation on its net income) and to participants in the 2021 Plan who are individual citizens or residents of the United States for federal income tax purposes ("U.S. Participants") of stock options which are ISOs, or stock options which are NQSOs, unrestricted stock, restricted stock, restricted stock units, performance stock, performance units, SARs, and dividend equivalent rights. This summary does not purport to cover all of the special rules that may apply, including special rules relating to limitations on our ability to deduct certain compensation, special rules relating to deferred compensation, golden parachutes, U.S. Participants subject to Section 16(b) of the Exchange Act or the exercise of a stock option with previously acquired ordinary shares. This summary assumes that U.S. Participants will hold their shares of common stock as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the "Code"). In addition, this summary does not address the foreign, state or local or other tax consequences, or any U.S. federal non-income tax consequences, inherent in the acquisition, ownership, vesting, exercise, termination or disposition of an award under the 2021 Plan or shares of common stock issued pursuant thereto. Participants are urged to consult with their own tax advisors concerning the tax consequences to them of an award under the 2021 Plan or shares issued thereunder.

A U.S. Participant generally does not recognize taxable income upon the grant of a NQSO if it is structured to be exempt from or comply with Code Section 409A. Upon the exercise of a NQSO, the U.S. Participant generally recognizes ordinary compensation income in an amount equal to the excess, if any, of the fair market value of the ordinary shares acquired on the date of exercise over the exercise price thereof, and the Company generally will be entitled to a deduction for such amount at that time. If the U.S. Participant later sells ordinary shares acquired pursuant to the exercise of a NQSO, the U.S. Participant recognizes a long-term or short-term capital gain or loss, depending on the period for which the ordinary shares were held. A long-term capital gain is generally subject to more favorable tax treatment than ordinary income or a short-term capital gain. The deductibility of capital losses is subject to certain limitations.

A U.S. Participant generally does not recognize taxable income upon the grant or, except for purposes of the U.S. alternative minimum tax ("AMT") the exercise, of an ISO. For purposes of the AMT, which is payable to the extent it exceeds the U.S. Participant's regular income tax, upon the exercise of an ISO, the excess of the fair market value of the ordinary shares subject to the ISO over the exercise price is a preference item for AMT purposes. If the U.S. Participant disposes of the ordinary shares acquired pursuant to the exercise of an ISO more than two years after the date of grant and more than one year after the transfer of the ordinary shares to the U.S. Participant, the U.S. Participant generally recognizes a long-term capital gain or loss, and the Company will not be entitled to a deduction. However, if the U.S. Participant disposes of such ordinary shares prior to the end of either of the required holding periods, the U.S. Participant will have ordinary compensation income equal to the excess (if any) of the fair market value of such shares on the date of exercise (or, if less, the amount realized on the disposition of such shares) over the exercise price paid for such shares, and the Company generally will be entitled to deduct such amount.

A U.S. Participant generally does not recognize income upon the grant of a SAR. The U.S. Participant recognizes ordinary compensation income upon exercise of the SAR equal to the increase in the value of the underlying shares, and the Company generally will be entitled to a deduction for such amount.

A U.S. Participant generally does not recognize income on the receipt of a performance stock award, performance unit award, restricted stock unit award, unrestricted stock award or dividend equivalent rights award until a cash payment or a distribution of ordinary shares is received thereunder. At such time, the U.S. Participant recognizes ordinary compensation income equal to the excess, if any, of the fair market value of the ordinary shares or the amount of cash received over any amount paid therefor, and the Company generally will be entitled to deduct such amount at such time.

A U.S. Participant who receives a restricted stock award generally recognizes ordinary compensation income equal to the excess, if any, of the fair market value of such ordinary shares at the time the restriction lapses over any amount paid for the ordinary shares. Alternatively, the U.S. Participant may make an election under Section 83(b) of the Code to be taxed on the fair market value of such ordinary shares at the time of grant. The Company generally will be entitled to a deduction at the same time and in the same amount as the income that is required to be included by the U.S. Participant.

401(k) Plan

Our eligible employees will be permitted to participate in our 401(k) beginning January 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 plan to match employee contributions using a benchmark to industry standards. 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.

10b5-1 Plan

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan,

without further direction from the director or officer. The director or officer may amend or terminate the plan in limited circumstances. Our directors and executive officers may also buy or sell additional shares of our common stock outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation, which will become effective upon completion of the offering, provides that no director of our company shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to us or our stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) in respect of unlawful dividend payments or stock redemptions or repurchases, or (iv) for any transaction from which the director derived an improper personal benefit. In addition, our amended and restated certificate of incorporation provides that if the Delaware General Corporation Law ("DGCL") is amended to authorize the further elimination or limitation of the liability of directors, then the liability of a director of our company shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

The amended and restated certificate of incorporation further provides that any repeal or modification of such article by our stockholders or amendment to the DGCL will not affect any right or protection existing at the time of such repeal or modification with respect to any acts or omissions occurring before such repeal or modification of a director serving at the time of such repeal or modification.

Our amended and restated certificate of incorporation also provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in or not opposed to our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation also provides that we will advance expenses to Indemnitees in connection with a legal proceeding, subject to limited exceptions.

Our amended and restated certificate of incorporation also permits us to secure insurance on behalf of ourselves and any director, officer, employee or agent of the Company or another corporation, partnership joint venture, trust or other enterprise, against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Company would have the power to indemnify such person against such expense, liability or loss under the DGCL.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation, each of which will be in effect upon the completion of this offering. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by them in any action or proceeding arising out of their services as a director or executive officer or at our request. We believe that these provisions in our amended and restated certificate of incorporation and indemnification agreements that will be in effect upon the completion of this offering are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation and our indemnification agreements, each of which will be in effect upon the completion of this offering is not complete and is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to the registration statement of which this prospectus is a part.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Non-Employee Director Compensation

Our policy with respect to the compensation payable to our non-employee directors provides that each non-employee director will be eligible to receive compensation for his or her service consisting solely of equity awards, specifically 18,000 stock options per year, of which 1,500 will vest for each month of service. Non-employee directors that serve as chair of audit committee, compensation committee and nominating and corporate governance committee receive an additional 5,000 stock options per year, of which 417 will vest for each month of service.

Directors may be reimbursed for travel, food, lodging and other expenses directly related to their service as directors. Directors will also be entitled to the protection provided by their indemnification agreements and the indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering.

The employment agreements for the Director who is a full-time employee expressly provides that his service on the Board does not entitle him to any additional compensation. The following table shows the total compensation paid or accrued to sitting non-employee members of our Board of Directors for the fiscal year ended December 31, 2021.

Name	Fees earned or paid in cash	Stock awards	Option awards (1)	All Other Compensation	Total
Tze-Liang Chiam(2)*	$ —	$ 13,750 (5)	— (5)	—	$ 13,750
Charlotte Tsou(3)*	$ —	$ — (6)	$ 11,414 (6)	—	$ 11,414
Steven Chaouki(4)	$ —	$ — (7)	$ 105,645 (7)	—	$ 105,645
Ramiro Guerrero	$ —	$ — (8)	$ 91,217 (8)	—	$ 91,217
Louie Ngar Yee	$ —	$ — (9)	$ 141,893 (9)	—	$ 141,893
Cristian Luput	$ —	$ 13,750 (10)	$ 91,217 (10)	—	$ 104,967
Stan V. Smith	$ —	$ — (11)	$ 121,763 (11)	—	$ 121,763
Laurentiu Vlad	$ —	$ — (12)	$ 91,217 (12)	—	$ 91,217
Leigh-Ann Durant(13)*	$ —	$ —	$ —	—	$ —
Wayne Klohs(14)*	$ —	$ —	$ —	—	$ —

(1) The aggregate grant date fair value of such awards were computed in accordance with Financial Accounting Standards Board ASC Topic 718, Stock Compensation (ASC Topic 718), and do not take into account estimated forfeitures related to service-based vesting conditions, if any. The valuation assumptions used in calculating these values are discussed in Note 7 of the Notes to Consolidated Financial Statements appearing elsewhere herein. These amounts do not represent actual amounts paid or to be realized. Amounts shown are not necessarily indicative of values to be achieved, which may be more or less than the amounts shown as awards may subject to time-based vesting.
(2) Tze-Liang Chiam's term as a director ended on September 15, 2021.
(3) Charlotte Tsou's term as a director ended on November 15, 2021.
(4) Steven Chaouki was appointed as a director on September 15, 2021
(5) Tze-Liang Chiam had 24,306 shares and 18,000 total options outstanding as of December 31, 2021.

(6) Charlotte Tsou had 0 shares and 28,159 total options outstanding as of December 31, 2021.
(7) Steven Chaouki had 0 shares and 21,000 total options outstanding as of December 31, 2021.
(8) Ramiro Guerrero had 33,334 shares and 36,000 total options outstanding as of December 31, 2021.
(9) Louie Ngar Yee had 11,111 shares and 46,000 total options outstanding as of December 31, 2021.
(10) Cristian Luput had 24,306 shares and 36,000 total options outstanding as of December 31, 2021.
(11) Stan V. Smith had 33,334 shares and 97,722 total options outstanding as of December 31, 2021.
(12) Laurentiu Vlad had 33,334 shares and 33,000 total options outstanding as of December 31, 2021.
(13) Leigh-Ann Durant's term as a director ended on November 15, 2021.
(14) Wayne Klohs term as a director ended on January 15, 2021.

*Received compensation for service on the board in 2021 but did not sit on the Board as of December 31, 2021.

PRINCIPAL STOCKHOLDERS

Based solely upon information made available to us, the following table sets forth information as of April 26, 2022 regarding the beneficial ownership of our common stock by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock;
- each of our named executive officers and directors; and
- all our executive officers and directors as a group.

The percentage ownership information shown in the table is based upon 7,951,320 shares of common stock outstanding as of April 26, 2022.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Except as otherwise indicated, each person or entity named in the table has sole voting and investment power with respect to all shares of our capital shown as beneficially owned, subject to applicable community property laws.

In computing the number and percentage of shares beneficially owned by a person as of a particular date, shares that may be acquired by such person (for example, upon the exercise of options or warrants) within 60 days of such date are counted as outstanding, while these shares are not counted as outstanding for computing the percentage ownership of any other person.

The address of each holder listed below, except as otherwise indicated, is c/o MAIA Biotechnology, Inc., 444 West Lake Street, Suite 1700, Chicago, IL 60606.

			Percentage of Beneficial Ownership	
Name and Address of Beneficial Owner	**Number of Common Shares of Beneficial Ownership Prior to the Offering[1]**		**Prior to Offering**	**After Offering**
Vlad Vitoc	3,138,976	(2)	31.70%	%
Joseph F. McGuire	1,953	(3)	*	*
Sergei M. Gryaznov	890,992	(4)	10.10%	%
Louie Ngar Yee	1,029,208	(5)	12.75%	%
Mihail Obrocea	90,703	(6)	1.13%	*
Ramiro Guerrero	291,461	(7)	3.65%	%
Steven Chaouki	54,750	(8)	*	*
Cristian Luput	314,631	(9)	3.94%	%
Stan V. Smith	671,510	(10)	8.17%	%
Laurentiu Vlad	406,898	(11)	5.09%	%
All directors and executive officers as a group (10 persons):	6,891,082		76.54%	%
Five Percent Shareholders				
Frank Perabo	492,544	(12)	6.21%	%
Jerry Shay	705,000	(13)	8.88%	%

* Less than 1%

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. In accordance with SEC rules, shares of common stock issuable upon the exercise of options or warrants which are currently exercisable or which become exercisable within 60 days following the date of the information in this table are deemed to be beneficially

owned by, and outstanding with respect to, the holder of such option or warrant, however none of the persons listed hereinabove has the right to acquire beneficial ownership in any other shares of the Company. Subject to community property laws where applicable, to our knowledge, each person listed is believed to have sole voting and investment power with respect to all shares of common stock owned by such person.

(2) Mr. Vitoc beneficially owns (i) 983,121 shares of common stock, which includes 200,000 shares of common stock owned by his spouse, and (ii) 2,155,855 shares of common stock issuable upon the conversion of options and warrants exercisable within 60 days of April 26, 2022.

(3) Mr. McGuire beneficially owns 1,953 shares of common stock issuable upon the conversion of options exercisable within 60 days of April 26, 2022.

(4) Mr. Gryaznov beneficially owns (i) 21,511 shares of common stock and (ii) 869,481 shares of common stock issuable upon the conversion of options exercisable within 60 days of April 26, 2022.

(5) Ms. Louie beneficially owns (i) 908,584 shares of common and (ii) 120,624 shares of common stock issuable upon the conversion of options and warrants exercisable within 60 days of April 26, 2022.

(6) Mr. Obrocea beneficially owns (i) 26,100 shares of common stock and (ii) 64,603 shares of common stock issuable upon the conversion of options and warrants exercisable within 60 days of April 26, 2022.

(7) Mr. Guerrero beneficially owns (i) 259,382 shares of common stock and (ii) 32,079 shares of common stock issuable upon the conversion of options and warrants exercisable within 60 days of April 26, 2022.

(8) Mr. Chaouki beneficially owns (i) 41,250 shares of common stock and (ii) 13,500 shares of common stock issuable upon the conversion of options exercisable within 60 days of April 26, 2022.

(9) Mr. Luput beneficially owns (i) 277,568 shares of common stock and (ii) 37,063 shares of common stock issuable upon the conversion of options and warrants exercisable within 60 days of April 26, 2022.

(10) Mr. Smith beneficially owns, through The Stan V. Smith Trust Dated 1993, (i) 401,128 shares of common stock and (ii) 270,382 shares of common stock issuable upon the conversion of options and warrants exercisable within 60 days of April 26, 2022.

(11) Mr. Vlad beneficially owns (i) 371,933 shares of common stock and (ii) 34,965 shares of common stock issuable upon the conversion of options and warrants exercisable within 60 days of April 26, 2022.

(12) Mr. Perabo beneficially owns 492,544 shares of common stock.

(13) Mr. Shay beneficially owns (i) 700,000 shares of common stock and (ii) 5,000 shares of common stock issuable upon the conversion of options exercisable within 60 days of April 26, 2022.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2020, to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 or one percent of the average of our total assets as of December 31, 2021 and 2020, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation."

Related Party Agreements in Effect Prior to this Offering

Consulting Services

Wayne Klohs is a shareholder and former member of the board of directors who also provided consulting services to the Company. During the year ended December 31, 2020, the Company incurred a total of $20,400 to Mr. Klohs for consulting services.

The Company did not receive consulting services from Mr. Klohs during the year ended December 31, 2021.

Leigh-Ann Durant, a former member of the Company's board of directors prior to her stepping down in November 2021, provides consulting services to the Company for which the Company incurred $129,171 for services provided during the year ended December 31, 2020, $53,981 of which is stock-based compensation which consist of options to purchase 47,569 shares of MAIA common stock.

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 MAIA common stock with a total fair value of $54,434 during the year ended December 31, 2021.

Mukesh Nyati was a minority shareholder of DGD and a consultant who received 222,500 shares of restricted stock in DGD during the year ended December 31, 2020, for his services along with cash. During 2020, the Company incurred $152,576 in research fees, $75,000 of which is stock-based compensation.

Dr. Nyati is also the one of the principal researchers at the University of Michigan who was working on the specific compound licensed from the University of Michigan.

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 will be settled in options for which the Company has not yet issued to Mr. Vitoc as of December 31, 2021. 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 (See Note 5), and also received 4,278 warrants to purchase shares of common stock at an exercise price of $6.00 per share.

CEO Loan Agreement

In addition, Vlad Vitoc, the Company's chief executive officer, lent the Company a total of $25,000 in August and September of 2018. Since January 1, 2019, the largest aggregate amount of principal outstanding under these loans was $25,000, and the Company has paid $3,633 of principal and no interest to Dr. Vitoc. The Company paid these loans in full on March 3, 2021, by paying principal of $367 and issuing Dr. Vitoc a convertible note in the amount of $21,000, which converted into 3,621 shares of our common stock on September 30, 2021.

Deferred Compensation Agreements

As of December 31, 2021 and December 31, 2020, the Company had $111,271 and $661,058, 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, 2021 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, 2021 and 2020, the Company accrued $384,750 and $780,000, respectively, in bonus expense relating to certain key 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 for the year ended December 31, 2021.

Indemnification Agreements

We intend to enter into indemnification agreements with each of our executive officers and directors that will be in effect upon the completion of this offering. The indemnification agreements will provide the executive officers and directors with contractual rights to indemnification, expense advancement and reimbursement, to the fullest extent permitted under the DGCL, subject to certain exceptions contained in those agreements.

Policies and Procedures for Related Person Transactions

Our board of directors will adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification by our audit committee of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds the lesser of $120,000 in any fiscal year or one percent of the average of our total assets as of the two previous fiscal years and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

DESCRIPTION OF CAPITAL STOCK

The following is a description of (i) the material terms of our amended and restated certificate of incorporation and amended and restated bylaws as they will be in effect upon the consummation of this offering and (ii) certain applicable provisions of Delaware law. We refer you to our amended and restated certificate of incorporation and amended and restated bylaws, copies of which will be filed as exhibits to the registration statement of which this prospectus is a part. In addition, with respect to the description of our warrants, we refer you to the forms of such warrants filed as exhibits to the registration statement of which this prospectus is a part.

Authorized Capitalization

Our authorized capital stock consists of 70 million shares of common stock, par value $0.0001 per share and 30 million shares of preferred stock, par value $0.0001 per share. Following the consummation of this offering, shares of common stock shall be issued and outstanding and no shares of preferred stock shall be issued or outstanding.

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. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. 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. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred 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, each as amended to become effective upon the completion of this offering, will 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.

Stockholder Meetings

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.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the 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

Our amended and restated bylaws, as amended to become effective upon the completion of this offering, 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.

Warrants

In connection with the sale of certain shares of our common stock to certain investors in October and November 2019, we issued to each such investors warrants as a buy-one-share, get-one-warrant arrangement. Each warrant is exercisable at an exercise price of $1.80 per share, and expire at the earlier of a change of control, or IPO or seven years from the issuance date. As of April 26, 2022, there are 442,501 of these warrants that are currently outstanding and exercisable.

During 2020, we issued warrants to certain consultants for services rendered during the year, 90,000 of these warrants have an exercise price of $1.80 per share and 20,520 of these warrants have an exercise price of $5.00 per share. These warrants expire at the earlier of a change of control, or an IPO, or various dates through December 2027. As of April 26, 2022, all of these warrants are currently outstanding and exercisable.

Finally, in connection with the sale of certain of our outstanding convertible promissory notes in 2020 and 2021, we issued to each such lender warrants equal to that number of shares of common stock as determined by multiplying the number of shares which would be issuable upon conversion of such note by 50%, for a total of 686,489 warrants at an exercise price of $6.00 per share. As of April 26, 2022, 681,985 of these warrants are outstanding and shall expire on the earlier of the occurrence of a change of control or September 2028.

Subsequent Event

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 will remove the IPO expiration provision from the warrant agreements, and the warrants shall only be exercisable, in whole or in part, during the exercise period ending on 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.

Crossover Round

In the First Quarter of 2022, we completed a crossover round with certain investors (the "Crossover Investors") consisting of sales of our common stock at a price of $9.00 per share ("Crossover Price), in the aggregate amount of approximately $2.4 million (the "Crossover Round"). In connection with the Crossover Round, in the event that the price per share of common stock sold in this offering (the "IPO Share Price") is less than the Crossover Price, then we plan to issue to the Crossover Investors, so long as such Crossover Investors continue to hold such common stock, that number of additional shares of our common stock such that the Crossover Price is equal to the IPO Share Price (the "Ratchet Shares").

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Inc. The transfer agent and registrar's address is Computershare Trust Company, N.A.

National Securities Exchange Listing

We intend to apply to have our common stock listed on the NYSE under the symbol "MAIA."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

"Upon the closing of this offering, we will have outstanding an aggregate of shares of common stock, assuming the issuance of shares of common stock offered by us in this offering, no exercise of options after , , 2022, and shares of common stock issuable to the Crossover Investors." Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Lock-Up Agreements

We, each of our officers, directors, and certain of our stockholders have agreed, 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 this prospectus, 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 6 months (or in the case of options with a weighted average exercise price of $1.80 or $1.83, for a period of 12 months) after the date of this 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. See the section of this prospectus entitled "Underwriting" for additional information. 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. See "Underwriting" for additional information.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume in our common stock on the NYSE during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and the NYSE concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the nine months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement. Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from an issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS

The following summary sets forth below certain material U.S. federal income tax consequences for Non-U.S. Holders (as defined below) of common stock as of the date hereof. This summary is based upon the Internal Revenue Code of 1986, as amended (the "Code"), the regulations promulgated by the U.S. Treasury Department, current administrative interpretations and practices of the U.S. Internal Revenue Service (the "IRS") and judicial decisions, all as currently in effect as of the date hereof and all of which are subject to differing interpretations or change, possibly with retroactive effect. No assurance can be given that the IRS will not assert, or that a court will not sustain a position contrary to any of the tax considerations described below. This summary does not discuss all aspects of U.S. federal income taxation that may be relevant to particular holders in light of their particular circumstances, and does not address the U.S. federal income tax consequences to holders that are subject to special tax rules, including, without limitation: financial institutions, insurance companies, mutual funds, pension plans, S corporations, controlled foreign corporations, broker-dealers, traders in securities that elect mark-to-market treatment, regulated investment companies, real estate investment trusts, partnerships and their partners, tax-exempt organizations (including private foundations), investors that hold common stock as part of a "straddle," "hedge," "conversion," "synthetic security," "constructive ownership transaction," "constructive sale" or other integrated transaction for U.S. federal income tax purposes, holders subject to the alternative minimum tax provisions of the Code, holders who acquired common stock directly or indirectly in connection with performance of services, pursuant to an exercise of employee options, in connection with employee incentive plans or otherwise as compensation, the Sponsor and its affiliates, persons who actually or constructively own 5% or more (by vote or value) of the common stock, persons required to accelerate the recognition of any item of gross income with respect to common stock as a result of such income being recognized on an applicable financial statement, and U.S. expatriates, all of whom may be subject to tax rules that differ materially from those summarized below. In addition, this summary does not discuss any state, local, or non-United States tax considerations, any non-income tax (such as gift or estate tax) considerations, the alternative minimum tax, the Medicare tax on certain net investment income, or any tax reporting obligations in respect of the ownership of common stock. This summary is limited to holders that hold common stock as "capital assets" (generally, property held for investment) under the Code.

If a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds common stock, the tax treatment of a partner in such partnership will generally depend upon the status of the partner, the activities of the partnership and the partner and certain determinations made at the partner level. If you are a partner of a partnership holding common stock, you are urged to consult your tax advisor.

For purposes of this discussion, a "Non-U.S. Holder" is a beneficial owner for U.S. federal income tax purposes of common stock that is not any of the following:

- an individual who is a United States citizen or resident of the United States;
- a corporation (including an entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust (i) the administration of which is subject to the primary supervision of a United States court and which has one or more United States persons (within the meaning of the Code) who have the authority to control all substantial decisions of the trust or (ii) that has in effect a valid election under applicable Treasury regulations to be treated as a United States person.

Gain on Sale, Taxable Exchange, or Other Taxable Disposition of Common Stock

Subject to the discussions below under "—Information Reporting and Backup Withholding" and "— FATCA," a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax in respect of gain recognized on a taxable disposition of its common stock, unless:

- the gain is effectively connected with the conduct of a trade or business by the Non-U.S. Holder within the United States (and, under certain income tax treaties, is attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. Holder), in which case, a non-corporate Non-U.S. Holder will be subject to tax on the net gain derived from the sale under regular graduated U.S. federal

income tax rates, and a corporate Non-U.S. Holder may be subject to an additional branch profits tax at a 30% rate (or lower rate as may be specified by an applicable income tax treaty);

- the Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year in which the disposition takes place and certain other conditions are met, in which case the Non-U.S. Holder will generally be subject to a 30% tax on the individual's net capital gain for the year; or
- the Company or has been a "United States real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. Holder held common stock, and, in the case where shares of common stock are regularly traded on an established securities market, the Non-U.S. Holder has owned, directly or constructively, more than 5% of the common stock at any time within the shorter of the five-year period preceding the disposition or such Non-U.S. Holder's holding period for the shares of common stock.

With respect to the third bullet point above (if applicable to a particular Non-U.S. Holder), gain recognized by such Non-U.S. Holder on the sale, exchange or other disposition of common stock will be subject to tax at generally applicable U.S. federal income tax rates. There can be no assurance that the common stock will be treated as regularly traded on an established securities market for this purpose. The Company does not believe that it is or has been a United States real property holding corporation for U.S. federal income tax purposes but there can be no assurance in this regard. The Company would be classified as a United States real property holding corporation if the fair market value of its "United States real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes.

Taxation of Distributions

Subject to the discussions below under "—Information Reporting and Backup Withholding" and "— FATCA," in general, any distributions the Company makes to a Non-U.S. Holder on shares of common stock, to the extent paid out of the Company's current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, under certain income tax treaties, attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. Holder), the applicable withholding agent will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such Non-U.S. Holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate. Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the Non-U.S. Holder's adjusted tax basis in its shares of common stock (and, subject to the discussion below under "—Information Reporting and Backup Withholding" and "— FATCA," and the third bullet point above under "—Gain on Sale, Taxable Exchange or Other Taxable Disposition of common stock," to the extent such distribution does not exceed the adjusted tax basis, such amount will generally not be subject to withholding) and, to the extent such distribution exceeds the Non-U.S. Holder's adjusted tax basis, as gain realized from the sale or other disposition of common stock, which will be treated as described above under "—Gain on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock." In addition, if the Company determines that it is classified as a United States real property holding corporation, it will withhold 15% of any distribution that exceeds the Company's current and accumulated earnings and profits.

Dividends the Company pays to a Non-U.S. Holder that are effectively connected with such Non-U.S. Holder's conduct of a trade or business within the United States (and, under certain income tax treaties, attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. Holder), generally will not be subject to U.S. federal withholding tax, provided such Non-U.S. Holder complies with certain certification and disclosure requirements. Instead, such dividends generally will be subject to U.S. federal income tax, net of certain deductions, at the same graduated individual or corporate rates applicable to United States persons as defined under the Code (subject to an exemption or reduction in such tax as may be provided by an applicable income tax treaty). If the Non-U.S. Holder is a corporation, dividends that are effectively connected income may also be subject to an additional "branch profits tax" at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

Information Reporting and Backup Withholding

The Company generally must report annually to the IRS and to each Non-U.S. Holder the amount of dividends paid to such holder and the tax withheld with respect to such dividends, regardless of whether withholding was required. A Non-U.S. Holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding requirements. The certification procedures required to claim a reduced rate of withholding under an applicable income tax treaty generally will satisfy a Non-U.S. Holder's certification requirements necessary to avoid backup withholding as well. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will generally be allowed as a refund or a credit against a Non-U.S. Holders U.S. federal income tax liability provided the required information is timely furnished to the IRS. Holders should consult their tax advisors regarding the application of information reporting and backup withholding to them.

FATCA

Under sections 1471 to 1474 of the Code, commonly referred to as the Foreign Account Tax Compliance Act ("FATCA"), a 30% withholding tax generally applies with respect to certain payments on and, subject to the regulatory relief described below, gross proceeds from a sale or disposition of, common stock if paid to (i) a foreign financial institution (as the beneficial owner or as an intermediary for the beneficial owner), unless such institution (a) enters into, and is in compliance with, a withholding and information reporting agreement with the U.S. government to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which would include certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or (b) is a resident in a country that has entered into an intergovernmental agreement with the United States in relation to such withholding and information reporting and the financial institution complies with the related information reporting requirements of such country or (ii) a foreign entity that is not a financial institution (as the beneficial owner or as an intermediary for the beneficial owner), unless such entity provides the withholding agent with a certification identifying the substantial United States owners of the entity, which generally includes any United States person who directly or indirectly owns more than 10% of the entity, or such entity otherwise qualifies for an exemption from these rules.

An intergovernmental agreement between the United States and the applicable foreign country, or future U.S. Treasury regulations or other guidance, may modify these requirements. Under proposed U.S. Treasury regulations that may be relied upon pending finalization, the withholding tax on gross proceeds would be eliminated and, consequently, FATCA withholding on gross proceeds is not expected to apply unless such proposed U.S. Treasury regulations are modified, withdrawn or replaced in a manner that would subject gross proceeds to FATCA withholding. Non-U.S. Holders should consult their tax advisors regarding the possible implications of such withholding tax.

NON-U.S. HOLDERS OF COMMON STOCK ARE URGED TO CONSULT THEIR TAX ADVISORS CONCERNING THE U.S. FEDERAL, STATE, LOCAL, AND FOREIGN INCOME AND OTHER TAX CONSEQUENCES THEREOF.

UNDERWRITING

ThinkEquity LLC is acting as representative of the underwriters of this offering. Subject to the terms and conditions of an underwriting agreement between us and the representative, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Underwriter	Number of Shares
ThinkEquity LLC	
Total	

The underwriters are committed to purchase all shares offered by us other than those covered by the over-allotment option described below, if any are purchased. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

The underwriters are offering the shares subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The underwriters propose to offer the shares offered by us to the public at the public offering price set forth on the cover of the prospectus. After the shares are released for sale to the public, the underwriters may change the offering price and other selling terms at various times.

Over-Allotment Option

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the representative to purchase a maximum of additional shares of common stock (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the representative exercises all or part of this option, it will purchase shares covered by the option at the initial public offering price per share that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total offering price to the public will be $ and the total net proceeds, before expenses, to us will be $.

Discount

The following table shows the initial public offering price, underwriting discounts and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Total Without Over- Allotment Option	Total With Over- Allotment Option
Initial public offering price	$	$	$
Underwriting discount (7.5%)	$	$	$
Proceeds, before expense, to us	$	$	$

We have agreed to pay a non-accountable expense allowance to the underwriters equal to 1.0% of the gross proceeds received in this offering (excluding proceeds received from exercise of the underwriters' over-allotment option).

We have paid an expense deposit of $50,000 to the representative for out-of-pocket-accountable expenses, which will be returned to us to the extent such out-of-pocket accountable expenses are not actually incurred in accordance with FINRA Rule 5110(f)(2)(C).

In addition, we have agreed to reimburse the representative for (i) fees and expenses of legal counsel to the underwriters in an amount not to exceed $125,000; (ii) fees and expenses related to the use of Ipreo's book building, prospectus tracking and compliance software for the offering in the amount of $29,500; (iii) up to $10,000 for background checks of our officers and directors; (iv) up to $10,000 for all fees, expenses and disbursements relating to the registration, qualification or exemption of such shares under the securities laws of such foreign jurisdictions as the Representative may reasonably designate; (iv) up to $10,000 for all fees, expenses and disbursements relating to the registration, qualification or exemption of such shares under the "blue sky" securities laws of such states, if applicable, and other jurisdictions as the Representative may reasonably designate; (v) $10,000 for data services and communications expenses; (vi) $3,000 for the costs associated with bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones; (vii) up to $10,000 for actual accountable "road show" expenses; and (viii) up to $30,000 for market making and trading, and clearing firm settlement expenses for the offering.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount and non-accountable expense allowance, will be approximately $.

Representative's Warrants

We have agreed to issue to the representative or its designees warrants to purchase up to a total of shares of our common stock (5% of the aggregate number of shares of common stock sold in this offering) (the "Representative's Warrants"). The Representative's Warrants will be exercisable at a per share exercise price equal to 125% of the public offering price per share of the shares of common stock sold in this offering. The Representative's Warrants are exercisable at any time, from time to time, in whole or in part, during the four and one half year period commencing six months from the effective date of the registration statement related to this offering.

The Representative's Warrants and the shares of common stock underlying the Representative's Warrants have been deemed compensation by FINRA and are, therefore, subject to a 180-day lock-up pursuant to FINRA Rule 5110(g)(1). The Representative or permitted assignees under such rule may not sell, transfer, assign, pledge, or hypothecate the Representative's Warrants or the securities underlying the Representative's Warrants, nor will the representative engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the Representative's Warrants or the underlying shares of common stock for a period of 180 days from the effective date of the registration statement. Additionally, the Representative's Warrants may not be sold, transferred, assigned, pledged, or hypothecated for a 180-day period following the effective date of the registration statement, except to any underwriter and selected dealer participating in the offering and their bona fide officers or partners. The Representative's Warrants will provide for adjustment in the number and price of the Representative's Warrants and the shares of common stock underlying the Representative's Warrants in the event of recapitalization, merger, stock split, or other structural transaction, or a future financing undertaken by us. The Representative's Warrants will provide for registration rights (including a one-time demand registration right and unlimited piggyback rights) consistent with FINRA Rule 5110.05. The demand for registration may be made at any time beginning on the initial exercise date of the Representative's Warrants and expiring on the fifth anniversary of the effective date of this registration statement in accordance with FINRA Rule 5110(g)(8)(C). In addition to the one-time demand registration right, the Representative's Warrants shall have unlimited piggyback rights, for a period of no more than two years from the initial exercise date of the Representative's Warrants in accordance with FINRA Rule 5110(g)(8)(D). The Representative's Warrants will also provide for customary anti-dilution provisions (for stock dividends and splits and recapitalizations) consistent with FINRA Rule 5110, and further, the number of shares underlying the Representative's Warrants shall be reduced if necessary to comply with FINRA rules and regulations.

Discretionary Accounts

The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements

We, each of our officers, directors, and certain of our stockholders have agreed, 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 this prospectus, without the prior written consent of the representative. All 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 6 months (or in the case of options with a weighted average exercise price of $1.80 or $1.83, for a period of 12 months) after the date of this 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.

Right of First Refusal

The Underwriting Agreement will provide that for a period of fifteen (15) months from the closing of the offering, we will grant the representative an irrevocable right of first refusal to act as a sole investment banker, sole book-runner, sole financial advisor, sole underwriter and/or sole placement agent, at the representative's sole discretion, for each and every future public and private equity and debt offering, including all equity linked financings, during such fifteen (15) month period for us, or any successor to or any subsidiary of us, on terms customary to the representative. The representative has the sole right to determine whether or not any other broker dealer shall have the right to participate in any such offering and the economic terms of any such participation.

Indemnification

To the extent permitted by law, we have agreed to indemnify the underwriters and its affiliates, stockholders, directors, officers, employees, members and controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of securities in excess of the number of securities that underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the

underwriters is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing securities in the open market.

Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase securities through exercise of the over-allotment option. If the underwriters sell more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be effected on the NYSE, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on the NYSE or on the OTCQB in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the securities and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Other Relationships

Certain of the underwriters and their affiliates may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they may receive customary fees and commissions. However, we have not yet had, and have no present arrangements with any of the underwriters for any further services.

Offer restrictions outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information

required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area—Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);
- to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2 and

D.411-1 to D.411-3, D. 744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2 and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with this offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Societa e la Borsa, or CONSOB), pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors ("Qualified Investors"), as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999, as amended ("Regulation no. 1197l"); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Regulation no. 1197l.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993, as amended, Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007, and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being

declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL") pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates.

This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to the Company. In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI33-105 regarding underwriter conflicts of interest in connection with this offering.

EXPERTS

The consolidated balance sheets of MAIA Biotechnology, Inc. and Subsidiaries as of December 31, 2021 and 2020, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the years then ended, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein. Such financial statements have been incorporated herein in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

LEGAL MATTERS

Loeb & Loeb LLP, New York, New York, will pass upon the validity of the shares of common stock offered hereby. Venable, LLP, New York, New York has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document is not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement is this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may read and copy the registration statement, the related exhibits and other material we file with the SEC at the SEC's public reference room in Washington, D.C. at 100 F Street, Room 1580, N.E., Washington, D.C. 20549. You can also request copies of those documents, upon payment of a duplicating fee, by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

Upon completion of this offering, we will become subject to the information and reporting requirements of the Securities Exchange Act of 1934, as amended, and, in accordance with this law, will be required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available on the website of the SEC referred to above. We also maintain a website at www.maiabiotech.com. Our website and the information contained on, or that can be accessed through, our website is not deemed to be incorporated by reference in, and is not considered part of, this prospectus. You should not rely on any such information in making your decision whether to purchase our common stock.

We have not authorized anyone to give you any information or to make any representations about us or the transactions we discuss in this prospectus other than those contained in this prospectus. If you are given any information or representations about these matters that is not discussed in this prospectus, you must not rely on that information. This prospectus is not an offer to sell or a solicitation of an offer to buy securities anywhere or to anyone where or to whom we are not permitted to offer or sell securities under applicable law.

MAIA Biotechnology, Inc. and Subsidiaries
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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 sheets of MAIA Biotechnology, Inc. and Subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the years 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 2020, and the results of its operations and its cash flows for each of the years 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 audits. 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 audits 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 audits, 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2021.

EISNERAMPER LLP
Iselin, New Jersey
April 8, 2022

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash	$ 10,574,292	$ 663,457
Prepaid expenses and other current assets	98,203	83,048
Total current assets	10,672,495	746,505
Deferred offering costs	651,582	—
Other assets	3,122	—
Total assets	$ 11,327,199	$ 746,505
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 960,401	$ 154,886
Accrued expenses	1,074,324	838,810
Due to related parties	—	7,037
Convertible notes payable - current portion	—	10,586
Loan payable to officer	—	21,367
Deferred compensation	111,271	661,058
Total current liabilities	2,145,996	1,693,744
Convertible notes payable, net of current portion	—	332,841
Convertible notes payable, related parties	—	98,960
Derivative liability for embedded conversion features on convertible notes payable and convertible notes payable, related parties	—	127,000
Warrant liability	—	85,260
Simple agreement for future equity payable	—	25,000
Total liabilities	2,145,996	2,362,805
Commitments and contingencies		
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value, 70,000,000 shares authorized, 0 shares issued and outstanding	—	—
Common stock, $0.0001 par value, 30,000,000 shares authorized, 7,584,980 and 4,433,644 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	758	443
Additional paid-in capital	37,618,438	12,599,585
Accumulated deficit	(28,437,993)	(15,934,113)
Stock subscription receivable	—	(2,002)
Total MAIA Biotechnology, Inc. stockholders' equity (deficit)	9,181,203	(3,336,087)
Noncontrolling interests	—	1,719,787
Total stockholders' equity (deficit)	9,181,203	(1,616,300)
Total liabilities and stockholders' equity (deficit)	$ 11,327,199	$ 746,505

See the accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Statements of Operations

	For the Year Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development expenses	$ 3,496,796	$ 1,412,409
General and administrative expenses	4,289,831	5,563,192
Total operating costs and expenses	7,786,627	6,975,601
Loss from operations	(7,786,627)	(6,975,601)
Other income (expense):		
Interest expense	(827,539)	(32,226)
Interest income	2,012	679
Paycheck protection program loan forgiveness	62,500	62,500
Australian research and development incentives	43,666	—
Change in fair value of embedded features	(203,000)	5,000
Change in fair value of warrant liability	(1,546,280)	(19,600)
Loss on extinguishment of convertible notes and convertible notes, related parties	(2,322,943)	—
Other income (expense), net	(4,791,584)	16,353
Net loss	(12,578,211)	(6,959,248)
Net loss attributable to noncontrolling interests	(74,331)	(322,588)
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (12,503,880)	$ (6,636,660)
Net loss per share		
Basic and diluted net loss per share	$ (2.37)	$ (1.50)
Weighted average common shares outstanding		
Basic and diluted	5,278,435	4,427,242

See the accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-In	Accumulated	Subscription	Total MAIA	Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Deficit	Receivable	Equity (Deficit)	Interest	Equity (Deficit)
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 the accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-In	Accumulated	Subscription	Total MAIA	Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Deficit	Receivable	Equity (Deficit)	Interest	Equity (Deficit)
Balance at December 31, 2019	4,416,977	$ 442	$ 9,228,546	$ (9,297,453)	$ (104,402)	$ (172,867)	$ 1,497,659	$ 1,324,792
Receipt of stock subscription receivable - MAIA	—	—	—	—	102,400	102,400	—	102,400
Receipt of stock subscription receivable - DGD	—	—	—	—	—	—	35,000	35,000
Issuance of restricted common shares	16,667	1	19,999	—	—	20,000	—	20,000
Issuance of DGD common stock	—	—	—	—	—	—	50,000	50,000
Stock-based compensation expense - MAIA	—	—	3,351,040	—	—	3,351,040	—	3,351,040
Stock-based compensation expense - DGD	—	—	—	—	—	—	307,928	307,928
Stock-based compensation expense - THIO	—	—	—	—	—	—	210,000	210,000
Return of capital - DGD	—	—	—	—	—	—	(58,212)	(58,212)
Net loss	—	—	—	(6,636,660)	—	(6,636,660)	(322,588)	(6,959,248)
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)

See the accompanying notes to the consolidated financial statements.

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

	For the Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss, including noncontrolling interests	$ (12,578,211)	$ (6,959,248)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,722,893	3,888,968
Loss on extinguishment of convertible notes	2,322,943	—
Gain from forgiveness of Paycheck Protection Program loan	(62,500)	(62,500)
Change in fair value of embedded features	203,000	(5,000)
Change in fair value of warrant liability	1,546,280	19,600
Amortization of debt discount	596,953	19,875
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(15,155)	(58,084)
Deferred offering costs	(651,582)	—
Other assets	(3,122)	—
Accounts payable	805,516	(2,304)
Accrued expenses	1,261,495	826,470
Due to related parties	(7,037)	4,938
Deferred compensation	(264,369)	483,122
Net cash used in operating activities	(4,122,896)	(1,844,163)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, warrants, and embedded conversion features	7,369,000	610,000
Proceeds from Paycheck Protection Program loan	62,500	62,500
Collections of subscriptions receivable - MAIA	322,002	102,400
Collections of subscriptions receivable - DGD	—	35,000
Proceeds from issuance of common stock, net of transaction costs - MAIA	5,742,171	—
Proceeds from issuance of common stock - DGD	—	50,000
Proceeds from exercise of stock options	9,000	—
Proceeds from exercise of warrants	529,425	—
Return of capital – DGD	—	(58,212)
Payment on loan payable to officer	(367)	(3,633)
Net cash provided by financing activities	14,033,731	798,055
Net increase (decrease) in cash	9,910,835	(1,046,108)
Cash at beginning of year	663,457	1,709,565
Cash at end of year	$ 10,574,292	$ 663,457
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 from officer	$ (21,000)	$ —

See the 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 cancelled 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.

Liquidity

At December 31, 2021, the Company had working capital of $8,526,499, an accumulated deficit of $28,437,993, cash of $10,574,292 and current liabilities of $2,145,996. 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.

The Company believes that it currently has sufficient funds to support operations through the next twelve months from the date the consolidated financial statements are issued, including funding of the THIO-101 lead-in and preliminary efficacy of the phase 2 THIO-101. However, further significant funding will be required to perform the necessary clinical trials, and to meet the Company’s long-term development and commercialization goals. The Company cannot make any assurances that additional financings will be available to it and, if available, on acceptable terms or at all. This could negatively impact the Company’s business and operations and could also lead to the reduction of the Company’s operations.

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. 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.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in its financial statements and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's financial statements relate to the valuation of common stock, stock options, warrants, the embedded features in convertible notes and the valuation allowance of deferred tax assets resulting from net operating losses. 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

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, 2021 and 2020, 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, 2021 and 2020, cash includes cash in a depository bank account; the Company has no cash equivalents as of December 31, 2021 and 2020.

Fair Value Measurements

ASC 820, *Fair Value Measurements*, provides guidance on the development and disclosure of fair value measurements. 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 year ended December 31, 2021, and 2020. The carrying amount of accounts payable approximated fair value as they are short term in nature. The fair value of warrants issued for services are estimated based on the Black-Scholes model during the year ended December 31, 2021. The carrying value of notes payable and convertible notes payable approximated the estimated fair values due to their recent issuances. The estimated fair value of the warrants issued with the convertible notes 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.

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.

Under the program, a percentage of eligible research and development expenses incurred by the Company through its subsidiary in Australia are reimbursed.

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 initial public 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 initial public 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.

The fair values of DGD and THIO common stock were based on sales of common stock to third parties for the year ended December 31, 2020. There were no issuances of common stock as it relates to DGD or THIO during the year ended December 31, 2021. The fair value of restricted stock awards is based on common stock value.

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 were 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. In accordance with ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, the measurement of equity-classified nonemployee 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 are included in other assets and consists of legal, accounting, underwriting fees and other costs incurred through the balance sheet date that are directly related to the planned initial public offering and that will be charged to additional paid-in capital upon the completion of the planned initial public offering. Should the planned initial public offering prove to be unsuccessful, these deferred costs, as well as additional expenses to be incurred, will be charged to operations.

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:

	Year ending December 31,	
	2021	**2020**
Shares issuable upon exercise of stock options	5,797,185	3,664,966
Shares issuable upon exercise of warrants	1,311,117	908,244
Unvested restricted stock awards	58,333	147,778

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.

Accounting Standards Issued, Not Yet Adopted

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 currently expects that none of its operating lease commitments will be subject to the new standard as the Company's leases are short-term in nature (i.e., less than twelve months). The Company will adopt this new standard as of January 1, 2022.

In June 2016, the FASB issued ASU No. 2016-13, Measurement of Credit Losses on Financial Instruments (ASU 2016-13), which requires a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. The

new standard is effective for the Company for fiscal years beginning after December 15, 2022. The Company is currently evaluating the impact of the pending adoption of the new standard on its financial statements and intends to adopt the standard as of January 1, 2023.

2. RELATED PARTY TRANSACTIONS

Consulting Services

Wayne Klohs is a shareholder and former member of the board of directors who also provided consulting services to the Company. During the year ended December 31, 2020, the Company incurred a total of $20,400 to Mr. Klohs for consulting services. The Company did not receive consulting services from Mr. Klohs during the year ended December 31, 2021.

Leigh-Ann Durant, a former member of the Company's board of directors prior to her stepping down in November 2021, provides consulting services to the Company for which the Company incurred $129,171 for services provided during the year ended December 31, 2020, $53,981 of which is stock-based compensation which consist of options to purchase 47,569 shares of common stock. 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.

Mukesh Nyati was a minority shareholder of DGD and a consultant who received 222,500 shares of restricted stock in DGD during the year ended December 31, 2020, for his services along with cash. During 2020, the Company incurred $152,576 in research fees, $75,000 of which is stock-based compensation. Dr. Nyati is also the one of the principal researchers at the University of Michigan who was working on the specific compound licensed from the University of Michigan.

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 will be settled in options for which the Company has not yet issued to Mr. Vitoc as of December 31, 2021. 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 (See Note 5), and also received 4,278 warrants to purchase shares of common stock at an exercise price of $6.00 per share.

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 (See Note 5).

Deferred Compensation Agreements

As of December 31, 2021 and December 31, 2020, the Company had $111,271 and $661,058, 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, 2021 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, 2021 and 2020, the Company accrued $384,750 and $780,000, respectively, in bonus expense relating to certain key 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.

3. ACCRUED EXPENSES

As of December 31, 2021 and 2020, accrued expenses consisted of the following:

	December 31,	
	2021	2020
Bonus	$ 384,750	780,000
Interest	—	12,678
Professional fees	380,277	46,132
Research and development costs	268,140	—
Other	41,157	$ —
Total accrued expenses	$ 1,074,324	$ 838,810

4. PAYCHECK PROTECTION PROGRAM

In May 2020, the Company applied for and received $62,500 in unsecured loan funding from the Paycheck Protection Program (the "PPP Loan"), established pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and administered by the U.S. Small Business Administration ("SBA"). The Company received full forgiveness of all outstanding principal and accrued and unpaid interest on the PPP Loan in December 2020.

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

	December 31, 2021	December 31, 2020
Convertible notes payable:		
Convertible note balance	$ —	$ 620,000
Debt discount	—	(177,613)
Carrying value of convertible notes payable	$ —	$ 442,387
Convertible note payable, current portion	$ —	$ 10,586
Convertible notes payable, related parties	—	98,960
Convertible notes payable, net of current portion	—	332,841
Carrying value of convertible notes payable	$ —	$ 442,387

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 $607 and $1,156 for the year ended December 31, 2021 and 2020, 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 and $414 as of December 31, 2021 and December 31, 2020, respectively. During the year ended December 31, 2021 and 2020, amortization of debt discount amounted to $310 and $586, 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 7). 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 $177,199 as of December 31, 2021 and 2020, respectively. During the year ended December 31, 2021 and 2020, amortization of debt discounts amounted to $83,608 and $19,461, respectively.

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 7) 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 7). 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, 2021 and 2020, amortization of debt discounts amounted to $513,035 and $0, 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 7) 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

Financial liabilities consisting of embedded derivative liabilities and warrant liabilities measured at fair value on a recurring basis are summarized below. The fair values of the embedded derivative liabilities and warrant liabilities recorded are as follows:

	Fair value at September 30, 2021			
	Total	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Derivative liability, bifurcated put contained in convertible notes payable	$ —	$ —	$ —	$ —
Warrant liability	—	—	—	—
Total liabilities	$ —	$ —	$ —	$ —

	Fair value at December 31, 2020			
	Total	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Derivative liability, bifurcated put contained in convertible notes payable	$ 127,000	$ —	$ —	$ 127,000
Warrant liability	85,260	—	—	85,260
Total liabilities	$ 212,260	$ —	$ —	$ 212,260

The table below provides a summary of the changes in fair value of the derivative liabilities and warrant liabilities measured on a recurring basis using significant unobservable inputs (Level 3):

	Year Ended December 31,	
Derivative liabilities:	**2021**	**2020**
Balance, beginning of period	$ 127,000	$ 1,000
Derivative liability on convertible notes payable	2,821,000	131,000
Loss (Gain) on fair value of embedded features	203,000	(5,000)
Extinguishment of derivative liability in connection with debt conversion	(3,151,000)	—
Balance, end of period	$ —	$ 127,000

	Year Ended December 31,	
Warrant liabilities:	**2021**	**2020**
Balance, beginning of period	$ 85,260	$ —
Warrant liability	320,460	65,660
Loss on fair value of warrant liability	1,546,280	19,600
Reclassification of warrant liability to equity	(1,952,000)	—
Balance, end of period	$ —	$ 85,260

Derivative Liability

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.

Convertible Note Warrants

The Warrants were separately measured at fair value, with changes in fair value recognized in current operations. The fair value of the Warrants was determined using the Black-Scholes-Merton option-pricing model utilizing inputs such as the fair value of the underlying stock, expected term, expected volatility of the underlying stock over the expected term, and the risk-free interest rate over the expected term. The Warrants were valued at each issuance date of the convertible notes and at each quarter end based on the assumptions for each of the conversion scenarios contained within each of the convertible notes. The following are the significant assumptions utilized in the Black-Scholes-Merton option-pricing model; risk-free interest rate 0.0% - 1.3%; expected term (in years) 0.46 - 6.61; expected volatility 81% - 106%; expected dividend yield 0% - 0%. Changes to these assumptions had an impact on the fair value of the Warrants and related fair value adjustments.

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 now exercisable for 686,489 shares of common stock with an exercise price of $6.00 and expire at various dates throughout fiscal 2028.

The Company determined as of September 30, 2021 the warrants should be equity classified and reclassified the fair value of the warrant liability of $1,952,000 into additional paid-in capital. The change in fair value of the warrant liability of $1,546,280 for the year ended December 31, 2021 is reflected in "Change in fair value of warrant liability" in the accompanying statement of operations.

8. STOCKHOLDERS' EQUITY

Upon incorporation, MAIA was authorized to issue 10,000,000 shares of common stock, with a par value of $0.0001 per share. In March 2020, the shareholders approved an amended and restated certificate of incorporation which authorizes MAIA to issue 100,000,000 shares of stock, as follows: 70,000,000 shares of preferred stock and 30,000,000 shares of common stock, all with a par value of $0.0001 per share. The rights, privileges, preferences, and restrictions of the classes of stock have yet to be established. As of December 31, 2021, each of the common stockholders have equal voting rights, and except in the case of restricted common shares, equal rights of participation in dividends and other distributions with other common stockholders.

Among other provisions, MAIA's shareholders agreement gives first MAIA, followed by the non-selling shareholders, the option to purchase the outstanding shares of a shareholder prior to the sale of shares to a third party. Should the non-selling shareholders decline to purchase any portion of the selling shareholders shares, MAIA shall have a final opportunity to repurchase the shares. The agreement also contains provisions for "drag-along" and "tag-along" rights, as described in the agreement.

MAIA Equity Financing

Between July 18, 2021 and December 31, 2021, the Company sold 772,563 shares of common stock at $8.00 per share for gross proceeds of approximately $6.2 million. In connection with this sale of common stock, all of the outstanding convertible notes principal and accrued and unpaid interest were automatically converted into 1,375,228 shares of the Company's common stock in accordance with the terms in the convertible notes (see Note 5).

MAIA Biotechnology, Inc. Restricted Stock Awards

Restricted Common Stock Awards to Founders - In October 2018, the Company awarded 2,100,000 restricted common shares to four founders. Vested shares may participate in any dividends and other distributions with other common stockholders, while the unvested shares, which are subject to forfeiture in the event the holder separates from service with the Company, do not participate in such events. The share awards are subject to service conditions, with 50% of the granted shares vesting immediately upon issuance, and the remaining 1,050,000 common shares vesting in 12 equal quarterly installments over a three-year period, with the first such quarterly installment vesting on January 1, 2019.

The related compensation expense was recognized 50% upon issuance, and the remainder is recognized ratably over the service period. In November 2019, upon termination of two of the founders, 400,000 of those founders' unvested shares were forfeited.

During the year ended December 31, 2021 and 2020, the Company recognized $202,500 and $270,000, respectively, in general and administrative expense related to the Founders' awards.

Restricted Common Stock Awards to Directors — During the year ended December 31, 2021, the Company awarded 15,278 restricted common shares to two directors. Vested shares may participate in any dividends and other distributions with other common stockholders. The share awards were subject to service conditions as defined in the agreements. The related compensation expense was recognized ratably over the service period. During the year ended December 31, 2021 the Company recognized $27,500 in general and administrative expense related to the Directors' awards, as they fully vested on December 31, 2021.

During the year ended December 31, 2020 the Company awarded 16,667 restricted common shares to one director. During the year ended December 31, 2020 the Company recognized $241,027 in general and administrative expense related to this Director's awards and previous Director's awards, as they fully vested by December 31, 2020.

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at January 1, 2020	420,848	$ 1.80
Granted	16,667	1.80
Vested	(289,737)	
Unvested balance at December 31, 2020	147,778	$ 1.80
Exchanged for THIO founder restricted shares	87,500	1.80
Granted	15,278	1.80
Vested	(186,666)	
Cancelled/forfeited	(5,557)	
Unvested balance at December 31, 2021	58,333	$ 1.80

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 cancelled 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 vest ratably each quarter through June 30, 2022 to replace the equivalent number of unvested THIO restricted shares. The remaining unvested shares in the above table as of December 31, 2021 are related to the founder's unvested restricted shares only.

During the year ended December 31, 2021, MAIA recognized $105,000 of stock compensation expense related to the MAIA restricted shares granted to the founder. The issuance of restricted shares in MAIA as a replacement for the shares the founder held in THIO was accounted for as a modification. There was no additional incremental stock compensation recorded as related to the cancellation of the founder's THIO restricted shares and concurrent grant of MAIA restricted shares as the fair value of the original THIO award immediately before the grant of the MAIA restricted shares and the fair value of the replacement award were equal. The unrecognized stock compensation expense for the 58,333 unvested restricted shares as of December 31, 2021 is approximately $52,500, which will be recognized through March 2022.

MAIA Stock Warrants

During 2020, the Company issued warrants to purchase 110,520 shares of common stock to certain consultants for services rendered during the year. Of these warrant grants, 90,000 have an exercise price of $1.80 and 20,520 have an exercise price of $5.00 per share. The warrants' total calculated value of $124,064 is included in operating expenses in the accompanying

consolidated statement of operations for the year ended December 31, 2020. As of December 31, 2021, all of these warrants, which expire at various dates through December 2027, are outstanding and exercisable.

In May 2020 through June 2021, the Company issued and sold convertible promissory notes with an aggregate principal amount of $8.0 million, which converted into 1,375,228 shares of its common stock on September 30, 2021, and warrants to purchase 686,489 shares of our common stock at $6.00 per share. As of December 31, 2021, 4,504 of these warrants have been exercised, and 681,985 warrants, which expire at various dates through September 2028, are outstanding and exercisable.

	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Balance at January 1, 2020	797,724	$ 1.80	9.85
Granted	110,520	2.39	9.44
Balance at December 31, 2020	908,244	1.87	8.89
Granted	686,489	6.00	7.00
Exercised	(283,616)	1.87	
Balance at December 31, 2021	1,311,117	$ 4.03	7.30

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, 2021 and 2020:

	2021	2020
Risk-free interest rate	0.6% - 1.3%	0.41% - 1.69%
Expected term (in years)	5 - 7	5 - 7
Expected volatility	81% - 106%	75.8% - 80.5%
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, under which 3,900,000 shares of common stock are reserved for stock option issuance, for the purposes of attracting, retaining, and motivating key employees, directors, and consultants of MAIA.

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 reserves 1,671,000 common shares for issuance, also for the purposes of attracting, retaining, and motivating key employees, directors, and consultants of MAIA. In November 2020, the MAIA 2020 Plan was amended to reserve a total of 3,171,000 shares of common stock. The MAIA 2020 Plan permits awards to take the form of stock options, restricted stock and restricted stock units. In April and July of 2021 there were amendments to the 2020 Plan to bring the plan to a total of 4,171,000 shares reserved for issuance. As of December 31, 2021, there was a remaining 331,815 shares available for issuance.

On November 5, 2021, the Company adopted the 2021 Equity Incentive Plan (the “2021 Plan”). The 2021 Plan was adopted to enhance the Company's ability to attract, retain and motivate employees, officers, directors, consultants and advisors by providing such persons with equity ownership opportunities and performance-based incentives. The 2021 Plan is a comprehensive incentive compensation plan under which the Company can grant equity-based and other incentive awards to officers, employees, directors, consultants and advisers. The purpose of the 2021 Plan is to help the Company attract, retain, and motivate such persons with awards under the 2021 Plan and thereby enhance shareholder value. Per the terms of the 2021 Plan, it is not effective until the occurrence of an IPO.

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 10 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 7 years. Outstanding options awarded under the MAIA 2020 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 such 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 cancelled ninety days after termination of an employee,

director, founder, or consultant. Unexercised options are cancelled 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, 2021, 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 as of December 31, 2021:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance at January 1, 2020	1,627,000	$ 1.80	9.30	—
Granted	2,287,466	1.80	10.00	
Cancelled/forfeited	(249,500)	1.80		—
Balance at December 31, 2020	3,664,966	$ 1.80	9.13	—
Granted	2,210,787	2.92	9.38	
Exercised	(5,000)	1.80		—
Cancelled/forfeited	(73,568)	1.82		—
Balance at December 31, 2021	5,797,185	$ 2.22	8.59	38,784,352
Options exercisable at December 31, 2021	5,012,181	$ 1.91	8.52	34,865,649

During the period of March 2021 through May 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 2021 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. Between June 2021 and October 2021, the fair value of the Company’s common stock, was determined based on sales of the Company’s shares at arm’s length to unrelated third parties at $8.00 per share.

During November 2021 and December 2021, the fair value of the Company’s common stock was determined to be $8.69 and $8.87, respectively. 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 value 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.

To determine the fair value of our common stock, we first determined our enterprise value using accepted valuation approaches; adjusted these valuation approaches with relevant discounts; weighted the results appropriately; and then allocated the equity value to our common stock and common stock equivalents. Our enterprise value was estimated using two generally accepted approaches: the income approach and the market approach. 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.

Following the initial public offering, it will not be necessary to determine the fair value of our common stock, as our shares will be traded in the public market.

The value of option grants are calculated using the Black-Scholes-Merton option pricing model with the following assumptions for options granted during the year ended December 31,:

	2021	2020
Risk-free interest rate	0.36% - 1.27%	0.35% - 1.39%
Expected term (in years)	5 - 6.50	5 - 5.5
Expected volatility	71.40% - 81.5%	76.5% - 80.7%
Expected dividend yield	—%	—%

The weighted-average grant date fair values of stock options issued during the years ended December 31, 2021 and 2020 were $3.55 and $1.11, respectively. At December 31, 2021, the total unrecognized compensation related to unvested employee and non-employee stock option awards granted was $3,116,815, which the Company expects to recognize over a weighted average period of approximately 2.71 years.

DGD Pharmaceuticals Corporation 2019 Stock Option Plan

As of December 31, 2020, there were options for the purchase of 805,000 shares of common stock outstanding. There were no stock options granted under the DGD plan during the year ended December 31, 2021. All options were cancelled upon the dissolution of DGD on August 13, 2021 (see Note 1). During the years ended December 31, 2021 and 2020, compensation expense associated with previously-issued options was recognized in general and administrative expenses in the amount of $5,208 and $19,802, respectively.

THIO Therapeutics, Inc. Amended and Restated 2020 Equity Incentive Plan

THIO's board of directors administered the THIO Therapeutics, Inc. Amended and Restated Equity Incentive Plan (the "THIO Plan"), under which 1,000,000 shares of THIO's common stock were reserved for issuance, as authorized by the board of directors in June 2020. The terms of the THIO Plan provided for the grant of options, restricted stock, and restricted stock units to employees, directors, and consultants of THIO.

As of August 13, 2021, the THIO Plan was terminated upon dissolution of THIO.

Stock based compensation related to the Company’s stock plans are as follows:

	For the Year Ended December 31,	
	2021	2020
General and administrative	$ 1,512,726	$ 3,033,248
Research and development	943,708	337,792
Total stock-based compensation	$ 2,456,434	$ 3,371,040

Other Equity Activity of DGD and THIO

DGD Pharmaceuticals Corporation

DGD was authorized to issue 10,000,000 shares (4,000,000 Class A and 6,000,000 Class B) of stock with a par value of $0.0001 per share. Holders of Class A common shares were entitled to one vote per share, whereas holders of Class B were entitled to two votes per share. As of December 31, 2020, 2,575,000 and 6,000,000 shares of Class A and Class B stock, respectively, were issued and outstanding. As of December 31, 2020, MAIA owned 690,000 and 6,000,000 Class A and Class B common shares, respectively. Class A common shareholders were entitled to one vote per share, whereas Class B common shareholders were entitled to two votes per share.

All shares of DGD common stock cease to exist as of August 13, 2021, when the entity was legally dissolved.

Restricted Common Stock Awards to Founders of DGD — In May 2019, DGD awarded 1,550,000 restricted Class A common shares to four founders. The fair value of these shares was determined to be $1.00 based on sales of common stock to third parties, for a total fair value of $1,550,000. Vested shares participated in any dividends and other distributions with other common stockholders, while the unvested shares, which were subject to forfeiture in the event the holder separated from service with DGD, do not participate in such events. The share award was subject to service conditions, with 50% of the

granted shares vesting at the date of grant, and the remaining 775,000 common shares vesting in 36 equal monthly installments over a three-year period, with the first such monthly installment vesting on June 1, 2019.

The related compensation expense is recognized ratably over the service period. For the year ended December 31, 2021 and 2020, the Company recognized $161,460 and $206,947, respectively, in compensation expense related to these awards which was presented in general and administrative expenses.

In addition, in December 2019, DGD issued 62,500 shares of Class A common stock to a stockholder which vested during 2020 as certain services were provided (Note 2). During 2020, the Company recorded $75,000 to research and development expenses in connection with this agreement.

On August 13, 2021, all remaining unvested restricted shares were cancelled upon the dissolution of DGD (see Note 1).

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at January 1, 2020	686,804	$ 1.00
Granted	12,500	1.00
Vested	(320,836)	
Unvested balance at December 31, 2020	378,468	$ 1.00
Cancelled	(378,468)	
Unvested balance at August 13, 2021	—	$ —

Other Issuances of Common Stock

In January 2020, DGD issued 322,000 shares of Class B common stock to MAIA for $321,968.

In January 2020, DGD issued 50,000 shares of Class A common stock to investors for $50,000.

In February 2020, DGD issued 690,000 shares of Class A common stock and 10,000 shares of Class B common stock to MAIA for $699,999.

THIO Therapeutics Inc.

THIO was authorized to issue 11,000,000 shares of common stock with a par value of $0.00001 per share. All shares of THIO common stock cease to exist as of August 13, 2021, when the entity was legally dissolved.

Restricted Common Stock Award to Founder — In April 2019, THIO awarded 700,000 restricted common shares to a founder. Any vested shares participated in dividends and other distributions with other common stockholders, while the unvested shares, which were subject to forfeiture in the event the founder separates from service with THIO, did not participate in such events. The share award was subject to service conditions, with 350,000 shares vesting at the date of grant, and the remaining 350,000 common shares vesting in twelve equal quarterly installments over a three-year period, with the first such quarterly installment vesting on July 1, 2019.

	Shares	Weighted Average Grant Date Fair Value
Balance at January 1, 2020	291,667	$ 1.80
Vested	(116,667)	
Balance at December 31, 2020	175,000	$ 1.80
Vested	(87,500)	
Cancelled	(87,500)	
Balance at August 13, 2021	—	$ —

The related compensation expense was recognized over the service period. For the years ended December 31, 2021 and 2020, THIO recognized $105,000 and $210,000, respectively, in compensation expense related to this award which was presented in general and administrative expenses.

On August 13, 2021, upon the dissolution of THIO and merger into MAIA, a founder's 612,500 fully vested THIO restricted shares were cancelled 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 vest ratably each quarter through June 30, 2022 to replace the equivalent number of unvested THIO restricted shares which were cancelled.

Other Issuances of Common Stock

During 2020, THIO issued an additional 200,000 shares of common stock to MAIA for a price of $320,000.

9. 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, 2021, 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, 2020, 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.

GMCI — In November 2018, MAIA entered into a Global PLA and Sponsored Research Agreement ("SRA") for Collaborative Research and Jointly Owned Intellectual Property for the GMC1 Family of Compounds for the Treatment of Prostate Cancer with the University of Texas El Paso ("UTEP"). The SRA requires MAIA to reimburse UTEP for research program expenditures up to $46,000. The SRA for background Intellectual Property term is the last date of expiration or termination of the patent rights (2035). As amended, the SRA extended the research program to May 2020 since which point it has continued on an at-will basis.

MJC13 — In January 2019, MAIA entered into a Global PLA and SRA for Collaborative Research and Jointly Owned Intellectual Property for the MJC13 Family of Compounds for the Treatment of Prostate Cancer with UTEP. The SRA requires MAIA to reimburse UTEP for research program expenditures up to $46,000. As amended, the SRA extended the research program to June 2020, since which point it has continued on an at-will basis.

10. INCOME TAXES

The Company's net deferred tax assets consist of the following components:

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 3,013,721	$ 1,418,873
Stock-based compensation	1,800,935	1,132,473
Deferred compensation	31,718	156,717
Accrued bonus	109,673	222,339
Other	71,107	—
Total net deferred tax assets before valuation allowance	5,027,154	2,930,402
Valuation allowance	(5,027,154)	(2,930,402)
Net deferred tax asset	$ —	$ —

At December 31, 2021, the Company has unused U.S. federal and state net operating loss ("NOL") carryforwards of $10.6 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 U.S. federal NOL carryforwards arising after January 1, 2021, are limited to 80 percent of taxable income.

The use of the Company's NOL 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, the Company recorded a valuation allowance to fully offset the gross deferred tax asset, because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets at December 31, 2021 and 2020. The valuation allowance increased by approximately $2.1 million and $1.7 million during the years ended December 31, 2021 and 2020, 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.

No provision or benefit for U.S. federal or state income taxes has been recorded for the years ended December 31, 2021 and 2020, as the Company has incurred a net loss for all of the periods presented, and the Company has provided a full valuation allowance against its deferred tax assets.

The income tax expense (benefit) differs from the expense (benefit) that would result from applying federal statutory rates to loss before income taxes as follows:

	December 31,	
	2021	2020
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal tax benefit	4.4%	6.5%
Stock-based compensation	(1.9)%	(2.6)%
Loss on extinguishment of debt	(3.9)%	— %
Other nondeductible expenses/(nontaxable income)	(2.8)%	0.2%
Change in valuation allowance	(16.8)%	(25.1)%
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, 2021 and 2020. The Company files income tax returns in the U.S. federal jurisdiction and several U.S. States, and Australia. The Company's tax returns since inception remain open to examination by the taxing authorities.

11. SUBSEQUENT EVENTS

Exercise of MAIA Warrants

During January 2022, 61,111 warrants were exercised, resulting in a total of 61,111 shares of MAIA common stock issued for proceeds of approximately $110,000.

Extension of MAIA Warrant Exercise Periods

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 will remove the IPO expiration provision from the warrant agreements, and the warrants shall only be exercisable, in whole or in part, during the exercise period ending on 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.

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 before transaction costs and expenses.

MAIA Option Exercises

In February 2022, two employees exercised a total of 26,500 stock options, resulting in proceeds of $47,700.

MAIA Option Grants

During March 2022, the Company issued 102,792 stock options to employees and consultants, with a weighted average exercise price of $9.00 per share.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 10,293,460	$ 10,574,292
Prepaid expenses and other current assets	234,628	98,203
Total current assets	10,528,088	10,672,495
Deferred offering costs	913,675	651,582
Other assets	2,800	3,122
Total assets	$ 11,444,563	$ 11,327,199
LLABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 895,108	$ 960,401
Accrued expenses	1,421,452	1,074,324
Deferred compensation	114,333	111,271
Total current liabilities	2,430,893	2,145,996
Total liabilities	2,430,893	2,145,996
Commitments and contingencies		
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value, 70,000,000 shares authorized, 0 shares issued and outstanding	—	—
Common stock, $0.0001 par value, 30,000,000 shares authorized, 7,936,320 and 7,584,980 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	794	758
Additional paid-in capital	40,862,993	37,618,438
Accumulated deficit	(31,851,838)	(28,437,993)
Accumulated other comprehensive income	1,721	—
Total stockholders' equity	9,013,670	9,181,203
Total liabilities and stockholders' equity	$ 11,444,563	$ 11,327,199

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development expenses	$ 2,077,329	$ 262,758
General and administrative expenses	1,366,229	787,955
Total operating costs and expenses	3,443,558	1,050,713
Loss from operations	(3,443,558)	(1,050,713)
Other income (expense):		
Interest expense	—	(62,767)
Interest income	472	141
Australian research and development incentives	29,241	—
Change in fair value of embedded features	—	(15,000)
Change in fair value of warrant liability	—	106,820
Other income (expense), net	29,713	29,194
Net loss	(3,413,845)	(1,021,519)
Net loss attributable to noncontrolling interests	—	(37,525)
Deemed divided on warrant modification	(450,578)	—
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (3,864,423)	$ (983,994)
Net loss per share		
Basic and diluted	$ (0.50)	$ (0.23)
Weighted average common shares outstanding		
Basic and diluted	7,752,042	4,329,088

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Net loss attributable MAIA Biotechnology, Inc. shareholders	(3,864,423)	(983,994)
Foreign currency translation adjustment	1,720	—
Comprehensive loss to MAIA Biotechnolgy, Inc.	$ 3,866,143	$ 983,994

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited)
For the Three Months ended March 31, 2022

	Common Stock							
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated other comprehensive income	Total MAIA Equity (Deficit)	Noncontrolling Interest	Total Stockholders' (Deficit) Equity
Balance at December 31, 2021	7,584,980	$ 758	$ 37,618,438	$ (28,437,993)	—	$ 9,181,203	—	$ 9,181,203
Issuance of common shares upon exercise of stock options	26,500	3	47,697	—	—	47,700	—	47,700
Issuance of common shares upon exercise of warrants	61,111	6	109,994	—	—	110,000	—	110,000
Issuance of common shares in connection with Equity Financing	263,729	27	2,373,534	—	—	2,373,561	—	2,373,561
Stock-based compensation expense	—	—	713,330	—	—	713,330	—	713,330
Modification of warrant in equity	—	—	450,478	—	—	—	—	—
Deemed dividend on modification of warrant	—	—	(450,478)	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	1,721	1,721	—	1,721
Net loss	—	—	—	(3,413,845)	—	(3,413,845)	—	(3,413,845)
Balance at March 31, 2022	7,936,320	794	$ 40,862,993	$ (31,851,838)	$ 1,721	$ 9,013,670	$ —	$ 9,013,670

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) (Unaudited)
For the Three Months ended March 31, 2021

	Common Stock							
	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 restricted common shares	15,278	2	27,498	—	—	27,500	—	27,500
Cancellation of restricted common shares	(5,557)	(1)	—	—	—	(1)	—	(1)
Issuance of common shares upon exercise of stock options	3,000	—	5,400	—	—	5,400	—	5,400
Receipt of stock subscription receivable	—	—	—	—	2,002	2,002	—	2,002
Stock-based compensation expense-MAIA	—	—	408,608	—	—	408,608	—	408,608
Stock-based compensation expense-DGD	—	—	—	—	—	—	64,584	64,584
Stock-based compensation expense-THIO	—	—	—	—	—	—	52,500	52,500
Net loss	—	—	—	(983,994)	—	983,994	(37,525)	(1,021,519)
Balance at March 31, 2021	4,446,365	444	$ 13,041,091	$ 16,918,107	—	$ 3,876,572	$ 1,799,346	$ (2,077,226)

See the accompanying notes to the unaudited condensed consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities:		
Net loss, including noncontrolling interests	$ (3,413,845)	$ (1,021,519)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	713,330	553,192
Change in fair value of embedded features	—	15,000
Change in fair value of warrant liability	—	(106,820)
Amortization of debt discount	—	45,265
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(134,341)	44,307
Other assets	322	(68,560)
Accounts payable	(67,120)	119,780
Accrued expenses	352,874	48,073
Due to related parties	—	(7,037)
Deferred compensation	3,062	125,004
Net cash used in operating activities	(2,545,718)	(253,315)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, warrants, and embedded conversion features	—	2,360,000
Deferred offering costs	(262,093)	—
Proceeds from Paycheck Protection Program loan	—	62,500
Collections of subscriptions receivable	0	2,002
Proceeds from issuance of common stock, net of transaction costs	2,373,561	—
Proceeds from exercise of stock options	47,700	5,400
Proceeds from exercise of warrants	110,000	—
Payment on loan payable to officer	—	(367)
Net cash provided by financing activities	2,269,168	2,429,535
Cash flows from financing activities foreign currency exchange rates:		
Effect of foreign currency exchange on cash	(4,282)	—
Net effect of foreign currency exchange on cash	(4,282)	—
Net increase (decrease) in cash	(280,832)	2,176,220
Cash at beginning of period	10,574,292	663,457
Cash at end of period	$ 10,293,460	$ 2,839,677
Supplemental disclosure of cash flow information:		
Issuance of convertible note for payment on loan to officer	$ —	$ 21,000

See the accompanying notes to the unaudited condensed 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 cancelled 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.

Liquidity

At March 31, 2022, the Company had working capital of $8,097,195, accumulated deficit of $32,302,416, cash of $10,293,460 and current liabilities of $2,430,893. 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, until 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.

The Company will require significant funding to perform the necessary clinical trials, and to meet the Company’s long-term development and commercialization goals. The Company believes that its cash as of March 31, 2022, subsequent cash proceeds from the exercise of warrants and planned capital raises will be sufficient to support operations through the next twelve months from the date the consolidated financial statements are issued, including funding of the THIO-101 lead-in and preliminary efficacy of the phase 2 THIO-101. The Company plans to meet its capital requirements primarily through issuances of equity securities. The Company cannot make any assurances that additional financings will be available, on acceptable terms or at all. If the Company is unable to raise the necessary funding, management will undertake cost cutting measures, as done in the past, to reduce compensation and reduce the scope of or delay its clinical programs. This could negatively impact the Company’s business and could also lead to the reduction of the Company’s operations.

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 has imposed one of the strictest COVID-19-related measures, including lock-downs. 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.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") as determined by Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results of operations for the periods presented. They may not include all of the information and footnotes required by GAAP for complete financial statements. Therefore, these financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2021. The results of operations for any interim periods are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

The unaudited interim condensed 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 unaudited interim condensed consolidated financial statements have been included.

Use of Estimates

The preparation of the Company's unaudited interim condensed financial statements in conformity with 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, warrants, the embedded features in convertible notes and the valuation allowance of deferred tax assets resulting from net operating losses. 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 subsidiary, 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 March 31, 2022 and December 31, 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 March 31, 2022 and December 31, 2021, cash includes cash in a depository bank account; the Company has no cash equivalents as of March 31, 2022 and December 31, 2021.

Fair Value Measurements

ASC 820, *Fair Value Measurements*, provides guidance on the development and disclosure of fair value measurements. 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 period ended March 31, 2022, and as of and during the period ended December 31, 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 periods ended March 31, 2022 and 2021. The carrying value of notes payable and convertible notes payable approximated the estimated fair values due to their recent issuances. The estimated fair value of the warrants issued with the convertible notes 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.

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 condensed consolidated statements of operations.

Under the program, a percentage of eligible research and development expenses incurred by the Company through its subsidiary in Australia are reimbursed.

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 options 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 initial public 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 initial public 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.

There were no issuances of common stock as it relates to DGD or THIO during the three months ended March 31, 2021. The fair value of restricted stock awards is based on the common stock price.

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. In accordance with ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, the measurement of equity-classified nonemployee 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 are included in other assets and consists of legal, accounting, underwriting fees and other costs incurred through the balance sheet date that are directly related to the planned initial public offering and that will be charged to additional paid-in capital upon the completion of the planned initial public offering. Should the planned initial public offering prove to be unsuccessful, these deferred costs, as well as additional expenses to be incurred, will be charged to operations.

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, longterm lease liabilities. The Company has elected not to recognize on the condensed consolidated balance sheet leases with terms of one-year or less when 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).

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:

	Three Months Ended March 31,	
	2022	**2021**
Shares issuable upon exercise of stock options	5,859,589	3,809,297
Shares issuable upon exercise of warrants	1,250,006	1,167,375
Unvested restricted stock awards	29,168	162,500

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.

In June 2016, the FASB issued ASU No. 2016-13, Measurement of Credit Losses on Financial Instruments (ASU 2016-13), which requires a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. The new standard is effective for the Company for fiscal years beginning after December 15, 2022. The Company is currently evaluating the impact of the pending adoption of the new standard on its financial statements and intends to adopt the standard as of January 1, 2023.

2. RELATED PARTY TRANSACTIONS

Consulting Services

A former member of the Company's board of directors prior to her stepping down in November 2021, provided legal consulting services to the Company during the three months ended March 31, 2021 for which the Company incurred $19,781 stock-based compensation which consist of options to purchase 17,431 shares of common stock. The Company did not incur any fees for consulting services provided by this person during the three months ended March 31, 2022.

The wife of the CEO, who was also a former member of the Company's board of directors prior to her stepping down in November 2021 provided consulting services to the Company during the three months ended March 31, 2022 for which the Company incurred $22,208 in stock based compensation.

The brother of the CEO, provides consulting services to the Company for which the Company incurred $15,900 in consulting services during the three months ended March 31, 2022. During the three months ended March 31, 2022, the Company paid for their services $7,950 in cash, and issued options to purchase 894 shares of common stock with a total fair value of $4,950. In addition the Company issued 226 options with a total fair value of $1,250 for December 2021 services during the three months ended March 31, 2022. The remaining $3,000 for services provided in the three months ended March 31, 2022 will be settled in options that have not yet been issued.

Deferred Compensation Agreements

As of March 31, 2022 and December 31, 2021, the Company had $114,333 and $111,271 of deferred compensation due to certain former 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 deferred a portion of their annual base salary to be paid upon a Qualified Fund Raising. A Qualifying Fund Raising shall be defined as an inflow of funds into the Company from any source, that in aggregate over time totals $12,000,000 beginning from the date of the incorporation of the Company. Once the Company achieves a Qualified Fund Raising the employees' salary will be increased up to the market rate set forth in the deferred compensation agreements, and all amounts pursuant to the agreements will be paid to the employees.

3. ACCRUED EXPENSES

As of March 31, 2022 and December 21, 2021, accrued expenses consisted of the following:

	March 31, 2022	December 31, 2021
Bonus	$ 561,873	384,750
Professional fees	377,473	380,277
Research and development costs	452,592	268,140
Other	29,514	41,157
Total accrued expenses	$ 1,421,452	$ 1,074,324

4. STOCKHOLDERS' EQUITY

Upon incorporation, MAIA was authorized to issue 10,000,000 shares of common stock, with a par value of $0.0001 per share. In March 2020, the shareholders approved an amended and restated certificate of incorporation which authorizes MAIA to issue 100,000,000 shares of stock, as follows: 70,000,000 shares of preferred stock and 30,000,000 shares of common stock, all with a par value of $0.0001 per share. The rights, privileges, preferences, and restrictions of the classes of stock have yet to be established. As of March 31, 2022, each of the common stockholders have equal voting rights, and except in the case of restricted common shares, equal rights of participation in dividends and other distributions with other common stockholders.

Among other provisions, MAIA's shareholders agreement gives first MAIA, followed by the non-selling shareholders, the option to purchase the outstanding shares of a shareholder prior to the sale of shares to a third party. Should the non-selling shareholders decline to purchase any portion of the selling shareholders shares, MAIA shall have a final opportunity to repurchase the shares. The agreement also contains provisions for "drag-along" and "tag-along" rights, as described in the agreement. MAIA's shareholders agreement, including the aforementioned provisions, will terminate upon the closing of MAIA's initial public offering.

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.

MAIA Biotechnology, Inc. Restricted Stock Awards

During the three months ended March 31, 2021, MAIA recognized $67,500 of stock compensation expense related to 37,500 options 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 cancelled 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 vest ratably each quarter through April 1, 2022 to replace the equivalent number of unvested THIO restricted shares. The remaining unvested shares as of March 31, 2022 are related to the founder's unvested restricted shares only.

During the three months ended March 31, 2022, MAIA recognized $52,500 of stock compensation expense related to the MAIA restricted shares granted to the founder. The issuance of restricted shares in MAIA as a replacement for the shares the founder held in THIO was accounted for as a modification. There was no additional incremental stock compensation recorded as related to the cancellation of the founder's THIO restricted shares and concurrent grant of MAIA restricted shares as the fair value of the original THIO award immediately before the grant of the MAIA restricted shares and the fair value of the replacement award were equal. There was no unrecognized stock

compensation expense for the 29,168 unvested restricted shares as of March 31, 2022 as the final shares vest on April 1, 2022.

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at January 1, 2022	58,333	$ 1.80
Vested	(29,165)	1.80
Unvested balance at March 31, 2022	29,168	$ 1.80

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 be exercisable, in whole or in part, during the exercise period ending on 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 the modified awards compared to the original awards immediately prior to the modification was calculated at $450,578 was treated as a deemed dividend for the three months ended 2022 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 approximately $110,000.

	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
Exercised	(61,111)	1.80	
Balance at March 31, 2022	1,250,006	$ 4.14	7.02

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, under which 3,900,000 shares of common stock are reserved for stock option issuance, for the purposes of attracting, retaining, and motivating key employees, directors, and consultants of MAIA. The 2018 plan was replaced by the Amended and Restated 2020 Equity Plan.

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 reserved 1,671,000 common shares for issuance, also for the purposes of attracting, retaining, and motivating key employees, directors, and consultants of MAIA. In November 2020, the MAIA 2020 Plan was amended to reserve a total of 3,171,000 shares of common stock. The MAIA 2020 Plan permits awards to take the form of stock options, restricted stock and restricted stock units. In April and July of 2021 there were amendments to the 2020 Plan to bring the plan to a total of 4,171,000 shares reserved for issuance. As of March 31, 2022 there are 242,911 shares available for future issuance under the 2020 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 10 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 7 years. Outstanding options awarded under the MAIA 2020 Plan may, but need not, vest and therefore become exercisable in periodic instalments that may, but need not, be equal. The option may be subject to such 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 cancelled ninety days after termination of an employee, director, founder, or consultant. Unexercised options are cancelled 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 March 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 for the three months ended March 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	102,792	9.00		
Exercised	(26,500)	1.83		
Cancelled/forfeited	(13,888)	1.80		
Balance at March 31, 2022	5,859,589	$ 2.35	8.37	39,134,325
Options exercisable at March 31, 2022	5,116,035	$ 2.02	8.28	35,690,410

During the three months ended March 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 value 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 March 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 February 28, 2022. Due to the lack of any single specific event that would have indicated a definitive change in the value of the Company, the fair value of the Company's common stock was determined based on sales of the Company's shares at arm's length to unrelated third parties at $9.00 per share through March 31, 2022.

During the three months ended March 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 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 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 2021 valuation 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.

The value of option grants is calculated using the Black-Scholes option pricing model with the following assumptions for options granted during the three months ended March 31:

	2022	2021
Risk-free interest rate	2.14%	0.36% - 0.92%
Expected term (in years)	5 - 6.25	5 - 5.17
Expected volatility	72.0% - 74.2%	74.8% - 75.9%
Expected dividend yield	—%	—%

The weighted-average grant date fair value of stock options issued during the three months ended March 31, 2022 and 2021 was $5.78 and $1.11, respectively. As of March 31, 2022, the total unrecognized compensation related to unvested employee and non-employee stock option awards granted was $3,152,581, which the Company expects to recognize over a weighted average period of approximately 3 years.

Stock based compensation related to the Company's stock plans are as follows:

	Three Months Ended March 31,	
	2022	2021
General and administrative	$ 440,551	$ 487,737
Research and development	272,779	65,455
Total stock-based compensation	$ 713,330	$ 553,192

5. 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 March 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 March 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.

MJC13 — In January 2019, MAIA entered into a Global PLA and SRA for Collaborative Research and Jointly Owned Intellectual Property for the MJC13 Family of Compounds for the Treatment of Prostate Cancer with UTEP. The SRA requires MAIA to reimburse UTEP for research program expenditures up to $46,000. As amended, the SRA extended the research program to June 2020, since which point it has continued on an at-will basis.

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 March 31, 2022 neither party has terminated the agreement.

6. INCOME TAXES

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of March 31, 2022, and December 31, 2021, the Company had a full valuation allowance against its deferred tax assets.

For the three months ended March 31, 2022 and 2021, the Company recorded zero income tax expense. No tax benefit has been recorded in relation to the pre-tax loss for the three months ended March 31, 2022 and 2021, due to a full valuation allowance to offset any deferred tax asset related to net operating loss carry forwards attributable to the losses.

7. SUBSEQUENT EVENTS

Issuance of Stock Options

During April 2022, the Company issued 23,778 options to employees and consultants to purchase MAIA common stock with an exercise price of $9.00 per share.

Exercise of MAIA Warrants

During April and May 2022, 153,000 warrants were exercised, resulting in a total of 153,000 shares of MAIA common stock issued for proceeds of approximately $275,400.

Romanian Subsidiary

In April 2022, the Company established a wholly owned Romanian subsidiary, MAIA BIOTECHNOLOGY ROMANIA S.R.L. to conduct various preclinical and clinical activities for the development of the Company's product candidates.

Shares of Common Stock

MAIA Biotechnology, Inc.

PRELIMINARY PROSPECTUS

ThinkEquity

,2022

Through and including , 2022 (the 25th day after the date of this offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II – INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13.Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee, the FINRA filing fee and the NYSE listing fee.

SEC registration fee	$	
FINRA filing fee	$	
Initial NYSE listing fee	$	*
Accounting fees and expenses	$	*
Legal fees and expenses	$	*
Transfer agent’s and registrar’s fees and expenses	$	*
Printing and engraving expenses	$	*
Non-accountable expenses to underwriters	$	*
Miscellaneous fees	$	*
Total	$	*

*To be filed by amendment.

Item 14.Indemnification of Directors and Officers.

Section 102 of the DGCL permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation provides that no director of the registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our amended and restated bylaws will authorize the indemnification of our officers and directors, consistent with Section 145 of the DGCL, as amended. Reference is made to Section 102(b)(7) of the DGCL, which enables a corporation in its original certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director for violations of the director's fiduciary duty, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL, which provides for liability of directors for unlawful payments of dividends of unlawful stock purchase or redemptions or (iv) for any transaction from which a director derived an improper personal benefit.

We intend to enter into indemnification agreements with each of our directors and officers that will be in effect upon the completion of this offering. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act, against certain liabilities.

Item 15.Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of capital stock issued by us within the past three years. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(a) Issuance of Common Stock

In March 2019 through June 2019, we issued and sold 246,668 shares of our common stock with an aggregate principal amount of $444,000.

In October and November 2019, we issued and sold 873,725 shares of our common stock with an aggregate principal amount of $1.573 million.

During July through October 2021, we issued and sold 772,563 shares of our common stock with an aggregate principal amount of approximately $6.2 million.

In September 2021, we issued 1,375,228 shares of our common stock as a result of the automatic conversion of the convertible notes referenced in Item 15(b) below.

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.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 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 recipients of securities in the transactions described above represented that they were accredited investors and were 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.

(b) Issuance of Convertible Notes & Warrants

In August 2019, we issued and sold a convertible promissory note with a principal amount of $10,000, which converted into 2,259 shares of our common stock on September 30, 2021.

In May 2020 through December 2020, we issued and sold convertible promissory notes with an aggregate principal amount of $610,000, which converted into 108,132 shares of our common stock on September 30, 2021, and warrants to purchase 54,066 shares of our common stock at $6.00 per share, for an aggregate purchase price of $324,396.

In February 2021 through June 2021, we issued and sold convertible promissory notes with an aggregate principal amount of $7.39 million, which converted into 1,264,837 shares of our common stock on September 30, 2021, and warrants to purchase 632,423 shares of our common stock at $6.00 per share, for an aggregate purchase price of $3,794,508.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (b) of Item 15 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 recipients of securities in the transactions described above represented that they were accredited investors and were 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.

(c) Stock Option Grants, Option Exercises, Warrant Grants and Warrant Exercises

Between January 1, 2019 and December 31, 2021, we have granted to our employees, officers, directors and other persons who provide services to us options to purchase up to 5,336,753 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 $2.26 per share. 5,000 of these options were exercised at a weighted average exercise price of $1.80. 1,749,568 of these options were terminated, expired without being exercised or were otherwise forfeited. In addition, we granted to certain of our directors and other persons who provided services to us warrants to purchase up to 1,594,733 shares of our common stock at $3.65 per share, which expire at various dates through September 2030 and vested upon issuance. 283,616 of these warrants were exercised at a weighted average exercise price of $1.87.

No underwriters were involved in the foregoing issuances of securities. The issuances of stock options described in this paragraph (c) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors, consultants and advisors, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to 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. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

Item 16.Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description of Document
1.1	Form of Underwriting Agreement (including the form of Lock-Up Agreement).
3.1*	Amended and Restated Certificate of Incorporation of MAIA Biotechnology, Inc.
3.2*	Amended and Restated Certificate of Incorporation of MAIA Biotechnology, Inc. to be in effect upon completion of the offering.
3.3*	Amended and Restated Bylaws of MAIA Biotechnology, Inc.
3.4*	Amended and Restated Bylaws of MAIA Biotechnology, Inc. to be in effect upon completion of the offering.
4.1*	Specimen Certificate representing shares of Common Stock.
4.2*	Form of Warrant.
4.3	Form of Representative's Warrant (included in Exhibit 1.1).
5.1*	Opinion of Loeb & Loeb LLP.
10.1†	Supply and Non-Exclusive License Agreement between the Company and Regeneron Pharmaceuticals, Inc. dated February 1, 2021.
10.2†	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.
10.3†	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.
10.4+*	Employment Agreement between Vlad Vitoc and the Company signed August 2, 2022.
10.5+*	Employment Agreement between Joseph F. McGuire and the Company signed August 10, 2022.
10.6+*	Employment Agreement between Mihail Obrocea and the Company signed August 2, 2022.
10.7+*	Form of Indemnification Agreement between the Company and each of its directors and executive officers.
10.8+*	MAIA Biotechnology, Inc. 2018 Stock Option Plan.
10.9+*	MAIA Biotechnology, Inc. Amended & Restated 2020 Equity Incentive Plan.
10.10+*	MAIA Biotechnology, Inc. 2021 Equity Incentive Plan.
14.1*	Code of Business Conduct and Ethics of MAIA Biotechnology, Inc.
21.1*	List of Subsidiaries of the Registrant.
23.1*	Consent of Loeb & Loeb LLP (included in Exhibit 5.1).
23.2*	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.
24.1*	Powers of Attorney (included on signature page to this registration statement).
107*	Calculation of Filing Fee Tables.

* Previously filed.

+ 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.

(b) Financial Statement Schedules.

See index to financial statements on page F-1. All schedules have been omitted because they are not required or are not applicable.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Chicago, State of Illinois, on May 31, 2022.

MAIA BIOTECHNOLOGY, INC.

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

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Name	Title	Date
/s/ Vlad Vitoc Vlad Vitoc	Chairman and Chief Executive Officer (Principal Executive Officer)	May 31, 2022
/s/ Joseph F. McGuire Joseph F. McGuire	Chief Financial Officer (Principal Financial Officer)	May 31, 2022
* Steven Chaouki	Director	May 31, 2022
* Ramiro Guerrero	Director	May 31, 2022
* Louie Ngar Yee	Director	May 31, 2022
* Cristian Luput	Director	May 31, 2022
* Stan V. Smith	Director	May 31, 2022
* Laurentiu Vlad	Director	May 31, 2022

*By: /s/ Vlad Vitoc
Vlad Vitoc
Attorney-in-Fact

Exhibit 1.1

UNDERWRITING AGREEMENT

between

MAIA BIOTECHNOLOGY, INC.

and

THINKEQUITY LLC

as Representative of the Several Underwriters

MAIA BIOTECHNOLOGY, INC.

UNDERWRITING AGREEMENT

New York, New York
[•], 2022

Think Equity LLC
As Representative of the several Underwriters named on Schedule 1 attached hereto
17 State Street, 22nd Fl
New York, NY 10004

Ladies and Gentlemen:

The undersigned, MAIA Biotechnology, Inc., a corporation formed under the laws of the State of Delaware (the "**Company**"), hereby confirms its agreement (this "**Agreement**") with ThinkEquity LLC (hereinafter referred to as "you" (including its correlatives) or the "**Representative**") and with the other underwriters named on Schedule 1 hereto for which the Representative is acting as representative (the Representative and such other underwriters being collectively called the "**Underwriters**" or, individually, an "**Underwriter**"). To the extent there are no additional underwriters named in Schedule I hereto other than you, the term Representative as used herein shall mean you, as Underwriter, and the terms "Representative" and "Underwriter" shall mean either the singular or the plural as the context requires.

1. Purchase and Sale of Shares.

1.1 *Firm Shares*.

1.1.1. Nature and Purchase of Firm Shares.

(i) On the basis of the representations and warranties herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell to the several Underwriters, an aggregate of **[•]** shares ("**Firm Shares**") of the Company's Class A common stock, par value $0.0001 per share (the "**Common Stock**").

(ii) The Underwriters, severally and not jointly, agree to purchase from the Company the number of Firm Shares set forth opposite their respective names on Schedule 1 attached hereto and made a part hereof at a purchase price of $**[•]** per share (**[•]**% of the per Firm Share offering price). The Firm Shares are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (as defined in Section 2.1.1 hereof).

1.1.2. Shares Payment and Delivery.

(i) Delivery and payment for the Firm Shares shall be made at 10:00 a.m., Eastern time, on the second (2nd) Business Day following the effective date (the "**Effective Date**") of the Registration Statement (as defined in Section 2.1.1 below) (or the third (3rd) Business Day following the Effective Date if the Registration Statement is declared effective after 4:01 p.m., Eastern time) or at such earlier time as shall be agreed upon by the Representative and the Company, at the offices of Venable LLP ("**Representative Counsel**"), or at such other place (or remotely by facsimile or other electronic transmission) as shall be agreed upon by the Representative and the Company. The hour and date of delivery and payment for the Firm Shares is called the "**Closing Date**."

(ii) Payment for the Firm Shares shall be made on the Closing Date by wire transfer in Federal (same day) funds, payable to the order of the Company upon delivery of the certificates (in form and substance satisfactory to the Underwriters) representing the Firm Shares (or through the facilities of the Depository Trust Company ("**DTC**")) for the account of the Underwriters. The Firm Shares shall be registered in such name or names and in such authorized denominations as the Representative may request in writing at least two (2) full Business Days prior to the Closing Date. The Company shall not be obligated to sell or deliver the Firm Shares except upon tender of payment by the Representative for all of the Firm Shares. The term "**Business Day**" means any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions are authorized or obligated by law to close in New York, New York.

1.2 *Over-allotment Option*.

1.2.1. Option Shares. For the purposes of covering any over-allotments in connection with the distribution and sale of the Firm Shares, the Company hereby grants to the Underwriters an option to purchase up to **[•]** additional shares of Common Stock, representing fifteen percent (15%) of the Firm Shares sold in the offering, from the Company (the "**Over-allotment Option**"). Such **[•]** additional shares of Common Stock, the net proceeds of which will be deposited with the Company's account, are hereinafter referred to as the "**Option Shares**." The purchase price to be paid per Option Share shall be equal to the price per Firm Share set forth in Section 1.1.1 hereof. The Firm Shares and the Option Shares are hereinafter referred to together as the "**Public Securities**." The offering and sale of the Public Securities is hereinafter referred to as the "**Offering**."

1.2.2. Exercise of Option. The Over-allotment Option granted pursuant to Section 1.2.1 hereof may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Shares within 45 days after the Effective Date. The Underwriters shall not be under any obligation to purchase any Option Shares prior to the exercise of the Over-allotment Option. The Over-allotment Option granted hereby may be exercised by the giving of oral notice to the Company from the Representative, which must be confirmed in writing by overnight mail or facsimile or other electronic transmission setting forth the number of Option Shares to be purchased and the date and time for delivery of and payment for the Option Shares (the "**Option Closing Date**"), which shall not be later than one (1) full Business Days after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of Representative Counsel or at such other place (including remotely by facsimile or other electronic transmission) as shall be agreed upon by the Company and the Representative. If such delivery and payment for the Option Shares does not occur on the Closing Date, the Option Closing Date will be as set forth in the notice. Upon exercise of the Over-allotment Option with respect to all or any portion of the Option Shares, subject to the terms and conditions set forth herein, (i) the Company shall become obligated to sell to the Underwriters the number of Option Shares specified in such notice and (ii) each of the Underwriters, acting severally and not jointly, shall purchase that portion of the total number of Option Shares then being purchased as set forth in Schedule 1 opposite the name of such Underwriter.

1.2.3. Payment and Delivery. Payment for the Option Shares shall be made on the Option Closing Date by wire transfer in Federal (same day) funds, payable to the order of the Company upon delivery to you of certificates (in form and substance satisfactory to the Underwriters) representing the Option Shares (or through the facilities of DTC) for the account of the Underwriters. The Option Shares shall be registered in such name or names and in such authorized denominations as the Representative may request in writing at least one (1) full Business Day prior to the Option Closing Date. The Company shall not be obligated to sell or deliver the Option Shares except upon tender of payment by the Representative for applicable Option Shares. The Option Closing Date may be simultaneous with, but not earlier than, the Closing Date, and in the event that such time and date are simultaneous with the Closing Date, the term "Closing Date" share refer to the time and date of delivery of the Firm Shares and the Option Shares.

1.3 *Representative's Warrants*.

1.3.1. Purchase Warrants. The Company hereby agrees to issue and sell to the Representative (and/or its designees) on the Closing Date (and the Option Closing Date, if applicable), an option ("**Representative's Warrant**") for the purchase of an aggregate number of shares of Common Stock representing 5% of the Public Securities, for an aggregate purchase price of $100.00. The Representative's Warrant Agreement, in the form attached hereto as Exhibit A (the "**Representative's Warrant Agreement**"), shall be exercisable, in whole or in part, commencing on a date which is six months after the Effective Date and expiring on the five-year anniversary of the Effective Date at an initial exercise price per share of Common Stock of $**[•]**, which is equal to 125% of the initial public offering price of the Firm Shares. The Representative's Warrant Agreement and the shares of Common Stock issuable upon exercise thereof are hereinafter referred to together as the "**Representative's Securities**." The Representative understands and agrees that there are significant restrictions pursuant to FINRA Rule 5110 against transferring the Representative's Warrant Agreement and the underlying shares of Common Stock during the one hundred eighty (180) days after the Effective Date and by its acceptance thereof shall agree that it will not sell, transfer, assign, pledge or hypothecate the Representative's Warrant Agreement, or any portion thereof, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of such securities for a period of one hundred eighty (180) days following the Effective Date to anyone other than (i) an Underwriter or a selected dealer in connection with the Offering, or (ii) a bona fide officer or partner of the Representative or of any such Underwriter or selected dealer; and only if any such transferee agrees to the foregoing lock-up restrictions.

1.3.2. Delivery. Delivery of the Representative's Warrant Agreement shall be made on the Closing Date and shall be issued in the name or names and in such authorized denominations as the Representative may request.

2. Representations and Warranties of the Company. The Company represents and warrants to the Underwriters as of the Applicable Time (as defined below), as of the Closing Date and as of the Option Closing Date, if any, as follows:

2.1 *Filing of Registration Statement*.

2.1.1. Pursuant to the Securities Act. The Company has filed with the U.S. Securities and Exchange Commission (the "**Commission**") a registration statement, and an amendment or amendments thereto, on Form S-1 (File No. 333-**[•]**), including any related prospectus or prospectuses, for the registration of the Public Securities and the Representative's Securities under the Securities Act of 1933, as amended (the "**Securities Act**"), which registration statement and amendment or amendments have been prepared by the Company in all material respects in conformity with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act (the "**Securities Act Regulations**") and will contain all material statements that are required to be stated therein in accordance with the Securities Act

and the Securities Act Regulations. Except as the context may otherwise require, such registration statement, as amended, on file with the Commission at the time the registration statement became effective (including the Preliminary Prospectus included in the registration statement, financial statements, schedules, exhibits and all other documents filed as a part thereof or incorporated therein and all information deemed to be a part thereof as of the Effective Date pursuant to paragraph (b) of Rule 430A of the Securities Act Regulations (the "**Rule 430A Information**")), is referred to herein as the "**Registration Statement**." If the Company files any registration statement pursuant to Rule 462(b) of the Securities Act Regulations, then after such filing, the term "Registration Statement" shall include such registration statement filed pursuant to Rule 462(b). The Registration Statement has been declared effective by the Commission on the date hereof.

Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information that was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a "**Preliminary Prospectus**." The Preliminary Prospectus, subject to completion, dated **[•]**, 2022, that was included in the Registration Statement immediately prior to the Applicable Time is hereinafter called the "**Pricing Prospectus**." The final prospectus in the form first furnished to the Underwriters for use in the Offering is hereinafter called the "**Prospectus**." Any reference to the "most recent Preliminary Prospectus" shall be deemed to refer to the latest Preliminary Prospectus included in the Registration Statement.

"**Applicable Time**" means [TIME] [a.m./p.m.], Eastern time, on the date of this Agreement.

"**Issuer Free Writing Prospectus**" means any "issuer free writing prospectus," as defined in Rule 433 of the Securities Act Regulations ("**Rule 433**"), including without limitation any "free writing prospectus" (as defined in Rule 405 of the Securities Act Regulations) relating to the Public Securities that is (i) required to be filed with the Commission by the Company, (ii) a "road show that is a written communication" within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Public Securities or of the Offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g).

"**Issuer General Use Free Writing Prospectus**" means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors (other than a "*bona fide* electronic road show," as defined in Rule 433 (the "**Bona Fide Electronic Road Show**")), as evidenced by its being specified in Schedule 2-B hereto.

"**Issuer Limited Use Free Writing Prospectus**" means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

"**Pricing Disclosure Package**" means any Issuer General Use Free Writing Prospectus issued at or prior to the Applicable Time, the Pricing Prospectus and the information included on Schedule 2-A hereto, all considered together.

2.1.2. Pursuant to the Exchange Act. The Company has filed with the Commission a Form 8-A (File Number 000-**[•]**) providing for the registration pursuant to Section 12(b) under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), of the shares of Common Stock. The registration of the shares of Common Stock under the Exchange Act has been declared effective by the Commission on or prior to the date hereof. The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the shares of Common Stock under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration.

2.2 Stock Exchange Listing. The shares of Common Stock have been approved for listing on the NASDAQ Capital Market (the "**Exchange**"), subject to official notice of issuance, and the Company has taken no action designed to, or likely to have the effect of, delisting the shares of Common Stock from the Exchange, nor has the Company received any notification that the Exchange is contemplating terminating such listing except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.3 No Stop Orders, etc. Neither the Commission nor, to the Company's knowledge, any state regulatory authority has issued any order preventing or suspending the use of the Registration Statement, any Preliminary Prospectus or the Prospectus or has instituted or, to the Company's knowledge, threatened to institute, any proceedings with respect to such an order. The Company has complied with each request (if any) from the Commission for additional information.

2.4 Disclosures in Registration Statement.

2.4.1. Compliance with Securities Act and 10b-5 Representation.

(i) Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus, including the prospectus filed as part of the Registration Statement as originally filed or as part of any amendment or supplement thereto, and the Prospectus, at the time each was filed with the Commission, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus delivered to the Underwriters for use in connection with this Offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(ii) Neither the Registration Statement nor any amendment thereto, at its effective time, as of the Applicable Time, at the Closing Date or at any Option Closing Date (if any), contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that this representation and warranty shall not apply to the Underwriters' Information (as defined below).

(iii) The Pricing Disclosure Package, as of the Applicable Time, at the Closing Date or at any Option Closing Date (if any), did not, does not and will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and each Issuer Limited Use Free Writing Prospectus hereto does not conflict with the information contained in the Registration Statement, any Preliminary Prospectus, the Pricing Prospectus or the Prospectus, and each such Issuer Limited Use Free Writing Prospectus, as supplemented by and taken together with the Pricing Prospectus as of the Applicable Time, did not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to statements made or statements omitted in reliance upon and in conformity with written information furnished to the Company with respect to the Underwriters by the Representative expressly for use in the Registration Statement, the Pricing Prospectus or the Prospectus or any amendment thereof or supplement thereto. The parties acknowledge and agree that such information provided by or on behalf of any Underwriter consists solely of the following disclosure contained in the "Underwriting" section of the Prospectus: the information under the subsections "Discretionary Accounts," "Electronic Offer, Sale and Distribution of Shares," "Stabilization," and "Passive Market Making" (the "**Underwriters' Information**"); and

(iv) Neither the Prospectus nor any amendment or supplement thereto (including any prospectus wrapper), as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Date or at any Option Closing Date, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to the Underwriters' Information.

2.4.2. Disclosure of Agreements. The agreements and documents described in the Registration Statement, the Pricing Disclosure Package and the Prospectus conform in all material respects to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the Securities Act Regulations to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or to be filed with the Commission as exhibits to the

Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus, or (ii) is material to the Company's business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company's knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the Company's knowledge, any other party is in default thereunder and, to the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder. To the Company's knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses (each, a "**Governmental Entity**"), including, without limitation, those relating to environmental laws and regulations.

2.4.3. Prior Securities Transactions. No securities of the Company have been sold by the Company or by or on behalf of, or for the benefit of, any person or persons controlling, controlled by or under common control with the Company, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Preliminary Prospectus.

2.4.4. Regulations. The disclosures in the Registration Statement, the Pricing Disclosure Package and the Prospectus concerning the effects of federal, state, local and all foreign regulation on the Offering and the Company's business as currently contemplated are correct in all material respects and no other such regulations are required to be disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus which are not so disclosed.

2.5 Changes After Dates in Registration Statement.

2.5.1. No Material Adverse Change. Since the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except as otherwise specifically stated therein: (i) there has been no material adverse change in the financial position or results of operations of the Company, nor any change or development that, singularly or in the aggregate, would result in a material adverse change, in or affecting the condition (financial or otherwise), results of operations,

business, assets or prospects of the Company (a "**Material Adverse Change**"); (ii) there have been no material transactions entered into by the Company, other than as contemplated pursuant to this Agreement; and (iii) no officer or director of the Company has resigned from any position with the Company.

2.5.2. Recent Securities Transactions, etc. Subsequent to the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, and except as may otherwise be indicated or contemplated herein or disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not: (i) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

2.6 Independent Accountants. To the knowledge of the Company, EisnerAmper LLP (the "**Auditor**"), whose report is filed with the Commission as part of the Registration Statement, the Pricing

Disclosure Package and the Prospectus, is an independent registered public accounting firm as required by the Securities Act and the Securities Act Regulations and the Public Company Accounting Oversight Board. The Auditor has not, during the periods covered by the financial statements included in the Registration Statement, the Pricing Disclosure Package and the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

2.7 Financial Statements, etc. The financial statements, including the notes thereto and supporting schedules included in the Registration Statement, the Pricing Disclosure Package and the Prospectus, fairly present in all material respects the financial position and the results of operations of the Company at the dates and for the periods to which they apply; and such financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("**GAAP**"), consistently applied throughout the periods involved (provided that unaudited interim financial statements are subject to year-end audit adjustments that are not expected to be material in the aggregate and do not contain all footnotes required by GAAP); and the supporting schedules included in the Registration Statement present fairly in all material respects the information required to be stated therein. Except as included therein, no historical or pro forma financial statements are required to be included in the Registration Statement, the Pricing Disclosure Package or the Prospectus under the Securities Act or the Securities Act Regulations. The pro forma and pro forma as adjusted financial information and the related notes, if any, included in the Registration Statement, the Pricing Disclosure Package and the Prospectus have been properly compiled and prepared in accordance with the applicable requirements of the Securities Act and the Securities Act Regulations and present fairly in all material respects the information shown therein, and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein. All disclosures contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission), if any, comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K of the Securities Act, to the extent applicable. Each of the Registration Statement, the Pricing Disclosure Package and the Prospectus discloses all material off-balance sheet transactions, arrangements, obligations (including contingent obligations), and other relationships of the Company with unconsolidated entities or other persons that may have a material current or future effect on the Company's financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenues or expenses. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (a) neither the Company nor any of its direct and indirect subsidiaries, including each entity disclosed or described in the Registration Statement, the Pricing Disclosure Package and the Prospectus as being a subsidiary of the Company (each, a "**Subsidiary**" and, collectively, the "**Subsidiaries**"), has incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions other than in the ordinary course of business, (b) the Company has not declared or paid any dividends or made any distribution of any kind with respect

to its capital stock, (c) there has not been any change in the capital stock of the Company or any of its Subsidiaries, or, other than in the course of business, any grants under any stock compensation plan, and (d) there has not been any material adverse change in the Company's long-term or short-term debt.

2.8 Authorized Capital; Options, etc. The Company had, at the date or dates indicated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the duly authorized, issued and outstanding capitalization as set forth therein. Based on the assumptions stated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company will have on the Closing Date the adjusted stock capitalization set forth therein. Except as set forth in, or contemplated by, the Registration Statement, the Pricing Disclosure Package and the Prospectus, on the Effective Date, as of the Applicable Time and on the Closing Date and any Option Closing Date, there will be no stock options, warrants, or other rights to purchase or otherwise acquire any authorized, but unissued shares of Common Stock of the Company or any security convertible or exercisable into shares of Common Stock of the Company, or any contracts or commitments to issue or sell shares of Common Stock or any such options, warrants, rights or convertible securities.

2.9 Valid Issuance of Securities, etc.

2.9.1. Outstanding Securities. All issued and outstanding securities of the Company issued prior to the transactions contemplated by this Agreement have been duly authorized and validly issued and are fully paid and non-assessable; the holders thereof have no rights of rescission with respect thereto, and are not subject to personal liability by reason of being such holders; and none of such securities were issued in violation of the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. The authorized shares of Common Stock conform in all material respects to all statements relating thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The offers and sales of the outstanding shares of Common Stock were at all relevant times either registered under the Securities Act and the applicable state securities or "blue sky" laws or, based in part on the representations and warranties of the purchasers of such Shares, exempt from such registration requirements.

2.9.2. Securities Sold Pursuant to this Agreement. The Public Securities have been duly authorized for issuance and sale and, when issued and paid for pursuant to the terms of this Agreement, will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; the Public Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company except as have been validly waived or complied with; and all corporate action required to be taken for the authorization, issuance and sale of the Public Securities has been duly and validly taken. The Representative's Securities have been duly authorized for issuance and sale and, when issued and paid for pursuant to the terms of the Representative's Warrant Agreement will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders and all corporate action required to be taken for the authorization, issuance and sale of the Representative's Warrant Agreement has been duly and validly taken; the shares of Common Stock issuable upon exercise of the Representative's Warrant have been duly authorized and reserved for issuance by all necessary corporate action on the part of the Company and when paid for and issued in accordance with the Representative's Warrant and the Representative's Warrant Agreement, such shares of Common Stock will be validly issued, fully paid and non-assessable; the holders of the Representative's Securities are not and will not be subject to personal liability by reason of being such holders; and such shares of Common Stock are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. The Public Securities and Representative's Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.10 Registration Rights of Third Parties. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no holders of any securities of the Company or any rights exercisable for or convertible or exchangeable into securities of the Company have the right to require the Company to register any such securities of the Company under the Securities Act or to include any such securities in a registration statement to be filed by the Company.

2.11 Validity and Binding Effect of Agreements. This Agreement and the Representative's Warrant Agreement have been duly and validly authorized by the Company, and, when executed and delivered, will constitute, the valid and binding agreements of the Company, enforceable against the Company in accordance with their respective terms, except: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

2.12 No Conflicts, etc. The execution, delivery and performance by the Company of this Agreement, the Representative's Warrant Agreement and all ancillary documents, the consummation by the Company of the transactions herein and therein contemplated and the compliance by the Company with the terms hereof and thereof do not and will not, with or without the giving of notice or the lapse of time or both: (i) result in a material breach of, or conflict with any of the terms and provisions of, or constitute a material default under, or result in the creation, modification, termination or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any agreement or instrument to which the Company is a party; (ii) result in any violation of the provisions of the Company's Certificate of Incorporation (as the same may be amended or restated from time to time, the "**Charter**") or the by-laws of the Company; or (iii) violate any existing applicable law, rule, regulation, judgment, order or decree of any Governmental Entity as of the date hereof.

2.13 No Defaults; Violations. No material default exists in the due performance and observance of any term, covenant or condition of any material license, contract, indenture, mortgage, deed of trust, note, loan or credit agreement, or any other material agreement or instrument evidencing an obligation for borrowed money, or any other material agreement or instrument to which the Company is a party or by which the Company may be bound or to which any of the properties or assets of the Company is subject. The Company is (i) not in violation of any term or provision of its Charter or by-laws, or (ii) in violation of any franchise, license, permit, applicable law, rule, regulation, judgment or decree of any Governmental Entity, except in the case of this clause (ii) for such violation that would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

2.14 Corporate Power; Licenses; Consents.

2.14.1. Conduct of Business. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has all requisite corporate power and authority, and has all necessary authorizations, approvals, orders, licenses, certificates and permits of and from all governmental regulatory officials and bodies that it needs as of the date hereof to conduct its business purpose as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except where failure to have such consents, authorizations, approvals, registrations, orders, licenses, certifications, and permits would not reasonably be expected to result in a Material Adverse Change.

2.14.2. Transactions Contemplated Herein. The Company has all corporate power and authority to enter into this Agreement and to carry out the provisions and conditions hereof, and all consents, authorizations, approvals and orders required in connection therewith have been obtained. No consent, authorization or

order of, and no filing with, any court, government agency or other body is required for the valid issuance, sale and delivery of the Public Securities and the consummation of the transactions and agreements contemplated by this Agreement and the Representative's Warrant Agreement and as contemplated by the Registration Statement, the Pricing Disclosure Package and the Prospectus, except with respect to applicable federal and state securities laws and the rules and regulations of the Financial Industry Regulatory Authority, Inc. ("**FINRA**").

2.15 D&O Questionnaires. To the Company's knowledge, all information contained in the questionnaires (the "**Questionnaires**") completed by each of the Company's directors and officers immediately prior to the Offering (the "**Insiders**") as supplemented by all information concerning the Company's directors, officers and principal shareholders as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, as well as in the Lock-Up Agreement (as defined in Section 2.24 below), provided to the Underwriters, is true and correct in all material respects and the Company has not become aware of any information which would cause the information disclosed in the Questionnaires to become materially inaccurate and incorrect.

2.16 Litigation; Governmental Proceedings. There is no material action, suit, proceeding, inquiry, arbitration, investigation, litigation or governmental proceeding pending or, to the Company's knowledge, threatened against, or involving the Company or, to the Company's knowledge, any executive officer or director which has not been disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus or in connection with the Company's listing application for the listing of the Public Securities on the Exchange, and which is resolved adversely to the Company would result in a Material Adverse Change or otherwise affect the Company's ability to consummate the Offering.

2.17 Good Standing. The Company has been duly organized and is validly existing as a corporation and is in good standing under the laws of the State of Delaware as of the date hereof, and is duly qualified to do business and is in good standing in each other jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to qualify, singularly or in the aggregate, would not have or reasonably be expected to result in a Material Adverse Change.

2.18 Insurance. The Company carries or is entitled to the benefits of insurance, with reputable insurers, in such amounts and covering such risks which the Company believes are adequate, including, but not limited to, directors and officers insurance coverage at least equal to $5,000,000 and all such insurance is in full force and effect. As of the date hereof, the Company has no reason to believe that it will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Change.

2.19 Transactions Affecting Disclosure to FINRA.

2.19.1. Finder's Fees. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no claims, payments, arrangements, agreements or understandings relating to the payment of a finder's, consulting or origination fee by the Company or any Insider with respect to the sale of the Public Securities hereunder or any other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its shareholders that may affect the Underwriters' compensation, as determined by FINRA.

2.19.2. Payments Within Twelve (12) Months. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not made any direct or indirect payments (in cash, securities or otherwise) to: (i) any person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who

raised or provided capital to the Company; (ii) any FINRA member; or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member, within the twelve (12) months prior to the Effective Date, other than the payment to the Underwriters as provided hereunder in connection with the Offering.

2.19.3. Use of Proceeds. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

2.19.4. FINRA Affiliation. To the Company's knowledge, there is no (i) officer or director of the Company, (ii) beneficial owner of 5% or more of any class of the Company's securities or (iii) beneficial owner of the Company's unregistered equity securities which were acquired during the 180-day period immediately preceding the filing of the Registration Statement that is an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

2.19.5. Information. All information provided by the Company and to the Company's knowledge all the information provided by its officers and directors in their FINRA questionnaires to Representative Counsel specifically for use by Representative Counsel in connection with its Public Offering System filings (and related disclosure) with FINRA is true, correct and complete in all material respects.

2.20 Foreign Corrupt Practices Act. None of the Company and its Subsidiaries or, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company and its Subsidiaries or any other person acting on behalf of the Company and its Subsidiaries, has, directly or indirectly, given or agreed to give any money, gift or similar benefit (other than legal price concessions to customers in the ordinary course of business) to any customer, supplier, employee or agent of a customer or supplier, or official or employee of any governmental agency or instrumentality of any government (domestic or foreign) or any political party or candidate for office (domestic or foreign) or other person who was, is, or may be in a position to help or hinder the business of the Company (or assist it in connection with any actual or proposed transaction) that (i) might subject the Company to any damage or penalty in any civil, criminal or governmental litigation or proceeding, (ii) if not given in the past, might have had a Material Adverse Change or (iii) if not continued in the future, might adversely affect the assets, business, operations or prospects of the Company. The Company has instituted and maintains policies and procedures designed to ensure, and which are reasonably expected to ensure, that the Company will continue to comply in all material respect with the Foreign Corrupt Practices Act of 1977, as amended.

2.21 Compliance with OFAC. None of the Company and its Subsidiaries or, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company and its Subsidiaries or any other person acting on behalf of the Company and its Subsidiaries, is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**"), and the Company will not, directly or indirectly, use the proceeds of the Offering hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

2.22 Money Laundering Laws. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "**Money Laundering Laws**"); and no action, suit or proceeding by or before any Governmental Entity involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

2.23 Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to you or to Representative Counsel shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

2.24 Lock-Up Agreements. Schedule 3 hereto contains a complete and accurate list of the Company's officers, directors and each owner of the Company's outstanding shares of Common Stock (or securities convertible or exercisable into shares of Common Stock) who will be subject to the Lock-Up Agreement (as defined below) (collectively, the "**Lock-Up Parties**"). The Company has caused each of the Lock-Up Parties to deliver to the Representative an executed Lock-Up Agreement, in the form attached hereto as Exhibit B (the "**Lock-Up Agreement**"), prior to the execution of this Agreement.

2.25 Subsidiaries. All direct and indirect Subsidiaries of the Company are duly organized and in good standing under the laws of the place of organization or incorporation, and each Subsidiary is in

good standing in each jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to qualify would not have a material adverse effect on the assets, business or operations of the Company taken as a whole. The Company's ownership and control of each Subsidiary is as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.26 Related Party Transactions. There are no business relationships or related party transactions involving the Company or any other person required to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus that have not been described as required.

2.27 Board of Directors. The Board of Directors of the Company is comprised of the persons set forth under the heading of the Pricing Prospectus and the Prospectus captioned "Management." The qualifications of the persons serving as board members and the overall composition of the board comply with the Exchange Act, the Exchange Act Regulations, the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder (the "**Sarbanes-Oxley Act**") applicable to the Company and the listing rules of the Exchange. At least one member of the Audit Committee of the Board of Directors of the Company qualifies as an "audit committee financial expert," as such term is defined under Regulation S-K and the listing rules of the Exchange. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent," as defined under the listing rules of the Exchange.

2.28 Sarbanes-Oxley Compliance.

2.28.1. Disclosure Controls. The Company has developed and currently maintains disclosure controls and procedures that will comply with Rule 13a-15 or 15d-15 under the Exchange Act Regulations, applicable to it, and except as described in the Registration Statement, the Pricing Disclosure Package or Prospectus and such controls and procedures are effective as of the date hereof to ensure that all material information concerning the Company will be made known on a timely basis to the individuals responsible for the preparation of the Company's Exchange Act filings and other public disclosure documents.

2.28.2. Compliance. The Company is, or at the Applicable Time and on the Closing Date will be, in material compliance with the provisions of the Sarbanes-Oxley Act applicable to it, and has implemented or will implement such programs and taken reasonable steps to ensure the Company's future compliance (not later than the relevant statutory and regulatory deadlines therefor) with all of the material provisions of the Sarbanes-Oxley Act (it being understood that this subsection shall not require the Company to comply with Section 404 of the Sarbanes-Oxley Act as of an earlier date then it would otherwise be required to comply under applicable law).

2.29 Accounting Controls. The Company and its Subsidiaries maintain systems of "internal control over financial reporting" (as defined under Rules 13a-15 and 15d-15 under the Exchange Act Regulations) that comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company is not aware of any material weaknesses in its internal controls. The Company's auditors and the Audit

Committee of the Board of Directors of the Company have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are known to the Company's management and that have adversely affected or are reasonably likely to adversely affect the Company' ability to record, process, summarize and report financial information; and (ii) any fraud known to the Company's management, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls over financial reporting.

2.30 No Investment Company Status. The Company is not and, after giving effect to the Offering and the application of the proceeds thereof as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, will not be, required to register as an "investment company," as defined in the Investment Company Act of 1940, as amended.

2.31 No Labor Disputes. No labor dispute with the employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is imminent.

2.32 Intellectual Property Rights. The Company and each of its Subsidiaries owns or possesses or has valid rights to use all patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, inventions, trade secrets and similar rights ("**Intellectual Property Rights**") necessary for the conduct of the business of the Company and its Subsidiaries as currently carried on and as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus. To the knowledge of the Company, no action or use by the Company or any of its Subsidiaries necessary for the conduct of its business as currently carried on and as described in the Registration Statement and the Prospectus will involve or give rise to any infringement of, or license or similar fees for, any Intellectual Property Rights of others. Neither the Company nor any of its Subsidiaries has received any notice alleging any such infringement, fee or conflict with asserted Intellectual Property Rights of others. Except as would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change (A) to the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any of the Intellectual Property Rights owned by the Company; (B) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the rights of the Company in or to any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim, that would, individually or in the aggregate, together with any other claims in this Section 2.34, reasonably be expected to result in a Material Adverse Change; (C) the Intellectual Property Rights owned by the Company and, to the knowledge of the Company, the Intellectual Property Rights licensed to the Company have not been adjudged by a court of competent jurisdiction invalid or unenforceable, in whole or in part, and there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging

the validity or scope of any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 2.34, reasonably be expected to result in a Material Adverse Change; (D) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company infringes, misappropriates or otherwise violates any Intellectual Property Rights or other proprietary rights of others, the Company has not received any written notice of such claim and the Company is unaware of any other facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 2.34, reasonably be expected to result in a Material Adverse Change; and (E) to the Company's knowledge, no employee of the Company is in or has ever been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company, or actions undertaken by the employee while employed with the Company and could reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change. To the Company's knowledge, all material technical information developed by and belonging to the Company which has not been patented or disclosed in a patent application has been kept confidential. The Company is not a party to or bound by any options, licenses or agreements with respect to the Intellectual Property Rights of any other person or entity that are required to be set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus and are not described therein. The Registration Statement, the Pricing Disclosure Package and the Prospectus contain in all material respects the same description of the matters set forth in the preceding sentence. None of the technology employed by the Company has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company or, to the Company's knowledge, any of its officers, directors or employees, or otherwise in violation of the rights of any persons..

2.33 Taxes. Each of the Company and its Subsidiaries has filed all returns (as hereinafter defined) required to be filed with taxing authorities prior to the date hereof or has duly obtained extensions of time for the filing thereof, except where the failure to do so would not reasonably be expected to result in a Material Adverse Change. Each of the Company and its Subsidiaries has paid all taxes (as hereinafter defined) shown as due on such returns that were filed and has paid all taxes imposed on or assessed against the Company or such respective Subsidiary. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all material accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. Except as disclosed in writing to the Underwriters or as would not reasonably be expected to have a Material Adverse Change, (i) no issues have been raised (and are currently pending) by any taxing authority in connection with any of the returns or taxes asserted as due from the Company or its Subsidiaries, and (ii) no waivers of statutes of limitation with respect to the returns or collection of taxes have been given by or requested from the Company or its Subsidiaries. The term "taxes" means all federal, state, local, foreign and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments or charges of any kind whatever, together with any interest and any penalties, additions to tax or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements and other documents required to be filed in respect to taxes.

2.34 ERISA Compliance. Except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change, the Company and any "employee benefit plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "**ERISA**")) established or maintained by the Company or its "ERISA Affiliates" (as defined below) are in compliance in all material respects with ERISA. "**ERISA Affiliate**" means, with respect to the Company, any member of any group of organizations described in

Sections 414(b),(c),(m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "**Code**") of which the Company is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates. No "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates, if such "employee benefit plan" were terminated, would have any "amount of unfunded benefit liabilities" (as defined under ERISA). Neither the Company nor any of its ERISA Affiliates has incurred or reasonably expects to incur any material liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and, to the knowledge of the Company, nothing has occurred, whether by action or failure to act, which would reasonably be expected to cause the loss of such qualification.

2.35 Compliance with Laws. The Company: (A) is and at all times has been in compliance in all material respects with all statutes, rules, or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company ("**Applicable Laws**"), except as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (B) has not received any warning letter, untitled letter or other correspondence or notice from any other governmental authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws ("**Authorizations**"), except as to noncompliance that would not reasonably be expected to result in a Material Adverse Change; (C) possesses all material Authorizations and such Authorizations are valid and in full force and effect and are not in material violation of any term of any such Authorizations; (D) has not received written notice of any material claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and has no knowledge that any such governmental authority or third party is considering any such material claim, litigation, arbitration, action, suit, investigation or proceeding; (E) has not received written notice that any governmental authority has taken, is taking or intends to take material action to limit, suspend, modify or revoke any Authorizations and has no knowledge that any such governmental authority is considering such material action; (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct in all material respects on the date filed (or were corrected or supplemented by a subsequent submission); and (G) has not,either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action, as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

2.36 Ineligible Issuer. At the time of filing the Registration Statement and any post-effective amendment thereto, at the time of effectiveness of the Registration Statement and any amendment thereto, at the earliest time thereafter that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) of the Securities Act Regulations) of the Public Securities and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

2.37 Real Property. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company and its Subsidiaries have good and marketable title in fee simple to, or have valid rights to lease or otherwise use, all items of real or personal property which are material to the business of the Company and its Subsidiaries taken as a whole, in each case free and clear of all liens, encumbrances, security interests, claims and defects that do not, singly or in the aggregate, materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company or its Subsidiaries; and all of the leases and subleases material to the business of the Company and its subsidiaries, considered as one enterprise, and under which the Company or any of its Subsidiaries holds properties described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, are in full force and effect, and neither the Company nor any Subsidiary has received any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company or any Subsidiary under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company or such Subsidiary to the continued possession of the leased or subleased premises under any such lease or sublease.

2.38 Contracts Affecting Capital. There are no transactions, arrangements or other relationships between and/or among the Company, any of its affiliates (as such term is defined in Rule 405 of the

Securities Act Regulations) and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity that could reasonably be expected to materially affect the Company's or its Subsidiaries' liquidity or the availability of or requirements for their capital resources required to be described or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus which have not been described or incorporated by reference as required.

2.39 Loans to Directors or Officers. There are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees or indebtedness by the Company or its Subsidiaries to or for the benefit of any of the officers or directors of the Company, its Subsidiaries or any of their respective family members, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.40 Smaller Reporting Company. As of the time of filing of the Registration Statement, the Company was a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act Regulations.

2.41 Industry Data. The statistical and market-related data included in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus are based on or derived from sources that the Company reasonably and in good faith believes are reliable and accurate or represent the Company's good faith estimates that are made on the basis of data derived from such sources.

2.42 Emerging Growth Company. From the time of the initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly in or through any Person authorized to act on its behalf in any Testing-the Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "**Emerging Growth Company**"). "**Testing-the-Waters Communication**" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

2.43 Testing-the-Waters Communications. The Company has not (i) alone engaged in any Testing-the-Waters Communications, other than Testing-the-Waters Communications with the written consent of the Representative and with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) authorized anyone other than the Representative to engage in Testing-the-Waters

Communications. The Company confirms that the Representative has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule 2-C hereto. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

2.44 Electronic Road Show. The Company has made available a Bona Fide Electronic Road Show in compliance with Rule 433(d)(8)(ii) of the Securities Act Regulations such that no filing of any "road show" (as defined in Rule 433(h) of the Securities Act Regulations) is required in connection with the Offering.

2.45 Margin Securities. The Company owns no "margin securities" as that term is defined in Regulation U of the Board of Governors of the Federal Reserve System (the "**Federal Reserve Board**"), and none of the proceeds of Offering will be used, directly or indirectly, for the purpose of purchasing or carrying any margin security, for the purpose of reducing or retiring any indebtedness which was originally incurred to purchase or carry any margin security or for any other purpose which might cause any of the shares of Common Stock to be considered a "purpose credit" within the meanings of Regulation T, U or X of the Federal Reserve Board.

3. Covenants of the Company. The Company covenants and agrees as follows:

3.1 Amendments to Registration Statement. The Company shall deliver to the Representative, prior to filing, any amendment or supplement to the Registration Statement or Prospectus proposed to be filed after the Effective Date and not file any such amendment or supplement to which the Representative shall reasonably object in writing.

3.2 Federal Securities Laws.

3.2.1. Compliance. The Company, subject to Section 3.2.2, shall comply with the requirements of Rule 430A of the Securities Act Regulations, and will notify the Representative promptly, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed; (ii) of the receipt of any comments from the Commission; (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or for additional information; (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any Preliminary Prospectus or the Prospectus, or of the suspension of the qualification of the Public Securities and Representative's Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the Securities Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the Securities Act in connection with the Offering of the Public Securities and Representative's Securities. The Company shall effect all filings required under Rule 424(b) of the Securities Act Regulations, in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and shall take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company shall use its reasonable best efforts to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof at the earliest possible moment.

3.2.2. Continued Compliance. The Company shall comply with the Securities Act, the Securities Act Regulations, the Exchange Act and the Exchange Act Regulations so as to permit the completion of the distribution of the Public Securities as contemplated in this Agreement and in the Registration Statement, the Pricing Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172 of the Securities Act Regulations ("**Rule 172**"), would be) required by the Securities Act to be delivered in connection with sales of the Public Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; (ii) amend or supplement the Pricing Disclosure Package or the Prospectus in order that the Pricing Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the Pricing Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the Securities Act or the Securities Act Regulations, the Company will promptly (A) give the Representative notice of such event; (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the Pricing Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representative with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Representative or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request. The Company has given the Representative notice of any filings made pursuant to the Exchange Act or the Exchange Act Regulations within 48 hours prior to the Applicable Time. The Company shall give the Representative notice of its intention to make any such filing from the Applicable Time until the later of the Closing Date and the exercise in full or expiration of the Over-allotment Option specified in Section 1.2 hereof and will furnish the Representative with copies of the related document(s) a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Representative or counsel for the Underwriters shall reasonably object.

3.2.3. Exchange Act Registration. For a period of three (3) years after the date of this Agreement, the Company shall use its reasonable best efforts to maintain the registration of the shares of Common Stock under the Exchange Act. The Company shall not deregister the shares of Common Stock under the Exchange Act without the prior written consent of the Representative.

3.2.4. Free Writing Prospectuses. The Company agrees that, unless it obtains the prior written consent of the Representative, it shall not make any offer relating to the Public Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus," or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the Representative shall be deemed to have consented to each Issuer General Use Free Writing Prospectus hereto and any "road show that is a written communication" within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Representative. The Company represents that it has treated or agrees that it will treat each such free writing prospectus consented to, or deemed consented to, by the Underwriters as an "issuer free writing prospectus," as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or

would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Underwriters and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

3.2.5. Testing-the-Waters Communications. If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company shall promptly notify the Representative and shall promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

3.3 Delivery to the Underwriters of Registration Statements. The Company has delivered or made available or shall deliver or make available to the Representative and counsel for the Representative, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and signed copies of all consents and certificates of experts, and will also deliver to the Underwriters, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) for each of the Underwriters. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

3.4 Delivery to the Underwriters of Prospectuses. The Company has delivered or made available or will deliver or make available to each Underwriter, without charge, as many copies of each Preliminary Prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the Securities Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the Securities Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

3.5 Effectiveness and Events Requiring Notice to the Representative. The Company shall use its reasonable best efforts to cause the Registration Statement to remain effective with a current prospectus for at least nine (9) months after the Applicable Time, and shall notify the Representative immediately and confirm the notice in writing: (i) of the effectiveness of the Registration Statement and any amendment thereto; (ii) of the issuance by the Commission of any stop order or of the initiation, or the threatening, of any proceeding for that purpose; (iii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Public Securities for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose; (iv) of the mailing and delivery to the Commission for filing of any amendment or supplement to the Registration Statement or Prospectus; (v) of the receipt of any comments or request for any additional information from the Commission; and (vi) of the happening of any event during the period described in this Section 3.5 that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement, the Pricing Disclosure Package or the Prospectus untrue or that requires the making of any changes in (a) the Registration Statement in order to make the statements therein not misleading, or (b) in the Pricing Disclosure Package or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such qualification at any time, the Company shall make every reasonable effort to obtain promptly the lifting of such order.

3.6 Review of Financial Statements. For a period of three (3) years after the date of this Agreement, the Company, at its expense, shall use its reasonable best efforts to cause its regularly engaged independent registered public accounting firm to review (but not audit) the Company's financial statements for each of the three fiscal quarters immediately preceding the announcement of any quarterly financial information.

3.7 Listing. The Company shall use its reasonable best efforts to maintain the listing of the shares of Common Stock (including the Public Securities) on the Exchange for at least three years from the date of this Agreement.

3.8 Financial Public Relations Firm. As of the Effective Date, the Company shall have retained a financial public relations firm, which firm shall be experienced in assisting issuers in public offerings of securities and in their relations with their security holders.

3.9 Reports to the Representative.

3.9.1. Periodic Reports, etc. For a period of three (3) years after the date of this Agreement, the Company shall use its reasonable best efforts to furnish or make available to the Representative copies of such financial statements and other periodic and special reports as the Company from time to time furnishes generally to holders of any class of its securities and also promptly furnish or make available to the Representative: (i) a copy of each periodic report the Company shall be required to file with the Commission under the Exchange Act and the Exchange Act Regulations; (ii) a copy of every press release and every news item and article with respect to the Company or its affairs which was released by the Company; (iii) a copy of each Form 8-K prepared and filed by the Company; (iv) five copies of each registration statement filed by the Company under the Securities Act; and (v) such additional documents and information with respect to the Company and the affairs of any future subsidiaries of the Company as the Representative may from time to time reasonably request; provided the Representative shall sign, if requested by the Company, a Regulation FD compliant confidentiality agreement which is reasonably acceptable to the Representative and Representative Counsel in connection with the Representative's receipt of such information. Documents filed with the Commission pursuant to its EDGAR system shall be deemed to have been delivered to the Representative pursuant to this Section 3.9.1.

3.9.2. Transfer Agent; Transfer Sheets. For a period of three (3) years after the date of this Agreement, the Company shall retain a transfer agent and registrar acceptable to the Representative (the "**Transfer Agent**") and shall furnish to the Representative at the Company's sole cost and expense such transfer sheets of the Company's securities as the Representative may reasonably request, including the daily and monthly consolidated transfer sheets of the Transfer Agent and DTC. Computershare is acceptable to the Representative to act as Transfer Agent for the shares of Common Stock.

3.9.3. Trading Reports. For a period of one (1) year after the date of this Agreement, the Company shall provide to the Representative, at the Company's expense, such reports published by Exchange relating to price trading of the Public Securities, as the Representative shall reasonably request.

3.10 Payment of Expenses

3.10.1. General Expenses Related to the Offering. The Company hereby agrees to pay on each of the Closing Date and the Option Closing Date, if any, to the extent not paid at the Closing Date, all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (a) all filing fees and communication expenses relating to the registration of the shares of Common Stock to be sold in the Offering (including the Over-allotment Shares) with the Commission; (b) all Public Filing System filing fees associated with the review of the Offering by FINRA; (c) all fees and expenses relating to the listing of such Public Securities on the Exchange and such other stock exchanges

as the Company and the Representative together determine; (d) all fees, expenses and disbursements relating to background checks of the Company's officers and directors in an amount not to $10,000 in the aggregate; (e) all fees, expenses and disbursements relating to the registration or qualification of the Public Securities under the "blue sky" securities laws of such states and other jurisdictions as the Representative may reasonably designate in an amount not to exceed $10,000 in the aggregate (f) all fees, expenses and disbursements relating to the registration, qualification or exemption of the Public Securities under the securities laws of such foreign jurisdictions as the Representative may reasonably designate in an amount not to exceed $10,000 in the aggregate; (g) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement, any Blue Sky Surveys and, if appropriate, any Agreement Among Underwriters, Selected Dealers' Agreement, Underwriters' Questionnaire and Power of Attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (h) the costs and expenses of a public relations firm; (i) the costs of preparing, printing and delivering certificates representing the Public Securities; (j) fees and expenses of the transfer agent for the shares of Common Stock; (k) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (l) to the extent approved by the Company in writing, the costs associated with post-Closing advertising the Offering in the national editions of the Wall Street Journal and New York Times; (m) the costs associated with one set of bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones, each of which the Company or its designee shall provide within a reasonable time after the Closing Date in such quantities as the Representative may reasonably request, not to exceed $3,000; (n) the fees and expenses of the Company's accountants; (o) the fees and expenses of the Company's legal counsel and other agents and representatives;

(p) the $29,500 cost associated with the Underwriter's use of Ipreo's book-building, prospectus tracking and compliance software for the Offering; (r) $10,000 for data services and communications expenses; (s) up to $10,000 of the Underwriters' actual accountable "road show"; (t) up to $30,000 of the Underwriter's market making and trading, and clearing firm settlement expenses for the Offering; (u) the fees and expenses of the Company's legal counsel and other agents and representatives; and (v) the fees and expenses of the Underwriter's legal counsel not to exceed $125,000. The Representative may deduct from the net proceeds of the Offering payable to the Company on the Closing Date, or the Option Closing Date, if any, the expenses set forth herein to be paid by the Company to the Underwriters.

3.10.2. Non-accountable Expenses. The Company further agrees that, in addition to the expenses payable pursuant to Section 3.10.1, on the Closing Date it shall pay to the Representative, by deduction from the net proceeds of the Offering contemplated herein, a non-accountable expense allowance equal to one percent (1%) of the gross proceeds received by the Company from the sale of the Firm Shares (excluding the Option Shares), less the Advance (as such term is defined in Section 8.3 hereof), provided, however, that in the event that the Offering is terminated, the Company agrees to reimburse the Underwriters pursuant to Section 8.3 hereof.

3.11 Application of Net Proceeds. The Company shall apply the net proceeds from the Offering received by it in a manner consistent with the application thereof described under the caption "Use of Proceeds" in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

3.12 Delivery of Earnings Statements to Security Holders. The Company shall make generally available to its security holders as soon as practicable, but not later than the first day of the fifteenth (15th) full calendar month following the date of this Agreement, an earnings statement (which need not be certified by independent registered public accounting firm unless required by the Securities Act or the Securities Act Regulations, but which shall satisfy the provisions of Rule 158(a) under Section 11(a) of the Securities Act) covering a period of at least twelve (12) consecutive months beginning after the date of this Agreement.

3.13 Stabilization. Neither the Company nor, to its knowledge, any of its employees, directors or shareholders (without the consent of the Representative) has taken, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under Regulation M of the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Public Securities.

3.14 Internal Controls. The Company shall use its reasonable best efforts to maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

3.15 Accountants. As of the date of this Agreement, the Company shall use its reasonable best efforts to retain an independent certified public accounting firm, reasonably acceptable to the Representative. The Representative acknowledges that the Auditor is acceptable to the Representative.

3.16 FINRA. The Company shall advise the Representative (who shall make an appropriate filing with FINRA) if it is or becomes aware that (i) any officer or director of the Company, (ii) any beneficial owner of 5% or more of any class of the Company's securities or (iii) any beneficial owner of the Company's unregistered equity securities which were acquired during the 180 days immediately preceding the filing of the Registration Statement is or becomes an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

3.17 No Fiduciary Duties. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual in nature and that none of the Underwriters or their affiliates or any selling agent shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement.

3.18 Company Lock-Up Agreements.

3.18.1. Restriction on Sales of Capital Stock. The Company, on behalf of itself and any successor entity, agrees that, without the prior written consent of the Representative, it will not, for a period of 180 days after the date of this Agreement (the "**Lock-Up Period**"), (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; (ii) file or caused to be filed any registration statement with the Commission (other than on a Form S-8, or successor form thereto) relating to the offering of any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; (iii) complete any offering of debt securities of the Company, other than entering into a line of credit with a traditional bank or (iv) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of capital stock of the Company, whether any such transaction described in clause (i), (ii), (iii) or (iv) above is to be settled by delivery of shares of capital stock of the Company or such other securities, in cash or otherwise.

The restrictions contained in this Section 3.18.1 shall not apply to (i) the shares of Common Stock to be sold hereunder, (ii) the issuance by the Company of shares of Common Stock upon the exercise of a stock option or warrant or the conversion of a security outstanding on the date hereof, which is disclosed in the

Registration Statement, Disclosure Package and Prospectus, provided that such options, warrants, and securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities or to extend the term of such securities, or (iii) the issuance by the Company of stock options or shares of capital stock of the Company under any equity compensation plan of the Company, provided that in each of (ii) and (iii) above, the underlying shares shall be restricted from sale during the entire Lock-Up Period.

Notwithstanding the foregoing, if (i) during the last 17 days of the Lock-Up Period, the Company issues an earnings release or material news or a material event relating to the Company occurs, or (ii) prior to the expiration of the Lock-Up Period, the Company announces that it will release earnings results or becomes aware that material news or a material event will occur during the 16-day period beginning on the last day of the Lock-Up Period, the restrictions imposed by this Section 3.18.1 shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of such material news or material event, as applicable, unless the Representative waives, in writing, such extension; provided, however, that this extension of the Lock-Up Period shall not apply to the extent that FINRA has amended or repealed NASD Rule 2711(f)(4), or has otherwise provided written interpretive guidance regarding such rule, in each case, so as to eliminate the prohibition of any broker, dealer, or member of a national securities association from publishing or distributing any research report, with respect to the securities of an Emerging Growth Company prior to or after the expiration of any agreement between the broker, dealer, or member of a national securities association and the Emerging Growth Company or its shareholders that restricts or prohibits the sale of securities held by the Emerging Growth Company or its shareholders after the initial public offering date.

3.18.2. Restriction on Continuous Offerings. Notwithstanding the restrictions contained in Section 3.18.1, the Company, on behalf of itself and any successor entity, agrees that, without the prior written consent of the Representative, it will not for a period of twelve (12) months, directly or indirectly in any "at-the-market," continuous equity or variable transaction, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company.

3.19 Release of D&O Lock-up Period. If the Representative, in its sole discretion, agrees to release or waive the restrictions set forth in the Lock-Up Agreements described in Section 2.24 hereof for an officer or director of the Company and provide the Company with notice of the impending release or waiver at least three (3) Business Days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit C hereto through a major news service at least two (2) Business Days before the effective date of the release or waiver.

3.20 Blue Sky Qualifications. The Company shall use its reasonable best efforts, in cooperation with the Underwriters, if necessary, to qualify the Public Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representative may designate and to maintain such qualifications in effect so long as required to complete the distribution of the Public Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

3.21 Reporting Requirements. The Company, during the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the Securities Act, will file all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act and Exchange Act Regulations. Additionally, the Company shall report the use of proceeds from the issuance of the Public Securities as may be required under Rule 463 under the Securities Act Regulations.

3.22 Emerging Growth Company Status. The Company shall promptly notify the Representative if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Public Securities within the meaning of the Securities Act and (ii) fifteen (15) days following the completion of the Lock-Up Period.

4. Conditions of Underwriters' Obligations. The obligations of the Underwriters to purchase and pay for the Public Securities, as provided herein, shall be subject to (i) the continuing accuracy of the representations and warranties of the Company as of the date hereof and as of each of the Closing Date and the Option Closing Date, if any; (ii) the accuracy of the statements of officers of the Company made pursuant to the provisions hereof; (iii) the performance by the Company of its obligations hereunder; and (iv) the following conditions:

4.1 Regulatory Matters.

4.1.1. Effectiveness of Registration Statement; Rule 430A Information. The Registration Statement has become effective not later than 5:00 p.m., Eastern time, on the date of this Agreement or such later date and time as shall be consented to in writing by you, and, at each of the Closing Date and any Option Closing Date, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the Securities Act, no order preventing or suspending the use of any Preliminary Prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated by the Commission. The Company has complied with each request (if any) from the Commission for additional information. The Prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) (without reliance on Rule 424(b)(8)) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A.

4.1.2. FINRA Clearance. On or before the date of this Agreement, the Representative shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement.

4.1.3. Exchange Stock Market Clearance. On the Closing Date, the Company's shares of Common Stock, including the Firm Shares, shall have been approved for listing on the Exchange, subject only to official notice of issuance. On the first Option Closing Date (if any), the Company's shares of Common Stock, including the Option Shares, shall have been approved for listing on the Exchange, subject only to official notice of issuance.

4.2 Company Counsel Matters.

4.2.1. Closing Date Opinion of Counsel. On the Closing Date, the Representative shall have received the favorable opinion of Loeb & Loeb LLP, counsel to the Company, dated the Closing Date and addressed to the Representative, in form and substance reasonably satisfactory to the Representative.

4.2.2. Opinion of Special Intellectual Property Counsel for the Company. On the Closing Date, the Representative shall have received the opinion of [IP COUNSEL NAME], special intellectual property counsel for the Company, dated the Closing Date, addressed to the Representative in form and substance reasonably satisfactory to the Representative.

4.2.3. Option Closing Date Opinions of Counsel. On the Option Closing Date, if any, the Representative shall have received the favorable opinions of each counsel listed in Sections 4.2.1 and 4.2.2, dated the Option Closing Date, addressed to the Representative and in form and substance reasonably satisfactory to the Representative, confirming as of the Option Closing Date, the statements made by such counsels in their respective opinions delivered on the Closing Date.

4.2.4. Reliance. In rendering such opinions, such counsel may rely: (i) as to matters involving the application of laws other than the laws of the United States and jurisdictions in which they are admitted, to the extent such counsel deems proper and to the extent specified in such opinion, if at all, upon an opinion or opinions (in form and substance reasonably satisfactory to the Representative) of other counsel reasonably acceptable to the Representative, familiar with the applicable laws; and (ii) as to matters of fact, to the extent they deem proper, on certificates or other written statements of officers of the Company and officers of departments of various jurisdictions having custody of documents respecting the corporate existence or good standing of the Company, provided that copies of any such statements or certificates shall be delivered to Representative Counsel if requested. The opinion of Loeb & Loeb LLP and any opinion relied upon by Loeb & Loeb LLP shall include a statement to the effect that it may be relied upon by Representative Counsel in its opinion delivered to the Underwriters.

4.3 Comfort Letters.

4.3.1. Cold Comfort Letter. At the time this Agreement is executed you shall have received a cold comfort letter containing statements and information of the type customarily included in accountants' comfort letters with respect to the financial statements and certain financial information contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus, addressed to the Representative and in form and substance satisfactory in all respects to you and to the Auditor, dated as of the date of this Agreement.

4.3.2. Bring-down Comfort Letter. At each of the Closing Date and the Option Closing Date, if any, the Representative shall have received from the Auditor a letter, dated as of the Closing Date or the Option Closing Date, as applicable, to the effect that the Auditor reaffirms the statements made in the letter furnished pursuant to Section 4.3.1, except that the specified date referred to shall be a date not more than three (3) business days prior to the Closing Date or the Option Closing Date, as applicable.

4.4 Officers' Certificates.

4.4.1. Officers' Certificate. The Company shall have furnished to the Representative a certificate, dated the Closing Date and any Option Closing Date (if such date is other than the Closing Date), of its Chief Executive Officer, its President and its Chief Financial Officer (on behalf of the Company and not in an individual capacity) stating that (i) such officers have carefully examined the Registration Statement, the Pricing Disclosure Package, any Issuer Free Writing Prospectus and the Prospectus and, in their opinion, the Registration Statement and each amendment thereto, as of the Applicable Time and as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date) did not include any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and the Pricing Disclosure Package, as of the Applicable Time and as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date), any Issuer Free Writing Prospectus as of its date and as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date), the Prospectus and each amendment or supplement thereto, as of the respective date thereof and as of the Closing Date, did not include any untrue statement of a material fact and did not omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances in which they were made, not misleading, (ii) since the effective date of the Registration Statement, no event has occurred which should have been set forth in a supplement or amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus, (iii) to their

knowledge after reasonable investigation, as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date), the representations and warranties of the Company in this Agreement are true and correct in all material respects (except for those representations and warranties that are qualified as to materiality, which shall be true and correct in all respects and except for those representations and warranties which refer to facts existing at a specific date, which shall be true and correct as of such date) and the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date (or any Option Closing Date if such date is other than the Closing Date), and (iv) there has not been, subsequent to the date of the most recent audited financial statements included or incorporated by reference in the Pricing Disclosure Package, any material adverse change in the financial position or results of operations of the Company, or any change or development that, singularly or in the aggregate, would result in a Material Adverse Change.

4.4.2. Secretary's Certificate. At each of the Closing Date and the Option Closing Date, if any, the Representative shall have received a certificate of the Company signed by the Secretary of the Company, dated the Closing Date or the Option Date, as the case may be, respectively, certifying: (i) that each of the Charter and Bylaws is true and complete, has not been modified and is in full force and effect; (ii) that the resolutions of the Company's Board of Directors relating to the Offering are in full force and effect and have not been modified; (iii) as to the accuracy and completeness of all correspondence between the Company or its counsel and the Commission; and (iv) as to the incumbency of the officers of the Company. The documents referred to in such certificate shall be attached to such certificate.

4.5 No Material Changes. Prior to and on each of the Closing Date and each Option Closing Date, if any: (i) there shall have been no Material Adverse Change from the latest dates as of which such condition is set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (ii) no action, suit or proceeding, at law or in equity, shall have been pending or threatened against the Company or any Insider before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding would reasonably be expected to materially adversely affect the business, operations, prospects or financial condition or income of the Company, except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (iii) no stop order shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or to the Company's knowledge threatened by the Commission; and (iv) the Registration Statement, the Pricing Disclosure Package and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the Securities Act Regulations and shall conform in all material respects to the requirements of the Securities Act and the Securities Act Regulations, and neither the Registration Statement, the Pricing Disclosure Package nor the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

4.6 Delivery of Agreements.

4.6.1. Lock-Up Agreements. On or before the date of this Agreement, the Company shall have delivered to the Representative executed copies of the Lock-Up Agreements from each of the persons listed in Schedule 3 hereto.

4.6.2. Representative's Warrant Agreement. On the Closing Date, the Company shall have delivered to the Representative executed copies of the Representative's Warrant Agreement.

4.7 Additional Documents. At the Closing Date and at each Option Closing Date (if any) Representative Counsel shall have been furnished with such documents and opinions as they may require for the purpose of enabling Representative Counsel to deliver an opinion to the Underwriters, or in order to

evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Public Securities and the Representative's Securities as herein contemplated shall be satisfactory in form and substance to the Representative and Representative Counsel.

5. Indemnification.

5.1 Indemnification of the Underwriters.

5.1.1. General. Subject to the conditions set forth below, the Company agrees to indemnify and hold harmless each Underwriter, its affiliates and each of its and their respective directors, officers, members, employees, representatives, partners, shareholders, affiliates, counsel, and agents and each person, if any, who controls any such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (collectively the "**Underwriter Indemnified Parties**," and each an "**Underwriter Indemnified Party**"), against any and all loss, liability, claim, damage and expense whatsoever (including but not limited to any and all legal or other expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between any of the Underwriter Indemnified Parties and the Company or between any of the Underwriter Indemnified Parties and any third party, or otherwise) to which they or any of them may become subject under the Securities Act, the Exchange Act or any other statute or at common law or otherwise or under the laws of foreign countries (a "**Claim**"), (i) arising out of or based upon any untrue statement of a material fact contained in (A) the Registration Statement, the Pricing Disclosure Package, any Preliminary Prospectus, the Prospectus, or in any Issuer Free Writing Prospectus or in any Written Testing-the-Waters Communication (as from time to time each may be amended and supplemented); (B) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the Offering, including any "road show" or investor presentations made to investors by the Company (whether in person or electronically); or (C) any application or other document or written communication (in this Section 5, collectively called "application") executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Public Securities and Representative's Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, the Exchange or any other national securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon, and in conformity with, the Underwriters' Information or (ii) otherwise arising in connection with or allegedly in connection with the Offering. The Company also agrees that it will reimburse each Underwriter Indemnified Party for all reasonable and documented fees and expenses (including but not limited to any and all reasonable legal or other expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between any of the Underwriter Indemnified Parties and the Company or between any of the Underwriter Indemnified Parties and any third party, or otherwise) (collectively, the "**Expenses**"), and further agrees wherever and whenever possible to advance payment of Expenses as they are incurred by an Underwriter Indemnified Party in investigating, preparing, pursuing or defending any Claim.

5.1.2. Procedure. If any action is brought against an Underwriter Indemnified Party in respect of which indemnity may be sought against the Company pursuant to Section 5.1.1, such Underwriter Indemnified Party shall promptly notify the Company in writing of the institution of such action and the Company shall assume the defense of such action, including the employment and fees of counsel (subject to the approval of such Underwriter Indemnified Party) and payment of actual expenses if an Underwriter Indemnified Party requests that the Company do so. Such Underwriter Indemnified Party shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense

of the Company, and shall be advanced by the Company. The Company shall not be liable for any settlement of any action effected without its consent (which shall not be unreasonably withheld). In addition, the Company shall not, without the prior written consent of the Underwriters, settle, compromise or consent to the entry of any judgment in or otherwise seek to terminate any pending or threatened action in respect of which advancement, reimbursement, indemnification or contribution may be sought hereunder (whether or not such Underwriter Indemnified Party is a party thereto) unless such settlement, compromise, consent or termination (i) includes an unconditional release of each Underwriter Indemnified Party, acceptable to such Underwriter Indemnified Party, from all liabilities, expenses and claims arising out of such action for which indemnification or contribution may be sought and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any Underwriter Indemnified Party.

5.2 Indemnification of the Company. Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, its directors, its officers who signed the Registration Statement and persons who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the foregoing indemnity from the Company to the several Underwriters, as incurred, but only with respect to untrue statements or omissions made in the Registration Statement, any Preliminary Prospectus, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or in any application, in reliance upon, and in strict conformity with, the Underwriters' Information. In case any action shall be brought against the Company or any other person so indemnified based on any Preliminary Prospectus, the Registration Statement, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or any application, and in respect of which indemnity may be sought against any Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other person so indemnified shall have the rights and duties given to the several Underwriters by the provisions of Section 5.1.2. The Company agrees promptly to notify the Representative of the commencement of any litigation or proceedings against the Company or any of its officers, directors or any person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, in connection with the issuance and sale of the Public Securities or in connection with the Registration Statement, the Pricing Disclosure Package, the Prospectus, or any Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication.

5.3 Contribution.

5.3.1. Contribution Rights. If the indemnification provided for in this Section 5 shall for any reason be unavailable to or insufficient to hold harmless an indemnified party under Section 5.1 or 5.2 in respect of any loss, claim, damage or liability, or any action in respect thereof, referred to therein, then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid or payable by such indemnified party as a result of such loss, claim, damage or liability, or action in respect thereof, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other, from the Offering of the Public Securities, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other, with respect to the statements or omissions that resulted in such loss, claim, damage or liability, or action in respect thereof, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other, with respect to such Offering shall be deemed to be in the same proportion as the total net proceeds from the Offering of the Public Securities purchased under this Agreement (before deducting expenses) received by the Company, as set forth in the table on the cover page of the Prospectus, on the one hand, and the total underwriting discounts and commissions received by the Underwriters with respect to the shares of the Common Stock purchased under this Agreement, as set forth in the table on the cover page of the Prospectus, on the other hand. The relative fault shall be

determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 5.3.1 were to be determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, damage or liability, or action in respect thereof, referred to above in this Section 5.3.1 shall be deemed to include, for purposes of this Section 5.3.1, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 5.3.1 in no event shall an Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the Offering of the Public Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

5.3.2. Contribution Procedure. Within fifteen (15) days after receipt by any party to this Agreement (or its representative) of notice of the commencement of any action, suit or proceeding, such party will, if a claim for contribution in respect thereof is to be made against another party ("contributing party"), notify the contributing party of the commencement thereof, but the failure to so notify the contributing party will not relieve it from any liability which it may have to any other party other than for contribution hereunder. In case any such action, suit or proceeding is brought against any party, and such party notifies a contributing party or its representative of the commencement thereof within the aforesaid 15 days, the contributing party will be entitled to participate therein with the notifying party and any other contributing party similarly notified. Any such contributing party shall not be liable to any party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution without the written consent of such contributing party. The contribution provisions contained in this Section 5.3.2 are intended to supersede, to the extent permitted by law, any right to contribution under the Securities Act, the Exchange Act or otherwise available. Each Underwriter's obligations to contribute pursuant to this Section 5.3 are several and not joint.

6. Default by an Underwriter.

6.1 Default Not Exceeding 10% of Firm Shares or Option Shares. If any Underwriter or Underwriters shall default in its or their obligations to purchase the Firm Shares or the Option Shares, if the Over-allotment Option is exercised hereunder, and if the number of the Firm Shares or Option Shares with respect to which such default relates does not exceed in the aggregate 10% of the number of Firm Shares or Option Shares that all Underwriters have agreed to purchase hereunder, then such Firm Shares or Option Shares to which the default relates shall be purchased by the non-defaulting Underwriters in proportion to their respective commitments hereunder.

6.2 Default Exceeding 10% of Firm Shares or Option Shares. In the event that the default addressed in Section 6.1 relates to more than 10% of the Firm Shares or Option Shares, you may in your discretion arrange for yourself or for another party or parties to purchase such Firm Shares or Option Shares to which such default relates on the terms contained herein. If, within one (1) Business Day after such default relating to more than 10% of the Firm Shares or Option Shares, you do not arrange for the purchase of such Firm Shares or Option Shares, then the Company shall be entitled to a further period of one (1) Business Day within which to procure another party or parties satisfactory to you to purchase said Firm Shares or Option

Shares on such terms. In the event that neither you nor the Company arrange for the purchase of the Firm Shares or Option Shares to which a default relates as provided in this Section 6, this Agreement will automatically be terminated by you or the Company without liability on the part of the Company (except as provided in Sections 3.9 and 5 hereof) or the several Underwriters (except as provided in Section 5 hereof); provided, however, that if such default occurs with respect to the Option Shares, this Agreement will not terminate as to the Firm Shares; and provided, further, that nothing herein shall relieve a defaulting Underwriter of its liability, if any, to the other Underwriters and to the Company for damages occasioned by its default hereunder.

6.3 Postponement of Closing Date. In the event that the Firm Shares or Option Shares to which the default relates are to be purchased by the non-defaulting Underwriters, or are to be purchased by another party or parties as aforesaid, you or the Company shall have the right to postpone the Closing Date or Option Closing Date for a reasonable period, but not in any event exceeding five (5) Business Days, in order to effect whatever changes may thereby be made necessary in the Registration Statement, the Pricing Disclosure Package or the Prospectus or in any other documents and arrangements, and the Company agrees to file promptly any amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus that in the opinion of counsel for the Underwriter may thereby be made necessary. The term "Underwriter" as used in this Agreement shall include any party substituted under this Section 6 with like effect as if it had originally been a party to this Agreement with respect to such shares of Common Stock.

7. Additional Covenants.

7.1 Board Composition and Board Designations. The Company shall use its reasonable best efforts to ensure that: (i) the qualifications of the persons serving as members of the Board of Directors and the overall composition of the Board comply with the Sarbanes-Oxley Act, with the Exchange Act and with the listing rules of the Exchange or any other national securities exchange, as the case may be, in the event the Company seeks to have its Public Securities listed on another exchange or quoted on an automated quotation system, and (ii) if applicable, at least one member of the Audit Committee of the Board of Directors qualifies as an "audit committee financial expert," as such term is defined under Regulation S-K and the listing rules of the Exchange.

7.2 Prohibition on Press Releases and Public Announcements. The Company shall not issue press releases or engage in any other publicity, without the Representative's prior written consent, for a period ending at 5:00 p.m., Eastern time, on the first (1st) Business Day following the fortieth (40th) day after the Closing Date, other than normal and customary releases issued in the ordinary course of the Company's business.

7.3 Right of First Refusal. Provided that the Firm Shares are sold in accordance with the terms of this Agreement, the Representative shall have an irrevocable right of first refusal (the "**Right of First Refusal**"), for a period of fifteen (15) months after the date the Offering is completed, to act as sole and exclusive investment banker, sole and exclusive book-runner, sole and exclusive financial advisor, sole and exclusive underwriter and/or sole and exclusive placement agent, at the Representative's sole and exclusive discretion, for each and every future public and private equity and debt offering, including all equity linked financings (each, a "**Subject Transaction**"), during such fifteen (15) month period, of the Company, or any successor to or subsidiary of the Company, on terms and conditions customary to the Representative for such Subject Transactions. For the avoidance of any doubt, the Company shall not retain, engage or solicit any additional investment banker, book-runner, financial advisor, underwriter and/or placement agent in a Subject Transaction without the express written consent of the Representative.

The Company shall notify the Representative of its intention to pursue a Subject Transaction, including the material terms thereof, by providing written notice thereof by registered mail or overnight courier service addressed to the Representative. If the Representative fails to exercise its Right of First Refusal with respect to any Subject Transaction within ten (10) Business Days after the mailing of such written notice, then the Representative shall have no further claim or right with respect to the Subject Transaction. The Representative may elect, in its sole and absolute discretion, not to exercise its Right of First Refusal with respect to any Subject Transaction; provided that any such election by the Representative shall not adversely affect the Representative's Right of First Refusal with respect to any other Subject Transaction during the fifteen (15) month period agreed to above.

8. Effective Date of this Agreement and Termination Thereof.

8.1 Effective Date. This Agreement shall become effective when both the Company and the Representative have executed the same and delivered counterparts of such signatures to the other party.

8.2 Termination. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or in your opinion will in the immediate future materially disrupt, general securities markets in the United States; or (ii) if trading on the New York Stock Exchange or the Nasdaq Stock Market LLC shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction; or (iii) if the United States shall have become involved in a new war or an increase in major hostilities; or (iv) if a banking moratorium has been declared by a New York State or federal authority; or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets; or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in your opinion, make it inadvisable to proceed with the delivery of the Firm Shares or Option Shares; or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder; or (viii) if the Representative shall have become aware after the date hereof of such a material adverse change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative's judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Public Securities or to enforce contracts made by the Underwriters for the sale of the Public Securities.

8.3 Expenses. Notwithstanding anything to the contrary in this Agreement, except in the case of a default by the Underwriters, pursuant to Section 6.2 above, in the event that this Agreement shall not be carried out for any reason whatsoever, within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Underwriters their actual and accountable out-of-pocket expenses related to the transactions contemplated herein then due and payable (including the fees and disbursements of Representative Counsel) up to $200,000, inclusive of the $50,000 advance for accountable expenses previously paid by the Company to the Representative (the "**Advance**") and upon demand the Company shall pay the full amount thereof to the Representative on behalf of the Underwriters; ***provided, however, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement***. Notwithstanding the foregoing, any advance received by the Representative will be reimbursed to the Company to the extent not actually incurred in compliance with FINRA Rule 5110(f)(2)(C).

8.4 Indemnification. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Section 5 shall remain in full force and effect and shall not be in any way affected by, such election or termination or failure to carry out the terms of this Agreement or any part hereof.

8.5 Representations, Warranties, Agreements to Survive. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company or (ii) delivery of and payment for the Public Securities.

9. Miscellaneous.

9.1 Notices. All communications hereunder, except as herein otherwise specifically provided, shall be in writing and shall be mailed (registered or certified mail, return receipt requested), personally delivered, sent by facsimile transmission or sent by email transmission, and confirmed and shall be deemed given when so delivered or faxed or emailed and confirmed or if mailed, two (2) days after such mailing.

If to the Representative:

ThinkEquity
17 State Street, 22nd Fl
New York, NY 10004
Attn: Mr. Eric Lord, Head of Investment Banking
Fax: (212) 349-2550

with a copy (which shall not constitute notice) to:

Venable LLP
1270 Avenue of the Americas, 24th Floor
New York, NY 10020
Attn: Mr. William N. Haddad
Fax No.: (212) 307-5598

If to the Company:
MAIA Biotechnology, Inc.
4444 West Lake Street, Suite 1700
Chicago, IL 60606
Attention: Mr. Vlad Vitoc
Fax No: **[•]**
Email: vvitoc@maiabiotech.com

with a copy (which shall not constitute notice) to:
Loeb & Loeb LLP
345 Park Avenue
New York, NY 10154
Attention: Mr. Mitchell S. Nussbaum & Ms. Janeane R. Ferrari
Fax No: (212) 407-4990
Email: mnussbaum@loeb.com; jferrari@loeb.com

9.2 Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Agreement.

9.3 Amendment. This Agreement may only be amended by a written instrument executed by each of the parties hereto.

9.4 Entire Agreement. This Agreement (together with the other agreements and documents being delivered pursuant to or in connection with this Agreement) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof and thereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof. Notwithstanding anything to the contrary set forth herein, it is understood and agreed by the parties hereto that all other terms and conditions of that certain engagement letter between the Company and ThinkEquity LLC dated June 5, 2021, shall remain in full force and effect.

9.5 Binding Effect. This Agreement shall inure solely to the benefit of and shall be binding upon the Representative, the Underwriters, the Company and the controlling persons, directors and officers referred to in Section 5 hereof, and their respective successors, legal representatives, heirs and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Agreement or any provisions herein contained. The term "successors and assigns" shall not include a purchaser, in its capacity as such, of securities from any of the Underwriters.

9.6 Governing Law; Consent to Jurisdiction; Trial by Jury. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Agreement shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any such process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 9.1 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. Each of the Company and the Underwriters agree that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.7 Execution in Counterparts. This Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement, and shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Delivery of a signed counterpart of this Agreement by facsimile or email/pdf transmission shall constitute valid and sufficient delivery thereof.

9.8 Waiver, etc. The failure of any of the parties hereto to at any time enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor to in any way effect the validity of this Agreement or any provision hereof or the right of any of the parties hereto to thereafter enforce each and every provision of this Agreement. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Agreement shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

[Signature Page Follows]

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between us.

Very truly yours,

MAIA Biotechnology, Inc.

By: _____
Name:
Title:

Confirmed as of the date first written above mentioned, on behalf of itself and as Representative of the several Underwriters named on Schedule 1 hereto:

THINKEQUITY LLC

By: _____
Name:
Title:

SCHEDULE 1

Underwriter	Total Number of Firm Shares to be Purchased	Number of Additional Shares to be Purchased if the Over-Allotment Option is Fully Exercised
ThinkEquity LLC	[•]	[•]
TOTAL	[•]	[•]

SCHEDULE 2-A

Pricing Information

Number of Firm Shares: **[•]**

Number of Option Shares: **[•]**

Public Offering Price per Share: $**[•]**

Underwriting Discount per Share: $**[•]**

Underwriting Non-accountable expense allowance per Share: $**[•]**

Proceeds to Company per Share (before expenses): $**[•]**

SCHEDULE 2-B

Issuer General Use Free Writing Prospectuses

[None.]

SCHEDULE 2-C

Written Testing-the-Waters Communications

[None.]

SCHEDULE 3

List of Lock-Up Parties

[•]

EXHIBIT A
Form of Representative's Warrant Agreement

THE REGISTERED HOLDER OF THIS PURCHASE WARRANT BY ITS ACCEPTANCE HEREOF, AGREES THAT IT WILL NOT SELL, TRANSFER OR ASSIGN THIS PURCHASE WARRANT EXCEPT AS HEREIN PROVIDED AND THE REGISTERED HOLDER OF THIS PURCHASE WARRANT AGREES THAT IT WILL NOT SELL, TRANSFER, ASSIGN, PLEDGE OR HYPOTHECATE THIS PURCHASE WARRANT FOR A PERIOD OF ONE HUNDRED EIGHTY DAYS FOLLOWING THE EFFECTIVE DATE (DEFINED BELOW) TO ANYONE OTHER THAN (I) THINKEQUITY LLC, OR AN UNDERWRITER OR A SELECTED DEALER IN CONNECTION WITH THE OFFERING, OR (II) A BONA FIDE OFFICER OR PARTNER OF THINKEQUITY LLC OR OF ANY SUCH UNDERWRITER OR SELECTED DEALER.

THIS PURCHASE WARRANT IS NOT EXERCISABLE PRIOR TO [_____] [**DATE THAT IS [180 DAYS] FROM THE EFFECTIVE DATE OF THE OFFERING**]. VOID AFTER 5:00 P.M., EASTERN TIME, [_____] [**DATE THAT IS FIVE YEARS FROM THE EFFECTIVE DATE OF THE OFFERING**].

WARRANT TO PURCHASE COMMON STOCK
MAIA BIOTECHNOLOGY, INC.

Warrant Shares: _____

Initial Exercise Date: _____, 2022

THIS WARRANT TO PURCHASE COMMON STOCK (the "Warrant") certifies that, for value received, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after ____, 2022 (the "Initial Exercise Date") and, in accordance with FINRA Rule 5110(g)(8)(A), prior to at 5:00 p.m. (New York time) on the date that is five (5) years following the Effective Date (the "Termination Date") but not thereafter, to subscribe for and purchase from MAIA Biotechnology, Inc., a Delaware corporation (the "Company"), up to _____ shares of Common Stock, par value $0.0001 per share, of the Company (the "Warrant Shares"), as subject to adjustment hereunder. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Agreement, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Commission" means the United States Securities and Exchange Commission.

"Effective Date" means the effective date of the registration statement on Form S-1 (File No. [333-**[•]**), including any related prospectus or prospectuses, for the registration of the Company's Class A common stock, par value $0.0001 per share and the Warrant Shares under the Securities Act, that the Company has filed with the Commission.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Trading Day" means a day on which the New York Stock Exchange is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of a share of Common Stock for such date (or the nearest preceding date) on the OTCQB or OTCQX as applicable, (c) if Common Stock is not then listed or quoted for trading on the OTCQB or OTCQX and if prices for Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of the Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

Section 2. Exercise.

a) Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile copy (or e-mail attachment) of the Notice of Exercise Form annexed hereto. Within two (2) Trading Days following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within five (5) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise Form within two (2) Business Days of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be **$_____1**, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. In lieu of exercising this Warrant by delivering the Exercise Price by wire transfer or cashier's check, at the election of the Holder, this Warrant may also be exercised, in whole or in

part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive the number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;
(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

1 125% of the public offering price per share of common stock and warrant in the offering.

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a "cashless exercise," the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised, and the holding period of the Warrants being exercised may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by its transfer agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder, or (B) the Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 and, in either case, the Warrant Shares have been sold by the Holder prior to the Warrant Share Delivery Date (as defined below), and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is two (2) Trading Days after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). If the Warrant Shares can be delivered via DWAC, the transfer agent shall have received from the Company, at the expense of the Company, any legal opinions or other documentation required by it to deliver such Warrant Shares without legend (subject to receipt by the Company of reasonable back up documentation from the Holder, including with respect to affiliate status) and, if applicable and requested by the Company prior to the Warrant Share Delivery Date, the transfer agent shall have received from the Holder a

confirmation of sale of the Warrant Shares (provided the requirement of the Holder to provide a confirmation as to the sale of Warrant Shares shall not be applicable to the issuance of unlegended Warrant Shares upon a cashless exercise of this Warrant if the Warrant Shares are then eligible for resale pursuant to Rule 144(b)(1)). The Warrant Shares shall be deemed to have been issued, and Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such shares for all purposes, as of the date the Warrant has been exercised, with payment to the Company of the Exercise Price (or by cashless exercise, if permitted) and all taxes required to be paid by the Holder, if any, pursuant to Section 2(d)(vi) prior to the issuance of such shares, having been paid. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the second Trading Day following the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after the second Trading Day following such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause its transfer agent to deliver to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise; provided, however, that the Holder shall be required to return any Warrant Shares or Common Stock subject to any such rescinded exercise notice concurrently with the return to Holder of the aggregate Exercise Price paid to the Company for such Warrant Shares and the restoration of Holder's right to acquire such Warrant Shares pursuant to this Warrant (including, issuance of a replacement warrant certificate evidencing such restored right).

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause its transfer agent to transmit to the Holder the Warrant Shares pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing

herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all transfer agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

viii. Signature. This Section 2 and the exercise form attached hereto set forth the totality of the procedures required of the Holder in order to exercise this Purchase Warrant. Without limiting the preceding sentences, no ink-original exercise form shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any exercise form be required in order to exercise this Purchase Warrant. No additional legal opinion, other information or instructions shall be required of the Holder to exercise this Purchase Warrant. The Company shall honor exercises of this Purchase Warrant and shall deliver Shares underlying this Purchase Warrant in accordance with the terms, conditions and time periods set forth herein.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and

the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Company's transfer agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain

unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification. For the purposes of clarification, the Exercise Price of this Warrant will not be adjusted in the event that the Company or any Subsidiary thereof, as applicable, sells or grants any option to purchase, or sell or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any Common Stock or Common Stock Equivalents, at an effective price per share less than the Exercise Price then in effect.

b) [RESERVED]

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend (other than cash dividends) or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of shares or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such

Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation). To the extent that this Warrant has not been partially or completely exercised at the time of such Distribution, such portion of the Distribution shall be held in abeyance for the benefit of the Holder until the Holder has exercised this Warrant.

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable by holders of Common Stock as a result of such Fundamental Transaction for each share of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of

the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly mail to the Holder a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be mailed a notice to the Holder at its last address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to provide such notice or any defect therein shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. Pursuant to FINRA Rule 5110(e)(1), neither this Warrant nor any Warrant Shares issued upon exercise of this Warrant shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which this Warrant is being issued, except the transfer of any security:

i. by operation of law or by reason of reorganization of the Company;

ii. to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period;

iii. if the aggregate amount of securities of the Company held by the Holder or related person do not exceed 1% of the securities being offered;

iv. that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or

v. the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period.

Subject to the foregoing restriction, any applicable securities laws and the conditions set forth in Section 4(d), this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

d) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 5. Registration Rights.

5.1. Demand Registration.

5.1.1 Grant of Right. The Company, upon written demand (a "Demand Notice") of the Holder(s) of at least 51% of the Warrants and/or the underlying Warrant Shares ("Majority Holders"), agrees to register, on one occasion, all or any portion of the Warrant Shares underlying the Warrants (collectively, the "Registrable Securities"). On such occasion, the Company will file a registration statement with the Commission covering the Registrable Securities within sixty (60) days after receipt of a Demand Notice and use its reasonable best efforts to have the registration statement declared effective promptly thereafter, subject to compliance with review by the Commission; provided, however, that the Company shall not be required to comply with a Demand Notice if the Company has filed a registration statement with respect to which the Holder is entitled to piggyback registration rights pursuant to Section 5.2 hereof and either: (i) the Holder has elected to participate in the offering covered by such registration statement or (ii) if such registration statement relates to an underwritten primary offering of securities of the Company, until the offering covered by such registration statement has been withdrawn or until thirty (30) days after such offering is consummated. The demand for registration may be made at any time beginning on the Initial Exercise Date and expiring on the fifth anniversary of the Effective Date. The Company covenants and agrees to give written notice of its receipt of any Demand Notice by any Holder(s) to all other registered Holders of the Warrants and/or the Registrable Securities within ten (10) days after the date of the receipt of any such Demand Notice.

5.1.2 Terms. The Company shall bear all fees and expenses attendant to the registration of the Registrable Securities pursuant to Section 5.1.1, but the Holders shall pay any and all underwriting commissions and the expenses of any legal counsel selected by the Holders to represent them in connection with the sale of the Registrable Securities. The Company agrees to use its reasonable best efforts to cause the filing required herein to become effective promptly and to qualify or register the Registrable Securities in such States as are reasonably requested by the Holder(s); provided, however, that in no event shall the Company be required to register the Registrable Securities in a State in which such registration would cause: (i) the Company to be obligated to register or license to do business in such State or submit to general service of process in such State, or (ii) the principal shareholders of the Company to be obligated to escrow their shares of capital stock of the Company. The Company shall cause any registration statement filed pursuant to the demand right granted under Section 5.1.1 to remain effective for a period of at least twelve (12) consecutive months after the date that the Holders of the Registrable Securities covered by such registration statement are first given the opportunity to sell all of such securities. The Holders shall only use the prospectuses provided by the Company to sell the Warrant Shares covered by such registration statement, and will immediately cease to use any prospectus furnished by the Company if the Company advises the Holder that such prospectus may no longer be used due to a material misstatement or omission.

Notwithstanding the provisions of this Section 5.1.2, the Holder shall be entitled to a demand registration under this Section 5.1.2 on only one (1) occasion and such demand registration right shall terminate on the fifth anniversary of the date of the Underwriting Agreement (as defined below) in accordance with FINRA Rule 5110(g)(8)(C).

5.2 "Piggy-Back" Registration.

5.2.1 Grant of Right. In addition to the demand right of registration described in Section 5.1 hereof, the Holder shall have the right, for a period of no more than two (2) years from the Initial Exercise Date in accordance with FINRA Rule 5110(g)(8)(D), to include the Registrable Securities as part of any other registration of securities filed by the Company (other than in connection with a transaction contemplated by Rule 145(a) promulgated under the Securities Act or pursuant to Form S-8 or any equivalent form); provided, however, that if, solely in connection with any primary underwritten public offering for the account of the Company, the managing underwriter(s) thereof shall, in its reasonable discretion, impose a limitation on the number of Shares which may be included in the Registration Statement because, in such underwriter(s)' judgment, marketing or other factors dictate such limitation is necessary to facilitate public distribution, then the Company shall be obligated to include in such Registration Statement only such limited portion of the Registrable Securities with respect to which the Holder requested inclusion hereunder as the underwriter shall reasonably permit. Any exclusion of Registrable Securities shall be made pro rata among the Holders seeking to include Registrable Securities in proportion to the number of Registrable Securities sought to be included by such Holders; provided, however, that the Company shall not exclude any Registrable Securities unless the Company has first excluded all outstanding securities, the holders of which are not entitled to inclusion of such securities in such Registration Statement or are not entitled to pro rata inclusion with the Registrable Securities.

5.2.2 Terms. The Company shall bear all fees and expenses attendant to registering the Registrable Securities pursuant to Section 5.2.1 hereof, but the Holders shall pay any and all underwriting commissions and the expenses of any legal counsel selected by the Holders to represent them in connection with the sale of the Registrable Securities. In the event of such a proposed registration, the Company shall furnish the then Holders of outstanding Registrable Securities with not less than thirty (30) days written notice prior to the proposed date of filing of such registration statement. Such notice to the Holders shall continue to be given for each registration statement filed by the Company during the two (2) year period following the Initial Exercise Date until such time as all of the Registrable Securities have been sold by the Holder. The holders of the Registrable Securities shall exercise the "piggy-back" rights provided for herein by giving written notice within ten (10) days of the receipt of the Company's notice of its intention to file a registration statement. Except as otherwise provided in this Warrant, there shall be no limit on the number of times the Holder may request registration under this Section 5.2.2; provided, however, that such registration rights shall terminate on the second anniversary of the Initial Exercise Date.

5.3 General Terms

5.3.1 Indemnification. The Company shall indemnify the Holder(s) of the Registrable Securities to be sold pursuant to any registration statement hereunder and each person, if any, who controls such Holders within the meaning of Section 15 of the Securities Act or Section 20 (a) of the Exchange Act against all loss, claim, damage, expense or liability (including all reasonable attorneys' fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which any of them may become subject under the Securities Act, the Exchange Act or otherwise, arising from such registration statement but only to the same extent and with the same effect as the provisions pursuant to which the Company has agreed to indemnify the Underwriters contained in Section 5.1 of the Underwriting Agreement between the Underwriters and the Company, dated as of **[•]**, 2022. The Holder(s) of the

Registrable Securities to be sold pursuant to such registration statement, and their successors and assigns, shall severally, and not jointly, indemnify the Company, against all loss, claim, damage, expense or liability (including all reasonable attorneys' fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which they may become subject under the Securities Act, the Exchange Act or otherwise, arising from information furnished by or on behalf of such Holders, or their successors or assigns, in writing, for specific inclusion in such registration statement to the same extent and with the same effect as the provisions contained in Section 5.2 of the Underwriting Agreement pursuant to which the Underwriters have agreed to indemnify the Company.

5.3.2 Exercise of Warrants. Nothing contained in this Warrant shall be construed as requiring the Holder(s) to exercise their Warrants prior to or after the initial filing of any registration statement or the effectiveness thereof.

5.3.3 Documents Delivered to Holders. The Company shall furnish to each Holder participating in any of the foregoing offerings and to each underwriter of any such offering, if any, a signed counterpart, addressed to such Holder or underwriter, of: (i) an opinion of counsel to the Company, dated the effective date of such registration statement (and, if such registration includes an underwritten public offering, an opinion dated the date of the closing under any underwriting agreement related thereto), and (ii) a "cold comfort" letter dated the effective date of such registration statement (and, if such registration includes an underwritten public offering, a letter dated the date of the closing under the underwriting agreement) signed by the independent registered public accounting firm which has issued a report on the Company's financial statements included in such registration statement, in each case covering substantially the same matters with respect to such registration statement (and the prospectus included therein) and, in the case of such accountants' letter, with respect to events subsequent to the date of such financial statements, as are customarily covered in opinions of issuer's counsel and in accountants' letters delivered to underwriters in underwritten public offerings of securities. The Company shall also deliver promptly to each Holder participating in the offering requesting the correspondence and memoranda described below and to the managing underwriter, if any, copies of all correspondence between the Commission and the Company, its counsel or auditors and all memoranda relating to discussions with the Commission or its staff with respect to the registration statement and permit each Holder and underwriter to do such investigation, upon reasonable advance notice, with respect to information contained in or omitted from the registration statement as it deems reasonably necessary to comply with applicable securities laws or rules of FINRA. Such investigation shall include access to books, records and properties and opportunities to discuss the business of the Company with its officers and independent auditors, all to such reasonable extent and at such reasonable times as any such Holder shall reasonably request.

5.3.4 Underwriting Agreement. The Company shall enter into an underwriting agreement with the managing underwriter(s), if any, selected by any Holders whose Registrable Securities are being registered pursuant to this Section 5, which managing underwriter shall be reasonably satisfactory to the Company. Such agreement shall be reasonably satisfactory in form and substance to the Company, each Holder and such managing underwriters, and shall contain such representations, warranties and covenants by the Company and such other terms as are customarily contained in agreements of that type used by the managing underwriter. The Holders shall be parties to any underwriting agreement relating to an underwritten sale of their Registrable Securities and may, at their option, require that any or all the representations, warranties and covenants of the Company to or for the benefit of such underwriters shall also be made to and for the benefit of such Holders. Such Holders shall not be required to make any representations or warranties to or agreements with the Company or the underwriters except as they may relate to such Holders, their Warrant Shares and their intended methods of distribution.

5.3.5 Documents to be Delivered by Holder(s). Each of the Holder(s) participating in any of the foregoing offerings shall furnish to the Company a completed and executed questionnaire provided by the Company requesting information customarily sought of selling security holders.

5.3.6 Damages. Should the registration or the effectiveness thereof required by Sections 5.1 and 5.2 hereof be delayed by the Company or the Company otherwise fails to comply with such provisions, the Holder(s) shall, in addition to any other legal or other relief available to the Holder(s), be entitled to obtain specific performance or other equitable (including injunctive) relief against the threatened breach of such provisions or the continuation of any such breach, without the necessity of proving actual damages and without the necessity of posting bond or other security.

Section 6. Miscellaneous.

a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i).

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then, such action may be taken or such right may be exercised on the next succeeding Trading Day.
d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment.

Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use reasonable best efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the underwriting agreement, dated **[•]** 2022, by and between the Company and ThinkEquity LLC as representatives of the underwriters set forth therein (the "Underwriting Agreement").

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant or the Underwriting Agreement, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Underwriting Agreement.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant

are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

MAIA BIOTECHNOLOGY, INC.

By: _____
Name:
Title:

NOTICE OF EXERCISE

TO: MAIA BIOTECHNOLOGY, INC.

_____

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please register and issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number or by physical delivery of a certificate to:

_____

_____

_____

(4) Accredited Investor. If the Warrant is being exercised via cash exercise, the undersigned is an "accredited investor" as defined in Regulation D promulgated under the Securities Act of 1933, as amended

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing warrant, execute
this form and supply required information.
Do not use this form to exercise the warrant.)

FOR VALUE RECEIVED, [____] all of or [_____] shares of the foregoing Warrant and all rights evidenced thereby are hereby assigned to _____ whose address is _____.

_____

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

_____

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatsoever. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

EXHIBIT B
Lock-Up Agreement

[•], 2022

ThinkEquity LLC
17 State Street, 22nd Floor
New York, NY 10004
As Representative of the several Underwriters named on Schedule 1 to the Underwriting Agreement referenced below
Ladies and Gentlemen:

The undersigned understands that ThinkEquity LLC (the "**Representative**"), proposes to enter into an Underwriting Agreement (the "**Underwriting Agreement**") with Maia Biotechnology, Inc., a Delaware corporation (the "**Company**"), providing for the initial public offering (the "**Public Offering**") of shares of common stock, par value $0.0001 per share, of the Company (the "**Common Shares**").

To induce the Representative to continue its efforts in connection with the Public Offering, the undersigned hereby agrees that, without the prior written consent of the Representative, the undersigned will not, during the period commencing on the date hereof and ending [twelve (12) months][1] [six (6) months][2] after the date of the Underwriting Agreement relating to the Public Offering (the "**Lock-Up Period**"), (1) offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, any Common Shares or any securities convertible into or exercisable or exchangeable for Common Shares, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition (collectively, the "**Lock-Up Securities**"); (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Lock-Up Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Lock-Up Securities, in cash or otherwise; (3) make any demand for or exercise any right with respect to the registration of any Lock-Up Securities; or (4) publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement relating to any Lock-Up Securities; except that for any securities held by the holders of the options with a weighted average exercise price of $1.80 or $1.83, the Lock-Up Period shall be twelve (12) months. Notwithstanding the foregoing, and subject to the conditions below, the foregoing sentence shall not apply to (a) transactions relating to Common Shares or other securities of the Company acquired in the initial Public Offering or in open market transactions after the completion of the Public Offering; provided, however, that no filing under Section 13 or Section 16(a) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or other public announcement shall be required or shall be voluntarily made in connection with subsequent sales of Common Shares or other securities of the Company acquired in the initial Public Offering or open market transactions; (b) transfers of Lock-Up Securities as a *bona fide* gift, by will or intestacy or to a family member or trust for the benefit of the undersigned or a family member (for purposes of this lock-up agreement, "family member" means any relationship by blood, marriage or adoption, not more remote than first cousin); (c) transfers of Lock-Up Securities to a charity or educational institution; (d) if the undersigned is a corporation, partnership, limited liability company or other business entity, (

[1] NTD: Applicable to all insiders, which shall mean directors, officers, ex-directors, ex-officers, and 10% or greater holders.

[2] NTD: Applicable to all non-insiders, which shall mean persons other than insiders.

i) any transfers of Lock-Up Securities to another corporation, partnership or other business entity that controls, is controlled by or is under common control with the undersigned or (ii) distributions of Lock-Up Securities to members, partners, stockholders, subsidiaries or affiliates (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned; (e) if the undersigned is a trust, to a trustee or beneficiary of the trust; and (f) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (b), (c), (d) or (e) above; provided that in the case of any transfer pursuant to the foregoing clauses (b), (c) (d), (e) or (f), (i) any such transfer shall not involve a disposition for value, (ii) each transferee shall sign and deliver to the Representative a lock-up agreement substantially in the form of this lock-up agreement and (iii) no filing under Section 13 or Section 16(a) of the Exchange Act or other public announcement shall be required or shall be voluntarily made; (f) the receipt by the undersigned from the Company of Common Shares upon the vesting of restricted stock awards or stock units or upon the exercise of options to purchase the Company's Common Shares issued under an equity incentive plan of the Company or an employment arrangement described in the Pricing Prospectus (as defined in the Underwriting Agreement) (the "**Plan Shares**") or the transfer of Common Shares or any securities convertible into Common Shares to the Company upon a vesting event of the Company's securities or upon the exercise of options to purchase the Company's securities, in each case on a "cashless" or "net exercise" basis or to cover tax obligations of the undersigned in connection with such vesting or exercise, but only to the extent such right expires during the Lock-up Period, provided that no filing under Section 13 or Section 16(a) of the Exchange Act or other public announcement shall be required or shall be voluntarily made within 90 days after the date of the Underwriting Agreement, and after such 90th day, if the undersigned is required to file a report under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of Common Shares during the Lock-Up Period, the undersigned shall include a statement in such schedule or report to the effect that the purpose of such transfer was to cover tax withholding obligations of the undersigned in connection with such vesting or exercise and, provided further, that the Plan Shares shall be subject to the terms of this lock-up agreement; (g) the transfer of Lock-Up Securities pursuant to agreements described in the Pricing Prospectus under which the Company has the option to repurchase such securities or a right of first refusal with respect to the transfer of such securities, provided that if the undersigned is required to file a report under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of Common Shares during the Lock-Up Period, the undersigned shall include a statement in such schedule or report describing the purpose of the transaction; (h) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Lock-Up Securities, provided that (i) such plan does not provide for the transfer of Lock-Up Securities during the Lock-Up Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such public announcement or filing shall include a statement to the effect that no transfer of Lock-Up Securities may be made under such plan during the Lock-Up Period; **[**(i) the conversion of the outstanding preferred stock of the Company into Common Shares, provided that such Common Shares remain subject to the terms of this agreement;**]2** (j) the transfer of Lock-Up Securities to the Company from an employee or director of the Company upon death, disability or termination of employment, in each case, of such employee or director; and (k) the transfer of Lock-Up Securities that occurs by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, provided that the transferee agrees to sign and deliver a lock-up agreement substantially in the form of this lock-up agreement for the balance of the Lock-Up Period, and provided further, that any filing under Section 13 or Section 16(a) of the Exchange Act that is required to be made during the Lock-Up Period as a result of such transfer shall include a statement that such transfer has occurred by operation of law; and (k) the transfer of Lock-Up Securities pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of the Common Shares involving a change of control (as defined below) of the Company after the closing of the Public Offering and approved by the Company's board of directors; provided that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Lock-Up Securities owned by the undersigned shall remain subject to the restrictions contained in this lock-up agreement. For purposes of clause (k) above, "change of control" shall mean the consummation of any bona fide third party tender offer, merger, amalgamation, consolidation or other similar transaction the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of a majority of total voting power of the voting stock of the Company. In the event that a non-insider of the Company purchases any securities in the Public Offering, then such securities purchased as part of the Public Offering shall be excluded from the definition of the Lock-Up Securities.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's Lock-Up Securities except in compliance with this lock-up agreement.

If the undersigned is an officer or director of the Company, (i) the undersigned agrees that the foregoing restrictions shall be equally applicable to any issuer-directed or "friends and family" Securities that the undersigned may purchase in the Public Offering; (ii) the Representative agrees that, at least three (3) business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of Lock-Up Securities, the Representative will notify the Company of the impending release or waiver; and (iii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two (2) business days before the effective date of the release or waiver. Any release or waiver granted by the Representative hereunder to any such officer or director shall only be effective two (2) business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer of Lock-Up Securities not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this lock-up agreement to the extent and for the duration that such terms remain in effect at the time of such transfer.

No provision of this Lock-Up Agreement shall be deemed to restrict or prohibit the exercise, exchange or conversion by the undersigned of any securities exercisable, exchangeable for or convertible into Common Shares as applicable, provided, that, the undersigned does not transfer Common Shares acquired on such exercise, exchange or conversion during the Lock-Up Period, unless otherwise permitted under the terms of this Lock-Up Agreement.

The undersigned understands that the Company and the Representative are relying upon this lock-up agreement in proceeding toward consummation of the Public Offering. The undersigned further understands that this lock-up agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns.

The undersigned understands that, if the Underwriting Agreement is not executed by **[•]**, or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Shares to be sold thereunder, then this lock-up agreement shall be void and of no further force or effect.

Whether or not the Public Offering actually occurs depends on a number of factors, including market conditions. Any Public Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Representative.

Very truly yours,

_____
(Name - Please Print)

_____
(Signature)

_____
(Name of Signatory, in the case of entities - Please Print)

_____
(Title of Signatory, in the case of entities - Please Print)
Address: _____

_____

_____

EXHIBIT C
Form of Press Release

MAIA BIOTECHNOLOGY, INC.

[Date]
MAIA Biotechnology, Inc. (the "Company") announced today that Think Equity LLC, acting as representative for the underwriters in the Company's recent public offering of _____ shares of the Company's common stock, is [waiving] [releasing] a lock-up restriction with respect to _____ shares of the Company's common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on _____, 20___, and the shares may be sold on or after such date.

This press release is not an offer or sale of the securities in the United States or in any other jurisdiction where such offer or sale is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the Securities Act of 1933, as amended.

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

SUPPLY AND NON-EXCLUSIVE LICENSE AGREEMENT

This **Supply and Non-Exclusive License Agreement ("Agreement")**, made as of February 1, 2021 (the **"Effective Date"**), is by and between **Regeneron Pharmaceuticals, Inc. ("Regeneron")**, having a place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591-6707 and MAIA Biotechnology, Inc. operating through its wholly owned subsidiary, THIO Therapeutics, Inc. **("Sponsor")**, having a place of business at 444 West Lake Street, Suite 1700, Chicago, IL 60606. Regeneron and Sponsor are each referred to herein individually as **"Party"** and collectively **"Parties".**

RECITALS

WHEREAS, Sponsor is developing the Sponsor Product;

WHEREAS, Regeneron is developing the Regeneron Product;

WHEREAS, Sponsor desires to sponsor and perform one or more clinical trials for the treatment of patients with various types of cancer, in which the Sponsor Product and the Regeneron Product would be dosed in sequential combination, as more particularly described in the Protocol for such clinical trial; and

WHEREAS, Regeneron desires to supply the Regeneron Product for the performance of each such clinical trial, and Sponsor and Regeneron otherwise desire to cooperate in connection with the performance of each such trial, all on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

1. DEFINITIONS. For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

1.1. **"Affiliate"** means, with respect to either Party, a firm, corporation or other entity which directly or indirectly owns or controls said Party, or is owned or controlled by said Party, or is under common ownership or control with said Party. The word **"control"** means (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, or (ii) possession, directly or indirectly, of the power to direct the management or policies

of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

1.2. **"Agreement"** means this agreement, as amended by the Parties from time to time, and as set forth in Section 18 below, together with all appendices attached or deemed attached hereto.

1.3. **"Applicable Law"** means applicable federal, state, local, national and supranational laws, statutes, rules and regulations of a Governmental Authority, including any rules, regulations, guidelines or other requirements of any Regulatory Authority, that may be in effect from time to time during the Term and applicable to a particular activity hereunder, including: export control and economic sanctions regulations which prohibit the shipment of United States origin products and technology to certain restricted countries, entities and individuals; all applicable data protection requirements such as those specified in the EU Data Protection Directive (if applicable) and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"); and laws and regulations governing payments to healthcare providers.

1.4. "**Business Day**" means any day other than a Saturday, Sunday, any public holiday or a day on which commercial banks are authorized or required by law to be closed in the country where the applicable obligations are to be performed.

1.5. "**cGMP**" means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Products.

1.6. "**Clinical Supply Quality Agreement**" means a clinical supply quality agreement entered into by the Parties for a particular Study in accordance with Section 9.11.

1.7. "**CMC**" means, with respect to a Product, the information contained in (or that would be contained in) the chemistry, manufacturing and controls section of an IND or application for Regulatory Approval for such Product in the United States, or the equivalent section of corresponding regulatory filings made outside the United States. For the avoidance of doubt, the information described in the preceding sentence is CMC information regardless of what document it is contained in or the form in which it is disclosed.

1.8. "**Combination**" means the use or method of using the Sponsor Product and the Regeneron Product in concomitant or sequential administration.

1.9. "**Combination Invention**" means any Invention, the practice of which necessarily requires the presence or direct use of both the Sponsor Product or a Telomere Targeting Product, on the one hand, and the Regeneron Product or a PD-1 Antagonist, on the other hand.

1.10. "**Combination Patent Applications**" has the meaning set forth in Section 11.4.

1.11. "**Combination Patents**" has the meaning set forth in Section 11.4.

1.12. "**Confidential Information**" means any confidential and proprietary information or Know-How furnished or otherwise made available to one Party by the other Party pursuant to this Agreement or generated in the performance of this Agreement, except to the extent that it can be established by the receiving Party that such information or Know-How: (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party as demonstrated by competent business records; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (d) was disclosed to the receiving Party by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or (e) was independently developed by the receiving Party without use of or access or reference to the disclosing Party's Confidential Information, as demonstrated by competent business records.

1.13. "**Control**" and "**Controlled by**" means, with respect to any Patent, data or other intellectual property right, possession by a Party or its Affiliates (whether by ownership, license grant or other means) of the legal right to grant the right to access or use, or to grant a license or a sublicense to, such Patent, data or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement between such Party (or any of its Affiliates) and any Third Party.

1.14. "**Delivery**" has the meaning set forth in Section 9.3 with respect to delivery of the Regeneron Product, and Section 9.4 with respect to the Sponsor Product.

1.15. "**Effective Date**" has the meaning set forth in the preamble.

1.16. "**EMA**" means the European Medicines Agency and any successor agency(ies) or authority having substantially the same function.

1.17. "**Exclusions List**" has the meaning set forth in the definition of Violation.

1.18. "**FDA**" means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

1.19. "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.20. "**Force Majeure**" has the meaning set forth in Article 17.

1.21. **1.21.** "**Forecast**" has the meaning set forth in Section 9.2.

1.22. "**GCP**" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Products.

1.23. "**Government Official**" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international or multilateral organization such as the World Bank, United Nations or the World Health Organization; who, when such Government Official is acting in an official capacity, or in an official decision making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions for or on behalf of a government or any department, agency, or instrument of a government with the potential to affect the activities of either of the Parties under this Agreement.

1.24. **"Governmental Authority"** means any court, agency, department, authority or other instrumentality of any national, supra-national, state, county, city or other political subdivision.

1.25. **"HIPAA"** has the meaning set forth in the definition of Applicable Law.

1.26. **"Invention"** means any development, modification, invention, derivative work or improvement, in each case whether or not patentable, including any Know How, and whether or not protectable as Intellectual Property, which is discovered, conceived, reduced to practice or developed or otherwise made by or on behalf of either Party or any of their Representatives in the performance of a Study Plan hereunder or otherwise generated in the performance of this Agreement.

1.27. **"IND"** means an application filed with a Regulatory Authority for authorization to commence clinical trials, including (a) an Investigational New Drug Application as defined in the FFDCA or any successor application or procedure filed with the FDA, (b) any equivalent of a United States IND in other countries or regulatory jurisdictions, (e.g., clinical trial application (CTA)), and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.28. **"Intellectual Property"** means any and all of the following rights whether protected, created or arising under Applicable Law in the United States or any other jurisdiction: ideas, inventions, conceptions, Know-How, data, compositions, results, databases, documentation, reports, materials, writings, and other information, including Patents, trade secrets, registered designs, design rights, copyrights (including rights in computer software and database rights), whether registered or not, and all legal means of establishing rights in and to and the aforesaid rights or property similar to any of the foregoing, in any part of the world, together with the rights to apply for the registration of any such right. For the avoidance of doubt, Intellectual Property for purposes of this Agreement expressly excludes all Trademark rights.

1.29. **"IRB/EC"** has the meaning set forth in Section 4.1.

1.30. **"Joint Patent Application"** has the meaning set forth in Section 11.6.

1.31. **"Joint Patents"** has the meaning set forth in Section 11.6.

1.32. **"Jointly Owned Invention"** has the meaning set forth in Section 11.5.

1.33. **"Know-How"** means any proprietary information, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

1.34. **"Liability"** has the meaning set forth in Section 15.2.1.

1.35. **"Manufacture," "Manufactured,"** or **"Manufacturing"** means all stages of the manufacture of a Product, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

1.36. **"Non-Conformance"** means, with respect to any Product, such Product deviates from (a) the applicable specifications for such Product (including, in the case of the Regeneron Product, the Specifications) or (b) any Applicable Law, including cGMP or health, safety or environmental protections.

1.37. **"Party"** has the meaning set forth in the preamble.

1.38. **"Patents"** means patents, patent disclosures and applications (including all patents issuing thereon), statutory invention registrations, divisionals, continuations, continuations-in-part, substitute applications of the foregoing and any extensions, reissues, restorations and reexaminations thereof, and all patent rights provided by international treaties or conventions, whether created or arising under the laws of the United States or any other jurisdiction.

1.39. **"PD-1 Antagonist"** means any molecule that selectively binds to and interferes with or otherwise blocks signaling of the programmed cell death 1 receptor (PD-1) pathway, other than the Regeneron Product.

1.40. **"Person"** means any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, entity or governmental entity.

1.41. **"Pharmacovigilance Agreement"** means a pharmacovigilance agreement entered into by the Parties for a particular Study with respect to the exchange of safety information related to the Regeneron Product (alone or in the Combination) as set forth in Section 4.5.

1.42. **"Product"** means the Sponsor Product or the Regeneron Product.

1.43. **"Project Manager"** has the meaning set forth in Section 2.5.

1.44. **"Protocol"** means a written protocol created pursuant to Section 5.1 for a particular Study, that describes such Study and sets forth specific activities to be performed as part of such Study, as such protocol may be amended from time to time by the Parties.

1.45. **"Protocol Synopsis"** means a written summary of the procedural method and design of the applicable Study. A Protocol Synopsis for the initial Study is attached hereto as Appendix A.

1.46. **"Regeneron"** has the meaning set forth in the preamble.

1.47. "**Regeneron Indemnitees**" has the meaning set forth in Section 15.2.1.

1.48. "**Regeneron Invention**" means any Invention, the practice of which necessarily requires the presence or direct use of the Regeneron Product or a PD-1 Antagonist or which requires the practice of any Regeneron Intellectual Property, and which is not a Sponsor Invention or Combination Invention

1.49. **"Regeneron Intellectual Property"** means Intellectual Property Controlled by Regeneron as of the Effective Date or during the Term pertaining to the Regeneron Product or a PD-1 Antagonist, including all such Intellectual Property of Regeneron that is provided to Sponsor under this Agreement or that is reasonably necessary for the conduct of a Study in accordance with this Agreement.

1.50. "**Regeneron Product**" means LIBTAYO® (cemiplimab).

1.51. "**Regulatory Approvals**" means, with respect to a Product and a country, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation, use (including use in clinical trials), distribution, sale or marketing of such Product in such country, including any pricing or reimbursement approvals.

1.52. "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council or other entity (e.g., the FDA and EMA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the development and commercialization of Products in the Territory.

1.53. "**Representatives**" means, with respect to a Party, its Affiliates or any employees, directors, contractors, agents or consultants of such Party or its Affiliates.

1.54. "**Restricted Period**" means,[***]

1.55. [***]

1.56. "**SCC Dispute**" has the meaning set forth in Section 2.4.

1.57. "**Sponsor**" has the meaning set forth in the preamble.

1.58. "**Sponsor Indemnitees**" has the meaning set forth in Section 15.2.2.

1.59. "**Sponsor Intellectual Property**" means Intellectual Property Controlled by Sponsor as of the Effective Date or during the Term pertaining to Sponsor Product or Telomere Targeting Product, including all Intellectual Property of Sponsor that is provided to Regeneron under this Agreement or that is reasonably necessary for the conduct of a Study in accordance with this Agreement.

1.60. **"Sponsor Intellectual Property Agreements"** means any license or other agreement pursuant to which Sponsor Controls any Sponsor Intellectual Property and which is listed in Appendix C hereto.

1.61. **"Sponsor Invention"** means any Invention, the practice of which necessarily requires the presence or direct use of the Sponsor Product or a Telomere Targeting Product, or which requires the practice of any Sponsor Intellectual Property, and which is not a Regeneron Invention or Combination Invention.

1.62. **"Sponsor Product"** means, for a particular Study, the product set forth in the Study Plan for such Study.

1.63. **"Specifications"** means, with respect to Regeneron Product, the set of specifications for such Product as set forth in the applicable Clinical Supply Quality Agreement.

1.64. **"Study"** means each clinical trial to be conducted by Sponsor under this Agreement pursuant to an executed Study Plan involving the concomitant or sequenced administration of the Combination for the treatment of patients in the applicable Study Field, as more particularly described in the applicable Protocol.

1.65. **"Study Completion"** has the meaning set forth in Section 3.9.

1.66. **"Study Coordination Committee"** or **"SCC"** has the meaning set forth in Section 2.1.

1.67. **"Study Data"** means, with respect to a particular Study, all data (including raw data) and results (including Study Results) generated in the performance of the Study Plan for such Study and including results obtained from testing or analysis of biological samples as part of a Study pursuant to the Protocol, if applicable, and any relevant monotherapy data generated in the course of the Study pertaining to the Sponsor Product within the Study Field.

1.68. **"Study Field"** means, with respect to a particular Study, the specific type(s) of cancer identified in the Study Plan.

1.69. **"Study Plan"** means, with respect to a particular Study, the plan, as it may be amended from time to time upon mutual written agreement of the Parties, for the clinical evaluation of the Combination in such Study. The initial Study Plan for the first Study is attached hereto, as Appendix B.

1.70. **"Study Results"** has the meaning set forth in Section 3.9.

1.71. **[***]**

1.72. "**Term**" has the meaning set forth in Section 7.1.

1.73. "**Territory**" means worldwide.

1.74. "**Third Party**" means any Person other than Sponsor, Regeneron or their respective Affiliates.

1.75. **"Trademark"** means any trademark, trade name, service mark, service name, brand, trade dress, logo, slogan, tag line or other indicia or origin of ownership, whether registered or unregistered, including the goodwill and goods and services associated therewith.

1.76. "**Transfer**" shall mean any sale, license, transfer, other disposal or the granting of any option to do any of the foregoing.

1.77. "**Violation**" means that a Party or any of its officers or directors or any other personnel (or other permitted agents of a Party performing activities hereunder) has been: (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (http://oig.hhs.gov/exclusions/authorities.asp); (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (http://exclusions.oig.hhs.gov/) or listed as having an active exclusion in the System for Award Management (http://www.sam.gov); (3) listed by any US Federal agency as being suspended, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) (each of (1), (2) and (3) collectively the "**Exclusions Lists**"); or (4) otherwise ineligible under Applicable Law (including United States law or any foreign equivalent) or any government programs for the performance of the Study or any other activities under this Agreement.

2. STUDY COORDINATION.

2.1. **Formation.** As soon as practical after the Effective Date (but in all cases within thirty (30) days thereafter), the Parties shall form a study coordination committee (the **"Study Coordination Committee"** or "**SCC**"), made up of an equal number of representatives of Regeneron and Sponsor. SCC members will be agreed by both Parties, such agreement not to be unreasonably withheld or delayed.

2.2. **Meetings.** The SCC shall meet as soon as practicable after the Effective Date (with respect to the initial Study) or the effective date of each Study Plan (for each other Study) and then once each calendar quarter, or at such other frequency as is mutually determined by the Parties, until the Study Results for the applicable Study have been provided to Regeneron.

2.3. **Role.** The SCC shall have the responsibility of coordinating and overseeing the conduct of each Study (and other related activities set forth in the applicable Study Plan, including regulatory activities) and shall enable the exchange of information between the Parties. In particular, the SCC is empowered to:

(i) serve as a forum for discussing Study activities;

(ii) review and approve the initial Study Plan for each Study and any amendments to the applicable Study Plan; for clarity, Regeneron's approval shall only be required for decisions relating to the Combination or the Regeneron Product;

(iii) review and approve the applicable Protocol for each Study and any amendments thereto; for clarity, Regeneron's approval shall only be required for decisions relating to the Combination or the Regeneron Product;

(iv) serve as a forum for discussing strategies to obtain Regulatory Approvals necessary to conduct the applicable Study and for coordinating all regulatory activities (including communications with Regulatory Authorities) for the applicable Study;

(v) serve as a forum for discussing strategies for any diagnostic product to be included in the applicable Study (including the selection of any Third Party to develop or provide any such diagnostic product for the applicable Study);

(vi) serve as a forum for discussing matters relating to supply and Manufacturing, including Forecasts, specifications, Delivery and Non-Conformances;

(vii) establish and oversee joint sub-teams agreed by the Parties to oversee particular projects or activities within the purview of the SCC; and

(viii) perform such other functions as are set forth herein, or as the Parties may mutually agree in writing.

2.4. **Decision Making.** The SCC will attempt to reach decisions by consensus, with the Sponsor representatives having collectively one vote and the Regeneron representatives having collectively one vote. If consensus is not achieved on any matter within thirty (30) days ("**SCC Dispute**"), the matter will be escalated to the Sponsor CEO and the Regeneron Senior Vice President, Global Clinical Development, provided however that (1) in the event that the matter relates solely to the Regeneron Product (including the dose and dosing regimen for the Regeneron Product) or any diagnostic for the Regeneron Product alone, Regeneron shall have final decision making authority and (2) in the event that the matter relates solely to the Sponsor Product (including the dose and dosing regimen for the Sponsor Product) or any diagnostic for the Sponsor Product alone, Sponsor shall have final decision making authority. If such SCC Dispute is not addressed by clause (1) or (2) of the previous sentence, the dispute shall be resolved as provided for in Article 23.

2.5. **Project Manager.** Each Party shall designate a project manager (the "**Project Manager**") who shall be responsible for implementing and coordinating activities, and facilitating the exchange of information between the Parties, with respect to a given Study. The Project

Managers shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information and shall serve as the primary point of contact for any issues arising under this Agreement. The Project Managers shall have the right to attend all SCC meetings and may bring to the attention of the SCC any matters or issues either of them reasonably believes should be discussed and shall have such other responsibilities as the Parties may mutually agree in writing. Prior to any meeting of the SCC, the Sponsor Project Manager shall provide an update in writing to the Regeneron Project Manager, which update shall contain information about overall Study progress, recruitment status, interim analysis (if results are available), final analysis and other information relevant to the conduct of the applicable Study and the applicable Study Data.

3. CONDUCT OF THE STUDY.

3.1. **General; Study Plans.** The Parties shall perform the initial Study in accordance with this Agreement, including the Study Plan for such Study, which is attached hereto. For each other Study that the Parties agree to perform under this Agreement, the Parties are to complete and execute a Study Plan, which, among other items, shall include the Protocol Synopsis or the Protocol for such Study and the obligations and activities to be performed by each Party in connection with such Study (including regulatory activities). Each Study Plan, once mutually agreed, shall be signed by an authorized representative of each Party and, once fully executed, shall be deemed incorporated into this Agreement by this reference. Sponsor shall act as the sponsor of each Study and shall hold each IND relating to each Study. Sponsor shall be solely responsible for designing each Study and for the Protocol therefor, provided that the SCC shall review and approve the Protocol pursuant to Section 2.3 and subject to each Party's decision-making rights as set forth in Section 5.2.

3.2. **Compliance.** Subject to Section 5.2, Sponsor shall be responsible for operational execution and management of, and will use commercially reasonable efforts to conduct, each Study. Sponsor shall ensure with respect to itself and its Affiliates that each Study is performed in accordance with: this Agreement, the Protocol for such Study, and all Applicable Laws, including GCP. Sponsor shall ensure that it has a valid and enforceable agreement with each of its subcontractors performing activities under this Agreement that obligates such subcontractor to perform each Study in accordance with this Agreement, the Protocol for such Study, and all Applicable Laws, including GCP.

3.3. **No Violation.** Neither Party shall knowingly employ or subcontract with any Person that is in Violation. Each Party shall notify the other Party in writing immediately if any such Violation comes to its attention with respect to any Person performing activities under this Agreement, and shall, with respect to any such Person in Violation, promptly remove such Person from performing activities or acting in any function or capacity related to any Study or otherwise related to activities under this Agreement.

3.4. **Records and Reports.** Each Party shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law in connection with each Study. Sponsor shall provide to Regeneron all Study information and documentation reasonably requested by Regeneron to enable Regeneron to (i) comply with any of its legal, regulatory and/or contractual obligations, or any request by any Regulatory Authority, related to

the Regeneron Product or (ii) determine whether the applicable Study has been performed in accordance with this Agreement.

3.5. **Consent.** Sponsor shall ensure that all patient authorizations and consents required under HIPAA, the General Data Protection Regulation (Regulation (EU) 2016/679) (if applicable) or any other similar Applicable Law in connection with each Study are obtained, are valid and permit the sharing of Study Data with Regeneron.

3.6. **Study Data Ownership and Copies.** Study Data will be owned by the Party who owns the respective Product to which the Study Data specifically pertains. Where Study Data pertains to either the Combination or the use of the Combination in the Study Field, the Parties shall own such data and information jointly. [***]

3.7. **Restrictions on Use.** Except as expressly set forth in this Agreement, each Party shall be permitted to use Study Data for any and all purposes; *provided* that each Party shall maintain Study Data as confidential and shall not disclose Study Data to any Third Party except that:

3.7.1. [***]

3.7.2. [***]

3.7.3. [***]

3.7.4. [***]

3.7.5. [***]

3.7.6. [***]

3.7.7. [***]

3.7.8. [***]

Notwithstanding the foregoing, Sponsor will not, without Regeneron's prior written consent, disclose to any Third Party or otherwise make available in any disclosure, any Study Data regarding the safety or efficacy of the Regeneron Product alone and Regeneron will not, without Sponsor's consent, disclose to any Third Party (other than Sanofi) or otherwise make available in any disclosure any Study Data regarding the safety or efficacy of the Sponsor Product alone, in each case, to the extent such Study Data is not otherwise publicly available and unless otherwise required by Applicable Law.

3.8. **Samples.** Each Party shall have the right to use biological samples obtained from subjects in each Study ("**Samples**") for the purposes set forth in the applicable Study Plan. [***]

3.9. **Report.** "**Study Completion**" for each Study shall occur upon final database lock of such Study with respect to the Study Field. Within four (4) months following Study Completion of a given Study in the Study Field, Sponsor shall provide Regeneron with a preliminary draft of

the final clinical study report and the tables and listings for such Study ("**Study Results**"), in electronic form. If Regeneron undertakes to submit comments to the draft clinical study report they shall be provided within thirty (30) days following Regeneron's receipt of the draft clinical study report. Sponsor shall consider in good faith any comments made by Regeneron to such report, and shall not include any statements pertaining to the Regeneron Product (or its use in the Combination) that have not been approved by Regeneron, provided that any objection by Regeneron shall be made in good faith. If Regeneron does not provide comments with respect to any such matter within the applicable period identified above, Regeneron's approval shall be deemed to have been provided. Sponsor shall provide Regeneron with the final version of the clinical study report within a reasonable time following Sponsor's receipt of Regeneron's comments, but in no event later than the date that is three (3) months after such receipt (or, if Regeneron does not provide comments, after the expiration of the thirty (30) day period following Regeneron's receipt of the draft clinical study report). If Regeneron does not provide comments with respect to any such matter within the applicable period identified above, Regeneron's approval shall be deemed to have been provided.

3.10. **License Grants.**

3.10.1. Subject to the terms of this Agreement, with respect to each Study, Regeneron hereby grants to Sponsor a non-exclusive, worldwide, non-transferable, royalty-free, limited license under Regeneron Intellectual Property for the Term of this Agreement, solely to the extent necessary to discharge Sponsor's obligations under this Agreement with respect to the conduct of its activities under the Study Plan for such Study.

3.10.2. Subject to the terms of this Agreement, with respect to each applicable Study, Sponsor hereby grants and agrees that it will grant to Regeneron a non-exclusive, worldwide, non-transferable, royalty-free, limited license under Sponsor Intellectual Property for the Term of this Agreement, solely to the extent necessary to discharge Regeneron's obligations under this Agreement with respect to the conduct of its activities, if any, under the Study Plan for each such applicable Study.

3.11. **Subcontractors; Study Sites, Investigators, and Agreement.** Each Party may delegate its activities under a given Study Plan to its own Affiliates without the other Party's consent. Each Party shall have the right to subcontract any portion of its obligations hereunder to Third Party subcontractors without the other Party's consent. Each Party shall remain solely and fully liable for the performance of its Affiliates and subcontractors. Subject to the applicable Clinical Supply Quality Agreement, either Party may, without consulting the other Party, subcontract Manufacturing with regards to either the Sponsor Product or the Regeneron Product, as applicable, to be provided for such Study. Each Party shall ensure that each of its Affiliates and subcontractors performs its obligations pursuant to the terms of this Agreement, including the Appendices attached hereto. Each Party shall obtain and maintain copies of documents relating to the obligations performed by such Affiliates and use commercially reasonable efforts to obtain and have maintained documents relating to the obligations performed by such subcontractors and that are required to be provided to the other Party under this Agreement. The clinical trial agreements with such Affiliates and subcontractors shall require the Study sites to comply with all Applicable Laws and will contain confidentiality provisions no less stringent than those contained in this Agreement and intellectual property provisions that are sufficient to enable the assignment, as set

forth in this Agreement (a) to Regeneron of all right, title and interest in and to all Regeneron Inventions, (b) to Sponsor of all right title and interest in and to all Sponsor Inventions and (c) to both Parties for an equal and undivided share in all right title and interest in and to all Combination Inventions. Sponsor shall ensure that each clinical research organization performing services for a Study acknowledges in writing to Regeneron that Regeneron is a third party beneficiary of the clinical research organization's indemnification obligations under its agreement(s) with Sponsor. Sponsor shall ensure that all clinical trial agreements with Study sites do not conflict with the terms of this Agreement. Any exceptions to the requirements of this Section 3.11 shall be made on a case-by-case basis and shall be subject to Regeneron's prior written consent which may be withheld in Regeneron's sole discretion.

4. REGULATORY AND SAFETY.

4.1. **Approvals.** Sponsor shall ensure that all directions from any Regulatory Authority or institutional review board or ethics committee ("**IRB/EC**") with jurisdiction over a Study are followed. Further, Sponsor shall ensure that all IRB/EC approvals, customs clearances, and Regulatory Approvals for each Study from any Regulatory Authority and/or IRB/EC with jurisdiction over such Study are obtained prior to initiating performance of such Study. Sponsor will be responsible for filing the IND for each Study.

4.2. **Interactions with Regulatory Authorities.** Regeneron shall have the right (but no obligation) to participate in any discussions between Sponsor and any Regulatory Authority regarding matters related specifically to the Regeneron Product in the Study, and, to the extent reasonably practicable, Sponsor shall provide sufficient advance notice (at least five (5) Business Days, unless a shorter response period is required by the applicable Regulatory Authority, in which case such notice shall be provided to Regeneron as soon as reasonably practicable) to Regeneron of any such discussions. If Sponsor receives any correspondence, comments or other inquiries from a Regulatory Authority that pertain to the Combination or the Regeneron Product, Sponsor shall promptly provide such correspondence, comments or inquiries to Regeneron at least five (5) Business Days before any response is due, unless a shorter response period is required by the applicable Regulatory Authority, in which case such correspondence, comments or inquiries shall be provided to Regeneron as soon as reasonably practicable. For all correspondence, comments or inquiries from a Regulatory Authority that pertain to the Combination, but not solely to the Regeneron Product, Regeneron may provide, and Sponsor will consider in good faith, Regeneron's reasonable comments provided within such five (5) Business Day (or if applicable, shorter) period. If such correspondence, comments or other inquiries pertain solely to the Regeneron Product, Regeneron will promptly review and respond within five (5) Business Days (or such shorter period as may be required), and Sponsor will forward such response to the Regulatory Authority on Regeneron's behalf. With respect to any correspondence, comments or other inquiries from a Regulatory Authority regarding a Study that pertain specifically to the Regeneron Product, Regeneron shall also be permitted to respond directly to such Regulatory Authority if Regeneron's response includes proprietary subject matter regarding Regeneron's Product that is not to be shared with the Sponsor. Subject to the conditions set forth in the foregoing sentence, if Regeneron elects to respond directly to such Regulatory Authority, Regeneron shall be responsible for providing its response within the deadline prescribed by such Regulatory Authority (if none, Regeneron shall nonetheless provide such response promptly).

4.3. **Right of Reference.** [***]

4.4. **Physician Payment Reporting.** To the extent that Regeneron is required by Applicable Law to report payments made by Sponsor and its subcontractors to physicians or teaching hospitals, Sponsor shall provide on a timely basis, in consultation with Regeneron, all information necessary to comply with Applicable Law.

4.5. **Adverse Event Reporting.** Sponsor will be solely responsible for compliance with all Applicable Law pertaining to safety reporting for each Study and related activities. As soon as reasonably practical after the Effective Date, but, in any event, prior to the first dosing of the first patient with the Regeneron Product in the first Study, the Parties will agree upon and execute a Pharmacovigilance Agreement. For all other Studies, the Parties will execute a Pharmacovigilance Agreement as soon as reasonably practicable following the execution of the Study Plan for such Study, but, in any event, prior to the first dosing of the first patient with a Product in the applicable Study. Each Pharmacovigilance Agreement will establish appropriate processes and timelines for exchanging relevant safety data to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety monitoring of the Regeneron Product (alone or in the Combination) in the applicable Study, and shall include safety data exchange procedures governing the coordination, collection, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Regeneron Product (alone or in the Combination) in the applicable Study. Such procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, all local and international regulatory reporting obligations to Regulatory Authorities and the clinical investigators.

5. PROTOCOL AND RELATED DOCUMENTS.

5.1. **Protocol.** A Protocol Synopsis for the initial Study has been agreed to by the Parties as of the Effective Date and is attached hereto as Appendix A. Within sixty (60) days after the Effective Date, but, in any event, no later than sixty (60) days prior to any meeting with an ethics committee or Regulatory Authority, as applicable, to discuss the Protocol for the initial Study, the Parties shall agree upon a Protocol for such Study, with reference to the Protocol Synopsis attached hereto as Appendix A, subject to each Party's decision-making rights as set forth in Section 5.2. For each other Study, the Sponsor shall prepare and provide to Regeneron a Protocol and, if mutually agreed to by the Parties pursuant to Section 2.3, such Protocol shall be included in the applicable Study Plan executed by the Parties. Any changes to the Protocol (whether or not material) shall require mutual written consent subject to each Party's decision-making rights as set forth in Section 5.2.

5.2. **Decision Making.** Notwithstanding anything to the contrary in this Agreement, each Party, in its sole discretion, will determine the dose and dosing regimen for such Party's Product and its use in the Combination and will have the final decision on all matters relating to such Party's Product and its use in the Combination (including any changes to the Protocol that would require such Party to provide additional Product) and any information regarding such Party's Product included in the Protocol. In addition, each Party will determine matters relating to any diagnostic to be used solely for its Product.

5.3. **Consent Form.** Sponsor shall prepare the patient informed consent form for each Study (it being understood that the portion of the informed consent form relating to the Regeneron Product will be provided by Regeneron). Sponsor shall ensure that any such patient informed consent form complies with GCP requirements and Applicable Laws.

5.4. **Financial Disclosure Information.** Sponsor shall (a) track and collect financial disclosure information from all "clinical investigators" involved in each Study and (b) prepare and submit the certification and/or disclosure of the same in accordance with all Applicable Law, including, but not limited to, Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA Guidance Documents. Sponsor shall track and collect from all "clinical investigators" involved in each Study one (1) "combined" certification and/or disclosure form for both Regeneron and Sponsor. For purposes of this Section 5.4, the term "clinical investigators" shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

6. CERTAIN COVENANTS.

6.1. **Clinical Trials.** [***] Notwithstanding the foregoing restrictions in this Section 6.1, neither Party shall be restricted from providing its Product for compassionate use purposes.

6.2. **Notifications of Potential Transfers in the Study Field**. n [***]

6.3. **Other studies.** Except as set forth in this Article 6, nothing in this Agreement shall (a) prohibit either Party from performing studies other than the Studies, including with its Product used individually or in combination with any other compound or product, in any therapeutic area, or (b) create an exclusive relationship between the Parties with respect to any Product.

6.4. **No further obligations.** Nothing in this Agreement obligates either Party to any further agreement or collaboration related to the products or studies in this Agreement.

7. TERM AND TERMINATION.

7.1. **Term.** The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until completion of all of the obligations of the Parties hereunder for all Studies, or until terminated by either Party pursuant to this Article 7 (the "**Term**"). The Parties shall be entitled to enter into Study Plans during the period of time commencing on the Effective Date and expiring on the fifth (5th) anniversary of the Effective Date.

7.2. **Unsafe Use of Regeneron Product.** In the event that (a) Regeneron in good faith believes that the Regeneron Product is being used in a manner that represents an unjustified risk to the safety of patients in the Study Field, and Sponsor fails to incorporate changes into the Protocol requested in writing by Regeneron to address such issue, or (b) the Regeneron Product is not being used as described in the Protocol and Sponsor fails to cure such misuse (if capable of cure) within thirty (30) days after receipt of written notice thereof from Regeneron, Regeneron thereafter has the right to immediately terminate this Agreement (or any Study being performed under this Agreement) and the supply of the Regeneron Product upon written notice to Sponsor.

7.3. **Certain Additional Termination Rights.** Either Party may terminate a Study Plan in the event that patient screening for the 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 under this Section 7.3, Sponsor shall reimburse Regeneron for Regeneron Product it received in connection with such Study Plan based on the actual out-of-pocket cost to Regeneron of such Regeneron Product.

7.4. **Termination for Material Breach.** Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach remains uncured thirty (30) days after receipt of written notice thereof from the non-breaching Party; provided that if such material breach cannot reasonably be cured within thirty (30) days, the breaching Party shall be given a reasonable period of time to cure such breach not to exceed one-hundred and twenty (120) days; provided further, that if such material breach is incapable of cure, then the notifying Party may terminate this Agreement effective after the expiration of such thirty (30)- day period. Notwithstanding the foregoing, if any such material breach relates solely to a particular Study and does not reasonably relate to or affect the breaching Party's performance of (or ability to perform) any other Study, then the non-breaching Party shall only have the right under this Section 7.4. to terminate such Study to which the breach relates. If Regeneron terminates for material breach by Sponsor, then Sponsor shall reimburse Regeneron for Regeneron Product it received in connection with the terminated Study to which the breach relates based on the actual out-of-pocket cost to Regeneron of such Regeneron Product.

7.5. **Pharmacovigilance Agreement.** Either Party may terminate a particular Study under this Agreement immediately upon written notice to the other Party if (a) the Parties do not execute a Pharmacovigilance Agreement for such Study within the timeframe set forth in Section 4.5 or (b) the terminating Party determines in good faith that such Study represents an unjustified risk to the safety of patients in the applicable Study Field.

7.6. **Mutual Termination for Regulatory Action; Other Reasons.** Either Party may terminate a particular Study (in whole or in part on a country-by-country basis) immediately upon written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that prohibits the terminating Party from supplying its Product for purposes of such Study. Additionally, either Party shall have the right to terminate a particular Study immediately upon written notice to the other Party in the event that it determines, in its sole discretion, to discontinue development of its Product within the Study Field for such Study, for medical, scientific or legal reasons.

7.7. **Mutual Termination for Corruption.** Either Party shall be entitled to terminate this Agreement immediately upon written notice to the other Party, if such other Party fails to perform its obligations in accordance with Section 14.5. The non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 7.7. To the extent (and only to the extent) that the laws of the Territory provide for any such compensation to be paid to the non-terminating Party upon the termination of this Agreement, the non-terminating Party hereby expressly agrees (to the extent possible under the laws of the Territory) to waive or to repay to the Party terminating this Agreement any such compensation.

7.8. **Survival.** The provisions of Sections 3.4 - 3.9, 4, 7.3 - 7.4, 10 - 16 and 20 shall survive the expiration or termination of this Agreement.

7.9. **Effects of Termination.**

7.9.1. *No Prejudice.* Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

7.9.2. *Return of Regeneron Product.* In the event that this Agreement or any Study is terminated, or in the event Sponsor remains in possession (including through any Affiliate or subcontractor) of Regeneron Product at the end of the Term, Sponsor shall, at Regeneron's sole discretion, promptly either return or destroy all such unused Regeneron Product pursuant to Regeneron's instructions subject to Section 7.9.4 below. If Regeneron requests that Sponsor destroy the unused Regeneron Product, as the case may be, Sponsor shall provide written certification of such destruction. In the event Sponsor terminates this Agreement pursuant to Section 7.4, all such return of unused Regeneron Product shall be at Regeneron's sole cost and expense and in all other instances shall be at Sponsor's sole cost and expense.

7.9.3. *Confidential Information.* Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the other Party or destroy any Confidential Information of the other Party (other than Study Data and Inventions in which such Party has an ownership interest) furnished to the receiving Party by the other Party, except that the receiving Party shall have the right to retain one copy for record keeping purposes and such retained copy shall be maintained in accordance with the non-disclosure and non-use restrictions set forth in Article 10.

7.9.4. *Wind-Down.* Upon receipt by either Party of a termination notice of this Agreement, subject to the terms of this Article 7, Sponsor shall submit a wind-down plan to Regeneron setting forth the tasks reasonably necessary or required in connection with the orderly termination of the Study and the proper plan for managing the patients enrolled in the Study, including any actions reasonably required to safely close out the Study or required by Applicable Laws. If patient safety considerations [***] require more time to safely close out the Study than the termination periods set forth herein, then the Parties agree that the Agreement shall be extended to the extent necessary to ensure patient safety[***].

8. COSTS OF STUDY PLAN.[***]

9. SUPPLY AND USE OF THE PRODUCTS.

9.1. **Supply.** Sponsor and Regeneron will each use commercially reasonable efforts to supply, or cause to be supplied, sufficient quantities of Sponsor Product and Regeneron Product, respectively, to satisfy the requirements of the Study Plan for each Study. Each Party shall also provide to the other Party a contact person for coordination of Product supply under this Agreement. Each Party shall supply its Product in accordance with the terms of this Agreement. Each Party shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of a Product as contemplated by this Agreement, and Sponsor and Regeneron shall cooperate to seek to promptly resolve such issue. Notwithstanding the foregoing, or anything to the contrary herein, in the event that either Party is not supplying its

Product in accordance with the terms of this Agreement, or is not allocating its Product under procedures agreed to under Section 9.9, then the other Party shall have no obligation to supply its Product, or may allocate proportionally. This Agreement does not create any obligation on the part of Regeneron to provide the Regeneron Product for any activities other than as set forth in a Study Plan, nor does it create any obligation on the part of Sponsor to provide the Sponsor Product for any activities other than those set forth in a Study Plan. Both Parties acknowledge and agree that any Regeneron Product procured by Sponsor prior to the Effective Date, or during the Term but not provided to Sponsor by Regeneron, shall be used in accordance with this Agreement.

9.2. **Forecast.** For each Study, the Study Plan shall include a forecast of quantities and delivery dates for the requirements of the Regeneron Product to be supplied under this Agreement for such Study (each a "**Forecast**"). If there is any change in the quantity of Regeneron Product required for a Study, Sponsor shall promptly notify Regeneron of such change upon becoming aware of the same. Promptly following receipt of any requested change to any Forecast, Regeneron shall notify Sponsor of its ability to supply the requirements of the modified Forecast. The Parties shall discuss the changes to the Forecast and Regeneron's ability to meet any such changes. In the event Regeneron notifies Sponsor that it is able to meet such requirements, then such modified Forecast shall be deemed accepted by Regeneron. If Regeneron notifies Sponsor that it is not able to meet such requirements, then Regeneron, at its option, may prepare and provide Sponsor with a time schedule for additional Manufacturing of the Regeneron Product to satisfy such requirements. Otherwise, the previous Forecast shall apply.

9.3. **Delivery; Storage.** Regeneron will deliver the Regeneron Product DAP (INCOTERMS 2010) to Sponsor's, or its designee's, location as specified by Sponsor and agreed to by Regeneron ("**Delivery**" with respect to such Regeneron Product). Risk of loss for the Regeneron Product shall transfer from Regeneron to Sponsor at Delivery. All costs associated with the subsequent transportation, warehousing and distribution of Regeneron Product, including all importation or customs taxes or duties, shall be borne by Sponsor. Sponsor will: (a) take delivery of the Regeneron Product supplied hereunder; (b) perform the acceptance procedures allocated to it under the Clinical Supply Quality Agreement; (c) subsequently label and pack (in accordance with Section 9.6), and promptly ship the Regeneron Product to the Study sites, in compliance with cGMP, GCP and other Applicable Law and the Clinical Supply Quality Agreement; and (d) provide, at the reasonable request of Regeneron, the following information: any applicable chain of custody forms, in transport temperature recorder(s), records and receipt verification documentation, such other transport or storage documentation as may be reasonably requested by Regeneron, and usage and inventory reconciliation documentation related to the Regeneron Product.

9.4. **Sponsor Product.** As between the Parties, Sponsor is solely responsible, at its own cost, for supplying (including all Manufacturing, acceptance and release testing) the Sponsor Product for each Study Plan, and the subsequent handling, storage, transportation, warehousing and distribution of the Sponsor Product supplied hereunder and shall use commercially reasonable efforts to perform such activities. Sponsor shall ensure that all such activities are conducted in compliance with cGMP, GCP and other Applicable Law and that the Sponsor Product meets Sponsor's specifications. For purposes of this Agreement, the "**Delivery**" of a given quantity of the Sponsor Product shall be deemed to occur when such quantity is packaged for shipment to a Study site or other site as set forth herein.

9.5. **Representations and Warranties.** Sponsor agrees to Manufacture and supply the Sponsor Product for purposes of the Study, as set forth in this Article 9, and Sponsor hereby represents and warrants to Regeneron that, at the time of Delivery of the Sponsor Product, such Sponsor Product shall have been Manufactured and supplied in compliance with all Applicable Law, including applicable cGMP and health, safety and environmental protections and that such Sponsor Product meets Sponsor's specifications. Regeneron agrees to Manufacture and supply the Regeneron Product for purposes of the Study, as set forth in this Article 9, and Regeneron hereby represents and warrants to Sponsor that, at the time of Delivery of the Regeneron Product, such Regeneron Product shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Regeneron Product; and (b) all Applicable Law, including applicable cGMP and health, safety and environmental protections. Without limiting the foregoing, each Party is responsible for obtaining all Regulatory Approvals (including facility licenses) that are required to Manufacture its Product in accordance with Applicable Law (provided that for clarity, Sponsor shall be responsible for obtaining Regulatory Approvals for each Study as set forth in Section 4.1). [***]

9.6. **Labeling and Packaging.** Regeneron shall provide the Regeneron Product to Sponsor in the form of unlabeled vials, and Sponsor shall be responsible for labeling, packaging and leafleting such Regeneron Product in accordance with the terms and conditions of the applicable Clinical Supply Quality Agreement and otherwise in accordance with all Applicable Law, including applicable cGMP, GCP, and health, safety and environmental protections. Sponsor shall be responsible for labeling, packaging and leafleting of the Sponsor Product in accordance with all Applicable Law, including applicable cGMP, GCP, and health, safety and environmental protections.

9.7. **Use, Handling and Storage.** Sponsor shall (a) use the Regeneron Product solely for purposes of performing the Study for which such Regeneron Product was provided; (b) not use the Regeneron Product in any manner that is inconsistent with this Agreement or for any commercial purpose; and (c) use, store, transport, handle and dispose of the Regeneron Product in compliance with Applicable Law and the applicable Clinical Supply Quality Agreement, as well as all instructions of Regeneron. Sponsor shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Regeneron Product, and in particular shall not analyze the Regeneron Product by physical, chemical or biochemical means except as necessary to perform its obligations under the applicable Clinical Supply Quality Agreement.

9.8. **Release.** A certificate of analysis shall accompany each shipment of the Regeneron Product to Sponsor. Sponsor shall be responsible for any failure of the Regeneron Product to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery to Sponsor hereunder. Sponsor shall, upon receipt of Regeneron Product and within the time defined in the applicable Clinical Supply Quality Agreement, perform the acceptance (including testing, if any) procedures allocated to it under such Clinical Supply Quality Agreement. Sponsor shall be solely responsible for taking all steps necessary to determine that Regeneron Product or Sponsor Product, as applicable, is suitable for release before making such Regeneron Product or Sponsor Product, as applicable, available for human use, consistent with the Clinical Supply Quality Agreement.

9.9. **Shortage; Allocation.** In the event of a shortage of a Product such that a Party reasonably believes that it will not be able to fulfill its supply obligations hereunder with respect to its Product, such Party will provide prompt written notice to the other Party thereof (including the quantity of its Product that such Party reasonably determines it will be able to supply) and, upon request, the Parties will promptly discuss such situation (including how the quantities of Product that such Party is able to supply hereunder will be allocated within the applicable Study). In such event, the Party experiencing such shortage shall use its commercially reasonable efforts to remedy the situation giving rise to such shortage as soon as practicable and to take action to minimize the impact of the shortage on the applicable Study.

9.10. **Records.** Sponsor will keep complete and accurate written records pertaining to its use and disposition of Regeneron Product (including its storage, shipping (cold chain) and chain of custody activities) and, upon the request of Regeneron made with reasonable notice, will make such records open to review by Regeneron for the purpose of conducting investigations for the determination of Regeneron Product safety and/or efficacy and Sponsor's compliance with this Agreement with respect to the Regeneron Product. Such requests for review by Regeneron shall not be made more than once per calendar year unless Regeneron has a reasonable basis for seeking more frequent review. Each Party shall maintain complete and accurate records pertaining to its Manufacture of its Product supplied hereunder, and, upon request of the other Party, will make such records open to review by such other Party for the purpose of confirming such Party's compliance with this Agreement with respect to its Manufacturing obligations hereunder. Such requests for review by the other Party shall not be made more than once per calendar year unless such Party has a reasonable basis for seeking more frequent review.

9.11. **Quality.** The Parties (or their Affiliates) shall enter into a Clinical Supply Quality Agreement for each Study with respect to the quality assurance of the Regeneron Product supplied by Regeneron hereunder for such Study. The Parties will execute the Clinical Supply Quality Agreement for the initial Study as soon as reasonably practicable following the Effective Date, but in any event, prior to the initiation of the shipment of Regeneron Product for a Study. For all other Studies, the Parties will execute the Clinical Supply Quality Agreement as soon as reasonably practicable following the execution of the Study Plan for such Study, but in any event, prior to the initiation of the shipment of Regeneron Product for such Study. Quality matters related to the Manufacture of Regeneron Product for a particular Study shall be governed by the terms of the Clinical Supply Quality Agreement for such Study, in addition to the relevant quality terms of this Agreement, provided that if there is a conflict between the terms of the applicable Clinical Supply Quality Agreement and the terms of this Agreement with respect to a particular Study, the terms of the Clinical Supply Quality Agreement shall govern with respect to any technical or quality matters and otherwise the terms of this Agreement shall govern.

Each Party shall use commercially reasonable efforts to supply its Products for each Study with sufficient shelf-life remaining at time of Delivery for its anticipated use in the relevant Study. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Product, and for validation, documentation and release of its Product and such other quality assurance and quality control procedures as are required by cGMPs and the applicable Clinical Supply Quality Agreement. Audit and inspection rights, recalls, rejection and non-conformances, in each case, with respect to the Regeneron Product and Sponsor Product, are governed by the terms of the applicable Clinical Supply Quality Agreement.

9.12. **Placebo.** Sponsor shall be responsible for the Manufacture and supply of placebo, comparator products and diagnostic products, in each case, as applicable and to the extent set forth in the applicable Study Plan; provided that, except as otherwise set forth in a Study Plan, Regeneron shall be responsible for the Manufacture and supply of placebo and diagnostic products for the Regeneron Product. The provisions of this Article 9 applicable to the supply of Product shall also apply to any such placebo or comparator product.

9.13. **Supporting Documentation.** After release of Regeneron Product by Regeneron (as described in the applicable Clinical Supply Quality Agreement) and concurrent with shipment of Regeneron Product to Sponsor, Regeneron shall provide Sponsor with such certificates and documentation as are described in the applicable Clinical Supply Quality Agreement, which documentation will support release of such Regeneron Product for human use.

9.14. **Non-Conformance Determination.** In the event that Sponsor becomes aware that the Regeneron Product may have a Non-Conformance, Sponsor shall promptly notify Regeneron by[***]. The Parties shall investigate any Non-Conformance and any discrepancy between them shall be escalated to the head of quality of each Party (or such person's designee) for resolution.

9.15. **Replacement.** In the event that any proposed or actual shipment of the Regeneron Product (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to Sponsor, then unless otherwise agreed to by the Parties, Regeneron shall replace such Regeneron Product as is found to have a Non-Conformance (with respect to the Regeneron Product that has not yet been administered in the course of performing the applicable Study). [***]

9.16. **Non-Conformance of Sponsor Product.** Sponsor shall be responsible for, and Regeneron shall have no obligations or liability with respect to, any amounts of Sponsor's Product supplied hereunder that is found to have a Non-Conformance. Sponsor shall replace, using diligent efforts, any of Sponsor's Product as is found to have a Non-Conformance (with respect to Sponsor Product that has not yet been administered in the course of performing the applicable Study). [***]

10. CONFIDENTIALITY.

10.1. **Confidential Information.** Sponsor and Regeneron agree to hold in confidence any Confidential Information provided or made available by the other Party, and neither Party shall use Confidential Information of the other Party except to fulfill such Party's obligations or exercise such Party's rights under this Agreement. Without limiting the foregoing, Regeneron may not use Confidential Information disclosed by or on behalf of Sponsor relating to the Sponsor Product other than for purposes of performance of a Study Plan or in exercising its rights as set forth in this Agreement. Sponsor may not use Confidential Information disclosed by or on behalf of Regeneron relating to the Regeneron Product other than for purposes of the performance of a Study Plan or in exercising its rights as set forth in this Agreement. Neither Party shall, without the prior written permission of the other Party, disclose any Confidential Information of the other Party to any Third Party except to the extent disclosure (a) is required by Applicable Law; (b) is pursuant to the terms of this Agreement; or (c) is reasonably necessary for the conduct of a Study Plan, and (d) provided that the disclosing Party shall otherwise provide reasonable advance notice to the other Party before making such disclosure and obtain prior approval therefor. For the avoidance of doubt, Sponsor may, without Regeneron's consent, disclose Confidential Information to clinical trial sites

and clinical trial investigators performing a Study, the data safety monitoring and advisory board relating to a Study, and Regulatory Authorities such as the FDA, EMA or other health authorities working with Sponsor on a Study, in each case to the extent necessary for the performance of the applicable Study and provided that such persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein. **[***]**

10.2. **Ownership of Certain Confidential Information.** Study Data regarding the safety or efficacy of the Regeneron Product alone shall be the Confidential Information of Regeneron and Study Data regarding the safety or efficacy of the Sponsor Product alone shall be the Confidential Information of Sponsor. Study Data regarding the Combination (including the safety of the Combination and/or efficacy in any Study Field) shall be the Confidential Information of both Parties; provided that each Party shall have the right to use and disclose such other Study Data in accordance with Section 3.7. The existence of this Agreement and the terms and conditions hereof are deemed to constitute both Parties' Confidential Information provided that each Party may disclose such terms and conditions to actual or potential investors, acquirors, licensees and collaborators on a need-to-know basis under the same confidentiality requirements set forth in this Section 10 that apply to each of the Parties under this Agreement. Inventions that constitute Confidential Information and are jointly owned by the Parties, shall constitute the Confidential Information of both Parties and each Party shall have the right to use such Confidential Information consistent with this Article 10 and Articles 11, 12 and 13. Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party and each Party shall have the right to use such Confidential Information consistent with this Article 10 and Articles 11, 12 and 13.

10.3. **Personally Identifiable Data.** All Confidential Information containing personal identifiable data shall be handled in accordance with all applicable data protection and privacy laws, rules and regulations applicable to such Party.

11. INTELLECTUAL PROPERTY.

11.1. **Sponsor Inventions.** Sponsor shall own all right, title and interest in and to Sponsor Inventions and all Intellectual Property rights thereto are the exclusive property of Sponsor, and Regeneron agrees to assign and hereby does assign all right, title and interest in and to Sponsor Inventions and all Intellectual Property rights thereto to Sponsor. Pursuant to this Section 11.1, Sponsor shall have the right (but not the obligation) to file in its own name Patents claiming Sponsor Inventions and to maintain such Patents.

11.2. **Regeneron Inventions.** All right, title and interest in and to Regeneron Inventions and all Intellectual Property rights thereto are the exclusive property of Regeneron, and Sponsor agrees to assign and hereby does assign all right, title and interest in and to Regeneron Inventions and all Intellectual Property rights thereto to Regeneron. Pursuant to this Section 11.2, Regeneron shall have the right (but not the obligation) to file in its own name Patents claiming Regeneron Inventions and to maintain such Patents.

11.3. **Combination Inventions.** All right, title and interest in and to all Combination Inventions shall belong jointly to Sponsor and Regeneron. Sponsor and Regeneron shall each be entitled to use, practice, exploit, license and otherwise transfer their respective rights and interests

in the Combination Inventions in accordance with the terms and conditions of this Agreement, and without accounting or financial payment to the other Party and without the consent of the other Party. For those countries where a specific license is required for a joint owner of a Combination Invention to practice such Combination Invention in such countries, each Party hereby grants and agrees to grant to the other Party a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up, transferable and, subject to Section 20, sublicensable (through multiple tiers) license, under the granting Party's right, title and interest in and to all Combination Inventions to practice such Combination Inventions in such countries. For clarity, the preceding sentence does not give either Party the right to practice any Intellectual Property owned or controlled by the other Party (other than Intellectual Property in and to the applicable Combination Inventions).

11.4. Sponsor shall, at its cost, have the first right to file and prosecute in both Parties' names any patent application claiming Combination Inventions ("**Combination Patent Applications**") and to maintain granted Patents ("**Combination Patents**"). Sponsor shall keep Regeneron apprised of the preparation, filing, prosecution (including prosecution strategy) and maintenance of Combination Patent Applications and Combination Patents, including defense of any invalidity challenges thereto. Sponsor shall provide Regeneron with copies of all formal submissions or filings with, and all formal communications from, relevant patent agencies regarding Combination Patent Applications and Combination Patents, and Regeneron shall have the right to review and comment upon such submissions, filings and communications. Sponsor shall consider all such comments in good faith. In the event that Sponsor desires not to file or abandons any Combination Patent Application in any country, it shall provide reasonable prior written notice to Regeneron, and Regeneron shall have the right, but not the obligation, at its cost, to file or assume responsibility for the prosecution and maintenance of any such Combination Patent Application (and the resulting Combination Patent if applicable) in such country, in both Parties' names.

11.5. If both Parties or both Parties' Representatives are joint inventors on any Invention, that is not a Regeneron Invention, Combination Invention, nor Sponsor Invention, such Invention shall be jointly owned ("**Jointly Owned Inventions**"), and each Party shall own an equal, undivided interest in such Joint Invention. Ownership of Inventions that are neither Regeneron Inventions, Combination Inventions, Sponsor Inventions nor Jointly Owned Inventions shall be determined in accordance with United States Patent laws. Sponsor and Regeneron shall each be entitled to use, practice, exploit, license and otherwise transfer their respective rights and interest in the Jointly Owned Invention for any and all purposes without accounting or financial payment to the other Party and without the consent of the other Party. For those countries where a specific license is required for a joint owner of a Jointly Owned Invention to practice such Jointly Owned Invention in such countries, each Party hereby grants to the other Party a perpetual, irrevocable, nonexclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable (through multiple tiers) license, under the granting Party's right, title and interest in and to all Jointly Owned Inventions to practice such Jointly Owned Inventions. For clarity, the preceding sentence does not give either Party the right to practice any Intellectual Property owned or controlled by the other Party (other than Intellectual Property in and to the applicable Jointly Owned Inventions).

11.6. Regeneron shall, at its cost, have the first right to file and prosecute a patent application in respect of any Jointly Owned Invention in each country (each, a "**Joint Patent Application**") in both Parties' names. In the event that Regeneron desires not to file or abandons

any Joint Patent Application in any country, it shall provide reasonable prior written notice to Sponsor, and Sponsor shall have the right, but not the obligation, at its cost, to file or assume responsibility for the prosecution and maintenance of any such Joint Patent Application (and resulting Joint Patent) in such country, in both Parties' names. In any event, the Parties shall reasonably cooperate with one another in the preparation, filing, prosecution (including prosecution strategy) and maintenance of Joint Patent Applications and any patents issuing therefrom ("**Joint Patents**"), including defense of any invalidity challenges thereto. Such cooperation shall include the right of the Party that is not responsible for the prosecution of any Joint Patent Application having the right to review and comment upon all formal submissions or filings with, or all formal communications from, relevant patent agencies regarding such Joint Patent Application and the Joint Patents issuing therefrom.

11.7. **Enforcement; Control.** Each Party shall promptly provide the other Party with written notice reasonably detailing any known or alleged infringement or misappropriation by a Third Party of Combination Patents or Joint Patents, as well as any declaratory judgment or similar action alleging the invalidity, unenforceability or non-infringement of Combination Patents or Joint Patents. The Parties shall cooperate as whether and how to initiate legal action to enforce Combination Patents or Joint Patents, or to defend any declaratory judgment action relating thereto, against any Third Party that is manufacturing, developing, marketing, or seeking to market a product that is believed to infringe the Combination Patent. [***]

11.8. **Patent Applications.** [***]

12. REPRINTS; RIGHTS OF CROSS-REFERENCE. Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to a Study Plan, which disclose the name of a Party, provided such use does not constitute an endorsement of any commercial product or service by the other Party.

13. PUBLICATIONS.

13.1. **Publicity.** Unless otherwise required by Applicable Law (including regulations under any stock exchange on which either Party or its Affiliates is listed), neither Party shall make any public announcement concerning this Agreement or any Study (including any postings to www.clinicaltrials.gov. under Section 13.2) or otherwise communicate with any news media without the prior written consent of the other Party. Without limiting the previous sentence, to the extent a Party desires to make such public announcement, such Party shall provide the other Party with a draft thereof at least seven (7) Business Days prior to the date on which such Party would like to make the public announcement, unless such ten day prior notice is not possible in order to comply with Applicable Laws (including regulations under any stock exchange on which either Party or its Affiliates is listed); further provided however, that, in such case such Party shall provide the other Party with as much advance notice as reasonably practicable**.**

13.2. **Registration.** Sponsor will register each Study with the Clinical Trials Registry located at www.clinicaltrials.gov as required by Applicable Law.

13.3. **Publications.** Sponsor shall have the first right to publish Study Results subject to Section 13.4 and shall use commercially reasonable efforts to publish or present scientific papers regarding the Study Plan and Study Results in accordance with accepted scientific practice. Regeneron agrees not to publish Study Results for any Study prior to the timely publication of the Study Results from such Study by Sponsor.

13.4. **Review.** The Parties agree that prior to submission of any Study Data for publication or presentation or any other dissemination of any such results, including oral dissemination, the publishing Party shall invite the other to comment on the content of the material to be published or presented according to the following procedure:

(i) At least forty-five (45) days prior to submission for publication of any paper, letter or any other publication, or thirty (30) days prior to submission for presentation of any abstract, poster, talk or any other presentation, the publishing Party shall provide to the other Party the full details of the proposed publication or presentation in an electronic version (cd rom or email attachment). Upon written request from the other Party, the publishing Party agrees not to submit data for publication/presentation for an additional sixty (60) days in order to allow for actions to be taken to preserve rights for patent protection.

(ii) The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in clause (i) of this Section 13.4 to modify the publication.

(iii) The publishing Party shall remove all Confidential Information of the other Party (but shall not remove jointly owned Study Data) before finalizing the publication.

13.5. **Acknowledgement.** Each Party agrees to identify the other Party and acknowledge its support in any press release and any other publication or presentation of the results of any Study.

14. REPRESENTATIONS AND WARRANTIES; DISCLAIMERS.

14.1. **Mutual Representations and Warranties.** Each of Sponsor and Regeneron represents and warrants to the other that it has the full right and authority to enter into this Agreement.

14.2. **Representations and Warranties of Sponsor.** Sponsor hereby represents and warrants to Regeneron that: (a) Sponsor has the full right, power and authority to grant all of the rights and licenses granted to Regeneron under this Agreement; (b) it will not transfer to any Third Party except to subcontractors acting on behalf of Sponsor pursuant to this Agreement, or sell or make commercially available any Regeneron Product for any use; (c) it will not use Regeneron Product in any manner that is inconsistent with or in conflict with the rights granted herein without the prior written consent of Regeneron in each instance; (d) that all of its Representatives are, or will be prior to generating Study Results or Inventions, contractually obligated to assign all Study Results and Inventions to Sponsor; and (e) that copies of all relevant Sponsor Intellectual Property Agreements have been provided to Regeneron.

14.3. **Representations and Warranties of Regeneron.** Regeneron hereby represents and warrants to Sponsor that Regeneron has the full right, power and authority to grant all of the rights and licenses granted to Sponsor under this Agreement and that all of its Representatives are, or will be prior to generating Study Results or Inventions, contractually obligated to assign Inventions to Regeneron.

14.4. **No Guarantee of Results.** Sponsor does not undertake that any Study shall lead to any particular result, nor is the success of any Study guaranteed. Neither Party accepts any responsibility for any use that the other Party may make of Study Data nor for advice or information given in connection therewith.

14.5. **Anti-Corruption.**

(i) In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of Sponsor and Regeneron and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner which is consistent in all material respects with all Applicable Law, including the U.S. Foreign Corrupt Practices Act, good business ethics, and such Party's ethics and other corporate policies.

(ii) Each Party represents and warrants that it and its Representatives have not, and covenants that it and its Representatives will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of (a) influencing, inducing or rewarding any act, omission or decision to secure an improper advantage, (b) improperly assisting it in obtaining or retaining business for it or the other Party or (c) public or commercial bribery.

(iii) Neither Party shall contact or otherwise knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

14.6. **Disclaimer**. EXCEPT AS EXPRESSLY PROVIDED HEREIN, REGENERON MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE REGENERON PRODUCT, AND SPONSOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE SPONSOR PRODUCT.

15. INSURANCE; INDEMNIFICATION; LIMITATION OF LIABILITY.

15.1. **Insurance.** Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Without limiting the foregoing, Sponsor shall procure insurance for the performance of each Study

and shall add Regeneron as an additional insured under each such policy with respect to the applicable Study. Upon request, a Party shall provide evidence of such insurance.

15.2. **Indemnification.**

15.2.1. *By Sponsor.* Sponsor agrees to defend, indemnify and hold harmless Regeneron, its Affiliates, and its and their employees, directors, subcontractors and agents ("**Regeneron Indemnitees**") from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) ("**Liability**") incurred in connection with any claim, proceeding, or investigation by a Third Party to the extent that it arises or results from (a) the negligence or intentional misconduct of Sponsor or any Sponsor Indemnitee conducting activities on behalf of Sponsor under this Agreement; (b) any breach by Sponsor of any provision of this Agreement; [***].

15.2.2. *By Regeneron.* Regeneron agrees to defend, indemnify and hold harmless Sponsor, its Affiliates, and its and their employees, directors, subcontractors and agents ("**Sponsor Indemnitees**") from and against any Liability incurred in connection with any claim, proceeding, or investigation by a Third Party to the extent that it arises or results from (a) the negligence or intentional misconduct of Regeneron or any Regeneron Indemnitee conducting activities on behalf of Sponsor under this Agreement; (b) any breach by Regeneron of any provision of this Agreement; or [***]

15.2.3. *Study Subject Injuries.* [***]

15.2.4. *Notice of Claim.* The obligations of Regeneron and Sponsor under this Section 15.2 are conditioned upon the delivery of written notice to Regeneron or Sponsor, as the case might be, of any potential Liability, as the case may be, within a reasonable time after the indemnified Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability if it has assumed responsibility for the suit or claim in writing. The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the indemnified Party, which shall not be unreasonably withheld. It shall be reasonable for the indemnifying Party to withhold consent if the settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the indemnified Party from all Liability with respect thereto or if it imposes any Liability or obligation on the indemnified Party without the prior written consent of the indemnified Party.

15.2.5. *Study Subjects.* [***]

15.3. **LIMITATION OF LIABILITY.** OTHER THAN WITH RESPECT TO THE OBLIGATIONS OF EACH PARTY UNDER SECTION 10.1, IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR, NOR SHALL ANY PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR

OTHERWISE, ARISING OUT OF (x) THE MANUFACTURE OR USE OF ANY PRODUCT SUPPLIED HEREUNDER OR (y) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER.

16. USE OF NAME. Except as otherwise provided herein, neither Party shall mention or otherwise use the name, logo, or trademark of the other party or any of its Affiliates (or any abbreviation or adaptation thereof) in any marketing publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance, consent of which may be held at the relevant Party's absolute discretion. The restrictions imposed by this Section shall not prohibit either Party from making any disclosure identifying the other Party that is required by applicable law. Subject to Sections 13.1 and 13.4, Sponsor may identify itself as an entity that was provided Regeneron Product for a Study.

17. FORCE MAJEURE. If in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (*e.g.*, war, riots, fire, strike, governmental laws, floods, earthquakes, hurricanes, acts of God, or pandemic-related lock down in relevant regions), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed ("**Force Majeure**"). The non-performing Party will notify the other Party of such Force Majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party will use commercially reasonable efforts to remedy its inability to perform.

18. ENTIRE AGREEMENT; MODIFICATION. The Parties agree to the full and complete performance of the mutual covenants contained in this Agreement. This Agreement, together with each Study Plan, Clinical Supply Quality Agreement and each Pharmacovigilance Agreement, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto.

19. ASSIGNMENT AND PERFORMANCE BY AFFILIATES. Neither Party shall assign or transfer this Agreement without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement without the other Party's consent to one or more of its Affiliates or to a Third Party that merges with, consolidates with or acquires all or substantially all of the business or assets or voting control of the assigning Party, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided that such Affiliates agree to be bound by this Agreement and the applicable Party shall remain responsible for and liable for all acts and omissions of such Party's Affiliate.

20. THIRD PARTY RIGHTS. The Parties acknowledge that the counterparties to the Sponsor Intellectual Property Agreements shall be third party beneficiaries of this Agreement solely with respect to Sections 3.10.2, 11.1, 11.3, 11.7 and 11.8 of this Agreement, and solely to the extent that such Sections pertain to Sponsor Intellectual Property licensed under such Sponsor Intellectual Property Agreements.

21. INVALID PROVISION. If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

22. NO ADDITIONAL OBLIGATIONS. Sponsor and Regeneron have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Studies. Neither Party is under any obligation to enter into another type of agreement at this time or in the future.

23. DISPUTE RESOLUTION AND JURISDICTION.

23.1. The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination or validity hereof or thereof, shall be governed by and construed in accordance with the substantive laws of the State of Delaware without giving effect to its choice of law principles. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the District of Delaware solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

23.2. Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction (without posting bond or other security) in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

24. NOTICES. All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile or, solely with respect to notices to be delivered to Sponsor, via email (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to Sponsor, to:

[***]

If to Regeneron, to:

[***]

25. RELATIONSHIP OF THE PARTIES. The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or take any actions, which are binding on the other Party, except with the prior written consent of the other Party to do so. All persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

26. COUNTERPARTS AND DUE EXECUTION. This Agreement and any amendment may be executed in two (2) or more counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, facsimile signatures, electronic signatures and signatures transmitted via PDF shall be treated as original signatures.

27. CONSTRUCTION. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall be deemed to be followed by the phrase "without limitation" or like expression. The term "will" as used herein means shall. References to "Article," "Section" or "Appendix" are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this "Agreement" shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

Regeneron Pharmaceuticals, Inc.		MAIA BIOTECHNOLOGY, Inc.	
By:	_____	By:	_____
Name:	[***]	Name:	[***]
Title:	[***]	Title:	[***]

Approved as to legal form per Regeneron Policy #950

APPENDIX A

PROTOCOL SYNOPSIS

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APPENDIX B

Initial Study Plan for the THIO-101 Drug Supply Agreement

[***]	[***]
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APPENDIX C

SPONSOR INTELLECTUAL PROPERTY AGREEMENTS

1. [***]

2. [***]

[***]

Exhibit 10.2

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

PATENT & TECHNOLOGY LICENSE AGREEMENT
AGT. NO. L2664-MAIA BIOTECHNOLOGY

This Patent and Technology License Agreement ("Agreement") is between The Board of Regents ("Board") of The University of Texas System ("System"), an agency of the State of Texas whose address is 210 West 7th Street, Austin, Texas 78701 on behalf of The University of Texas Southwestern Medical Center ("UT Southwestern"), a component institution of System, whose address is 5323 Harry Hines Boulevard, Dallas, Texas 75390-9094 ("Licensor") and MAIA Biotechnology, Inc., a Delaware corporation, with its principal place of business at 444 West Lake Street, Suite 1700, Chicago, IL 60606 ("Licensee") (collectively, "Parties", or singly, "Party").

This Agreement has an "Effective Date" of the date of the last signature hereto.

No binding agreement between the Parties will exist until the Agreement has been signed by both Parties. Unsigned drafts of the Agreement shall not be considered offers.

Background

Licensor owns or controls Licensed Subject Matter (defined below). Licensee desires to secure the right and license to use, develop, manufacture, market, and commercialize the Licensed Subject Matter. Licensor has determined that such use, development, and commercialization of the Licensed Subject Matter is in the public's best interest and is consistent with Licensor's educational and research missions and goals. Licensor desires to have the Licensed Subject Matter developed and used for the benefit of Licensee, the inventors, Licensor, and the public.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the Parties hereby agree as follows:

1. Definitions

"**Affiliate**" means any business entity more than 50% owned by Licensee, any business entity which owns more than 50% of Licensee, or any business entity that is more than 50% owned by a business entity that owns more than 50% of Licensee.

"**Combination Product**" means any product which contains a Licensed Product or Licensed Service and one or more other products, product components or processes that do not use Patent Rights or Technology Rights.

"**Common Stock**" means shares of Licensee's common stock, par value $0.0001 per share.

"**Contract Quarter**" means the three-month periods ending on March 31, June 30, September 30, and December 31, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"**Contract Year**" means the 12-month periods ending on December 31, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"**Derivative**" means with respect to a compound, any compound that is directed to the same biological target, [***]

"**Fair Market Value**" means the cash consideration an unaffiliated, unrelated buyer would pay in an arm's length sale of a substantially identical item sold in the same quantity, under the same terms, and at the same time and place.

"**First Commercial Sale**" means the first Sale of Licensed Product or Licensed Service by Licensee or any Sublicensee to a third party in a national jurisdiction following Regulatory Approval of such Licensed Product or Licensed Service in such national jurisdiction.

"**FDA**" means United States Food and Drug Administration or any successor agency thereto.

"**Field**" means all therapeutic, prophylactic and diagnostic fields of use for all indications, including discovery and development uses.

"**Government**" means any agency, department or other unit of the United States of America or the State of Texas.

"**Gross Consideration**" means all cash and non-cash consideration (e.g., securities).

"**Improvement**" means any patentable invention, or portion thereof, which (a) is conceived or reduced to practice solely by [***]

"Indication" means an intended use of any Licensed Product or Licensed Service requiring new clinical investigations essential to regulatory approval, and which is to be used in a disease which, in the practice of medicine, is different from any disease being treated by any Licensed Product or Licensed Service pursuant to regulatory approval, or to be treated upon receiving regulatory approval.

"**Initiation**" with respect to clinical studies means the date of first administration of a placebo or Licensed Product to a patient.

"**Inventors**" (or singly, "**Inventor**") means collectively and individually, inventors named in patents and patent applications listed in Exhibit A to the Agreement.

"**Licensed Process**" means a method or process whose practice or use is covered by a Valid Claim or uses Technology Rights.

"**Licensed Product**" means any product or component (i) whose manufacture, use, sale, offer for sale or import is covered by any Valid Claim or incorporates any Technology Rights, or (ii) which is made using a Licensed Process.

"**Licensed Service**" means performance of a service for any consideration using a Licensed Product, or the practice of a Licensed Process. For clarity, research and development of Licensed Products by Licensee or a Sublicensee does not constitute a Licensed Service.

"**Licensed Subject Matter**" means Patent Rights and/or Technology Rights.

"**Milestone Fees**" means all fees identified as Milestone Fees in Section 3.1(b).

"**Net Product Sales**" means the Gross Consideration from the Sale of Licensed Products [***]

In the event that the Licensed Products are Sold as part of a Combination Product, Net Product Sales from the Sale of such Combination Product shall be calculated by multiplying the Net Product Sales (as determined without reference to this paragraph) of such Combination Product by a fraction

(i) [***]

(ii) [***]

In the event that the average Gross Consideration cannot be determined for

(i) the Licensed Products without other therapeutically active components, or

(ii) the product containing the other therapeutically active components included in the Combination Product, [***]

[***]

"Net Sales" means Net Product Sales and/or Net Service Sales

"**Net Service Sales**" means the Gross Consideration received from the Sale of Licensed Services less the following items[***]

In the event that the Licensed Services are Sold as part of a Combination Product, Net Service Sales from the Sale of such Combination Product shall be calculated [***]

(i) [***]

(ii) [***]

In the event that the average Gross Consideration cannot be determined for

(i) the Licensed Services without other processes, or

(ii) [***]

[***]

"**Non-Royalty Sublicensing Consideration**" means the Gross Consideration received by the Licensee [***]

"**Patent Rights**" means the Licensor's rights in (a) the patents and patent applications listed in Exhibit A to the Agreement; (b) all non-provisional patent applications that claim priority to any provisional application listed in Exhibit A to the Agreement to the extent the claims of such non- provisional applications are entitled to claim priority to the aforesaid provisional patent applications; and (c) all divisionals, continuations, and such claims of continuations-in-part as are entitled to claim priority to the aforesaid patents and/or patent applications, and all reissues, reexaminations, and extensions of such patents and/or patent applications; (d) any patents that issue with respect to the aforesaid patent applications; and (e) foreign counterparts of any of the foregoing. From time to time during the term of the Agreement, upon written request by any Party to the other Party, Licensee and Licensor shall update, by written agreement in accordance with Section 19.6, the list of patent applications and patents listed in Exhibit A to the Agreement to include all Patent Rights.

"**Phase 1 Clinical Studies**" means that portion of the drug development and review process which provides for the initial introduction of an investigational new drug into humans, in a manner that is generally consistent with 21 CFR § 312.21(a), as amended (or its successor regulation), or an equivalent study in any national or multinational jurisdiction other than the United States.

"**Prosecution Counsel**" means the law firm, attorney or agent who is handling the prosecution of the Patent Rights in a given jurisdiction. Prosecution Counsel as of the Effective Date is identified in Exhibit A to the Agreement.

"**Quarterly Payment Deadline**" means the day that is 45 days after the last day of any particular Contract Quarter.

"**Regulatory Approval**" means any and all approvals, licenses, registrations, or authorizations of any Regulatory Authority in a particular national jurisdiction that are necessary to market, Sell and use a Licensed Product or Licensed Service in that national jurisdiction.

"**Regulatory Authority**" means any country, federal, supranational, state, or local regulatory agency, department, bureau, or other government entity responsible for granting any necessary licenses or approvals for the marketing, Sale and use of a Licensed Product or Licensed Service in a particular national jurisdiction, including

without limitation FDA, European Medicines Agency or Koseisho (i.e. the Japanese Ministry of Health and Welfare).

"**Sell**", "**Sale**" or "**Sold**" means any transfer or other disposition of Licensed Products or Licensed Services for which consideration is received by Licensee or Sublicensees. A Sale of Licensed Products or Licensed Services will be deemed completed at the time Licensee or its Sublicensee receives such consideration.

"**Sublicense Agreement**" means any agreement or arrangement pursuant to which Licensee (or Sublicensee) grants to any third party any of the license rights granted to the Licensee under the Agreement.

"**Sublicense Fee**" means the fee specified in Section 3.1(d).

"**Sublicensee**" means any entity to whom an express sublicense has been granted under the Patent Rights and/or Technology Rights. [***]

"**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 UT Southwestern and within the Field which are not covered by a Valid Claim but which are necessary or reasonably useful for practicing Patent Rights.

"**Territory**" means worldwide.

"Valid Claim" means a claim of (i) an issued and unexpired patent included within the Patent Rights unless the claim has been held unenforceable or invalid by the final, un-reversed, and un- appealable decision of a court or other government body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or determined to be invalid, un-patentable or unenforceable, whether through reissue, reexamination, disclaimer or otherwise, or (ii) a pending patent application within the Patent Rights to the extent the claim continues to be prosecuted in good faith.

2. License Grant and Commercialization

2.1 Grant

(a) Licensor grants to Licensee a royalty-bearing exclusive license under the Patent Rights to develop, manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Field in the Territory and/or to perform Licensed Services in the Field in the Territory.

(b) Licensor grants to Licensee a royalty-bearing non-exclusive license under 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 in the Territory and/or to perform Licensed Services in the Field in the Territory.

(c) This grant is subject to (i) the payment by Licensee to Licensor of all consideration required under the Agreement, (ii) any rights of, or obligations to, the Government as set forth in Section 11.2 (Government Rights), and (iii) rights retained by Licensor to:

(1) Publish the scientific findings from research related to the Patent Rights; and

(2) Use the Licensed Subject Matter for teaching, research, education, and other educationally-related, non-commercial purposes; for the avoidance of doubt the purposes identified in this clause do not included clinical trials.

(3) Grant rights to, and transfer material embodiments of, the Licensed Subject Matter to other academic institutions or non-profit research institutions for the purposes identified in clauses (1) and (2) above.

(d) Licensor grants Licensee the first right to negotiate an exclusive license under any patent rights covering or claiming any Improvement ("Option Patent Rights"). Licensor shall promptly disclose to Licensee in writing (which shall constitute Licensor's Confidential Information) all Improvements disclosed to Licensor. If, within [***] after receipt of such notice, Licensee notifies Licensor of its desire to negotiate a license to the Option Patent Rights, the Parties shall exclusively negotiate in good faith for a period of [***] ("Option Period") an exclusive license to Licensee under the Option Patent Rights. If Licensee elects to exercise the option, Licensee shall be required to pay any legal costs associated with such Improvements during the Option Period.

(e) Licensor reserves all rights not expressly granted in the Agreement and disclaims the grant of any implied rights to Licensee.

2.2 Sublicensing

Licensee has the right to grant Sublicense Agreements under the Licensed Subject Matter consistent with the terms of the Agreement, subject to the following:

(a) A Sublicense Agreement shall not exceed the scope and rights granted to Licensee hereunder. Sublicensee must agree in writing and the terms of the Sublicense Agreement must be consistent with the applicable terms and conditions of this Agreement. The Sublicense Agreement shall indicate that Licensor is a third party beneficiary of the Sublicense Agreement. In the event of termination of this Agreement, continued sublicense rights shall be governed by Section 7.5(a) (Effect of Termination). Licensee may grant a Sublicensee the right to grant further sub- Sublicense Agreements, in which case such sub-Sublicense

Agreements shall be treated as "Sublicense Agreements" and such sub-Sublicensees shall be treated as "Sublicensees" for purposes of the Agreement.

(b) Licensee shall deliver to Licensor a true, complete, and correct copy of each Sublicense Agreement granted by Licensee or Sublicensee, and any modification or termination thereof, within 30 days following the applicable execution, modification, or termination of such Sublicense Agreement. If the Sublicense Agreement is not in English, Licensee shall provide Licensor an accurate English translation in addition to a copy of the original agreement.

(c) Notwithstanding any such Sublicense Agreement, Licensee will remain primarily liable to Licensor for all of the Licensee's duties and obligations contained in the Agreement, including without limitation the payment of running royalties due under Section 3.2 whether or not paid to Licensee by a Sublicensee. In the event of any act or omission of a Sublicensee that would be a breach of this Agreement if performed by Licensee, Licensee will use commercially reasonable efforts to actively pursue the Sublicensee to either remedy such act or omission or terminate the Sublicense Agreement. Each Sublicense Agreement will contain a right of termination by Licensee in the event that the Sublicensee breaches the payment or reporting obligations affecting Licensor or any other terms and conditions of the Sublicense Agreement that would constitute a breach of the Agreement if such acts were performed by Licensee.

2.3 Diligent Commercialization

Licensee by itself or through its Sublicensees will use diligent efforts to make one or more Licensed Products and/or Licensed Services (as applicable) commercially available in the Field within the Territory. Without limiting the foregoing, Licensee will:

(a) maintain a bona fide, funded, ongoing and active research, development, manufacturing, regulatory, marketing or sales program (all as commercially reasonable) to make one or more Licensed Products and/or Licensed Services commercially available to the public as soon as commercially practicable

(b) Intentionally Omitted.

(c) any time after 2 years from the Effective Date and within 90 days after receiving written notice from Licensor's written request, provide written evidence satisfactory to Licensor that Licensee or its Sublicensee(s) has:
(i) Sales in non-oncology Indication; or
(ii) an effective, ongoing and active research, development, manufacturing, marketing or sales program as appropriate, directed toward

obtaining regulatory approval, and/or production and/or Sales of a Licensed Product in non-oncology Indication.

If the Licensee's obligations under this Section 2.3 are not fulfilled, Licensor may treat such failure as a breach in accordance with Section 7.3(b).

3. Compensation

In consideration of rights granted to Licensee, Licensee will pay Licensor the following fees and royalties. All fees and royalties are not refundable and are not creditable against other fees and royalties. Each payment will reference the Agreement number and will be sent to Licensor's payment and accounting contact in Section 18 (Notices).

3.1 Non-Royalty Payments due from Licensee

(a) [***]

i. [***]

ii. [***]

iii. [***]

iv. [***]

(b) *Milestone Fees*. Following the achievement of any milestone event, Licensee will pay Licensor the corresponding Milestone Fee on or before the Quarterly Payment Deadline for the Contract Quarter in which the milestone event is achieved, as follows:

Milestone Events	**Milestone Fees**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***]

(c) *License Upfront Fee*. [***]

(d) *Sublicense Fees*. Licensee will pay the following Non-Royalty Sublicense Fees on or before the Quarterly Payment Deadline for the Contract Quarter in which the applicable Non-Royalty Sublicensing Consideration is received by the Licensee:

Field of the Sublicense Agreement	**Sublicense Fee**
[***]	[***]
[***]	[***]

[***]

(e) *Assignment Fee*. [***]

3.2 Royalties

Licensee will pay Licensor the following running royalties for each Contract Year for Licensed Products and Licensed Services covered by a Valid Claim, payable on or before the Quarterly Payment Deadline for the last Contract Quarter of such Contract Year:

[***]	[***]	[***]
	[***]	[***]
[***]	[***]	[***]
	[***]	[***]

Payment of any such royalties shall be subject to the following:

(a) Licensee's obligation to pay royalties on Net Sales under this Section 3.2 shall continue, on a country-by-country basis, [***]

(b) [***]

(c) [***]

(d) [***]

[***]

(e) Upon expiration of the Royalty Term in a country, the licenses under Section 2.1 will become royalty-free, and fully-paid up in such country.

3.3 Royalty Stacking

(a) [***]

3.4 [***]

[***]

4. Reports and Plans

The reports specified in this Section 4 will be sent to Licensor's payment and reporting contact identified in Section 18 (Notices). If Licensor reasonably requests to have information submitted in a particular format, Licensee will use reasonable efforts to comply with such request.

4.1 Quarterly Payment and Milestone Reports

From and after the First Commercial Sale, on or before each Quarterly Payment Deadline, Licensee will deliver to Licensor a true and accurate report, certified by an officer of Licensee, giving such particulars of the business conducted by Licensee and its Sublicensees (including copies of reports provided by Sublicensees to Licensee) during the preceding Contract Quarter under the Agreement as necessary for Licensor to account for Licensee's payments, including royalties, hereunder, even if no payments are due. Notwithstanding the foregoing, Licensee shall not be required to include in any report information [***]. The report shall include:

(a) The name of the Licensee, the Agreement number, and the period covered by the report;

(b) The name of any Sublicensees whose activities are also covered by the report;

(c) Identification of each Licensed Product and Licensed Service for which any royalty payments have become payable;

(d) Net Product Sales and Net Service Sales segregated on a product-by-product basis, and a country-by-country basis, or an affirmative statement that no Sales were made. [***];

(e) [***];

(f) [***]

(g) [***];

(h) [***]

(i) [***].

4.2 Biannual Progress Meeting and Annual Written Report

Until the First Commercial Sale, Licensee will meet with representatives of UT Southwestern (in person or by videoconference or teleconference, as agreed to by the Parties) semi-annually to provide an update on the Licensee, including (i) Licensee's efforts and accomplishments during the half year to develop and, if

applicable, commercialize Licensed Products, and (ii) Licensee's development and commercialization plans with respect to Licensed Products for the next half year. The update shall also cover such activities by Sublicensees. Within 30 days following the end of each Contract Year until the first Sale of a Licensed Product or Licensed Service, Licensee will deliver to Licensor a true and accurate signed written progress report, which shall contain the following information to the extent relevant to the activities under the Agreement:

(a) The name of the Licensee, the Agreement number, the names of any Sublicensees, and the Licensed Products and Licensed Services being developed and/or commercialized;

(b) The progress toward completing and the plans for completing the applicable milestone events pursuant to Sections 2.3 and 3.1(b); and

(c) A summary of the research and development activities with respect to Licensed Products and Licensed Services, including status and plans for obtaining any necessary Regulatory Approvals, performed during the past year, and the plans for research and development activities for the next year; and

(d) Any plans for starting any clinical trials with respect to Licensed Products in the next Contract Year, indicating (i) whether UT Southwestern will be considered as a study site and (ii) the name or nomenclature for the Licensed Product being provided for such clinical trials.

4.3 Government and Economic Development Reporting

If Licensor requests, Licensee will provide information for Licensor's Government and economic development reporting purposes, including, to the extent such information is required to be disclosed under federal or state law, the following:

(a) Number and geographic location of new full-time employees created during the past Contract Year; total number and geographic location of full-time employees of Licensee at the end of such Contract Year;

(b) Dollar amount of new equity financing received by Licensee during the past Contract Year, and current capitalization, including number and class of outstanding securities;

(c) Location and square footage of facilities; and

(d) Other information required under Federal and state law.

This information shall be treated as Licensee's Confidential Information; provided that Licensor is entitled to combine such information with similar information from other Licensor licensees and publicly report such combined aggregate information, without identifying Licensee's separate specific applicable

numbers. If and when Licensee has more than 200 full-time employees, then no further economic development reports will be required from Licensee.

5. Payment, Records, and Audits

5.1 Payments

All amounts referred to in the Agreement are expressed in U.S. dollars without deductions for taxes, assessments, fees, or charges of any kind. Each payment will reference the Agreement number set forth at the beginning of the Agreement. All payments to Licensor will be made in U.S. dollars by check or wire transfer (Licensee to pay all wire transfer fees) payable to the payee identified in Section 18 and sent to the payment and reporting contact in Section 18 (Notices).

5.2 Sales Outside the U.S.

If any currency conversion shall be required in connection with the calculation of payments hereunder, such conversion shall be made using the rate used by Licensee for its financial reporting purposes in accordance with Generally Accepted Accounting Principles (or foreign equivalent) or, in the absence of such rate, using the average of the buying and selling exchange rate for conversion between the foreign currency and U.S. Dollars, for current transactions as reported in *The Wall Street Journal* on the last business days of the Contract Quarter to which such payment pertains. Licensee may not make any tax withholdings from payments to Licensor, but Licensor agrees to supply to Licensee, upon written request, appropriate evidence from appropriate U.S. governmental agencies showing that Licensor is a resident of the United States of America for purposes of the U.S. income tax laws and is tax-exempt under such income tax laws.

5.3 Late Payments

Amounts that are not paid when due will accrue a late charge from the due date until paid, at a rate equal to [***] per month (or the maximum allowed by law, if less).

5.4 Records

For a period of five years after the Contract Year to which the records pertain, Licensee agrees that it and its Sublicensees will each keep complete and accurate records of their Sales, Net Product Sales, Net Service Sales, Milestone Fees, and Non-Royalty Sublicensing Consideration in sufficient detail to enable such payments to be determined and audited.

5.5 Auditing

Licensee will permit Licensor or its representatives, at Licensor's expense, to periodically examine books, ledgers, and records during regular business hours, at Licensee's place of business, on at least 30 days advance notice, to the extent necessary to verify any payment or report required under the Agreement. For each Sublicensee from whom Licensee is entitled to Gross Consideration pursuant to the terms of a Sublicense Agreement, Licensee shall obtain such audit rights for

Licensor or itself. If Licensee obtains such audit rights for itself, it will promptly conduct an audit of the Sublicensee's records upon Licensor's request, and Licensee will furnish to Licensor a copy of the findings from such audit. [***]If the amount of underpayment is equal to or greater than [***] of the total amount due for the records so examined, Licensee will pay the reasonable out-of-pocket costs incurred by Licensor in conducting such audit. If any audit reveals any overpayment by Licensee to Licensor, then the amount of such overpayment shall be offset against any amount that becomes due to Licensor in connection with any subsequent period. All information examined pursuant to this Section 5.5 shall be deemed to be the Confidential Information of the Licensee.

6. Patent Expenses and Prosecution

6.1 Patent Expenses

Subject to Section 3.1(a), except as described below in this Section 6.1, Licensee shall pay for all patent services expenses, if any, incurred by Licensor following the Effective Date of this Agreement, for filing, prosecuting, defending, and maintaining Patent Rights and related patent searches and all such future expenses incurred by Licensor, for so long as, and in such countries as, the Agreement remains in effect. Licensee will pay all such expenses within 30 days after Licensee's receipt of an invoice from Licensor. Nothing in this Section 6.1 shall affect Licensee's ability to select legal counsel of its own choosing to perform such patent services, at Licensee's sole expense. Except as described in Section 3.1(a), Licensor is not aware of any pending, unpaid patent services expenses as described in this Section 6.1.

6.2 Direction of Prosecution

Licensor will confer with Licensee to develop a strategy for the prosecution and maintenance of Patent Rights. With respect to prosecution activities occurring after the Effective Date of this Agreement, Licensor will request that copies of all documents received from government patent offices and foreign patent counsel and copies of all documents prepared by the Prosecution Counsel for submission to governmental patent offices be provided to Licensee for review and comment prior to filing, to the extent practicable under the circumstances. [***] If Licensee wishes to instruct Prosecution Counsel directly or change Prosecution Counsel, Licensee may request to do so by following the Licensor's procedures for such. Licensor reserves in its sole discretion the ability to change Prosecution Counsel and to approve or disapprove any requested changes by Licensee. The Parties agree that they share a common legal interest to get valid enforceable patents and that Licensee will maintain as privileged all information received pursuant to this Section.

6.3 Ownership

All patent applications and patents will be in the name of Licensor (and any co-owner identified in Exhibit A) and owned by Licensor (and such co-owner, if any). No payments due under the Agreement will be reduced as the result of co-ownership interests in the Patent Rights by Licensee or any other party.

6.4 Foreign Filings

In addition to the U.S., the Patent Rights shall, subject to applicable bar dates, be pursued in such foreign countries as Licensee so designates in writing to Licensor in sufficient time to reasonably enable the preparation of such additional filings, and in those foreign countries in which Licensor has filed applications prior to the Effective Date. If Licensee does not choose to pursue patent rights in a particular foreign country and Licensor chooses to do so, Licensor shall so notify Licensee and thereafter said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights or obligations thereto. Licensor shall have the right to make alternative arrangements with Licensee for upfront payment of foreign patent expenses.

6.5 Withdrawal from Paying Patent Expenses

If at any time Licensee wishes to cease paying for any costs for a particular Patent Right or for patent prosecution in a particular jurisdiction, Licensee must give Licensor at least 90 days prior written notice and Licensee will continue to be obligated to pay for the patent expenses which reasonably accrue during said notice period. Thereafter, said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights or obligations thereto.

6.6 U.S. Patent and Trademark Office Entity Size Status

Licensee represents that as of the Effective Date the entity size status of Licensee in accordance with the regulations of the U.S. Patent and Trademark Office is as set forth in Exhibit A. Licensee will inform Licensor in writing on a timely basis of any change in its U.S. Patent and Trademark Office entity size status.

7. Term and Termination

7.1 Term

The term of the Agreement will commence on the Effective Date and continue until the earliest of: (i) termination as provided herein; (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. [***]

7.2 Termination by Licensee

Licensee, at its option, may terminate the Agreement by providing Licensor written notice of intent to terminate, which such termination will be effective 90 days following receipt of such notice by Licensor.

7.3 Termination by Licensor

Licensor, at its option, may immediately terminate the Agreement, or any part of Licensed Subject Matter, or any part of the Field, or any part of the Territory, or the exclusive nature of the license grant, upon delivery of written notice to Licensee of Licensor’s decision to terminate, if any of the following occur:

(a) Licensee becomes in arrears in any payments due under the Agreement, and Licensee fails to make the required payment within 30 days after delivery of written notice from Licensor; or

(b) Licensee is in breach of any material non-payment provision of the Agreement, and does not cure such breach within 60 days after delivery of written notice from Licensor.

(c) Licensor delivers notice to Licensee of three or more actual breaches of the Agreement in any 12-month period, even in the event that Licensee cures such breaches in the allowed period.

7.4 Other Conditions of Termination

The Agreement will terminate:

(a) Immediately without the necessity of any action being taken by Licensor or Licensee, (i) if Licensee has a petition in bankruptcy filed for or against it, or (ii) Licensee's Board of Directors elects to liquidate majority of its assets or dissolve its business, or (iii) Licensee ceases its business operations, or (iv) Licensee makes an assignment for the benefit of creditors or (v) if the business or assets of Licensee are otherwise placed in the hands of a receiver, assignee for the benefit of creditors or trustee, whether by voluntary act of Licensee or otherwise; or

(b) At any time by mutual written agreement between Licensee and Licensor.

7.5 Effect of Termination

If the Agreement is terminated for any reason:

(a) All rights and licenses of Sublicensees shall terminate upon termination of the Agreement; provided however, if the Sublicense Agreement is for all of the Field for all of the Territory, and the Sublicensee is not then in breach of the Sublicense Agreement and agrees in writing to assume all of the obligations of Licensee and provides Licensor with written notice thereof within 30 days after notice of termination of the Agreement, then such Sublicense Agreement shall survive; and

(b) Licensee shall cease making, having made, distributing, having distributed, using, selling, offering to sell, leasing, loaning and importing any Licensed Products and performing Licensed Services by the effective date of termination; and

(c) Licensee shall tender payment of all accrued royalties and other payments due to Licensor as of the effective date of termination; and

(d) Intentionally Omitted.

(e) Nothing in the Agreement will be construed to release either Party from any obligation that matured prior to the effective date of termination; and

(f) The provisions of Sections 8 (Confidentiality), 9 (Infringement and Litigation), 11 (Representations and Disclaimers), 12 (Limit of Liability), 13 (Indemnification), 14 (Insurance), 17 (Use of Name), 18 (Notices), and 19 (General Provisions) will survive any termination or expiration of the Agreement. In addition, the provisions of Sections 3 (Compensation), 4.1 (Quarterly Payment and Milestone Reports), 5 (Payment, Records and Audits), and 6.1 (Patent Expenses) shall survive with respect to all activities and payment obligations accruing prior to the termination or expiration of the Agreement.

8. Confidentiality

8.1 Definition

"**Confidential Information**" means, with respect to any Party, all confidential or proprietary information or material regarding or embodying such Party's technology, products, business information or objectives, that is disclosed by or on behalf of such Party (the "Disclosing Party") to the other Party (the "Receiving Party") in connection with the Agreement, but only to the extent that such information or material (i) if disclosed in tangible form, is marked "confidential" or otherwise designated in writing as "confidential" at the time of disclosure or within 30 days thereafter, (ii) if disclosed orally or in non- tangible form, is identified by the Disclosing Party as "confidential" at the time of disclosure and, within 30 days thereafter, the Disclosing Party provides a written summary of such information or material marked or otherwise designated in writing as "confidential", or (iii) is of the nature that it would be reasonable under the circumstances to be considered confidential or proprietary information or material of the Disclosing Party.

8.2 Protection and Marking

All Confidential Information of the Disclosing Party: (i) is to be held in strict confidence by the Receiving Party, (ii) is to be used by and under authority of the Receiving Party only as authorized in the Agreement, and (iii) shall not be disclosed by the Receiving Party, its agents or employees to any third party without the prior written consent of the Disclosing Party or as authorized in the Agreement. Licensee has the right to use and disclose Confidential Information of Licensor reasonably in connection with the exercise of its rights and performance of its obligations under the Agreement, including without limitation disclosing such Confidential Information to Sublicensees, potential investors, acquirers, and others on a need to know basis, if such Confidential Information is provided under conditions which reasonably protect the confidentiality thereof. The Receiving Party has the right to disclose the Disclosing Party's Confidential Information to its agent and employees to the extent necessary for the Receiving Party to exercise its rights or perform its obligations under the Agreement, provided that each agent and employee receiving such Confidential Information is subject to

appropriate confidentiality obligations substantially similar to those of this Section 8. Each Party's obligation of confidence hereunder includes, without limitation, using at least the same degree of care with the disclosing Party's Confidential Information as it uses to protect its own Confidential Information, but always at least a reasonable degree of care. The Receiving Party shall be solely liable for any disclosure or use of the Disclosing Party's Confidential Information in

violation of this Agreement by any agents, employees, advisors, actual or potential Sublicensees, acquirers or investors of the Receiving Party.

8.3 Confidentiality of Terms of Agreement

Each Party agrees not to disclose to any third party the terms of the Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of the Agreement: (a) to advisors, actual or potential Sublicensees, acquirers or investors on a need to know basis, in each case, under appropriate confidentiality obligations substantially similar to those of this Section 8; and (b) to the extent necessary, in the reasonable opinion of the Receiving Party's counsel, to comply with applicable laws, regulations and court orders (including, without limitation, The Texas Public Information Act, as may be amended from time to time, other open records laws, decisions and rulings, and securities laws, regulations and guidance). If the Agreement is not for all fields of use, then Licensor may disclose the Field to other potential third party licensees. Notwithstanding the foregoing, the existence of the Agreement shall not be considered Confidential Information.

8.4 Disclosure Required by Court Order or Law

If the Receiving Party is required to disclose Confidential Information of another Party hereto, or any terms of the Agreement, pursuant to the order or requirement of a court, administrative agency, or other governmental body or applicable law, the Receiving Party may disclose such Confidential Information or terms to the extent required, provided that the Receiving Party shall provide the Disclosing Party with reasonable advance notice thereof (unless prohibited by law) to enable the Disclosing Party to seek a protective order and otherwise seek to prevent such disclosure. To the extent that Confidential Information so disclosed does not become part of the public domain by virtue of such disclosure, it shall remain Confidential Information protected pursuant to Section 8.

8.5 Copies

Each Party agrees not to copy or record any of the Confidential Information of the other Party, except as reasonably necessary to exercise its rights or perform its obligations under the Agreement, and for archival and legal purposes.

8.6 Continuing Obligations

Subject to the exclusions listed in Section 8.7, the Parties' confidentiality obligations under the Agreement will survive termination of the Agreement and will continue for a period of five years thereafter.

8.7 Exclusions

Information shall not be considered Confidential Information of a Disclosing Party under the Agreement to the extent that the Receiving Party can establish by competent written proof that such information:

(a) Was in the public domain at the time of disclosure; or

(b) Later became part of the public domain through no act or omission of the Receiving Party, its employees, agents, successors or assigns in breach of the Agreement; or

(c) Was lawfully disclosed to the Receiving Party by a third party having the right to disclose it not under an obligation of confidentiality; or

(d) Was already known by the Receiving Party at the time of disclosure; or

(e) Was independently developed by the Receiving Party without use of the disclosing Party's Confidential Information.

8.8 Copyright Notice

The placement of a copyright notice on any Confidential Information will not be construed to mean that such information has been published and will not release the other Party from its obligation of confidentiality hereunder.

8.9 Remedies

In the event of a breach, threatened breach or intended breach of the terms of this Section 8 by either of the Parties, the Disclosing Party, in addition to any other rights and remedies available to it at law or in equity, shall be entitled to seek preliminary and final injunctions, enjoining and restraining such breach, threatened breach or intended breach of such Disclosing Party's Confidential Information.

9. Infringement and Litigation

9.1 Notification

If either Licensor's designated office for technology commercialization or Licensee becomes aware of any infringement or potential infringement of Patent Rights, each Party shall promptly notify the other of such in writing.

9.2 Licensee's Enforcement Rights

Licensee may enforce the Patent Rights against any infringement by a third party. Licensee shall be responsible for payment of all fees and expenses associated with such enforcement incurred by Licensee and incurred by Licensor in providing cooperation or joining as a party as provided in Section 9.4. Any monetary recovery for actual damages or punitive damages in excess of Licensee's documented, third-party expenses in enforcing the Patent Rights and amounts actually reimbursed by Licensee to Licensor under this Section 9.2 shall be shared

by Licensee with Licensor in the same manner as Non-Royalty Sublicensing Consideration.

9.3 Licensor's Enforcement Rights

If Licensee does not file suit within six months after a written request by Licensor to initiate an infringement action, then Licensor shall have the right, at its sole discretion, to bring suit to enforce any Patent Right licensed hereunder against the infringing activities, with Licensor retaining all recoveries from such enforcement. If Licensor pursues such infringement action, Licensor may, as part of the resolution of such efforts, grant non- exclusive license rights to the alleged infringer notwithstanding Licensee's exclusive license rights.

9.4 Cooperation between Licensor and Licensee

In any infringement suit or dispute, the Parties agree to cooperate fully with each other. At the request of the Party bringing suit, the other Party will permit reasonable access after reasonable advance notice to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours.

If it is necessary to name Licensor as a party in such action, then Licensee must first obtain Licensor's prior written permission, which permission shall not be unreasonably withheld, provided that Licensor shall have reasonable prior input on choice of counsel on any matter where such counsel represents Licensor, and Licensee and such counsel agree to follow all required procedures of the Texas Attorney General regarding retention of outside counsel for state entities.

10. Export Compliance

Licensee understands that the Arms Export Control Act (AECA), including its implementing International Traffic In Arms Regulations (ITAR), and the Export Administration Act (EAA), including its Export Administration Regulations (EAR), are some (but not all) of the laws and regulations that comprise the U.S. export laws and regulations. Licensee further understands that the U.S. export laws and regulations include (but are not limited to): (a) ITAR and EAR product/service/data- specific requirements; (b) ITAR and EAR ultimate destination-specific requirements; (c) ITAR and EAR end user-specific requirements; (d) Foreign Corrupt Practices Act; and (e) anti-boycott laws and regulations. Licensee will comply with all then-current applicable export laws and regulations of the U.S. Government (and other applicable U.S. laws and regulations) pertaining to the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information). Licensee certifies that it will not, directly or indirectly, export (including any deemed export), nor re-export (including any deemed re-export) the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information) in violation of applicable U.S. laws and regulations. Licensee will include a provision in its agreements, substantially similar to this Section 10, with its Sublicensees, third party wholesalers and distributors, and physicians, hospitals or other healthcare providers who

purchase a Licensed Product, requiring that these parties comply with all then-current applicable U.S. export laws and regulations and other applicable U.S. laws and regulations.

11. Representations and Disclaimers

11.1 Licensor Representations

Except for the rights, if any, of the Government as set forth in Section 11.2, Licensor represents and warrants to Licensee that to the knowledge of Licensor's designated office for technology commercialization (i) Licensor is the owner or agent of the entire right, title, and interest in and to Patent Rights (other than the right, title and interest of any joint owner identified in Exhibit A), (ii) Licensor has the right to grant all licenses including Patent Rights and/or Technology Rights granted under the Agreement, (iii) Licensor has not granted and will not grant licenses or other rights under the Patent Rights that are in conflict with the terms and conditions in the Agreement, (iv) Licensor has not received any written notice that a product or process claimed in the Patent Rights or otherwise comprising the Licensed Subject Matter is alleged to infringe any intellectual property rights of a third party, (v) Licensor has not notified any third party that such third party's products or processes infringe any claim of the Patent Rights, and (vi) with respect to the products and processes claimed in or covered by the Patent Rights and the other Licensed Subject Matter, all inventors thereof have fully assigned all rights thereto to the Licensor and have no remaining claims on any such invention.

11.2 Government Rights

Licensee understands that Licensed Subject Matter may have been developed under a funding agreement with Government and, if so, that Government may have certain rights relative thereto. The Agreement is made subject to the Government's rights under any such agreement and under any applicable Government law or regulation. To the extent that there is a conflict between any such agreement, such applicable law or regulation and the Agreement, the terms of such Government agreement, and applicable law or regulation, shall prevail. Licensee agrees that, to the extent required by U.S. laws and regulations, Licensed Products used or Sold in the U.S. will be manufactured substantially in the U.S., unless a written waiver is obtained in advance from the U.S. Government.

11.3 Licensor Disclaimers

EXCEPT AS SPECIFICALLY SET FORTH IN SECTION 11.1, LICENSEE UNDERSTANDS AND AGREES THAT LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, AS TO THE LICENSED PRODUCTS OR LICENSED SERVICES, OR AS TO THE OPERABILITY OR FITNESS FOR ANY USE OR PARTICULAR PURPOSE, MERCHANTABILITY, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT, PATENTABILITY, AND/OR BREADTH OF PATENT RIGHTS. LICENSOR

MAKES NO REPRESENTATION AS TO WHETHER ANY PATENT WITHIN PATENT RIGHTS IS VALID, OR AS TO WHETHER THERE ARE ANY PATENTS NOW HELD, OR WHICH WILL BE HELD, BY OTHERS OR BY LICENSOR THAT MIGHT BE REQUIRED FOR USE OF PATENT RIGHTS IN FIELD. NOTHING IN THE AGREEMENT WILL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS TO ANY PATENTS OR TECHNOLOGY OF LICENSOR OTHER THAN THE PATENT RIGHTS, WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS, OR THE TECHNOLOGY RIGHTS SPECIFICALLY DESCRIBED HEREIN.

11.4 Licensee Representations

By execution of the Agreement, Licensee represents, acknowledges, covenants and agrees

(a) that Licensee has not been induced in any way by Licensor or its employees to enter into the Agreement, and (b) that Licensee has been given an opportunity to conduct sufficient due diligence with respect to all items and issues pertaining to this Section 11 (Representations and Disclaimers) and all other matters pertaining to the Agreement; and

(b) that Licensee has adequate knowledge and expertise, or has utilized knowledgeable and expert consultants, to adequately conduct the due diligence, and (d) that Licensee accepts all risks inherent herein. Licensee represents that it is a duly organized, validly existing entity of the form indicated in the preamble to the Agreement, and is in good standing under the laws of its jurisdiction of organization as indicated in the preamble of the Agreement, and has all necessary corporate or other appropriate power and authority to execute, deliver and perform its obligations hereunder.

12. Limit of Liability

IN NO EVENT SHALL LICENSOR, THE UNIVERSITY SYSTEM IT GOVERNS, ITS MEMBER INSTITUTIONS, INVENTORS, REGENTS, OFFICERS, EMPLOYEES, STUDENTS, AGENTS OR AFFILIATED ENTERPRISES, BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER ANY SUCH PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. OTHER THAN FOR CLAIMS AGAINST LICENSEE FOR INDEMNIFICATION (SECTION 13) OR FOR MISUSE OR MISAPPROPRIATION OR INFRINGEMENT OF LICENSOR'S INTELLECTUAL PROPERTY RIGHTS, LICENSEE WILL NOT BE LIABLE TO LICENSOR FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT

OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER LICENSEE KNOWS OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES.

13. Indemnification

13.1 Indemnification Obligation

Subject to Section 13.2, Licensee agrees to hold harmless, defend and indemnify Licensor, the university system it governs, its member institutions, its Regents, officers, employees, students and agents as well as any entity listed in Exhibit A as a co-owner of any licensed patent, along with their respective officers, employees, students and agents (collectively the "**Indemnified Parties**") from and against any liabilities, damages, causes of action, suits, judgments, liens, penalties, fines, losses, costs and expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) (collectively "**Liabilities**") resulting from claims or demands brought by third parties against an Indemnified Party on account of any injury or death of persons, damage to property, or any other damage or loss arising out of or in connection with the Agreement or the exercise or practice by or under authority of Licensee or its Sublicensees, or third party wholesalers or distributors, or physicians, hospitals or other healthcare providers who purchase a Licensed Product, of the rights granted hereunder.

13.2 Conditions of Indemnification

Licensee shall have no responsibility or obligation under Section 13.1 for any Liabilities to the extent caused by the gross negligence or willful misconduct by Licensor. Obligations to indemnify and hold harmless under Section 13.1 are subject to: (a) to the extent authorized by the Texas Constitution and the laws of the State of Texas and subject to the statutory duties of the Texas Attorney General, the Indemnified Party giving Licensee control of the defense and settlement of the claim and demand; and (b) to the extent authorized by the Texas Constitution and the laws of the State of Texas and subject to statutory duties of the Texas Attorney General, the Indemnified Party providing the assistance reasonably requested by Licensee, at Licensee's expense.

14. Insurance

14.1 Insurance Requirements

Prior to any Licensed Product being used or Sold (including for the purpose of obtaining Regulatory Approval), and prior to any Licensed Service being performed by Licensee or by a Sublicensee, and for a period of five years after the Agreement expires or is terminated, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in commercially reasonable and appropriate amounts for the Licensed Product being used or Sold or the Licensed Service being performed. Licensee shall use commercially reasonable efforts to have Licensor named as an additional insured. Such commercial general liability insurance shall provide, without limitation: (i)

product liability coverage; (ii) broad form contractual liability coverage for Licensee's indemnification obligations under the Agreement; and (iii) coverage for litigation costs.

14.2 Evidence of Insurance and Notice of Changes
Upon request by Licensor, Licensee shall provide Licensor with written evidence of such insurance. Additionally, Licensee shall provide Licensor with written notice of at least 45 days prior to Licensee cancelling, not renewing, or materially changing such insurance.

15. Assignment

The Agreement may not be assigned by Licensee without the prior written consent of Licensor, which consent will not be unreasonably withheld. For clarity, an assignment shall not include any sublicensing by MAIA Biotechnology to a MAIA Affiliate. A merger or other transaction in which the equity holders of Licensee prior to such event hold less than a majority of the equity of the surviving or acquiring entity shall be considered an assignment of the Agreement. For any permitted assignment to be effective, (a) Licensee must be in good standing under this Agreement, (b) the Licensee must pay Licensor the assignment fee pursuant to Section 3.1(e), and (c) the assignee must assume in writing (a copy of which shall be promptly provided to Licensor) all of Licensee's interests, rights, duties and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if assignee were an original Party to the Agreement.

16. Governmental Markings

16.1 Patent Markings
Licensee agrees that all Licensed Products Sold by Licensee or Sublicensees within the United States will be marked in accordance with 35 U.S.C. § 287. Licensee agrees that all Licensed Products and/or Services Sold by Licensee or Sublicensees outside the United States will be marked in accordance with the relevant laws and regulations established in those other jurisdictions.

16.2 Governmental Approvals and Marketing of Licensed Products and/or Licensed Services Licensee will be responsible for obtaining all necessary governmental approvals for the development, production, distribution, Sale, and use of any Licensed Product or performance of any Licensed Service, at Licensee's expense, including, without limitation, any safety studies. Licensee will have sole responsibility for any warning labels, packaging and instructions as to the use and the quality control for any Licensed Product or Licensed Service.

16.3 Foreign Registration and Laws
Licensee agrees to register the Agreement with any foreign governmental agency that requires such registration and Licensee will pay all costs and legal fees in connection with such registration. Licensee is responsible for compliance with all foreign laws affecting the Agreement or the Sale of Licensed Products and

Licensed Services to the extent there is no conflict with United States law, in which case United States law will control.

17. Use of Name

Neither Party will use the name, trademarks or other marks of the other Party (including, in the case of Licensor, the name of the university system it governs, its member institutions, any of its Regents or employees) without the advance written consent of the other Party. Notwithstanding the foregoing, Licensor may use Licensee's name and/or logo for various reports required by governmental law, rule or regulation and for internal reports without the prior written consent of the Licensee.

18. Notices

Any notice or other communication of the Parties required or permitted to be given or made under the Agreement will be in writing and will be deemed effective when sent in a manner that provides confirmation or acknowledgement of delivery and received at the address set forth below (or as changed by written notice pursuant to this Section 18).

Licensee Contacts	**Licensor Contacts**
Contact for Notice: Vlad Vitoc, MD, MBA Chief Executive Officer MAIA Biotechnology, Inc. 444 West Lake Street, Suite 1700 Chicago, IL 60606 Office: [***] Cell: [***] Email: [***]	Contact for Notice: UT Southwestern Medical Center Office for Technology Development Attn: Director for Technology Commercialization 5323 Harry Hines Boulevard, Dallas, Texas 75390-9094 Fax: [***] Phone: [***] E-mail: [***] Payment and financial reporting contact: Checks in U.S. dollars payable to "UT SOUTHWESTERN" referencing L2664-MAIA, UT Southwestern Medical Center Lock Box 845477 Dallas, Texas 75284-5477

Patent prosecution contact: [***]	Patent prosecution contact: Attn: Director for Technology Commercialization Office for Technology Development 5323 Harry Hines Boulevard, Dallas, Texas 75390-9094 [***]

Notices required under the Agreement may be delivered via E-mail provided such notice is confirmed in writing as indicated. Notices shall be provided to each Party as specified in the "Contact for Notice" address. Each Party shall update the other Party in writing with any changes in such contact information.

19. General Provisions

19.1 Binding Effect
The Agreement is binding upon and inures to the benefit of the Parties hereto, their respective executors, administrators, heirs, permitted assigns, and permitted successors in interest.

19.2 Construction of Agreement
Headings are included for convenience only and will not be used to construe the Agreement. The Parties acknowledge and agree that both Parties substantially participated in negotiating the provisions of the Agreement; therefore, both Parties agree that any ambiguity in the Agreement shall not be construed more favorably toward one Party than the other Party, regardless of which Party primarily drafted the Agreement.

19.3 Counterparts and Signatures
The Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. A Party may evidence its execution and delivery of the Agreement by transmission of a signed copy of the Agreement via facsimile or email. In such event, the Party shall promptly provide the original signature page(s) to the other Party.

19.4 Compliance with Laws
Licensee will comply with all applicable national, state and local laws and regulations, including, without limitation, all export laws and regulations.

19.5 Governing Law
The Agreement will be construed and enforced in accordance with laws of the U.S. and the State of Texas, without regard to choice of law and conflicts of law principles.

19.6 Modification
Any modification of the Agreement will be effective only if it is in writing and signed by duly authorized representatives of both Parties. No modification will be made by email communications.

19.7 Severability
If any provision hereof is held to be invalid, illegal or unenforceable in any jurisdiction, the Parties hereto shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties, and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such other provisions in any other jurisdiction, so long as the essential essence of the Agreement remains enforceable.

19.8 Third Party Beneficiaries
Nothing in the Agreement, express or implied, is intended to confer any benefits, rights or remedies in this Agreement on any entity, other than the Parties and their permitted successors and assigns.

19.9 Waiver
Neither Party will be deemed to have waived any of its rights under the Agreement unless the waiver is in writing and signed by such Party. No delay or omission of a Party in exercising or enforcing a right or remedy under the Agreement shall operate as a waiver thereof.

19.10 Sovereign Immunity
Nothing in the Agreement shall be deemed or treated as any waiver of Licensor's sovereign immunity.

19.11 Entire Agreement
The Agreement constitutes the entire Agreement between the Parties regarding the subject matter hereof, and supersedes all prior written or verbal agreements, representations and understandings relative to such matters.

19.12 Claims Against Licensor for Breach of Agreement
Licensee acknowledges that any claim for breach of the Agreement asserted by Licensee against Licensor shall be subject to Chapter 2260 of the Texas Government Code and that the process provided therein shall be Licensee's sole and exclusive process for seeking a remedy for any and all alleged breaches of the Agreement by Licensor or the State of Texas.

20. No Other Promises and Agreements; Representation by Counsel.

Licensee expressly warrants and represents and does hereby state and represent that no promise or agreement which is not herein expressed has been made to Licensee in executing the Agreement except those explicitly set forth herein, and that Licensee is not

relying upon any statement or representation of Licensor or its representatives. Licensee is relying on Licensee's own judgment and has had the opportunity to be represented by legal counsel. Licensee hereby warrants and represents that Licensee understands and agrees to all terms and conditions set forth in the Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Patent License Agreement.

LICENSOR: BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM	LICENSEE: MAIA Biotechnology, Inc.
By: [***]	By: [***]
Date	Date:

Approved as to Content:

By:
[***]

EXHIBIT A TO
PATENT LICENSE AGREEMENT

PATENT RIGHTS

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Exhibit 10.3

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

PATENT & TECHNOLOGY LICENSE AGREEMENT
AGT. NO. L3648-MAIA BIOTECHNOLOGY

This Patent and Technology License Agreement ("Agreement") is between The Board of Regents ("Board") of The University of Texas System ("System"), an agency of the State of Texas whose address is 210 West 7th Street, Austin, Texas 78701 on behalf of The University of Texas Southwestern Medical Center ("UT Southwestern"), a component institution of System, whose address is 5323 Harry Hines Boulevard, Dallas, Texas 75390-9094 ("Licensor") and MAIA Biotechnology, Inc., a Delaware corporation, with its principal place of business at 444 West Lake Street, Suite 1700, Chicago, IL 60606 ("Licensee") (collectively, "Parties", or singly, "Party").

This Agreement has an "Effective Date" of the date of the last signature hereto.

No binding agreement between the Parties will exist until the Agreement has been signed by both Parties. Unsigned drafts of the Agreement shall not be considered offers.

Background

Licensor and Licensee have previously entered into "Patent & Technology License Agreement Agt. No. L2664-MAIA Biotechnology," as amended, which was executed December 8, 2020. This agreement and all of its exhibits and schedules and including any and all amendments to any of the foregoing will be referred to collectively in this agreement as the "Original Agreement." As set forth in the Original Agreement, Licensee had the option to obtain additional licenses to technology developed by the Licensor. The instant Agreement between the Licensor and Licensee is directed to granting Licensee such additional license rights.

In that regard, Licensor owns or controls Licensed Subject Matter (defined below). Licensee desires to secure the right and license to use, develop, manufacture, market, and commercialize the Licensed Subject Matter. Licensor has determined that such use, development, and commercialization of the Licensed Subject Matter is in the public's best interest and is consistent with Licensor's educational and research missions and goals. Licensor desires to have the Licensed Subject Matter developed and used for the benefit of Licensee, the inventors, Licensor, and the public.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the Parties hereby agree as follows:

1. Definitions

"**Affiliate**" means any business entity more than 50% owned by Licensee, any business entity which owns more than 50% of Licensee, or any business entity that is more than 50% owned by a business entity that owns more than 50% of Licensee.

"**Combination Product**" means any product which contains a Licensed Product or Licensed Service and one or more other products, product components or processes that do not use Patent Rights or Technology Rights.

"**Common Stock**" means shares of Licensee's common stock, par value $0.0001 per share.

"**Contract Quarter**" means the three-month periods ending on March 31, June 30, September 30, and December 31, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"**Contract Year**" means the 12-month periods ending on December 31, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"**Derivative**" means with respect to a compound, any compound that is directed to the same biological target,[***].

"**Fair Market Value**" means the cash consideration an unaffiliated, unrelated buyer would pay in an arm's length sale of a substantially identical item sold in the same quantity, under the same terms, and at the same time and place.

"**First Commercial Sale**" means the first Sale of Licensed Product or Licensed Service by Licensee or any Sublicensee to a third party in a national jurisdiction following Regulatory Approval of such Licensed Product or Licensed Service in such national jurisdiction.

"**FDA**" means United States Food and Drug Administration or any successor agency thereto.

"**Field**" means all therapeutic, prophylactic and diagnostic fields of use for all indications, including discovery and development uses.

"**Government**" means any agency, department or other unit of the United States of America or the State of Texas.

"**Gross Consideration**" means all cash and non-cash consideration (e.g., securities).

"**Improvement**" means any patentable invention, or portion thereof, which (a) is conceived or reduced to practice solely by[***].

"Indication" means an intended use of any Licensed Product or Licensed Service requiring new clinical investigations essential to regulatory approval, and which is to be used in a disease which, in the practice of medicine, is different from any disease being treated by any Licensed Product or Licensed Service pursuant to regulatory approval, or to be treated upon receiving regulatory approval.

"**Initiation**" with respect to clinical studies means the date of first administration of a placebo or Licensed Product to a patient.

"**Inventors**" (or singly, "**Inventor**") means collectively and individually, inventors named in patents and patent applications listed in Exhibit A to the Agreement.

"**Licensed Process**" means a method or process whose practice or use is covered by a Valid Claim or uses Technology Rights.

"**Licensed Product**" means any product or component (i) whose manufacture, use, sale, offer for sale or import is covered by any Valid Claim or incorporates any Technology Rights, or (ii) which is made using a Licensed Process.

"**Licensed Service**" means performance of a service for any consideration using a Licensed Product, or the practice of a Licensed Process. For clarity, research and development of Licensed Products by Licensee or a Sublicensee does not constitute a Licensed Service.

"**Licensed Subject Matter**" means Patent Rights and/or Technology Rights.

"**Milestone Fees**" means all fees identified as Milestone Fees in Section 3.1(b).

"**Net Product Sales**" means the Gross Consideration from the Sale of Licensed Products [***]

In the event that the Licensed Products are Sold as part of a Combination Product, Net Product Sales from the Sale of such Combination Product shall be calculated by multiplying the Net Product Sales (as determined without reference to this paragraph) of such Combination Product by a fraction

(i) [***]

(ii) [***]

In the event that the average Gross Consideration cannot be determined for

(i) the Licensed Products without other therapeutically active components, or

(ii) the product containing the other therapeutically active components included in the Combination Product, [***]

[***].

"Net Sales" means Net Product Sales and/or Net Service Sales

"**Net Service Sales**" means the Gross Consideration received from the Sale of Licensed Services less the following items [***]

In the event that the Licensed Services are Sold as part of a Combination Product, Net Service Sales from the Sale of such Combination Product shall be calculated [***]

(i) [***]

(ii) [***]

In the event that the average Gross Consideration cannot be determined for

(i) the Licensed Services without other processes, or

(ii) the services containing the other processes included in the Combination Product, [***]

[***].

"**Non-Royalty Sublicensing Consideration**" means the Gross Consideration received by the Licensee [***]

"Original Agreement" means the "Patent & Technology License Agreement Agt. No. L2664-MAIA Biotechnology," and all of its exhibits and schedules, entered into by and between the Parties on November 29th, 2018, as amended on December 8, 2020.

"**Patent Rights**" means the Licensor's rights in (a) the patents and patent applications listed in Exhibit A to the Agreement; (b) all non-provisional patent applications that claim priority to any provisional application listed in Exhibit A to the Agreement to the extent the claims of such non- provisional applications are entitled to claim priority to the aforesaid provisional patent applications; and (c) all divisionals, continuations, and such claims of continuations-in-part as are entitled to claim priority to the aforesaid patents and/or patent applications, and all reissues, reexaminations, and extensions of such patents and/or patent applications; (d) any patents that issue with respect to the aforesaid patent applications; and (e) foreign counterparts of any of the foregoing. From time to time during the term of the Agreement, upon written request by any Party to the other Party, Licensee and Licensor shall update, by written agreement in accordance with Section 19.6, the list of patent applications and patents listed in Exhibit A to the Agreement to include all Patent Rights.

"**Phase 1 Clinical Studies**" means that portion of the drug development and review process which provides for the initial introduction of an investigational new drug into humans, in a manner that is generally consistent with 21 CFR § 312.21(a), as amended (or its successor regulation), or an equivalent study in any national or multinational jurisdiction other than the United States.

"**Prosecution Counsel**" means the law firm or attorney who is handling the prosecution of the Patent Rights. Prosecution Counsel as of the Effective Date is identified in Exhibit A to the Agreement.

"**Quarterly Payment Deadline**" means the day that is 45 days after the last day of any particular Contract Quarter.

"**Regulatory Approval**" means any and all approvals, licenses, registrations, or authorizations of any Regulatory Authority in a particular national jurisdiction that are necessary to market, Sell and use a Licensed Product or Licensed Service in that national jurisdiction.

"**Regulatory Authority**" means any country, federal, supranational, state, or local regulatory agency, department, bureau, or other government entity responsible for granting any necessary licenses or approvals for the marketing, Sale and use of a Licensed Product or Licensed Service in a particular national jurisdiction, including without limitation FDA, European Medicines Agency or Koseisho (i.e. the Japanese Ministry of Health and Welfare).

"**Sell**", "**Sale**" or "**Sold**" means any transfer or other disposition of Licensed Products or Licensed Services for which consideration is received by Licensee or Sublicensees. A Sale of Licensed Products or Licensed Services will be deemed completed at the time Licensee or its Sublicensee receives such consideration.

"**Sublicense Agreement**" means any agreement or arrangement pursuant to which Licensee (or Sublicensee) grants to any third party any of the license rights granted to the Licensee under the Agreement.

"**Sublicense Fee**" means the fee specified in Section 3.1(d).

"**Sublicensee**" means any entity to whom an express sublicense has been granted under the Patent Rights and/or Technology Rights. [***]

"**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 UT Southwestern and within the Field which are not covered by a Valid Claim but which are necessary or reasonably useful for practicing Patent Rights.

"**Territory**" means worldwide.

"Valid Claim" means a claim of (i) an issued and unexpired patent included within the Patent Rights unless the claim has been held unenforceable or invalid by the final, un-reversed, and un- appealable decision of a court or other government body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or determined to be invalid, un-patentable or unenforceable, whether through reissue, reexamination, disclaimer or otherwise, or (ii) a pending patent

application within the Patent Rights to the extent the claim continues to be prosecuted in good faith.

2. License Grant and Commercialization

2.1 Grant

(a) Licensor grants to Licensee a royalty-bearing exclusive license under the Patent Rights to develop, manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Field in the Territory and to perform Licensed Services in the Field in the Territory.

(b) Licensor grants to Licensee a royalty-bearing non-exclusive license under 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 in the Territory and to perform Licensed Services in the Field in the Territory.

(c) This grant is subject to (i) the payment by Licensee to Licensor of all consideration required under the Agreement, (ii) any rights of, or obligations to, the Government as set forth in Section 11.2 (Government Rights), and (iii) rights retained by Licensor to:

(1) Publish the scientific findings from research related to the Patent Rights; and

(2) Use the Licensed Subject Matter for teaching, research, education, and other educationally-related, non-commercial purposes (the "Non- Commercial Purposes"); for the avoidance of doubt the Non-Commercial Purposes identified in this clause to not include clinical trials for Licensed Products, unless Licensor is otherwise engaged by Licensee, Affliate, or Sublicensee pursuant to the terms of a separate agreement to conduct such clinical trials, in which case use of the Licensed Subject Matter in connection with such clinical trials will be governed by the terms of such separate agreement.

(3) Grant rights to, and transfer material embodiments of, the Licensed Subject Matter to other academic institutions or non-profit research institutions for the purposes identified in clauses (1) and (2) above.

(d) Licensor grants Licensee the first right to negotiate an exclusive license under any patent rights covering or claiming any Improvement ("Option Patent Rights"). Licensor shall promptly disclose to Licensee in writing (which shall constitute Licensor's Confidential Information) all Improvements disclosed to Licensor. If, within [***] after receipt of such notice, Licensee notifies Licensor of its desire to negotiate a license to the

Option Patent Rights, the Parties shall exclusively negotiate in good faith for a period of [***] ("Option Period") an exclusive license to Licensee under the Option Patent Rights. If Licensee elects to exercise the option, Licensee shall be required to pay any legal costs associated with such Improvements during the Option Period.

(e) Licensor reserves all rights not expressly granted in the Agreement and disclaims the grant of any implied rights to Licensee.

2.2 Sublicensing

Licensee has the right to grant Sublicense Agreements under the Licensed Subject Matter consistent with the terms of the Agreement, subject to the following:

(a) A Sublicense Agreement shall not exceed the scope and rights granted to Licensee hereunder. Sublicensee must agree in writing to be bound by the applicable terms and conditions of the Agreement and shall indicate that Licensor is a third party beneficiary of the Sublicense Agreement. In the event of termination of this Agreement, continued sublicense rights shall be governed by Section 7.5(a) (Effect of Termination). Licensee may grant a Sublicensee the right to grant further sub-Sublicense Agreements, in which case such sub-Sublicense Agreements shall be treated as "Sublicense Agreements" and such sub-Sublicensees shall be treated as "Sublicensees" for purposes of the Agreement.

(b) Licensee shall deliver to Licensor a true, complete, and correct copy of each Sublicense Agreement granted by Licensee or Sublicensee, and any modification or termination thereof, within 30 days following the applicable execution, modification, or termination of such Sublicense Agreement. If the Sublicense Agreement is not in English, Licensee shall provide Licensor an accurate English translation in addition to a copy of the original agreement.

(c) Notwithstanding any such Sublicense Agreement, Licensee will remain primarily liable to Licensor for all of the Licensee's duties and obligations contained in the Agreement, including without limitation the payment of running royalties due under Section 3.2 whether or not paid to Licensee by a Sublicensee. In the event of any act or omission of a Sublicensee that would be a breach of this Agreement if performed by Licensee, Licensee will use commercially reasonable efforts to actively pursue the Sublicensee to either remedy such act or omission or terminate the Sublicense Agreement. Each Sublicense Agreement will contain a right of termination by Licensee in the event that the Sublicensee breaches the payment or reporting obligations affecting Licensor or any other terms and conditions of the Sublicense Agreement that would constitute a breach of the Agreement if such acts were performed by Licensee.

2.3 Diligent Commercialization

Licensee by itself or through its Sublicensees will use diligent efforts to make one or more Licensed Products and/or Licensed Services (as applicable) commercially available in the Field within the Territory. Without limiting the foregoing, Licensee will:

(a) maintain a bona fide, funded, ongoing and active research, development, manufacturing, regulatory, marketing or sales program (all as commercially reasonable) to make one or more Licensed Products and/or Licensed Services commercially available to the public as soon as commercially practicable

(b) Intentionally Omitted.

(c) any time after 2 years from the Effective Date and within 90 days after receiving written notice from Licensor's written request, provide written evidence satisfactory to Licensor that Licensee or its Sublicensee(s) has:
(i)Sales in non-oncology Indication; or
(ii)an effective, ongoing and active research, development, manufacturing, marketing or sales program as appropriate, directed toward obtaining regulatory approval, and/or production and/or Sales of a Licensed Product in non-oncology Indication.

If the Licensee's obligations under this Section 2.3 are not fulfilled, Licensor may treat such failure as a breach in accordance with Section 7.3(b).

3. Compensation

In consideration of rights granted to Licensee, Licensee will pay Licensor the following fees and royalties. All fees and royalties are not refundable and are not creditable against other fees and royalties. Each payment will reference the Agreement number and will be sent to Licensor's payment and accounting contact in Section 18 (Notices).

3.1 Non-Royalty Payments due from Licensee

(a) [***],

(b) *Milestone Fees*. Following the achievement of any milestone event, Licensee will pay Licensor the corresponding Milestone Fee on or before the Quarterly Payment Deadline for the Contract Quarter in which the milestone event is achieved, as follows:

Milestone Events	**Milestone Fees**
[***]	[***]
[***]	[***]

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***]

(c) *License Upfront Fee*.[***]

(d) *Sublicense Fees*. Licensee will pay the following Non-Royalty Sublicense Fees on or before the Quarterly Payment Deadline for the Contract Quarter in which the applicable Non-Royalty Sublicensing Consideration is received by the Licensee:

Field of the Sublicense Agreement	**Sublicense Fee**
[***]	[***]
[***]	[***]

[***]

(e) *Assignment Fee*.[***]

3.2 Royalties

Licensee will pay Licensor the following running royalties for each Contract Year for Licensed Products and Licensed Services covered by a Valid Claim, payable on or before the Quarterly Payment Deadline for the last Contract Quarter of such Contract Year:

[***]	[***]	[***]
	[***]	[***]
[***]	[***]	[***]
	[***]	[***]

Payment of any such royalties shall be subject to the following:

(a) Licensee's obligation to pay royalties on Net Sales under this Section 3.2 shall continue, on a country-by-country basis,[***]

(b) [***]

(c) [***]

(d) [***]

[***]

(e) Upon expiration of the Royalty Term in a country, the licenses under Section 2.1 will become royalty-free, and fully-paid up in such country.

3.3 Royalty Stacking

(a) [***]

(b) [***]

3.4 Non-cash Consideration
[***]

4. Reports and Plans

The reports specified in this Section 4 will be sent to Licensor's payment and reporting contact identified in Section 18 (Notices). If Licensor reasonably requests to have

information submitted in a particular format, Licensee will use reasonable efforts to comply with such request.

4.1 Quarterly Payment and Milestone Reports

From and after the First Commercial Sale, on or before each Quarterly Payment Deadline, Licensee will deliver to Licensor a true and accurate report, certified by an officer of Licensee, giving such particulars of the business conducted by Licensee and its Sublicensees (including copies of reports provided by Sublicensees to Licensee) during the preceding Contract Quarter under the Agreement as necessary for Licensor to account for Licensee's payments, including royalties, hereunder, even if no payments are due. Notwithstanding the foregoing, Licensee shall not be required to include in any report information [***]. The report shall include:

(a) The name of the Licensee, the Agreement number, and the period covered by the report;

(b) The name of any Sublicensees whose activities are also covered by the report;

(c) Identification of each Licensed Product and Licensed Service for which any royalty payments have become payable;

(d) Net Product Sales and Net Service Sales segregated on a product-by-product basis, and a country-by-country basis, or an affirmative statement that no Sales were made.[***];

(e) [***];

(f) [***];

(g) [***];

(h) [***]

(i) [***].

4.2 Biannual Progress Meeting and Annual Written Report

Until the First Commercial Sale, Licensee will meet with representatives of UT Southwestern (in person or by videoconference or teleconference, as agreed to by the Parties) semi-annually to provide an update on the Licensee, including (i) Licensee's efforts and accomplishments during the half year to develop and, if applicable, commercialize Licensed Products, and (ii) Licensee's development and commercialization plans with respect to Licensed Products for the next half year. The update shall also cover such activities by Sublicensees. Within 30 days following the end of each Contract Year until the first Sale of a Licensed Product or Licensed Service, Licensee will deliver to Licensor a true and accurate signed

written progress report, which shall contain the following information to the extent relevant to the activities under the Agreement:

(a) The name of the Licensee, the Agreement number, the names of any Sublicensees, and the Licensed Products and Licensed Services being developed and/or commercialized;

(b) The progress toward completing and the plans for completing the applicable milestone events pursuant to Sections 2.3 and 3.1(b); and

(c) A summary of the research and development activities with respect to Licensed Products and Licensed Services, including status and plans for obtaining any necessary Regulatory Approvals, performed during the past year, and the plans for research and development activities for the next year; and

(d) Any plans for starting any clinical trials with respect to Licensed Products in the next Contract Year, indicating (i) whether UT Southwestern will be considered as a study site and (ii) the name or nomenclature for the Licensed Product being provided for such clinical trials.

4.3 Government and Economic Development Reporting

If Licensor requests, Licensee will provide information for Licensor's Government and economic development reporting purposes, including, to the extent such information is required to be disclosed under federal or state law, the following:

(a) Number and geographic location of new full-time employees created during the past Contract Year; total number and geographic location of full-time employees of Licensee at the end of such Contract Year;

(b) Dollar amount of new equity financing received by Licensee during the past Contract Year, and current capitalization, including number and class of outstanding securities;

(c) Location and square footage of facilities; and

(d) Other information required under Federal and state law.

This information shall be treated as Licensee's Confidential Information; provided that Licensor is entitled to combine such information with similar information from other Licensor licensees and publicly report such combined aggregate information, without identifying Licensee's separate specific applicable numbers. If and when Licensee has more than 200 full-time employees, then no further economic development reports will be required from Licensee.

5. Payment, Records, and Audits

5.1 Payments

All amounts referred to in the Agreement are expressed in U.S. dollars without deductions for taxes, assessments, fees, or charges of any kind. Each payment will reference the Agreement number set forth at the beginning of the Agreement. All payments to Licensor will be made in U.S. dollars by check or wire transfer (Licensee to pay all wire transfer fees) payable to the payee identified in Section 18 and sent to the payment and reporting contact in Section 18 (Notices).

5.2 Sales Outside the U.S.

If any currency conversion shall be required in connection with the calculation of payments hereunder, such conversion shall be made using the rate used by Licensee for its financial reporting purposes in accordance with Generally Accepted Accounting Principles (or foreign equivalent) or, in the absence of such rate, using the average of the buying and selling exchange rate for conversion between the foreign currency and U.S. Dollars, for current transactions as reported in *The Wall Street Journal* on the last business days of the Contract Quarter to which such payment pertains. Licensee may not make any tax withholdings from payments to Licensor, but Licensor agrees to supply to Licensee, upon written request, appropriate evidence from appropriate U.S. governmental agencies showing that Licensor is a resident of the United States of America for purposes of the U.S. income tax laws and is tax-exempt under such income tax laws.

5.3 Late Payments

Amounts that are not paid when due will accrue a late charge from the due date until paid, at a rate equal to [***] per month (or the maximum allowed by law, if less).

5.4 Records

For a period of five years after the Contract Year to which the records pertain, Licensee agrees that it and its Sublicensees will each keep complete and accurate records of their Sales, Net Product Sales, Net Service Sales, Milestone Fees, and Non-Royalty Sublicensing Consideration in sufficient detail to enable such payments to be determined and audited.

5.5 Auditing

Licensee will permit Licensor or its representatives, at Licensor's expense, to periodically examine books, ledgers, and records during regular business hours, at Licensee's place of business, on at least 30 days advance notice, to the extent necessary to verify any payment or report required under the Agreement. For each Sublicensee from whom Licensee is entitled to Gross Consideration pursuant to the terms of a Sublicense Agreement, Licensee shall obtain such audit rights for Licensor or itself. If Licensee obtains such audit rights for itself, it will promptly conduct an audit of the Sublicensee's records upon Licensor's request, and Licensee will furnish to Licensor a copy of the findings from such audit. [***] If the amount of underpayment is equal to or greater than [***] of the total amount due for the records so examined, Licensee will pay the reasonable out-of-pocket

costs incurred by Licensor in conducting such audit. If any audit reveals any overpayment by Licensee to Licensor, then the amount of such overpayment shall be offset against any amount that becomes due to Licensor in connection with any subsequent period. All information examined pursuant to this Section 5.5 shall be deemed to be the Confidential Information of the Licensee.

6. Patent Expenses and Prosecution

6.1 Patent Expenses

Subject to Section 3.1(a), except as described below in this Section 6.1, Licensee shall pay for all patent services expenses, if any, incurred by Licensor following the Effective Date of this Agreement, for filing, prosecuting, defending, and maintaining Patent Rights and related patent searches and all such future expenses incurred by Licensor, for so long as, and in such countries as, the Agreement remains in effect. Licensee will pay all such expenses within 30 days after Licensee's receipt of an invoice from Licensor. Nothing in this Section 6.1 shall affect Licensee's ability to select legal counsel of its own choosing to perform such patent services, at Licensee's sole expense. Except as described in Section 3.1(a), Licensor is not aware of any pending, unpaid patent services expenses as described in this Section 6.1.

6.2 Direction of Prosecution

Licensor will confer with Licensee to develop a strategy for the prosecution and maintenance of Patent Rights. With respect to prosecution activities occurring after the Effective Date of this Agreement, Licensor will request that copies of all documents received from government patent offices and foreign patent counsel and copies of all documents prepared by the Prosecution Counsel for submission to governmental patent offices be provided to Licensee for review and comment prior to filing, to the extent practicable under the circumstances. [***] If Licensee wishes to instruct Prosecution Counsel directly or change Prosecution Counsel, Licensee may request to do so by following the Licensor's procedures for such. Licensor reserves in its sole discretion the ability to change Prosecution Counsel and to approve or disapprove any requested changes by Licensee. The Parties agree that they share a common legal interest to get valid enforceable patents and that Licensee will maintain as privileged all information received pursuant to this Section.

6.3 Ownership

All patent applications and patents will be in the name of Licensor (and any co-owner identified in Exhibit A) and owned by Licensor (and such co-owner, if any). No payments due under the Agreement will be reduced as the result of co-ownership interests in the Patent Rights by Licensee or any other party.

6.4 Foreign Filings

In addition to the U.S., the Patent Rights shall, subject to applicable bar dates, be pursued in such foreign countries as Licensee so designates in writing to Licensor in sufficient time to reasonably enable the preparation of such additional filings,

and in those foreign countries in which Licensor has filed applications prior to the Effective Date. If Licensee does not choose to pursue patent rights in a particular foreign country and Licensor chooses to do so, Licensor shall so notify Licensee and thereafter said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights or obligations thereto. Licensor shall have the right to make alternative arrangements with Licensee for upfront payment of foreign patent expenses.

6.5 Withdrawal from Paying Patent Costs

If at any time Licensee wishes to cease paying for any costs for a particular Patent Right or for patent prosecution in a particular jurisdiction, Licensee must give Licensor at least 90 days prior written notice and Licensee will continue to be obligated to pay for the patent costs which reasonably accrue during said notice period. Thereafter, said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights or obligations thereto.

6.6 U.S. Patent and Trademark Office Entity Size Status

Licensee represents that as of the Effective Date the entity size status of Licensee in accordance with the regulations of the U.S. Patent and Trademark Office is as set forth in Exhibit A. Licensee will inform Licensor in writing on a timely basis of any change in its U.S. Patent and Trademark Office entity size status.

7. Term and Termination

7.1 Term

Unless earlier terminated as provided herein, the term of the Agreement will commence on the Effective Date and continue until the last date of expiration or termination of the Patent Rights, or if Technology Rights are licensed and no Patent Rights are applicable, for a term of 20 years. [***]

7.2 Termination by Licensee

Licensee, at its option, may terminate the Agreement by providing Licensor written notice of intent to terminate, which such termination will be effective 90 days following receipt of such notice by Licensor.

7.3 Termination by Licensor

Licensor, at its option, may immediately terminate the Agreement, or any part of Licensed Subject Matter, or any part of the Field, or any part of the Territory, or the exclusive nature of the license grant, upon delivery of written notice to Licensee of Licensor's decision to terminate, if any of the following occur:

(a) Licensee becomes in arrears in any payments due under the Agreement, and Licensee fails to make the required payment within 30 days after delivery of written notice from Licensor; or

(b) Licensee is in breach of any material non-payment provision of the Agreement, and does not cure such breach within 60 days after delivery of written notice from Licensor.

(c) Licensor delivers notice to Licensee of three or more actual breaches of the Agreement in any 12-month period, even in the event that Licensee cures such breaches in the allowed period.

7.4 Other Conditions of Termination

The Agreement will terminate:

(a) Immediately without the necessity of any action being taken by Licensor or Licensee, (i) if Licensee has a petition in bankruptcy filed for or against it, or (ii) Licensee's Board of Directors elects to liquidate majority of its assets or dissolve its business, or (iii) Licensee ceases its business operations, or (iv) Licensee makes an assignment for the benefit of creditors or (v) if the business or assets of Licensee are otherwise placed in the hands of a receiver, assignee for the benefit of creditors or trustee, whether by voluntary act of Licensee or otherwise; or

(b) At any time by mutual written agreement between Licensee and Licensor.

7.5 Effect of Termination
If the Agreement is terminated for any reason:

(a) All rights and licenses of Sublicensees shall terminate upon termination of the Agreement; provided however, if the Sublicense Agreement is for all of the Field for all of the Territory, and the Sublicensee is not then in breach of the Sublicense Agreement and agrees in writing to assume all of the obligations of Licensee and provides Licensor with written notice thereof within 30 days after notice of termination of the Agreement, then such Sublicense Agreement shall survive; and

(b) Licensee shall cease making, having made, distributing, having distributed, using, selling, offering to sell, leasing, loaning and importing any Licensed Products and performing Licensed Services by the effective date of termination; and

(c) Licensee shall tender payment of all accrued royalties and other payments due to Licensor as of the effective date of termination; and

(d) Intentionally Ommitted.

(e) Nothing in the Agreement will be construed to release either Party from any obligation that matured prior to the effective date of termination; and

(f) The provisions of Sections 8 (Confidentiality), 9 (Infringement and Litigation), 11 (Representations and Disclaimers), 12 (Limit of Liability), 13 (Indemnification), 14 (Insurance), 17 (Use of Name), 18 (Notices), and 19 (General Provisions) will survive any termination or expiration of the Agreement. In addition, the provisions of Sections 3 (Compensation), 4.1

(Quarterly Payment and Milestone Reports), 5 (Payment, Records and Audits), and 6.1 (Patent Expenses) shall survive with respect to all activities and payment obligations accruing prior to the termination or expiration of the Agreement.

8. Confidentiality

8.1 Definition

"**Confidential Information**" means, with respect to any Party, all confidential or proprietary information or material regarding or embodying such Party's technology, products, business information or objectives, that is disclosed by or on behalf of such Party (the "Disclosing Party") to the other Party (the "Receiving Party") in connection with the Agreement, but only to the extent that such information or material (i) if disclosed in tangible form, is marked "confidential" or otherwise designated in writing as "confidential" at the time of disclosure or within 30 days thereafter, (ii) if disclosed orally or in non- tangible form, is identified by the Disclosing Party as "confidential" at the time of disclosure and, within 30 days thereafter, the Disclosing Party provides a written summary of such information or material marked or otherwise designated in writing as "confidential", or (iii) is of the nature that it would be reasonable under the circumstances to be considered confidential or proprietary information or material of the Disclosing Party.

8.2 Protection and Marking

All Confidential Information of the Disclosing Party: (i) is to be held in strict confidence by the Receiving Party, (ii) is to be used by and under authority of the Receiving Party only as authorized in the Agreement, and (iii) shall not be disclosed by the Receiving Party, its agents or employees to any third party without the prior written consent of the Disclosing Party or as authorized in the Agreement. Licensee has the right to use and disclose Confidential Information of Licensor reasonably in connection with the exercise of its rights and performance of its obligations under the Agreement, including without limitation disclosing such Confidential Information to Sublicensees, potential investors, acquirers, and others on a need to know basis, if such Confidential Information is provided under conditions which reasonably protect the confidentiality thereof. The Receiving Party has the right to disclose the Disclosing Party's Confidential Information to its agent and employees to the extent necessary for the Receiving Party to exercise its rights or perform its obligations under the Agreement, provided that each agent and employee receiving such Confidential Information is subject to appropriate confidentiality obligations substantially similar to those of this Section 8. Each Party's obligation of confidence hereunder includes, without limitation, using at least the same degree of care with the disclosing Party's Confidential Information as it uses to protect its own Confidential Information, but always at least a reasonable degree of care. The Receiving Party shall be solely liable for any disclosure or use of the Disclosing Party's Confidential Information in violation of this Agreement by any agents, employees, advisors, actual or potential Sublicensees, acquirers or investors of the Receiving Party.

8.3 Confidentiality of Terms of Agreement

Each Party agrees not to disclose to any third party the terms of the Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of the Agreement: (a) to advisors, actual or potential Sublicensees, acquirers or investors on a need to know basis, in each case, under appropriate confidentiality obligations substantially similar to those of this Section 8; and (b) to the extent necessary, in the reasonable opinion of the Receiving Party's counsel, to comply with applicable laws, regulations and court orders (including, without limitation, The Texas Public Information Act, as may be amended from time to time, other open records laws, decisions and rulings, and securities laws, regulations and guidance). If the Agreement is not for all fields of use, then Licensor may disclose the Field to other potential third party licensees. Notwithstanding the foregoing, the existence of the Agreement shall not be considered Confidential Information.

8.4 Disclosure Required by Court Order or Law

If the Receiving Party is required to disclose Confidential Information of another Party hereto, or any terms of the Agreement, pursuant to the order or requirement of a court, administrative agency, or other governmental body or applicable law, the Receiving Party may disclose such Confidential Information or terms to the extent required, provided that the Receiving Party shall provide the Disclosing Party with reasonable advance notice thereof (unless prohibited by law) to enable the Disclosing Party to seek a protective order and otherwise seek to prevent such disclosure. To the extent that Confidential Information so disclosed does not become part of the public domain by virtue of such disclosure, it shall remain Confidential Information protected pursuant to Section 8.

8.5 Copies

Each Party agrees not to copy or record any of the Confidential Information of the other Party, except as reasonably necessary to exercise its rights or perform its obligations under the Agreement, and for archival and legal purposes.

8.6 Continuing Obligations

Subject to the exclusions listed in Section 8.7, the Parties' confidentiality obligations under the Agreement will survive termination of the Agreement and will continue for a period of five years thereafter.

8.7 Exclusions

Information shall not be considered Confidential Information of a Disclosing Party under the Agreement to the extent that the Receiving Party can establish by competent written proof that such information:

(a) Was in the public domain at the time of disclosure; or

(b) Later became part of the public domain through no act or omission of the Receiving Party, its employees, agents, successors or assigns in breach of the Agreement; or

(c) Was lawfully disclosed to the Receiving Party by a third party having the right to disclose it not under an obligation of confidentiality; or

(d) Was already known by the Receiving Party at the time of disclosure; or

(e) Was independently developed by the Receiving Party without use of the disclosing Party's Confidential Information.

8.8 Copyright Notice
The placement of a copyright notice on any Confidential Information will not be construed to mean that such information has been published and will not release the other Party from its obligation of confidentiality hereunder.

8.9 Remedies
In the event of a breach, threatened breach or intended breach of the terms of this Section 8 by either of the Parties, the Disclosing Party, in addition to any other rights and remedies available to it at law or in equity, shall be entitled to seek preliminary and final injunctions, enjoining and restraining such breach, threatened breach or intended breach of such Disclosing Party's Confidential Information.

9. Infringement and Litigation

9.1 Notification
If either Licensor's designated office for technology commercialization or Licensee becomes aware of any infringement or potential infringement of Patent Rights, each Party shall promptly notify the other of such in writing.

9.2 Licensee's Enforcement Rights
Licensee may enforce the Patent Rights against any infringement by a third party. Licensee shall be responsible for payment of all fees and expenses associated with such enforcement incurred by Licensee and incurred by Licensor in providing cooperation or joining as a party as provided in Section 9.4. Any monetary recovery for actual damages or punitive damages in excess of Licensee's documented, third-party expenses in enforcing the Patent Rights and amounts actually reimbursed by Licensee to Licensor under this Section 9.2 shall be shared by Licensee with Licensor in the same manner as Non-Royalty Sublicensing Consideration.

9.3 Licensor's Enforcement Rights
If Licensee does not file suit within six months after a written request by Licensor to initiate an infringement action, then Licensor shall have the right, at its sole discretion, to bring suit to enforce any Patent Right licensed hereunder against the infringing activities, with Licensor retaining all recoveries from such enforcement. If Licensor pursues such infringement action, Licensor may, as part of the resolution of such efforts, grant non-exclusive license rights to the alleged infringer notwithstanding Licensee's exclusive license rights.

9.4 Cooperation between Licensor and Licensee

In any infringement suit or dispute, the Parties agree to cooperate fully with each other. At the request of the Party bringing suit, the other Party will permit reasonable access after reasonable advance notice to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours.

If it is necessary to name Licensor as a party in such action, then Licensee must first obtain Licensor's prior written permission, which permission shall not be unreasonably withheld, provided that Licensor shall have reasonable prior input on choice of counsel on any matter where such counsel represents Licensor, and Licensee and such counsel agree to follow all required procedures of the Texas Attorney General regarding retention of outside counsel for state entities.

10. Export Compliance

Licensee understands that the Arms Export Control Act (AECA), including its implementing International Traffic In Arms Regulations (ITAR), and the Export Administration Act (EAA), including its Export Administration Regulations (EAR), are some (but not all) of the laws and regulations that comprise the U.S. export laws and regulations. Licensee further understands that the U.S. export laws and regulations include (but are not limited to): (a) ITAR and EAR product/service/data- specific requirements; (b) ITAR and EAR ultimate destination-specific requirements; (c) ITAR and EAR end user-specific requirements; (d) Foreign Corrupt Practices Act; and (e) anti-boycott laws and regulations. Licensee will comply with all then-current applicable export laws and regulations of the U.S. Government (and other applicable U.S. laws and regulations) pertaining to the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information). Licensee certifies that it will not, directly or indirectly, export (including any deemed export), nor re-export (including any deemed re-export) the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information) in violation of applicable U.S. laws and regulations. Licensee will include a provision in its agreements, substantially similar to this Section 10, with its Sublicensees, third party wholesalers and distributors, and physicians, hospitals or other healthcare providers who purchase a Licensed Product, requiring that these parties comply with all then-current applicable U.S. export laws and regulations and other applicable U.S. laws and regulations.

11. Representations and Disclaimers

11.1 Licensor Representations

Except for the rights, if any, of the Government as set forth in Section 11.2, Licensor represents and warrants to Licensee that to the knowledge of Licensor's designated office for technology commercialization (i) Licensor is the owner or agent of the entire right, title, and interest in and to Patent Rights (other than the right, title and interest of any joint owner identified in Exhibit A), (ii) Licensor

has the right to grant all licenses including Patent Rights and/or Technology Rights granted under the Agreement, (iii) Licensor has not granted and will not grant licenses or other rights under the Patent Rights that are in conflict with the terms and conditions in the Agreement, (iv) Licensor has not received any written notice that a product or process claimed in the Patent Rights or otherwise comprising the Licensed Subject Matter is alleged to infringe any intellectual property rights of a third party, (v) Licensor has not notified any third party that such third party's products or processes infringe any claim of the Patent Rights, and (vi) with respect to the products and processes claimed in or covered by the Patent Rights and the other Licensed Subject Matter, all inventors thereof have fully assigned all rights thereto to the Licensor and have no remaining claims on any such invention.

11.2 Government Rights

Licensee understands that Licensed Subject Matter may have been developed under a funding agreement with Government and, if so, that Government may have certain rights relative thereto. The Agreement is made subject to the Government's rights under any such agreement and under any applicable Government law or regulation. To the extent that there is a conflict between any such agreement, such applicable law or regulation and the Agreement, the terms of such Government agreement, and applicable law or regulation, shall prevail. Licensee agrees that, to the extent required by U.S. laws and regulations, Licensed Products used or Sold in the U.S. will be manufactured substantially in the U.S., unless a written waiver is obtained in advance from the U.S. Government.

11.3 Licensor Disclaimers

EXCEPT AS SPECIFICALLY SET FORTH IN SECTION 11.1, LICENSEE UNDERSTANDS AND AGREES THAT LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, AS TO THE LICENSED PRODUCTS OR LICENSED SERVICES, OR AS TO THE OPERABILITY OR FITNESS FOR ANY USE OR PARTICULAR PURPOSE, MERCHANTABILITY, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT, PATENTABILITY, AND/OR BREADTH OF PATENT RIGHTS. LICENSOR MAKES NO REPRESENTATION AS TO WHETHER ANY PATENT WITHIN PATENT RIGHTS IS VALID, OR AS TO WHETHER THERE ARE ANY PATENTS NOW HELD, OR WHICH WILL BE HELD, BY OTHERS OR BY LICENSOR THAT MIGHT BE REQUIRED FOR USE OF PATENT RIGHTS IN FIELD. NOTHING IN THE AGREEMENT WILL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS TO ANY PATENTS OR TECHNOLOGY OF LICENSOR OTHER THAN THE PATENT RIGHTS, WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS, OR THE TECHNOLOGY RIGHTS SPECIFICALLY DESCRIBED HEREIN.

11.4 Licensee Representations

By execution of the Agreement, Licensee represents, acknowledges, covenants and agrees

(a) that Licensee has not been induced in any way by Licensor or its employees to enter into the Agreement, and (b) that Licensee has been given an opportunity to conduct sufficient due diligence with respect to all items and issues pertaining to this Section 11 (Representations and Disclaimers) and all other matters pertaining to the Agreement; and

(b) that Licensee has adequate knowledge and expertise, or has utilized knowledgeable and expert consultants, to adequately conduct the due diligence, and (d) that Licensee accepts all risks inherent herein. Licensee represents that it is a duly organized, validly existing entity of the form indicated in the preamble to the Agreement, and is in good standing under the laws of its jurisdiction of organization as indicated in the preamble of the Agreement, and has all necessary corporate or other appropriate power and authority to execute, deliver and perform its obligations hereunder.

12. Limit of Liability

IN NO EVENT SHALL LICENSOR, THE UNIVERSITY SYSTEM IT GOVERNS, ITS MEMBER INSTITUTIONS, INVENTORS, REGENTS, OFFICERS, EMPLOYEES, STUDENTS, AGENTS OR AFFILIATED ENTERPRISES, BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER ANY SUCH PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. OTHER THAN FOR CLAIMS AGAINST LICENSEE FOR INDEMNIFICATION (SECTION 13) OR FOR MISUSE OR MISAPPROPRIATION OR INFRINGEMENT OF LICENSOR'S INTELLECTUAL PROPERTY RIGHTS, LICENSEE WILL NOT BE LIABLE TO LICENSOR FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER LICENSEE KNOWS OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES.

13. Indemnification

13.1 Indemnification Obligation

Subject to Section 13.2, Licensee agrees to hold harmless, defend and indemnify Licensor, the university system it governs, its member institutions, its Regents, officers, employees, students and agents ("**Indemnified Parties**") from and against any liabilities, damages, causes of action, suits, judgments, liens, penalties, fines, losses, costs and expenses (including, without limitation,

reasonable attorneys' fees and other expenses of litigation) (collectively "**Liabilities**") resulting from claims or demands brought by third parties against an Indemnified Party on account of any injury or death of persons, damage to property, or any other damage or loss arising out of or in connection with the Agreement or the exercise or practice by or under authority of Licensee or its Sublicensees, or third party wholesalers or distributors, or physicians, hospitals or other healthcare providers who purchase a Licensed Product, of the rights granted hereunder.

13.2 Conditions of Indemnification

Licensee shall have no responsibility or obligation under Section 13.1 for any Liabilities to the extent caused by the gross negligence or willful misconduct by Licensor. Obligations to indemnify and hold harmless under Section 13.1 are subject to: (a) to the extent authorized by the Texas Constitution and the laws of the State of Texas and subject to the statutory duties of the Texas Attorney General, the Indemnified Party giving Licensee control of the defense and settlement of the claim and demand; and (b) to the extent authorized by the Texas Constitution and the laws of the State of Texas and subject to statutory duties of the Texas Attorney General, the Indemnified Party providing the assistance reasonably requested by Licensee, at Licensee's expense.

14. Insurance

14.1 Insurance Requirements

Prior to any Licensed Product being used or Sold (including for the purpose of obtaining Regulatory Approval), and prior to any Licensed Service being performed by Licensee or by a Sublicensee, and for a period of five years after the Agreement expires or is terminated, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in commercially reasonable and appropriate amounts for the Licensed Product being used or Sold or the Licensed Service being performed. Licensee shall use commercially reasonable efforts to have Licensor named as an additional insured. Such commercial general liability insurance shall provide, without limitation: (i) product liability coverage; (ii) broad form contractual liability coverage for Licensee's indemnification obligations under the Agreement; and (iii) coverage for litigation costs.

14.2 Evidence of Insurance and Notice of Changes

Upon request by Licensor, Licensee shall provide Licensor with written evidence of such insurance. Additionally, Licensee shall provide Licensor with written notice of at least 45 days prior to Licensee cancelling, not renewing, or materially changing such insurance.

15. Assignment

The Agreement may not be assigned by Licensee without the prior written consent of Licensor, which consent will not be unreasonably withheld. For clarity, an assignment

shall not include any sublicensing by MAIA Biotechnology to a MAIA Affiliate. A merger or other transaction in which the equity holders of Licensee prior to such event hold less than a majority of the equity of the surviving or acquiring entity shall be considered an assignment of the Agreement. For any permitted assignment to be effective, (a) Licensee must be in good standing under this Agreement, (b) the Licensee must pay Licensor the assignment fee pursuant to Section 3.1(e), and (c) the assignee must assume in writing (a copy of which shall be promptly provided to Licensor) all of Licensee's interests, rights, duties and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if assignee were an original Party to the Agreement.

16. Governmental Markings

16.1 Patent Markings
Licensee agrees that all Licensed Products Sold by Licensee or Sublicensees will be legibly marked with the number of any applicable patent(s) licensed hereunder as part of the Patent Rights in accordance with each country's patent marking laws, including Title 35, U.S. Code, or if such marking is not practicable, shall so mark the accompanying outer box or product insert for Licensed Products accordingly.

16.2 Governmental Approvals and Marketing of Licensed Products and or Licensed Services Licensee will be responsible for obtaining all necessary governmental approvals for the development, production, distribution, Sale, and use of any Licensed Product or performance of any Licensed Service, at Licensee's expense, including, without limitation, any safety studies. Licensee will have sole responsibility for any warning labels, packaging and instructions as to the use and the quality control for any Licensed Product or Licensed Service.

16.3 Foreign Registration and Laws
Licensee agrees to register the Agreement with any foreign governmental agency that requires such registration and Licensee will pay all costs and legal fees in connection with such registration. Licensee is responsible for compliance with all foreign laws affecting the Agreement or the Sale of Licensed Products and Licensed Services to the extent there is no conflict with United States law, in which case United States law will control.

17. Use of Name

Neither Party will use the name, trademarks or other marks of the other Party (including, in the case of Licensor, the name of the university system it governs, its member institutions, any of its Regents or employees) without the advance written consent of the other Party. Notwithstanding the foregoing, Licensor may use Licensee's name and logo for various reports required by governmental law, rule or regulation and for internal reports without the prior written consent of the Licensee.

18. Notices

Any notice or other communication of the Parties required or permitted to be given or made under the Agreement will be in writing and will be deemed effective when sent in a manner that provides confirmation or acknowledgement of delivery and received at the address set forth below (or as changed by written notice pursuant to this Section 18).

Licensee Contacts	**Licensor Contacts**
Contact for Notice: Vlad Vitoc, MD, MBA Chief Executive Officer MAIA Biotechnology, Inc. 444 West Lake Street, Suite 1700 Chicago, IL 60606 Office: [***] Cell: [***] Email: [***] Patent prosecution contact: [***]	Contact for Notice: UT Southwestern Medical Center Office for Technology Development Attn: Director for Technology Commercialization 5323 Harry Hines Boulevard, Dallas, Texas 75390-9094 [***] [***] E-mail: [***] Payment and financial reporting contact: Checks in U.S. dollars payable to "UT SOUTHWESTERN" referencing L2664-MAIA, UT Southwestern Medical Center Lock Box 845477 Dallas, Texas 75284-5477 Patent prosecution contact: Attn: Director for Technology Commercialization Office for Technology Development 5323 Harry Hines Boulevard, Dallas, Texas 75390-9094 [***]

Notices required under the Agreement may be delivered via E-mail provided such notice is confirmed in writing as indicated. Notices shall be provided to each Party as specified in the "Contact for Notice" address. Each Party shall update the other Party in writing with any changes in such contact information.

19. General Provisions

19.1 Binding Effect

The Agreement is binding upon and inures to the benefit of the Parties hereto, their respective executors, administrators, heirs, permitted assigns, and permitted successors in interest.

19.2 Construction of Agreement

Headings are included for convenience only and will not be used to construe the Agreement. The Parties acknowledge and agree that both Parties substantially participated in negotiating the provisions of the Agreement; therefore, both Parties agree that any ambiguity in the Agreement shall not be construed more favorably toward one Party than the other Party, regardless of which Party primarily drafted the Agreement.

19.3 Counterparts and Signatures

The Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. A Party may evidence its execution and delivery of the Agreement by transmission of a signed copy of the Agreement via facsimile or email. In such event, the Party shall promptly provide the original signature page(s) to the other Party.

19.4 Compliance with Laws

Licensee will comply with all applicable national, state and local laws and regulations, including, without limitation, all export laws and regulations.

19.5 Governing Law

The Agreement will be construed and enforced in accordance with laws of the U.S. and the State of Texas, without regard to choice of law and conflicts of law principles.

19.6 Modification

Any modification of the Agreement will be effective only if it is in writing and signed by duly authorized representatives of both Parties. No modification will be made by email communications.

19.7 Severability

If any provision hereof is held to be invalid, illegal or unenforceable in any jurisdiction, the Parties hereto shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties, and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such other provisions in any other jurisdiction, so long as the essential essence of the Agreement remains enforceable.

19.8 Third Party Beneficiaries

Nothing in the Agreement, express or implied, is intended to confer any benefits, rights or remedies on any entity, other than the Parties and their permitted successors and assigns.

19.9 Waiver

Neither Party will be deemed to have waived any of its rights under the Agreement unless the waiver is in writing and signed by such Party. No delay or omission of a Party in exercising or enforcing a right or remedy under the Agreement shall operate as a waiver thereof.

19.10 Sovereign Immunity
Nothing in the Agreement shall be deemed or treated as any waiver of Licensor's sovereign immunity.

19.11 Entire Agreement
The Agreement constitutes the entire Agreement between the Parties regarding the subject matter hereof, and supersedes all prior written or verbal agreements, representations and understandings relative to such matters.

19.12 Claims Against Licensor for Breach of Agreement
Licensee acknowledges that any claim for breach of the Agreement asserted by Licensee against Licensor shall be subject to Chapter 2260 of the Texas Government Code and that the process provided therein shall be Licensee's sole and exclusive process for seeking a remedy for any and all alleged breaches of the Agreement by Licensor or the State of Texas.

20. No Other Promises and Agreements; Representation by Counsel.

Licensee expressly warrants and represents and does hereby state and represent that no promise or agreement which is not herein expressed has been made to Licensee in executing the Agreement except those explicitly set forth herein, and that Licensee is not relying upon any statement or representation of Licensor or its representatives. Licensee is relying on Licensee's own judgment and has had the opportunity to be represented by legal counsel. Licensee hereby warrants and represents that Licensee understands and agrees to all terms and conditions set forth in the Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Patent License Agreement.

LICENSOR: BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM	Licensee: AMIA Biotechnology, Inc.
By [***]	By [***]
Date	Date

EXHIBIT A TO
PATENT LICENSE AGREEMENT

PATENT RIGHTS

[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]