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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number 001-41455

MAIA BIOTECHNOLOGY, INC.
(Exact name of Registrant as specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**83-1495913** **(I.R.S. Employer Identification No.)**
444 West Lake Street, Suite 1700 **Chicago, IL** **(Address of principal executive offices)**	**60606** **(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	MAIA	NYSE American

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

The aggregate market value of the voting stock and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter ended June 30, 2025 was $48,948,795 based upon the closing price of the registrant's common stock of $1.80 on the NYSE American as of that date.

The number of shares of Registrant's Common Stock outstanding as of March 23, 2026 was 60,671,491.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the annual stockholder meeting to be held in 2026 are incorporated by reference into Part III of this Annual Report on Form 10-K as noted herein. The registrant intends to file its proxy statement within 120 days after its fiscal year end.

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Special Note Regarding Forward-Looking Statements

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

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

- our financial performance;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our drug candidates;
- the ability to receive FDA clearance for clinical trials;
- the ability to secure clinical sites, enroll patients, and initiate clinical trials;
- the ability of our clinical trials to demonstrate safety and efficacy of our drug candidates, and other positive results;
- the success, cost and timing of our development activities, preclinical studies and clinical trials;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- our plans relating to commercializing our drug candidates, if approved;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any drug candidates for which we obtain approval;
- our ability to attract and retain key scientific and clinical personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our reliance on third parties to conduct clinical trials of our drug candidates, and for the manufacture of our drug candidates for preclinical studies and clinical trials;
- our ability to establish our own manufacturing facilities domestically;
- our ability to expand our drug candidates into additional indications and patient populations;
- the success of competing therapies that are or may become available;
- the beneficial characteristics, safety and efficacy of our drug candidates;
- regulatory developments in the United States and other jurisdictions;
- our ability to obtain and maintain regulatory approval of our drug candidates, and any related restrictions, limitations and/or warnings in the label of any approved drug candidate;
- our plans relating to the further development and manufacturing of our drug candidates, including additional indications for which we may pursue;
- our plans and ability to obtain or protect intellectual property rights;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology; and
- potential claims relating to our intellectual property.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K. You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we do not intend to update any of these forward-looking statements after the date of this Annual Report on Form 10-K or to conform these statements to actual results or revised expectations.

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

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

PART I

Item 1. Business.

Our Company

MAIA Biotechnology, Inc. (MAIA, the Company, we, or us) is a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer. Ateganosine (THIO, 6-thio-dG or 6-thio-2 '-deoxyguanosine), our lead asset, is an investigational dual mechanism of action drug candidate incorporating telomere targeting and immunogenicity. In July 2022, the first patient was administered with ateganosine in our Phase 2 human trial (THIO-101) in Australia. In December 2022, regulatory authorities in three European countries, Hungary, Poland, and Bulgaria, approved the implementation of THIO-101, Phase 2 clinical trial evaluating ateganosine in patients with Non-Small Cell Lung Cancer (NSCLC). In the trial, patients with advanced NSCLC are treated first with ateganosine followed a few days later by the immune checkpoint inhibitor Libtayo® (cemiplimab), manufactured and commercialized by Regeneron. Cemiplimab is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 on T-cells. Cemiplimab has been approved in the United States and the rest of the world for multiple cancer indications, including NSCLC. In February 2021, we signed a clinical supply agreement with Regeneron to receive cemiplimab at no cost, which represents a significant cost-savings for the study. In return, we have granted Regeneron exclusive development rights in combination with PD-1 inhibitors for NSCLC for the study period. In July 2025, we initiated an expansion of the THIO-101 trial focused on third-line NSCLC patients who are resistant to checkpoint inhibitors and chemotherapy. The expansion will enroll up to 48 patients with two arms: Arm 1, continuing the evaluation of ateganosine sequenced with Libtayo® (cemiplimab); and Arm 2, evaluating ateganosine as a monotherapy, to further gain experience of ateganosine in the contribution of components. Based on the clinical data generated by our THIO-101 trial, we plan to seek filing for an accelerated approval of ateganosine in the United States for the treatment of patients with advanced NSCLC in 2026, but even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the Food and Drug Administration (FDA).We initiated a Phase 3 pivotal trial in 2025, named THIO-104, to evaluate the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) in third-line NSCLC patients who are resistant to checkpoint inhibitors and chemotherapy. The multicenter, open-label, pivotal Phase 3 trial is designed to provide a direct comparison to chemotherapy in a 1:1 randomization of up to 300 patients. In addition, the originally planned Phase 2 clinical trial in multiple tumor indications (THIO-102) is now divided into different trials for one tumor indication each: hepatocellular carcinoma (HCC), colorectal cancer (CRC) and small cell lung cancer (SCLC). Phase 2 clinical trials in HCC, CRC and SCLC are planned to be initiated in 2026, evaluating treatment with ateganosine administered in sequence with BeOne Medicines's immune checkpoint inhibitor, tislelizumab. Clinical trials with other solid tumors (ST), such as breast, prostate, gastric, pancreatic and ovarian, may still be considered for potential future trials.

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

Our Lead Product Candidate

Ateganosine is a telomere-targeting agent currently in clinical development to evaluate its activity in NSCLC. Telomeres, along with the enzyme telomerase, play a fundamental role in the survival of cancer cells and their resistance to current therapies. Ateganosine is being developed as a second- or later line of treatment for NSCLC for patients that have progressed beyond the standard-of-care regimen of existing checkpoint inhibitors.

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

Our regulatory strategy includes a filing of an Investigational New Drug application (IND) with the United States Food and Drug Administration (U.S. FDA or FDA). This was granted and will allow U.S. sites to participate in the THIO-101 NSCLC trial. The human safety data generated in Australia and Europe constituted the basis of the IND application. Although we plan to rely solely on the safety and efficacy data we generate in our own clinical trials in support of our planned New Drug Application (NDA) filing, and do not plan to rely on clinical data generated by unaffiliated third parties, we take added confidence in the potential tolerability of ateganosine in light of the fact that the ateganosine dose selected of 180 mg/cycle is 14 times lower than the maximum tolerated dose tested in the earlier clinical trials sponsored by the National Cancer Institute (NCI) in the 1970s. The THIO-101 Phase 2 trial is a proof-of-concept study that may be modified depending on interim results to include both primary and secondary endpoints and be consistent with previously approved cancer treatments. In September 2022, we submitted a pre-IND meeting request to the FDA to discuss, among other elements, the existing non-clinical and clinical data to support the conduct of our planned THIO-101 Phase 2 trial under an IND to include patients from the U.S. MAIA received feedback in-line with the proposed plans from the FDA regarding its manufacturing, preclinical and clinical development plan. MAIA also obtained guidance from the FDA on the assessment of its safety and efficacy in the THIO-101 Phase 2 trial that was incorporated in the U.S. IND application. The U.S. IND was granted in 2023.

The THIO-101 study protocol was amended in December 2024 to increase the number of patients enrolled in an expansion arm to further evaluate efficacy of the treatment in third-line NSCLC patients resistant to checkpoint inhibitor and chemotherapy. The study may undergo modification of the statistical analysis, a change in the trial design, and/or primary endpoints. Based on the clinical data we aim to generate in the THIO-101 study and assuming ateganosine achieves its intended clinical effect with a manageable safety profile at one of the doses tested in the study, we expect to seek early FDA guidance on the possibility of utilizing one or more of FDA's expedited programs for serious conditions, such as fast track designation (FTD), breakthrough therapy designation, priority review and/or accelerated approval designation. Accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA. In July 2025, the FDA granted fast track designation for ateganosine and we intend to utilize the incentives of the Fast Track Program to expedite the development and review of ateganosine.

On April 11, 2023, we announced positive topline data related to the completion of Part A, safety lead-in portion of the THI0-101 trial which showed that administration of ateganosine, at the highest dose of 360 mg/cycle in sequential combination with Regeneron's anti-PD-1 therapy, Libtayo® was well tolerated with no dose limiting toxicities or significant treatment-related adverse events reported.

On April 18, 2023, we published data in Hepatocellular Carcinoma (HCC) models: as monotherapy, ateganosine achieved complete and durable responses in HCC, the dominant histology in primary liver cancer (90%), in in vivo models. When combined with Libtayo®, duration of response was further potentiated. Even upon rechallenge with two times more cancer cells and no additional treatment, tumor growth was completely prevented. Administration of ateganosine alone and in combination with Libtayo® generated anticancer immune memory.

On April 20, 2023, we announced preliminary survival data from Part A of THIO-101. The first two patients enrolled in Part A of the study continued to be alive, approximately 10 and 9 months respectively, from treatment initiation. Both patients have advanced Stage IV metastatic disease and are heavily pretreated, receiving third and fourth line of therapy respectively after previously failing treatment with an immune checkpoint inhibitor. They continue to be progression free following their last dose of ateganosine, 7 and 6 months respectively, with no new treatment. The current treatment options in patients with advanced relapsed or refractory NSCLC who failed two or more therapy regimens are limited and show minimal benefit. Furthermore, discontinuation of treatment is rapidly followed by physical decline and death, therefore seeing patients with such survival and no disease progression in this clinical setting, is noteworthy. In real-world clinical practice, observed survival in such heavily pretreated patients is 3-4 months.

On June 20, 2023, we announced updates in enrollment in THIO-101 in Europe. To that date, 29 patients have been dosed in THIO-101. With the addition of sites in Hungary, Poland, and Bulgaria in March 2023, THIO-101 has rapidly increased the number of patients enrolled and dosed with ateganosine. Thirteen sites were activated with another two new additional sites ready to open shortly afterward.

On July 10, 2023, we announced updates on preliminary survival data in the Part A safety lead-in of THIO-101. The first 2 patients enrolled in the study continued to be alive, approximately 12.2 and 11.5 months respectively, from treatment initiation. Both patients have advanced Stage IV metastatic disease and failed 2 prior lines of therapy, including one line with an immune CPI, and platinum-based chemotherapy. Following the conclusion of study treatment, they have remained free of disease progression for 10.2 and 8.5 months, respectively, without requiring any additional therapy.

On July 11, 2023, we announced updates on disease control data in the part A safety lead-in of THIO-101. Of the first 11 patients enrolled in THIO-101 to complete at least 1 post baseline response assessment, 9 (82%) met the primary endpoint of disease control (defined as a Complete Response, Partial Response, or Stable Disease per RECIST 1.1). All patients enrolled have previously failed 2 or more prior lines of treatment including an immune CPI and platinum-based chemotherapy for advanced NSCLC.

On October 24, 2023, we reported unprecedented interim disease control rate (DCR) of 100% in second-line treatment that far surpasses standard of care (SoC) DCR of 53-64%, presented at ESMO 2023. DCR is far stronger than overall response rate (ORR) in predicting overall survival benefit, as shown in a recent meta-analysis of 74 clinical trials worldwide in NSCLC.

On December 19, 2023, we announced dose selection for THIO-101, a Phase 2 clinical trial evaluating its lead asset, ateganosine, in sequential combination with Regeneron's anti-PD-1 cemiplimab (Libtayo®) in patients with advanced NSCLC. During the dose-finding stage of THIO-101, patients were administered either 60mg, 180mg, or 360mg of ateganosine per cycle, followed by 350mg of cemiplimab (Libtayo®). The selected dose, 180mg/cycle, presented better safety profile and outperformed the other doses in the key measures of efficacy for NSCLC trials. Subsequently, all future trial participants will be treated with ateganosine 180mg/cycle.

On January 17, 2024, we announced new interim data for our ongoing THIO-101 Phase 2 trial in NSCLC. In the latest available data from THIO-101 (November 13, 2023), 60 patients had been dosed with ateganosine in sequential combination with Libtayo®. The patients received either 60mg, 180mg, or 360mg of ateganosine per dose, and 42 had at least one post baseline assessment completed. The observed disease control was well sustained compared to previous scans.

On February 7, 2024, we announced publication of international Patent Cooperation Treat (PCT) application titled "Dinucleotides and Their Use in Treating Cancer." The new dinucleotides disclosed in the patent application are telomere-targeting molecules, such as ateganosine fragments or other ateganosine analogues. These compounds are key next-generation telomere-targeting agents, an important extension of MAIA's innovative cancer treatment platform. The PCT system streamlines the process for obtaining patent protection globally. Under the PCT, applicants can seek patent protection in a large number of countries.

On February 22, 2024, we announced completion of enrollment in Phase 2 THIO-101 go-to-market clinical trial. The trial reached the enrollment target of 41 patients for the 180mg/dose on February 19, 2024. As of the latest data available for the trial, 79 patients had received either 60mg (24 patients), 180mg (41 patients) or 360mg (14 patients). The original trial design targeted up to 182 patients, including all patients in the safety lead-in and 41 patients in each of the 3 tested doses (60mg, 180mg, and 360mg). Following the selection of 180 mg/cycle as the optimal dose in December 2023, all patients were subsequently enrolled at the 180mg/cycle dose and trial enrollment was completed ahead of schedule.

On March 6, 2024, we announced interim efficacy data for THIO-101 Phase 2 trial in NSCLC. In the latest data available (January 8, 2024), the overall response rate (ORR), characterized as partial or complete response to therapy, was 38% (3 out of 8 patients) in the efficacy evaluable population for combination ateganosine 180mg + cemiplimab in third-line treatment for NSCLC patients who failed treatment with immune checkpoint inhibitors in prior lines of therapy, with or without chemotherapy.

On March 27, 2024, we evaluated additional clinical data from its Phase 2 clinical trial, THIO-101. At such time, a total of 68 patients have been dosed and had a post-baseline scan in MAIA's Phase 2 clinical trial, THIO-101, evaluating ateganosine in sequential combination with an immune checkpoint inhibitor in patients with advanced NSCLC. Preliminary efficacy across all lines of therapy in this March 2024 data cut were consistent with previous reports including: (i) 75% of patients receiving ateganosine 180mg as third-line therapy for NSCLC have surpassed the overall survival (OS) threshold of 5.8 months; (ii) 88% of patients in the same setting (3L, 180mg) also crossed the 2.5 months progression free survival (PFS) threshold and have shown ORR of 38%, greatly improving on current chemo treatment that have ORRs of around 6-10%; and (iii) across all third-line patients, DCR of 85% remained superior to current chemotherapy options, which ranges from 25-35% DCR.

On June 4, 2024, we announced new preliminary efficacy data from the Phase 2 THIO-101 clinical trial. The updated included that as of April 30, 2024: (i) all evaluable patients had completed ≥1 post-baseline assessment; (ii) third-line treatment across all doses had shown DCR of 85% for ateganosine, 65% of patients crossed the 5.8 month OS threshold identified in literature, 85% of patients crossed the 2.5 month PFS threshold, median survival follow-up time was 9.1 months; and (iii) third-line treatment with ateganosine 180mg had shown median PFS of 5.5 months, 78% OS rate at 6 months, 38% ORR, 75% of patients crossed the 5.8 month OS threshold, 88% of patients crossed the 2.5 month PFS threshold and median survival follow-up time observed was 9.1 months.

On June 6, 2024, we announced MAIA highlights and key achievements year-to-date, including: (i) exceptional measures of efficacy by lead drug ateganosine in Phase 2 clinical trial, with 38% ORR in third-line (3L) setting (ateganosine 180mg) compared to ~6% for currently available treatments in a similar population and 5.5 months median progression-free survival (PFS) (3L, ateganosine 180mg); and (ii) secured continued insider investment through independent board members' participation in private placement equity financings, with funding of more than $12M year-to-date.

On June 7, 2024, we announced the validation of clinical and regulatory pathways for viable therapies leveraging the cell's telomeric functions as evidenced by the FDA approval of imetelstat, a treatment for low- to intermediate-risk hematologic malignancies (myelodysplastic syndromes) from Geron Corporation, illuminating the role of telomere targeting as a viable therapeutic strategy for cancer treatment.

On July 23, 2024, we announced treatment updates from our Phase 2 clinical trial of ateganosine. As of June 12, the latest clinical cut-off date: (i) 6 patients remain on treatment following at least 12 months of therapy; (ii) treatment with ateganosine followed by cemiplimab has been well tolerated throughout the trial, with lower toxicity compared to standard-of-care treatments; and (iii) the longest-treated patients have completed 21 cycles of ateganosine sequenced with cemiplimab.

On September 10, 2024, we announced updates from our lead clinical candidate ateganosine, in our Phase 2 clinical trial, THIO-101. The updates included: (i) As of August 1, 2024, 16 patients had survival follow-up surpassing 12 months, including 9 in third line treatment (3L); (ii) Interim median survival follow-up in 3L was 10.6 months.; and (iii) ateganosine's substantial survival benefit in third line surpasses comparable standard-of-care overall survival of 5.8 months.

On December 3, 2024, we announced the amendment of the 2021 clinical supply agreement with Regeneron for the expansion portion of THIO-101, its Phase 2 clinical trial evaluating ateganosine in sequential administration with cemiplimab (Libtayo®). The new expansion will further assess the efficacy of MAIA's lead asset, ateganosine, sequenced with immune checkpoint inhibitor (CPI) Libtayo® (cemiplimab) for advanced non-small cell lung cancer (NSCLC) patients receiving third-line therapy who were resistant to previous checkpoint inhibitor treatments and chemotherapy. The original 2021 agreement between MAIA and Regeneron was designed to supply the original THIO-101 trial through the dose selection and safety evaluation process.

On December 16, 2024, we announced that the FDA has designated ateganosine for the treatment of pediatric-type diffuse high-grade gliomas (PDHGG) as a drug for a "rare pediatric disease" (RPDD). Upon FDA approval of a future new drug application in PDHGG, MAIA would be eligible to receive a priority review voucher that can be redeemed by drug developers for FDA priority review of a different product or transferred or sold to another sponsor.

On January 7, 2025, we announced that we had entered into a clinical supply agreement with global oncology company BeiGene to assess the efficacy of ateganosine, its small molecule telomere-targeting anticancer agent, in combination with BeiGene's immune CPI tislelizumab in three cancer indications. The single arm pivotal Phase 2 trials will study the drug combination in HCC, SCLC and CRC. Under the terms of the collaboration, MAIA will sponsor and fund the planned clinical trials and BeiGene will provide tislelizumab. MAIA maintains global development and commercial rights to ateganosine and is free to develop the programs in combination with other agents and in other indications. Since May 2025, BeiGene has changed its company name to BeOne Medicines.

On February 4, 2025, we announced positive updated data from THIO-101 Phase 2 clinical trial evaluating its lead clinical candidate, ateganosine, sequenced with Regeneron's immune CPI cemiplimab (Libtayo®) in patients with advanced NSCLC who failed two or more standard-of-care therapy regimens. As of January 15, 2025, third line (3L) data updates showed that: (i) median overall survival (OS) of 16.9 months for the 22 NSCLC patients who received at least one dose of ateganosine (the intent-to-treat population) in parts A and B of the trial. (ii) The analysis demonstrated a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months. (iii) The treatment has been generally well-tolerated to date in this heavily pre-treated population.

On February 26, 2025, we announced the trial design for the expansion of its THIO-101 pivotal Phase 2 trial in NSCLC. The expansion of the study will assess overall response rates (ORR) in advanced NSCLC patients receiving third line (3L) therapy who were resistant to previous checkpoint inhibitor treatments (CPI) and chemotherapy. The THIO-101 study in 3L will enroll up to 48 patients with two arms: Arm 1, continuing the evaluation of ateganosine sequenced with Libtayo® (cemiplimab); and Arm 2, evaluating ateganosine as a monotherapy, to further gain experience of ateganosine in the contribution of components. Treatment cycles for patients in both arms will administer ateganosine on 3 consecutive days, followed by immune activation on day 4. Arm 1 will administer Libtayo on day 5. The Company plans to enroll an additional 100 patients for the registration phase of the trial. MAIA expects to conduct the trials in the U.S. and select countries in Europe and Asia.

On February 27, 2025, we announced plans to initiate a Phase 3 pivotal trial in 2025, named THIO-104, to evaluate the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) in third-line non-small cell lung cancer (NSCLC) patients who are resistant to checkpoint inhibitors and chemotherapy. The multicenter, open-label, pivotal Phase 3 trial is designed to provide a direct comparison to chemotherapy in a 1:1 randomization of up to 300 patients.

On March 18, 2025, we announced that the United States Adopted Names (USAN) Council had approved "ateganosine" as the nonproprietary (generic) name for its lead molecule a telomere-targeting anticancer agent in clinical development as a first-in-class treatment for advanced non-small cell lung cancer (NSCLC). The company chose a name inspired by the mechanism of action of THIO: altering telomeric guanosine of the cancer cells. The generic name ateganosine is a unique and consistent identity that aims to support clear communication between healthcare providers, patients and researchers. MAIA will retain the name THIO in its clinical trial designations (THIO-101, THIO-102, THIO-103, THIO-104).

On March 20, 2025, we announced the publication of preclinical data for our lead proprietary telomere-targeting ateganosine dimer in the peer-reviewed scientific journal Naunyn-Schmiedeberg's Archives of Pharmacology. In a preclinical study, ateganosine and its new described dimer form were found to be potent inhibitors of Glutathione S-transferase Pi (GSTP1), a key enzyme implicated in cancer progression and chemoresistance and a highly important factor for the detoxification of cancer cells. The findings suggest that the dimerized form of ateganosine could enhance chemotherapeutic efficacy by effectively targeting GSTP1 and reducing drug resistance. The article, titled "Investigation of the inhibitory effects of the telomere-targeted compounds on glutathione S-transferase P1," was published on February 15, 2025.

On June 5, 2025, we announced updated data from its THIO-101 pivotal Phase 2 clinical trial. As of May 15, 2025, third line (3L) data showed median overall survival (OS) of 17.8 months for the 22 NSCLC patients who received at least one dose of ateganosine (the intent-to-treat population) in parts A and B of the trial. The updated analysis continues to demonstrate a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months. The Company also mentioned that treatment had been generally well-tolerated to date in this heavily pre-treated population.

On June 5, 2025, we announced that a new partial response (PR) was identified in a patient after 20 months of treatment in our Phase 2 THIO-101 clinical trial. A partial response is defined as a decrease in tumor size of at least 30%.

On June 18, 2025, we announced its entry into a clinical master supply agreement with Roche for future studies investigating the combination of MAIA's telomere targeting agent ateganosine (THIO), sequenced with Roche's checkpoint inhibitor (CPI), atezolizumab (Tecentriq®), for the treatment of multiple hard-to-treat cancers.

On June 24, 2025, we announced the appointment of two prominent oncologists to its Scientific Advisory Board (SAB), Claudia Fulgenzi, MD, and David J. Pinato, MD, MRCP (UK), PhD. Both are specialists in hepatocellular carcinoma (HCC), a tumor type to be studied in future clinical trials of MAIA's lead candidate ateganosine (THIO) sequenced with a checkpoint inhibitor.

On July 9, 2025, we announced the dosing of the first patient in Taiwan in the expansion phase of our THIO-101 Phase 2 trial for advanced non-small cell lung cancer (NSCLC). The trial's entry into another continent marks a key milestone for MAIA, opening a significantly larger patient pool for its evaluations of ateganosine (THIO). MAIA also announced that screening for the trial is ongoing in Europe and Asia.

On July 17, 2025, we announced the publication of preclinical data from its second generation ateganosine prodrugs platform in Nucleic Acids Research (NAR), a leading open-access peer-reviewed scientific journal. The study, titled "Novel Telomere-Targeting Dual-Pharmacophore Dinucleotide Prodrugs for Anticancer Therapy," details MAIA's lead ateganosine (THIO)-derived second-generation prodrugs as promising new molecules in its strategy for enhancing cancer treatment and overcoming drug resistance. The manuscript with the data was published on June 26, 2025, in Volume 53, Issue 12 of the NAR journal.

On July 28, 2025, we announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ateganosine (THIO, 6-thio-dG or 6-thio2'-deoxyguanosine) for the treatment of non-small cell lung cancer (NSCLC). Ateganosine is currently being evaluated in a pivotal Phase 2 THIO-101 clinical trial evaluating its anti-tumor activity when followed by a checkpoint inhibitor.

On August 13, 2025, we announced that the European Patent Office granted a patent broadly covering a portfolio of ateganosine-based analogues for telomere targeting anticancer therapy and methods of using ateganosine (THIO) alone or before administration of checkpoint inhibitors (CPIs). The patent, titled "Mercaptopurine Ribonucleoside Analogues for Altering Telomerase Mediated Telomere," was invented by MAIA's Chief Scientific Officer Sergei M. Gryaznov, PhD and Scientific Advisory Board member Jerry W. Shay, PhD. MAIA's global patent and patent-pending estate covers several areas including telomerase mediated telomere altering compounds and treatment of therapy-resistant cancers. Further, ateganosine's immunogenic treatment strategy, which focuses on sequential combination with checkpoint inhibitors, has been filed worldwide. MAIA's IP portfolio for ateganosine currently comprises 10 issued patents worldwide including Europe (validated in 19 countries) along with 24 pending patent applications.

On August 27, 2025, we announced that a manuscript detailing developments in its Phase 2 THIO-101 clinical trial was accepted and published in the international peer-reviewed open access scientific journal, Cells, in a special issue, "Cellular Mechanisms of Anti-Cancer Therapies." The manuscript, titled "Perioperative Management of Non-Small Cell Lung Cancer in the Era of Immunotherapy," was authored by a group of oncology researchers in Turkey and the U.S. including MAIA scientists Sergei Gryaznov, Ph.D., Chief Scientific Officer and Ilgen Mender, Director of Biology Research, along with MAIA Scientific Advisory Board members Z. Gunnur Dikmen, M.D., Ph.D. and Saadettin Kiliçkap, M.D., M.Sc.

On September 11, 2025, we highlighted positive efficacy data from its Phase 2 clinical trial, THIO-101, including that as of June 30, 2025: (i) estimated median progression free survival (PFS) in third-line treatment (180 mg dose) was 5.6 months; (ii) Estimated median overall survival (OS) was 17.8 months, with a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months, consistent with the prior data readout (May 15, 2025); (iii) Across patients of all treatment lines, 2 patients have completed 33 cycles of therapy, highlighting ateganosine' potential for extended dosing, which usually translates into longer patient survival.

On October 23, 2025, we announced that as of September 17, 2025, a patient that began therapy in March 2023 has shown survival of 30 months, or 912 days, an outstanding measure relative to many of the high-risk cancers. The patient with thirty month survival received therapy every three weeks and concluded treatment upon reaching the maximum treatment duration of 2 years based on protocol requirements.

On October 27, 2025, we announced that we have enrolled five patients from Taiwan and Turkey in the expansion phase of its THIO-101 Phase 2 trial.

On November 20, 2025, we announced Romania as an additional country to begin screening patients for the expansion phase of its THIO-101 Phase 2 clinical trial which evaluates ateganosine sequenced with an immune checkpoint inhibitor as a third-line treatment for non-small cell lung cancer (NSCLC).

On November 21, 2025, we announced that we have enrolled 12 patients from Taiwan, Turkey, Hungary and Poland in the expansion phase of its THIO-101 Phase 2 trial.

On December 11, 2025, we announced that the first patient has been dosed in THIO-104 Phase 3 pivotal trial evaluating the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) as a third-line treatment for advanced non-small cell lung cancer (NSCLC). The multicenter, open-label trial is designed to assess overall survival for ateganosine sequenced with a CPI compared to investigator's choice of chemotherapy in a 1:1 randomization of up to 300 patients. MAIA has received regulatory approval to screen patients in Taiwan, Turkey, select European Medicines Agency (EMA) countries, and Georgia. Screening and enrollment are now underway.

On January 20, 2026, we provided a corporate update on 2025 achievements and highlighted key targeted milestones and growth catalysts for 2026. The targeted milestones include: (i) initial measures of efficacy from Phase 3 study, with interim disease control rates (DCR), overall response rates (ORR) and progression free survival (PFS) analysis of ateganosine compared to the control arm will support regulatory discussions; (ii) expected conclusion of Part C of Phase 2 study, which will provide additional clinical efficacy data to support regulatory review for commercial approval; (iii) Plan to engage in regulatory interactions with the FDA to expand ongoing FDA dialogue under the Fast Track designation, including discussions around trial enhancements and prospects for Accelerated Approval and Priority Review; (iv) clinical development of second-generation molecules planned to start in Phase 1 trials, with additional small molecules fully developed in-house with better expected efficacy compared to ateganosine.

In addition to NSCLC, HCC, SCLC and CRC we plan to conduct clinical trials evaluating ateganosine (THIO) in sequential combination with an immune checkpoint inhibitor in several other cancer indications, including solid tumors, such as breast, prostate, gastric, pancreatic and ovarian cancers.

Our Science—Driven Telomere Targeting Approach

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

Telomere maintenance is a fundamental biologic process for cell proliferation and resilience in cancer cells and thus represents one of the key therapeutic targets for cancer treatment. Telomerase is an enzyme that is present in a majority of human cancer cells (over 85% in the aggregate), across various tumor types. In contrast, its activity is detected in less than 1% of normal cells. Ateganosine has only been shown to be active in cancer cells that are telomerase positive (TERT+) and actively dividing. Cancer cells are constantly telomerase positive due to an uncontrolled division process, while a relatively small number of normal cells are telomerase positive only transiently. Therefore, ateganosine activity is expected to be highly specific to cancer cells versus normal cells. Cancer-specific disturbance of telomeric structure, mediated by telomerase, is likely to lead to disruption in the cell cycle, followed by a very rapid and telomere-length independent cell death. Ateganosine was observed in preliminary in vitro and in vivo studies to induce cancer-specific telomere disruption, by using the enzyme telomerase which differentiates ateganosine from all other available cancer therapies currently in clinical use. We are also currently developing potential next-generation small molecule telomere modifying agents with the goal of identifying additional proprietary drug candidates, across multiple cancer types. We have generated eighty-two (82) new telomere-targeting compounds of which sixty (60) compounds have been evaluated in vitro. Currently, seven (7) molecules have been selected for further evaluation in additional in vitro and in vivo models.

Human clinical trials prior to approval are typically conducted in three sequential Phases that may overlap or be combined. In Phase 1, the drug or biologic is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In Phase 2, the drug or biologic is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule for patients having the specific disease. In Phase 3, larger-scale clinical trials are undertaken to evaluate clinical efficacy and safety and the overall risk/benefit ratio of the product. Post-approval studies, or Phase 4 clinical trials, may be conducted voluntarily, or as a condition of FDA's approval of a drug. These studies may be used to confirm preliminary efficacy results, gain additional experience from the treatment of certain patient populations, or to support additional indications or labeling changes.

We completed our selection process for the clinical sites for our Phase 2 study in Australia and Europe and our application to start the Phase 2 study in Australia was approved on March 1, 2022, by the Australian Regulatory Agency—Bellberry Human Research Ethics Committee. In July 2022, the first patient was administered with ateganosine in our Phase 2 human trial (THIO-101) in Australia. In December 2022, regulatory authorities in three European countries, Hungary, Poland, and Bulgaria, approved the implementation of THIO-101, Phase 2 clinical trial evaluating ateganosine in patients with NSCLC. In July 2025, we initiated an expansion of the THIO-101 trial focused on third-line NSCLC patients who are resistant to checkpoint inhibitors and chemotherapy.

We initiated a Phase 3 pivotal trial in 2025, named THIO-104, to evaluate the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) in third-line NSCLC patients who are resistant to checkpoint inhibitors and chemotherapy. The multicenter, open-label, pivotal Phase 3 trial is designed to provide a direct comparison to chemotherapy in a 1:1 randomization of up to 300 patients.

In March 2022, the FDA granted Orphan Drug Designation (ODD) to ateganosine for the treatment of HCC, in May 2022, the FDA granted the second ODD to ateganosine for the treatment of small cell lung cancer, and in late 2023, a third ODD for Malignant Gliomas Brain Cancer. The FDA's Office of Orphan Products Development may grant orphan designation status to drugs and biologics that are intended for the treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. ODD provides certain benefits, including financial incentives, to support clinical development and the potential for up to seven years of market exclusivity for the drug for the designated orphan indication in the U.S. if the drug is ultimately approved for its designated indication.

In December 2024, the FDA granted rare pediatric disease designation (RPDD) for ateganosine for the treatment of pediatric-type diffuse high-grade gliomas (PDHGG). Upon FDA approval of a future new drug application in PDHGG, MAIA would be eligible to receive a priority review voucher that can be redeemed or sold as an asset. Rare pediatric disease priority review vouchers (PRVs) can be redeemed by drug developers for FDA priority review of a different product or transferred or sold to another sponsor. Since 2015, FDA priority review vouchers have sold as assets at an average amount of $100 million.

In July 2025, the FDA granted fast track designation (FTD) for the treatment of NSCLC. Ateganosine is currently being evaluated in a pivotal Phase 2 THIO-101 clinical trial evaluating its anti-tumor activity when followed by a checkpoint inhibitor. The FDA Fast Track is a process designed to facilitate development and expedite the review of drugs for treating serious conditions and filling an unmet medical need, as in providing a therapy where none exists or which may be potentially better than available therapy. If relevant criteria are met during the Fast Track process, a drug will be eligible for FDA Accelerated Approval and Priority Review.

Our Second Generation Molecule Candidates

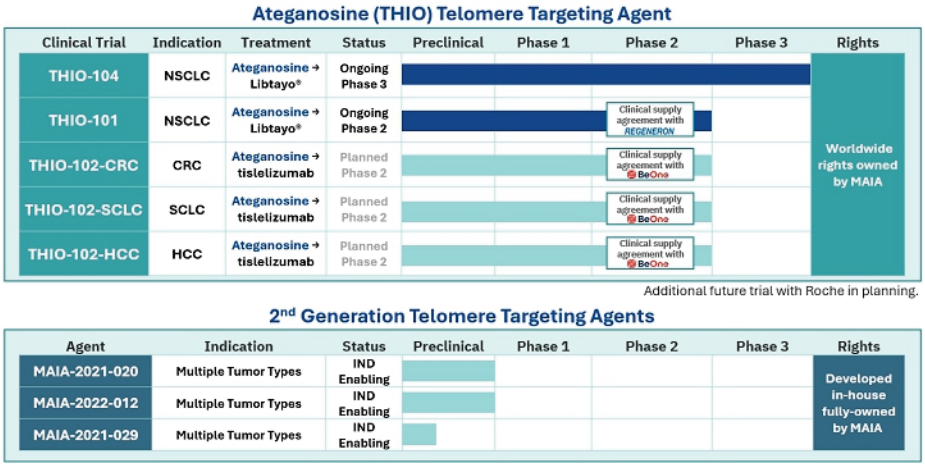
We have initiated an early-stage research and discovery program aimed at identifying new compounds capable of acting through similar mechanisms of activity as ateganosine, such as the targeting and modifying telomeric structures of cancer cells through cancer-cell intrinsic telomerase activity. The main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

Our current 2nd-generation pipeline of potential telomere-targeting agents includes seven compounds that have successfully undergone in vitro inhibitory testing in five cancer models. The data from those studies showed a significantly lower 50% inhibitory concentration (IC50) for those compounds compared to ateganosine. Based on those data, we have progressed those seven compounds to in vivo testing. In January 2023, we nominated one lead new molecular entity candidate (designated as MAIA-2021-20) and one back-up new molecular entity candidate (MAIA-2022-12) for further advancement into preclinical GLP-toxicity and other studies and may advance one of these candidates into human clinical trials upon completion of the required preclinical evaluations. A third candidate (MAIA-2021-029) was selected in June 2023.

MAIA has filed three different families of patent applications that cover its 2nd-generation of compounds. One family (Dinucleotides and Their Use in Treating Cancer) is filed in the US, AU, BR, CA, CH, EPO, KR, MX, JP and TW. The second family (Tumor Redox-Activated 6-thiopurine Containing Dimer Compounds) has been filed in the US, AU, BR, CA, CN, EP, IL, JP, KR, MX, RU, and SG. The third patent application (Dinucleotides And Their Use In Treating Cancer) has been filed in the US and under the PCT (Patent Cooperation Treaty) and will undergo national phase filings in March 2026.

OUR PIPELINE

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



Our Therapeutic Strategy

Our goal is to be the leader in the discovery, development and commercialization of cancer telomere targeting agents and other similar small molecules. Our initial focus is to efficiently advance our clinical programs with ateganosine in sequential combination with a checkpoint inhibitor for the treatment of NSCLC. Ultimately, our goal would be to position ateganosine as a patient anticancer immunity priming treatment for all immune-activating agents used in the treatment of cancer. To date THIO-101 and THIO-104 are the only clinical trials testing ateganosine in combination with a checkpoint inhibitor. The key elements of our strategy are to:

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

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

Ateganosine Market Opportunity and Unmet Medical Need

Most cancer cells are telomerase positive (TERT+), including 57% to 100% of primary human cancers dependent upon tumor type, indicating a significant potential therapeutic utilization for ateganosine across most of the tumor types. We believe successful targeting of telomeres in TERT+ cancers may represent a significant potential for broad therapeutic utilization.

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

Sources: A Survey of Telomerase Activity in Human Cancer – JW Shay, S Bacchetti – European Journal of Cancer, 33,5,787-791, 1997. Telomerase Active in Human Liver Tissues; H Tahara, et al; Cancer Research 55, 2734-2736 1995; Highly /aggressive Metastatic Melanoma Cell Unable to Maintain Telomere Length; N Viceconte et al; Cell Reports 2017; Clinical Relevance of Telomerase Status and Telomerase Activity in Colorectal Cancer; T Femandez et al; PLOS one 2016; and Telomeres, Telomerase, and Cancer: Mechanisms, Biomarkers, and Therapeutics; Shou et al; Experimental Hematology & Oncology 14:8 2025.

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 ateganosine offers a desirable profile with significant commercial potential.

Tumor Type	Incidence 2022 (M)	5-Year Prevalence 2022 (M)	Mortality 2022 (M)	Annual Sales 2025 ($B)	Annual Sales 2029 ($B) (projected)
Non-Small Cell Lung Cancer	2.1	2.7	1.5	30.8	48.9
Breast	2.3	8.1	0.7	26.2	31.1
Prostate	1.5	5.0	0.4	16.1	22.5
Colorectal	1.9	5.7	0.9	17.1	20.3
Liver	0.9	1.1	0.8	3.1	5.5
Small Cell Lung Cancer	0.4	0.5	0.3	1.9	2.4

Sources: Global incidence, prevalence, mortality (Global Cancer Observatory / WHO); Global sales (Global Data; BioSpace).

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

Current Landscape of Checkpoint Inhibitor Franchises

Drug	Company	2024 Sales ($B)	Indications (tumor types)	NSCLC	SCLC	CRC	HCC
				Year of FDA Approval			
KEYTRUDA (pembrolizumab)	Merck	29.4	20	2015	2019	2017	2018
OPDIVO (nivolumab)	BMS / Ono	10.2	11	2015	2018	2017	2017
TECENTRIQ (atezolizumab)	Genentech / Roche	4.1	6	2016	2019		2020
IMFINZI (durvalumab)	AstraZeneca	4.7	5	2018	2020		2022
LIBTAYO (cemiplimab)	Regeneron	1.2	3	2021			
TEVIMBRA (tislelizumab)	BeOne Medicines	0.4	4	2024			
TYVYT (sintilimab)	Eli Lilly / Innovent	0.6	3				
BAVENCIO (avelumab)	Pfizer / Merck AG	0.6	3				
JEMPERLI (dostarlimab)	GSK	0.6	2				
TOTAL		51.8					

Source: BioMed Tracker 2025

Intellectual Property

Our global patent and patent-pending estate covers several areas. Telomerase mediated telomere altering compounds and treatment of therapy-resistant cancers. Further, ateganosine's immunogenic treatment strategy, which focuses on sequential combination with checkpoint inhibitors has been filed worldwide. With respect to ateganosine IP, we maintain three (3) issued US patents, nine (9) issued foreign patents and have four (4) pending US patent applications and eleven (11) pending foreign patent applications.

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

We file for patents, both directly and in collaboration with our licensing partners, in the United States with counterparts in certain countries in Europe and certain key market countries in the rest of the world, thereby covering the major pharmaceutical markets.

On December 8, 2020, we entered into an amended and restated agreement (of our prior November 29, 2018 agreement) with The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center (collectively, UTSW). Pursuant to the amended and restated agreement, which we refer to as the UTSW1 Agreement, we obtained (1) an exclusive, worldwide license to develop and commercialize the following patent families, which are generally directed to methods of using ateganosine and are owned and/or controlled by UTSW:

THIO (ateganosine) Intellectual Property
a.) US patent no. 10,463,685 entitled, Telomerase Mediated Telomere Altering Compounds issued in the US on November 5, 2019. The patent claims priority to U.S. application No.14/247,967. Related foreign patents based on PCT/US2014/033330 have also issued in the following foreign countries, CA, EPO (validated in AT, BE, CH, CZ, DE, ES, FR, GB, HU, IE, IS, IT, LI, LU, MC, NL, PL, PT), MX, NZ, and RU (all method of use). The application is pending in BR, and SG.
b.) 6-Thio-2'-Deoxyguanosine (6-Thio-dG) Results in Telomerase Dependent Telomere Dysfunction and Cell Death in Various Models of Therapy-Resistant Cancer Cells (Method of Use) / PCT/US2017/O34706 (WO2017/0205756), is issued in CA (patent No. 3035533), pending in the US, and EPO.
c) Use of 6-thio-dG to Treat Therapy-Resistant Telomerase positive Pediatric Brain Tumors / pending in the US (U.S. application No. 18/511,417) and has received a Notice of Allowance (method of use)
d) Treatment of Drug Resistant Proliferative Diseases with Telomerase Mediated Telomere Altering Compounds, (issued in the US as patent no.12,070,472) which was based on US application No.16/450,430. A continuation of application 16/450,430 is pending (US application No. 18,781,413).

and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW1 Agreement includes an exclusive license to US patent no. 10,463,685 (expires April 8, 2034), and US patent no. 12,070,472 (having an anticipated expiration of March 23, 2037), and patent application No. 18/511,417 (having an earliest expiration of March 22, 2039, if a patent is granted). All patents are method of use.

On December 23, 2020, we entered into a second agreement with UTSW, which granted the Company option rights in the UTSW1 Agreement and obtaining additional license rights. This second license with UTSW, which we refer to as the UTSW2 Agreement, we obtained (1) an exclusive, worldwide license to develop and commercialize the following UTSW patent family:

Sequential Treatment of Cancers Using 6-Thio-dG and Checkpoint Inhibitors
PCT/US2021/022090, issued in the RU, EP (validated in AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LI, LT, LU, MC, MK, MT, NL, NO, PL, PT, RO, SE, TR) (method of use), pending in AU, BR, CA, CN, IL, JP, KR, MX, and SG.

and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW2 Agreement includes an exclusive license to issued US patent no. 12,097,213 (having an earliest expiration of July 28, 2041, which includes 138 days of patent term adjustment). This patent is generally directed to methods of using ateganosine in combination with immune checkpoint inhibitors.

On July 13, 2022, MAIA Biotechnology filed PCT/US23/70177, US 18/352,220, and TW 112126229, Dinucleotides and their use in treating cancer, for Dinucleotide compounds that target telomers in cancer cells and method for using the dinucleotide compounds in treating cancers alone and in combination with other anticancer-agents and therapies, such as in combination with checkpoint inhibitors and radiation therapy. Pending in AU, BR, CA, CH, EPO, KR, MX, JP, US, and TW.

On May 30, 2023, MAIA Biotechnology filed PCT/US2024/031754, Tumor Redox-Activated 6-Thiopurine containing dimer compounds, for 6-thiopurine containing compounds that target telomers in cancer cells and methods for using the compounds in treating cancers alone and in combination with other anticancer agents and therapies. Pending in AU, BR, CA, CN, EPO, IL, KR, MX, RU, and SG.

On October 29, 2024, MAIA Biotechnology filed PCT/US2024/053473 and US application No. 18/930,974, entitled Telomere-Targeting Phosphatidyl-THIO Conjugates, for Telomere-targeting phosphatidyl-THIO conjugates that target telomers in cancer cells and methods for using the telomere-targeting phosphatidyl-THIO conjugates compounds to treat cancers. The applications are pending in the PCT and US.

On August 13, 2025, MAIA Biotechnology was granted a patent by the European Patent Office application No. 20155920.0, entitled Mercaptopurine Ribonucleoside Analogues for Altering Telomerase Mediated Telomere, covering a portfolio of ateganosine-based analogues for telomere targeting anticancer therapy and methods of using ateganosine alone or before administration of checkpoint inhibitors. The patent was granted and validated in AT, BE, BG, CH, CY, DE, DK, ES, FI, FR, GB, GR, HU, IE, IT, LI, LT, MK, MT, NL, NO, PL, PT, RO, SE, SI, and TR.

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 25 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 Scientific Officer, Sergei M. Gryaznov, is a Ph.D. who is an internationally recognized scientist and expert in the areas of modern drug discovery and development, oncology, telomerase, immune-regulatory therapeutics, nucleosides, nucleotides, DNA and RNA analogues, lipid and other conjugates, small molecules and nucleic acid based therapeutic agents. He is the co-inventor of a novel telomere-by-telomerase-targeting therapeutic approach to potential cancer treatment and responsible for leading the research team that characterized ateganosine's telomere targeting activity.

- Our Head of Finance and principal financial and accounting officer, Jeffrey Himmelreich, has extensive finance, accounting and public company reporting experience. Prior to his recent appointment, since September 2023, Mr. Himmelreich acted as the Company's Director of Accounting and Financial Reporting, where he provided oversight for the Company's filings with the U.S. Securities and Exchange Commission ("SEC") and other related financial, accounting or reporting matters. From July 2021 to September 2023, Mr. Himmelreich acted as the Chief Financial Officer of Microtech Knives, Inc., a private manufacturer of hand tools. Further, from December 2018 to July 2021, Mr. Himmelreich served as the Director of Finance and Accounting at Avadim Health Inc., a healthcare-related private company, during which time he assisted with SEC filings of Avadim Health Inc. for a proposed initial public offering. Mr. Himmelreich has a Bachelor of Science (B.S.) in Accounting from the Indiana University of Pennsylvania, and a Master of Business Administration from Pennsylvania State University.

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

1. 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

2. 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 ateganosine 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 ateganosine 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.

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

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

4. 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

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

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

6. Remus Vezan, M.D., Ph.D. – Vice President, Global Clinical Development at BeOne Medicines, formerly known as BeiGene

    - Completed his medical training (M.D. and Ph.D.) at the University of Medicine and Pharmacy Cluj, Romania and University of Bern, Switzerland
    - Seasoned leader in drug development of novel therapeutic modalities, including cell and gene therapies, with over 20 years of academic and biopharmaceutical industry experience, and had a seminal contribution to the development and approval of multiple products, including TECARTUS®, YESCARTA® or IMBRUVICA®
    - On our SAB, will assist in development and strategy for approval of ateganosine in multiple tumor types

7. Saadettin Kiliçkap, M.D., M.Sc – Faculty member at İstinye University Faculty of Medicine, Department of Internal Medicine, Türkiye

    - Graduated from Gazi University Faculty of Medicine, completed his Internal Medicine specialty training at Hacettepe University Faculty of Medicine. Completed the education programme of Medical Oncology at Hacettepe University Oncology Institute and the Cancer Epidemiology Thesis Master's Program at Hacettepe University Oncology Institute Preventive Oncology Department, granting him the title of "Master of Science"
    - Received more than 20 oral presentations or best work awards at national congresses, has more than 240 scientific articles published in international peer-reviewed journals and more than 50 papers presented at international congresses. He took part as principle or sub-investigator in more than 50 national and international multicenter phase 2 and phase 3 clinical studies
    - On our SAB, will assist in development and strategy for approval of ateganosine in multiple solid tumor types, including lung cancer, breast cancer, melanoma, and the gastrointestinal tract

8. David J. Pinato, MD, MRCP (UK) FRCPath, MRes, PhD – Director of Developmental Cancer Therapeutics at Imperial College in London (UK).

- David has led the inception of a portfolio of first-in-class studies of immune checkpoint inhibitors in liver cancer, which has represented David's focus of research since graduation with highest honors at the University of Piemonte Orientale "A. Avogadro" in Novara, Italy.
- David was a three-time recipient of a Merit Award from the American Society of Clinical Oncology (ASCO) in 2016, 2017, 2019 as well as a fourth Merit Award jointly awarded by ASCO and by the Society for Immunotherapy of Cancer (SITC) in 2019.
- On our SAB, will assist with developing ateganosine for the treatment of liver cancer

9. Claudia A.M. Fulgenzi, M.D. – Specialist in Medical Oncology at Imperial College in London (UK)

- Graduated in Medicine from the University of Rome Tor Vergata in 2017 and subsequently specialized in Medical Oncology at the University Campus Bio-Medico of Rome, Italy. During her training, Dr. Fulgenzi developed a strong interest in gastrointestinal cancers, particularly hepatobiliary malignancies.
- Her contributions to the field have been recognized with several prestigious awards, including the ASCO Merit Award and the Young Investigator Award from the International Liver Cancer Association (ILCA) in 2022, followed by another Merit Award from the American Society of Clinical Oncology in 2023.
- On our SAB, will assist with developing ateganosine for the treatment of liver cancer

Our SAB is primarily compensated by way of the grant of stock options as determined by the Company as appropriate in recognition of the specific services or areas of expertise of each member. We are also supported by a seasoned board of directors, whose members have significant entrepreneurial skills in company building and corporate financing as well as decades of collective leadership and board experience.

Our Programs

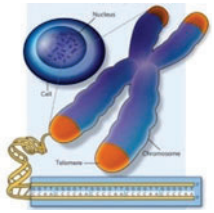
Telomere Targeting Program

Targeting Telomeres via Telomerase Leads to Cancer Cell Death

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

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

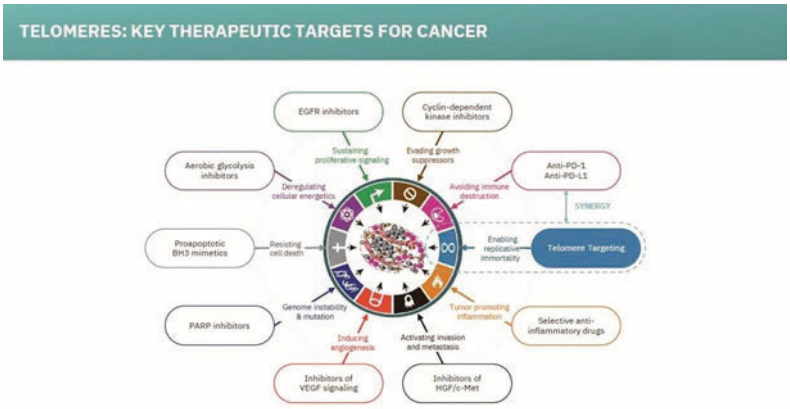
Adapted from Transcendental Meditation and lifestyle modification increase telomerase, December 6, 2015.



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

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

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



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

Role of the Enzyme Telomerase

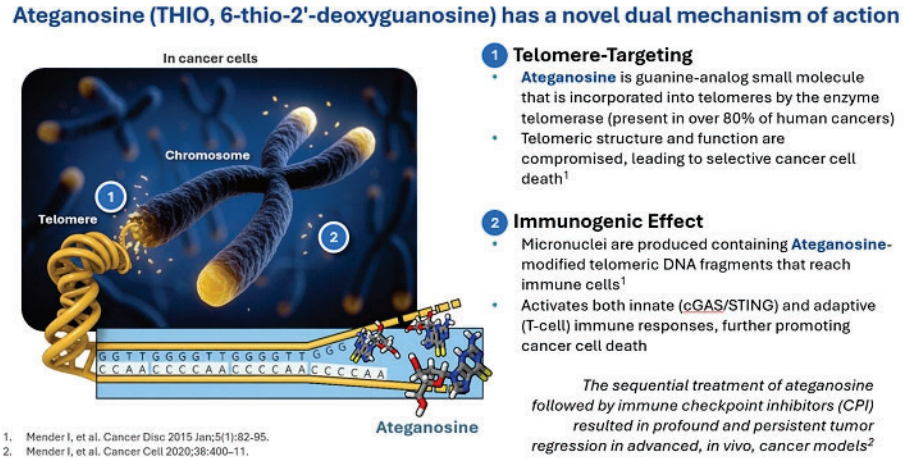
Telomerase is a ribonucleoprotein enzyme (reverse transcriptase) that synthesizes telomere repeats from the beginning, or de novo. In human cells, the telomerase holoenzyme consists of a high-molecular-weight complex with a template region-containing RNA subunit, hTR, and a protein component, the catalytic subunit human telomerase reverse transcriptase (hTERT). In most normal somatic cells, telomerase activity is absent and telomere repeats are lost with cell division and with aging. Telomerase is especially important in fetal tissues, reproductive cells and other tissues where extensive cell proliferation is necessary. However, most adult normal tissues are telomerase silent. Telomere attrition, beyond a certain threshold, results in the uncapping of chromosome ends, which subsequently induces DNA damage and onset of replicative senescence. In contrast, about 57% 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 Ateganosine, a Telomere-Targeting Agent

Ateganosine (THIO, 6-thio-2'-deoxyguanosine or 6-thio-dG) is a small molecule telomere targeting agent that uses the enzyme telomerase for DNA integration predominantly in the telomeric structure. Based on pre-clinical studies, ateganosine's telomere targeting activity is believed to be primarily cancer-specific in tumor cells with active telomerase, but not in normal cells. Based on our extensive review of publicly-available information, to our knowledge ateganosine's direct telomere targeting action utilizing telomerase is different from other commercially available cancer therapies and those currently in publicly disclosed clinical trials. Telomeres, along with the enzyme telomerase, play a fundamental role in the survival of cancer cells and their resistance to current therapies. The statements above are not intended to give any indication that ateganosine has been proven effective or that it will receive regulatory approval.

In non-clinical studies, published initially in 2014 along with subsequent studies, ateganosine was found to be converted, in cells, into the substrate recognized by telomerase, and then incorporated into telomeres of the cancer cells. Once incorporated, ateganosine 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, ateganosine showed a very prompt effect, causing telomere uncapping and leading to cancer cell death, independent of the initial tumor telomere length.



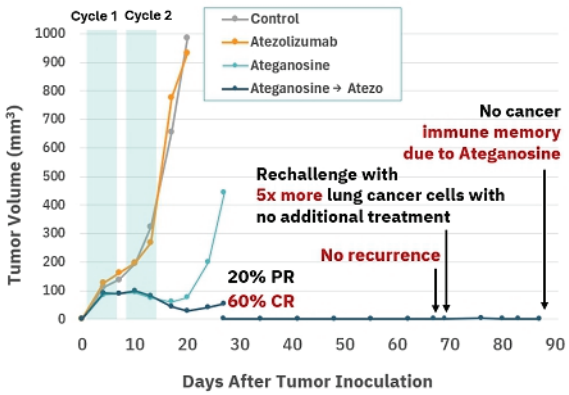
The above graphic represents an established method of action from previously conducted research in rodents that forms the scientific rationale for further clinical studies.

In 2019, further non-clinical research in syngeneic and humanized mouse models of telomerase-expressing cancers uncovered previously unknown telomere targeting activity of ateganosine specifically resulting from its breakdown of cancer cells. The ateganosine-containing DNA fragments, resulting from ateganosine 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, ateganosine 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 ateganosine 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 ateganosine-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 ateganosine 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 ateganosine, aimed to activate the immune system via ateganosine-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 ateganosine to induce immune memory, if confirmed in human clinical trials, would be a distinct feature of ateganosine'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 ateganosine as a telomere-targeted agent first, to activate the immune system against the specific cancer, followed by immunotherapy or other immune-activating therapy.



- In Non-Small Cell Lung Cancer (NSCLC), **Ateganosine (THIO)** followed by CPI results in 60% complete response
- Only 2 cycles of therapy were administered on weeks 1 and 2; no further therapy throughout the study
- No recurrence after long-term follow-up
- Anticancer immune memory has been induced: no cancer after rechallenge with 5x more lung cancer (LLC) cells with no additional therapy

Source: Mender et al, Cancer Cell, 2020; Ateganosine (THIO) followed by Tecentriq (atezolizumab; Roche/Genentech) tested first; repeated later with Ateganosine followed by Keytruda (pembrolizumab; Merck); and Libtayo (cemiplimab; Regeneron). Data from preclinical results.

Limitations of Other Therapeutic Approaches

In contrast to ateganosine, 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.

Ateganosine: A Telomere Targeting Agent

Background

Ateganosine (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, ateganosine was extensively investigated in at least 19 clinical trials with over 600 cancer patient subjects (adult and pediatric) treated, both as monotherapy or in combination with other commonly used standard agents of the time. See "Ateganosine Clinical Trials" below for more information about these trials. A traditional treatment strategy was used where patients were treated to maximum tolerated dose (MTD), a common approach for cancer therapy drug development. Although study results were promising, development was abandoned in favor of other therapies.

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

Further detailed analysis of the body of prior ateganosine 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. Ateganosine's detailed telomere targeting mechanism and resulting immune activation.

2. At high drug exposure (MTD), ateganosine can be immunosuppressive.

3. Proper administration of ateganosine to activate the immune system followed by immunotherapy to achieve best response.

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

Ateganosine is believed to selectively target telomerase positive (TERT+) cancer cells, where the enzyme is activated, versus normal cells. 57% to 100% of primary human cancers are TERT+ dependent upon tumor type, indicating a significant potential therapeutic utilization for ateganosine in almost all tumor types. Ateganosine's cancer-specific disturbance of telomeric structure by telomerase leads to disruption in the cell cycle, followed by rapid cell death. Based on extensive review of publicly-available information, ateganosine's direct telomere targeting action utilizing telomerase is different from other commercially available cancer therapies and those currently in publicly disclosed clinical trials.

In 2019, the MAIA research team showed that in mouse models ateganosine-produced telomere modification and disruption induced cancer-specific innate and adaptive immune response against immunologically "cold" or unresponsive tumor types. When ateganosine 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 ateganosine, administered in advance of immune-activating therapies (e.g., checkpoint inhibitors, radiation therapy, etc.), at dose levels significantly lower than the levels evaluated in previous clinical trials, will "prime" the tumor environment and initiate an overall anti-tumor immune response. This represents an entirely new therapeutic approach for ateganosine and forms the basis for the new clinical strategy for planned future trials.

Ateganosine Preclinical Development

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

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

In vitro: in summary, EC50 values (the concentrations at which half of the total number of cancer cells are dead) were approximately 0.4 μM to 1.5 μM. ateganosine was not cytotoxic in normal, untransformed telomerase-negative cells at concentrations up to 100 μM.

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

In March 2022, the FDA granted Orphan Drug Designation (ODD) to ateganosine for the treatment of HCC, in May 2022, the FDA granted the second ODD to ateganosine for the treatment of small cell lung cancer, and in late 2023, a third ODD for Malignant Gliomas Brain Cancer). The FDA's Office of Orphan Products Development may grant orphan designation status to drugs and biologics that are intended for the treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. ODD provides certain benefits, including financial incentives, to support clinical development and the potential for up to seven years of market exclusivity for the drug for the designated orphan indication in the U.S. if the drug is ultimately approved for its designated indication.

In December 2024, the FDA granted rare pediatric disease designation (RPDD) for ateganosine for the treatment of pediatric-type diffuse high-grade gliomas (PDHGG). Upon FDA approval of a future new drug application in PDHGG, MAIA would be eligible to receive a priority review voucher that can be redeemed or sold as an asset. Rare pediatric disease priority review vouchers (PRVs) can be redeemed by drug developers for FDA priority review of a different product or transferred or sold to another sponsor. Since 2015, FDA priority review vouchers have sold as assets at an average amount of $100 million.

In July 2025, the FDA granted fast track designation (FTD) for the treatment of NSCLC. Ateganosine is currently being evaluated in a pivotal Phase 2 THIO-101 clinical trial evaluating its anti-tumor activity when followed by a checkpoint inhibitor. The FDA Fast Track is a process designed to facilitate development and expedite the review of drugs for treating serious conditions and filling an unmet medical need, as in providing a therapy where none exists or which may be potentially better than available therapy. If relevant criteria are met during the Fast Track process, a drug will be eligible for FDA Accelerated Approval and Priority Review (FDA decision within six months).

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

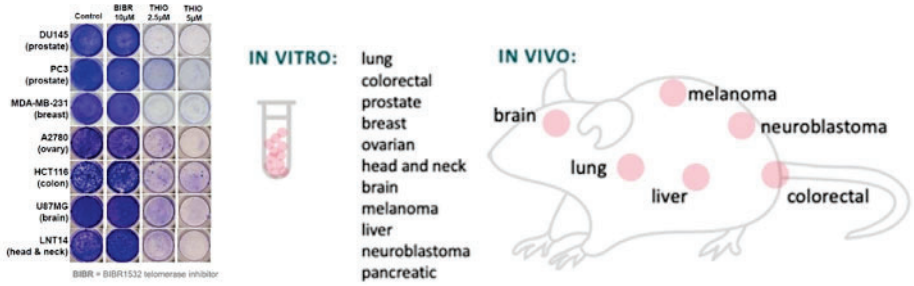
In vivo, ateganosine, at 3 mg/kg/dose, (which corresponds to a 20 mg/patient/day low-dose), administered followed by a one-day break, followed by an immune checkpoint inhibitor (either anti-programmed cell death protein 1 (PD-1) or anti-programmed death ligand 1 (PD-L1) products), resulted in complete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

At this low dose, ateganosine 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).

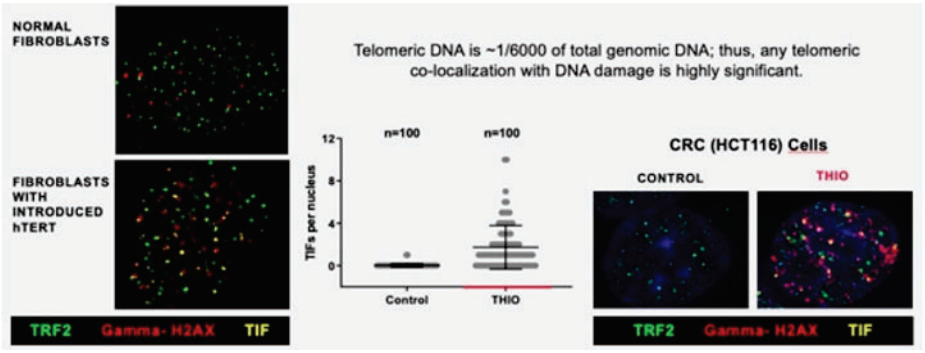
These responses were achieved through telomerase-dependent and cancer cell specific activation of a) DNA damage responses, and b) cGAS/STING pathways by ateganosine. This body of research represents the basis for the new immune-activation treatment strategy.

The following represents key highlights from ateganosine preclinical research:

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



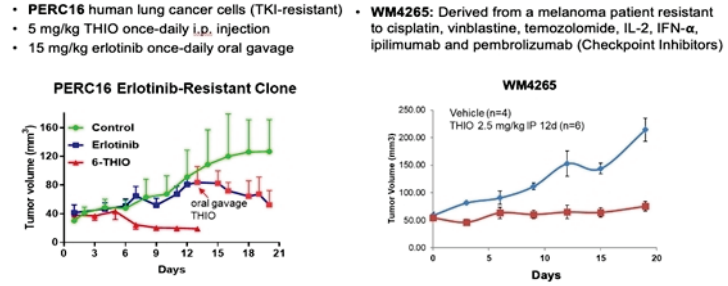
- Ateganosine demonstrated potential to selectively cause cancer cell death with active enzyme telomerase versus normal cells in vitro. The below graphic illustrates formation of telomeric damage foci (TIFs) in telomerase activity-positive cancer cells, but not in normal non-cancerous cells, resulting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



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

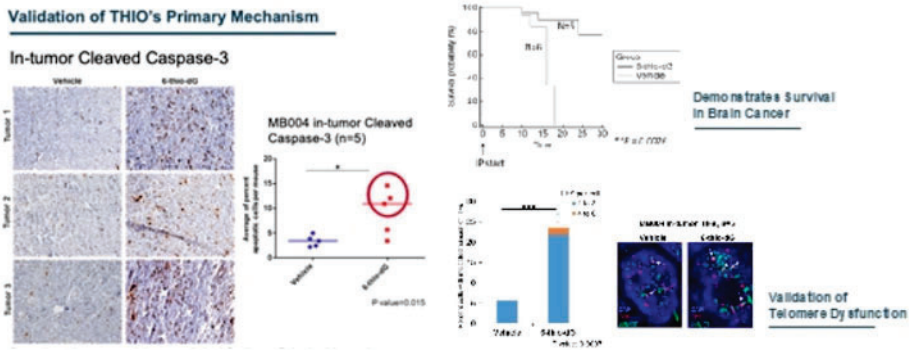
*TIF – telomere damages induced foci
*TRF2 – protein associated with telomeres
* Gamma-H2AX – protein associated with induction of DNA damage
*CRC – colorectal cancer
*hTERT – protein components of telomerase enzyme

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



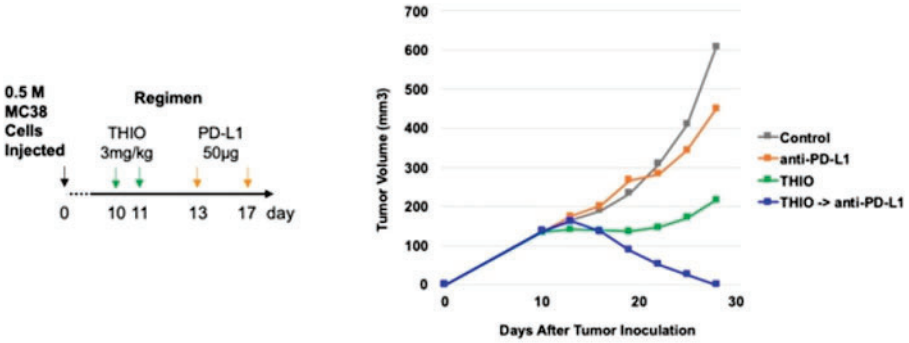
*i.p. – intraperitoneal injection
*IL-2 – cytokine interleukin 2
*IFN-a – interferon alfa

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

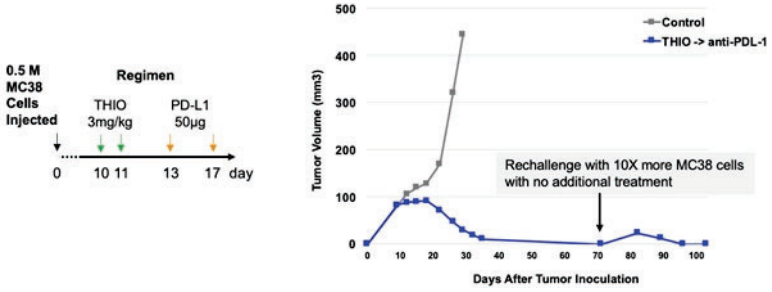


*TIF – telomere damage induced foci
*MB004 – brain cancer cell line

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



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



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

It is therefore hypothesized that ateganosine, administered in advance of immune-activating therapies (e.g., checkpoint inhibitors, radiation therapy, etc.), at dose levels significantly lower than the levels evaluated in previous clinical trials, will "prime" the tumor environment and initiate an overall anti-tumor immune response. If confirmed through additional clinical studies, this could represent an entirely new therapeutic approach for ateganosine and form the basis for the new clinical strategy for planned future trials.

Ateganosine (THIO) Clinical Trials

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

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

Phase 1

Study	Tumor Type	Regimen/Dose Schedule	Evaluable Subjects	Description of Observed Adverse Events	Responses
C76-92	Pediatric Acute Leukemia who received prior 6-mercaptopurine (6-MP) or 6-thioguanine	Ateganosine (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/m2given every 12 hours for 3 doses every 2 weeks	31	Reversible urate nephropathy, elevations of liver enzymes, nausea and vomiting, alopecia, and skin reactions	Therapeutic Responses observed in 6/23 (26%) patients comprised of 2 complete responses and 4 partial responses

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

Phase 2 – Single Agent Studies

Protocol	Tumor Type	Regimen/ Dose Schedule	Evaluable Subjects	ORR (Overall Response)	PR (Partial Response)	CR (Complete Response)	Observed Adverse Events
SEG-248	**Total Patients**		**117**	**27 (23%)**	**11 (9%)**	**16 (14%)**	Leukopenia Thrombocytopenia Skin rash Alopecia (reversible) Nausea and vomiting
	Acute Myelocytic Leukemia (AML)	300 mg/m2 daily for 5 days	17	4 (24%)	1 (6%)	3 (18%)	
		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)	Ateganosine (THIO) 100 mg/m2 daily for 5 days every 3 weeks vs MeCCNU 175 mg/m2 every 8 weeks	61	3 (5%)	3 (5%)	-	Leukopenia, thrombocytopenia, nausea and vomiting
			55	5 (9%)	5 (9%)	-	

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

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

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

To date, ateganosine has not received marketing approval in any country; therefore, there is no marketing experience to be reported.

The planned clinical trials will assess a novel ateganosine therapeutic strategy: - evaluate the safety and efficacy of low potentially immunogenic doses of ateganosine administered to activate the immune system against the tumor to be treated, followed by standard-of-care immunotherapy (checkpoint inhibitor) or other immune activating therapies.

Ateganosine Developmental Initiatives and Objectives

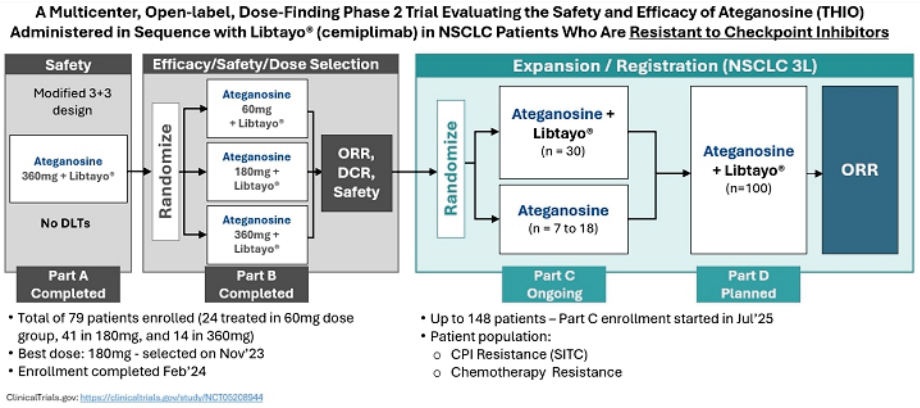
Phase 2 and 3 Programs

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

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

The trial design has two primary objectives: (1) safety of ateganosine administered as a priming immune system agent prior to cemiplimab administration and (2) clinical efficacy of ateganosine using Overall Response Rate (ORR) as the primary clinical endpoint. An expansion arm has been amended to the trial protocol on December 2024 to further assess the efficacy of ateganosine in combination with cemiplimab in third-line NSCLC patients who are resistant to chemotherapy and checkpoint inhibitors.

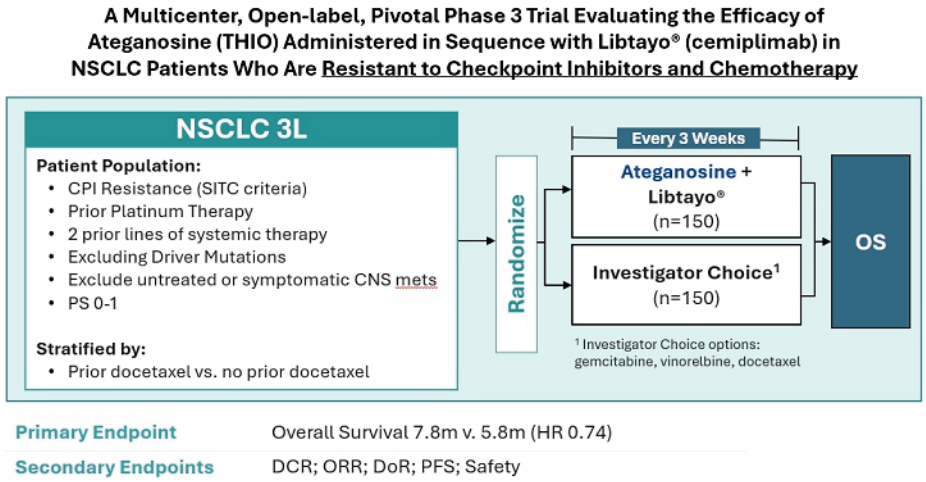
The following chart sets forth the design of the THIO-101 trial:



This Phase 2 “dose-finding” trial is designed to assess the safety, mechanism of activity, and immune system activation of three ateganosine doses tested out in separate arms administered in parallel. Each dosing arm will be further evaluated for efficacy based on Overall Response Rate (ORR), Duration of Response (DoR) and Progression Free Survival (PFS) to determine to optimal (safe and effective) dose of ateganosine administered in sequence with cemiplimab. Dose selection was completed in November 2023 and and enrollment was completed in February 2024, but monitoring and assessment of dosed subjects are ongoing as patients continue to with the postbaseline scans and data matures. In July 2025, an expansion of the THIO-101 trial was initiated focused on third-line NSCLC patients who are resistant to checkpoint inhibitors and chemotherapy. The expansion will enroll up to 48 patients with two arms: Arm 1, continuing the evaluation of ateganosine sequenced with Libtayo® (cemiplimab); and Arm 2, evaluating ateganosine as a monotherapy, to further gain experience of ateganosine in the contribution of components.

A Phase 3 pivotal trial, named THIO-104, initiated in 2025 to evaluate the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) in third-line NSCLC patients who are resistant to checkpoint inhibitors and chemotherapy. The multicenter, open-label, pivotal Phase 3 trial is designed to provide a direct comparison to chemotherapy in a 1:1 randomization of up to 300 patients.

The following chart sets forth the design of the THIO-104 trial:



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

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

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

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

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

Second Generation of Telomere Targeting Agents

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

Strategic Collaborations and Key Agreements

Through our licensing agreements with The University of Texas Southwestern Medical Center ("UTSW"), we have commercial rights to certain U.S. patents, as well as their foreign counterparts, for the use of ateganosine in treating telomerase-expressing lung and colon cancer cells. We are currently using this technology to study a treatment regimen comprising the use of ateganosine 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 ateganosine for additional cancer indications.

Clinical Supply Agreements

In 2021, we entered into a clinical supply agreement with Regeneron Pharmaceuticals, Inc. (Regeneron) to supply cemiplimab for the THIO-101 study. Regeneron will contribute the drug supply without cost, which represents a significant direct cost savings for our program. In exchange, Regeneron will receive development exclusivity for NSCLC indication during the study period, which means that MAIA cannot study ateganosine in NSCLC with any other PD-1 antagonist (a product sub-class of immune checkpoint inhibitors). All other tumor types remain open, and we are in discussions with other pharmaceutical companies to evaluate additional agreements that may be appropriate to support the expanded development of ateganosine. The supply agreement will remain in force until all of the obligations of the parties' related to the studies contemplated by the agreement are completed, or until terminated by either party. The agreement may be terminated in the event of unsafe use of cemiplimab, material breach, regulatory action or corruption. On December 3, 2024, we announced the amendment of the 2021 clinical supply agreement with Regeneron for the expansion portion of THIO-101, its Phase 2 clinical trial evaluating ateganosine in sequential administration with cemiplimab (Libtayo®). The new expansion will further assess the efficacy of MAIA's lead asset, ateganosine, sequenced with immune checkpoint inhibitor (CPI) Libtayo® (cemiplimab) for advanced non-small cell lung cancer (NSCLC) patients receiving third-line therapy who were resistant to previous checkpoint inhibitor treatments and chemotherapy. The original 2021 agreement between MAIA and Regeneron was designed to supply the original THIO-101 trial through the dose selection and safety evaluation process.

In January 2025, we announced a clinical supply agreement with BeOne Medicines, formerly known as BeiGene, Ltd (BeOne) to supply tislelizumab for the upcoming THIO-102 studies in HCC, CRC and SCLC.

In June 2025, we entered into a clinical master agreement with Roche for future studies investigating the combination of MAIA's telomere-targeting agent ateganosine (THIO), sequenced with Roche's checkpoint inhibitor (CPI), atezolizumab (Tecentriq®), for the treatment of multiple hard-to-treat cancers.

We are in discussions with other pharmaceutical companies to evaluate additional agreements that may be appropriate to support the expanded development of ateganosine. The supply agreement will remain in force until all of the obligations of the parties' related to the studies contemplated by the agreement are completed, or until terminated by either party. The agreement may be terminated in the event of unsafe use of tislelizumab, material breach, regulatory action or corruption.

In addition, our management believes that strong partnership interest will develop from other pharmaceutical companies who have checkpoint inhibitor franchises or those with cancer immunotherapy interest. We expect to continue discussions with several companies that have expressed interest and plan to expand discussions to capitalize on these opportunities. The checkpoint inhibitor market is large, and our goal is to ultimately position ateganosine as the foundational priming treatment to be used prior to all checkpoint inhibitors.

The University of Texas Southwestern Medical Center License Agreement 1

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

THIO (ateganosine) Intellectual Property
a.) US patent no. 10,463,685 entitled, Telomerase Mediated Telomere Altering Compounds issued in the US on November 5, 2019. The patent claims priority to U.S. application No.14/247,967. Related foreign patents based on PCT/US2014/033330 have also issued in the following foreign countries, CA, EPO (validated in AT, BE, CH, CZ, DE, ES, FR, GB, HU, IE, IS, IT, LI, LU, MC, NL, PL, PT), MX, NZ, and RU (all method of use). The application is pending in BR, and SG.
b.) 6-Thio-2'-Deoxyguanosine (6-Thio-dG) Results in Telomerase Dependent Telomere Dysfunction and Cell Death in Various Models of Therapy-Resistant Cancer Cells (Method of Use) /
PCT/US2017/034706 (WO2017/0205756) filed on 26 May 2017, is issued in CA (patent No. 3035533), and the EPO (Patent No. validated in AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB,GR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, and TR and pending in the US (serial no. 18/329,381), and EPO (application No. 17803670.3).
c.) Use of 6-thio-dG to Treat Therapy-Resistant Telomerase positive Pediatric Brain Tumors /
pending in the US (U.S. application No. 18/511,417) which has received a Notice of Allowance (method of use).
d.) Treatment of Drug-Resistant Proliferative Diseases with Telomerase Mediated Telomere Altering Compounds), issued in the US as patent no.12,070,472) which was based on US application No.16/450,430. A continuation of application 16/450,430 is pending (US application No. 18,781,413).

Under the UTSW1 Agreement, we agreed to pay UTSW a minimal license fee, deferred license fees, milestone fees, and running royalties beginning on the first net sale (among others). For additional details regarding our relationship with UTSW, see the section entitled "Business — Intellectual Property —License Agreement 1 with The Board of Regents of The University of Texas System / The University of Texas Southwestern Medical Center." The UTSW1 Agreement includes an exclusive license to US patent no. 10,463,685 (expires April 8, 2034), and US patent no. 12,070,472 (having an earliest expiration of March 23, 2037), and 16,982,979 (having an earliest expiration of March 22, 2039, if a patent is granted).

The University of Texas Southwestern Medical Center License Agreement 2

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

Sequential Treatment of Cancers Using 6-Thio-dG and Checkpoint Inhibitors (Method of Use)
PCT/US2021/022090, issued in the RU, EP (validated in AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LI, LT, LU, MC, MK, MT, NL, NO, PL, PT, RO, SE, TR), pending in AU, BR, CA, CN, IL, JP (received notice of allowance), KR, MX, and SG.

and (2) a non-exclusive worldwide license to develop and commercialize related technology rights. The UTSW2 Agreement includes an exclusive license to issued US patent no. 12,097,213 (having an earliest expiration of July 28, 2041, which includes 138 days of patent term adjustment). This patent is directed to methods of using ateganosine in combination with immune checkpoint inhibitors.

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

Ateganosine (THIO) Program

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

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

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

Title / PCT Application Number
a.) Telomerase Mediated Telomere Altering Compounds / PCT/US2014/33330 (WO2014/168947), issued in the US (patent no. 10,463,685), CA, MX, NZ and RU (all method of use) pending in BR, EPO (received an Intent to Grant), HK and SG.
b.) 6-Thio-2'-Deoxyguanosine (6-Thio-dG) Results in Telomerase Dependent Telomere Dysfunction and Cell Death in Various Models of Therapy-Resistant Cancer Cells / PCT/US2017/34706 (WO2017/205756), pending in the US (method of use), CA, and EPO.
c.) Use of 6-thio-dG to Treat Therapy-Resistant Telomerase positive Pediatric Brain Tumors /PCT/US2019/023596 (WO2019/183482), pending in the US (method of use)
d.) Treatment of Drug Resistant Proliferative Diseases with Telomerase Mediated Telomere Altering Compounds / PCT/US2017/023858 (WO/2017/165675), issued in the US (patent no. 12,070,472) (method of use).

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

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

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

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

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

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

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

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

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

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

The UTSW1 Agreement contains a representation that UTSW has the rights and authority to grant to Company the licensed rights and is to its knowledge unaware of any third-party infringer or any infringement of third-party intellectual property rights. The UTSW1

Agreement also requires the Company to indemnify UTSW and other related parties against any liabilities, damages, causes of action, suits, judgments, liens, penalties, fines, losses, costs and expenses arising out of any product the Company produces under the UTSW1 Agreement, and requires the Company, beginning with the earlier of the first clinical trial or commercial sale or other commercialization, to obtain liability insurance.

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

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

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

On December 23, 2020 (the "Effective Date"), we entered into a second agreement with The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center, (collectively, UTSW), which set forth the agreement between the parties pursuant to the Company exercising its option rights in the UTSW1 Agreement and obtaining additional license rights ("the UTSW2 Agreement"). The license is exclusive as to worldwide Patent Rights for all uses in the Field, which is defined as all therapeutic, prophylactic and diagnostic fields of use for all indications, including discovery and development uses. The license is sublicensable with prior UTSW written approval consistent with the terms of UTSW2 Agreement.

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

Sequential Treatment of Cancers Using 6-Thio-dG and Checkpoint
Sequential Treatment of Cancers Using 6-Thio-dG and Checkpoint Inhibitors / PCT/US2021/022090, issued in the EPO, and RU (method of use), pending in AU, BR, CA, CN, IL,JP (has received Notice of Allowance), KR, MX, and SG.

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

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

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

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

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

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

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

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

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

Competition

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

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

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

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

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any pharmaceutical candidate that we develop must be approved by the United States Food and Drug Administration, or FDA, before it may be legally marketed in the United States and by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

United States Government Regulation

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

Approval Processes

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

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

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

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

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

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

Clinical trials involve the administration of the drug or biological candidate to healthy volunteers or patients having the disease being studied under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed.

Human clinical trials prior to approval are typically conducted in three sequential Phases that may overlap or be combined:

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

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

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

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

U.S. Review and Approval Processes

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

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

After the NDA or BLA submission is accepted for filing, the FDA reviews the application to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. In addition to its own review, the FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the approval process, the FDA also will determine whether special marketing conditions or restrictions under a risk evaluation and mitigation strategy, or REMS, are necessary to assure the safe use of the drug or biologic. If the FDA concludes that a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required.

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

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

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

Companion Diagnostics

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

As stated in its Guidance, the FDA may decide that it is appropriate to approve such a product without an approved or cleared in vitro companion diagnostic device when the drug or therapeutic biologic is intended to treat a serious or life-threatening condition for which no satisfactory alternative treatment exists and the FDA determines that the benefits from the use of a product with an unapproved or uncleared in vitro companion diagnostic device are so pronounced as to outweigh the risks from the lack of an approved or cleared in vitro companion diagnostic device. The FDA encourages sponsors considering developing a therapeutic product that requires a companion diagnostic to request a meeting with both relevant device and therapeutic product review divisions to ensure that the product development plan will produce sufficient data to establish the safety and effectiveness of both the therapeutic product and the companion diagnostic. To date, no product targeting TERT+ cancer patients has been approved by FDA, and the applicability to ateganosine 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 ateganosine, the cost and length of time to fully develop and receive approval (if at all) of ateganosine may both be increased, as described in more detail in the section Risk Factors – Risks Relating to Government Regulation. Because the FDA's policy on companion diagnostics is set forth only in guidance, this policy is subject to change and is not legally binding.

Expedited Development and Review Programs

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

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

The Hatch-Waxman Amendments and Generic Competition

Orange Book Listing

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

Patent Term Extensions

Depending upon the timing, duration and specifics of FDA approval of the use of our therapeutic candidates, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product or therapeutic candidate's approval date. The patent term restoration period is generally one half of the time between the effective date of an IND and the submission date of a NDA, plus the time between the submission date of a NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product or therapeutic candidate is eligible for the extension and the application for extension must be made prior to expiration of the patent. The United States Patent and Trademark Office (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.

Abbreviated New Drug Application (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 Federal Food, Drug, and Cosmetic Act (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 thirty 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 ten 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. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

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

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

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

Coverage, Pricing and Reimbursement

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

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

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

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product and therapeutic candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product and therapeutic candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product and therapeutic candidates. For example, in the United States, the system for FDA to collect and expend user fees paid by manufacturers of drugs, biologics, and medical devices must be reauthorized by statute every five years, and since 1992, each reauthorization legislation has included, to greater or lesser degrees, various other changes to the FDA's regulatory systems and procedures. The current legislative authority for FDA user fees expired in September 2022, new legislation will be required for FDA to continue collecting prescription drug user fees in future fiscal years. The 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 effected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation.

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

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

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

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

Other Healthcare Laws

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

- The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, prohibit, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Actions under these laws may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices;
- The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, includes federal, civil and criminal provisions that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

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

Manufacturing

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

Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's current good manufacturing practices, or cGMP, regulations. cGMP regulations require, among other things, quality control and quality assurance as well as corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented.

Regulations - Environmental

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

Digital Asset Treasury Strategy

On October 7, 2025, we announced our launch of a new digital asset treasury strategy focused on top-tier cryptocurrency assets. On October 6, 2025, our Board of Directors authorized holdings of up to 90% of the Company's liquid assets in various cryptocurrencies. Corporate officers are authorized to purchase and sell Bitcoin (BTC), Ethereum (ETH), and USD Coin (USDC) initially. Management will regularly consult with the Board on cryptocurrency transactions and holdings, cybersecurity procedures, accounting policies, risks, and material developments. Due to cryptocurrency volatility, the Company's digital asset strategy is currently on hold. As of the date of this report, the Company holds approximately $0 in digital assets.

Employees

As of December 31, 2025, we had a total of 13 full-time employees which includes one employee employed by our Romanian subsidiary. We believe that we maintain a satisfactory working relationship with our employees, and we have not experienced any significant labor disputes or any difficulty in recruiting staff for our operations. None of our employees are represented by a labor union.

Human Capital Resources

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

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

Our Corporate Information

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

Implications of Being an Emerging Growth Company

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

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

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

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933 (the "Securities Act") for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We intend to take advantage of the benefits of this extended transition period.

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

Implications of Being a Smaller Reporting Company

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

Item 1A. Risk Factors.

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

Summary Risk Factors

- We have incurred losses since our inception and anticipate that we will continue to incur increasing losses for the foreseeable future.
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of ateganosine.
- 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 ateganosine, 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 ateganosine 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 ateganosine, if approved, may be smaller than we anticipate.
- Development of ateganosine 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 ateganosine.
- If we are unable to obtain FDA approval for our IND application for the planned ateganosine Phase 2 trial, our clinical development of ateganosine may be significantly delayed and our business may be substantially harmed.
- Even if we obtain FDA approval for ateganosine or any other candidates in the United States, we may never obtain approval for or commercialize ateganosine 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 ateganosine and any other candidate we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies.
- Even if ateganosine 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 ateganosine, 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 ateganosine and intend to rely on CMOs for the production of commercial supply of ateganosine, if approved. Our dependence on CMOs may impair the development and commercialization of the drug, which would adversely impact our business and financial position.
- We intend to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.
- We depend on license agreements with the University of Texas Southwestern, or UTSW, to permit us to use patents and patent applications, as well as to exploit specific technological know-how. Termination of these rights or the failure to comply with obligations under these agreements could materially harm our business and prevent us from developing or commercializing our product candidates.

- We have been granted licenses of use to patent applications. There can be no assurance that any of the patent applications that we have licenses to will result in issued patents. As a result, our ability to protect our proprietary technology in the marketplace may be limited.
- Our patents may be challenged in courts or in patent offices which could result in the invalidation, narrowing or unenforceability of our patents and our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.
- Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Intellectual property rights do not address all potential threats to our competitive advantage.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.
- If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.
- We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.
- We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- The launch of central bank digital currencies ("CBDCs") may adversely impact our business.
- Absent federal regulations, there is a possibility that any digital asset we acquire may be classified as a "security." Any classification of any digital asset we acquire as a "security" would subject us to additional regulation and could materially impact the operation of our business.
- If we were deemed to be an investment company under the 1940 Act, applicable restrictions likely would make it impractical for us to continue segments of our business as currently contemplated.
- We may be subject to regulatory developments related to crypto assets and crypto asset markets, which could adversely affect our business, financial condition, and results of operations.
- We are not subject to legal and regulatory obligations that apply to investment companies such as mutual funds and exchange-traded funds, or to obligations applicable to investment advisers.
- We have limited history in generating staking revenues from digital assets, which could adversely affect our business, financial condition and operating results.
  Competition from other companies staking and utilizing digital assets in their treasury plan
- The price of our common stock may be volatile and you could lose all or part of your investment.
- We do not intend to pay dividends for the foreseeable future, and our ability to pay dividends to our stockholders is restricted by applicable laws and regulations.
- We may, in the future, issue additional capital stock, which would reduce investors' percent of ownership and may dilute our share value.
- Our failure to meet the continued listing requirements of NYSE American could result in a delisting of our common stock.
- Our failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, financial condition, and results of operations.
- The limited public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U.S. securities laws, which could have a materially adverse effect on our business.
- Our shares of common stock are currently listed on NYSE American. If we are unable to maintain listing of our securities on NYSE American or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a clinical stage biopharmaceutical company with a limited operating history and have incurred losses since our formation. We incurred net losses of $22,396,172 and $23,254,656 for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $109,631,005. 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 ateganosine 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:

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

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of ateganosine and launch and commercialize ateganosine, if we receive regulatory approval. We will require additional capital for the further development and potential commercialization of ateganosine and may also need to raise additional funds sooner to pursue a more accelerated development of ateganosine. 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. 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 ateganosine or any other future candidates;
- clinical development plans we establish for ateganosine and any other future candidates;
- obligation to make royalty and non-royalty sublicense receipt payments to third-party licensors, if any, under our licensing agreements;
- number and characteristics of candidates that we discover or in-license and develop;
- outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- effects of competing technological and market developments;
- costs and timing of the implementation of commercial-scale manufacturing activities; and
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

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

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

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

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

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

We were incorporated in Delaware and began our operations in August 2018. Our operations to date have been limited to financing and staffing our company, licensing candidates, conducting preclinical studies, manufacturing clinical supply, and preparing for and executing clinical studies of ateganosine. 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 Trials, Manufacturing and Regulatory Approval

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

We do not have any products that have gained regulatory approval. Currently, our lead clinical stage candidate is ateganosine. 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 ateganosine in a timely manner. We cannot commercialize ateganosine in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize ateganosine outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of ateganosine 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 ateganosine 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 ateganosine 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 ateganosine 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 ateganosine, 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 ateganosine, we may not be able to earn sufficient revenue to continue our business.

Pandemics, such as COVID-19, may adversely impact our business, results of operations, financial condition, liquidity and cash flows and that of our clients.

The COVID-19 pandemic and efforts to control its spread had an impact on our operations. For example, one of our initial clinical studies is taking place in Australia, which previously imposed one of the strictest COVID-19-related measures, including lock-downs, and may do so again in the future. Pandemics, such as COVID-19, may have a material economic effect on our business because our research and development may be affected as a result of delays in study monitoring and data analysis; some participants and clinical investigators may not be able to comply with clinical trial protocols; any quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, resulting in our inability to conduct our research activities, including our clinical trials; and infections and deaths related to a pandemic may disrupt the United States' healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay FDA review and/or approval of our product candidates. While the potential economic impact brought by such pandemics may be difficult to assess or predict, it has caused, and may result in further significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from a health pandemic could materially and adversely affect our business and the value of our common stock.

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, ateganosine 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 ateganosine 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 or similar pandemics. 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 ateganosine 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 ateganosine or any other candidates. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval of a NDA from the FDA. Our ability to obtain approval by the FDA or other regulatory authorities can be adversely impacted for various reasons including:

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

Prior to obtaining approval to commercialize a candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The 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 ateganosine achieves its intended effects and does not exhibit unacceptable safety risks, we plan to seek filing for accelerated approval of ateganosine based on positive results of the expanded Phase 2 THIO-101 trial in 2026, followed by full approval based on the results of a single phase 3 clinical study, as opposed to the traditional approach of conducting two or more phase 3 studies. Even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA. A single-study approach is permissible in certain circumstances, particularly in oncology, but such circumstances are exceptional and FDA may not agree with that proposed approach, and thus we may be required to conduct two phase 3 trials.

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

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

Of the large number of drugs that enter clinical development, only a small percentage successfully complete the regulatory approval processes and are approved and commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market ateganosine 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; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion

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 ateganosine 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 ateganosine 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. ateganosine 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 ateganosine 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 ateganosine, if approved, may be smaller than we anticipate.

We expect to initially seek approval for ateganosine 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 ateganosine 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 ateganosine.

Ateganosine 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 ateganosine 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 ateganosine would take longer, be more expensive, and could become impractical.

Even if we obtain FDA approval for ateganosine or any other candidates in the United States, we may never obtain approval for or commercialize ateganosine 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 ateganosine 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 ateganosine 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 ateganosine or one or more of our other candidates. Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). For purposes of Breakthrough Therapy designation, clinically significant endpoint generally refers to an endpoint that measures an effect on irreversible morbidity or mortality (IMM) or on symptoms that represent serious consequences of the disease. A clinically significant endpoint can also refer to findings that suggest an effect on IMM or serious symptoms. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for fast track designation (under a separate request), priority review, or accelerated approval, if supported by clinical data at the time the NDA is submitted to the FDA. FDA encourages a Breakthrough Therapy designation request to be submitted, and received by FDA, no later than the end-of-phase-2 meetings. Even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA.

Designation as a Breakthrough Therapy is within the discretion of the FDA both at the time of the submission of such a request, and during FDA's review of the drug and supporting data. Even if we believe that one of our candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation or may grant such a designation and subsequently rescind the designation prior to approval. Even if we receive and maintain Breakthrough Therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of ateganosine 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 ateganosine 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 ateganosine 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 ateganosine. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ateganosine, 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 ateganosine 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 ateganosine 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 ateganosine. 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 ateganosine. 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 ateganosine 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 ateganosine, 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 ateganosine, but such exclusivity is only determined by the FDA after a drug is approved and the FDA may determine that ateganosine is not eligible for NCE Exclusivity, or that approval of ateganosine 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 ateganosine 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 ateganosine 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 ateganosine, 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 ateganosine 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 ateganosine 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 ateganosine, if approved.

We do not have any infrastructure for the sales, marketing or distribution of ateganosine, 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 ateganosine, 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 ateganosine 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 ateganosine, 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 ateganosine, 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 ateganosine 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 ateganosine at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to it or otherwise agree to terms unfavorable to us. Any of these occurrences may have an adverse effect on our business, operating results and prospects.

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

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

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

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;

- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- the expansion of the Russian military invasion of Ukraine;
- the expansion of the Israel and Hamas conflict;
- 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 ateganosine and intend to rely on CMOs for the production of commercial supply of ateganosine, 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 ateganosine 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 ateganosine drug substance to enable us to complete our clinical trials, and we have also engaged a CMO to provide clinical and commercial supply of the drug product.

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

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

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

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

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

We rely, and will continue to rely, on CROs, CRO-contracted vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including our Phase 2 and Phase 3 trials of ateganosine. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards.

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

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

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

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

If any collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed, and we may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of any collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all.

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

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

Risks Related to Healthcare Laws and Other Legal Compliance Matters

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

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

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

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

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

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

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

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

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

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

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

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, or FCA, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. A claim includes "any request or demand" for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

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

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

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

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

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

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

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

While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going-forward basis. We intend to work with our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of a patent covering each product candidate under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a non-expired patent which claims a human drug product, a method of using the product, or a method of manufacturing the product, as compensation for effective patent term lost during product development and the FDA regulatory review process. Moreover, only one patent may be extended covering the drug product and the total patent term including the extension cannot exceed 14 years following regulatory approval. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

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

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

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

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

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

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

- others may be able to make products that are similar to ateganosine 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 ateganosine and any future product candidates, and we expect to collaborate with third parties on the development of ateganosine 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 ateganosine or our future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize ateganosine 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 ateganosine.

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 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 ateganosine or any other product candidate could be delayed.

Risks Relating to Investing in Digital Securities

The launch of central bank digital currencies ("CBDCs") may adversely impact our business.

The introduction of a government-issued digital currency could eliminate or reduce the need or demand for private-sector issued crypto currencies, or significantly limit their utility. National governments around the world could introduce CBDCs, which could in turn limit the size of the market opportunity for cryptocurrencies, including Solana.

Absent federal regulations, there is a possibility that any digital asset we acquire may be classified as a "security." Any classification of any digital asset we acquire as a "security" would subject us to additional regulation and could materially impact the operation of our business.

We intend to only acquire digital assets that we believe would not be considered a "security" by the SEC and other U.S. federal or state regulator publicly stated may not agree our assessment. Despite the Trump Administration's Executive Order titled "Strengthening American Leadership in Digital Financial Technology" which includes as an objective, "protecting and promoting the ability of individual citizens and private sector entities alike to access and … to maintain self-custody of digital assets," leading digital assets that we intend to acquire, such as Solana, have not yet been classified with respect to U.S. federal securities laws. Therefore, while (for the reasons discussed below) we intend to only invest in leading digital assets, that we conclude are not a "security" within the meaning of the U.S. federal securities laws, and registration of the Company under The Investment Company Act of 1940, as amended (the "1940 Act") is therefore not required under the applicable securities laws, we acknowledge that a regulatory body or federal court may determine otherwise. Our conclusion, even if reasonable under the circumstances, would not preclude legal or regulatory action based on such a finding that any leading digital asset we acquire, such as Solana, is a "security" which would require us to register as an investment company under the 1940 Act.

We intend to adapt our process for analyzing the U.S. federal securities law status of any cryptocurrencies we acquire over time, as guidance and case law have evolved. As part of our U.S. federal securities law analytical process, we intend to take into account a number of factors, including the various definitions of "security" under U.S. federal securities laws and federal court decisions interpreting the elements of these definitions, such as the U.S. Supreme Court's decisions in the *Howey* and *Reves* cases, as well as court rulings, reports, orders, press releases, public statements, and speeches by the SEC Commissioners and SEC Staff providing guidance on when a digital asset or a transaction to which a digital asset may relate may be a security for purposes of U.S. federal securities laws.

Application of securities laws to the specific facts and circumstances of digital assets is complex and subject to change. As such, we are at risk of enforcement proceedings against us, which could result in potential injunctions, cease-and-desist orders, fines, and penalties if any digital asset we acquires is determined to be a security by a regulatory body or a court. Such developments could subject us to fines, penalties, and other damages, and adversely affect our business, results of operations, financial condition, and prospects.

If we were deemed to be an investment company under the 1940 Act, applicable restrictions likely would make it impractical for us to continue segments of our business as currently contemplated.

Under Sections 3(a)(1)(A) and (C) of the 1940 Act, a company generally will be deemed to be an "investment company" if (i) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities or (ii) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding, or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, and cash items) on an unconsolidated basis. Rule 3a-1 under the 1940 Act generally provides that notwithstanding the Section 3(a)(1)(C) test described in clause (ii) above, an entity will not be deemed to be an "investment company" for purposes of the 1940 Act if no more than 45% of the value of its assets (exclusive of U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, and cash items) consists of, and no more than 45% of its net income after taxes (for the past four fiscal quarters combined) is derived from, securities other than U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, securities issued by employees' securities companies, securities issued by qualifying majority owned subsidiaries of such entity, and securities issued by qualifying companies that are controlled primarily by such entity. We do not believe that we are an "investment company" as such term is defined in either Section 3(a)(1)(A) or Section 3(a)(1)(C) of the 1940 Act.

Since our formation, we have been a biopharmaceutical industry with a focus is on developing targeted immunotherapies for cancer. Recently, we have begun focusing on pursuing opportunities to expand our portfolio into digital assets. We only intend to acquire digital assets that we conclude are investment securities, and as such do not intend to hold ourselves out as being engaged primarily, or propose to engage primarily, in the business of investing, reinvesting, or trading in securities within the meaning of Section 3(a)(1)(A) of the 1940 Act.

With respect to Section 3(a)(1)(C), we believe we satisfy the elements of Rule 3a-1 and therefore are deemed not to be an investment company under, and we intend to conduct our operations such that we will not be deemed an investment company under, Section 3(a)(1)(C). We believe that we are not an investment company pursuant to Rule 3a-1 under the 1940 Act because, on a consolidated basis with respect to wholly-owned subsidiaries but otherwise on an unconsolidated basis, no more than 45% of the value of the Company's total assets (exclusive of U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, and cash items) consists of, and no more than 45% of the Company's net income after taxes (for the last four fiscal quarters combined) is derived from, securities other than U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, securities issued by employees' securities companies, securities issued by qualifying majority owned subsidiaries of the Company, and securities issued by qualifying companies that are controlled primarily by the Company.

Digital assets, as well as new business models and transactions enabled by blockchain technologies, present novel interpretive questions under the 1940 Act. There is a risk that assets or arrangements that we conclude are not securities prior to acquisition could be deemed to be securities by the SEC or another authority for purposes of the 1940 Act, which would increase the percentage of securities held by us for 1940 Act purposes. The SEC has requested information from a number of participants in the digital assets ecosystem, regarding the potential application of the 1940 Act to their businesses. For example, in an action unrelated to the Company, in February 2022, the SEC issued a cease-and-desist order under the 1940 Act to BlockFi Lending LLC, in which the SEC alleged that BlockFi was operating as an unregistered investment company because it issued securities and also held more than 40% of its total assets, excluding cash, in investment securities, including the loans of digital assets made by BlockFi to institutional borrowers.

If we were deemed to be an investment company, Rule 3a-2 under the 1940 Act is a safe harbor that provides a one year grace period for transient investment companies that have a bona fide intent to be engaged primarily, as soon as is reasonably possible (in any event by the termination of such one year period), in a business other than that of investing, reinvesting, owning, holding, or trading in securities, with such intent evidenced by the company's business activities and an appropriate resolution of its board of directors. The grace period is available not more than once every three years and runs from the earlier of (i) the date on which the issuer owns securities and/or cash having a value exceeding 50% of the issuer's total assets on either a consolidated or unconsolidated basis or (ii) the date on which the issuer owns or proposes to acquire investment securities having a value exceeding 40% of the value of such issuer's total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis. Accordingly, the grace period may not be available at the time that we seek to rely on Rule 3a-2; however, Rule 3a-2 is a safe harbor and we may rely on any exemption or exclusion from investment company status available to us under the 1940 Act at any given time. Furthermore, reliance on Rule 3a-2, Section 3(a)(1)(C), or Rule 3a-1 could require us to take actions to dispose of securities, limit our ability to make certain investments or enter into joint ventures, or otherwise limit or change our service offerings and operations. If we were to be deemed an investment company in the future, restrictions imposed by the 1940 Act—including limitations on our ability to issue different classes of stock and equity compensation to directors, officers, and employees and restrictions on management, operations, and transactions with affiliated persons—likely would make it impractical for us to continue our business as contemplated, and could have a material adverse effect on our business, results of operations, financial condition, and prospects.

We may be subject to regulatory developments related to crypto assets and crypto asset markets, which could adversely affect our business, financial condition, and results of operations.

As digital assets are relatively novel and the application of state and federal securities laws and other laws and regulations to digital assets is unclear in certain respects, it is possible that regulators in the United States or foreign countries may interpret or apply existing laws and regulations in a manner that adversely affects the price any digital assets we may hold in the future. The U.S. federal government, states, regulatory agencies, and foreign countries may also enact new laws and regulations, or pursue regulatory, legislative, enforcement or judicial actions, that could materially impact the price of any digital assets we acquire in the future or the ability of individuals or institutions to own or transfer digital assets.

If any digital asset we acquire is determined to constitute a security for purposes of the federal securities laws, the additional regulatory restrictions imposed by such a determination could adversely affect the market price of such digital security and in turn adversely affect the market price of our common stock. Moreover, the risks of us engaging in a cryptocurrency treasury strategy have created, and could continue to create complications due to the lack of experience that third parties have with companies engaging in such a strategy, such as increased costs of director and officer liability insurance or the potential inability to obtain such coverage on acceptable terms in the future.

Cryptocurrency assets are less liquid than our existing cash and cash equivalents and may not be able to serve as a source of liquidity for us to the same extent as cash and cash equivalents.

Historically, the crypto markets have been characterized by: significant volatility in price, limited liquidity and trading volumes compared to sovereign currencies markets; relative anonymity; a developing regulatory landscape; potential susceptibility to market abuse and manipulation; compliance and internal control failures at exchanges; and various other risks inherent in its entirely electronic, virtual form and decentralized network. During times of market instability, we may not be able to sell any digital assets we hold at favorable prices or at all. Further, any digital assets which we hold with our custodians will not enjoy the same protections as are available to cash or securities deposited with or transacted by institutions subject to regulation by the Federal Deposit Insurance Corporation or the Securities Investor Protection Corporation. If we are unable to sell any digital assets we hold, enter into additional capital raising transactions using any digital assets we hold as collateral, or otherwise generate funds using any digital assets we hold, or if we are forced to sell any digital assets we hold at a significant loss, in order to meet our working capital requirements, our business and financial condition could be negatively impacted.

We are not subject to legal and regulatory obligations that apply to investment companies such as mutual funds and exchange-traded funds, or to obligations applicable to investment advisers.

Mutual funds, exchange-traded funds and their directors and management are subject to extensive regulation as "investment companies" and "investment advisers" under U.S. federal and state law; this regulation is intended for the benefit and protection of investors. We are not subject to, and do not otherwise voluntarily comply with, these laws and regulations. This means, among other things, that the execution of or changes to our Treasury Reserve Policy or our cryptocurrency strategy, our use of leverage, the manner in which our cryptocurrency assets are custodied, our ability to engage in transactions with affiliated parties and our operating and investment activities generally are not subject to the extensive legal and regulatory requirements and prohibitions that apply to investment companies and investment advisers. Consequently, our board of directors has broad discretion over the investment, leverage and cash management policies it authorizes, in respect of any activities we may pursue, and has the power to change our current policies, including our strategy of acquiring and holding digital assets.

If we or our third-party service providers experience a security breach or cyberattack and unauthorized parties obtain access to any of our acquired digital assets, or if our private keys are lost or destroyed, or other similar circumstances or events occur, we may lose some or all of our digital assets and our financial condition and results of operations could be materially adversely affected.

We expect that any digital asset we own will be held in custody accounts at U.S.-based institutional-grade digital asset custodians. Security breaches and cyberattacks are of particular concern with respect to digital assets. Cryptocurrencies and the entities that provide services to participants in such ecosystem have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities. For example, in October 2021 it was reported that hackers exploited a flaw in the account recovery process and stole from the accounts of at least 6,000 customers of the Coinbase exchange, although the flaw was subsequently fixed and Coinbase reimbursed affected customers. Similarly, in November 2022, hackers exploited weaknesses in the security architecture of the FTX Trading digital asset exchange and reportedly stole over $400 million in digital assets from customers. A successful security breach or cyberattack could result in:

- a partial or total loss of our digital assets in a manner that may not be covered by insurance or the liability provisions of the custody agreements with the custodians who hold our Solana;
- harm to our reputation and brand;
- improper disclosure of data and violations of applicable data privacy and other laws; or
- significant regulatory scrutiny, investigations, fines, penalties, and other legal, regulatory, contractual and financial exposure.

Further, any actual or perceived data security breach or cybersecurity attack directed at other companies with digital assets or companies that operate digital asset networks, regardless of whether we are directly impacted, could lead to a general loss of confidence in the broader cryptocurrency ecosystem, which could negatively impact us.

Attacks upon systems across a variety of industries, including cryptocurrency industries, are increasing in frequency, persistence, and sophistication, and, in many cases, are being conducted by sophisticated, well-funded and organized groups and individuals, including state actors. The techniques used to obtain unauthorized, improper or illegal access to systems and information (including personal data and digital assets), disable or degrade services, or sabotage systems are constantly evolving, may be difficult to detect quickly, and often are not recognized or detected until after they have been launched against a target. These attacks may occur on our systems or those of our third-party service providers or partners. We may experience breaches of our security measures due to human error, malfeasance, insider threats, system errors or vulnerabilities or other irregularities. In particular, we expect that unauthorized parties will attempt to gain access to our systems and facilities, as well as those of our partners and third-party service providers, through various means, such as hacking, social engineering, phishing and fraud. Threats can come from a variety of sources, including criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage, and insiders. In addition, certain types of attacks could harm us even if our systems are left undisturbed. For example, certain threats are designed to remain dormant or undetectable, sometimes for extended periods of time, or until launched against a target and we may not be able to implement adequate preventative measures. Further, there has been an increase in such activities due to the increase in work-from-home arrangements. The risk of cyberattacks could also be increased by cyberwarfare in connection with the ongoing Russia-Ukraine and Israel-Hamas conflicts, or other future conflicts, including potential proliferation of malware into systems unrelated to such conflicts. Any future breach of our operations or those of others in the cryptocurrency industry, including third-party services on which we rely, could materially and adversely affect our financial condition and results of operations.

We have limited history in generating staking revenues from digital assets, which could adversely affect our business, financial condition and operating results.

Until recently, our business focus was in the biopharmaceutical industry with a focus is on developing targeted immunotherapies for cancer.

We have recently shifted the focus of our operations to include a treasury policy under which our resources will be allocated to digital assets.

We have a limited operating history with the current scale of our business, which makes it difficult to forecast our prospects and future results of operations. You should take into account the risks and uncertainties frequently encountered by companies in rapidly evolving markets. If our assumptions regarding the risks and uncertainties of the cryptocurrency market, which we use to plan our business, are incorrect or change, or if we do not address these risks successfully, our business would be harmed.

Competition from other companies staking and utilizing digital assets in their treasury plans.

We expect to contend with other companies also focused on developing digital asset staking operations. Market participants with sufficient knowledge and capital has the ability acquire tokens on the open market and start staking, which would increase competition.

We may fail to develop and execute successful investment or trading strategies.

The success of our investment and trading activities will depend on the ability of our investment team to identify overvalued and undervalued investment opportunities and to exploit price discrepancies. This process involves a high degree of uncertainty. No assurance can be given that we will be able to identify suitable or profitable investment opportunities in which to deploy our capital. The success of any trading activities will depend on our ability to remain competitive with other over-the-counter traders and liquidity providers. Competition in trading is based on price, offerings, level of service, technology, relationships and market intelligence. The success of investment activities depends on our ability to source deals and obtain favorable terms. Competition in investment activities is based on relationships. The barrier to entry in each of these businesses is very low and competitors can easily and will likely provide similar services in the near future. The success of our venture investments and trading business could suffer if we are not able to remain competitive.

We may make, or otherwise be subject to, trade errors.

Errors may occur with respect to any trades executed on our behalf. Trade errors can result from a variety of situations, including, for example, when the wrong investment is purchased or sold or when the wrong quantity is purchased or sold. Trade errors frequently result in losses, which could be material. To the extent that an error is caused by a third party, we may seek to recover any losses associated with the error, although there may be contractual limitations on any third party's liability with respect to such error.

Risks Relating to Our Common Stock

If we are unable to comply with the continued listing requirements of the NYSE American, then our Common Stock would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our Common Stock and subject us to additional trading restrictions.

Our Common Stock is currently listed on the NYSE American and the continued listing of our Common Stock on the NYSE American is contingent on our continued compliance with a number of listing requirements. If we are unable to comply with the continued listing requirements of the NYSE American, our Common Stock would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our Common Stock and subject us to additional trading restrictions. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders' equity and a minimum number of public stockholders, as well as satisfy other listing requirements of the NYSE American. In addition to these objective standards, NYSE American may delist the securities of any issuer for other reasons involving the judgment of NYSE American.

Section 1003(a)(i) of the NYSE American Company Guide requires a listed company to have stockholders' equity of $50 million if the listed company has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. Our stockholders' equity was approximately $2 million as of December 31, 2025, and we had losses from continuing operations and/or net losses in each of our fiscal years ended December 31, 2021, 2022, 2023, 2024 and 2025. However, we are in compliance with NYSE American listing standards as we currently satisfy the alternate compliance standards provided in Section 1003(a) which provide that the NYSE American will not normally consider suspending dealings in, or removing from the list, the securities of an issuer which is below any stockholders' equity requirement described above if the issuer is in compliance with the following of the NYSE American Company Guide since: (i) total value of our market capitalization is at least $50,000,000 or total assets and revenue of $50,000,000 each in its last fiscal year, or in two of its last three fiscal years; and (ii) the issuer has at least 1,100,000 shares publicly held, a market value of publicly held shares of at least $15,000,000 and 400 round lot shareholders. There is no assurance that we will be able to regain or maintain compliance with the NYSE American continued listing standards and/or continue our listing on the NYSE American in the future.

If the NYSE American delists our Common Stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect the Common Stock would qualify to be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- substantially impair our ability to raise additional funds;
- the loss of institutional investor interest and a decreased ability to issue additional securities or obtain additional financing in the future;
- a determination that our Common Stock is a "penny stock," which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- potential breaches of representations or covenants of our agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements, which, regardless of merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

Our shares of common stock are thinly traded, and the price may not reflect our value; there can be no assurance that there will be an active market for our shares now or in the future.

We have a trading symbol for our common stock ("MAIA") and our common stock is currently listed on the NYSE American.

Our shares of common stock are thinly traded, and as such the price, if traded, may not reflect our value. There can be no assurance that there will be an active market for our shares of common stock either now or in the future. The market liquidity will be dependent on, among other things, the perception of our operating business and any steps that our management might take to bring us to the awareness of investors. There can be no assurance given that there will be any awareness generated or, if given, that it will be positive.

Consequently, investors may not be able to liquidate their investment or may be able to liquidate it only at a price that does not reflect the value of the business. If a more active market should develop, the price may be highly volatile. Due to the possibility of our common stock being priced lower than its actual value, many brokerage firms may not be willing to effect transactions in the securities. Even if an investor finds a broker willing to effect a transaction in the shares of our common stock, the combination of brokerage commissions, transfer fees, taxes, if any, and any other selling costs may exceed the selling price.

The price of our common stock may be volatile.

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

- market conditions in the broader stock market;
- actual or anticipated variations in our quarterly results of operations;
- developments in our industry in general;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- adverse results or delays in clinical trials;
- failure to commercialize our product candidates;

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

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

We could be subject to securities class action litigation.

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

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

At the time of this date of this Annual Report on Form 10-K, we have 1,752,945 shares of Common Stock issuable upon exercise of options outstanding under the MAIA Biotechnology, Inc. 2018 Stock Option Plan (the "MAIA 2018 Plan") with a weighted-average exercise price of $1.80 per share; 3,503,589 shares of Common Stock issuable upon exercise of options outstanding under the MAIA Biotechnology, Inc. Amended and Restated 2020 Equity Incentive Plan (the "MAIA 2020 Plan") with a weighted-average exercise price of $2.49 per share; 7,663,631 shares of Common Stock issuable upon exercise of options outstanding under our 2021 Equity Incentive Plan (the "MAIA 2021 Plan") with a weighted-average exercise price of $2.14 per share; 367,890 shares of Common Stock reserved for future issuance under the MAIA 2021 Plan and 13,086,220 shares issuable upon the exercise of warrants to purchase shares of common stock at a weighted average exercise price of $1.92 per share. In addition, we have $5,519,076 of common stock available for sale our At-the-Market Offering Agreement dated March 22, 2025 with H.C. Wainwright and Co. 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, 13,572,866 are restricted securities within the meaning of Rule 144 under the Securities Act and subject to certain restrictions on resale. Restricted securities may be sold in the public market only if they are registered under the Securities Act, or are sold pursuant to an exemption from registration such as Rule 144 or Rule 701.

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

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law. Pursuant to our amended and restated bylaws and the DGCL, our directors will not be liable to the Company or any stockholders for damages for any breach of fiduciary duty, except (i) acts that breach his or her duty of loyalty to the Company or its stockholders; (ii) acts or omissions without good faith or involving intentional misconduct or knowing violation of the law; (iii) pursuant to Section 174 of the DGCL regarding director liability for unlawful payment of a dividend or unlawful stock purchase or redemption; or (iv) for any transaction from which the director derived an improper personal benefit. In addition, we have entered into indemnification agreements with each of our executive officers and directors. The indemnification agreements provide the executive officers and directors with contractual rights to indemnification, expense advancement and reimbursement, to the fullest extent permitted under the DGCL. The bylaws also require us, if so requested, to advance expenses that such director or officer incurred in defending or investigating a threatened or pending action, suit or proceeding, provided that such person will return any such advance if it is ultimately determined that such person is not entitled to indemnification by us. Any claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

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

We have the right to raise additional capital or incur borrowings from third parties to finance our business. The issuance of additional equity securities, whether pursuant to that certain At-the-Market ("ATM") Offering Agreement dated February 14, 2024 with H.C. Wainwright & Co., LLC pursuant to each of which we may also sell an amount of shares of common stock that does not exceed the number or dollar amount of shares of common stock that would cause the Company or the offering of the Shares to not satisfy the eligibility and transaction requirements for use of Form S-3, including, if applicable, General Instruction I.B.6 of Registration Statement on Form S-3, as more fully described elsewhere in this Annual Report on Form 10-K or otherwise, will dilute the holdings of existing stockholders and may reduce the share price of our common stock. We may also implement public or private mergers, business combinations, business acquisitions and similar transactions pursuant to which it would issue substantial additional capital stock to outside parties, causing substantial dilution in the ownership of the Company by our existing stockholders. Our Board of Directors has the authority, without the consent of any of the stockholders, to cause us to issue more shares of common stock and/or preferred stock at such price and on such terms and conditions as are determined by the Board of Directors in its sole discretion. The issuance of additional shares of capital stock by us will dilute your ownership percentage in the Company and could impair our ability to raise capital in the future through the sale of equity securities.

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

Our directors and executive officers own as of March 23, 2026, an aggregate of 5,042,557 shares of our common stock, which constitutes 8.6% of our issued and outstanding common stock. As a result, our directors and executive officers may have a significant influence on our affairs and management, as well as on all matters requiring stockholder approval, including electing and removing members of our Board of Directors, causing us to engage in transactions with affiliated entities, causing or restricting our sale or merger, and certain other matters. Such concentration of ownership and control could have the effect of delaying, deferring or preventing a change in control of us even when such a change of control would be in the best interests of our stockholders.

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

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

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

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

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

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

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

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

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

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

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

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

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

General Risk Factors

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

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

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

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

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Our auditors will also need to attest to the effectiveness of our internal control over financial reporting upon losing our Emerging Growth Company status and becoming an accelerated filer or a large accelerated filer. If we are unable to assert that our internal control over financial reporting is effective in the future or 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.

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.

Unstable global market and economic conditions may have serious adverse consequences on our business, financial condition and results of operations.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the Russia-Ukraine conflict and the conflict between U.S., Israel and Iran have created extreme volatility in the global capital markets and may continue to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of geopolitical unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 10-K.

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We believe cybersecurity is critical to advancing our technological advancements. As a biopharmaceutical company, we face a multitude of cybersecurity threats that range from attacks common to most industries, such as ransomware and denial-of service. Our customers, suppliers, subcontractors, and business partners face similar cybersecurity threats, and a cybersecurity incident impacting us or any of these entities could materially adversely affect our operations, performance, and results of operations. These cybersecurity threats and related risks make it imperative that we expend resources on cybersecurity.

Our Board of Directors oversees management's processes for identifying and mitigating risks, including cybersecurity risks, to help align our risk exposure with our strategic objectives. Senior leadership, including our cybersecurity consultant, regularly briefs the Board of Directors on our cybersecurity and information security posture and the Board of Directors is apprised of cybersecurity incidents deemed to have a moderate or higher business impact, even if immaterial to us. The full Board retains oversight of cybersecurity because of its importance. In the event of an incident, we intend to follow our detailed incident response playbook, which outlines the steps to be followed from incident detection to mitigation, recovery, and notification, including notifying functional areas (e.g., legal), as well as senior leadership and the Board, as appropriate. Our Cybersecurity consultant has extensive information technology and program management experience. We have implemented a governance structure and processes to assess, identify, manage, and report cybersecurity risks.

As a biopharmaceutical company, we must comply with extensive regulations, including requirements imposed by the Federal Drug Administration related to adequately safeguarding patient information and reporting cybersecurity incidents to the SEC. We work with our cybersecurity consultant on assessing cybersecurity risk and on policies and practices aimed at mitigating these risks. We believe we are positioned to meet the requirements of the SEC. In addition to following SEC guidance and implementing pre-existing third party frameworks, we have developed our own practices and frameworks, which we believe enhance our ability to identify and manage cybersecurity risks. Third parties also play a role in our cybersecurity. We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, or consulting on best practices to address new challenges. Assessing, identifying, and managing cybersecurity related risks are factored into our overall business approach.

We rely heavily on our supply chain to deliver our products and services, and a cybersecurity incident at a supplier, subcontractor or business partner could materially adversely impact us. We require that our subcontractors report cybersecurity incidents to us so that we can assess the impact of the incident on us. Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. While we maintain cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be fully insured. See “Risk Factors” for a discussion of cybersecurity risks.

Item 2. Properties.

Our headquarters is in Chicago, Illinois where we currently lease office space with approximately 124 square feet under a twelve month lease starting in April 2025, under which we currently pay $3,325 per month. We believe that this space is sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms. Additionally, we intend to maintain our business model designed to leverage virtual technology to minimize brick and mortar facilities while optimizing our ability to attract top talented employees that may reside in any geography.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable

PART II

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

Market Information and Holders

Our common stock is traded on NYSE American under the symbol "MAIA". As of March 23, 2026, 60,671,491 shares of the Company's common stock were issued and outstanding and were owned by approximately 171 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Dividend Policy

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

Recent Sales of Unregistered Securities

On November 13, 2025, we issued 7,951 restricted shares of common stock to Prevail InfoWorks, Inc. in consideration of research and development services rendered having a value of $14,550. We did not receive any proceeds from the issuance of these shares.

On November 14, 2025, we issued 32,211 restricted shares of common stock to FGMK, LLC in consideration of accounting and consulting services rendered having a value of $33,500. We did not receive any proceeds from the issuance of these shares.

On December 3, 2025, we issued 301,608 restricted shares of common stock to HitGen, Inc. in consideration of research and development services rendered having a value of $277,480. We did not receive any proceeds from the issuance of these shares.

On December 5, 2025, we issued 16,724 restricted shares of common stock to Prevail InfoWorks, Inc. in consideration of research and development services rendered having a value of $29,101. We did not receive any proceeds from the issuance of these shares.

On January 12, 2026, the Company issued 8,362 shares of common stock having a value of $14,550.36 (based on $1.74 price using the calculated by using 120% of the dollar value weighted average price of our common stock on the New York Stock Exchange for the thirty (30) trading days immediately preceding the date of the purchase payment or the minimum share price of $1.74) to a service provider under a master services agreement in consideration of services rendered.

On February 20, 2026, the Company issued 5,449 shares of common stock having a value of $14,550.36 (based on $2.67 price using the calculated by using 120% of the dollar value weighted average price of our common stock on the New York Stock Exchange for the thirty (30) trading days immediately preceding the date of the purchase payment or the minimum share price of $1.74) to a service provider under a master services agreement in consideration of services rendered.

On March 12, 2026, the Company issued 6,037 shares of common stock having a value of $14,550.36 (based on $2.41 price using the calculated by using 120% of the dollar value weighted average price of our common stock on the New York Stock Exchange for the thirty (30) trading days immediately preceding the date of the purchase payment or the minimum share price of $1.74) to a service provider under a master services agreement in consideration of services rendered.

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

Issuers Purchases of Equity Securities

None.

Item 6. [Reserved]

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

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

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 236,000 new cases in the US in 2022, representing 12.3% of all cancers, and over 130,000 deaths, or 21.4% 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. Ateganosine (THIO, 6-thio-dG or 6-thio-2 '-deoxyguanosine), our lead asset, is an investigational dual mechanism of action drug candidate incorporating telomere targeting and immunogenicity.

We are a clinical-stage biopharmaceutical company developing targeted immunotherapies for cancer. Ateganosine (THIO, 6-thio-dG or 6-thio-2 '-deoxyguanosine), our lead asset, is an investigational dual mechanism of action drug candidate incorporating telomere targeting and immunogenicity. In July 2022, the first patient was administered with ateganosine in our Phase 2 human trial (THIO-101) in Australia. In December 2022, regulatory authorities in three European countries, Hungary, Poland, and Bulgaria, approved the implementation of THIO-101, Phase 2 clinical trial evaluating ateganosine in patients with Non-Small Cell Lung Cancer (NSCLC). In the trial, patients with advanced NSCLC are treated first with ateganosine followed a few days later by the immune checkpoint inhibitor Libtayo® (cemiplimab), manufactured and commercialized by Regeneron. Cemiplimab is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 on T-cells. Cemiplimab has been approved in the United States and the rest of the world for multiple cancer indications, including NSCLC. In February 2021, we signed a clinical supply agreement with Regeneron to receive cemiplimab at no cost, which represents a significant cost-savings for the study. In return, we have granted Regeneron exclusive development rights in combination with PD-1 inhibitors for NSCLC for the study period. In July 2025, we initiated an expansion of the THIO-101 trial focused on third-line NSCLC patients who are resistant to checkpoint inhibitors and chemotherapy. The expansion will enroll up to 48 patients with two arms: Arm 1, continuing the evaluation of ateganosine sequenced with Libtayo® (cemiplimab); and Arm 2, evaluating ateganosine as a monotherapy, to further gain experience of ateganosine in the contribution of components. Based on the clinical data generated by our THIO-101 trial, we plan to seek filing for an accelerated approval of ateganosine in the United States for the treatment of patients with advanced NSCLC in 2026, but even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the Food and Drug Administration (FDA).We initiated a Phase 3 pivotal trial in 2025, named THIO-104, to evaluate the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) in third-line NSCLC patients who are resistant to checkpoint inhibitors and chemotherapy. The multicenter, open-label, pivotal Phase 3 trial is designed to provide a direct comparison to chemotherapy in a 1:1 randomization of up to 300 patients. In addition, the originally planned Phase 2 clinical trial in multiple tumor indications (THIO-102) is now divided into different trials for one tumor indication each: hepatocellular carcinoma (HCC), colorectal cancer (CRC) and small cell lung cancer (SCLC). Phase 2 clinical trials in HCC, CRC and SCLC are planned to be initiated in 2026, evaluating treatment with ateganosine administered in sequence with BeOne's immune checkpoint inhibitor, tislelizumab. Clinical trials with other solid tumors (ST), such as breast, prostate, gastric, pancreatic and ovarian, may still be considered for potential future trials.

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

We accomplished the following key milestones in the fiscal year ended December 31, 2025 and the first quarter of 2026:

- On January 7, 2025, we announced that we had entered into a clinical supply agreement with global oncology company BeiGene to assess the efficacy of ateganosine, its small molecule telomere-targeting anticancer agent, in combination with BeiGene's immune checkpoint inhibitor (CPI) tislelizumab in three cancer indications. The single arm pivotal Phase 2 trials will study the drug combination in hepatocellular carcinoma (HCC), small cell lung cancer (SCLC) and colorectal cancer (CRC). Under the terms of the collaboration, MAIA will sponsor and fund the planned clinical trials and BeiGene will provide tislelizumab. MAIA maintains global development and commercial rights to ateganosine and is free to develop the programs in combination with other agents and in other indications. Since May 2025, BeiGene has changed its company name to BeOne Medicines.

- On February 4, 2025, we announced positive updated data from THIO-101 Phase 2 clinical trial evaluating its lead clinical candidate, ateganosine, sequenced with Regeneron's immune checkpoint inhibitor (CPI) cemiplimab (Libtayo®) in patients with advanced non-small cell lung cancer (NSCLC) who failed two or more standard-of-care therapy regimens. As of January 15, 2025, third line (3L) data updates showed that: (i) median overall survival (OS) of 16.9 months for the 22 NSCLC patients who received at least one dose of ateganosine (the intent-to-treat population) in parts A and B of the trial. (ii) The analysis demonstrated a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months. (iii) The treatment has been generally well-tolerated to date in this heavily pre-treated population.

- On February 24, 2025, we issued and sold 1,810,000 shares of our common stock and warrants to purchase 1,810,000 shares of our common stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated February 18, 2025 at a price per share of $1.50 for which we received gross proceeds of approximately $2.72 million. The warrants issued in the private placement have an exercise price of $1.87, are exercisable one year after issuance and expire five years after the initial exercise date. The securities sold to our directors participating in the private placement were issued pursuant to our 2021 Equity Incentive Plan.

- On February 26, 2025, we announced the trial design for the expansion of its THIO-101 pivotal Phase 2 trial in non-small cell lung cancer (NSCLC). The expansion of the study will assess overall response rates (ORR) in advanced NSCLC patients receiving third line (3L) therapy who were resistant to previous checkpoint inhibitor treatments (CPI) and chemotherapy. The THIO-101 study in 3L will enroll up to 48 patients with two arms: Arm 1, continuing the evaluation of ateganosine sequenced with Libtayo® (cemiplimab); and Arm 2, evaluating ateganosine as a monotherapy, to further gain experience of ateganosine in the contribution of components. Treatment cycles for patients in both arms will administer ateganosine on 3 consecutive days, followed by immune activation on day 4. Arm 1 will administer Libtayo on day 5. The Company plans to enroll an additional 100 patients for the registration phase of the trial. MAIA expects to conduct the trials in the U.S. and select countries in Europe and Asia.

- On February 27, 2025, we announced plans to initiate a Phase 3 pivotal trial in 2025, named THIO-104, to evaluate the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) in third-line non-small cell lung cancer (NSCLC) patients who are resistant to checkpoint inhibitors and chemotherapy. The multicenter, open-label, pivotal Phase 3 trial is designed to provide a direct comparison to chemotherapy in a 1:1 randomization of up to 300 patients.

- On March 3, 2025, we issued and sold 952,300 shares of our common stock and warrants to purchase 952,300 shares of our common stock in a non-brokered private placement to accredited investors and certain Company directors pursuant to securities purchase agreements dated February 24, 2025 at a price per share of $1.50 for which we received gross proceeds of approximately $1.43 million, prior to offering expenses payable by the Company. The warrants issued in the private placement have an exercise price of $1.85, are exercisable one year after issuance and expire five years after the initial exercise date. The securities sold to our directors participating in the private placement were issued pursuant to our 2021 Equity Incentive Plan.

- On March 18, 2025, MAIA announced that the United States Adopted Names (USAN) Council had approved “ateganosine” as the nonproprietary (generic) name for its lead molecule THIO, a telomere-targeting anticancer agent in clinical development as a first-in-class treatment for advanced non-small cell lung cancer (NSCLC). The company chose a name inspired by the mechanism of action of THIO: altering telomeric guanosine of the cancer cells. The generic name ateganosine is a unique and consistent identity that aims to support clear communication between healthcare providers, patients and researchers. MAIA will retain the name ateganosine in its clinical trial designations (THIO-101, THIO-102, THIO-103, THIO-104).

- On March 20, 2025, we announced the publication of preclinical data for its lead proprietary telomere-targeting ateganosine dimer in the peer-reviewed scientific journal Naunyn-Schmiedeberg’s Archives of Pharmacology. In a preclinical study, ateganosine and its new described dimer form were found to be potent inhibitors of Glutathione S-transferase Pi (GSTP1), a key enzyme implicated in cancer progression and chemoresistance and a highly important factor for the detoxification of cancer cells. The findings suggest that the dimerized form of ateganosine could enhance chemotherapeutic efficacy by effectively targeting GSTP1 and reducing drug resistance. The article, titled “Investigation of the inhibitory effects of the telomere-targeted compounds on glutathione S-transferase P1,” was published on February 15, 2025.

- On May 8, 2025, we issued and sold 719,999 shares of our common stock and warrants to purchase 719,999 shares of our common stock in a non-brokered private placement to accredited investors and certain Company directors pursuant to securities purchase agreements dated May 5, 2025 at a price per share of $1.50 for which we received gross proceeds of approximately $1.08 million, prior to offering expenses payable by the Company. The warrants issued in the private placement have an exercise price of $2.05, are exercisable one year following issuance and have a term of six years from the issuance date The securities being sold to the Company directors participating in the offering are being issued pursuant to the Company’s 2021 Equity Incentive Plan.

- On June 3, 2025, we issued and sold 463,332 shares of our common stock and warrants to purchase 463,332 shares of our common stock in a non-brokered private placement to accredited investors and a Company director pursuant to securities purchase agreements dated May 27, 2025 at a price per share of $1.50 for which we received gross proceeds of approximately $0.7 million, prior to offering expenses payable by the Company. The warrants issued in the private placement have an exercise price of $1.71, are exercisable six months following issuance and have a term of five years from the issuance date The securities being sold to the Company director participating in the offering are being issued pursuant to the Company's 2021 Equity Incentive Plan.

- On June 5, 2025, we announced updated data from its THIO-101 pivotal Phase 2 clinical trial. As of May 15, 2025, third line (3L) data showed median overall survival (OS) of 17.8 months for the 22 NSCLC patients who received at least one dose of ateganosine (the intent-to-treat population) in parts A and B of the trial. The updated analysis continues to demonstrate a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months. The Company also mentioned that treatment had been generally well-tolerated to date in this heavily pre-treated population.

- On June 5, 2025, we announced that a new partial response (PR) was identified in a patient after 20 months of treatment in our Phase 2 THIO-101 clinical trial. A partial response is defined as a decrease in tumor size of at least 30%.

- On June 18, 2025, we announced its entry into a clinical master supply agreement with Roche for future studies investigating the combination of MAIA's telomere targeting agent ateganosine (THIO), sequenced with Roche's checkpoint inhibitor (CPI), atezolizumab (Tecentriq®), for the treatment of multiple hard-to-treat cancers.

- On June 24, 2025, we announced the appointment of two prominent oncologists to its Scientific Advisory Board (SAB), Claudia Fulgenzi, MD, and David J. Pinato, MD, MRCP (UK), PhD. Both are specialists in hepatocellular carcinoma (HCC), a tumor type to be studied in future clinical trials of MAIA's lead candidate ateganosine (THIO) sequenced with a checkpoint inhibitor.

- On July 9, 2025, we announced the dosing of the first patient in Taiwan in the expansion phase of our THIO-101 Phase 2 trial for advanced non-small cell lung cancer (NSCLC). The trial's entry into another continent marks a key milestone for MAIA, opening a significantly larger patient pool for its evaluations of ateganosine (THIO). MAIA also announced that screening for the trial is ongoing in Europe and Asia.

- On July 17, 2025, we announced the publication of preclinical data from its second generation ateganosine prodrugs platform in Nucleic Acids Research (NAR), a leading open-access peer-reviewed scientific journal. The study, titled "Novel Telomere-Targeting Dual-Pharmacophore Dinucleotide Prodrugs for Anticancer Therapy," details MAIA's lead ateganosine (THIO)-derived second-generation prodrugs as promising new molecules in its strategy for enhancing cancer treatment and overcoming drug resistance. The manuscript with the data was published on June 26, 2025, in Volume 53, Issue 12 of the NAR journal.

- On July 28, 2025, we announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ateganosine (THIO, 6-thio-dG or 6-thio2'-deoxyguanosine) for the treatment of non-small cell lung cancer (NSCLC). Ateganosine is currently being evaluated in a pivotal Phase 2 THIO-101 clinical trial evaluating its anti-tumor activity when followed by a checkpoint inhibitor.

- On August 13, 2025, we announced that the European Patent Office granted a patent broadly covering a portfolio of ateganosine-based analogues for telomere targeting anticancer therapy and methods of using ateganosine (THIO) alone or before administration of checkpoint inhibitors (CPIs). The patent, titled "Mercaptopurine Ribonucleoside Analogues for Altering Telomerase Mediated Telomere," was invented by MAIA's Chief Scientific Officer Sergei M. Gryaznov, PhD and Scientific Advisory Board member Jerry W. Shay, PhD. MAIA's global patent and patent-pending estate covers several areas including telomerase mediated telomere altering compounds and treatment of therapy-resistant cancers. Further, ateganosine's immunogenic treatment strategy, which focuses on sequential combination with checkpoint inhibitors, has been filed worldwide. MAIA's IP portfolio for ateganosine currently comprises 10 issued patents worldwide including Europe (validated in 19 countries) along with 24 pending patent applications.

- On August 27, 2025, we announced that a manuscript detailing developments in its Phase 2 THIO-101 clinical trial was accepted and published in the international peer-reviewed open access scientific journal, Cells, in a special issue, "Cellular Mechanisms of Anti-Cancer Therapies". The manuscript, titled "Perioperative Management of Non-Small Cell Lung Cancer in the Era of Immunotherapy," was authored by a group of oncology researchers in Turkey and the U.S. including MAIA scientists Sergei Gryaznov, Ph.D., Chief Scientific Officer and Ilgen Mender, Director of Biology Research, along with MAIA Scientific Advisory Board members Z. Gunnur Dikmen, M.D., Ph.D. and Saadettin Kiliçkap, M.D., M.Sc.

- On September 11, 2025, we highlighted positive efficacy data from its Phase 2 clinical trial, THIO-101, including that as of June 30, 2025: (i) estimated median progression free survival (PFS) in third-line treatment (180 mg dose) was 5.6 months; (ii) Estimated median overall survival (OS) was 17.8 months, with a 95% confidence interval (CI) lower bound of 12.5 months and a 99% CI lower bound of 10.8 months, consistent with the prior data readout (May 15, 2025); (iii) Across patients of all treatment lines, 2 patients have completed 33 cycles of therapy, highlighting ateganosine' potential for extended dosing, which usually translates into longer patient survival.

- On September 24, 2025, announced today that the National Institutes of Health (NIH) has awarded a $2.3 million grant for the expansion of its THIO-101 Phase 2 clinical trial evaluating ateganosine as a third-line treatment for patients with advanced non-small cell lung cancer (NSCLC).

- On October 1, 2025, we issued and sold 1,733,766 shares of our common stock and warrants to purchase 1,733,766 shares of our common stock in a non-brokered private placement to accredited investors and certain Company directors pursuant to securities purchase agreements dated September 29, 2025 at a price per share of $1.30 for which we received gross proceeds of approximately $2.25 million, prior to offering expenses payable by the Company. The warrants issued in the private placement have an exercise price of $1.57, are exercisable six months following issuance and have a term of three after the initial exercise date. The securities sold to our directors participating in the private placement were issued pursuant to our 2021 Equity Incentive Plan.

- On October 7, 2025 we announced our launch of a new digital asset treasury strategy focused on top-tier cryptocurrency asset. Due to cryptocurrency volatility, the Company's digital asset strategy is currently on hold. As of the date of this report, the Company holds approximately $0 in digital assets.

- On October 16, 2025, we issued and sold 603,769 shares of our common stock and warrants to purchase 603,769 shares of our common stock in a non-brokered private placement to accredited investors pursuant to securities purchase agreements dated October 13, 2025 at a price per share of $1.22 for which we received gross proceeds of approximately $736,600, prior to offering expenses payable by the Company. The warrants issued in the private placement have an exercise price of $1.52, are exercisable six months following issuance and have a term of three years from the issuance date.

- On October 23, 2025, we announced that as of September 17, 2025, a patient that began therapy in March 2023 has shown survival of 30 months, or 912 days, an outstanding measure relative to many of the high-risk cancers. The patient with thirty month survival received therapy every three weeks, and concluded treatment upon reaching the maximum treatment duration of 2 years based on protocol requirements.

- On October 27, 2025, we announced that we have enrolled five patients from Taiwan and Turkey in the expansion phase of its THIO-101 Phase 2 trial.

- On November 20, 2025, we announced Romania as an additional country to begin screening patients for the expansion phase of its THIO-101 Phase 2 clinical trial which evaluates ateganosine sequenced with an immune checkpoint inhibitor as a third-line treatment for non-small cell lung cancer (NSCLC).

- On November 21, 2025, we announced that we have enrolled twelve patients from Taiwan, Turkey, Hungary and Poland in the expansion phase of its THIO-101 Phase 2 trial.

- On December 11, 2025, we announced that the first patient has been dosed in THIO-104 Phase 3 pivotal trial evaluating the efficacy of ateganosine administered in sequence with a checkpoint inhibitor (CPI) as a third-line treatment for advanced non-small cell lung cancer (NSCLC). The multicenter, open-label trial is designed to assess overall survival for ateganosine sequenced with a CPI compared to investigator's choice of chemotherapy in a 1:1 randomization of up to 300 patients. MAIA has received regulatory approval to screen patients in Taiwan, Turkey, select European Medicines Agency (EMA) countries, and Georgia. Screening and enrollment are now underway.

- On December 22, 2025, we issued and sold 1,233,488 shares of our common stock and warrants to purchase 1,233,488 shares of our common stock in a non-brokered private placement to accredited investors and certain Company directors pursuant to securities purchase agreements dated December 16, 2025 at a price per share of $1.224 for which we received gross proceeds of approximately $1.51 million, prior to offering expenses payable by the Company. The warrants issued in the private placement have an exercise price of $1.36, are exercisable six months following issuance and have a term of three years after the initial exercise date. The securities sold to our directors participating in the private placement were issued pursuant to our 2021 Equity Incentive Plan.

- On January 20, 2026, we provided a corporate update on 2025 achievements and highlighted key targeted milestones and growth catalysts for 2026. The targeted milestones include: (i) initial measures of efficacy from Phase 3 study, with interim disease control rates (DCR), overall response rates (ORR) and progression free survival (PFS) analysis of ateganosine compared to the control arm will support regulatory discussions; (ii) expected conclusion of Part C of Phase 2 study, which will provide additional clinical efficacy data to support regulatory review for commercial approval; (iii) Plan to engage in regulatory interactions with the FDA to expand ongoing FDA dialogue under the Fast Track designation, including discussions around trial enhancements and prospects for Accelerated Approval and Priority Review; (iv) clinical development of second-generation molecules planned to start in Phase 1 trials, with additional small molecules fully developed in-house with better expected efficacy compared to ateganosine.

- On March 4, 2026, we issued and sold 20,000,000 shares of our common stock in a underwritten public offering at a price of $1.50 per share for aggregate gross proceeds of $30 million, prior to deducting underwriting discounts and other offering expenses. In addition, on March 9, 2026, the Company closed on the partial exercise of underwriter over-allotment option for the above referenced public offering for an additional 2,005,875 shares of common stock at the public offering price of $1.50 per share resulting in additional gross proceeds of approximately $3 million. After giving effect to the partial exercise of the over-allotment option, the total number of shares sold by Company in the public offering increased to 22,005,875 and gross proceeds increased to approximately $33 million

- In addition to NSCLC, HCC, SCLC and CRC we plan to conduct clinical trials evaluating ateganosine in sequential combination with an immune checkpoint inhibitor in several other cancer indications, including solid tumors, such as breast, prostate, gastric, pancreatic and ovarian cancers. THIO-103 is a Phase 2 clinical trial planned to evaluate treatment with ateganosine in first-line patients for both NSCLC and SCLC.

Impact of the War in Ukraine and the conflict in Iran on Our Operations

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

Financial Operations Overview and Analysis For the Years Ended December 31, 2025 and 2024

Comparison of the Years Ended December 31, 2025 and 2024

	Years Ended December 31,		Change	
	2025	2024	Dollars	Percentage
Operating expenses:				
Research and development expenses	$ 14,547,332	$ 10,009,229	$ 4,538,103	45%
General and administrative expenses	9,722,354	6,947,981	2,774,373	40%
Total operating costs and expenses	24,269,686	16,957,210	7,301,585	43%
Loss from operations	(24,269,686)	(16,957,210)	(7,312,476)	43%
Other income (expense):				
Interest expense	—	(57)	57	(100)%
Interest income	313,954	318,367	(4,413)	(1)%
Australian research and development incentives	—	79,954	(79,954)	(100)%
Grant income	361,350	—	361,350	—%
Change in fair value of warrant liability	1,198,210	(6,682,758)	7,880,968	(118)%
Loss on fair value of warrants over proceeds	—	(12,952)	12,952	(110)%
Other income (expense), net	1,873,514	(6,297,446)	8,170,960	(130)%
Net loss	$ (22,396,172)	$ (23,254,656)	$ 858,484	(4)%

Operating Expenses

Research and development expenses

Research and development expenses increased by approximately $4,538,000 (or approximately 45%) from approximately $10,009,000 for the year ended December 31, 2024 to approximately $14,547,000 for the year ended December 31, 2025. The increase was primarily related to an increase in payroll expense of approximately $377,000 related to an increase in salaries of research and development employees, an increase in stock based compensation of approximately $204,000, an increase in Scientific pre-clinical research of approximately $1,699,000, an increase of other expenses related to research and development of approximately $47,000, an increase in clinical expenses related to the clinical trial of ateganosine of approximately $2,174,000, and an increase in professional fees of $37,000.

General and administrative expenses

General and administrative expenses increased by approximately $2,775,000 (or approximately 40%) from approximately $6,948,000 for the year ended December 31, 2024 to approximately $9,722,000 for the year ended December 31, 2025. The increase was primarily related to an increase in other expenses of approximately $1,548,000 related to higher investor relations expenses, an increase in payroll expense of approximately $281,000 relating to the increase in salaries of general and administrative employees, an increase in stock-based compensation of approximately $515,000, and an increase in professional fees of approximately $431,000,

Other income (expense), net

Other income (expense), net increased by approximately $8,171,000 (or approximately 130%) from other expense, net of approximately $6,297,000 for the year ended December 31, 2024 to other income, net of approximately $1,874,000 for the year ended December 31, 2025. The increase was primarily related to the change in the loss on fair value of the warrant liability of approximately $7,881,000, a change in the loss on fair value of warrants over proceeds of approximately $13,000, an increase for grant income of approximately $361,000, offset by a reduction in the Australia research and development incentives of approximately $80,000 and a reduction of interest income, net of approximately $4,000.

Liquidity and Capital Resources

The following table presents selected financial information and statistics as of and for the years ended December 31, 2025 and 2024:

Years Ended December 31, 2025 and 2024

	As of December 31,	
	2025	**2024**
Balance Sheet Data:		
Cash	$ 8,658,031	$ 9,601,298
Working capital (1)	3,865,458	6,322,441
Total assets	9,704,656	10,155,279
Accrued bonus	1,199,955	941,098
Total stockholders' equity	2,375,863	3,634,636

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

Capital Resources

Sale of Common Stock

Between February 14, 2024 and December 31, 2024, we sold 3,274,360 shares of Common Stock at an average price of approximately $3.09 per share, resulting in aggregate gross proceeds of approximately $10,111,996 under the ATM Agreements dated February 14, 2024 and May 15, 2024, for which we paid Wainwright approximately $303,350 in commissions and $355,451 in other issuance costs resulting in net proceeds to us of approximately $9,453,195.

On March 14, 2024, we issued and sold 2,496,318 shares of our Common Stock and warrants to purchase 2,496,318 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated March 11, 2024 at a price $1.17 per share, for which we received gross proceeds of approximately $2.92 million. The warrants are exercisable at a price per Share of $1.30, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing six months following issuance and have a term of five and a half years from the initial issuance date. The securities sold to our directors participating in the March 14, 2024 private placement were issued pursuant to the MAIA 2021 Plan. The following Company directors participated in the aforementioned private placement as follows: (i) Stan Smith purchased 170,940 shares and 170,940 warrants for an aggregate purchase price of $200,0000; (ii) Louie Ngar Yee purchased 170,940 shares and 170,940 warrants for an aggregate purchase price of $200,000; (iii) Cristian Luput purchased 69,282 shares and 69,282 warrants for an aggregate purchase price of $81,060 (iv) Steven Chaouki purchased 34,641 shares of common stock and 34,461 warrants for an aggregate purchase price of $40,530 and (v) Ramiro Guerrero purchased 6,928 shares and 6,928 warrants for an aggregate purchase price of $8,106.

On March 28, 2024, we issued and sold 578,643 shares of our Common Stock and warrants to purchase 578,643 shares of our Common Stock in a private placement to certain accredited investors pursuant to securities purchase agreements dated March 25, 2024 at a price of $2.295 per share, for which we received gross proceeds of approximately $1.33 million. The warrants are exercisable at a price per Share of $2.55, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing six months following issuance and have a term of five and a half years from the initial issuance date.

On April 25, 2024, we issued and sold 494,096 shares of our Common Stock and warrants to purchase 494,096 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated April 22, 2024 at a price of $2.034 per share, for which we received gross proceeds of approximately $1.0 million. The warrants are exercisable at a price per Share of $2.26, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing six months following issuance and have a term of five and a half years from the initial issuance date. The securities sold to our directors participating in the April 25, 2024 private placement were issued pursuant to the MAIA 2021 Plan. Company director Stan Smith purchased 147,492 shares and 147,492 warrants for an aggregate purchase price of approximately $300,000 and Company director Louie Ngar Yee purchased 19,665 shares and 19,665 warrants for an aggregate purchase price of approximately $40,000.

On November 1, 2024, we issued and sold 1,079,784 shares of our Common Stock and warrants to purchase 1,079,784 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated October 28, 2024 at a price of $2.259 per share, for which we received gross proceeds of approximately $2.44 million. The warrants are exercisable at a price per Share of $2.51, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing six months following issuance and have a term of five and a half years from the initial issuance date. The securities sold to our directors participating in the November 1, 2024 private placement were issued pursuant to the MAIA 2021 Plan. Company director Stan Smith purchased 100,000 shares and 100,000 warrants for an aggregate purchase price of approximately $225,900; Company director Ramiro Guerrero purchased 88,534 shares and 88,534 warrants for an aggregate purchase price of approximately $200,000; Company director Steven Chaouki purchased 22,133 shares and 22,133 warrants for an aggregate purchase price of approximately $50,000; and Company director Cristian Luput purchased 22,133 shares and 22,133 warrants for an aggregate purchase price of approximately $50,000. In addition, the son of Company director Stan Smith purchased 40,000 shares and 40,000 warrants for an aggregate purchase price of approximately $90,360 and related party 5% stockholder FGMK Business Holdings, LLC purchased 243,470 shares and 243,670 warrants for a purchase price of approximately $550,000.

On December 13, 2024, we issued and sold 507,364 shares of our Common Stock and warrants to purchase 507,364 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated December 9, 2024 at a price of $1.872 per share, for which we received gross proceeds of approximately $950,000. The warrants are exercisable at a price per Share of $2.08, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing six months following issuance and have a term of five and a half years from the initial issuance date. The securities sold to our directors participating in the December 13, 2024 private placement were issued pursuant to the MAIA 2021 Plan. Company director Stan Smith purchased 25,000 shares and 25,000 warrants for an aggregate purchase price of approximately $46,800 and Company director Ramiro Guerrero purchased 53,418 shares and 53,418 warrants for an aggregate purchase price of approximately $100,000. In addition, Sylvia Guerrero, the sister of one of the Company directors purchased 5,341 shares and 5,341 warrants for an aggregate purchase price of approximately $10,000.

From October 1, 2025 thru December 31, 2025, we sold 236,271 shares of Common Stock through Wainwright under the ATM Agreement dated March 22, 2025 at an average price of approximately $1.78 per share, resulting in aggregate gross proceeds of approximately $420,780, for which we paid Wainwright approximately $12,623 in commissions and other issuance costs of 1,459, resulting in net proceeds to us of approximately $406,698. From January 1, 2025 through December 31, 2025, we sold 3,782,335 shares of Common Stock through Wainwright under the ATM Agreements dated December 19, 2024 and March 22, 2025 at an average price of approximately $1.90 per share, resulting in aggregate gross proceeds of approximately $7,202,016, for which we paid Wainwright approximately $216,060 in commissions and other issuance costs of $111,555, resulting in net proceeds to us of approximately $6,874,401.

On February 24, 2025, we issued and sold 1,810,000 shares of our Common Stock and warrants to purchase 1,810,000 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated February 18, 2025 at a price of $1.50 per share, for which we received gross proceeds of approximately $2.7 million. The warrants are exercisable at a price per Share of $1.87, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing one year following issuance and have a term of six years from the initial issuance date. The securities sold to our directors participating in the February 24, 2025 private placement were issued pursuant to the MAIA 2021 Plan. Company director Stan Smith purchased 50,000 shares and 50,000 warrants for an aggregate purchase price of approximately $75,000 and Company director Ramiro Guerrero purchased 73,333 shares and 73,333 warrants for an aggregate purchase price of approximately $110,000. In addition, related party 5% stockholder FGMK Business Holdings, LLC purchased 1,350,000 shares and 1,350,000 warrants for a purchase price of approximately $550,000.

On March 3, 2025, we issued and sold 952,633 shares of our Common Stock and warrants to purchase 952,633 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated February 24, 2025 at a price of $1.50 per share, for which we received gross proceeds of approximately $1.4 million. The warrants are exercisable at a price per Share of $1.85, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing one year following issuance and have a term of six years from the initial issuance date. The securities sold to our directors participating in the March 3, 2025 private placement were issued pursuant to the MAIA 2021 Plan. Company director Stan Smith purchased 25,000 shares and 25,000 warrants for an aggregate purchase price of approximately $37,500 and Company director Ramiro Guerrero purchased 33,333 shares and 33,333 warrants for an aggregate purchase price of approximately $50,000.

On May 8, 2025, we issued and sold 719,999 shares of our Common Stock and warrants to purchase 719,999 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated May 5, 2025 at a price of $1.50 per share, for which we received gross proceeds of approximately $1.1 million. The warrants are exercisable at a price per Share of $2.05, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing one year following issuance and have a term of six years from the initial issuance date. The securities sold to our directors participating in the May 8, 2025 private placement were issued pursuant to the MAIA 2021 Plan. Company director Stan Smith purchased 66,666 shares and 66,666 warrants for an aggregate purchase price of approximately $100,000 and Company director Ramiro Guerrero purchased 20,000 shares and 20,000 warrants for an aggregate purchase price of approximately $30,000.

On June 3, 2025, we issued and sold 463,332 shares of our Common Stock and warrants to purchase 463,332 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated May 27, 2025 at a price of $1.50 per share, for which we received gross proceeds of approximately $0.7 million. The warrants are exercisable at a price per Share of $1.71, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing six months following issuance and have a term of five years from the initial issuance date. The securities sold to our directors participating in the June 3, 2025 private placement were issued pursuant to the MAIA 2021 Plan. Company director Stan Smith purchased 33,333 shares and 33,333 warrants for an aggregate purchase price of approximately $50,000.

On October 1, 2025, we issued and sold 1,733,766 shares of our Common Stock and warrants to purchase 1,733,766 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated September 29, 2025 at a price of $1.30 per share, for which we received gross proceeds of approximately $2.3 million. The warrants are exercisable at a price per Share of $1.57, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing six months following issuance and have a term of three years from the initial issuance date. The securities sold to our directors participating in the October 1, 2025 private placement were issued pursuant to the MAIA 2021 Plan. Company director Stan Smith purchased 19,230 shares and 19,230 warrants for an aggregate purchase price of approximately $25,000.

On October 16, 2025, we issued and sold 603,769 shares of our Common Stock and warrants to purchase 603,769 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated October 13, 2025 at a price of $1.22 per share, for which we received gross proceeds of approximately $0.7 million. The warrants are exercisable at a price per Share of $1.52, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing six months following issuance and have a term of three years from the initial issuance date.

On December 22, 2025, we issued and sold 1,233,488 shares of our Common Stock and warrants to purchase 1,233,488 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated December 16, 2025 at a price of $1.224 per share, for which we received gross proceeds of approximately $1.5 million. The warrants are exercisable at a price per Share of $1.36, which price represents the greater of the book or market value of the stock on the date the purchase agreement was executed, are exercisable commencing six months following issuance and have a term of three years from the initial issuance date. The securities sold to our directors participating in the December 22, 2025 private placement were issued pursuant to the MAIA 2021 Plan. Company director Louie Ngar Yee purchased 81,699 shares and 81,699 warrants for an aggregate purchase price of approximately $100,000, Company director Stan Smith purchased 57,189 shares and 57,189 warrants for an aggregate purchase price of approximately $70,000, and Company director Steven Chaouki purchased 40,849 shares and 40,849 warrants for an aggregate purchase price of approximately $50,000,

National Institute of Health Grant

On September 24, 2025, we announced that the National Institutes of Health (NIH) has awarded us a $2.3 million grant for the expansion of its THIO-101 Phase 2 clinical trial evaluating ateganosine as a third-line treatment for patients with advanced non-small cell lung cancer (NSCLC)

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

Cash Flows

Cash Flows Years Ended December 31, 2025 and 2024

	Years Ended December 31,	
	2025	**2024**
Net cash flows used in operating activities	$ (18,844,598)	$ (15,704,461)
Net cash flows provided by financing activities	17,906,547	18,176,609
Effect of foreign currency exchange rate changes on cash	(5,216)	(21,545)
Net (decrease) increase in cash	$ (943,267)	$ 2,450,603

Operating Activities

For the year ended December 31, 2025, net cash used in operating activities was approximately $18,845,000, which consisted of a consolidated net loss of approximately $22,396,000 offset by non-cash charges of approximately $2,052,000 which primarily includes approximately $2,631,000 in stock-based compensation, approximately $619,000 of expense related restricted shares issued for consulting services, and a gain of approximately $1,198,000 related to the changes in fair value of the warrant liability. Total changes in operating assets and liabilities of approximately $1,499,000 were primarily driven by an approximate $520,000 increase in accounts payable, an approximate $1,479,000 increase in accrued expenses, an approximate increase of $80,000 in Australian research and development incentives receivable, and an approximate $580,000 decrease in prepaid expenses and other current assets.

For the year ended December 31, 2024, net cash used in operating activities was approximately $15,704,000, which consisted of a consolidated net loss of approximately $23,255,000 offset by non-cash charges of approximately $8,788,000 which primarily includes approximately $1,913,000 in stock-based compensation, approximately $179,000 of expense related restricted shares issued for consulting services, and a loss of approximately $6,683,000 related to the changes in fair value of the warrant liability, and the loss on fair value of warrants over proceeds of approximately $13,000. Total changes in operating assets and liabilities of approximately $1,238,000 were primarily driven by an approximate $119,000 decrease in accounts payable, an approximate $980,000 decrease in an accrued expenses, an approximate increase of $57,000 in Australian research and development incentives receivable, and an approximate $196,000 decrease in prepaid expenses and other current assets.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 was approximately $17,907,000 and consisted primarily of approximately $10,419,000 in gross proceeds from private placement offerings, proceeds from the at-the-market offering of approximately $7,202,000, proceeds from the exercise of stock options of approximately $1,000, proceeds from the exercise of warrants of approximately $902,000 and were offset by approximately $617,000 of offering costs.

Net cash provided by financing activities for the year ended December 31, 2024 was approximately $18,177,000 and consisted primarily of approximately $8,643,000 in gross proceeds from private placement offerings, proceeds from the at-the-market offering of approximately $10,112,000, proceeds from the exercise of stock options of $217,000, and were offset by approximately $795,000 of offering costs.

Critical Accounting Policies and Significant Judgments and Estimates

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

Stock-based compensation

Our stock-based awards are classified as equity (restricted stock awards and stock options). We recognize related stock-based compensation expense based on the grant date fair value of the awards. The fair value of restricted stock awards is based on the trading value of the Company's common stock. We estimate the fair value of stock options and warrants using the Black-Scholes-Merton valuation model which requires the use of subjective assumptions that could materially impact the estimation of fair value and related compensation expense to be recognized. One of these assumptions include the expected volatility of our stock price. Developing this assumption requires the use of judgment. The Company lacks sufficient 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, while corroborating these volatilities with our actual limited historical volatility information.

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

Prepaid and Accrued Research and Development Expenses

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

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

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. The scope of services under these contracts can be modified and some of the agreements may be canceled by either party upon written notice. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed we may report amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates and the amount actually incurred.

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

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Under the supervision of and with the participation of our management, including our Chief Executive Officer, who is our principal executive officer, and our Head of Finance, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2025, the end of the period covered by this Annual Report. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and Head of Finance concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2025, our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework – 2013 (1992 Framework). Based on this assessment, management concluded that, as of December 31, 2025, our internal controls over financial reporting were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting

This Annual Report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the company's registered public accounting firm pursuant to rules of the SEC.

Item 9B. Other Information.

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2026 annual meeting of stockholders to be filed not later than 120 days after the end of the 2025 fiscal year and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to all our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on the investor relations section of our website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Conduct by posting such information on the website address and location specified above.

We have adopted an insider trading policy applicable to our directors, officers, employees, and other covered persons, and have implemented processes for the company, that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations, and the NYSE American listing standards. Our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2026 annual meeting of stockholders to be filed not later than 120 days after the end of the 2025 fiscal year, and is incorporated herein by reference.

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

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2026 annual meeting of stockholders to be filed not later than 120 days after the end of the 2025 fiscal year, and is incorporated herein by reference.

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

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2026 annual meeting of stockholders to be filed not later than 120 days after the end of the 2025 fiscal year, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item will be set forth in our definitive proxy statement with respect to our 2026 annual meeting of stockholders to be filed not later than 120 days after the end of the 2025 fiscal year, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The consolidated financial statements required by this item are submitted in a separate section beginning on page F-2 of this Annual Report on Form10-K.

(a)(2) Exhibits.

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

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Description
1.1	At The Market Offering Agreement dated February 14, 2024 between MAIA Biotechnology, Inc. and H.C. Wainwright & Co., LLC, filed as Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 14, 2024 and incorporated herein by reference.
1.2	Underwriting Agreement dated March 7, 2026, by and between MAIA Biotechnology, Inc. and Konik Capital Partners LLC, filed as Exhibit 1.1 to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 4, 2026.
3.1(1)	Amended and Restated Certificate of Incorporation of MAIA Biotechnology, Inc
3.2(1)	Amended and Restated Bylaws of MAIA Biotechnology, Inc.
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of MAIA Biotechnology, Inc., filed as Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 23, 2025 and incorporated herein by reference.
4.1*	Description of Registrant's Securities.
4.2(1)	Form of Representative's Warrant (Included in Exhibit 10.19)
4.3(3)	Form of Warrant
4.4(3)	Specimen certificate representing shares of common stock
4.5	Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 16, 2023 and incorporated herein by reference.
4.6	Form of Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 17, 2023 and incorporated herein by reference.
4.7	Form of Wainwright Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 17, 2023 and incorporated herein by reference.
4.8	Form of Investor Warrants, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 13, 2024 and incorporated herein by reference.
4.9	Form of Director Warrants, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 13, 2024 and incorporated herein by reference.
4.10	Form of Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 25, 2024 and incorporated herein by reference.
4.11	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 23, 2024.
4.12	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 23, 2024.
4.13	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 29, 2024.
4.14	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 29, 2024.
4.15	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2024
4.16	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2024.
4.17	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 19, 2025
4.18	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 19, 2025.
4.19	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2025
4.20	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2025.

4.21	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 19, 2025.
4.22	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 19, 2025.
4.23	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2025.
4.24	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2025.
4.25	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 6, 2025.
4.26	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 6, 2025.
4.27	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 6, 2025 and incorporated by reference.
4.28	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 6, 2025 and incorporated by reference.
4.29	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 28, 2025 and incorporated by reference.
4.30	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 28, 2025 and incorporated by reference.
4.31	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 30, 2025 and incorporated by reference.
4.32	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 30, 2025 and incorporated by reference.
4.33	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 14, 2025 and incorporated by reference.
4.34	Form of Investor Warrant, filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 17, 2025 and incorporated by reference.
4.35	Form of Director Warrant, filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 17, 2025 and incorporated by reference.
10.1(1)	Form of Indemnification Agreement.
10.2	Employment Agreement, dated as of February 1, 2025, between the Company and Vlad Vitoc., filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 6, 2025 and incorporated herein by reference.
10.3	Employment Agreement, dated as of February 1, 2025, between the Company and Sergei Gryaznov, filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 6, 2025 and incorporated herein by reference.
10.4†(3)	Supply and Non-Exclusive License Agreement between the Company and Regeneron Pharmaceuticals, Inc. dated February 1, 2021.
10.5†(3)	Patent & Technology License Agreement between the Company and The Board of Regents of The University of Texas System on behalf of The University of Texas Southwestern Medical Center dated December 8, 2020.
10.6†(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.
10.7+(4)	MAIA Biotechnology, Inc. 2018 Stock Option Plan.
10.8+(4)	MAIA Biotechnology, Inc. Amended & Restated 2020 Equity Incentive Plan.
10.9+(5)	MAIA Biotechnology, Inc. 2021 Equity Incentive Plan.
10.10+	Amendment to the MAIA Biotechnology Inc 2021 Equity Incentive Plan, filed as Annex A to the Registrants Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on April 19, 2023 and incorporated herein by reference
10.11+(5)	Form of Director Stock Option Award under Amended & Restated 2020 Equity Incentive Plan.
10.12+(5)	Form of Compensatory Management Stock Option Award Agreement under Amended & Restated 2020 Equity Incentive Plan.
10.13+(5)	Form of Consulting Stock Option Award Agreement under Amended & Restated 2020 Equity Incentive Plan.

10.14+(5)	Form of Employee Stock Option Award Agreement under Amended & Restated 2020 Equity Incentive Plan.
10.15+(6)	Form of Incentive Stock Option Award under 2021 Equity Incentive Plan.
10.16+(6)	Form of Non-qualified Stock Option Award under 2021 Equity Incentive Plan.
10.17+(6)	Form of Director and Consultant Non-qualified Stock Option Award under 2021 Equity Incentive Plan.
10.18(1)	Underwriting Agreement dated as of July 27, 2022 between the Company and ThinkEquity, LLC
10.19	Sales Agreement dated September 1, 2023 by and between MAIA Biotechnology, Inc. and ThinkEquity LLC filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 1, 2023 and incorporated herein by reference.
10.20	Employment Agreement dated August 30, 2023 between Jeffrey Himmelreich and MAIA Biotechnology, Inc., filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on November 15, 2023 and incorporated herein by reference.
10.21	Form of Securities Purchase Agreement, filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on November 17, 2023 and incorporated herein by reference.
10.22	Form of Lock-Up Agreement, filed as Exhibit 10.2 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on November 17, 2023 and incorporated herein by reference.
10.23	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 13, 2024 and incorporated herein by reference.
10.24	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 26, 2024 and incorporated herein by reference.
10.25	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 23, 2024 and incorporated herein by reference.
10.26	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 29, 2024 and incorporated herein by reference.
10.27	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2024 and incorporated herein by reference.
10.28	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 19, 2025 and incorporated herein by reference.
10.29	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2025 and incorporated herein by reference.
10.30	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 19, 2025 and incorporated herein by reference.
10.31	Form of Securities Purchase Agreement, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2025 and incorporated herein by reference.
10.32	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 6, 2025 and incorporated herein by reference.
10.33	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 6, 2025 and incorporated herein by reference.
10.34	Form of Securities Purchase Agreement, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 28, 2025 and incorporated herein by reference.
10.35	Form of Inducement Letter, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2025 and incorporated herein by reference.

10.36	Stock Purchase Agreement dated June 24, 2025 between MAIA Biotechnology, Inc. and Prevail Partners, LLC, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2025 and incorporated herein by reference.
10.37	Form of Inducement Letter, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 18, 2025 and incorporated herein by reference.
10.38	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 30, 2025 and incorporated herein by reference.
10..39	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 14, 2025 and incorporated herein by reference.
10.40	Form of Securities Purchase Agreement, filed as Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 17, 2025 and incorporated herein by reference.
10.41	Form of Lock-up Agreement, filed as Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 4, 2026.
19.1	Insider Trading Policy filed as Exhibit 19.1 of the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 21, 2025 and incorporated herein by reference.
21.1	List of Subsidiaries of the Registrant, filed as Exhibit 21.1 to the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 21, 2024 and incorporated herein by reference.
23.1*	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Clawback Policy, filed as Exhibit 97.1 to the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 21, 2024 and incorporated herein by reference.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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

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

SIGNATURES

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

Dated: March 23, 2026.

MAIA BIOTECHNOLOGY, INC.

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

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

Name	Title	Date
/s/ Vlad Vitoc Vlad Vitoc	Chairman and Chief Executive Officer (Principal Executive Officer)	March 23, 2026
/s/ Jeffrey C. Himmelreich Jeffrey C. Himmelreich	Head of Finance (Principal Financial Officer)	March 23, 2026
/s/ Steven Chaouki Steven Chaouki	Director	March 23, 2026
/s/ Ramiro Guerrero Ramiro Guerrero	Director	March 23, 2026
/s/ Louie Ngar Yee Louie Ngar Yee	Director	March 23, 2026
/s/ Cristian Luput Cristian Luput	Director	March 23, 2026
/s/ Stan V. Smith Stan V. Smith	Director	March 23, 2026
/s/ Jean-Manassé Theagène Jean-Manassé Theagène	Director	March 23, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
MAIA Biotechnology, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of MAIA Biotechnology, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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/ GRANT THORNTON LLP

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

Charlotte, North Carolina
March 23, 2026

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash	$ 8,658,031	$ 9,601,298
Prepaid expenses and other current assets	1,043,825	473,834
Australia research and development incentives receivable	—	77,347
Total current assets	9,701,856	10,152,479
Other assets	2,800	2,800
Total assets	$ 9,704,656	$ 10,155,279
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,038,803	$ 1,512,436
Accrued expenses	3,797,595	2,317,602
Total current liabilities	5,836,398	3,830,038
Long term liabilities:		
Warrant liability	1,492,395	2,690,605
Total liabilities	7,328,793	6,520,643
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit)		
Preferred stock, 0.0001 par value, 30,000,000 shares authorized at December 31, 2025 and December 31, 2024, 0 shares issued and outstanding	—	—
Common stock, $0.0001 par value, 150,000,000 and 70,000,000 shares authorized at December 31, 2025 and December 31, 2024, 38,624,289 and 26,157,788 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	3,863	2,616
Additional paid-in capital	112,053,233	90,897,468
Accumulated deficit	(109,631,005)	(87,234,833)
Accumulated other comprehensive loss	(50,228)	(30,615)
Total stockholders' equity	2,375,863	3,634,636
Total liabilities and stockholders' equity	$ 9,704,656	$ 10,155,279

See the accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc. and Subsidiaries
Consolidated Statements of Operations

	Years Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development expenses	$ 14,547,332	$ 10,009,229
General and administrative expenses	9,722,354	6,947,981
Total operating expenses	24,269,686	16,957,210
Loss from operations	(24,269,686)	(16,957,210)
Other income (expense):		
Interest expense	—	(57)
Interest income	313,954	318,367
Australian research and development incentives	—	79,954
Grant income	361,350	—
Change in fair value of warrant liability	1,198,210	(6,682,758)
Loss on fair value of warrants over proceeds	—	(12,952)
Other income (expense) net:	1,873,514	(6,297,446)
Net loss	$ (22,396,172)	$ (23,254,656)
Net loss per share		
Basic and diluted	$ (0.70)	$ (1.05)
Weighted average common shares outstanding basic and diluted	32,114,608	22,197,517

See the accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,	
	2025	**2024**
Net loss	$ (22,396,172)	$ (23,254,656)
Foreign currency translation adjustment	(19,613)	(14,355)
Comprehensive loss	$ (22,415,785)	$ (23,269,011)

See the accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc.
Consolidated Statements of Changes in Stockholders' Equity
for the Year ended December 31, 2025

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2024	—	$ —	26,157,788	$ 2,616	$ 90,897,468	$ (87,234,833)	$ (30,615)	$ 3,634,636
Issuance of restricted stock	—	—	506,823	50	618,763	—	—	618,813
Exercise of stock options	—	—	570	—	844	—	—	844
Stock-based compensation expense	—	—	—	—	2,631,652	—	—	2,631,652
Issuance of common shares in connection with At-The-Market financing, net of $327,615 of issuance costs	—	—	3,782,335	379	6,874,022	—	—	6,874,401
Issuance of common shares in connection with the Private Placement Offerings, net of $289,518 of issuance costs	—	—	7,516,987	752	6,023,757	—	—	6,024,509
Issuance of warrants in connection with the Private Placement Offerings	—	—	—	—	4,105,215	—	—	4,105,215
Exercise of warrants	—	—	659,786	66	901,512	—	—	901,578
Foreign currency translation adjustment	—	—	—	—	—	—	(19,613)	(19,613)
Net loss	—	—	—	—	—	(22,396,172)	—	(22,396,172)
Balance at December 31, 2025	—	$ —	38,624,289	$ 3,863	$ 112,053,233	$ (109,631,005)	$ (50,228)	$ 2,375,863

See the accompanying notes to the consolidated financial statements.

MAIA Biotechnology, Inc.
Consolidated Statements of Changes in Stockholders' Equity
for the Year ended December 31, 2024

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	—	$ —	16,986,254	$ 1,699	$ 64,472,249	$ (63,980,177)	$ (16,260)	$ 477,511
Issuance of restricted stock	—	—	75,550	7	179,483	—	—	179,490
Exercise of stock options	—	—	120,110	12	217,146	—	—	217,158
Stock-based compensation expense	—	—	—	—	1,912,744	—	—	1,912,744
Issuance of common shares in connection with At-The-Market financing, net of $658,801 of issuance costs	—	—	3,274,360	328	9,452,867	—	—	9,453,195
Issuance of common shares in connection with the Private Placement Offerings, net of $136,456 of issuance costs	—	—	5,156,205	516	2,683,987	—	—	2,684,503
Issuance of warrants in connection with the Private Placement Offerings	—	—	—	—	1,917,075	—	—	1,917,075
Exercise of warrants	—	—	545,309	54	3,191,621	—	—	3,191,675
Reclassification of liability classified warrants to equity	—	—	—	—	6,870,296	—	—	6,870,296
Foreign currency translation adjustment	—	—	—	—	—	—	(14,355)	(14,355)
Net loss	—	—	—	—	—	(23,254,656)	—	(23,254,656)
Balance at December 31, 2024	—	$ —	26,157,788	$ 2,616	$ 90,897,468	$ (87,234,833)	$ (30,615)	$ 3,634,636

See the accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (22,396,172)	$ (23,254,656)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,631,652	1,912,744
Restricted shares issued for consulting and research expense	618,813	179,490
Change in fair value of warrant liability	(1,198,210)	6,682,758
Loss on fair value of warrants over proceeds	—	12,952
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(579,766)	(195,935)
Australia research and development incentives receivable	80,410	56,805
Accounts payable	519,720	(118,827)
Accrued expenses	1,478,955	(979,792)
Net cash used in operating activities	(18,844,598)	(15,704,461)
Cash flows from financing activities:		
Proceeds from exercise of stock options	844	217,158
Proceeds from exercise of warrants	901,578	—
Proceeds from private placement round 1 2024	—	2,920,696
Proceeds from private placement round 2 2024	—	1,327,990
Proceeds from private placement round 3 2024	—	1,004,999
Proceeds from private placement round 4 2024	—	2,439,236
Proceeds from private placement round 5 2024	—	949,791
Proceeds from private placement round 1 2025	2,715,000	—
Proceeds from private placement round 2 2025	1,428,949	—
Proceeds from private placement round 3 2025	1,079,998	—
Proceeds from private placement round 4 2025	694,999	—
Proceeds from private placement round 5 2025	2,253,900	—
Proceeds from private placement round 6 2025	736,600	—
Proceeds from private placement round 7 2025	1,509,796	—
Proceeds from At-The-Market offering	7,202,016	10,111,996
Payment of offering transactions costs	(617,133)	(795,257)
Net cash provided by financing activities	17,906,547	18,176,609
Net effect of foreign currency exchange on cash	(5,216)	(21,545)
Net (decrease) increase in cash	(943,267)	2,450,603
Cash at beginning of period	9,601,298	7,150,695
Cash at end of period	$ 8,658,031	$ 9,601,298
Supplemental disclosure of cash flow information:		
Warrants issued in connection with private placement offering 1 2024	$ —	$ 2,049,600
Warrants issued in connection with private placement offering 2 2024	$ —	$ 1,190,111
Warrants issued in connection with private placement offering 3 2024	$ —	$ 677,919
Warrants issued in connection with private placement offering 4 2024	$ —	$ 1,800,389
Warrants issued in connection with private placement offering 5 2024	$ —	$ 635,345
Warrants issued in connection with private placement offering 1 2025	$ 1,107,202	$ —
Warrants issued in connection with private placement offering 2 2025	$ 571,566	$ —
Warrants issued in connection with private placement offering 3 2025	$ 462,592	$ —
Warrants issued in connection with private placement offering 4 2025	$ 300,245	$ —
Warrants issued in connection with private placement offering 5 2025	$ 865,348	$ —
Warrants issued in connection with private placement offering 6 2025	$ 251,539	$ —
Warrants issued in connection with private placement offering 7 2025	$ 546,723	$ —

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:

- In July 2021, the Company established a wholly owned Australian subsidiary, MAIA Biotechnology Australia Pty Ltd, to conduct various pre-clinical and clinical activities for the development of the Company's product candidates.

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

Liquidity

At December 31, 2025, the Company had working capital of $3,865,458, an accumulated deficit of $109,631,005, cash of $8,658,031 and current liabilities of $5,836,398. Since its 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.

Impact of the War in Ukraine and War in Israel on Our Operations

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

Basis of Presentation and Consolidation Principles

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

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

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker ("CODM") in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's Chief Executive Officer, view the Company's operations and manage its business as a single operating segment, which is the business of discovering and developing products for the treatment of immunotherapies for cancer. Segment Assets are reported on the consolidated balance sheets as total assets. For additional information, see Note 9 - Segment Information.

Use of Estimates

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

Certain Risks and Uncertainties

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

Foreign Currency Translation

The financial statements of the Company's foreign subsidiaries, where the local currency is the functional currency, are translated using exchange rates in effect as of the applicable balance sheet dates for assets and liabilities and average exchange rates during the period for results of operations. The resulting foreign currency translation adjustment is included in stockholders' equity as accumulated other comprehensive loss.

Off-Balance Sheet Risk and Concentrations of Credit Risk

The Company has no significant off-balance sheet risks, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Cash accounts are maintained at financial institutions that potentially subject the Company to concentrations of credit risk. At December 31, 2025 and 2024, substantially all of the Company's cash was deposited in accounts at two financial institutions. The Company maintains its cash deposits, which at times may exceed the federally insured limits of $250,000 per financial institution, with a reputable financial institutions. 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, 2025 and 2024, the Company has no cash equivalents.

Fair Value Measurements

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

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

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

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of and during the years ended December 31, 2025 and 2024. The carrying amount of accounts payable approximated fair value as they are short term in nature. The fair value of warrants issued for services is estimated based on the Black-Scholes model during the years ended December 31, 2025 and 2024. The estimated fair value of the warrants issued with the convertible notes, warrants issued to underwriters and embedded features, represented Level 3 measurements.

General and Administrative

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

Research and Development

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

As part of the process of preparing the consolidated financial statements, the Company is required to estimate its prepaid or accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice the Company monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its prepaid or accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to the Company at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. The significant estimates in the Company's prepaid or accrued research and development expenses are related to expenses incurred with respect to CROs and other vendors in connection with research and development and manufacturing activities.

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

Research and Development Incentive

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

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

National Institute of Health (NIH) Grant

The Company entered into an agreement with the National Cancer Institute for SBIR grant. Under the terms of the agreement, the National Cancer Institute has committed to reimburse the Company up to $2,297,863 of qualifying research and development expenses over the three year term of the grant. The Company's ability to receive these funds is contingent upon incurring eligible costs and achieving certain performance objectives. For additional information, see Note 10 – Government Grants.

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. The Company has warrant liabilities deemed derivative instruments. Total warrant liabilities for the years ended December 31, 2025 and December 31, 2024 was $1,492,395 and $2,690,605, respectively.

Stock-Based Compensation

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

The Company uses the Black-Scholes-Merton option pricing model to determine the fair value of stock options. 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.

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

Common Stock Warrants

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

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

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.

Effective January 1, 2025, the Company adopted ASU 2023-09, Improvements to Income Tax Disclosures, which expanded income tax disclosure requirements, including disaggregation of pretax income (loss) and income tax expense (benefit) by jurisdiction and disclosure of income taxes paid (net of refunds received). The adoption affected disclosures only and did not impact the Company's financial position, results of operations, or cash flows.

In July 2025, the One Big Beautiful Bill Act (Public Law 119-21) was enacted. The Company recognized the income tax effects of the legislation in the period of enactment in accordance with ASC 740. The legislation did not have a material impact on the Company's consolidated financial statements for the year ended December 31, 2025. The Company will continue to evaluate the impact of the legislation on future periods.

No provision or benefit for U.S. federal, state, or Australian income taxes has been recorded for the years ended December 31, 2025 and 2024, mainly due to net losses incurred by the Company. A provision of approximately $2,000 and $2,000 for Romanian income tax was recorded for the years ended December 31, 2025 and 2024.

Deferred Offering Costs

Deferred offering costs consists of legal, accounting, underwriting fees and other costs that are directly related to a planned offerings and will be charged to additional paid-in capital upon the completion of the follow on offering. The Company had no offering costs as of December 31, 2025 and December 31, 2024, respectively.

Net Loss Per Share

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

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

	Years Ended December 31,	
	2025	**2024**
Shares issuable upon exercise of stock options	12,878,381	9,769,992
Shares issuable upon exercise of warrants	13,086,220	6,718,176

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. At the inception of an arrangement the Company determines whether the arrangement is or contains a lease based on the circumstances present. All leases with a term greater than one year are recognized on the consolidated balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the consolidated balance sheet leases with terms of one year or less. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. At the inception of an arrangement the Company determines whether the arrangement is or contains a lease based on the circumstances present. Currently none of the Company's operating lease commitments are subject to the standard as its leases are short-term in nature (i.e., less than twelve months).

Recent Accounting Standards

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures, which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The adoption did not have an impact on the Company's financial condition or results of operations. See Note 8 – Income Taxes.

In March 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses, which requires detailed disclosure of significant expense components and additional clarity when expenses are classified by function. ASU No. 2024-03 is effective for fiscal years beginning after December 15, 2026 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. We do not expect the amendments in this ASU to have a material impact on our consolidated financial statements.

In December 2025, the FASB issued ASU 2025-10, Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities, which requires recognizing grants when compliance with conditions is probable. ASU 2025-10 is effective for fiscal years beginning after December 15, 2028 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The adoption did have an immaterial impact on the Company's financial condition or results of operations. See Note 10 – Government Grants.

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.

2. RELATED PARTY TRANSACTIONS

Consulting Services

The consulting firm FGMK, LLC and its affiliate FGMK Business Holdings, LLC beneficially owns more than 5% of the stock of the Company and is therefore a related party. On June 2, 2025, the Company expensed $31,570 related to the grant of 18,040 restricted shares of Common Stock for payment of their accounting, tax and valuation services. On November 14, 2025, the Company expensed $33,500 related to the grant of 32,211 restricted shares of Common Stock for payment of their accounting, tax and valuation services. In addition, FGMK Business Holdings, LLC participated in the February 2025 private placement and purchased 1,350,000 shares of the Company's Common Stock and warrants to purchase 1,350,000 shares of the Company's Common Stock for an aggregate purchase price of approximately $2,025,000. FGMK Business Holdings, LLC also participated in the October 2025 private placement and purchased 769,230 shares of the Company's Common Stock and warrants to purchase 769,230 shares of the Company's Common Stock for an aggregate purchase price of approximately $999,999. On September 18, 2025, FGMK Business Holdings, LLC participated in the Warrant Inducement and exercised 243,470 warrants for a purchase price of approximately $317,000. In addition, FGMK Business Holdings, LLC participated in the Warrant Amendment on September 29, 2025, reducing the exercise price of certain warrants they hold from $1.87 to $1.30 per share.

10b5-1 Plan

Certain of our directors and executive officers previously adopted written plans, known as Rule 10b5-1 plans, in which they contracted with a broker to buy shares of our Common Stock on a periodic basis. Each of these plans have expired as of the date of the accompanying consolidated financial statements. Our directors and executive officers may, in the future, adopt Rule 10b5-1 plans in which they 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 at the time was entered into, 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.

Private Placements

The following Company directors participated in the March 2024 private placement as follows: (i) Stan Smith purchased 170,940 shares of our Common Stock and warrants to purchase up to 170,940 shares of our Common Stock for an aggregate purchase price of approximately $200,000; (ii) Louie Ngar Yee purchased 170,940 shares of our Common Stock and warrants to purchase up to 170,940 shares of our Common Stock for an aggregate purchase price of approximately $200,000; (iii) Cristian Luput purchased 69,282 shares of our Common Stock and warrants to purchase up to 69,282 shares of our Common Stock for an aggregate purchase price of approximately $81,060; (iv) Steven Chaouki purchased 34,641 shares of our Common Stock and warrants to purchase up to 34,641 shares of our Common Stock for an aggregate purchase price of approximately $40,530; and (v) Ramiro Guerrero purchased 6,928 shares of our Common Stock and warrants to purchase up to 6,928 shares of our Common Stock for an aggregate purchase price of approximately $8,106.

The following Company directors participated in the April 2024 private placement as follows: (i) Stan Smith purchased 147,492 shares of our Common Stock and warrants to purchase up to 147,492 shares of our Common Stock for an aggregate purchase price of approximately $300,000; and (ii) Louie Ngar Yee purchased 19,665 shares of our Common Stock and warrants to purchase up to 19,665 shares of our Common Stock for an aggregate purchase price of approximately $40,000.

The following Company directors participated in the November 2024 private placement as follows: (i) Stan Smith purchased 100,000 shares of our Common Stock and warrants to purchase up to 100,000 shares of our Common Stock for an aggregate purchase price of approximately $225,900; (ii) Ramiro Guerrero purchased 88,534 shares of our Common Stock and warrants to purchase up to 88,534 shares of our Common Stock for an aggregate purchase price of approximately $200,000; (iii) Cristian Luput purchased 22,133 shares of our Common Stock and warrants to purchase up to 22,133 shares of our Common Stock for an aggregate purchase price of approximately $50,000; and (iv) Steven Chaouki purchased 22,133 shares of our Common Stock and warrants to purchase up to 22,133 shares of our Common Stock for an aggregate purchase price of approximately $50,000. In addition, the son of Company director Stan Smith purchased 40,000 shares and 40,000 warrants for an aggregate purchase price of approximately $90,360 and 5% stockholder FGMK Business Holdings, LLC purchased 243,470 shares and 243,470 warrants for a purchase price of approximately $550,000.

The following Company directors participated in the December 2024 private placement as follows: (i) Stan Smith purchased 25,000 shares of our Common Stock and warrants to purchase up to 25,000 shares of our Common Stock for an aggregate purchase price of approximately $46,800; and (ii) Ramiro Guerrero purchased 54,518 shares of our Common Stock and warrants to purchase up to 53,418 shares of our Common Stock for an aggregate purchase price of approximately $100,000. In addition, Sylvia Guerrero, the sister of one of the Company directors, purchased 5,341 shares and 5,341 warrants for an aggregate purchase price of approximately $10,000.

The following Company directors participated in the February 2025 private placement as follows: (i) Stan Smith purchased 50,000 shares of our Common Stock and warrants to purchase up to 50,000 shares of our Common Stock for an aggregate purchase price of approximately $75,000; and (ii) Ramiro Guerrero purchased 73,333 shares of our Common Stock and warrants to purchase up to 73,333 shares of our Common Stock for an aggregate purchase price of approximately $110,000.

The following Company directors participated in the March 2025 private placement as follows: (i) Stan Smith purchased 25,000 shares of our Common Stock and warrants to purchase up to 25,000 shares of our Common Stock for an aggregate purchase price of approximately $37,500; and (ii) Ramiro Guerrero purchased 33,333 shares of our Common Stock and warrants to purchase up to 33,333 shares of our Common Stock for an aggregate purchase price of approximately $50,000.

The following Company directors participated in the May 2025 private placement as follows: (i) Stan Smith purchased 66,666 shares of our Common Stock and warrants to purchase up to 66,666 shares of our Common Stock for an aggregate purchase price of approximately $99,999; and (ii) Ramiro Guerrero purchased 20,000 shares of our Common Stock and warrants to purchase up to 20,000 shares of our Common Stock for an aggregate purchase price of approximately $30,000.

The following Company director participated in the June 2025 private placement as follows: Stan Smith purchased 33,333 shares of our Common Stock and warrants to purchase up to 33,333 shares of our Common Stock for an aggregate purchase price of approximately $50,000.

The following Company director participated in the October 2025 private placement as follows: Stan Smith purchased 19,230 shares of our Common Stock and warrants to purchase up to 19,230 shares of our Common Stock for an aggregate purchase price of approximately $25,000.

The following Company directors participated in the December 2025 private placement as follows: (i) Stan Smith purchased 57,189 shares of our Common Stock and warrants to purchase up to 57,189 shares of our Common Stock for an aggregate purchase price of approximately $70,000; (ii) Louie Ngar Yee purchased 81,699 shares of our Common Stock and warrants to purchase up to 81,699 shares of our Common Stock for an aggregate purchase price of approximately $100,000; and (iii) Steven Chaouki purchased 40,849 shares of our Common Stock and warrants to purchase 40,849 shares of our Common Stock for an aggregate purchase price of approximately $50,000.

3. ACCRUED EXPENSES

As of December 31, 2025 and 2024, accrued expenses consisted of the following:

	December 31, 2025	December 31, 2024
Bonus	$ 1,199,955	$ 941,098
Professional fees	288,077	123,317
Research and development costs	2,061,497	1,035,355
Other	248,066	217,832
Total accrued expenses	$ 3,797,595	$ 2,317,602

Accrued Bonus

During the years ended December 31, 2025 and 2024, the Company accrued $1,199,955 and $941,098, respectively, in bonus expense relating to employees and officers of the Company. In April 2025, the Compensation Committee determined that bonuses relating to 2024 would not be paid to all executive and non-executive employees. This change in estimated bonuses was recorded against the same general ledger accounts that the original estimate was recorded to and is reflected within the general and administrative expenses and research and development expenses on the statement of operations for the year ended December 31, 2025.

4. FAIR VALUE OF FINANCIAL LIABILITIES

Derivative Liability

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

	Fair value at December 31, 2025			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	$ 1,492,395	$ —	$ —	$ 1,492,395
Total liabilities	$ 1,492,395	$ —	$ —	$ 1,492,395

	Fair value at December 31, 2024			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	$ 2,690,605	$ —	$ —	$ 2,690,605
Total liabilities	$ 2,690,605	$ —	$ —	$ 2,690,605

As of December 31, 2025 and 2024, the Company had warrant liabilities of $1,492,395 and $2,690,605, respectively. The table below provides a summary of the changes in fair value of the warrant liabilities measured on a recurring basis using significant unobservable inputs (Level 3):

	Years Ended December 31,	
Warrant liabilities:	2025	2024
Balance, beginning of period	$ 2,690,605	$ 2,152,188
Issuance of warrants	—	3,917,630
Exercise of warrants	—	(3,191,675)
Amendment of warrants	—	(6,870,296)
(Gain) loss on fair value of warrant liability	(1,198,210)	6,682,758
Balance, end of period	$ 1,492,395	$ 2,690,605

5. STOCKHOLDERS' EQUITY

At-the-Market Offering (H.C. Wainwright)

On February 14, 2024, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), to sell shares of its Common Stock having an aggregate sales price of up to $1,445,000, from time to time, through an "at-the-market offering" program under which Wainwright will act as sales agent. Effective March 25, 2024, the Company filed a prospectus supplement to amend, supplement and supersede certain information contained in the earlier prospectus and prospectus supplement, which increased the number of shares of Common Stock the Company may offer and sell under the ATM Agreement to an aggregate offering price of up to $4,950,000 from time to time. Effective May 15, 2024, the Company filed a prospectus supplement to amend, supplement and supersede certain information contained in the earlier prospectus and prospectus supplement, which increased the number of Shares the Company may offer and sell under the ATM Agreement to an aggregate offering price of up to $11,280,000 from time to time. Effective December 23, 2024, the Company filed a prospectus supplement to amend, supplement and supersede certain information contained in the earlier prospectus and prospectus supplement, which increased the number of Shares the Company may offer and sell under the ATM Agreement to an aggregate offering price of up to $30,000,000 from time to time. Effective March 22, 2025, the Company filed a prospectus supplement to amend, supplement and supersede certain information contained in the earlier prospectus and prospectus supplement, which reduced the number of Shares the Company may offer and sell under the ATM Agreement to an aggregate offering price of up to $11,200,000 from time to time.

As of the date of this Annual Report, the Company has sold 3,782,335 shares of its Common Stock under the ATM Agreement at an average price of $1.90 per share, resulting in aggregate gross proceeds of approximately $7,202,016, for which we paid Wainwright $216,060 in commissions and other financing expenses of $111,555 resulting in net proceeds to us of approximately $6,874,401.

Private Placements

On March 14, 2024, the Company issued and sold 2,496,318 shares of our Common Stock and warrants to purchase 2,496,318 shares of its Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated March 11, 2024 at a price $1.17 per share, for which we received gross proceeds of approximately $2.92 million. The warrants are exercisable at a price per Share of $1.30, are exercisable commencing six months following issuance have a term of five and a half years from the initial issuance date., and expiring on September 14, 2029 The securities sold to the Company's directors participating in the private placement were issued pursuant to the MAIA Biotechnology, Inc. 2021 Equity Plan (the "MAIA 2021 Plan").

On March 28, 2024, the Company issued and sold 578,643 shares of our Common Stock and warrants to purchase 578,643 shares of its Common Stock in a private placement to certain accredited investors pursuant to securities purchase agreements dated March 25, 2024 at a price of $2.295 per share, for which we received gross proceeds of approximately $1.33 million. The warrants are exercisable at a price per Share of $2.55, are exercisable commencing six months following issuance, have a term of five and a half years from the initial issuance date and expiring on September 28, 2029.

On April 25, 2024, the Company issued and sold 494,096 shares of its Common Stock and warrants to purchase 494,096 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated April 22, 2024 at a price of $2.034 per share, for which we received gross proceeds of approximately $1.0 million. The warrants are exercisable at a price per Share of $2.26, are exercisable commencing six months following issuance, have a term of five and a half years from the initial issuance date, and expiring October 25, 2029. The securities sold to the Company's directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

On November 1, 2024, the Company issued and sold 1,079,784 shares of its Common Stock and warrants to purchase 1,079,784 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated October 28, 2024 at a price of $2.259 per share, for which we received gross proceeds of approximately $2.44 million. The warrants are exercisable at a price per Share of $2.51, are exercisable commencing six months following issuance, have a term of five and a half years from the initial issuance date, and expiring on May 1, 2030. The securities sold to the Company's directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

On December 13, 2024, the Company issued and sold 507,364 shares of its Common Stock and warrants to purchase 507,364 shares of our Common Stock in a private placement to certain accredited investors and to our participating directors pursuant to securities purchase agreements dated December 9, 2024 at a price of $1.872 per share, for which we received gross proceeds of approximately $950,000. The warrants are exercisable at a price per Share of $2.08, are exercisable commencing six months following issuance and have a term of five and a half years from the initial issuance date, and expiring June 13, 2030. The securities sold to the Company's directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

On February 24, 2025, the Company issued and sold 1,810,000 shares of its Common Stock and warrants to purchase 1,810,000 shares of its Common Stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated February 18, 2025 at a price per share of $1.50 for which the Company received gross proceeds of approximately $2.7 million. The warrants are exercisable at a price per share of $1.87, are exercisable commencing one year following issuance, have a term of six years from the issuance date, and expiring on February 24, 2031. The securities sold to Company directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

On March 3, 2025, the Company issued and sold 952,633 shares of its Common Stock and warrants to purchase 952,633 shares of its Common Stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated February 24, 2025 at a price per share of $1.50 for which the Company received gross proceeds of approximately $1.4 million. The warrants are exercisable at a price per share of $1.85, are exercisable commencing one year following issuance, have a term of six years from the issuance date, and expiring on March 3, 2031. The securities sold to Company directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

On May 8, 2025, the Company issued and sold 719,999 shares of its Common Stock and warrants to purchase 719,999 shares of its Common Stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated May 5, 2025 at a price per share of $1.50 for which the Company received gross proceeds of approximately $1.08 million. The warrants are exercisable at a price per share of $2.05, are exercisable commencing one year following issuance, have a term of six years from the issuance date, and expiring on May 8, 2031. The securities sold to Company directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

On June 3, 2025, the Company issued and sold 463,332 shares of its Common Stock and warrants to purchase 463,332 shares of its Common Stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated May 27, 2025 at a price per share of $1.50 for which the Company received gross proceeds of approximately $0.7 million. The warrants are exercisable at a price per share of $1.71, are exercisable commencing six months following issuance, have a term of five years from the issuance date, and expiring on June 3, 2030. The securities sold to Company directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

On October 1, 2025, the Company issued and sold 1,733,766 shares of its Common Stock and warrants to purchase 1,733,766 shares of its Common Stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated September 29, 2025 at a price per share of $1.30 for which the Company received gross proceeds of approximately $2.3 million. The warrants are exercisable at a price per share of $1.57, are exercisable commencing six months following issuance, have a term of three years from the issuance date, and expiring on October 1, 2028. The securities sold to Company directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

On October 16, 2025, the Company issued and sold 603,769 shares of its Common Stock and warrants to purchase 603,769 shares of its Common Stock in a private placement to certain accredited investors pursuant to securities purchase agreements dated October 13, 2025 at a price per share of $1.22 for which the Company received gross proceeds of approximately $0.7 million. The warrants are exercisable at a price per share of $1.52, are exercisable commencing six months following issuance, have a term of three years from the issuance date, and expiring on October 16, 2028.

On December 22, 2025, the Company issued and sold 1,233,488 shares of its Common Stock and warrants to purchase 1,233,488 shares of its Common Stock in a private placement to certain accredited investors and Company directors pursuant to securities purchase agreements dated December 16, 2025 at a price per share of $1.224 for which the Company received gross proceeds of approximately $1.5 million. The warrants are exercisable at a price per share of $1.36, are exercisable commencing six months following issuance, have a term of three years from the issuance date, and expiring on December 22, 2028. The securities sold to Company directors participating in the private placement were issued pursuant to the MAIA 2021 Plan.

MAIA Biotechnology, Inc. Restricted Stock Awards

During the year ended December 31, 2024, the Company expensed $179,490 for investor services and accounting, tax and valuation services under general and administrative expenses related to the grant of 75,550 restricted shares of Common Stock. There are no unvested restricted shares as of December 31, 2024.

During the year ended December 31, 2025, the Company expensed $165,070 for investor services and accounting, tax and valuation services under general and administrative expenses related to the grant of 114,767 restricted shares of Common Stock, and the Company expensed $453,745 for research and development services under research and development expenses related to the grant of 392,056 restricted shares of Common Stock. There are no unvested restricted shares as of December 31, 2025.

MAIA Stock Warrants

Concurrently with the closing of the Company's initial public offering, the Company issued warrants to purchase an aggregate of up to 100,000 shares of its Common Stock to the Representative or its designees, at an exercise price of $6.25 per share (the "Representative's Warrants"). The Representative's Warrants are exercisable beginning on January 23, 2023, and expire on July 27, 2027, pursuant to the terms and conditions of the Representative's Warrants. On August 3, concurrently with the full exercise of the Underwriter's over-allotment option, the Company issued additional warrants to purchase an aggregate of up to 15,000 shares of its Common Stock to the Representative or its designees on the same terms. The warrants are not indexed to the Company's own stock and therefore meet the definition of a derivative liability. The warrants are liability classified instruments and were initially recorded as $343,735, which was the value determined using the Black-Scholes-Merton method using a term of five years, risk free interest rate of 2.82% and volatility of 77.5%. As of December 31, 2025 and December 31, 2024 the Company remeasured the warrant liability resulting in a value of $27,455 and $71,672, respectively. The gain on remeasurement of the warrant liability in the amount of $44,217 and the loss on the remeasurement of $31,461 was included in other (expense) income for the years ended December 31, 2025 and December 31, 2024, respectively.

Concurrently with the closing of the Company's follow-on offering, the Company issued warrants to purchase an aggregate of up to 127,775 shares of its Common Stock to the Representative or its designees, at an exercise price of $2.81 per share (the "Follow-On Representative's Warrants"). The Follow-On Representative's Warrants are exercisable beginning on October 24, 2023, and expire on April 24, 2028, pursuant to the terms and conditions of the Follow-On Representative's Warrants. The Follow-On Representative's Warrants are equity classified instruments and the value of the Follow-On Representative's Warrants determined using the Black-Scholes-Merton method was $241,109 using the term of five years, risk free interest rate of 4.09% and volatility of 86.3%. During 2024, 116,532 warrants were exercised on various dates in cashless exercises and the investors were issued 22,869 shares of Common Stock. There were no warrants exercised in 2025. As of December 31, 2025, there are 11,243 warrants exercisable through April 24, 2028.

On November 9, 2023, the Company issued warrants to purchase an aggregate of up to 239,234 shares of its Common Stock to Alumni Capital LP, at an exercise price of $2.09 per share. The warrants are exercisable beginning on November 10, 2023, and expire on November 10, 2027, pursuant to the terms and conditions of the warrants. The warrants are not indexed to the Company's own stock and therefore meet the definition of a derivative liability. On November 13, 2023, 131,578 warrant shares vested in accordance with the terms. The warrants are liability classified instruments and were initially recorded as $84,251, which was the value determined using the Black-Scholes-Merton method using a term of 3.87 years, risk free interest rate of 3.93% and volatility of 90.0%. Laidlaw & Company Ltd. acted as the financial advisor to the Company in connection with the warrant and were paid a cash fee of $13,750. The warrants were exercised on May 22, 2024 in a cashless exercise and Alumni was issued 54,976 shares of Common Stock. The Company remeasured the warrant liability at the time of the exercise resulting in a value of $375,705. The warrant liability was removed to reflect the warrants being exercised and equity was increased by the value of $375,705. As of December 31, 2025, the warrant liability resulted in a value of $0 and as of December 31, 2024, $291,454 was included in other (expense) income.

On November 17, 2023, the Company issued warrants concurrently with the Company's registered direct offering to purchase an aggregate of up to 2,424,243 shares of its Common Stock to the investors in a registered direct offering at an exercise price of $1.86 per share (subject to customary adjustments set forth in the warrants). The warrants are exercisable six months following issuance and have a term of five years from the initial exercise date. The warrants contain customary anti-dilution adjustments to the exercise price, including share splits, share dividends, rights offerings and pro rata distributions. The warrants are not indexed to the Company's own stock and therefore meet the definition of a derivative liability. The warrants are liability classified instruments and were initially recorded as $1,903,915, which was the value determined using the Black-Scholes-Merton method using a term of 5.38 years, risk free interest rate of 3.85% and volatility of 90.0%. In 2024, 909,091 warrants were exercised on various dates in cashless exercises and the investor was issued 909,091 shares of Common Stock. There were no warrants exercised in 2025. As of December 31, 2025 and December 31, 2024, the Company remeasured the warrant liability resulting in a value of $1,216,774 and $2,189,478, respectively. The gain on remeasurement of the warrant liability of $972,704 and the loss on the remeasurement of $3,101,533 was included in other (expense) income for the years ended December 31, 2025 and December 31, 2024, respectively.

On November 17, 2023, concurrently with the closing of the Company's registered direct offering, the Company issued warrants to purchase an aggregate of 169,697 shares of its Common Stock to the Representative or its designees, at an exercise price of $2.06 per share. These representative's warrants were exercisable beginning November 15, 2023, and expire on November 15, 2028, pursuant to their terms and conditions. The representative's warrants are not indexed to the Company's own stock and therefore meet the definition of a derivative liability. The representative's warrants are liability classified instruments and were initially recorded as $123,811, which was determined using the Black-Scholes-Merton method using a term of 4.88 years, risk free interest rate of 3.84% and volatility of 90.0%. As of December 31, 2025 and December 31, 2024, the Company remeasured the warrant liability resulting in a value of $130,553 and $230,038, respectively. The gain on remeasurement of the warrant liability in the amount of $99,485 and the loss on the remeasurement of $106,227 is included in other (expense) income for the years ended December 31, 2025 and December 31, 2024, respectively.

Concurrently with the closing of the Company's private placement on March 14, 2024, the Company issued warrants to purchase an aggregate of up to 2,496,318 shares of its Common Stock to the investors in the private placement, at an exercise price of $1.30 per share are exercisable beginning on September 14, 2024, and expire on September 14, 2029. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 452,731 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan and are equity classified instruments, and the value of these warrants determined using the Black-Scholes-Merton method was $230,685 using a term of 5.5 years, risk free interest rate of 4.20% and volatility of 95%. The warrants to purchase 2,043,587 share of the Company's Common Stock issued to non-affiliated investors were not indexed to the Company's own stock and therefore met the definition of a derivative liability. The warrants issued to non-affiliated investors were liability classified instruments when issued and were initially recorded at a value of $2,049,600, which was determined using the Black-Scholes-Merton method using a term of 5.5 years, risk free interest rate of 4.20% and volatility of 95.0%. In May 2024, the Company amended the warrant agreements to adjust them to be indexed to the Company's own stock, and they were therefore reclassed to equity classified instruments in a non-cash transaction. When the warrant agreements were amended, the Company remeasured the warrant liability resulting in a final warrant value of $5,089,063. The warrant liability for these warrants was removed and equity was increased by $5,089,063 to account for the equity classification. The loss on the remeasurement of the warrant liability in the amount of $0 and $3,039,463 is included in other (expense) income for the years ended December 31, 2025 and December 31, 2024, respectively.

Concurrently with the closing of the Company's private placement offering on March 28, 2024, the Company issued warrants to purchase an aggregate of up to 578,643 shares of its Common Stock to the investors in the private placement at an exercise price of $2.55 per share. The warrants are exercisable beginning on September 28, 2024, and expire on September 28, 2029. The warrants were not indexed to the Company's own stock and therefore meet the definition of a derivative liability. The warrants were liability classified instruments when issued and were initially recorded at a value of $1,190,111, which was determined using the Black-Scholes-Merton method using a term of 5.5 years, risk free interest rate of 4.20% and volatility of 95.0%. In May 2024, the Company amended the warrant agreements related to 437,031 warrants to adjust them to be indexed to the Company's own stock, and they were therefore reclassed to equity classified instruments in a non-cash transaction. When the warrants agreements were amended, the Company remeasured the warrant liability resulting in a final warrant value of $1,011,562. The warrant liability for these 437,031 warrants was removed and equity was increased by $1,011,562 to account for the equity classification. The loss on the remeasurement of the warrant liability in the amount of $0 and $112,708 is included in other (expense) income for the years ended December 31, 2025 and December 31, 2024, respectively. In 2025, 108,931 equity classified warrants were exercised on various dates and the investors were issued 108,931 shares of Common Stock. The remaining 141,612 warrants remain liability classified instruments. As of December 31, 2025 and December 31, 2024, the Company remeasured the warrant liability, resulting in a value of $117,613 and $199,417, respectively. The gain on remeasurement of the warrant liability in the amount of $81,804 and $91,840 is included in other (expense) income for the years ended December 31, 2025 and December 31, 2024, respectively.

Concurrently with the closing of the Company's private placement offering on April 25, 2024, the Company issued warrants to purchase an aggregate of up to 494,096 shares of its Common Stock to the investors in the private placement at an exercise price of $2.26 per share. The warrants are exercisable beginning on October 25, 2024, and expire on October 25, 2029. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 167,157 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $346,606 using a term of 5.5 years, risk free interest rate of 4.70% and volatility of 95%. The warrants to purchase 326,939 shares of the Company's Common Stock issued to non-affiliated investors were not indexed to the Company's own stock and therefore met the definition of a derivative liability. The warrants were liability classified instruments when issued and were initially recorded at a value of $677,919, which was determined using the Black-Scholes-Merton method using a term of 5.5 years, risk free interest rate of 4.70% and volatility of 95.0%. In May 2024, the Company amended these warrant agreements to adjust them to be indexed to the Company's own stock, and they were therefore reclassed to equity classified instruments in a non-cash transaction. When the warrant agreements were amended, the Company remeasured the warrant liability resulting in a final warrant value of $769,671. The warrant liability for these warrants were removed and equity was increased by $769,671 to account for the equity classification. In 2025, 12,291 warrants were exercised on various dates and the investors were issued 12,291 shares of Common Stock. The loss on the remeasurement of the warrant liability in the amount of $0 and $91,752 is included in other (expense) income for the years ended December 31, 2025 and December 31, 2024, respectively.

Concurrently with the closing of the Company's private placement offering on November 1, 2024, the Company issued warrants to purchase an aggregate of up to 1,079,784 shares of its Common Stock to the investors in the private placement at an exercise price of $2.51 per share. The warrants are exercisable beginning on May 1, 2025, and expire on May 1, 2030. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 232,800 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $494,851 using a term of 5.5 years, risk free interest rate of 4.22% and volatility of 95%. The warrants to purchase 846,984 shares of the Company's Common Stock issued to non-affiliated investors are indexed to the Company's own stock, and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $1,800,389 using a term of 5.5 years, risk free interest rate of 4.22% and volatility of 95%. In 2025, 379,970 warrants were exercised on various dates and the investors were issued 379,970 shares of Common Stock.

Concurrently with the closing of the Company's private placement offering on December 13, 2024, the Company issued warrants to purchase an aggregate of up to 507,364 shares of its Common Stock to the investors in the private placement at an exercise price of $2.08 per share. The warrants are exercisable beginning on June 13, 2025, and expire on June 13, 2030. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 78,418 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $116,151 using a term of 5.5 years, risk free interest rate of 4.25% and volatility of 95%. The warrants to purchase 428,946 shares of the Company's Common Stock issued to non-affiliated investors are indexed to the Company's own stock and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $635,345 using a term of 5.5 years, risk free interest rate of 4.25% and volatility of 95%. In 2025, 80,127 warrants were exercised on various dates and the investors were issued 80,127 shares of Common Stock.

Concurrently with the closing of the Company's private placement offering on February 24, 2025, the Company issued warrants to purchase an aggregate of up to 1,810,000 shares of its Common Stock to the investors in the private placement at an exercise price of $1.87 per share. The warrants are exercisable beginning on February 24, 2026, and expire on February 24, 2031. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to affiliated and non-affiliated investors. The warrants to purchase 123,333 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $176,680 using a term of 6 years, risk free interest rate of 4.23% and volatility of 95%. The warrants to purchase 1,686,667 shares of the Company's Common Stock issued to affiliated and non-affiliated investors are indexed to the Company's own stock and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $2,416,223 using a term of 6 years, risk free interest rate of 4.23% and volatility of 95%. The total fair value ascribed to the warrants combined with the fair value of the common stock issued in the private placement was then used for purposes of allocation of the equity classified warrant value within the consolidated statements of changes in the stockholders' equity.

Concurrently with the closing of the Company's private placement offering on March 3, 2025, the Company issued warrants to purchase an aggregate of up to 952,633 shares of its Common Stock to the investors in the private placement at an exercise price of $1.85 per share. The warrants are exercisable beginning on March 3, 2026, and expire on March 3, 2031. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 58,333 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $80,894 using a term of 6 years, risk free interest rate of 3.97% and volatility of 95%. The warrants to purchase 894,300 shares of the Company's Common Stock issued to non-affiliated investors are indexed to the Company's own stock and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $1,240,185 using a term of 6 years, risk free interest rate of 3.97% and volatility of 95%. The total fair value ascribed to the warrants combined with the fair value of the common stock issued in the private placement was then used for purposes of allocation of the equity classified warrant value within the consolidated statements of changes in the stockholders' equity.

Concurrently with the closing of the Company's private placement offering on May 8, 2025, the Company issued warrants to purchase an aggregate of up to 719,999 shares of its Common Stock to the investors in the private placement at an exercise price of $1.50 per share. The warrants are exercisable beginning on May 8, 2026, and expire on May 8, 2031. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 86,666 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $133,131 using a term of 6 years, risk free interest rate of 4.09% and volatility of 95%. The warrants to purchase 633,333 shares of the Company's Common Stock issued to non-affiliated investors are indexed to the Company's own stock and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $972,890 using a term of 6 years, risk free interest rate of 4.09% and volatility of 95%. The total fair value ascribed to the warrants combined with the fair value of the common stock issued in the private placement was then used for purposes of allocation of the equity classified warrant value within the consolidated statements of changes in the stockholders' equity.

Concurrently with the closing of the Company's private placement offering on June 3, 2025, the Company issued warrants to purchase an aggregate of up to 463,332 shares of its Common Stock to the investors in the private placement at an exercise price of $1.71 per share. The warrants are exercisable beginning on December 3, 2025, and expire on June 3, 2030. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 33,333 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $43,358 using a term of 5 years, risk free interest rate of 4.04% and volatility of 95%. The warrants to purchase 429,999 shares of the Company's Common Stock issued to non-affiliated investors are indexed to the Company's own stock and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $559,324 using a term of 5 years, risk free interest rate of 4.04% and volatility of 95%. The total fair value ascribed to the warrants combined with the fair value of the common stock issued in the private placement was then used for purposes of allocation of the equity classified warrant value within the consolidated statements of changes in the stockholders' equity.

On June 17, 2025, the Company executed a Warrant Inducement Offer to select warrant holders allowing them to exercise their warrants held at a reduction of the exercise price for cash. The warrant's exercise price was reduced to $1.50 per share. Certain warrant holders accepted the offer and warrants were exercised, resulting in the issuance of 219,283 shares of MAIA Common Stock for proceeds of approximately $328,924. The fair value of the modified warrants was greater than the fair value of the original warrants at the modification date by $105,154; therefore, the incremental cost was recognized as an increase to warrant additional paid in capital and a decrease to additional paid in capital, there was no net equity difference.

On September 18, 2025, the Company executed a Warrant Inducement Offer to select warrant holders allowing them to exercise their warrants held at a reduction of the exercise price for cash. The warrant's exercise price was reduced to $1.30 per share. Certain warrant holders accepted the offer and warrants were exercised, resulting in the issuance of 440,503 shares of MAIA Common Stock for proceeds of approximately $572,654. The fair value of the modified warrants was greater than the fair value of the original warrants at the modification date by $60,275; therefore, the incremental cost was recognized as an increase to warrant additional paid in capital and a decrease to additional paid in capital, there was no net equity difference.

On September 29, 2025, the Company amended the price of selected warrants to select warrant holders reducing the exercise price from $1.87 to $1.30 per share. The fair value of the modified warrant cost was greater than the fair value of the original warrants at the modification date by $124,127; therefore, the incremental cost was recognized as an increase to warrant additional paid in capital and a decrease to additional paid in capital, there was no net equity difference.

Concurrently with the closing of the Company's private placement offering on October 1, 2025, the Company issued warrants to purchase an aggregate of up to 1,733,766 shares of its Common Stock to the investors in the private placement at an exercise price of $1.57 per share. The warrants are exercisable beginning on April 1, 2026, and expire on October 1, 2028. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 19,230 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $18,818 using a term of 3 years, risk free interest rate of 3.56% and volatility of 90%. The warrants to purchase 1,714,536 shares of the Company's Common Stock issued to non-affiliated investors are indexed to the Company's own stock and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $1,677,758 using a term of 3 years, risk free interest rate of 3.56% and volatility of 90%. The total fair value ascribed to the warrants combined with the fair value of the common stock issued in the private placement was then used for purposes of allocation of the equity classified warrant value within the consolidated statements of changes in the stockholders' equity.

Concurrently with the closing of the Company's private placement offering on October 16, 2025, the Company issued warrants to purchase an aggregate of up to 603,769 shares of its Common Stock to the investors in the private placement at an exercise price of $1.52 per share. The warrants are exercisable beginning on April 16, 2026, and expire on October 16, 2028. The warrants to purchase 603,769 shares of the Company's Common Stock issued to non-affiliated investors are indexed to the Company's own stock and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $475,967 using a term of 3 years, risk free interest rate of 3.42% and volatility of 90%. The total fair value ascribed to the warrants combined with the fair value of the common stock issued in the private placement was then used for purposes of allocation of the equity classified warrant value within the consolidated statements of changes in the stockholders' equity.

As part of the closing of the Company's private placement offering on October 16, 2025, the Company issued warrants to purchase an aggregate 11,475 shares of its Common Stock as compensation to the Placement Agent at an exercise price of $1.52 per share. The warrants were issued as of November 5, 2025, are exercisable beginning on May 5, 2026, and expire on November 5, 2028. The warrants to purchase 11,475 shares of the Company's Common Stock issued to non-affiliated investors are indexed to the Company's own stock and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $6,518 using a term of 3 years, risk free interest rate of 3.65% and volatility of 90%.

Concurrently with the closing of the Company's private placement offering on December 22, 2025, the Company issued warrants to purchase an aggregate of up to 1,233,488 shares of its Common Stock to the investors in the private placement at an exercise price of $1.36 per share. The warrants are exercisable beginning on June 22, 2026, and expire on December 22, 2028. The warrants issued were divided into two groups: warrants issued to directors and warrants issued to non-affiliated investors. The warrants to purchase 179,737 shares of the Company's Common Stock issued to directors were deemed options issued under the MAIA 2021 Plan (as defined below) and are equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $138,784 using a term of 3 years, risk free interest rate of 3.56% and volatility of 90%. The warrants to purchase 1,053,751 shares of the Company's Common Stock issued to non-affiliated investors are indexed to the Company's own stock and they were therefore equity classified instruments and the value of these warrants determined using the Black-Scholes-Merton method was $813,657 using a term of 3 years, risk free interest rate of 3.56% and volatility of 90%. The total fair value ascribed to the warrants combined with the fair value of the common stock issued in the private placement was then used for purposes of allocation of the equity classified warrant value within the consolidated statements of changes in the stockholders' equity.

	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Balance at January 1, 2025	6,718,176	$ 2.37	4.56
Issued	7,027,830	1.58	—
Exercised	(659,786)	1.37	—
Expired	—	—	—
Balance at December 31, 2025	13,086,220	$ 1.92	3.13

	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Balance at January 1, 2024	3,650,278	$ 2.82	5.00
Issued	4,225,099	1.87	—
Exercised	(1,157,201)	1.98	—
Expired	—	—	—
Balance at December 31, 2024	6,718,176	$ 2.37	4.56

The Company's warrant liability, which relates to warrants to purchase shares of common stock, is measured at fair value at each reporting period and changes in fair value are recorded in other income (expense) within the statement of operations until the warrants are exercised, expire, or are reclassified to stockholders' equity. The weighted-average fair values of warrants issued during the years ended December 31, 2025 and 2024 were $1.58 and $1.87, respectively. The warrants vested as of December 31, 2025 and 2024 were 9,702,689 and 5,442,246, respectively.

	2025	2024
Risk-free interest rate	3.42% - 4.70%	4.2% - 4.7%
Expected term (in years)	3 - 6	5.5
Expected volatility	90% - 95%	95%
Expected dividend yield	—%	—%

MAIA Biotechnology, Inc. Stock Award Plans

In 2018, the Company adopted the MAIA Biotechnology, Inc. 2018 Stock Option Plan (the "MAIA 2018 Plan"). MAIA's board of directors administers the MAIA Plan for the purposes of attracting, retaining, and motivating key employees, directors, and consultants of MAIA. The terms of the MAIA 2018 Plan continue to govern the 1,773,912 options outstanding in the plan of December 31, 2025.

In 2020, the Company adopted the MAIA Biotechnology, Inc. Amended and Restated 2020 Equity Incentive Plan (the "MAIA 2020 Plan"), also administered by the board of directors. The MAIA 2020 Plan permitted awards to take the form of stock options, restricted stock and restricted stock units. The terms of the MAIA 2020 Plan continue to govern the 3,503.589 options outstanding in the plan as of December 31, 2025. There are no shares reserved for future issuance in the MAIA 2018 Plan or the MAIA 2020 Plan.

On August 1, 2022 the Company approved the MAIA Biotechnology, Inc. 2021 Equity Incentive Plan (the "MAIA 2021 Plan") with 1,909,518 shares of Common Stock reserved for issuance. On May 25, 2023, the MAIA 2021 Plan was amended to include an automatic increase to the plan in an amount equal to ten percent (10%) of the total number of shares of stock outstanding on a fully diluted basis on December 31 of the preceding calendar year (the "Increase Date"); provided that, the board of directors may act prior to any Increase Date to provide that there will be no increase for such year or that the increase for such year will be a lesser number of shares of stock. The amount reserved for issuance under the MAIA 2021 Plan increased by 1,956,993 based on the fully diluted shares outstanding as of December 31, 2022. The amount reserved for issuance under the MAIA 2021 Plan increased by 2,838,668 on January 1, 2024 based on the fully diluted shares outstanding as of December 31, 2023. The amount reserved for issuance under the MAIA 2021 Plan increased by 2,250,000 shares on January 1, 2025 based on the fully diluted shares outstanding as of December 31, 2024. As of December 31, 2025, there were 431,153 shares of Common Stock available for future issuance under the MAIA 2021 Plan and 7,600,880 options outstanding in the MAIA 2021 Plan. On December 31, 2025, the Company's board of directors increased the amount of shares available under the 2021 Plan by 6,458,889 shares to 6,890,042 shares effective January 1, 2026 pursuant to the annual increase provision, based on the fully diluted shares outstanding as of December 31, 2025.

Stock options are to be granted with an exercise price which is at least equal to the stock's estimated fair value at the date of grant, and with a contractual term of no more than ten years from the date of grant. In the case of an option granted to a 10% stockholder, the exercise price shall be generally no less than 110% of the fair market value per share on the date of grant, and the contractual term shall be seven years. Outstanding options awarded under the MAIA 2021 Plan may, but need not, vest and therefore become exercisable in periodic installments that may, but need not, be equal. The option may be subject to other terms and conditions as to the time or times when it may be exercised (which may be based on performance or other criteria) as the board of directors may deem appropriate. Unexercised options are canceled ninety days after termination of an employee, director, founder, or consultant. Unexercised options are canceled immediately if an employee, director, founder, or consultant is terminated for cause; under certain other circumstances, the period to cancellation may differ as described in the respective plan documents. Certain clauses in the MAIA 2018 Plan, the MAIA 2020 Plan, and the MAIA 2021 Plan (collectively, the "Plans") also govern the Company's exercise repurchase rights and various other features of awards granted under the Plans.

The following table summarizes the activity and information regarding MAIA's outstanding and exercisable options classified as equity awards as of December 31, 2025:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance at January 1, 2025	9,769,992	$ 2.43	6.68	-
Granted	4,019,830	1.73		
Exercised	(570)	1.48		
Cancelled/forfeited	(910,871)	2.69		
Balance at December 31, 2025	12,878,381	$ 2.19	6.42	$ 326,666
Options exercisable at December 31, 2025	9,562,606	$ 2.27	5.77	$ 231,171

The value of option grants are calculated using the Black-Scholes-Merton option pricing model with the following assumptions for options granted during the years ended December 31, 2025 and 2024.

	2025	2024
Risk-free interest rate	3.53% - 4.43%	3.51% - 4.77%
Expected term (in years)	5 – 6.10	5 - 6.25
Expected volatility	90.0% - 95.0%	95.0% - 152.5%
Expected dividend yield	—	—

The weighted-average fair values of stock options issued during the years ended December 31, 2025 and 2024 were $1.73 and $2.41, respectively. As of December 31, 2025, the total unrecognized compensation related to unvested employee and non-employee stock option awards granted was $3,507,096 which the Company expects to recognize over a weighted average period of approximately 2.35 years.

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

	Years Ended December 31,	
	2025	2024
General and administrative	$ 1,789,142	$ 1,274,206
Research and development	842,510	638,538
Total stock-based compensation	$ 2,631,652	$ 1,912,744

6. EMPLOYEE RETIREMENT PLAN

Our eligible employees have been permitted to participate in our 401(k) beginning October 1, 2022. Participation in the 401(k) plan is offered for the benefit of our employees, including our named executive officers, who remain employed with us, and who satisfy certain eligibility requirements. We match employee contributions using a benchmark to industry standards. The Company will make a safe harbor matching contribution equal to 100% of employee salary deferrals that do not exceed 1% of their compensation plus 50% of their salary deferrals between 1% and 6% of their compensation. The 2025 Company match is immaterial. 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.

7. 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

Ateganosine (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 ("ateganosine", "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 ateganosine. 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, 2025, 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 ateganosine 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, 2025, 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 ateganosine reaching specified sales levels in the respective jurisdictions) royalty payments on net sales up to $1,000,000, and 2.5-5% on net sales above $1,000,000,000.

The Company will also pay UTSW running royalties on a yearly basis as a percentage of Net Sales of the Company or its sublicensee. There are single digit royalty rates for licensed products and licensed services covered by a Valid Claim (as defined in the agreement) and dependent on whether Net Sales are greater than or less than/equal to $1,000,000,000, with Net Sales above that amount commanding a slightly higher percentage. In each case, the royalty percentage is lower before patent issuance in each jurisdiction. In the event that the licensed product or licensed service is not covered by a Valid Claim, the running royalty rates are reduced by fifty percent (50%). The royalty obligations continue on a country-by-country basis until the later of expiration of the last Valid Claim in each country or ten (10) years after the First Commercial Sale (as defined in UTSW2 Agreement) in each country.

Regeneron - In February 2021, the Company reached an agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron") to perform one clinical trial for the treatment of patients with Non-Small Cell Lung Cancer (NSCLC) involving a Regeneron drug candidate that utilizes one of the Company's compounds/agents. The Company is responsible for all costs of the study with Regeneron supplying their drug cemiplimab representing a cost savings for the Company. The overall term of the agreement is for five years unless earlier terminated for certain reasons as defined in the agreement. Either party may terminate a study plan in the event that patient screening for the clinical study does not commence within twelve (12) months after (a) the Effective Date, with respect to the initial study, or (b) the execution of the applicable study plan, with respect to each other study. If either party terminates a study plan, the Company shall reimburse Regeneron for the Regeneron product it received in connection with such study plan based on the actual out-of-pocket cost to Regeneron of such Regeneron product. The THIO-101 study protocol was amended in December 2024 to increase the number of patients enrolled in an expansion arm to further evaluate efficacy of the treatment in third-line NSCLC patients resistant to checkpoint inhibitor and chemotherapy. As of December 31, 2025 neither party has terminated the agreement.

BeOne Medicines, formerly known as BeiGene - In December 2024, the Company reached an agreement with BeiGene Swizerland GmbH, ("BeOne") to perform certain clinical trials for the treatment of patients with small cell lung cancer (SCLC), liver cancer (HCC), and colorectal cancer (CRC) involving a BeOne drug candidate that utilizes one of the Company's compounds/agents. The Company is responsible for all costs of the study with BeOne supplying their drug tislelizumab representing a cost savings for the Company. The overall term of the agreement is for seven years unless earlier terminated for certain reasons as defined in the agreement. As of December 31, 2025 neither party has terminated the agreement.

Roche - In June 2025, the Company reached an agreement with F. Hoffmann-La Roche Ltd, ("Roche") to perform certain clinical trials for the treatment of patients hard-to-treat cancers that utilizes one of the Company's compounds/agents. This agreement will continue in force for five years, unless terminated earlier by either party for certain reasons as defined in the agreement. The parties may mutually agree in writing to extend the term of this Agreement. As of December 31, 2025 neither party has terminated the agreement.

8. INCOME TAXES

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

	December 31,	
	2025	**2024**
Deferred tax assets:		
Net operating loss carryforwards	$ 13,883,039	$ 8,238,806
Stock-based compensation	2,290,106	1,753,825
Research and development	6,314,771	4,622,097
Accrued compensation	395,645	524,012
Other	—	49,420
Total net deferred tax assets before valuation allowance	22,883,561	15,188,160
Valuation allowance	(22,883,561)	(15,188,160)
Net deferred tax asset	$ —	$ —

At December 31, 2025, the Company has unused U.S. federal and state net operating loss ("NOL") carryforwards of $54.7 million that may be applied against future taxable income. The state NOL carryforwards begin to expire in 2030. The U.S. federal NOL carryforwards may be carried forward indefinitely, however are limited to 80 percent of taxable income. The Company has unused Australian NOL carryforwards of $0.3 million that may be carried forward indefinitely. The Company has unused U.S. federal research and development ("R & D") tax credits of $.07 million that begin to expire in 2041.

The use of the Company's NOL and R & D credit carryforwards may, however, be subject to limitations as a result of an ownership change. A corporation undergoes an "ownership change," in general, if a greater than 50% change (by value) in its equity ownership by one or more five-percent stockholders (or certain groups of non-five-percent stockholders) over a three year period occurs. After such an ownership change, the corporation's use of its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income is subject to an annual limitation determined by the equity value of the corporation on the date the ownership change occurs multiplied by a rate determined monthly by the Internal Revenue Service.

If an ownership change occurs and if the Company earns net taxable income, the Company's ability to use its pre-change NOLs to offset U.S. federal and taxable income would be subject to these limitations, which could potentially result in increased future tax liability compared to the tax liability the Company would incur if its use of NOL carryforwards were not so limited. In addition, for state income, franchise and similar tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase the Company's state income, franchise, or similar taxes.

In accordance with ASC 740, "Income Taxes," the Company recorded a valuation allowance to fully offset its deferred tax assets, because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets at December 31, 2025 and 2024.The valuation allowance increased by approximately $7.7 million during the year ended December 31, 2025, related to U.S. federal, state, and foreign jurisdictions in the amounts of $4.8 million, $2.8 million, and $0.1 million, respectively. The valuation allowance increased by approximately $4.8 million during the year ended December 31, 2024, related to the U.S. federal, state and foreign jurisdictions in the amount of $3.3 million, $1.5 million and zero, respectively Increases to the valuation allowance were mainly due to increases in the NOL carryforward and other deferred tax assets. The Company will continue to assess the realizability of the deferred tax assets at each interim and annual balance sheet date based upon actual and forecasted operating results.

The following table presents (loss) before income taxes disaggregated between U.S. domestic and foreign jurisdictions (in thousands):

	2025	2024
U.S. domestic	$ (22,181)	$ (23,120)
Foreign	(211)	(133)
Total	$ (22,392)	$ (23,253)

The following table presents income tax expense (benefit) disaggregated by jurisdiction and by type (current or deferred) (in thousands):

	2025 Current	2025 Deferred	2025 Total	2024 Current	2024 Deferred	2024 Total
U.S. federal	$ —	$ —	$ —	$ —	$ —	$ —
U.S. state	—	—	—	—	—	—
Foreign	2	—	2	2	—	2
Total	$ 2	$ —	$ 2	$ 2	$ —	$ 2

The foreign current income tax expense relates to Romania and is immaterial in relation to the Company's consolidated results of operations.

Income taxes paid (net of refunds received) were immaterial for the years ended December 31, 2025 and 2024. For disclosure purposes, amounts were zero or rounded to zero (in thousands):

	2025	2024
U.S. federal	$ —	$ —
U.S. state	—	—
Foreign	3	3
Total	$ 3	$ 3

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

	December 31,			
	2025		2024	
U.S. statutory federal income tax	$ (4,702)	21.0%	$ (4,883)	21.0%
State taxes, net of federal tax benefit	—	—%	—	—%
Foreign tax effects:				
Australia:				
Non-deductible research expenses	44	(0.2)%	19	(0.1)%
Other	3	0.0%	11	0.0%
Romania:				
Other	1	0.0%	2	0.0%
Effect of changes in tax laws or rates	—	—%	—	—%
Research tax credit	(240)	1.1%	(15)	0.1%
Change in U.S. federal valuation allowance	4,848	(21.7)%	3,328	(14.3)%
Nontaxable or nondeductible items:				
Stock-based compensation	313	(1.4)%	151	(0.7)%
Warrant amendments	(252)	1.1%	1,403	(6.0)%
Change in uncertain tax positions	—	—%	—	—%
Other adjustments:				
Global Intangible Low Taxed Income	—	0.0%	16	(0.1)%
Deferred tax asset adjustments	(13)	0.1%	(30)	0.1%
Income tax expense	$ 2	—%	$ 2	—%

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes any interest and penalties accrued related to unrecognized tax benefits as income tax expense. The Company did not have any significant unrecognized tax benefits during the years ended December 31, 2025 and 2024. The Company files income tax returns in the U.S. federal jurisdiction, several U.S. States, Australia, and Romania. The Company's tax returns since inception remain open to examination by the taxing authorities.

9. **SEGMENT INFORMATION**

The Company operates in one reportable segment. This determination is based on the Company's structure, the manner in which the chief operating decision maker ("CODM") reviews the operating results to assess performance and allocate resources, and the nature of the Company's operations. The CODM, who is the Chief Executive Officer, regularly reviews consolidated financial information, such as consolidated net loss. The CODM's review is for the purpose of assessing performance and making decisions about resource allocation. See our consolidated financial statement in Part II, "Item 8, Financial Statements and Supplementary Data", and Note 1, "Description of Business, Organization, and Principles of Consolidation" for additional information about these line items and the related accounting policies.

10. **GOVERNMENT GRANTS**

The Company receives research grants from the National Institutes of Health (NIH) to support specific primary research and clinical development projects. In accordance with ASU 2025-10, the Company accounts for these as government grants and has elected the income-related approach. Grant proceeds are recognized in the consolidated statements of operations when there is reasonable assurance that the Company will comply with the conditions attached to the grant and the grant will be received. The Company has elected to present these grant proceeds as a component of Other income, net, rather than as a reduction of the related Research and Development (R&D) expenses.

During the fiscal year ended December 31, 2025, the Company operated under one active NIH Small Business Innovation Research (SBIR) awards (Award #1R44CA309843-01). These grants are cost-reimbursable, meaning the Company is entitled to payment only after incurring allowable costs as defined by the NIH Grants Policy Statement. As of December 31, 2025, the Company has recognized a receivable of $0.4 million for qualified R&D expenditures that have been incurred but not yet reimbursed by the NIH.

NIH grants are subject to audit and retrospective adjustment by the granting agency to ensure compliance. While the Company believes it has complied with all material terms of the grant agreements, any costs found to be unallowable upon audit could be subject to repayment. As of December 31, 2025, no such repayment is deemed probable.

11. SUBSEQUENT EVENTS

Issuance of Options

From January 1 to March 23, 2026, the Company issued 463,263 options at a weighted exercise price of $1.53 to consultants.

Issuance of Stock

On January 12, 2026, the Company issued 8,362 shares of common stock having a value of $14,550.36 (based on $1.74 price using the calculated by using 120% of the dollar value weighted average price of our common stock on the New York Stock Exchange for the thirty (30) trading days immediately preceding the date of the purchase payment or the minimum share price of $1.74) to a service provider under a master services agreement in consideration of services rendered. The issuance was exempt under Section 4(a)(2) of the Securities Act of 1993, as amended.

On February 20, 2026, the Company issued 5,449 shares of common stock having a value of $14,550.36 (based on $2.67 price using the calculated by using 120% of the dollar value weighted average price of our common stock on the New York Stock Exchange for the thirty (30) trading days immediately preceding the date of the purchase payment or the minimum share price of $1.74) to a service provider under a master services agreement in consideration of services rendered. The issuance was exempt under Section 4(a)(2) of the Securities Act of 1993, as amended.

On March 12, 2026, the Company issued 6,037 shares of common stock having a value of $14,550.36 (based on $2.41 price using the calculated by using 120% of the dollar value weighted average price of our common stock on the New York Stock Exchange for the thirty (30) trading days immediately preceding the date of the purchase payment or the minimum share price of $1.74) to a service provider under a master services agreement in consideration of services rendered. The issuance was exempt under Section 4(a)(2) of the Securities Act of 1993, as amended.

Underwritten Public Offering

On March 4, 2026, the Company closed an underwritten public offering of 20,000,000 shares of its common stock at a public offering price of $1.50 per share for aggregate gross proceeds of $30 million, prior to deducting underwriting discounts and other offering expenses. In addition, on March 9, 2026, the Company closed on the partial exercise of underwriter over-allotment option for the above referenced public offering for an additional 2,005,875 shares of common stock at the public offering price of $1.50 per share resulting in additional gross proceeds of approximately $3 million. After giving effect to the partial exercise of the over-allotment option, the total number of shares sold by Company in the public offering increased to 22,005,875 and gross proceeds increased to approximately $33 million.

These subsequent events may have a material impact on the Company’s financial position, results of operations, and cash flows in future periods, and they are disclosed here for informational purposes. Investors should consider the potential impact of these events on their assessments of the Company’s financial condition and performance.

Liquidity Considerations

Subsequent to December 31, 2025, the Company successfully executed an underwritten public offering resulting in gross proceeds of approximately $33 million. The Company’s current cash position provides sufficient liquidity to meet its obligations for at least twelve months from the issuance date of this report. As a result of receiving these proceeds, management has concluded that substantial doubt regarding the Company’s ability to continue as a going concern no longer exists.