As submitted confidentially to the U.S. Securities and Exchange Commission on October 15, 2021. This draft registration statement has not been publicly filed with the U.S. Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

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

FORM S-1

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.)

4444 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.
4444 West Lake Street, Suite 1700
Chicago, IL 60606
(312) 416-8592

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:

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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. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be registered(1)	Proposed Maximum Aggregate Offering Price Per Share	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
Common Stock, $0.0001 par value per share		$	$	$

(1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes securities that the underwriters have the option to purchase to cover overallotments. See "Underwriting".

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.

Explanatory Note

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our unaudited financial statements as of June 30, 2021 and for each of the six months ended June 30, 2020 and 2021 because they relate to historical periods that we believe will not be required to be included in the prospectus at the time the prospectus is filed publicly. We intend to amend the registration statement to include all financial information required by Regulation S-X at the date of such amendment before publicly filing the registration statement.

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 OCTOBER 15, 2021**

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 have applied to have our common stock listed on the NASDAQ Capital Market LLC, or Nasdaq, under the symbol "MAIA."

Investing in our common stock involves a high degree of risk. See "*Risk Factors*" beginning on page 15. 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 134 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 , 2021.

ThinkEquity

The date of this prospectus is , 2021

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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 15 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 novel cancer therapies aimed at overcoming treatment resistant diseases. Our lead therapeutic candidate, THIO, is entering a Phase 2 proof-of-concept clinical study where it will be administered in advance of treatment with the immune check point inhibitor cemiplimab in Non-Small Cell Lung Cancer (NSCLC), to validate newly discovered immunogenic activity of THIO. Other considered indications for THIO include colorectal cancer (CRC), small cell lung cancer (SCLC) and liver cancer (Hepatocellular Carcinoma or HCC). Based on recently discovered evidence of immunogenic activity, we believe that THIO may have considerable therapeutic potential in multiple cancers. In February 2021, we signed a clinical supply agreement with Regeneron to receive cemiplimab at no upfront cost, representing a significant savings for the study, in exchange for granting Regeneron exclusive development rights for NSCLC during the study period. This agreement represents the first positive step in our strategy to collaborate with pharmaceutical and biotechnology companies that have immune-activating therapies for various potential indications of THIO.

Our Lead Product Candidate

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a potential first-in-class telomere targeting agent with a novel mechanism of action. THIO is currently in clinical development, evaluating its activity in multiple tumor types. The unique primary activity of THIO is based on two distinct Nobel Prize winning discoveries. Telomeres, along with the enzyme telomerase, play a fundamental role in the survival of cancer cells and their resistance to current therapies.

In 2019, our research team discovered that THIO produced telomere modifications and disruption, which ultimately induced cancer-specific innate and adaptive immune response against immunogenically "cold" or unresponsive tumor types, tested in syngeneic and humanized mouse models of telomerase-expressing cancers. When THIO was administered to mice at low doses, followed by a break to activate the immune system against a specific cancer, then followed by an immune-activating agent, such as an immune check point inhibitor (either PD-1 or PD-L1), complete tumor regression with no recurrence was achieved, representing a curative or nearly curative effect. In addition, there were no observed toxicities. These new findings were published in the prominent research scientific journal *Cancer Cell* in July 2020. Similar high and durable anticancer activities of THIO have been consistently demonstrated in multiple preclinical models, when administered in advance of different immune activating therapies, including standard-of-care checkpoint inhibitors, and with radiation therapy.

Based on these recent discoveries, a new therapeutic approach has been designed to advance THIO to a Phase 2 clinical trial (THIO-101) in 2nd line or later advanced Non-Small Cell Lung Cancer (NSCLC) patients, who have progressed following treatment with a standard-of-care (SOC) regimen that includes a checkpoint inhibitor. This study will be conducted in Australia and Europe. Building upon the expected early data results from the THIO-101 study, we plan to initiate an additional Phase 2 basket study to evaluate NSCLC, Colorectal Cancer (CRC), Hepatocellular Carcinoma (HCC) and other cancers. We plan to pursue an accelerated regulatory approval pathway to commercialize THIO in the United States (US) and approvals in key international regions including the European Union (EU), Australia and Japan.

Our Telomere Targeting Approach

Telomeres are regions of repetitive nucleotide sequences that are associated with specialized proteins at the ends of linear chromosomes in cells. Telomere maintenance is essential for unlimited cell proliferation and confers immortality in cancer cells, and thus represents a key therapeutic target for cancer.

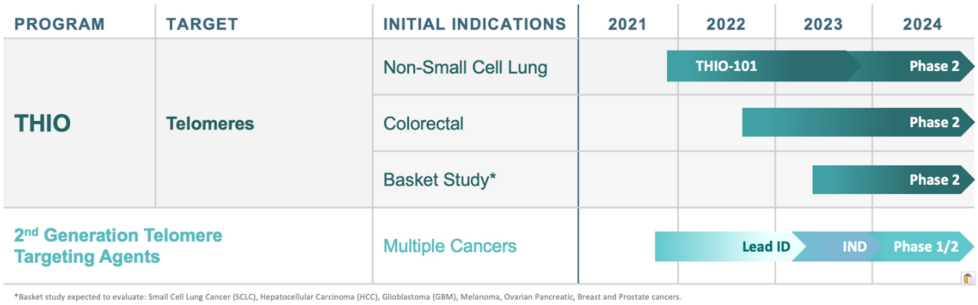
Telomerase is an enzyme that is present in almost all human cancer cells, across tumor types. In contrast, its activity is detected in less than 1% of normal cells. THIO is only active in cells that are telomerase positive (TERT+). Cancer cells are telomerase positive continuously, while normal cells are telomerase positive only transiently. Thus, THIO activity is highly specific to cancer cells versus normal cells.

Cancer-specific disturbance of telomeric structure, mediated by telomerase, is expected to lead to disruption in the cell cycle, followed by rapid cell death. THIO's cancer-specific telomere targeting by using the enzyme telomerase was shown to be specific to cancer cells based on pre-clinical studies and may differentiate THIO from all other available cancer therapies currently in clinical use.

Our research team is actively developing next generation small molecule telomere modifying agents with improved features. We believe this will lead to the development of additional novel cancer drugs with potentially increased efficacy and reduced side effects, which may lead to significant improvement in cure rates for cancer patients across cancer types.

Our Development Pipeline

Our THIO program drives our development pipeline of second-generation telomere targeting agents as summarized in the chart below:



Our Leadership 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.

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., Cephalon Inc., Geron Corporation, AbbVie Bio Corp., Agouron Pharmaceuticals (a Pfizer company), and Novo Nordisk Pharmaceuticals Inc., among others.

Our Strategy

Our goal is to be the leader in the development and commercialization of cancer telomere targeting agents and other novel small molecule oncology therapies. Our initial focus is to leverage the existing pre-clinical and clinical history of THIO to support rapid and cost-efficient development using its recently discovered immunogenic treatment approach.

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

1. Transforming "cold" tumors into "hot" tumors, rendering them responsive to immunotherapy.
2. Improving immunotherapy efficacy in "hot" tumors.
3. Restoring immunotherapy efficacy in patients who have progressed.

The key elements of our strategy are to:

- Rapidly advance our lead product candidate, THIO, through clinical studies and toward accelerated approval as a priming agent administered in advance of the immune-activating agent cemiplimab for second-line or later treatment of NSCLC, and ultimately, as the foundation of first-line therapy regimens in multiple indications and geographies.
- Broaden the clinical development of THIO by exploring synergistic administration prior to other standard-of care immune activating therapies.
- Selectively enter strategic collaborations with pharmaceutical and biotechnology companies that have immune-activating therapies, similar to and potentially more broadly than our existing agreement with Regeneron.
- Develop a franchise of telomere targeted cancer therapies to establish a position as a leader in this area within the oncology therapy field.
- Build a leading oncology company while maintaining a strong and diverse culture and putting cancer patients first.

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 (312) 416-8592. 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. 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 trial of THIO 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.
Dividend policy	We do not anticipate paying any dividends on our common stock in the foreseeable future; however, we may change this policy in the future. See "Dividend Policy."
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 have applied to list our common stock for trading on the Nasdaq 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 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 sell, offer, agree to sell, contract to sell, hypothecate, pledge, grant any option to purchase, make any short sale of, or otherwise dispose of or hedge, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock, for a period of 180 days 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.

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

- assumes the underwriters do not exercise their over-allotment option;
- gives effect to our amended and restated certificate of incorporation, which will be in effect prior to the consummation of this offering;
- excludes (i) an aggregate of shares of common stock reserved for issuance under our 2018 Stock Option Plan (the "MAIA 2018 Plan"), (ii) shares of common stock reserved for issuance under our Amended and Restated 2020 Equity Incentive Plan (the "MAIA 2020 Plan"), (iii) 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, (iv) warrants for shares of common stock (the "MAIA Stock Warrants"), inclusive of warrants which will vest upon the pricing of this offering, and (v) the conversion by holders under the simple agreement for future equity agreement (the "SAFE Agreement") for shares of common stock;

- excludes an aggregate shares of common stock reserved for issuance under our 2021 Equity Incentive Plan that we intend to adopt in connection with this offering; and
- assumes 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.

The total number of shares of our common stock outstanding as of September 30, 2021 was , which excludes shares of common stock reserved for issuance pursuant to currently outstanding options and warrants.

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.
- 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. 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.
- 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 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.
- 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.
- 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.
- 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.
- Our proprietary information may be lost, or we may suffer security breaches.
- 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 may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

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, 2020 and December 31, 2019 and the consolidated balance sheet data as of December 31, 2020 are derived from our audited financial statements included elsewhere in this prospectus.

The summarized financial information presented below is derived from and should be read in conjunction with our audited consolidated financial statements including the notes to those financial statements, which are included elsewhere in this prospectus along with the sections entitled "Selected Historical 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.

	Nine Months Ended September 30,		Years Ended December 31,	
	2021	2020	2020	2019
	(Unaudited)			
Total operating expenses			$ 6,975,601	$ 6,921,356
Loss from operations			(6,975,601)	(6,921,356)
Other expense, net			16,353	242
Net loss			(6,959,248)	(6,921,114)
Net loss attributable to MAIA Biotechnology, Inc. shareholders			(6,636,660)	(6,492,782)
Net loss per common share - basic and diluted (1)			$ (1.50)	$ (1.72)
Weighted average common shares outstanding - basic and diluted (1)			4,427,242	3,769,880
Pro forma net loss (unaudited)				
Pro forma net loss per common share - basic and diluted (unaudited)				
Pro forma weighted average common shares outstanding - basic and diluted (unaudited)				

(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.

	September 30, 2021	December 31, 2020	December 31, 2019
Balance Sheet Data:			
Cash		$ 663,457	$ 1,709,565
Working (deficit) capital (2)		(947,239)	1,359,964
Total assets		746,505	1,734,529
Total liabilities		2,362,805	409,737
Total stockholders' (deficit) equity		(1,616,300)	1,324,792

(2) We define working (deficit) capital 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 $6,959,248 and $6,921,114 for each of the years ended December 31, 2020 and 2019. As of December 31, 2020, we had an accumulated deficit of $15,934,113. 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 September 30, 2021, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 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 have been 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.

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 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. 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.

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. 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;
- 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 not be able 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 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 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 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 have applied to list our common stock on the Nasdaq 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 sell, offer, agree to sell, contract to sell, hypothecate, pledge, grant any option to purchase, make any short sale of, or otherwise dispose of or hedge, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock, for a period of 180 days after the date of this prospectus, without the prior written consent of the representative. 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 future exercise of any outstanding options to purchase shares of our common stock will cause you to experience additional dilution. See “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 September 30, 2021, an aggregate of shares of our common stock, which currently constitutes % 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 initial public 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. The federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any action asserting a claim arising under the Securities Act, the Exchange Act, or the rules and regulations promulgated 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 principle 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 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 Nasdaq, 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.

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. While we believe that the statistical data, market data and other industry data and forecasts are reliable, we have not independently verified the data. 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, to fund the planned trial of THIO and 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 into 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 12 months. 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.

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 September 30, 2021:

- on an actual basis;
- on an 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 as adjusted 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.

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.

The net tangible book value of our common stock as of September 30, 2021, was $ million, or $ 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 September 30, 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 September 30, 2021	$	
Increase in net tangible book value per share attributable to new investors	$	
As adjusted net tangible book value per share as of September 30, 2021, 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 for the years ended December 31, 2020 and 2019 from our audited financial statements appearing at the end of this prospectus. Our historical results are not necessarily indicative of results that should be expected in any future period.

	As of	As of December 31,	
	September 30, 2021	2020	2019
Balance Sheet Data:			
Cash		$ 663,457	$ 1,709,565
Working (deficit) capital (1)		(947,239)	1,359,622
Total assets		746,505	1,734,529
Accrued bonus		780,000	—
Deferred compensation		661,058	177,936
Accrued Interest		12,678	342
Convertible note payable, current portion		10,586	—
Convertible notes payable, net of current portion		332,841	9,172
Derivative liability for embedded conversion features on convertible notes payable and convertible notes payable, related parties		127,000	1,000
Convertible notes payable, related parties		98,960	—
Warrant liability		85,260	—
Simple agreement for future equity payable		25,000	25,000
Total stockholders' (deficit) equity		(1,616,300)	1,324,792

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

	Nine Months Ended September 30,		Years Ended December 31,	
	2021	2020	2020	2019
	(Unaudited)			
Statement of Operations Data:				
Operating expenses:				
Research and development expenses	$	$	$ 1,412,409	$ 1,911,882
General and administrative expenses			5,563,192	5,009,474
Total operating expenses			6,975,601	6,921,356
Loss from operations			(6,975,601)	(6,921,356)
Other income (expense), net			16,353	242
Net loss			(6,959,248)	(6,921,114)
Net loss attributable to noncontrolling interest			(322,588)	(428,332)
Net loss attributable to MAIA Biotechnology, Inc.			$ (6,636,660)	$ (6,492,782)
Net loss per common share - basic and diluted (1)			$ (1.50)	$ (1.72)
Weighted average common shares outstanding - basic and diluted (1)			4,427,242	3,769,880
Pro forma net loss (unaudited)				
Pro forma net loss per common share - basic and diluted (unaudited)				
Pro forma weighted average common shares outstanding - basic and diluted (unaudited)				

(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.

The lead compound, THIO, is a potentially first-in-class telomere targeting agent, which has demonstrated curative or near-curative effect in preclinical models of telomerase positive cancers when administered in advance of immune activating therapies like checkpoint inhibitors (immunotherapy agents). In the aggregate, more than 85% of cancers are telomerase positive.

We have 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 curative data for THIO, when administered in advance of atezolizumab (TecentriQ®; Genentech), in colorectal and lung cancer preclinical models.
- In Q1-2020, 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 Q1-2021 and expires in 2041.
- In Q1-2021, 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 is valued up to $29 million because it 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 Q1-2021, 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 Q2-2021, we completed a convertible note funding round in the amount of approximately $7.4 million.
- In Q3-2021, we completed a crossover round consisting of sales of common shares of MAIA in the amount of approximately $5.8 million. After this round, we feel that we have raised sufficient capital to fund THIO-101 clinical trials worldwide through safety and preliminary efficacy high level data results.
- In Q4-2021, we initiated the THIO-101 clinical trial in Australia. The trial is anticipated to enroll up to 164 patients with advanced NSCLC, with preliminary safety results targeted to be received in the first half of 2022.

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.

Financial Operations Overview and Analysis for the Years Ended December 31, 2020 and 2019

Comparison of the Years Ended December 31, 2020 and 2019

	Year Ended December 31,		Change	
	2020	2019	Dollars	Percentage
Operating expenses:				
Research and development expenses	$ 1,412,409	$ 1,911,882	(499,473)	(26)%
General and administrative expenses	5,563,192	5,009,474	553,718	11%
Total operating costs and expenses	6,975,601	6,921,356	54,245	1%
Loss from operations	(6,975,601)	(6,921,356)	(54,245)	(1)%
Other income (expense):				
Paycheck protection program loan forgiveness	62,500	—	62,500	100%
Interest (expense) income, net	(31,547)	242	(31,789)	(13,136)%
Change in fair value of embedded features	5,000	—	5,000	100%
Change in fair value of warrant liability	(19,600)	—	(19,600)	(100)%
Other income (expense), net	16,353	242	16,111	6,657%
Net loss	(6,959,248)	(6,921,114)	(38,134)	(1)%
Net loss attributable to noncontrolling interests	(322,588)	(428,332)	$ 105,744	25%
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (6,636,660)	$ (6,492,782)	$ (143,878)	(2)%

Operating Expenses

Research and development expenses

Research and development expenses decreased by approximately $499,000 or 26%, from approximately $1,912,000 for the year ended December 31, 2019 to approximately $1,412,000 for the year ended December 31, 2020 primarily due to the reduced costs resulting from the transition from preclinical research to the clinical preparation of THIO, partially offset by an increase in compensation expense.

General and administrative expenses

General and administrative expenses increased by approximately $554,000 or 11% from approximately $5,009,000 for the year ended December 31, 2019 to approximately $5,563,000 for the year ended December 31, 2020. The increase was primarily related to the increase in payroll expense, including stock-based compensation expense and bonus expense.

Other income (expense), net

Other income (expense), net is approximately $16,000 and primarily consists of a gain on the forgiveness of the paycheck protection program loan of $62,500 and a gain resulting from the change in fair value of the embedded

features of the convertible notes payable of $5,000, offset by net interest expense of approximately $32,000 related to the convertible notes payable, and a loss resulting from the change in the fair value of the warrant liability of $19,600.

Liquidity and Capital Resources

Capital Resources

As of December 31, 2020, our available cash totaled approximately $663,000 which represented a decrease of approximately $1,046,000 compared to December 31, 2019. As of December 31, 2020, we had a working capital deficit of approximately $947,000 which represents a decrease of approximately $2,307,000 compared to the year ended December 31, 2019. 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, and the attainment of profitable 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 accrues on the outstanding principal at the rate of 1% per annum. The PPP Loan is eligible for forgiveness if the funds are used for qualifying payroll expenses. If not forgiven, the loan is to be repaid in monthly installments beginning in 2022. The loan is unsecured and is not guaranteed.

Convertible Notes

Between February 16, 2021 and June 29, 2021, we issued unsecured convertible notes payable to investors for a total of $7,390,000. The notes bear simple interest at 6% per annum and mature two years from issuance. The notes also contain 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 shall 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, as a result of the equity financing of gross proceeds in excess of $5 million referred to below.

Sales of Common Stock

Between July 15, 2021 and September 29, 2021, the Company sold 725,563 shares of common stock at $8 per share for gross proceeds of approximately $5.8 million. 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 Notes, 2020 Convertible Notes, and convertible notes issued in 2021 into 1,357,228 shares of the Company's common stock on September 30, 2021.

Accordingly, we believe that we currently have sufficient funds to support operations through the next twelve months from the date of the consolidated financial statements are issued. We cannot make any assurances that additional financings will be available to us and, if available, on acceptable terms or at all. This could negatively impact our business and operations and could also lead to the reduction of our operations.

Cash Flows

Years Ended December 31, 2020 and 2019

	Year Ended December 31,	
	2020	**2019**
Net cash flows used in operating activities	$ (1,844,163)	$ (1,565,112)
Net cash flows provided by investing activities	—	187,556
Net cash flows provided by financing activities	798,055	2,222,305
Net (decrease) increase in cash and cash equivalents	$ (1,046,108)	$ 844,749

Operating Activities

For the years ended December 31, 2020, net cash used in operating activities was approximately $1,800,000, which consisted of a net loss of approximately $6,960,000 offset by non-cash charges of approximately $3,861,000 which primarily includes $3,888,968 in stock-based compensation offset by $62,500 related to gain from forgiveness of Paycheck Protection Program loan and a loss of $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 $19,600 and amortization of debt discount on convertible notes of $19,875. Total changes in operating assets and liabilities of approximately $1,254,000 were primarily driven by a $483,122 increase in deferred compensation, $58,084 increase in prepaid expenses and other current assets, a $31,830 increase in accounts payable, a $780,000 increase in accrued bonus, and a $4,938 increase in related party payables.

For the year ended December 31, 2019 net cash used in operating activities was $1,565,112, which consisted of a net loss of $6,921,114, offset by non-cash charges of approximately $5,087,000, which primarily includes $4,136,650 in stock-based compensation, issuance of common stock for the THIO intellectual property of $949,723, and amortization of debt discount of $172. Total changes in operating assets and liabilities of approximately $269,000 were primarily driven by a $15,734 increase in prepaid expenses and other current assets, offset by an increase in deferred compensation of $177,936, a $104,826 increase in accounts payable, and a $2,087 increase in related party payables.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2019 consisted of $187,556 of cash related to the THIO asset acquisition which was paid for in common stock.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 consisted of proceeds from issuance of convertible notes totaling $610,000, collections of subscriptions receivable of $102,400 and $35,000 for MAIA and DGD, respectively, proceeds from the paycheck protection program loan totaling $62,500, and proceeds from the issuance of common stock of DGD totaling $50,000, offset by return of capital - DGD totaling $58,212.

Net cash provided by financing activities for the year ended December 31, 2019 consisted of proceeds from issuance of common stock of $1,912,305 and $175,000 for MAIA and DGD, respectively, collections of subscription receivable of $100,000 for MAIA common stock, proceeds from the issuance of simple agreement for future equity payable of $25,000, and proceeds from the issuance of convertible notes of $10,000.

Contractual Obligations and Commitments

See Note 9, Commitments and Contingencies, of the notes to our consolidated financial statements for the years ended December 31, 2020 and 2019 included elsewhere in this registration statement for further discussion of our commitments and contingencies.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

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

Prior to the initial public offering, in order to determine the fair value of shares of our common stock, the Company's board of directors considered, among other things, contemporaneous valuations of our common stock, our business, financial condition and results of operations, including related industry trends affecting our 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 have been based on sales of common stock to third parties.

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. 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. The fair value of restricted stock awards is based on common stock price.

Derivative Liability for Embedded Conversion Features

We do not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. We evaluate all of our 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. Bifurcated embedded derivatives are classified with the related host contract in our balance sheet.

Warrant liability

We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrants' specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to our own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of our control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent

quarterly period end date while the warrants are outstanding. Liability classified warrants are recognized at fair value, with changes in fair value recognized in the statement of operations each period.

Under ASC 815-40-35, we follow a sequencing policy whereby, in the event that reclassification of contracts from equity to assets or liabilities is necessary pursuant to ASC 815 due to our inability to demonstrate that we have sufficient authorized shares as a result of certain securities with a potentially indeterminable number of shares, shares will be allocated on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest grants receiving the first allocation of shares. Pursuant to ASC 815, issuance of securities to our employees or directors are not subject to the sequencing policy.

BUSINESS

Our Company

We are a clinical-stage biopharmaceutical company developing novel cancer therapies aimed at overcoming treatment resistant diseases. Our lead therapeutic candidate, THIO, is entering a Phase 2 proof-of-concept clinical study where it will be administered in advance of treatment with the immune check point inhibitor cemiplimab in Non-Small Cell Lung Cancer (NSCLC), to validate newly discovered immunogenic activity of THIO. Other considered indications for THIO include colorectal cancer (CRC), small cell lung cancer (SCLC) and liver cancer (Hepatocellular Carcinoma or HCC). Based on recently discovered evidence of immunogenic activity, we believe that THIO may have considerable therapeutic potential in multiple cancers. In February of 2021, we signed a clinical supply agreement with Regeneron to receive cemiplimab at no upfront cost, representing a significant savings for the study, in exchange for granting Regeneron exclusive development rights for NSCLC indication during the study period. This agreement represents the first positive step in our strategy to collaborate with pharmaceutical and biotechnology companies that have immune-activating therapies for various potential indications of THIO.

Our Lead Product Candidate

THIO (6-thio-dG or 6-thio-2'-deoxyguanosine) is a potential first-in-class telomere targeting agent with a novel mechanism of action. It is currently in clinical development, evaluating its activity in multiple tumor types. The unique primary activity of THIO is based on two distinct Nobel Prize winning discoveries. Telomeres, along with the enzyme telomerase, play a fundamental role in the survival of cancer cells and their resistance to current therapies.

In 2019, our research team discovered that THIO produced telomer modifications and disruption, which ultimately induced cancer-specific innate and adaptive immune response against immunogenically "cold" or unresponsive tumor types, tested in syngeneic and humanized mouse models of telomerase-expressing cancers. When THIO was administered to mice at low doses, followed by a break to activate the immune system against a specific cancer, then followed by an immune-activating agent, such as an immune check point inhibitor (either PD-1 or PD-L1), complete tumor regression with no recurrence was achieved, representing a curative or nearly curative effect. In addition, there were no observed toxicities. These new findings were published in the prominent research scientific journal *Cancer Cell* in July 2020. Similar high and durable anticancer activities of THIO have been consistently demonstrated in multiple preclinical models, when administered in advance of different immune activating therapies, including standard-of-care checkpoint inhibitors, and with radiation therapy.

Based on these recent discoveries, a new therapeutic approach has been designed to advance THIO to a Phase 2 clinical trial (THIO-101) in 2nd line or later advanced Non-Small Cell Lung Cancer (NSCLC) patients, who have progressed following treatment with a standard-of-care (SOC) regimen that includes a checkpoint inhibitor. This study will be conducted in Australia and Europe. Building upon the expected early data results from the THIO-101 study, we plan to initiate an additional Phase 2 basket study to evaluate Colorectal Cancer (CRC), Small Cell Lung Cancer (SCLC), Ovarian, Pancreatic, Brain (Glioblastoma, or GBM), Melanoma, Hepatocellular Carcinoma (HCC) and potentially other cancers. We plan to pursue an accelerated regulatory approval pathway to commercialize THIO in the United States (US) and approvals in key international regions including the European Union (EU) and Australia and Japan.

Our Telomere Targeting Approach

Telomeres are regions of repetitive nucleotide sequences that are associated with specialized proteins at the ends of linear chromosomes in cells. Telomere maintenance is essential for unlimited cell proliferation and confers immortality in cancer cells, and thus represents a key therapeutic target for cancer.

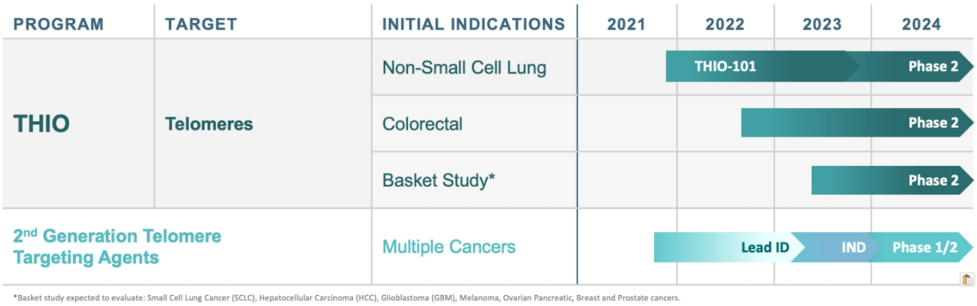
Telomerase is an enzyme that is present in almost all human cancer cells, across tumor types. In contrast, its activity is detected in less than 1% of normal cells. THIO is only active in cells that are telomerase positive (TERT+). Cancer cells are telomerase positive continuously, while normal cells are telomerase positive only transiently. Thus, THIO activity is highly specific to cancer cells versus normal cells.

Cancer-specific disturbance of telomeric structure, mediated by telomerase, is expected to lead to disruption in the cell cycle, followed by rapid cell death. THIO's cancer-specific telomere targeting by using the enzyme telomerase was shown to be specific to cancer cells based on clinical studies and may differentiate THIO from all other available cancer therapies currently in clinical use.

Our research team is actively developing next generation small molecule telomere modifying agents with improved features. We believe this will lead to the development of additional novel cancer drugs with potentially increased efficacy and reduced side effects, which may lead to significant improvement in cure rates for cancer patients across cancer types.

Our Development Pipeline

Our THIO program drives our development pipeline of second-generation telomere targeting agents as summarized in the chart below:



Our Strategy

Our goal is to be the leader in the development and commercialization of cancer telomere targeting agents and other novel small molecule oncology therapies. Our initial focus is to leverage the existing pre-clinical and clinical[1] history of THIO to support rapid and cost-efficient development using its recently discovered immunogenic treatment approach.

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

1. Transforming "cold" tumors into "hot" tumors, rendering them responsive to immunotherapy.
2. Improving immunotherapy efficacy in "hot" tumors.
3. Restoring immunotherapy efficacy in patients who have progressed.

The key elements of our strategy are to:

- Rapidly advance our lead product candidate, THIO, through clinical studies and toward accelerated approval as a priming agent administered in advance of the immune-activating agent cemiplimab for second-line or later treatment of NSCLC, and ultimately, as the foundation of first-line therapy regimens in multiple indications and geographies.
- Broaden the clinical development of THIO by exploring synergistic administration prior to other standard-of care immune activating therapies.

- Selectively enter strategic collaborations with pharmaceutical and biotechnology companies that have immune-activating therapies, similar to and potentially more broadly than our existing agreement with Regeneron.
- Develop a franchise of telomere targeted cancer therapies to establish a position as a leader in this area within the oncology therapy field.
- Build a leading oncology company while maintaining a strong and diverse culture and putting cancer patients first.

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%

A Survey of Telomerase Activity in Human Cancer – JW Shay, s Bacchetti – European Joumal 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
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
Pancreatic	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

Current Landscape of Checkpoint Inhibitor Franchises

Drug	Company	2020 Sales ($B)	Indications (tumor types)	NSCLC	SCLC	CRC	HCC	PanC	OC
KEYTRUDA (*pembrolizumab*)	Merck	14.4	19	2015	2019	2017	2018	Ph 3	Ph 3
OPDIVO (*nivolumab*)	BMS	7.7	10	2015	2018	2017	2017	Ph 2	Ph 3
TecentriQ (*atezolizumab*)	Genentech / Roche	3.4	6	2016	2019	Ph 3	2020	Ph 1/2	Ph 3
IMFINZI (*durvalumab*)	AstraZeneca	2.0	2	2018	2020		2021		Ph 3
LIBTAYO (*cemiplimab*)	Regeneron	0.4	3	2021					
BAVENCIO (*avelumab*)	Pfizer / Merck AG	0.4	3	2021			Ph 1		
TYVYT (*sintilimab*)	Eli Lilly	0.3	1	2021			Ph 3		
JEMPERLI (*dostarlimab*)	GSK		1						2021

Source: Biomed Tracker 2021

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 certain UTSW patent families generally directed to methods of using THIO and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW1 Agreement includes an exclusive license to certain US patents and patent applications.

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 an additional UTSW patent family and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW2 Agreement also includes an exclusive license to a pending US patent application.

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 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 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.
- Our Chief Operating Officer, Daniel Relovsky, has served in the pharmaceutical and biotechnology industries for over 30 years, including in various general management, operations, and commercialization roles. He has a broad track record of success including while at Novo-Nordisk Inc., IQVIA, Agouron, Inc., Cephalon Inc., and Puma Biotechnology, Inc., having led new product planning, business development, global alliance management, product launch teams as well as overall operations in medical and commercial areas, finance, business planning and oversight across these functional areas.

We have engaged the following advisors, who are leading, internationally recognized experts in oncology, telomeres and telomerase research, to be a part of our Special Advisory Board ("SAB"):

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 Chidren'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.

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.

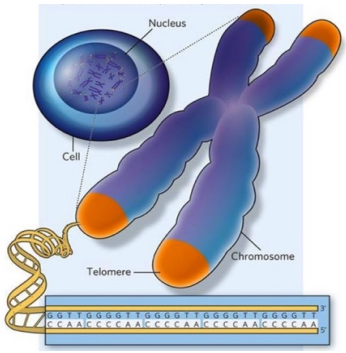
Our Programs

Telomere Targeting Program

Targeting Telomeres via Telomerase to Kill Cancer

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.

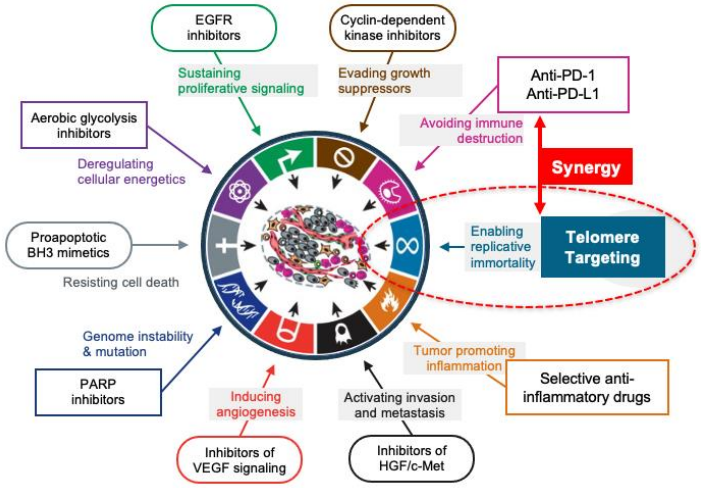
Maintenance of telomeres is essential for unlimited cellular proliferation and confers immortality in cancer cells. Telomeres in human cells consist of double-stranded and single-stranded repeats of the sequence TTAGGG, which terminate in a single-stranded 3´- extension overhang of the G-rich strand. 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.



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 one of the specific capabilities or “hallmarks” cancer cells use for tumor growth and progression. Our lead drug candidate, THIO, targets two major hallmarks:

- 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.



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

Role of the Enzyme Telomerase

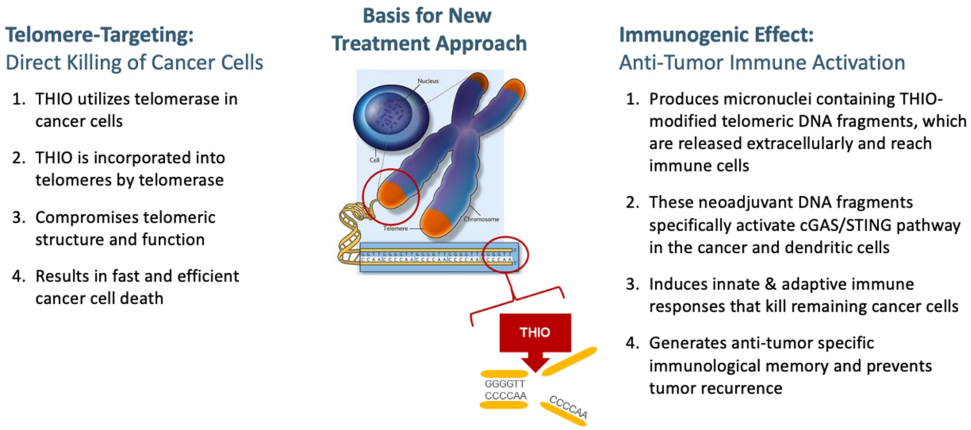
Telomerase is a ribonucleoprotein enzyme (reverse transcriptase) that synthesizes telomere repeats from the beginning, or *de novo*. In human cells, the telomerase holoenzyme consists of a high-molecular-weight complex with a template region-containing RNA subunit, hTR, and a protein component, the catalytic 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 potential first-in-class, 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 activity was shown to be primarily cancer-specific in tumor cells with active telomerase, but not in normal cells. THIO inhibited the cancer cell viability of colon and lung cancers while normal human cells were largely unaffected.

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 a theoretical method of action that has not been proven in human clinical trials.

In 2019, further non-clinical research in syngeneic and humanized mouse models of telomerase-expressing cancers uncovered previously unknown activity of THIO, specifically resulting from its efficient killing 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 Potential First-in-Class 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, the efficacy, safety and pharmacokinetics of THIO were 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 due to a lack of clinical activity in favor of other therapies.

As a result of these prior human studies, THIO has a well-established safety profile. Moreover, all prior studies were conducted primarily in heavily pre-treated, refractory patients, including most having undergone other purine analog therapy prior to THIO. Thus, it is anticipated that purine analog-naïve patients would be expected to tolerate and respond better to THIO, relative to what has been recorded in previous studies.

In addition to a well-established safety profile, THIO has shown a promising efficacy profile in prior clinical and human studies as compared to other cancer treatments currently on the market, for example:

- The colorectal cancer salvage setting (CRC-3+) is notoriously difficult to treat and carries a very poor prognosis. THIO monotherapy showed a 5% overall response rate (ORR) in a previous clinical study of CRC-3+. In comparison, in September 2012, regorafenib was approved for CRC-3+ based on the CORRECT trial, which was a randomized Phase 3 pivotal trial testing treatment with regorafenib versus a placebo. The results were as follows:
    - Overall Survival (OS): 6.4m v 5.0m (HR 0.77; p=0.0052)
    - Progression-Free Survival (PFS): 1.9m v 1.7m
    - Overall Response Rate (ORR): 1.0% v 0.4%
    - Disease Control Rate (DCR): 44.8% v 15.3% (p<0.0001)
- Regorafenib is the current SOC in CRC-3+. THIO had a greater ORR than regorafenib in the previous clinical study as a monotherapy, although ORR is not the only clinical criteria for FDA approval and results of unrelated clinical trials of different drugs cannot be relied upon as proof of comparative efficacy or safety.
- The pancreatic cancer (PanC) salvage setting is even more difficult to treat. THIO showed a 6% ORR in the previous clinical study as a monotherapy against PanC. In comparison, in October 2015, liposomal irinotecan was approved for PanC line 2+ based on the NAPOLI-1 trial, which was a Phase 3 pivotal trial

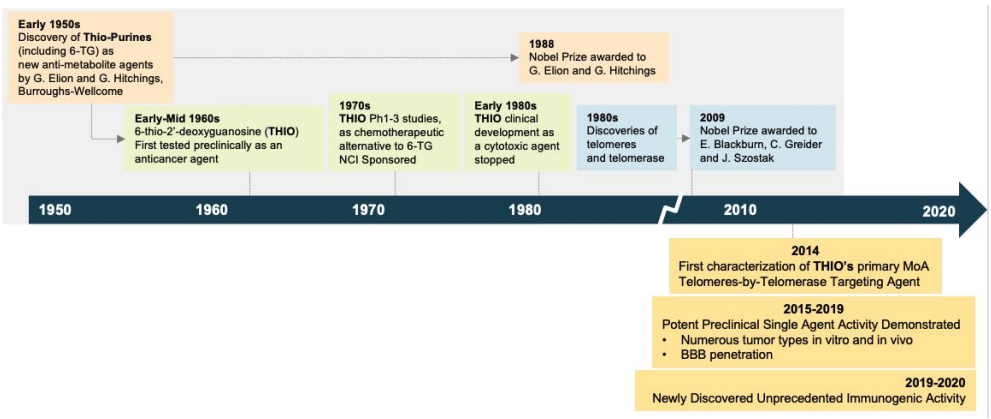
testing treatment with a combination of liposomal irinotecan together with fluorouracil (5FU) against liposomal irinotecan as monotherapy and 5FU as a monotherapy. The results were as follows:

- OS: 6.2m v 4.9m v 4.2m (HR 0.75)
- PFS: 3.1m v 2.7m v 1.5m
- ORR: 17% v 6% v 1%
- DCR: 52% v 44% v 24%

- ONYVIDE is the current SOC in PanC-2+ (=salvage setting). THIO as a monotherapy had comparable ORR to ONYVIDE monotherapy, although ORR is not the only clinical criteria for FDA approval, and results of unrelated clinical trials of different drugs cannot be relied upon as proof of comparative efficacy or safety, these results are promising.

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.



The unique primary activity of THIO was established based on two distinct Nobel Prize winning discoveries related to telomeres. *Telomeres* are vital DNA-structures found 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 also crucial for the survival of cancer cells. 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. To our knowledge, THIO's cancer-specific telomere targeting by using telomerase is different from all other available cancer therapies and those currently in 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 effectively "*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 with curative premise 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, killing cancer cells via telomerase-mediated DNA damage.

THIO alone has shown high anti-cancer 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, the average half maximal effective concentration (or EC_{50}) values were approximately 0.4 to 1.5 microM. THIO was not cytotoxic in normal, untransformed telomerase-negative cells at concentrations up to 100 microM.

In vivo: in summary, the efficacious doses 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.

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

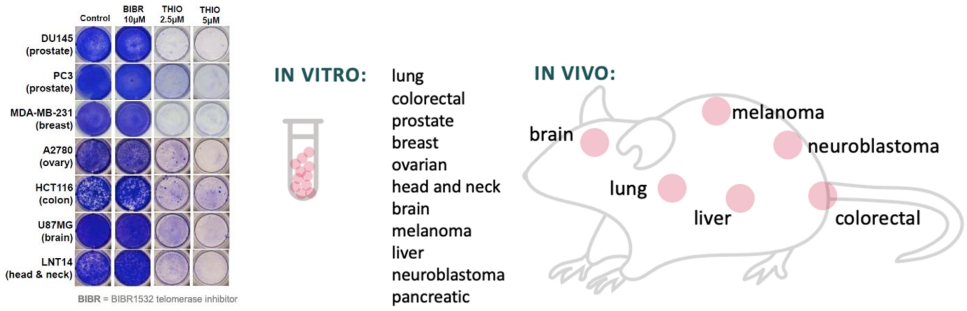
In vivo, THIO, at 3 mg/kg/dose, (which corresponds to a 20 mg/patient/day low-dose), administered followed by a one-day break, followed by an immune checkpoint inhibitor (either anti-programmed cell death protein 1 (PD-1) or anti-programmed death ligand 1 (PD-L1) products), resulted in cures in NSCLC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

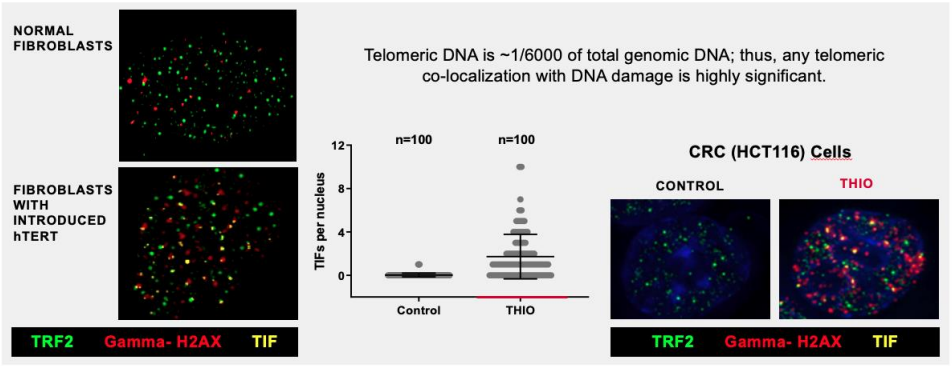
These responses were achieved through telomerase-dependent and cancer cell specific activation of a) DNA damage responses, and b) cGAS/STING pathways by THIO. This body of research represents the basis for the new immune-activation treatment strategy

The following represents key highlights from THIO preclinical research:

- THIO has demonstrated high activity in multiple preclinical studies evaluating various tumor types *in vitro* including in lung, colorectal, prostate, breast, ovarian, head and neck, brain, melanoma, liver, and *in vivo* in lung, colorectal, brain, melanoma, liver and other cancers.



- THIO appears to be highly effective *in vitro* at *selectively* killing cancer cells with active enzyme telomerase versus normal cells.

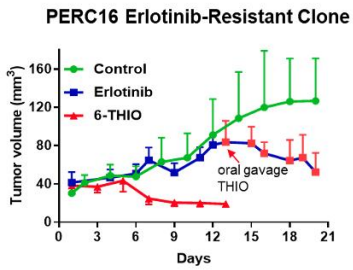


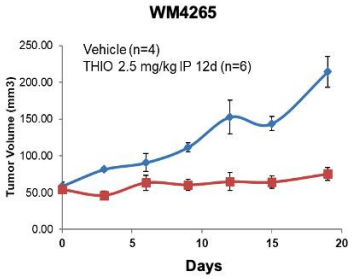
Mender I. et al., Cancer Discovery (2015)

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

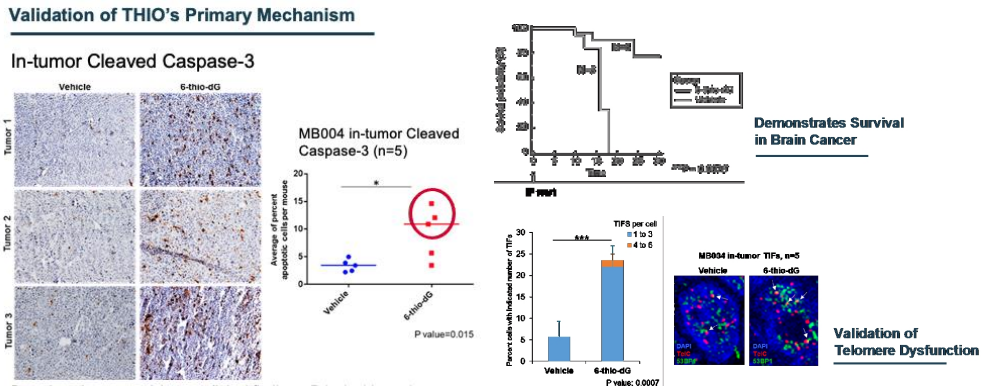
- **PERC16** human lung cancer cells (TKI-resistant)
- 5 mg/kg THIO once-daily i.p. injection
- 15 mg/kg erlotinib once-daily oral gavage

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

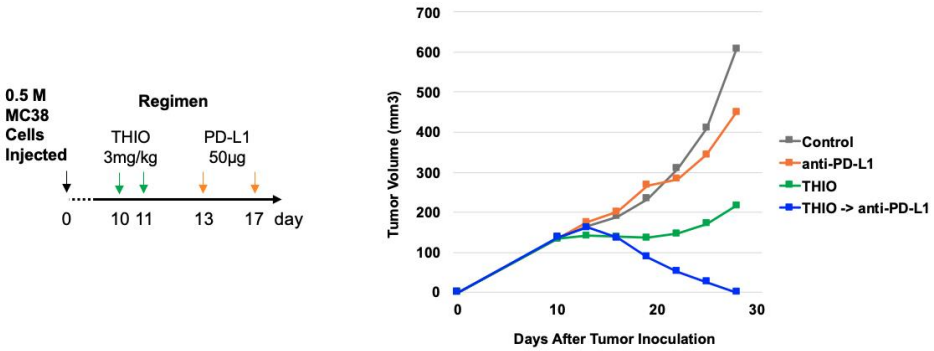




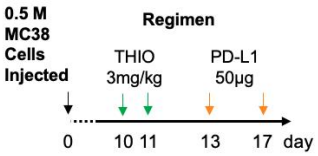
- THIO was observed to penetrate the blood-brain barrier and inhibits tumor growth, inducing in-tumor telomere dysfunction and cancer cell death, in *in vitro* models of difficult to treat pediatric brain cancer, where no therapy exists.

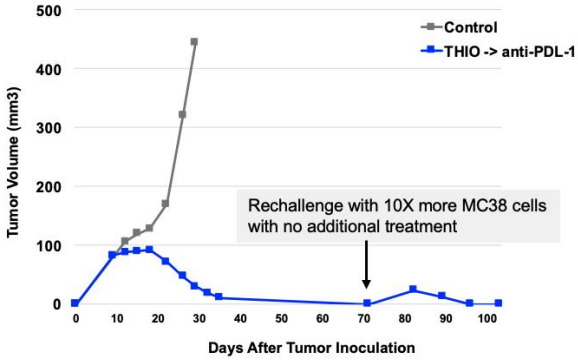


- THIO transformed "cold" tumors into "hot" tumors that were responsive to immunotherapy. THIO utilized a telomere targeting pathway that synergized with checkpoint inhibitors and other immune-activating therapies. The tumor-specific immune activation, resulting from THIO's primary mode of action, overcame resistance to current check point inhibitor (CPI) standard-of-care therapy, as illustrated in the following Colorectal Cancer model.



- Immunological memory was observed in mouse models, where the immune system continued to be active against the specific treated tumor cell type for up to 100 days post-tumor inoculation.





Moreover, due to the cGAS/STING activation caused by THIO, antitumor 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 effectively "*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 with curative premise for planned future trials.

THIO Clinical Trials

The efficacy, safety, and pharmacokinetics of THIO were investigated in numerous clinical trials in the 1970s to the mid-80s in a variety of solid tumors and hematological malignancies. The compound was evaluated in at least nineteen (19) Phase 1 to 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. Few studies, utilizing THIO as a single agent, have been published in peer-reviewed journals which we will reference as the most relevant for the planned THIO use today. Several different drug schedules examined both safety and efficacy.

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

Phase 1 Study

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 summarized in this section presents some limitations as it dates to the 1970s and early 1980s when the implementation of ICH Good Clinical Practices were not yet in effect. Notwithstanding these limitations, the available data provides substantial information on the safety 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. As a result, THIO has a well-established safety profile in humans that we plan to use to support our current clinical development program.

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 evaluate the new THIO immunogenic therapeutic strategy - evaluating the safety and efficacy of low immunogenic doses of THIO administered to activate the immune system against the tumor to be treated, then followed by standard-of-care immunotherapy (checkpoint inhibitor) or other immune activating therapy (radiation therapy).

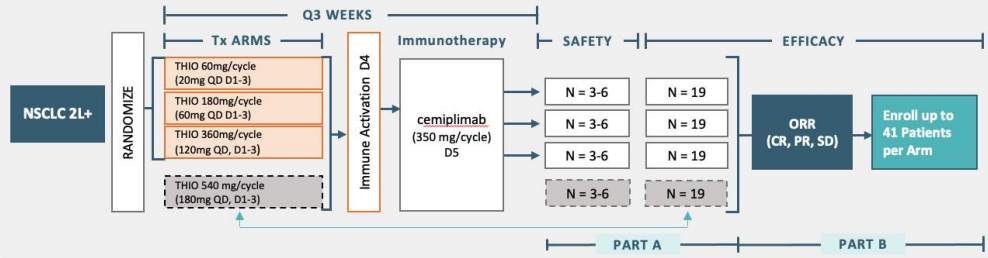
THIO Developmental Initiatives and Objectives

Based on the extensive historical clinical data, we believe it is possible to immediately enter the next human clinical study with the new low dose immunogenic approach with THIO. We believe there is reduced safety risk (compared to higher doses used in early clinical studies) and increased chance of efficacy based on the previously shown clinical effects of THIO combined with the current insights from the recently identified evidence of its immune-activating effects. We plan to approach the FDA to request a modified toxicity requirement based on the prior human experience, allowing us a reduced time and expenditure to IND in the United States. 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 during the first half of 2022.

Our primary short-term objective is to assess this approach in a Proof-of-Concept study outlined below, a Multicenter, Open-Label, Phase 2 Study Evaluating the Safety and Efficacy of THIO Sequenced with cemiplimab in

Subjects with Advanced NSCLC Tumors. This trial (THIO-101) will be the first human study to test THIO's immune system activation followed by administration of the checkpoint inhibitor cemiplimab, allowing for immune activation and PD-1 sensitivity to take effect.

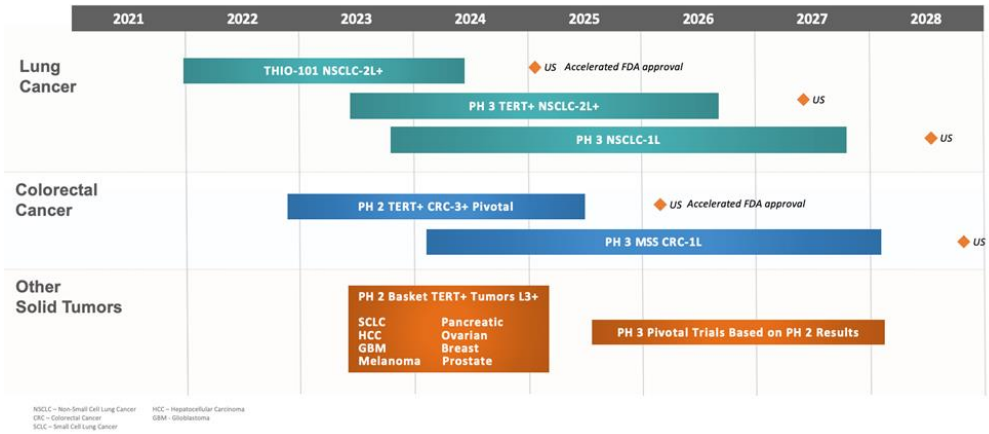
The trial will test the hypothesis that low doses of THIO administered prior to checkpoint inhibitor treatment will enhance and prolong immune response in patients with advanced NSCLC who did not respond or progressed after the first-line treatment regimen containing a checkpoint inhibitor. The following chart sets forth the design of the THIO-101 trial with the primary objectives to establish the (1) safety of THIO administered as an immune system priming dose prior to cemiplimab and (2) clinical efficacy of THIO using Overall Response Rate (ORR) as the primary clinical endpoint. We expect the study to be conducted in Australia and Europe.



The trial will assess the safety, mechanism of activity, and immune system activation of four THIO dosage strengths, each in separate arms. Each dosing arm will then be evaluated further for efficacy based on Overall Response Rate (ORR), Duration of Response (DoR), Progression Free Survival (PFS) and Overall Survival (OS). 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.

Our objectives for the longer term include the initiation of additional studies in other tumor types, upon indication of efficacy from the THIO-101 trial. These are to include, but not limited to, Colorectal Cancer (CRC), Hepatocellular Carcinoma (HCC), and Small Cell Lung Cancer (SCLC). If we observe appropriate efficacy in the THIO-101 trial, we plan to immediately expand to a robust clinical development program in multiple tumor types and regulatory approval pathways where THIO has demonstrated its most promising preclinical and early clinical effects. We plan to model other successful development programs to seek accelerated marketing authorizations for several indications such as NSCLC and colorectal cancers. Subsequently, we expect to target earlier lines of therapy (1st line) in pivotal Phase 3 confirmatory studies in those indications. We are actively evaluating other regulatory strategies and pathways that may accelerate and/or expand indications.

Projected Timeline of the THIO Clinical Development Program



The actual extent of the THIO clinical development program will be limited by the available financing for the expansion, ability to enter into collaboration with other pharmaceutical companies, and results of the clinical trials. 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:

1. Transform "cold" tumors into "hot", rendering them responsive to immunotherapy
2. Improve immunotherapy efficacy in "hot" tumors
3. Restore immunotherapy efficacy in patients who have progressed

Thus, we expect to pursue parallel partnerships to both expand THIO's utilization with other standard-of-care therapies and to offset the study costs leveraging the expected interest of pharmaceuticals companies in enhancing their respective programs.

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 in collaboration with Regeneron to study a treatment regimen comprising the use of THIO treatment followed by cemiplimab 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 have entered into a Clinical Supply Agreement with Regeneron Pharmaceuticals, Inc. (REGN) to supply cemiplimab for the THIO-101 study. Regeneron will contribute drug supply representing up to $29 million, a significant direct cost savings for our program. Regeneron receives development exclusivity for NSCLC during the study period, the exclusivity means that MAIA cannot study THIO in NSCLC with any 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 collaboration agreements that may be appropriate to support the expanded development of THIO.

In addition, we expect strong partnership interest 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 certain UTSW patent families generally directed to methods of using THIO and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW1 Agreement includes an exclusive license to certain US patents and patent applications.

The University of Texas Southwestern Medical Center License Agreement 2

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 an additional UTSW patent family and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW2 Agreement also includes an exclusive license to a pending US patent application.

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, 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 certain UTSW patent families generally directed to methods of using THIO (the "Patent Rights")
and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW1 Agreement includes an exclusive license to certain US patents and patent applications.

The UTSWI Agreement requires MAIA to reimburse UTSW for agreed-upon expenses related to THIO. The UTSWI 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. The UTSWI 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.

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, 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 an additional UTSW patent family and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW2 Agreement also includes an exclusive license to a pending US patent application.

The UTSW2 Agreement has a term of 20 years and requires the Company to reimburse UTSW for certain agreed-upon expenses. The UTSW2 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. The UTSW2 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 (as defined in the UTSW2 Agreement) 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 UTSW2 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.

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. 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.

Although there currently are no direct competitors (those with like mechanisms of action) to our programs, we expect competitors will be developed, given the magnitude of anticipated clinical effect and revenue stream, and we factor them accordingly in our revenue forecast modeling and net present value calculations.

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 Guidances, 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.

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 1,000 square feet under an annual lease, under which we currently pay $2,700 per month. We believe that this space is sufficient to

meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms. Additionally, we intend to maintain our business model designed to leverage virtual technology to minimize brick and mortar facilities while optimizing our ability to attract top talented employees that may reside in any geography.

Employees

As of October 11, 2021, we had a total of five key full-time employees and are in the process of recruiting only the minimum necessary level of up to 10 additional full-time employees required to initiate our initial clinical studies and support our financial and accounting administration, and operations through the first half of 2022. 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	51	Co-Founder President, Chief Executive Officer, Chairman of the Board of Directors
Sergei Gryaznov	61	Chief Scientific Officer
Mihail Obrocea	61	Chief Medical Officer
Joseph McGuire	63	Chief Financial Officer
Daniel Relovsky	51	Chief Operating 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	74	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

Our Chief Executive Officer and President, Vlad Vitoc, M.D., MBA, 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.

Our Chief Scientific Officer, Sergei M. Gryaznov, Ph.D., 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 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.

Our Chief Medical Officer, Mihail Obrocea, M.D. 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. Mr. Obrocea received an M.D. from the Carol Davila University of Medicine & Pharmacy in Bucharest, Romania.

Our Chief Financial Officer, Joseph F McGuire 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.

Our Chief Operating Officer, Daniel Relovsky, is a general management, operations, and commercialization specialist who has served in the pharmaceutical/biotechnology industry for over 30 years. Mr. Relovsky has led new product planning and commercial launch teams as well as overall operational business planning and oversight across functional areas. He received a Bachelor of Science in Finance from Drexel University in Philadelphia, PA.

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 executive 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 BabesBolyai, 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 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, 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 Mr. 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 Nasdaq 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 director is Ramiro Guerrero; and
- our Class III directors are Laurentiu Vlad, Stan Smith, and Cristian Luput.

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 Nasdaq 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 will adopt effective prior to the listing of our common stock, 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 Nasdaq rules. The composition of our compensation committee meets the requirements for independence under the Nasdaq listing standards, including the applicable transition rules. We will adopt, effective prior to the listing of our common stock, 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 will provide 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 will be 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 Nasdaq and the SEC.

Nominating and Governance Committee

Effective upon completion of this offering, our nominating and governance committee is comprised of Ms. Louie, Mr. Luput and Mr. Vlad, with Ms. Louie serving as the chair of the committee. We will adopt, effective prior to the listing of our common stock, 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 will provide 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 will be 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.

Prior to our initial business combination, holders of our public shares will not have the right to recommend director candidates for nomination to our Board of Directors.

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, 2019 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, 2020 (our "named executive officers").

Name and Principal Position	Year	Salary	Bonus	Option Awards(1)	Non-Qualified Deferred Compensation Earnings	All Other Compensation	Total
Vlad Vitoc, M.D. M.B.A.	2020	$ 75,000	$ 240,000	$ 1,197,071	—	$ 125,000	$ 1,637,071 2
Chief Executive Officer and President	2019	$ 94,728	$ —	$ 337,270	—	$ 42,772	$ 474,770
Angela Wang(2)	2020	$ 65,096	$ 180,000	$ 599,107	—	$ 119,281	$ 963,484
Chief Financial Officer	2019	$ —	$ —	$ —	—	$ —	$ —
Daniel Relovsky	2020	$ 75,000	$ 180,000	$ 381,982	—	$ 149,840	$ 786,822
Chief Operating Officer	2019	$ 6,250	$ —	$ 258,825	—	$ 10,417	$ 275,492

(1) All of the bonuses earned by our named executive officers in 2020 were paid out by the issuance of stock options on April 16, 2021. Mr. Vitoc received 219,550 options and Ms. Wang and Mr. Relovsky each received 164,662 options, in each case 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 8 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) Ms. Wang served as the CFO of the Company from February 18, 2020 through May 5, 2021, so did not have any compensation from the Company in 2019.

Employment Agreements

Prior to the offering we will enter into executive employment agreements with each of our named 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 Mr. Vitoc's employment agreement dated , Mr. Vitoc is entitled to an initial annual base salary of $430,000, which is his current base salary. Mr. Vitoc is eligible to receive an annual bonus of up to 40% of his then-current base salary based on achievement of certain individual and corporate targets in the sole discretion of our board of directors. This agreement also provides for the following severance payments upon termination by us without Cause (as defined below), or by Mr. Vitoc for Good Reason (as defined below): (i) payment of his then-current base salary for a period of 12 months following termination; (ii) acceleration of unvested equity awards that would have vested during the 12 months following the date of termination; and (iii) continued coverage under our group health insurance plan with the cost of such coverage shared in the same relative proportion by us and Mr. Vitoc as in effect on his last day of employment until the earlier of 12 months from termination or the date Mr. Vitoc becomes eligible for medical benefits with another employer. Further, the agreement provides that upon termination by us without Cause or by Mr. Vitoc for Good Reason within a period of one year following a Change of Control (as defined below), or 90 days preceding the earlier to occur of a Change of Control or the execution of a definitive agreement the consummation of which would result in a Change of Control, Mr. Vitoc will be entitled to receive: (i) a lump sum payment equal to 18 months of his then-current base salary; (ii) a lump sum payment equal to 1.5 times

the target bonus for the year of termination; (iii) acceleration of all unvested equity awards as of the date of termination; and (iv) continued coverage under our group health insurance plan with the cost of such coverage shared in the same relative proportion by us and Mr. Vitoc as in effect on his last day of employment until the earlier of 18 months from termination or the date Mr. Vitoc becomes eligible for medical benefits with another employer. Payment in each case is subject to Mr. Vitoc's execution of a release satisfactory to us following such termination. In addition, if Mr. Vitoc's employment terminates as a result of disability or death, he shall be entitled to receive a pro-rated target bonus for the period during which Mr. Vitoc was employed in the year of termination.

In addition, in consideration of the payments and benefits provided under his employment agreement, Mr. Vitoc has agreed to certain invention assignment, confidentiality and other restrictive covenants, including, among other things, non-competition and non-solicitation provisions that apply during the term of Mr. Vitoc's employment and for 12 months thereafter.

"Cause" means the Executive's: (i) willful misconduct with respect to the Company, which causes material harm to the Company or its reputation; (ii) continuing failure to materially perform Executive's essential job duties (other than upon a Disability), provided that Executive's failure to achieve Company operating goals by itself, will not constitute a basis for Cause if Executive attempts in good faith to meet such operating goals; (iii) refusal to follow a lawful directive of the Board that is materially related to and reasonably consistent with the provisions of the agreement; (iv) material failure to comply with the Company's Code of Business Conduct and Ethics and material policies; (v) act of fraud with respect to the Company or willful and knowing misappropriation of Company property; (vi) commission of any felony or any crime involving moral turpitude; or (vii) material breach of any material term of the agreement or of any separate proprietary information and invention assignment agreement between Executive and the Company, provided, however, that, in the event of conduct described in clauses (i), (ii), (iii) or (iv) that is reasonably capable of being cured, Cause shall exist only if the Company provides written notice to Executive within sixty (60) days following the initial occurrence of such event giving rise to Cause reasonably detailing such grounds for Cause and Executive fails to cure such grounds for Cause to the reasonable satisfaction of the Company within thirty (30) business days after delivery to Executive of such written notice. Executive's date of termination in the event Executive's employment is terminated for Cause shall be the date on which Executive is given notice of termination, except, if a notice period is required, Executive's date of termination shall be upon the expiration of said notice period if Executive fails to previously cure the grounds giving rise to Cause.

"Good Reason" means (i) any action or inaction that constitutes a material breach by the Company of the employment agreement or the indemnification agreement between the Company and Executive; (ii) a material reduction in Executive's Base Salary (a reduction of more than 10% of Base Salary), except for reductions that are expressly permissible under the agreement; (iii) any change in Executive's title or reporting line or a reduction in authority or duties of employment; or (iv) the Company no longer permits full-time remote working; provided, in each case, (x) Executive has provided the Company with written notice reasonably detailing such grounds for Good Reason within ninety (90) days after the occurrence thereof, and (y) the Company fails to cure such grounds for Good Reason within thirty (30) days after delivery to it of such written notice.

Summary of Employment Agreement with Sergei Gryaznov

Under the terms of Mr. Gryaznov's employment agreement dated , Mr. Gryaznov is entitled to an initial annual base salary of $330,000, which is his current base salary. Mr. Gryaznov is eligible to receive an annual bonus of up to 35% of his then-current base salary based on achievement of certain individual and corporate targets in the sole discretion of our board of directors. This agreement also provides for severance payments upon termination by us without Cause (as defined above), or by Mr. Gryaznov for Good Reason (as defined above) as described above in the summary of Mr. Vitoc's agreement.

Summary of Employment Agreement with Mihail Obrocea

Under the terms of Mr. Obrocea's employment agreement dated , Mr. Obrocea is entitled to an initial annual base salary of $380,000, which is his current base salary. Mr. Obrocea is eligible to receive an annual bonus of up to 35% of his then-current base salary based on achievement of certain individual and corporate targets in the sole discretion of our board of directors. This agreement also provides for severance payments upon termination by us

without Cause (as defined above), or by Mr. Obrocea for Good Reason (as defined above) as described above in the summary of Mr. Vitoc's agreement.

Summary of Employment Agreement with Joseph McGuire

Under the terms of Mr. McGuire's employment agreement dated , Mr. McGuire is entitled to an initial annual base salary of $300,000, which is his current base salary. Mr. McGuire is eligible to receive an annual bonus of up to 35% of his then-current base salary based on achievement of certain individual and corporate targets in the sole discretion of our board of directors. This agreement also provides for severance payments upon termination by us without Cause (as defined above), or by Mr. McGuire for Good Reason (as defined above) as described above in the summary of Mr. Vitoc's agreement. 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.

Summary of Employment Agreement with Daniel Relovsky

Under the terms of Mr. Relovsky's employment agreement dated , Mr. Relovsky is entitled to an initial annual base salary of $330,000, which is his current base salary. Mr. Relovsky is eligible to receive an annual bonus of up to 35% of his then-current base salary based on achievement of certain individual and corporate targets in the sole discretion of our board of directors. This agreement also provides for severance payments upon termination by us without Cause (as defined above), or by Mr. Relovsky for Good Reason (as defined above) as described above in the summary of Mr. Vitoc's agreement.

Outstanding Equity Awards as of December 31, 2020

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2020.

	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	11/3/20	705,789	—	$ 1.80	11/2/30		
	41/20	169,500	—	$ 1.80	3/31/30		
	6/17/19	20,500	—	$ 1.80	6/16/29		
	10/1/18	498,750	306,250	$ 1.80	9/30/28		
	10/21/18					87,500	$ 157,500
Angela Wang	2/18/20	266,000		$ 1.80	2/17/30		
	4/1/20	42,000		$ 1.80	3/31/30		
	11/3/20	225,219		$ 1.80	11/2/30		
Daniel Relovsky	11/3/20	236,493		$ 1.80	11/2/30		
	4/1/20	54,000		$ 1.80	3/31/30		
	12/1/19	266,000		$ 1.80	11/30/29		

(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."

(2) All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors or compensation committee.
(3) Calculated based on fair market value of the common stock of $1.80 per share on December 31, 2020, as determined in good faith by the board, as the Company's common stock has not previously been publicly traded.

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 shares for issuance. On November 1, 2020, we approved the second amendment of the 2020 Plan to reserve a total of 3,171,000 common shares 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. No more than 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 (15^{th}) day of the third (3^{rd}) 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 intend to enter 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.

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.

Name	Fees earned or paid in cash	Stock awards	Option awards (1)	All Other Compensation	Total
Leigh-Ann Durant*	—	$ 58,005 (2)	3,997 (2)	—	$ 62,002
Ramiro Guerrero	—	$ 28,003 (3)	$ 2,570 (3)	—	$ 30,573
Louie Ngar Yee	—	$ 25,000 (4)	$ 2,570 (4)	—	$ 27,570
Cristian Luput	—	$ 22,009 (5)	$ 2,570 (5)	—	$ 24,579
Stan Smith	—	$ 28,003 (6)	$ 2,570 (6)	—	$ 30,572
Laurentiu Vlad	—	$ 28,003 (7)	$ 2,570 (7)	—	$ 30,572
Tze-Liang Chiam*	—	$ 28,003 (8)	$ 2,570 (8)	—	$ 30,572
Wayne Klohs*	$ 12,000	$ 24,002 (9)	$ 3,283 (9)	—	$ 39,285

(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 8 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) 53,334 shares and 3,500 total options outstanding as of December 31, 2020.
(3) 33,334 shares and 2,250 total options outstanding as of December 31, 2020.
(4) 13,389 shares and 2,250 total options outstanding as of December 31, 2020.
(5) 16,667 shares and 2,250 total options outstanding as of December 31, 2020.
(6) 33,334 shares and 2,250 total options outstanding as of December 31, 2020.
(7) 33,334 shares and 2,250 total options outstanding as of December 31, 2020.
(8) 16,667 shares and 2,250 total options outstanding as of December 31, 2020.
(9) 30,000 shares and 2,875 total options outstanding as of December 31, 2020.
*Received compensation for service on the board in 2020 but are not currently on the board.

PRINCIPAL STOCKHOLDERS

Based solely upon information made available to us, the following table sets forth information as of September 30, 2021 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 shares of common stock outstanding as of September 30, 2021.

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., 4444 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	2,750,262	%	%
Joseph McGuire	1,953	*	*
Sergei Gryaznov	882,044	%	%
Daniel Relovsky	787,957	%	%
Mihail Obrocea	97,654	*	*
Ramiro Guerrero	277,112	%	%
Louie Ngar Yee	1,055,424	%	%
Cristian Luput	304,402	%	%
Stan Smith	650,788	%	%
Laurentiu Vlad	400,100	%	%
Steven Chaouki	31,250	*	*
All directors and executive officers as a group (11 persons):	7,238,946	%	%

*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.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2019, 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, 2020 and 2019, 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 former member of the Company's board of directors who also provided consulting services to the Company during 2020, for which the Company incurred a total of $20,400.

Leigh-Ann Durant is a former member of the Company's board of directors who also provided consulting services to the Company during 2020, for which the Company incurred a total of $125,380, $50,190 of which was stock-based compensation which consisted of options to purchase 67,842 shares of the Company's common stock, 99,349 shares of DGD common stock, and 71,086 shares of common stock of THIO Therapeutics, Inc., or THIO.

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 Mr. Vitoc. The Company paid these loans in full on March 3, 2021, by paying principal of $367 and issuing Mr. Vitoc a convertible note in the amount of $21,000, which converted into 3,621 shares of our common stock on September 30, 2021.

THIO Asset Acquisition

During the year ended December 31, 2018, the Company incurred $214,164 in legal fees in connection with the acquisition of THIO, which were paid by Laurentiu Vlad (Director), Leah Dimascio (former Chief Operating Officer), Ramiro Guerrero (Director), Tze-Liang Chiam (former Director), Stan Smith (Director), Vlad Vitoc (CEO), and Frank Perabo (former President), resulting in a related party payable recorded in the consolidated balance sheet at December 31, 2018. During 2019, the aforementioned officers and directors were issued a total of 118,980 shares of restricted common stock for reimbursement, settling the related party payable. In addition, at the time of the transaction Vlad Vitoc was the CEO of the Company and also the CEO of THIO and certain stockholders of the Company were also stockholders of THIO.

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 million shares of common stock, par value $0.0001 per share and million shares of preferred stock, par value $0.0001 per share. Following the consummation of this offering, shares 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. 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 various dates through November 2024. These warrants 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 various dates through December 2027. These warrants are currently outstanding and exercisable.

Finally, in connection with the sale of certain of our outstanding convertible promissory notes in 2020, 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. These warrants are currently outstanding.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Inc. The transfer agent and registrar's address is .

National Securities Exchange Listing

We have applied to have our common stock listed on the Nasdaq 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 and no exercise of options after , 2021. 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 sell, offer, agree to sell, contract to sell, hypothecate, pledge, grant any option to purchase, make any short sale of, or

otherwise dispose of or hedge, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock, for a period of 180 days after the date of this prospectus, without the prior written consent of the representative. 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.

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 Nasdaq 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 Nasdaq 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. We have entered into an underwriting agreement dated , 2021 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase from us, at the initial public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of common shares 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 $35,000 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 fees and expenses of legal counsel to the underwriters in an amount not to exceed $125,000, 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, up to $10,000 for background checks of our officers and directors, up to $10,000 for all fees, $10,000 for data services and communications expenses, $3,000 for the costs associated with bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones, up to $10,000 for actual accountable "road show" expenses and 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) and 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

Pursuant to certain "lock-up" agreements, we, our executive officers and directors and certain of our our stockholders, have agreed not to, without the prior written consent of the representative, offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, for a period of 180 days from the date of this prospectus.

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 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 Nasdaq, 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 Nasdaq 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

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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, 2020 and 2019, 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
Index to Financial Statements

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, 2020 and 2019, and the related consolidated statements of operations, changes in stockholders' (deficit) equity, 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 consolidated financial position of the Company as of December 31, 2020 and 2019, and the consolidated 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
October 15, 2021

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash	$ 663,457	$ 1,709,565
Prepaid expenses and other current assets	83,048	24,964
Total assets	$ 746,505	$ 1,734,529
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 201,018	$ 169,188
Accrued interest	12,678	342
Due to related parties	7,037	2,099
Accrued bonus	780,000	—
Convertible notes payable - current portion	10,586	—
Loan payable to officer	21,367	25,000
Deferred compensation	661,058	177,936
Total current liabilities	1,693,744	374,565
Convertible notes payable, net of current portion	332,841	9,172
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	1,000
Warrant liability	85,260	—
Simple agreement for future equity payable	25,000	25,000
Total liabilities	2,362,805	409,737
Commitments and contingencies		
Stockholders' (deficit) equity		
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 and 10,000,000 shares authorized, 4,433,644 and 4,416,977 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	443	442
Additional paid-in capital	12,599,585	9,228,546
Accumulated deficit	(15,934,113)	(9,297,453)
Stock subscription receivable	(2,002)	(104,402)
Total MAIA Biotechnology, Inc. stockholders' deficit	(3,336,087)	(172,867)
Noncontrolling interests	1,719,787	1,497,659
Total stockholders' (deficit) equity	(1,616,300)	1,324,792
Total liabilities and stockholders' (deficit) equity	$ 746,505	$ 1,734,529

See the accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Statements of Operations

	For the Year Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development expenses	$ 1,412,409	$ 1,911,882
General and administrative expenses	5,563,192	5,009,474
Total operating costs and expenses	6,975,601	6,921,356
Loss from operations	(6,975,601)	(6,921,356)
Other income (expense):		
Paycheck protection program loan forgiveness	62,500	—
Interest (expense) income, net	(31,547)	242
Change in fair value of embedded features	5,000	—
Change in fair value of warrant liability	(19,600)	—
Other income (expense), net	16,353	242
Net loss	(6,959,248)	(6,921,114)
Net loss attributable to noncontrolling interests	(322,588)	(428,332)
Net loss attributable to MAIA Biotechnology, Inc. shareholders	$ (6,636,660)	$ (6,492,782)
Net loss per share		
Basic and diluted	$ (1.50)	$ (1.72)
Weighted average common shares outstanding		
Basic and diluted	4,427,242	3,769,880

See the accompanying notes to the consolidated financial statements.

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

	Preferred Stock		Common Stock		Additional Paid-	Accumulated	Subscription	Total MAIA Equity	Noncontrolling	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	In Capital	Deficit	Receivable	(Deficit)	Interest	Equity
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 Changes in Stockholders' (Deficit) Equity

	Preferred Stock		Common Stock		Additional Paid-	Accumulated	Subscription	Total MAIA Equity	Noncontrolling	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	In Capital	Deficit	Receivable	(Deficit)	Interest	Equity
Balance at December 31, 2018	—	$ —	2,805,780	$ 281	$ 3,474,835	$ (2,804,671)	$ (100,000)	$ 570,445	$ —	$ 570,445
Issuance of restricted common shares	—	—	140,002	14	161,992	—	—	162,006	—	162,006
Issuance of common shares for THIO Asset Acquisition	—	—	631,822	63	1,137,279	—	—	1,137,342	—	1,137,342
Issuance of restricted common shares to reimburse related parties for payment of legal costs incurred in connection with the THIO Asset Acquisition	—	—	118,980	12	214,152	—	—	214,164	—	214,164
Forfeitures of unvested restricted common shares	—	—	(400,000)	(40)	40	—	—	—	—	—
Stock issued via subscription agreements	—	—	1,120,393	112	2,016,595	—	(104,402)	1,912,305	—	1,912,305
Receipt of stock subscription receivable	—	—	—	—	—	—	100,000	100,000	—	100,000
Issuance of DGD common stock	—	—	—	—	—	—	—	—	175,000	175,000
Stock-based compensation expense - MAIA	—	—	—	—	2,223,653	—	—	2,223,653	—	2,223,653
Stock-based compensation expense - DGD	—	—	—	—	—	—	—	—	963,491	963,491
Stock-based compensation expense - THIO	—	—	—	—	—	—	—	—	787,500	787,500
Net loss	—	—	—	—	—	(6,492,782)	—	(6,492,782)	(428,332)	(6,921,114)
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

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,	
	2020	**2019**
Cash flows from operating activities:		
Net loss, including noncontrolling interests	$ (6,959,248)	$ (6,921,114)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,888,968	4,136,650
Research and development – THIO intellectual property acquired for common stock	—	949,723
Gain from forgiveness of Paycheck Protection Program loan	(62,500)	—
Change in fair value of embedded features	(5,000)	—
Change in fair value of warrant liability	19,600	—
Amortization of debt discount	19,875	172
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(58,084)	(15,734)
Accounts payable and accrued expenses	31,830	104,826
Accrued interest	12,336	342
Due to related parties	4,938	2,087
Accrued bonus	780,000	—
Deferred compensation	483,122	177,936
Net cash used in operating activities	(1,844,163)	(1,565,112)
Cash flows from investing activities:		
Cash received in connection with the THIO asset acquisition	—	187,556
Net cash provided by investing activities	—	187,556
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, warrants, and embedded conversion features	610,000	10,000
Proceeds from issuance of simple agreement for future equity payable	—	25,000
Proceeds from Paycheck Protection Program loan	62,500	—
Collections of subscriptions receivable - MAIA	102,400	100,000
Collections of subscriptions receivable - DGD	35,000	—
Proceeds from issuance of common stock - MAIA	—	1,912,305
Proceeds from issuance of common stock - DGD	50,000	175,000
Return of capital - DGD	(58,212)	—
Payment on loan payable to officer	(3,633)	—
Net cash provided by financing activities	798,055	2,222,305
Net (decrease) increase in cash	(1,046,108)	844,749
Cash at beginning of year	1,709,565	864,816
Cash at end of year	$ 663,457	$ 1,709,565
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of common stock for THIO asset acquisition	$ —	$ 1,137,342
Issuance of restricted shares for THIO legal expenses	$ —	$ 214,164

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, and was 93% and 86% owned by MAIA as of December 31, 2020 and 2019, respectively;
- DGD Pharmaceuticals Corporation ("DGD"), incorporated in the state of Delaware of April 1, 2019, and was 78% and 76% owned by MAIA as of December 31, 2020 and 2019, respectively;
- MAIA Drug Development Corporation ("MAIA DD") incorporated in the state of Texas on September 10, 2018, and 100% owned by MAIA as of December 31, 2020 and 2019.

The Company's operational structure is such that THIO, DGD, and MAIA DD serve as separate research and development centers for different research initiatives of the Company, with MAIA providing operational oversight, management, and strategic services to the subsidiaries. The Company operates as one operating and reporting segment.

In June 2020, DGD terminated a license agreement which had provided the sole impetus for its research efforts (Note 6), which resulted in the cessation of DGD's research and development activities. 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. As of December 31, 2020, minimal assets and liabilities remain in DGD.

Liquidity

At December 31, 2020, the Company had a working capital deficit of $947,239, an accumulated deficit of $15,934,113, cash of $663,457 and current liabilities of $1,693,744. 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.

Between February 16, 2021 and June 29, 2021, the Company issued unsecured convertible notes payable to investors for a total of $7,390,000. Between July 15, 2021 and September 29, 2021, the Company sold 725,563 shares of common stock at $8 per share for gross proceeds of approximately $5.8 million (refer to Note 11). In connection with this sale of common stock, all of the outstanding principal and accrued and unpaid interest was automatically converted into 1,375,228 shares of the Company’s common stock in accordance with the terms in the convertible notes (refer to Note 11).

Accordingly, the Company believes that it currently has sufficient funds to support operations through the next twelve months from the date of the consolidated financial statements are issued. 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 such, the Company cannot estimate the full magnitude that the pandemic will have on the Company’s business. If the COVID-19 Outbreak continues, it may have a material adverse effect on the Company’s financial condition, liquidity, and future results of operations. Management is actively monitoring the impact of the global pandemic on its financial condition, liquidity, operations, industry, and workforce. Given the daily evolution of the COVID-19 Outbreak and the global responses to curb its spread, the Company is not able to estimate the effects of the COVID-19 Outbreak on its results of operations, financial condition, or liquidity.

Basis of Presentation

The Company's financial statements have been prepared in conformity 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, 2020 and 2019, 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, 2020 and 2019, cash includes cash in a depository bank account; the Company has no cash equivalents as of December 31, 2020 and 2019.

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 years ended December 31, 2020 and 2019. 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 year ended December 31, 2020. 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, represent 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 expense and 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.

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 determine the fair value of shares of our common stock, the Company's board of directors considered, among other things, contemporaneous valuations of our common stock, our business, financial condition and results of operations, including related industry trends affecting our 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 have been based on sales of common stock to third parties. The fair value of restricted stock awards is based on 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. Under ASC 815-40-35, the Company follows a sequencing policy whereby, in the event that reclassification of contracts from equity to assets or liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares as a result of certain securities with a potentially indeterminable number of shares, shares will be allocated on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest grants receiving the first allocation of shares. Pursuant to ASC 815, issuance of securities to the Company's employees or directors are not subject to the sequencing policy.

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.

Asset Acquisitions

The Company follows the guidance in ASC 805, Business Combinations ("ASC 805"), for determining the appropriate accounting treatment for asset acquisitions. ASU No. 2017-01, Clarifying the Definition of a Business, provides an initial fair value screen to determine if substantially all of the fair value of the assets acquired is concentrated in a single asset or group of similar assets. If the initial screening test is not met, the set is considered a business based on whether there are inputs and substantive processes in place. Based on the results of this analysis and conclusion on an acquisition's classification of a business combination or an asset acquisition, the accounting treatment is derived.

If the acquisition is deemed to be a business, the purchase method of accounting is applied. Identifiable assets acquired and liabilities assumed at the acquisition date are recorded at fair value. If the transaction is deemed to be an asset acquisition, the cost accumulation and allocation model is used whereby the assets and liabilities are recorded based on the purchase price and allocated to the individual assets and liabilities based on relative fair values.

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 outstanding shares of common stock equivalents were excluded from the computation of the diluted net loss per share attributable to common stock for the periods presented because their effect would have been anti-dilutive. The table below provides total shares outstanding, as of December 31:

	2020	2019
Shares issuable upon exercise of stock options	3,664,966	1,627,000
Shares issuable upon exercise of warrants to purchase common stock	908,244	797,724
Unvested restricted stock awards	147,778	420,848

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 is expected to 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.

In August 2020, the FASB issued ASU No. 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies an issuer's accounting for convertible instruments by reducing the number of accounting models that require separate accounting for embedded conversion features. ASU 2020-06 also simplifies the settlement assessment that entities are required to perform to determine whether a contract qualifies for equity classification and makes targeted improvements to the disclosures for convertible instruments and earnings-per-share (EPS) guidance. This update will be effective for the Company's fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Entities can elect to adopt the new guidance through either a modified retrospective method of transition or a fully retrospective method of transition. 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, 2024.

2. THIO ASSET ACQUISITION

On January 10, 2019 the Company acquired all outstanding stock of THIO through a share exchange agreement under which MAIA issued 631,822 shares of its common stock. The Company estimated the fair value of the total aggregate stock consideration to be $1,137,342, based on the value of MAIA stock. At the time of the transaction, certain stockholders of MAIA were also stockholders of THIO and the CEO of MAIA was also the CEO of THIO. Substantially all of the fair value of the net assets acquired from THIO was determined to be concentrated in a single identifiable asset, In-Process Research & Development. The Company concluded that the acquisition of THIO met the requirements to be accounted for as an asset

acquisition as THIO does not meet the definition of a business in accordance with ASC 805-10-55. The total consideration transferred was first allocated to cash received of approximately $187,556, and the remainder was allocated to In-Process Research & Development and was immediately expensed to Research & Development, as the In-Process Research & Development acquired from THIO was determined to have no alternative future use as of the acquisition date.

3. RELATED PARTY TRANSACTIONS

Consulting Services

Wayne Klohs is a shareholder and former member of the board of directors who also provides consulting services to the Company. During 2019 and 2020, the Company incurred a total of $12,000 and $20,400, respectively, to Mr. Klohs for consulting services.

Leigh-Ann Durant, a member of the Company's board of directors, provides consulting services to the Company for which the Company incurred $125,380 during 2020, $50,190 of which is stock-based compensation which consist of options to purchase 67,842 shares of MAIA common stock, 99,349 shares of DGD common stock, and 71,086 shares of THIO common stock.

Mukesh Nyati is a minority shareholder of DGD and a consultant who received 222,500 and 1,000,000 shares of restricted stock in DGD during the years ended December 31, 2020 and 2019, respectively, for his services along with cash. During 2020, the Company incurred $152,576 in research fees, $75,000 of which is stock-based compensation. Nyati also received 10,000 options to purchase DGD common stock in 2019, resulting in $1,213 and $606 of stock-based compensation expense for the years ended December 31, 2020 and 2019, respectively.

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.

THIO Asset Acquisition

During the year ended December 31, 2018, the Company incurred $214,176 in legal fees in connection with the THIO Asset Acquisition which were paid by certain board members and officers of the Company, resulting in a related party payable recorded in the consolidated balance sheet at December 31, 2018. During 2019, these board members and officers of the Company were issued a total of 118,980 shares of restricted common stock for reimbursement, settling the related party payable.

In addition, at the time of the transaction certain stockholders of MAIA were also stockholders of THIO and the CEO of MAIA was also the CEO of THIO.

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, which are unsecured, have no stated interest rate, and no stated repayment terms, are included in current liabilities on the accompanying consolidated balance sheet under the caption "Loan payable to officer." The Company repaid $3,633 of the loan to the CEO during 2020. The Company paid these loans in full on March 3, 2021, by issuing the chief executive officer a convertible note in the amount of $21,367.

Related Party Convertible Notes

As of December 31, 2020, the Company had outstanding convertible notes of $110,000 payable to certain shareholders or their family trusts (Note 5).

Deferred Compensation Agreements

As of December 31, 2020 and 2019, the Company had $661,058 and $177,936 of deferred compensation due to certain employees and officers of the Company pursuant to deferred compensation agreements executed during 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.

In 2021, the Company achieved a Qualified Fund Raising pursuant to the deferred compensation agreements and paid $418,537 in cash and issued 268,769 options to settle deferred compensation payable.

Accrued Bonus

During the year ended December 31, 2020, the Company accrued $780,000 in bonus expense relating to certain key employees and officers of the Company. The accrued bonus balance was paid out by issuance of 713,536 stock options on April 16, 2021.

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").

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. Interest expense under the PPP Loan was nominal for the year ended December 31, 2020.

The Company received full forgiveness of all outstanding principal and accrued and unpaid interest on the PPP Loan in December 2020. 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, 2020.

5. CONVERTIBLE NOTES PAYABLE

Convertible Notes Payable

	December 31,	
	2020	**2019**
Convertible notes payable:		
Convertible note balance	$ 620,000	$ 10,000
Debt discount	(177,613)	(828)
Carrying value of convertible notes payable	$ 442,387	$ 9,172
Convertible note payable, current portion	$ 10,586	$ —
Convertible notes payable, related parties	98,960	—
Convertible notes payable, net of current portion	332,841	9,172
Carrying value of convertible notes payable	$ 442,387	$ 9,172

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 bears interest at 8% per annum, is unsecured, and scheduled maturity date of December 31, 2021. The 2019 Convertible Note contains an automatic conversion feature, such that in the event the Company consummates an Equity Financing, as defined in the agreement, prior to the 2019 Convertible Note's scheduled maturity, the outstanding principal and interest shall be 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 was set at 65% of the price of the preferred stock issued in the aforementioned Equity Financing.

Embedded Put Feature

The Company has determined that the terms related to the Equity Financing conversion, (the "Embedded Put Feature") was determined to not be 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 with an offset to the 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 $1,156 and $342 for the years ended December 31, 2020 and 2019, 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 $414 and $828 as of December 31, 2020 and 2019, respectively. During the years ended December 31, 2020 and 2019, amortization of debt discount amounted to $586 and $172, 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 bear interest at 6% per annum, are unsecured, and have 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.

Preferred 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 determined to not be 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 with an offset to the 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.

The Company may not prepay the Convertible Notes without the written consent of the 2020 Convertible Note holders, except in connection with a Change of Control.

Interest expense on the 2020 Convertible Notes totaled $11,523 and $0 for the years ended December 31, 2020 and 2019, 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 with an offset to the 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.

As of December 31, 2020, none of these contingently exercisable warrants have been exercised, as warrants become exercisable upon the conversion of the 2020 Convertible Notes.

Debt discounts on the 2020 Convertible Notes totaled $177,199 and $0 as of December 31, 2020 and 2019, respectively. During the years ended December 31, 2020 and 2019, amortization of debt discounts amounted to $19,461 and $0, respectively.

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.

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 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

	Fair value at December 31, 2019			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Derivative liability, bifurcated put contained in convertible notes payable	$ 1,000	$ —	$ —	$ 1,000
Total liabilities	$ 1,000	$ —	$ —	$ 1,000

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) during the year ended December 31:

	2020	2019
Balance, beginning of period	$ 1,000	$ —
Derivative liability on convertible notes payable	131,000	1,000
Gain on fair value of embedded features	(5,000)	—
Balance, end of period	$ 127,000	$ 1,000

	2020	2019
Balance, beginning of period	$ —	$ —
Warrant liability	65,660	—
Loss on fair value of warrant liability	19,600	—
Balance, end of period	$ 85,260	$ —

Derivative Liability

The Embedded Put Features are separately measured at fair value, with changes in fair value recognized in current operations. The Company used a scenario-based analysis to estimate the fair value of the Embedded Put Features at issuance of the Convertible Notes and as of December 31, 2020 and 2019. 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. The recurring Level 3 fair value measurements of the embedded derivative liability included the following significant unobservable inputs as of December 31, 2020. 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 99%; and the probability of default, change in control or dissolution was estimated to be approximately 1%. Estimating fair values of Embedded Put Features requires the development of significant and subjective estimates that may, and are likely to, change 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 will reflect the volatility in these estimate and assumption changes.

Warrant Liability

The Warrants are 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 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 option-pricing model; risk-free interest rate 0.1% - 0.6%; expected term (in years) 0.75 - 7.01; expected volatility 85% - 124%; expected dividend yield 0% - 0%. Changes to these assumptions could have a significant impact on the fair value of the Warrants and related fair value adjustments.

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, 2020, 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.

In addition, both DGD and THIO have shareholder agreements with similar provisions in place.

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 may be 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 years ended December 31, 2020 and 2019, the Company recognized $270,000 and $540,000, respectively, in general and administrative expense related to the Founders' awards. As of December 31, 2020, unrecognized stock-based compensation expense related to the unvested shares was $202,500 which the Company expects to recognize over a weighted average period of approximately 1.00 years.

Restricted Common Stock Awards to Directors - During the years ended December 31, 2020, 2019, and 2018 the Company awarded 16,667, 140,002, and 76,668 restricted common shares to one, seven, and five director(s), respectively which vest over a year from issuance. Vested shares may participate in any dividends and other distributions with other common stockholders, while the unvested shares, which may be 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 as defined in the agreements. The related compensation expense is recognized ratably over the service period. For the years ended December 31, 2020 and 2019, the Company recognized $241,027 and $161,992 in general and administrative expense related to the Directors' awards, respectively. As of December 31, 2020, unrecognized stock-based compensation expense related to the unvested shares was $5,000 which the Company expects to recognize over a weighted average period of approximately 0.25 years.

Restricted Common Stock Awards for Reimbursement of Legal Fees - During the year ended December 31, 2019, the Company issued 118,980 restricted common shares for reimbursement of legal fees paid by certain directors and officers of the Company in connection with the THIO Asset Acquisition. These restricted shares vested immediately upon issuance.

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at January 1, 2019	1,120,008	$ 1.80
Granted	258,982	1.80
Vested	(558,142)	
Cancelled/forfeited	(400,000)	
Unvested balance at December 31, 2019	420,848	$ 1.80
Granted	16,667	1.80
Vested	(289,737)	
Cancelled/forfeited	—	
Unvested balance at December 31, 2020	147,778	$ 1.80

Equity Classified MAIA Stock Warrants

In October and November 2019, the Company issued to certain investors who had purchased shares of common stock as a buy-one-share, get-one-warrant arrangement. MAIA issued warrants for 797,724 shares of common stock at an exercise price of $1.80 per share. The value associated with the warrants was recorded to additional paid in capital as part of the proceeds received from the common stock. As of December 31, 2020, all of the warrants, which expire at various dates through November 2024, remain outstanding and are exercisable.

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. As of December 31, 2020, all of these warrants, which expire at various dates through December 2027, are outstanding and exercisable.

	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Balance at January 1, 2019	—	$ —	—
Granted	797,724	1.80	10.00
Balance at December 31, 2019	797,724	1.80	9.85
Granted	110,520	2.39	9.44
Balance at December 31, 2020	908,244	$ 1.87	8.89

The value of the warrants was calculated using the Black-Scholes option pricing model with the following assumptions for warrants granted during the year ended December 31, 2020:

	2020
Risk-free interest rate	0.41% - 1.69%
Expected term (in years)	5 - 7
Expected volatility	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.

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 December 31, 2020, 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, 2020:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance at January 1, 2019	2,215,000	$ 1.80	9.75	—
Granted	838,500	1.80	10.00	—
Cancelled/forfeited	(1,426,500)	1.80		
Balance at December 31, 2019	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	—
Options exercisable at December 31, 2020	1,099,969	$ 1.80	8.51	—

The fair value of the Company’s common stock, which equaled the exercise price of stock options granted during the years ended December 31, 2020 and 2019, respectively, was determined based on sales of the Company’s shares at arm’s length to unrelated third parties. The fair value of the Company’s common stock was estimated to be $1.80 at December 31, 2020 and 2019. The value of option grants is calculated using the Black-Scholes option pricing model with the following assumptions for options granted during the years ended December 31, 2020 and 2019:

	2020	2019
Risk-free interest rate	0.35% - 1.39%	1.39% - 3.00%
Expected term (in years)	5 - 5.5	5 - 6.25
Expected volatility	76.5% - 80.7%	81.1% - 83.5%
Expected dividend yield	—%	—%

The weighted-average grant date fair value of stock options issued during the years ended December 31, 2020 and 2019 was $1.11 and $1.19, respectively. During the year ended December 31, 2020, compensation expense associated with these and previously-issued options was recognized in research and development expenses in the amount of $337,793, and in general and administrative expenses in the amount of $2,398,155. During the year ended December 31, 2019, compensation expense associated with these and previously-issued options was recognized in research and development expenses in the amount of $258,825, and in general and administrative expenses in the amount of $1,424,828. At December 31, 2020, the total unrecognized compensation related to unvested employee and non-employee stock option awards granted was $548,838, which the Company expects to recognize over a weighted average period of approximately 0.88 years.

DGD Pharmaceuticals Corporation 2019 Stock Option Plan

DGD's board of directors administers the DGD Pharmaceuticals Corporation 2019 Stock Option Plan (the “DGD Plan"), under which 1,000,000 shares of DGD's Class A common stock are reserved for issuance upon the exercise of options granted by DGD. The terms of the DGD Plan provide for the grant of options to employees, non-employee members of the board of directors, and consultants.

Stock options are generally granted with an exercise price equal to the stock's estimated fair market value at the date of grant and a contractual term of 10 years from the date of grant. In the case of an option granted to a 10% stockholder, the option shall have an exercise price at least equal to 110% of the stock's estimated fair market value at the date of grant and a contractual term of 7 years from the date of grant. Outstanding options awarded under the DGD 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 m be based on performance or other criteria) as DGD's board of directors may deem appropriate.

Awards granted by DGD during 2019 and 2020 include 30,000 and 25,000 options, respectively, with service/vesting terms of twelve months from the date of grant; compensation expense is being recognized ratably over the respective twelve-month period that began the dates of grant. During the year ended December 31, 2020, compensation expense associated with these and previously-issued options was recognized in general and administrative expenses in the amount of $19,802. During the year ended December 31, 2019, compensation expense associated with these and previously-issued options was recognized in general and administrative expenses in the amount of $16,280. As of December 31, 2020, the unrecognized stock-based compensation expense related to nonvested service based stock options outstanding is $3,069, which the Company expects to recognize over a weighted average period of approximately 0.14 years.

DGD also granted 750,000 options during 2019 which vest upon the occurrence of a contingent event, the regulatory approval of a compound that is the subject of the DGD's research and development efforts. As of December 31, 2020, this contingent event had not occurred and was not probable of occurring. As such, no compensation expense associated with these performance based options has been recognized to date. The future recognition and timing of the performance-based options is uncertain.

The following table summarizes the activity and information regarding the DGD Plan's outstanding and exercisable options as of December 31, 2020:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance at January 1, 2019	—	$ —	—	—
Granted	780,000	0.30	10.00	—
Exercised	—	0.30		
Cancelled/forfeited	—	0.30		
Balance at December 31, 2019	780,000	$ 0.30	9.34	—
Granted	25,000	0.30	10.00	
Exercised	—	0.30		
Cancelled/forfeited	—	0.30		
Balance at December 31, 2020	805,000	$ 0.30	8.37	—
Options exercisable at December 31, 2020	48,750	$ 0.30	8.68	—

To calculate the value of its options, DGD used the Black-Scholes pricing model with the following assumptions for grants during the year ended December 31, 2020 and 2019:

	2020	2019
Risk-free interest rate	0.66%	2.30%
Expected term (in years)	5	5
Expected volatility	72.5%	72.5%
Expected dividend yield	—%	—%

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

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

As of December 31 , 2020, no stock options have been issued pursuant to the THIO Plan.

Other Equity Activity of DGD and THIO

DGD Pharmaceuticals Corporation

DGD is 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 are entitled to one vote per share, whereas holders of Class B are 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 owns 690,000 and 6,000,000 Class A and Class B common shares, respectively. Class A common shareholders are entitled to one vote per share, whereas Class B common shareholders are entitled to two votes per share.

Restricted Common Stock Awards to Founders of DGD — In May 2019, DGD awarded 1,550,000 restricted Class A common shares to four founders. Vested shares may participate in any dividends and other distributions with other common stockholders, while the unvested shares, which may be subject to forfeiture in the event the holder separates from service with DGD, do not participate in such events. The share award is 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 years ended December 31, 2020 and 2019, the Company recognized $206,947 and $947,211, respectively, in compensation expense related to these awards which was presented in general and administrative expenses. As of December 31, 2020, unrecognized stock-based compensation expense related to the unvested portion of these shares was $344,440, which the Company expects to recognize over a weighted average period of approximately 1.33 years.

In May 2019, DGD awarded 750,000 restricted Class B common shares to three other founders which vest upon the regulatory approval of a compound that is the subject of the DGD's research and development efforts. To date, the event is not deemed to be probable, and as such, no stock compensation expense was recorded. In November 2019, 500,000 of these restricted Class B common shares were forfeited, and the other 250,000 were re-purchased by MAIA at par value for a total of $25.

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 3). During 2020, the Company recorded $75,000 to research and development expenses in connection with this agreement.

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at January 1, 2019	—	$ —
Granted	2,362,500	1.00
Vested	(925,696)	
Repurchased	(250,000)	
Forfeited	(500,000)	
Unvested balance at December 31, 2019	686,804	$ 1.00
Granted	12,500	$ —
Vested	(320,836)	
Unvested balance at December 31, 2020	378,468	$ 1.00

Other Issuances of Common Stock — In addition, during 2019, DGD issued 453,000 shares of common stock (35,000 Class A and 418,000 Class B) to investors for a price of $453,000. The agreements permitted future payment to the Company by the stockholders, and accordingly, the Company recorded subscriptions receivable of $453,000 related to these issuances of common stock, $418,000 of which relates to MAIA. The entirety of the subscriptions receivable was collected during 2020.

In April 2019, upon incorporation of the legal entity, DGD issued 5,000,000 shares of Class B common stock to MAIA for no consideration.

In June 2019, DGD issued 250,000 shares of Class B common stock to MAIA for $300,000.

In December 2019, DGD issued 175,000 shares of Class A common stock to investors for $175,000.

In December 2019, DGD also issued 35,000 shares of Class A common stock to investors, but did not collect the proceeds during 2019. A subscription receivable was recorded for DGD in the amount of $35,000 as of December 31, 2019. The full amount was received in 2020.

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. As of December 31, 2020, there are 10,231,250 shares issued and outstanding, 9,531,250 of which are owned by MAIA. As of December 31, 2019, there are 10,031,250 shares issued and outstanding, 9,331,250 of which are owned by MAIA.

Restricted Common Stock Award to Founder — In April 2019, THIO awarded 700,000 restricted common shares to a founder. Any vested shares may participate in dividends and other distributions with other common stockholders, while the unvested shares, which may be subject to forfeiture in the event the founder separates from service with THIO, do not participate in such events. The share award is 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, 2019	—	$ —
Granted	700,000	1.80
Vested	(408,333)	
Balance at December 31, 2019	291,667	$ 1.80
Granted	—	$ —
Vested	(116,667)	
Balance at December 31, 2020	175,000	$ 1.80

The related compensation expense is recognized over the service period. For the years ended December 31, 2020 and 2019, THIO recognized $210,000 and $787,500, respectively, in compensation expense related to this award which was presented in general and administrative expenses. As of December 31, 2020, unrecognized stock-based compensation expense related to the unvested shares was $262,500, which the Company expects to recognize over a weighted average period of approximately 0.79 years.

Other Issuances of Common Stock — In addition, during 2019, THIO issued 31,250 shares of common stock to MAIA, pursuant to subscription agreements, for a price of $50,000.

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, 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 $1,000,000,000, 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.

DGD1202 Patent Licensing Agreement - On May 3 2019, DGD entered into a Global PLA with the University of Michigan ("UofM") for a license to a specific compound (DGD1202) from UofM. In connection therewith, DGD entered into an SRA with UofM. The SRA requires DGD to reimburse UofM for agreed-upon expenses related to DGD1202. The PLA required a license issue fee of $10,000 and milestone payments ranging from between $15,000 and $1,000,000,000 for specific development and commercial events. It also requires a running royalty of 2% of net sales. In addition, UofM was entitled to receive equity interest in DGD equaling 2% ownership of DGD upon the earlier of a financing by DGD or one year from the date of the license agreement. The PLA continued to June 2020, at which point DGD and UofM agreed to end their licensing arrangement. The Company recorded $158,935 in expenses to UofM during 2020 related to these agreements. None of the defined milestones were completed and therefore no payments came due related to the milestones. No equity interests in DGD were issued to UofM.

As this license had provided sole impetus for DGD's research efforts, DGD ceased its research and development activities, and in July 2020, the board of directors approved the dissolution of DGD, as well as a special dividend/return of capital to the stockholders shortly thereafter. As of December 31, 2020, minimal assets and liabilities remain in DGD.

10. INCOME TAXES

The Company's net deferred tax assets are as follows:

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 1,418,873	$ 849,234
Stock-based compensation	1,132,473	325,014
Deferred compensation	156,717	50,721
Accrued bonuses	222,339	—
Total net deferred tax assets before valuation allowance	2,930,402	1,224,969
Valuation allowance	(2,930,402)	(1,224,969)
Net deferred tax asset	$ —	$ —

At December 31, 2020, the Company has unused U.S. federal and state net operating loss ("NOL") carryforwards of $4.9 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, 2020 and 2019. The valuation allowance increased by approximately $1.7 million and $1.2 million during the years ended December 31, 2020 and 2019, respectively. 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 federal or state income taxes has been recorded for the years ended December 31, 2020 and 2019, 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,	
	2020	2019
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal tax benefit	6.5%	4.5%
Stock-based compensation	(2.6)%	(8.5)%
Other nondeductible expenses/(nontaxable income)	0.2%	—%
Change in valuation allowance	(25.1)%	(17.0)%
Income tax expense	—%	—%

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law. The Act contains several new or changed income tax provisions, including but not limited to the following: increased limitation threshold for determining deductible interest expense; class life changes to qualified improvements (in general, from 39 years to 15 years); and the ability to carry back net operating losses incurred from tax years 2018 through 2020 up to the five preceding tax years. The Company has evaluated the new tax provisions of the CARES Act and determined the impact to be either immaterial or not applicable.

The Company did not have any significant unrecognized tax benefits during the years ended December 31, 2020 and 2019. The Company files income tax returns in the U.S. federal jurisdiction and several U.S. States. The Company's tax returns since inception remain open to examination by the taxing authorities.

11. SUBSEQUENT EVENTS

Convertible Notes

Between February 16, 2021 and June 29, 2021, MAIA issued unsecured convertible notes payable to investors for a total of $7,390,000. The notes bear interest at 6% and mature two years from issuance. The notes also contain an automatic conversion feature, such that in the event the Company consummates an equity financing, as defined in the agreement, prior to the note's maturity, the outstanding principal and interest shall be converted into preferred shares of the Company which may be issued in connection with the equity financing. The conversion price will be set at 75% of the price of the preferred stock issued in the aforementioned equity financing. The notes also contain a clause that accelerates their maturity upon a change in control of the Company, as defined. The notes are accompanied by warrants, one warrant for each two converted shares, and with a warrant exercise price equal the note conversion price.

Paycheck Protection Program Loan

On January 31, 2021, the Company received a second PPP loan with a bank in the amount of $62,500. Under the terms of the PPP loan, interest accrues on the outstanding principal at the rate of 1% per annum. The PPP Loan is eligible for forgiveness if the funds are used for qualifying payroll expenses. If not forgiven, the loan is to be repaid in monthly installments beginning in 2022. The loan is unsecured and is not guaranteed.

Equity Transactions

In January and February 2021, the Company issued an additional 18,278 shares of common stock. In addition, the board of directors authorized an additional 500,000 shares of MAIA's common stock be reserved for issuance under the MAIA Plan.

Supply and Non-Exclusive License Agreement

In February 2021, the Company reached an agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron") for Regeneron to perform one clinical trial for the treatment of patients with Non-Small Cell Lung Cancer (NSCLC) involving one of the Company's compounds/agents. The Company is generally 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.

Accrued Bonus Pay-out

During the year ended December 31, 2020, the Company accrued $780,000 in bonus expense relating to certain key employees and officers of the Company. Pursuant to an April 11, 2021 Compensation Committee written consent, on April 16, 2021, the Company granted 713,536 MAIA stock options, vesting immediately, in lieu of paying cash for the entire amount accrued as of December 31, 2020.

Deferred Compensation Pay-out

Pursuant to an April 11, 2021 Compensation Committee written consent, on April 16, 2021, the Company paid $418,537 and granted 268,769 MAIA stock options, vesting immediately, to settle $549,788 of 2019 and 2020 deferred compensation payable, and $154,167 of 2021 deferred compensation payable.

2020 Plan Amendments

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.

Sales of Common Stock

Between July 15, 2021 and September 29, 2021, the Company sold 725,563 shares of common stock at $8.00 per share for gross proceeds of approximately $5.8 million before transaction costs and expenses.

Australia Pty Ltd.

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.

MAIA-THIO Merger

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 Dissolution

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.

Conversion of 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 convertible notes issued in 2021 into 1,375,228 shares of the Company’s common stock on September 30, 2021.

Conversion of SAFE Agreement

In connection with the sale of common stock in fiscal 2021, an Equity Financing, the SAFE Agreement in the amount of $25,000 was converted into 5,208 shares of the Company’s common stock on September 30, 2021.

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 632,418 shares of our common stock at $6.00 per share, for an aggregate purchase price of $3,794,508.

Shares of Common Stock

MAIA Biotechnology, Inc.

PRELIMINARY PROSPECTUS

ThinkEquity

, 2021

Through and including , 2021 (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 Nasdaq listing fee.

SEC registration fee	$	[ ]
FINRA filing fee	$	[ ]
Initial Nasdaq 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 318,819 shares of common stock with an aggregate principal amount of $574,000.

In October and November 2019, we issued and sold 980,393 shares of common stock with an aggregate principal amount of $1.764 million.

In July through September 2021, we issued and sold common stock with an aggregate principal amount of approximately $5.8 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.

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 632,418 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

Since January 1, 2018, we have granted to our employees, officers, directors and other persons who provide services to us options to purchase up to 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 $ per share. 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 shares of our common stock at $ per share, which expire on and vested .

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.
3.1*	Amended and Restated Certificate of Incorporation of MAIA Biotechnology, Inc.
3.3*	Amended and Restated Certificate of Incorporation of MAIA Biotechnology, Inc. to be in effect upon completion of the offering.
3.4*	Amended and Restated Bylaws of MAIA Biotechnology, Inc.
3.5*	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.
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 dated.
10.5*+†	Employment Agreement between Joseph McGuire and the Company dated.
10.6*+†	Employment Agreement between Mihail Obrocea and the Company dated.
10.7*+†	Employment Agreement between Sergei Gryaznov and the Company dated.
10.8*+†	Employment Agreement between Daniel Relovsky and the Company dated.
10.9*+	Form of Indemnification Agreement between the Company and each of its directors and executive officers.
10.10*+	MAIA Biotechnology, Inc. 2018 Stock Option Plan.
10.11*+	MAIA Biotechnology, Inc. Amended & Restated 2020 Equity Incentive Plan.
10.12*+	Form of 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).

* To be filed by amendment.

+ Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv). The Registrant agrees to furnish an unredacted copy of any such exhibit to the SEC upon its request.

(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 , 2021.

MAIA BIOTECHNOLOGY, INC.

By: _____
Name: Vlad Vitoc
Title: Chief Executive Officer and Chairman

POWER OF ATTORNEY

We, the undersigned officers and directors of MAIA Biotechnology, Inc., hereby severally constitute and appoint Vlad Vitoc and Joseph McGuire, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution in each of them for him or her and in his or her name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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
_____ Vlad Vitoc	Chairman and Chief Executive Officer (Principal Executive Officer)	, 2021
_____ Joseph McGuire	Chief Financial Officer (Principal Financial Officer)	, 2021
_____ Steven Chaouki	Director	, 2021
_____ Ramiro Guerrero	Director	, 2021
_____ Louie Ngar Yee	Director	, 2021
_____ Cristian Luput	Director	, 2021
_____ Stan Smith	Director	, 2021
_____ Laurentiu Vlad	Director	, 2021