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 **001-40804**

PASITHEA THERAPEUTICS CORP.
(Exact name of registrant as specified in its charter)

Delaware	**85-1591963**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
1111 Lincoln Road, Suite 500 Miami Beach, Florida	**33139**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(786) 977-3380**

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, par value $0.0001 per share	KTTA	The Nasdaq Capital Market
Warrants to purchase shares of Common Stock, par value $0.0001 per share	KTTAW	The Nasdaq Capital Market

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 Section 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☒
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 Act). Yes ☐ No ☒

The aggregate market value of the common stock, par value $0.0001 per share ("Common Stock"), held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2025) was $5.1 million.

As of March 24, 2026, there were 24,939,948 shares of the registrant's Common Stock outstanding. This number does not include 64,053,335 shares of Common Stock issuable upon the exercise of pre-funded warrants outstanding as of March 24, 2026 (which are immediately exercisable at an exercise price of $0.001 per share of Common Stock,

subject to beneficial ownership limitations).

DOCUMENTS INCORPORATED BY REFERENCE

None.

PASITHEA THERAPEUTICS CORP.
2025 FORM 10-K ANNUAL REPORT

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. These forward-looking statements speak only as of the date of filing this annual report with the SEC and include, without limitation, statements about the following:

- our limited operating history;
- the expectation that we will incur significant operating losses for the foreseeable future and will need significant additional capital;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our plans to develop and commercialize our product candidates involves a lengthy and expensive process, with an uncertain outcome;
- the initiation, enrollment, timing, progress, results, and cost of our research and development programs and our current and future preclinical and non-clinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available;
- the timing of interim data and final results from our clinical trials for PAS-004;
- the potential safety and efficacy of our product candidates and the therapeutic implications of clinical and preclinical data;
- potential impacts of increased trade tariffs, import quotas or other trade restrictions or measures taken by the United States and other countries, including the recent and potential changes in U.S. trade policies that have been and may continue to be made by the federal administration;
- the timing and focus of our future preclinical and non-clinical studies and clinical trials, and the reporting of data from those studies and trials;
- the size of the market opportunity for our future product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- the success of competing therapies that are or may become available;

- the beneficial characteristics, safety, efficacy and therapeutic effects of our future product candidates;
- our ability to obtain and maintain regulatory approval of our future product candidates;
- our plans relating to the further development of our future product candidates, including additional disease states or indications we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our dependence on third parties;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our plans and ability to obtain or protect intellectual property rights, including extensions of patent terms where available and our ability to avoid infringing the intellectual property rights of others;
- our financial performance and sustaining an active trading market for our Common Stock and Warrants (each, as defined below);
- our ability to regain and maintain compliance with Nasdaq listing standards;
- our ability to restructure our operations to comply with any potential future changes in government regulation; and
- the impact of global economic and market conditions and political developments on our business, including, among others, rising inflation and capital market disruptions, economic sanctions, bank failures, regional conflicts around the world, and economic slowdowns or recessions that may result from such developments which could harm our research and development efforts as well as the value of our Common Stock and our ability to access capital markets.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the "Risk Factors" section of this annual report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We operate in an evolving environment and new risk factors and uncertainties may emerge from time to time. It is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should review the factors and risks and other information we describe herein and in the other reports we file from time to time with the SEC (as defined below).

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage biotechnology company focused on the discovery, research and development of innovative treatments for RASopathies, MAPK pathway-driven tumors, and other diseases, including central nervous system (CNS) disorders.

Our Therapeutic Pipeline

We are advancing a pipeline of two therapeutic product candidates, with a focus on our lead product candidate, PAS-004, a next-generation macrocyclic (as defined below) Mitogen-Activated Protein Kinase ("MEK") inhibitor, that we believe may address the limitations and liabilities associated with existing drugs with a similar mechanism of action. PAS-004 is a small molecule allosteric inhibitor of MEK 1 and 2 ("MEK 1/2") for potential use in the treatment of a range of RASopathies, including neurofibromatosis type 1 ("NF1"), a number of MAPK pathway driven tumors, such as those driven by BRAFv600 mutations and BRAF fusion tumors, amyotrophic lateral sclerosis ("ALS"), among other indications including ETS2 driven diseases, such as inflammatory bowel disease ("IBD"), primary sclerosing cholangitis and ankylosing spondylitis.

MEK 1/2 are two of several protein kinases involved in a signaling cascade, known as the mitogen-activated protein kinase, or MAPK pathway. The MAPK pathway is an important pathway in cellular biology which has been a frequent target for drug discovery efforts. The MAPK pathway has been implicated in a variety of diseases, as it functions to drive cell proliferation, differentiation, survival and a variety of other cellular functions that, when abnormally upregulated, are critical for the formation and progression of tumors, fibrosis and other diseases. MEK inhibitors block phosphorylation (activation) of extracellular signal-regulated kinases ("ERK"), which can lead to cell death and inhibition of tumor growth.

Existing MEK inhibitors approved by the U.S. Food and Drug Administration (the "FDA") are marketed for a range of diseases, including (i) certain cancers and (ii) symptomatic, inoperable NF1-associated plexiform neurofibromas ("NF1-PN"). For NF1-PN, Koselugo (selumitinib) and Gomekli (mirdametinib) are FDA approved for adult and pediatric NF1-PN patients. We believe that current FDA-approved MEK inhibitors have certain limitations, including known toxicities and high rates of adverse events ("AEs") that may lead to dose interruptions and/or discontinuations and poor tolerability. Unlike currently FDA-approved MEK inhibitors, PAS-004 features a macrocyclic structure, a characteristic that we believe improves selectivity, provides higher oral bioavailability, and offers better metabolic stability. Macrocyclic molecules also provide structural rigidity, enabling stronger binding with target receptors. PAS-004's macrocyclic design was specifically developed to improve metabolic stability and optimize its pharmacokinetic ("PK") profile. The structure of PAS-004 is distinct from other earlier generation MEK inhibitors as it maintains critical protein/ligand contacts but does not possess a primary alcohol or hydroxamate functionality, a known metabolic liability in earlier generation MEK inhibitors. As described in greater detail below, PAS-004 offers a long half-life, a low peak ("Cmax") to trough ("Cmin") drug concentration ratio, and stable steady-state drug levels over time. We believe that sustained suppression of the MAPK pathway may result in improved efficacy, safety, and a broader therapeutic window (the dosage range of a drug that provides safe and effective treatment with minimal adverse effects, spanning from the minimum effective concentration to the minimum toxic concentration) as compared to current FDA-approved MEK inhibitors for NF1-PN, which have shorter half-lives, higher Cmax to Cmin ratios, and require twice-daily dosing. However, the ultimate safety and efficacy profile of PAS-004 will require clinical testing to be completed.

In December 2023, the FDA cleared our Investigational New Drug application (the "IND") for PAS-004 and we received a study may proceed letter for our first-in-human Phase 1 multicenter, open-label trial of PAS-004 in patients with MAPK pathway-driven advanced tumors with a documented RAS, NF1 or RAF mutation or patients who have failed BRAF/MEK inhibition (the "FIH Phase 1 Advanced Cancer Study"). We are currently conducting the FIH Phase 1 Advanced Cancer Study at four clinical sites in the U.S. and three sites in Eastern Europe and expect to complete the FIH Phase 1 Advanced Cancer Study in 2028. The primary objective of the FIH Phase 1 Advanced Cancer Study is to assess the safety and tolerability of PAS-004 when administered as a single dose (day 1) and as multiple doses (28-day treatment cycles). Secondary objectives are (i) to characterize the PK profile of PAS-004 when administered as a single dose and as multiple doses, (ii) to evaluate the pharmacodynamics ("PD") effect of PAS-004, (iii) to evaluate the preliminary anticancer activity (efficacy) of PAS-004 per Response Evaluation Criteria in Solid Tumors ("RECIST") 1.1 criteria, and (iv) to define the preliminary recommended Phase 2 dose(s) of PAS-004 in adults with MAPK pathway driven advanced solid tumors.

On September 9, 2024, we announced the successful completion of long-term chronic toxicology studies for PAS-004. On September 26, 2024, we announced safety, tolerability, pharmacokinetic (PK) and preliminary efficacy data from the first two cohorts of patients in our FIH Phase 1 Advanced Cancer Study.

To date, we have completed dose escalation through cohort 8 (45 mg capsule) with a total of 34 patients receiving PAS-004. No patients have discontinued treatment or interrupted dosing due to treatment-related AEs ("TRAEs"). The AE profile of PAS-004 has been characterized by grade 1 and grade 2 TRAEs, with the most frequently reported of these TRAEs being nausea, vomiting, and diarrhea through the 35-day DLT (as defined below) period. The interim data through a cut-off date of December 26, 2025, shows that PAS-004 is observed to be well tolerated and supports PAS-004's potential favorable safety and tolerability profile.

We have observed no dose limiting toxicities ("DLTs") in any of the cohorts assessed to date and have not reached the maximum tolerated dose ("MTD"). As such, we plan to file a protocol amendment to continue dose escalation in the FIH Phase 1 Advanced Cancer Study using our tablet formulation of PAS-004 in an effort to continue exploring the safety, PK, and early signals of efficacy at higher dose levels of PAS-004. Simultaneously, a pilot food effect assessment is planned in a subset of patients who agree to participate in this optional component of the study. The objective of the pilot food effect study is to determine if the PK properties of PAS-004 are impacted when PAS-004 is dosed in a fasted or fed state. To date, all patients have fasted when being administered PAS-004.

All TRAEs have been either Grade 1 or Grade 2, with no dose interruptions or modifications, which support PAS-004's potential favorable safety and tolerability profile. Additionally, PAS-004 has demonstrated favorable PK properties, including a long half-life of approximately 60 hours, a low peak to trough (Cmax to Cmin) ratio (ratio below 2) as compared to other FDA approved MEK inhibitors, and linear pharmacokinetics. Additionally, we have observed preliminary efficacy signals in a subset of advanced cancer patients with BRAF-mutated tumors.

In May 2025, we initiated our Phase 1/1b multicenter, open-label, dose escalation trial of PAS-004 in adult patients with symptomatic and inoperable, incompletely resected, or recurrent NF1-PNs (the "Phase1/1b Adult NF1 Trial"). In addition, many of these patients also presented with cutaneous neurofibromas ("CNs"). The Phase1/1b Adult NF1 Trial is currently being conducted at five clinical trial sites in the United States, Australia and South Korea.

The primary objective of the Phase1/1b Adult NF1 Trial is to evaluate the safety and tolerability of PAS-004 when administered for one 28-day treatment cycle in adult NF1 participants with at least one and up to two additional target PNs that are symptomatic and inoperable, incompletely resected, or recurrent. Secondary objectives are (i) to identify the recommended Part B dose ("RPBD") and/or the MTD of PAS-004, (ii) to characterize the PK and PD profile of PAS-004, (iii) to evaluate the preliminary efficacy of PAS-004 on target PN volume utilizing Response Evaluation in Neurofibromatosis and Schwannomatosis ("REiNS") criteria, (iv) to evaluate the preliminary efficacy of PAS-004 on the size, appearance, and associated symptoms of CNs, and (v) to evaluate the impact of PAS-004 on quality of life ("QOL") and any physical symptoms attributed to the target PN. Experimental objectives are (i) to evaluate the impact of PAS-004 on QOL and any physical symptoms attributed to CNs, (ii) to evaluate the impact of PAS-004 on pain and function attributed to PNs, and (iii) to investigate PAS-004 effects on CN tumor cellular and molecular biology.

The Phase1/1b Adult NF1 Trial is being conducted in two parts. In Part A (dose escalation phase), following a screening period of up to 28 days, up to 24 eligible participants will be enrolled sequentially to receive one of four initially planned dose levels of PAS-004 tablets (4 mg, 8 mg, 12 mg, 18 mg) in a modified 3+3 design. Part A will identify the recommended RPBD. During Part B (expansion phase), approximately 24 eligible participants will be enrolled in parallel to receive one of two planned dose levels of PAS-004 tablets. Participants will be dosed at the RPBD level and at a dose level below the RPBD for up to six continuous 28-day treatment cycles. Part B will identify the RP2D.

The initial indications we plan to seek FDA marketing approval for PAS-004 is the treatment of symptomatic, inoperable NF1-PNs in both adult and pediatric patients. As such, we aim to conduct a Phase 1 trial for pediatric NF1-PN patients and ultimately complete registrational clinical trials in both adult and pediatric NF1-PN populations. Pending dialogue with the FDA and other regulatory agencies, we may plan to pursue a second IND focused on the treatment of NF1-CNs.

Additionally, PAS-004 has received orphan-drug designation from the FDA for the treatment of NF1.

Our PAS-001 discovery program is in the early stage of development and aims to develop a brain penetrant small molecule targeting the complement component 4A ("C4A") for the treatment of schizophrenia. Recent findings implicate C4A in synaptic loss (fewer connections between nerve cells), which has been shown to occur in schizophrenia. In humans, structural variation in the complement 4 gene (C4) is an important genetic risk factor for schizophrenia.

During the year ended December 31, 2025, we determined to cease further development of our PAS-003 program for ALS due to several factors including the significant capital, resources and time required to develop the program, among others.

Our Strategy

Our mission is to develop innovative therapies to address areas of high unmet medical need, initially in RASopathies for NF1. To achieve our mission, we are executing a near-term strategy with the following key elements:

- ***Expand and complete our first-in-human clinical trial of PAS-004 in advanced cancer patients.*** In February 2024 we opened the first clinical site of our FIH Phase 1 Advanced Cancer Study of PAS-004 in patients with MAPK pathway driven advanced solid tumors. The objective of the FIH Phase 1 Advanced Cancer Study is to assess the safety, tolerability, PK, and PD of PAS-004 as well as to evaluate the preliminary anticancer activity (efficacy) of PAS-004 and to define the preliminary recommended Phase 2 dose. We have completed the initial eight cohorts through 45 mg capsule and have not reached the MTD. We plan to submit a protocol amendment to continue dose escalation in the FIH Phase 1 Advanced Cancer Study. As such, we expect to complete the trial in 2028.

- ***Complete our advance Phase 1/1b clinical trial of PAS-004 for adult NF1-PN patients.*** Our primary focus is to advance the clinical development of PAS-004 for NF1-PN, the initial indication for which we plan to seek marketing approval. In May 2025, we initiated the Phase 1/1b Adult NF1 Trial with the first patient dosed in late July 2025. This Phase 1/1b Adult NF1 Trial is being conducted at clinical sites in the United States, Australia, and South Korea. To date, we have completed enrollment and dosing of three patients in each of the initial four cohorts in Part A. All patients currently remain on trial and patients are being offered the opportunity to remain on trial for up to one year. We expect to complete Part A by the end of 2026 and move to Part B in 2027 following dialogue with the FDA.

- ***Complete key regulatory-required studies of PAS-004 prior to initiating registrational trials.*** In 2026 and 2027, we plan to complete non-clinical absorption, distribution, metabolism and excretion ("ADME") studies, non-clinical developmental and reproductive toxicology studies, and clinical human ADME studies that are key regulatory-required studies prior to initiating a registration trial for PAS-004. Additionally, during 2027 and 2028, we plan to initiate and complete a drug-drug interaction ("DDI") study to evaluate how PAS-004 interacts with other medications as well as a food effect study to fully determine if PAS-004 can be dosed in a fed state.

- ***Expand utility of PAS-004 for other indications.*** Based on results from preclinical studies and current understanding of certain disorders, we believe that PAS-004 may have potential for the treatment of other diseases, such as NF1-CN, ALS, ETS2 gene driven diseases, (such as IBD, primary sclerosing cholangitis and ankylosing spondylitis), Noonan syndrome, LMNA cardiomyopathy and other MAPK-mutation driven cancers (such as BRAF V600 and BRAF fusion tumors). We plan to continue testing PAS-004 in various preclinical models to further demonstrate the potential utility of PAS-004 in several indications.

- ***Expand formulation development for PAS-004.*** PAS-004 is currently being administered orally in capsule formulation in the ongoing FIH Phase 1 Advanced Cancer Study in adult patients and tablet formulation in the ongoing Phase 1/1b. Adult NF1 Trial. We believe that tablet formulation will be our commercial formulation for PAS-004. We are currently evaluating additional formulations of PAS-004, such as a liquid formulation for the treatment of certain pediatric patients. Additionally, we may explore the development of a topical formulation for indications where topical treatment is preferred.

- ***Maximize the potential of PAS-004 utilizing investigator-initiated trials.*** In November 2025, the ALS Association announced a $1 million award through the ALS Association's Hoffman Clinical Trial Awards Program to study the efficacy, safety and tolerability of PAS-004 in ALS. This award may be applied to support an investigator-initiated trial, terms of which are being negotiated. We may continue to explore non-dilutive funding and collaborative opportunities to enhance the potential of PAS-004 in additional indications.

Overview of Our Lead Program: PAS-004

MAPK Pathway Overview

Signaling pathways describe a series of biological mechanisms in which a group of molecules work together to control a cell function. A cell receives signals from its environment when a molecule binds to a specific receptor on or in the cell. This process may be repeated multiple times through the entire signaling pathway until the last receptor is activated and the cell function is carried out. Abnormal activation of signaling pathways may lead to diseases.

The MAPK pathway, which relies upon the Ras/Raf/MEK/ERK signaling cascade, represents a central biological pathway in all human cells that is responsible for regulating cellular transcription, proliferation and survival. The general structure of the pathway consists of Ras, a small GTPase, and three downstream protein kinases, Raf, MEK and ERK. ERK 1 and 2 ("ERK 1/2") are structurally similar protein-serine/threonine kinases that regulate a variety of cellular processes including adhesion, migration, survival, differentiation, metabolism, proliferation, transcription, cytoskeletal remodeling and cell cycle progression. MEK 1/2 catalyzes the phosphorylation of ERK 1/2, which is required for enzyme activation. Phosphorylated ERK 1/2 moves to the nucleus, and in turn activates many transcription factors, regulates gene expression, and controls various physiological processes, finally inducing cell repair or cell death.

In addition, at the level of Ras, the pathway is negatively regulated by several proteins, including neurofibromin, the protein encoded by the NF1 gene. Given its direct regulation of ERK, which directly controls downstream signaling through the MAPK pathway, MEK occupies a pivotal position in this signaling cascade and represents a rational small-molecule therapeutic target for multiple diseases, including RASopathies (such as NF1), CNS indications (such as ALS), cardiomyopathies (such as LMNA cardiomyopathy) and oncology indications, where overactivation of the MAPK pathway contributes to disease onset and/or progression.

Background of MEK Inhibitors

MAPK represents one of the most highly targeted signaling pathways in drug development. Several allosteric inhibitors of MEK 1/2 are currently in clinical development with six already approved by the FDA; four for various oncological indications, and two for the treatment of adult and pediatric patients with symptomatic, inoperable NF1-PNs. A limitation of current FDA approved MEK inhibitors for the treatment of NF1-PNs is their high rates of TRAEs, which may contribute to dose modifications and discontinuations. These FDA-approved MEK inhibitors for NF1-PN have short half-lives (approximately 6-7 hours) and require twice per day dosing. Additionally, their PK profiles are characterized by high Cmax to Cmin ratios. This fluctuation in drug concentration potentially leads to periods of sub-therapeutic effect (around Cmin) and periods around the Cmax level characterized by a full pathway suppression potentially resulting in AEs.

Our rationale in developing PAS-004 is to attempt to address these shortcomings to potentially provide patients with improved safety and tolerability with similar or superior outcomes, as well as a more convenient once per day dosing regimen.

RASopathies Overview

RASopathies are a clinically defined group of genetic syndromes caused by germline mutations in genes that encode components or regulators of the MAPK pathway. These disorders include neurofibromatosis type 1 (NF1), Noonan syndrome, capillary malformation–arteriovenous malformation syndrome, Costello syndrome, cardio-facio-cutaneous syndrome, and Legius syndrome. Because of the common underlying MAPK pathway dysregulation amongst all of these syndromes, RASopathies exhibit numerous overlapping phenotypic features, including CNS abnormalities. The MAPK pathway plays an essential role in regulating various cell cycle functions, which are critical to normal human development. Therefore, we believe there is a strong scientific rationale for targeting the MAPK pathway with small-molecule therapeutics to treat various RASopathies.

Neurofibromatosis type 1 (NF1) Overview

The initial indication we plan to seek marketing approval for PAS-004 is the treatment of NF1-PN. NF1 is a RASopathy and part of a group of conditions known as neurocutaneous disorders, conditions that affect the skin and the CNS. NF1 affects approximately one in 3,000 newborns throughout the world, with approximately 114,000 patients living in U.S. with NF1.

NF1 arises from mutations in the NF1 gene which encodes the tumor suppressor neurofibromin. Loss of NF1 function leads to loss of neurofibromin activity, leading to Ras being locked in its active confirmation, which stimulates MEK, and then ERK activity.

NF1 is characterized by multiple café au lait (light brown) skin spots and neurofibromas (small benign growths) on or under the skin, and/or freckling in the armpits or groin. Individuals with NF1 may have other manifestations of the disorder, including cardiac malformations, cardiovascular disease, vasculopathy, hypertension, vitamin D deficiency, brain malformations, and seizures. About 50% of people with NF1 also have learning disabilities. Softening and curving of bones, and curvature of the spine (scoliosis) may occur in some patients with NF1. Occasionally, tumors may develop in the brain, on cranial nerves, or on the spinal cord. NF1 is usually diagnosed during childhood.

Throughout their lifetime, about 30% to 50% of NF1 patients progress to develop plexiform neurofibromas ("PNs"), which are tumors that grow in an infiltrative pattern along the peripheral nerve sheath and can cause severe disfigurement, pain and functional impairment. In rare cases NF1-PN may be fatal. NF1-PN are most often diagnosed within the first twenty years of life. These tumors are characterized by aggressive growth, which is typically more rapid during childhood. While NF1-PN are initially benign, these tumors can undergo malignant transformation, leading to malignant peripheral nerve sheath tumors ("MPNST"). NF1 patients have an 8% to 13% lifetime risk of developing MPNST, a diagnosis that carries a 12-month survival rate of under 50%. In addition to MPNST, NF1 patients are at an increased risk of developing other malignancies, including breast cancer and gliomas.

Until recently, the only treatment option for NF1-PN was the surgical removal of the tumors. However, because NF1-PN arise from nerve cells and grow in an infiltrative pattern, it is challenging to successfully resect tumors and surgery can lead to severe comorbidities, such as permanent nerve damage. Patients that are ineligible for surgery or those who have had a recurrence post-surgery are often treated with a variety of off-label therapies. Among these off-label therapies are various systemic treatments, such as chemotherapy and immunotherapy, which have not been shown to consistently confer a clinical benefit. Given that NF1-PN is driven by dysregulation in the MAPK pathway, MEK inhibitors have emerged as the only FDA approved therapy for the treatment of inoperable NF1-PNs.

Additionally, over 95% of NF1 patients develop cutaneous neurofibromas ("CNs"), which are considered one of the hallmarks of the disease.

CNs are a neoplasm of peripheral nerve Schwann cells that present as a soft nodule in the dermis of the skin at virtually any location in the body. Despite their benign nature, people with NF1 consider CNs to be the most burdensome feature of the disease. Physical symptoms include irritation, pain, and itching. Improper drying after wetting may lead to other complications including maceration, skin breakdown, and superficial infections. Individuals may have hundreds to thousands of CNs over the body leading to physical disfigurement. CNs are linked to a lower quality of life due to feelings of embarrassment, interference with daily activities and adverse social implications. People with NF1 may suffer from lower socioeconomic status as a result of their lower self-esteem and risk aversion, and many of those with NF1 suffer from major depressive disorder likely contributed by their CN burden.

Physical removal or destruction has been the mainstay of therapy.

Limitations of Current Standard of Care

Koselugo (selumetinib), a MEK inhibitor, was first approved by the FDA in April 2020 for NF1 pediatric patients two years of age and older who have symptomatic, inoperable PNs based on results from the SPRINT trial, a Phase 2 registrational trial. In November 2025, Koselugo was approved by the FDA for adult NF1 patients with symptomatic, inoperable PNs based on results from the KOMET study, a randomized, placebo-controlled, parallel, double-blind Phase 3 study. In February 2025, Gomekli (mirdametinib) was approved by the FDA for adult and pediatric patients aged two and older with NF1 who have symptomatic PNs not amenable to complete resection based on clinical results from the ReNu Phase 2b clinical trial. In addition to Koselugo and Gomekli, we are aware of other MEK inhibitors in clinical trials for this indication, as well as the off-label use of other drugs, such as bevacizumab, for the treatment of NF1.

We believe that Koselugo, Gomekli and other earlier generation MEK inhibitors approved for indications other than NF1 suffer from limitations, such as known toxicities, high rates of drug discontinuation, limited efficacy and a dosing schedule that requires dosing twice a day. We believe that this creates a significant market opportunity for a next-generation MEK inhibitor that addresses these shortcomings, has a PK and tolerability profile suitable for long-term once-a-day or less dosing and that can arrest or reverse tumor growth.

There are no therapies approved by the FDA for the treatment of NF1-CNs.

Preclinical Profile and Mechanism of Action of PAS-004

PAS-004 is a next-generation MEK inhibitor that was rationally designed to have a macrocyclic structure by taking into consideration the metabolic liabilities of earlier generation MEK inhibitors. The structure of PAS-004 is distinct from other earlier generation MEK inhibitors as it maintains critical protein/ligand contacts but does not possess a primary alcohol or hydroxamate functionality, a known metabolic liability in earlier generation MEK inhibitors. It is generally observed that macrocyclic scaffolds improve drug-like properties including target binding, selectivity, and oral bioavailability.

PAS-004 has displayed promising PK properties in IND-enabling toxicology studies of both rats and dogs. In these toxicology studies, PAS-004 has demonstrated a half-life of 11.5 hours in rats and 52 hours in dogs.

Preclinical Studies Overview

In vitro Preclinical Studies of PAS-004

In a screen of 99 protein kinases, a single high dose of PAS-004 (10 μM) was used to assess kinase inhibition specificity. This assay demonstrated that PAS-004 is a strong inhibitor of only the MEK 1 (~95%) and MEK 2 (>99%) kinases.

In an unpublished preclinical study, the effects of PAS-004 were compared to selumetinib in tests for the ability to inhibit the growth of three NF1 mutant neurofibroma-derived Schwann cell lines, the tumorigenic cell of origin for NF1-PN, and two human wild-type Schwann cell lines. Cells were treated for 48 hours and all PAS-004 treated cell lines showed dose-dependent growth inhibition, with 60-80% growth inhibition in the three neurofibroma-derived NF1 mutant cell lines and less than 20% inhibition of the wild-type cell lines tested. Growth inhibition with PAS-004 was greater than the maximal growth inhibition seen with equivalent doses of selumetinib. In addition, the inhibition did not plateau at the highest doses used in the study, compared to a plateau effect with selumetinib.

Additionally, PAS-004 was compared to selumetinib in an *in vitro* potency assay. Western blots from this unpublished preclinical study showed that cells treated with PAS-004 demonstrated greater reduction in ERK 1/2 phosphorylation as compared to cells treated with selumetinib.

We believe these *in vitro* preclinical results support PAS-004's favorable potency and dose-dependent inhibitory activity against cellular proliferation in NF1 deficient Schwann cells, demonstrating a profile that appears similar to selumetinib, an FDA approved MEK inhibitor.

In vivo Preclinical Studies of PAS-004

In an unpublished preclinical study, the effects of PAS-004 were assessed in the *in vivo* Colo-205 xenograft tumor model, a common mouse model used for preclinical therapies. Results showed that PAS-004 dosed at 5 mg/kg once daily reduced tumor volume. The magnitude of tumor volume reduction was similar to selumetinib dosed at 25mg/kg, twice daily, as published in *Molecular Cancer Therapeutics* in 2007.

In an unpublished preclinical pilot study, PAS-004 was tested for tolerability and preliminary biological efficacy in a genetically engineered mouse model of NF1-PN. These mice were engineered to develop plexiform neurofibromas that closely phenocopy the human tumors by four months of age with 100% penetrance. In this pilot study, selumetinib was administered in a parallel group, which served as a positive control. Both PAS-004 and selumetinib were administered as single-agents to six mice per group. PAS-004 was administered at 10 mg/kg once daily and selumetinib was administered at the established maximum tolerated dose of 10 mg/kg, twice daily. Treatment began when the mice reached four months of age and was continued for 12 weeks or until death. Mice were monitored for signs of toxicity, as well as survival. Results demonstrated that both PAS-004 and selumetinib showed similar toxicity profiles and both PAS-004 ($p=0.0123$) and selumetinib ($p=0.0048$) significantly reduced the tumor size compared to vehicle-treated mice based on statistical analysis using uncorrected Fisher's least significant difference.

We believe the results from this preclinical pilot study illustrate that PAS-004 may be effective in reducing tumor burden of NF1-associated plexiform neurofibromas. When administered at 10 mg/kg once daily, PAS-004 and selumetinib, which was dosed at 10mg/kg twice daily, demonstrated similar results. We believe that the longer half-life of PAS-004, as compared to selumetinib, could potentially enhance efficacy by allowing more sustained MEK/ERK signaling inhibition. Additionally, it may allow for longer dosing intervals, such as a once-daily regimen, compared to the twice-daily dosing required for selumetinib.

Mutations in the LMNA gene, which encodes nuclear lamins A and C, cause diseases affecting various organs, including the heart. Studies have found that the ERK 1/2 kinase branches of the MAPK signaling pathway were abnormally hyperactivated prior to the onset of significant cardiac impairment.

PAS-004 was studied in the LMNA-cardiomyopathy $Lmna^{H222P/H222P}$ mouse model, a validated model of cardiomyopathy caused by LMNA mutations in humans. In this study, male mice were orally administered placebo, PAS-004 at 3 mg/kg/day or PAS-004 at 6 mg/kg/day starting at 14 weeks of age when symptoms of cardiomyopathy were present. Results of this preclinical study were published in *Bioorganic & Medicinal Chemistry* in 2017 and are summarized as follows:

- The effects of PAS-004 on phosphorylated ERK 1/2 were studied. Following six weeks of systemic administration, both doses of PAS-004 led to significant decreases in phosphorylated ERK 1/2 relative to total ERK 1/2 in the heart and liver when compared to placebo, whereas only the 6 mg/kg/day group produced a significant decrease in phosphorylated ERK 1/2 relative to total ERK 1/2 in quadricep muscles.

- The effects of PAS-004 on echocardiographic parameters of the heart that correlate with left ventricular function were studied. Following six weeks of systemic administration, both doses of PAS-004 resulted in significant increases in left ventricular fractional shortening, the percentage the left ventricular diameter decreases with each contraction as compared to placebo.

- The effects of PAS-004 on cardiac fibrosis were studied. Following six weeks of systemic administration, both doses of PAS-004 resulted in significant decreased fibrosis based on staining with Masson trichrome of fixed sections of left ventricles, when compared to placebo. Results showed that treatment of PAS-004 lead to dose-dependent statistically significant decreases in fibrosis when compared to placebo, as scored on a histologic scale of 0 to 4 by a pathologist blind to treatment group, when compared to placebo.

- The effects of PAS-004 on survival were studied. Mice were followed until death or euthanasia. 23 mice treated with placebo had a median survival of 202 days, whereas median survival was 225 days for 17 mice treated with 3 mg/kg/day of PAS-004 and 225 days for 15 mice treated with 6 mg/kg/day of PAS-004. Results showed the median survival based on Kaplan-Meier plots of mice treated with both doses of PAS-004 were statistically significantly ($P<0.05$) longer than that for mice treated with placebo.

- A preliminary analysis of potential tissue toxicity of PAS-004 was performed. Following six weeks of systemic administration, serum alkaline phosphatase activity, alanine aminotransferase activity and bilirubin concentration were measured to assess possible hepatic injury and liver function. Serum creatinine and blood urea nitrogen concentrations were also measured as indicators of renal function and serum amylase activity as a marker of pancreatic injury. Results showed that there were no statistically significant differences in any of these parameters between groups. A histopathological evaluation by a pathologist blind to treatment determined there were no consistent or specific abnormalities in liver, kidney or spleen of mice receiving either doses of PAS-004 and no alterations were observed that typically occur with drug toxicity.

In unpublished preclinical *in vivo* studies, PAS-004 was tested for anti-tumor efficacy in NRAS mutation cancer xenograft models. In the first study, PAS-004 exhibited dose-dependent anti-tumor efficacy in the lung cancer NCI-H1299 cell-line-derived xenograft model. PAS-004 at dose levels of 10 mg/kg and 5 mg/kg, once daily, significantly inhibited tumor growth as compared to vehicle control. The anti-tumor efficacy of PAS-004, when taken at equivalent doses, was shown to be superior to that of binimetinib and selumetinib. In the second study, PAS-004 exhibited dose-dependent anti-tumor efficacy in the liver cancer xHepG2 cell-line-derived xenograft model. PAS-004 at dose levels of 10 mg/kg and 5 mg/kg, once daily, produced significant antitumor activities as compared to vehicle control. The anti-tumor efficacy of PAS-004, when taken at equivalent doses was shown to be similar to that of binimetinib and superior to that of selumetinib.

PAS-004 has demonstrated dose-dependent response in vivo across several preclinical cancer, LMNA cardiomyopathy and NF1-PN models.

Toxicology Studies

28-day toxicological studies were performed in both rats and dogs under good laboratory practices ("GLP") on PAS-004 by WuXi AppTec (Suzhou) Co., Ltd. and demonstrated a sufficient safety and toxicology profile of PAS-004 to support our IND with the FDA. Additionally, we have completed repeat dose toxicity and toxicokinetic studies in Sprague Dawley rats of up to 26 weeks' duration and in Beagle dogs up to 39 weeks' duration with 14 or 28-day recovery periods to support chronic dosing of PAS-004.

Additional Indications: ETS2 Driven Diseases

A 2024 *Nature* publication titled "A disease-associated gene desert directs macrophage inflammation through ETS2" demonstrated that the ETS2 gene is a central regulator for multiple inflammatory functions in human macrophages and that ETS2 has a key pathogenic role in IBD. Further, this publication identified that MEK inhibitors as a class are the strongest known ETS2 inhibitors, providing potent anti-inflammatory activity and that MEK inhibition reduced inflammatory cytokine release to similar levels as infliximab, an anti-TNF antibody that is widely used for the treatment of IBD. Blocking ETS2 signaling through MEK 1/2 inhibition was showed to affect multiple cytokines, including TNF and IL-23, which are targets of existing therapies. Based on this publication, we tested PAS-004 in pre-clinical models of ETS2 signaling at the Francis Crick Institute in London, U.K.

Unpublished results from this *in vitro* study demonstrated that PAS-004 provides superior inhibition of ETS2-driven inflammatory responses compared to selumetinib in a human macrophage model of chronic inflammation that mimics the inflammatory milieu seen in IBD. RNA sequencing was used to measure gene expression, with PAS-004 consistently outperforming selumetinib across all tested doses (0.01 μM, 0.1 μM, and 1 μM), showing greater downregulation of ETS2 target genes, as well as experimentally validated MEK1/2 pathway genes. These data suggest more robust and durable MEK inhibition by PAS-004 under inflammatory conditions. PAS-004 significantly reduced ETS2-dependent functions such as cytokine production, phagocytosis, and reactive oxygen species (ROS) generation, all known to be central to chronic inflammation. Gene Set Enrichment Analysis revealed that PAS-004's effects more closely mirrored ETS2 knockout profiles, with a higher normalized enrichment score (-3.96 vs -3.56) and greater statistical significance (1.2×10^{-250} vs 3.7×10^{-74}) as compared to selumetinib.

Completion of GMP-Compliant Manufacturing

In June 2023, we announced the successful completion of manufacturing the GMP-compliant Phase 1 clinical supplies of the active pharmaceutical ingredient ("API") of our lead product candidate PAS-004. Utilizing this drug substance, we have manufactured the drug product in capsule form that we are utilizing in our ongoing FIH Phase 1 Advanced Cancer Study. In 2024, we completed a second batch of API and we have manufactured the drug product in tablet formulation to support our ongoing Phase 1/1b Adult NF1 Trial. In 2025, we improved the synthesis process of PAS-004 and have optimized the manufacturing process of API for commercial scale. In 2026, we plan to complete manufacturing of a third batch of API and drug product in tablet formulation to support our ongoing clinical trials and planned non-clinical studies. Throughout 2025 we continued to improve the synthesis process of PAS-004, and we believe we have further optimized the manufacturing process for commercial scale.

Clinical Development Overview

We are currently conducting two ongoing global clinical trials of PAS-004. Our clinical development plan for PAS-004 is to continue our Phase 1/1b clinical trial in adult patients with NF1-PN followed by pediatric NF1-PN patients and ultimately complete registrational clinical trials in these patient populations, which are the initial indications that we plan to seek marketing approval of PAS-004 for. In addition, we plan to analyze the NF1-CN results in the ongoing Phase 1/1b Adult NF1 Trial and may engage the FDA and necessary regulatory agencies for a separate clinical development path for the treatment of NF1-CN.

FIH Phase 1 Advanced Cancer Study

The FIH Phase 1 Advanced Cancer Study is a multicenter open-label study designed to evaluate the safety, tolerability, PK, PD, and preliminary efficacy of PAS-004 in cancer patients with MAPK pathway driven advanced solid tumors. Patients are being enrolled across four clinical sites in the U.S. and three clinical sites in Eastern Europe (Bulgaria and Romania) into dosing cohorts under a modified 3+3 dose escalation study design. If the first three patients enrolled into a dosing cohort reach the end of the first 28-day treatment cycle on day 35 without experiencing a DLT, following a review of safety, PK, and PD data by the safety committee, enrollment into the next highest dosing cohort begins. If two or more of the first three patients experience a DLT by day 35, dose-escalation will stop and cannot proceed at or above the current dose level. However, if one of the first three patients enrolled into a dosing cohort experiences a DLT by day 35, an additional three patients will be enrolled into the dosing cohort (six patients total). If only one of six patients experiences a DLT by day 35, following review of safety, PK and PD by the safety committee, enrollment into the next highest dose level begin; however, if two or more of the six patients experience a DLT, dose escalation will stop, and the prior dose level will be declared the MTD. Participants have sequentially received one of eight planned dose levels of PAS-004 in capsule formulation (2 mg, 4 mg, 8 mg, 15 mg, 22 mg, 30 mg, 37 mg and 45 mg) taken orally. Additionally, we have completed a dosing cohort using a 4 mg tablet formulation of PAS-004. PAS-004 is administered as a single dose on day 1, followed by a 7-day observation period, before initiating continuous 28-day treatment cycles of PAS-004.

To date, we have completed dose escalation through cohort 8 (45 mg capsule), with a of a total of 34 patients receiving PAS-004. No patients have discontinued treatment or interrupted dosing due to TRAEs). The AE profile of PAS-004 has been characterized by grade 1 and grade 2 TRAEs, with the most frequently reported of these TRAEs being nausea, vomiting, and diarrhea through the 35-day DLT period. The interim data shows that PAS-004 is observed to be well tolerated and support PAS-004's potential favorable safety and tolerability profile.

We have observed no DLTs in any of the cohorts assessed to date and have not reached the MTD. As such, we have filed a protocol amendment to continue dose escalation in the FIH Phase 1 Advanced Cancer Study using our tablet formulation of PAS-004 in an effort to continue to explore the safety, PK, and early signals of efficacy at higher dose levels of PAS-004. Simultaneously, a pilot food effect assessment is planned in a subset of patients who agree to participate in this optional component of the study. The objective of the pilot food effect study is to determine if the PK properties of PAS-004 are impacted when PAS-004 is dosed in a fasted or fed state. To date, all patients have fasted when being administered PAS-004.

Interim PK results have demonstrated a half-life of approximately 60 hours for PAS-004, dose proportionality and linear PK. At steady-state, little fluctuations in drug concentrations are observed with a ratio of Cmax to Cmin below 2. Additionally, we have observed preliminary efficacy signals in a subset of advanced cancer patients with BRAF-mutated tumors.

We plan to provide additional interim data throughout 2026 and currently expect to complete the FIH Phase 1 Advanced Cancer Study in 2028.

Phase 1/1b Adult NF1 Trial

The Phase 1/1b Adult NF1 Trial is a multicenter, open-label study designed to evaluate the safety, tolerability, PK and PD of PAS-004, in adult participants with NF1 with symptomatic and inoperable, incompletely resected, or recurrent PNs. This trial is being conducted at five clinical sites in the U.S., Australia, and South Korea. We opened our first clinical trial site in Australia in May 2025 and dosed the first patient in July 2025.

The primary objective of the study is to evaluate the safety and tolerability of PAS-004 when administered for one 28-day treatment cycle in adult NF1participants with at least one and up to two additional target PNs that are symptomatic and inoperable, incompletely resected, or recurrent. Secondary objectives are (i) to identify the RPBD or MTD of PAS-004, (ii) to characterize the PK and PD profile of PAS-004, (iii) to evaluate the preliminary efficacy of PAS-004 on target PN volume, (iv) to evaluate the preliminary efficacy of PAS-004 on the size and appearance, and associated symptoms of CNs, and (v) to evaluate the impact of PAS-004 on QOL and any physical symptoms attributed to the target PN. Experimental objectives are (i) to evaluate the impact of PAS-004 on QOL and any physical symptoms attributed to CNs, (ii) to evaluate the impact of PAS-004 on pain and function attributed to PNs, and (iii) to investigate PAS-004 effects on CN tumor cellular and molecular biology.

The primary endpoints are (i) the evaluation of DLTs, (ii) the evaluation of all AEs, (iii) the evaluation of AEs leading to interruption or discontinuation of PAS-004, and (iv) the evaluation of cardiac and visual function, hematology and clinical chemistry laboratory parameters. The secondary endpoints are (i) the evaluation of PK parameters, (ii) the evaluation of PD parameters including percentage of ERK phosphorylation inhibition from baseline in peripheral blood mononuclear cells ("PBMCs"), (iii) the evaluation of clinical benefit rate in terms of complete response, partial response, stable disease, and progressive disease over time on magnetic resonance imaging ("MRI") with volumetric analysis using REiNS criteria, (iv) the evaluation of the best objective response rate over time on MRI with volumetric analysis using the REiNS criteria, (v) the evaluation of time to maximal response on MRI with volumetric analysis using the REiNS criteria, (vi) the evaluation of CN appearance and size metrics over time using photography and quantitative measurements, (vii) the evaluation of changes from baseline in physical functioning using the Patient-Reported Outcomes Measurement Information System (PROMIS), Physical Function (PF) assessment, and in QOL using the Plexi-QOL survey.

Following a screening period of up to 28 days, up to 24 eligible participants in Part A will be enrolled sequentially to receive one of four planned dose levels of PAS-004 (4 mg, 8 mg, 12 mg, and 18 mg) tablets to be taken orally once daily.

The dose escalation phase (Part A) is following a modified 3+3 study design. At the first planned dose level of 4 mg (day 1), participants will be provided with PAS-004 to be taken once daily during a continuous 28-day treatment cycle. If the first three participants enrolled into each dosing cohort complete the 28-day treatment cycle without experiencing a DLT, following a review of safety and available PK and PD data by the safety review committee, enrollment into the next higher dosing cohort will begin. If two or more of the first three participants experience a DLT, dose-escalation will stop and cannot proceed at or above that current dose level. However, if only one of the first three participants enrolled into a dosing cohort experiences a DLT by day 28, an additional three participants will be enrolled into the same dosing cohort (six participants in total). If no additional participants develop a DLT, enrollment into the next highest dose level may begin after review of safety and available PK and PD data by the safety review committee for all six participants. The dose escalation can be adjusted by the safety review committee based on the safety considerations. However, if two or more of the six participants experience a DLT, dose escalation will stop, and the prior dose level will be declared the MTD. The RPBD will be identified as the dose level where at least three participants in a dosing cohort demonstrate optimal ERK phosphorylation inhibition and 0 of 3 participants or greater than 1 of 6 participants experience a DLT. The RPBD will be a dose level at or below the MTD.

Participants in Part A will be treated at their assigned dose level of PAS-004 for six treatment cycles. Each 28-day treatment cycle consists of once daily continuous dosing. Part A of the study also includes an optional treatment extension period of up to an additional six treatment cycles (up to 12 cycles in total). If the RPBD for Part B has not yet been selected, participants in Part A who have completed six treatment cycles may continue treatment for up to an additional six treatment cycles in Part A. This is to allow qualifying participants to continue in Part A without treatment interruption before enrolling in Part B and for continued safety data collection at the dose levels evaluated in Part A.

Participants in Part A will have their PNs and up to seven CNs measured at baseline. PNs will be measured on MRI at baseline and at the end of cycle 4 and cycle 6 as well as cycle 9 and cycle 12 for participants in the optional treatment extension period. CNs will be measured using digital calipers and two-dimensional photography at baseline and at the end of cycle 1, cycle 4, cycle 6, as well as cycle 9 and cycle 12 for participants in the optional treatment extension period.

To date, we have completed enrollment and dosing of three patients in each of the initial four cohorts in Part A. All patients currently remain on trial with the opportunity to remain on study for up to 12 cycles. We expect to complete Part A by the end of 2026 and move to Part B in 2027 following dialogue with the FDA and other regulatory agencies. We expect to complete Part B of the trial in 2028.

Our clinical development plan for PAS-004 is to continue our Phase 1/1b clinical trial in adult patients with NF1-PN followed by pediatric NF1-PN patients and ultimately complete registrational clinical trials in these two age indications, which are the initial indications that we plan to seek marketing approval of PAS-004 for. In addition, we plan to analyze the NF1-CN results and may engage the FDA for a separate development path for NF1-CN.

Overview of Our Discovery Program: PAS-001

Schizophrenia Overview

Schizophrenia is a chronic and disabling psychiatric illness characterized by positive psychotic symptoms, such as delusions and hallucinations, negative symptoms, such as social withdrawal and amotivation, and impairment in cognitive domains, including attention, working memory, verbal learning and executive function. According to the World Health Organization ("WHO") schizophrenia affects up to 24 million people in the world. Schizophrenia has a low lifetime prevalence of about 1%, however the burden of the disease is substantial. Schizophrenia is a leading cause of adult disease burden and has been ranked 12th in the top global causes of disability for the last decade, leading to substantial healthcare and societal costs, with annual associated costs in the U.S. estimated to be more than $150 billion.

Current pharmacological treatments for schizophrenia all act on dopamine D2 receptors. Although they are effective in reducing positive symptoms, they have little effect on both cognitive and negative symptoms. Furthermore, up to 30% of patients show only partial benefit with antipsychotics and have treatment resistant schizophrenia. This highlights the need for new therapeutic strategies.

Despite extensive research, the molecular etiology remains unknown. The current dopamine hypothesis postulates that excessive striatal dopamine transmission and reduced frontal dopamine stimulation underlie the pathophysiology of positive and negative symptoms, respectively. However, converging lines of genetic, epidemiological and clinical evidence indicate that inflammatory pathways are also altered in schizophrenia. More recently, a leading hypothesis proposes that synaptic terminal loss is central to the pathophysiology of schizophrenia, leading to impaired cortical function, and symptoms, including cognitive impairments.

Scientific Background and Rationale for Targeting C4A for the Treatment of Schizophrenia

The complement system is a group of proteins found in both the blood and the CNS. In the brain, the complement system plays in almost every aspect of normal brain development, including neurogenesis, neuronal migration and synaptic refinement, and is now also recognized as a signaling cascade that facilitate microglial removal of synapses. Microglia are phagocytes residing in the CNS. Unlike other phagocytes, which primarily function in immunity, microglia are heavily involved in shaping and supporting brain tissue and are key modulators of neuronal development. There are nine major complement proteins, labeled C1 through C9. Complement protein C4 is the only complement protein that has two different isotypes encoded by two different genes: C4A and C4B.

According to the synaptic pruning hypothesis, schizophrenia is thought to arise from a faulty pruning process and excessive synaptic elimination.

The largest genome-wide association study (GWAS) in schizophrenia in 2014 identified 128 independent associations spanning 108 conservatively defined loci that meet genome-wide significance. The most strongly associated GWAS locus is located in the extended Major Histocompatibility Complex (MHC) region on chromosome 6. This locus contains multiple copies of two closely related genes that codes for variants of C4: C4A and C4B. Their analyses revealed that C4A copy numbers, as well as other structural variance leading to increased C4A mRNA expression, to a large degree explained schizophrenia risk originating from this locus. This variant remains the strongest polygenic risk factor for schizophrenia identified to date, making C4A the first gene linked to a specific mechanism underlying the disease. Importantly, schizophrenia risk was not influenced by copy numbers of the closely related C4B gene.

Animal models of increased C4A expression show reduced levels of synaptic proteins and increased phagocytosis of synaptic terminals by microglia. Moreover, preclinical models showed C4A overexpression leads to reduced neurotransmission in prefrontal cortical neurons, reduced social interaction and impaired memory, which mimic similar abnormalities seen in schizophrenia patients. Finally, excessive microglial synapse elimination has been observed in schizophrenia patient-derived neural cultures. Post-mortem brain analyses showed that C4A is expressed at significantly higher levels in people with schizophrenia than controls. C4A levels in cerebro-spinal fluid ("CSF") have shown to be elevated in patients with schizophrenia relative to matched controls and correlates with CSF measurements of synapse density. C4A levels have also been found to be elevated in plasma in schizophrenia, and higher levels predict poorer outcomes in first episode patients.

Several other studies in scientific journals have also reported increased complement gene expression, protein concentration, and overall activity in the serum or plasma of schizophrenia cases compared to controls. Further, a 2020 study published in *Brain, Behavior and Immunity*, found that C4A was overexpressed in the dorsolateral prefrontal cortex, parietal cortex, superior temporal gyrus and associative striatum of patients with schizophrenia and that C4A expression was not altered in the peripheral tissues of schizophrenia patients. Further, the study found lifelong C4Aoverexpression in the brain of schizophrenia patients. Taken together, this evidence has led to the hypothesis that C4A may play an important role in the pathophysiology of schizophrenia.

We are currently developing a brain-penetrant small molecule able to down regulate C4A, for the systemic treatment of schizophrenia. To our knowledge, no other company is exploring this potentially important target. To date, we have created over 100 analogs of our 20 priority hits as provided via our past screening partnership with Evotec. In addition, we have used assays to assess C4 selectivity. We have prioritized several analogs for PK testing in mice. To date, we have demonstrated C4 selectivity in astrocytes and are expanding into additional cell types in vitro. We are continuing to conduct additional work for target deconvolution to identify a lead candidate. Our goal is to continue screening and proceeding with early development of PAS-001 while seeking partnerships and/or collaborators to support further development of the program including IND-enabling studies.

Acquisitions

Alpha-5 Integrin Therapeutics, LLC

On June 21, 2022, we entered into a Membership Interest Purchase Agreement (the "Alpha-5 Agreement") with PD Joint Holdings, LLC Series 2016-A and Prof. Lawrence Steinman (the "Alpha-5 Sellers"), pursuant to which we purchased from the Alpha-5 Sellers all of the issued and outstanding equity of Alpha-5 Integrin, LLC, a Delaware limited liability ("Alpha-5"). The Alpha-5 Sellers were the sole title and beneficial owners of 100% of the equity interests of Alpha-5. In consideration of the equity of Alpha-5, the Alpha-5 Sellers received (i) an aggregate of 163,044 shares (the "Alpha-5 Shares") of our Common Stock, (ii) warrants to purchase 50,000 shares of our Common Stock at an exercise price of $37.60 per share (the "Alpha-5 Warrants"), and (iii) contingent earn-out payments of an aggregate of 2% to 4% of net sales generated from the sale of a drug currently in development by Alpha-5.

Prof. Lawrence Steinman, one of the Alpha-5 Sellers, is our Executive Chairman and Co-Founder, and as such is considered a related party. The terms of the Alpha-5 Agreement were approved by (i) the disinterested members of the audit committee ("Audit Committee") of Board and (ii) the disinterested members the Board, under the Company's related party transaction policy.

In connection with the Alpha-5 Agreement, each of the employees of Alpha-5 entered into employment agreements with the Company. In 2024, we terminated each of the former Alpha-5 employees following the closure of our research laboratory in South San Francisco.

AlloMek Therapeutics, LLC

On October 11, 2022, we entered into a Membership Interest Purchase Agreement, dated October 11, 2022 (the "AlloMek Agreement"), by and among the Company, AlloMek Therapeutics, LLC, a Delaware limited liability company (the "AlloMek"), the persons listed on Schedule 1.1 thereto (each individually a "AlloMek Seller" and collectively, the "AlloMek Sellers"), and Uday Khire, not individually but in his capacity as the representative of Sellers (the "AlloMek Representative"), pursuant to which we purchased all of the issued and outstanding equity of AlloMek. The AlloMek Sellers were the sole title and beneficial owners of 100% of the equity interests of AlloMek. In consideration of the sale of the equity of AlloMek, the AlloMek Sellers received (i) an aggregate of 135,000 shares of our Common Stock, (ii) warrants to purchase an aggregate of 50,000 shares of our Common Stock (the "AlloMek Warrants") at an exercise price of $37.60 per share, which may be exercised on a cashless basis, for a period of five years commencing on the date of issuance, (iii) a cash payment in the amount of $1.05 million, (iv) the right to certain milestone payments in an amount up to $5.0 million, and (v) the right to contingent earn-out payments ranging from 3% to 5% of net sales of the Drug currently in development (as defined in the AlloMek Agreement) depending on the amount of such net sales in the applicable measurement period.

Pursuant to the AlloMek Agreement, we are required to offer to sell the Drug (as defined in the AlloMek Agreement) and certain intellectual property rights back to the AlloMek Sellers at a price set forth in the AlloMek Agreement within 30 days of the following two conditions being met: (1) there is a Change of Control (as defined in the AlloMek Agreement) and (2) we fail to meet our obligations regarding development and commercialization under the AlloMek Agreement, including by commencing a wind-up, a wind-down, a sale, liquidation or distribution of all or substantially all of our assets, an assignment for the benefit of creditors, or a bankruptcy, or by exiting or announcing an intention to exit the biotechnology business. The AlloMek Sellers have one year from the date of notice of our repurchase offer to accept such offer.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technologies, intense competition, and an emphasis on proprietary product candidates. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors may 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. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. These 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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Moreover, potential competitors have or may have patents or other rights that conflict with patents covering our technologies.

The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, side effects, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop. 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. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

PAS-004

Companies with FDA approved MEK inhibitors include: GSK plc, which received FDA approval for Mekinist (trametinib), that was subsequently sold to Novartis AG; Pfizer Inc., which received FDA approval for Mektovi (binimetinib); Genentech, Inc., a member of the Roche Company, which received FDA approval for Cotellic (cobimetinib); Verastem, Inc. which received FDA approval for Avutometinib co-packed as Avmapki Fakzynja; AstraZeneca PLC and Merck & Co., Inc., which received FDA approval for Koselugo (selumetinib); and SpringWorks Therapeutics, Inc. (acquired by Merck KGaA, Darmstadt, Germany), which received FDA approval for Gomekli (mirdametinib).

Koselugo (selumetinib) marketed by AstraZeneca PLC was the first FDA approved therapy for the treatment of pediatric NF1-PN patients in April 2020. In December 2025, Koselugo was approved by the FDA for adult NF1-PN patients. Gomekli (mirdametinib) marketed by Merck KGA via the acquisition of SpringWorks Therapeutics was approved by the FDA in February 2025 for adult and pediatric patients aged two and older with NF1 who have symptomatic PNs not amenable to complete resection. Mekinist, Mektovi, Cotellic, and Avmapki Fakzynja Co-Pack are approved for certain oncology indications.

We are aware that other companies are, or may be, developing products for NF1-PN, including, but not limited to Array BioPharma Inc. (a subsidiary of Pfizer), Chia Tai Tianqing Pharmaceutical Group Co., LTD, Healx Ltd., Infixion Bioscience, Inc., Novartis International AG, and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., and Shanghai Kechow Pharma, Inc. We are also aware of several therapies, some of which are generic, that are used off-label for the treatment of NF1-PN. These therapies include radiotherapy and various systemic treatments, such as chemotherapy and immunotherapy. NFlection Therapeutics, Inc. is developing a topical MEK inhibitor for NF1-CN.

There are other MEK inhibitors in various stages of clinical trials for multiple indications, including various cancers and NF1-PN. Additionally, there are other FDA approved small molecule therapeutics that target the MAPK signaling pathway.

Intellectual Property

Our ability to obtain, maintain and enforce intellectual property protection for our products candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries is fundamental to the long-term success of our business. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require invention assignment agreements to us of the ideas, developments, discoveries and inventions important to our business.

We generally control access to our proprietary and confidential information through the use of internal controls that are subject to periodic review. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. For further discussion of the risks relating to intellectual property, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Our patent portfolio includes issued and pending applications worldwide for each of our programs.

PAS-004

For PAS-004, we have issued patents titled "Novel MEK inhibitors, useful in the treatment of diseases" that have claims directed to composition of matter and methods of use, and includes granted patents in the United States, Australia, Canada, China, Germany, Spain, France, Italy, Great Britain, India and Japan, that are expected to expire in October of 2030 (without consideration of patent term adjustment ("PTA") and patent term extension ("PTE")). We have a pending application directed to solid forms of PAS-004 including claims directed to polymorphic forms and methods of use and a pending application directed to tablet formulations and uses thereof. We also have a pending application directed to stereoisomers of PAS-004 that have claims directed to composition of matter and methods of use. Patents that may be issued in these families will have a statutory expiration date of 2045 (without consideration of PTA and PTE).

Grant Agreements

FightMND Grant

In connection with the acquisition of Alpha-5, we legally assumed rights under a three-year grant agreement with FightMND, a not-for-profit Australian charity, which was entered into by Alpha-5 on September 23, 2021. FightMND supports preclinical research, development and assessment of therapeutics for Motor Neuron Disease/Amyotrophic Sclerosis. Under the grant agreement, we are entitled to reimbursements for costs incurred up to $967,010 AUD for research related to a monoclonal antibody targeting a5b1 integrin as a potential treatment for ALS. For the years ended December 31, 2025, and 2024, the Company recorded grant income of $43,000 and $0, respectively, as a contra expense within research and development.

Manufacturing

We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials in accordance with the FDA's cGMP (as defined below) regulations, and we intend to continue to do so in the future. For PAS-004, we currently work with one contract manufacturing organization ("CMO") for GMP materials, WuXi STA, a subsidiary of WuXi AppTec ("WuXi"), for the manufacture of PAS-004 drug substance and drug product for our clinical trials. We do not own or operate and currently have no plans to establish any manufacturing facilities.

The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control. Replacement of any of our CMOs would require us to qualify new manufacturers and negotiate and execute contractual agreements with them. If any of our supply or service agreements with our existing CMOs are terminated, we may experience delays and additional expenses in the completion of the development of and obtaining regulatory approval for our product candidates. To mitigate the risks above we utilize outside chemistry, manufacturing and controls ("CMC") consultants with pharmaceutical development and manufacturing experience to assist with the management of the relationships with our CMO.

We believe that the use of contract CMOs eliminates the need to directly invest in manufacturing facilities, equipment and additional staff.

As we further develop our product candidates, we expect to consider secondary or back-up manufacturers for both active pharmaceutical ingredients and drug product manufacturing. To date, our CMO has met the manufacturing requirements for our product candidates in a timely manner. We expect third-party manufacturers to be capable of providing sufficient quantities of our product candidates to meet our current needs, but we have not assessed these capabilities beyond the supply of clinical materials to date.

Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer. If we are unable to obtain sufficient quantities of our products candidates or receive raw materials in a timely manner, we could be required to delay our ongoing clinical trials and seek alternative manufacturers, which could be costly and time-consuming.

We currently engage CMOs on a fee for services based on the needs of our current development plans.

Employees & Human Capital

As of December 31, 2025, we had five full-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement.

We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel. In particular, we depend on the skills, experience and performance of our senior management and clinical operations personnel. We compete for qualified personnel with other medical pharmaceutical and healthcare companies, as well as universities and non-profit research institutions.

We provide competitive compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs (which vary by country/region and employment classification) include incentive compensation plans, healthcare and insurance benefits, retirement investments, paid time off, and family leave, among others. We also use targeted equity-based grants with vesting conditions to facilitate retention of personnel, particularly for our key employees.

The success of our business is fundamentally connected to the well-being of our people. Accordingly, we are committed to the health and safety of our employees.

We consider our relations with our employees to be good.

Facilities

Our principal executive office is located at 1111 Lincoln Road, Suite 500, Miami Beach, FL 33139. We rent approximately 300 square feet of space, which includes our executive offices.

Our website is *www.pasithea.com*. On our website, investors can obtain, free of charge, a copy of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our Code of Conduct and Business Ethics, including disclosure related to any amendments or waivers thereto, other reports and any amendments thereto filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we file such material electronically with, or furnish it to, the Securities and Exchange Commission, or the SEC. None of the information posted on our website is incorporated by reference into this Annual Report. The SEC also maintains a website at http://www.sec.gov that contains reports, proxy and information statements and other information regarding us and other companies that file materials with the SEC electronically.

Government Regulation and Drug Approval

Government authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of pharmaceutical products, such as our future product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Government Regulation

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations and other federal, state and local statutes and regulations. In the case of biologics, the section of the FDCA that governs the approval of drugs via New Drug Applications ("NDAs") does not apply to the approval of biologics. Rather, biologics, such as monoclonal antibodies and gene therapy products, are approved for marketing under provisions of the Public Health Service Act ("PHSA") via a Biologics License Application ("BLA"). However, the application process and requirements for approval of BLAs are very similar to those for NDAs. Drugs and biologics are also subject to other federal, state and local statutes and regulations. Accordingly, we have and plan to continue to investigate our products through the IND framework and seek approval through the NDA and BLA pathways. The process required by the FDA before our product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication in accordance with good clinical practice ("GCP");
- submission to the FDA of an NDA or BLA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the NDA or BLA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient ("API"), and finished drug product are produced and tested to assess compliance with good manufacturing practices ("cGMP") regulations; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal studies or other human studies with the investigational new drug, as appropriate, as well as manufacturing information, analytical data and any other available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's institutional review board ("IRB") before the trial may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug or biologic is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

- *Phase I*. Phase I includes the initial introduction of an investigational new drug into humans. Phase I clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, pharmacokinetics, absorption, distribution and metabolism and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase II clinical trials. The total number of participants included in Phase I clinical trials varies but is generally in the range of 20 to 80.

- *Phase II*. Phase II generally includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase II clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.

- *Phase III*. Phase III clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product, and to provide an adequate basis for product approval. Phase III clinical trials usually involve several hundred to several thousand participants.

A pivotal study is a clinical study which adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are also Phase III studies but may be Phase II studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

The FDA, the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of the use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product and to demonstrate that the company is able to manufacture the product according to specified quality and manufacturing standards and requirements and to the satisfaction of the FDA.

After an NDA or BLA submission is received by FDA, the FDA has 60 days to decide whether to accept it for filing so it can be reviewed. Once the NDA or BLA submission has been accepted for filing, within 60 days following submission, the FDA's goal is to review applications for new molecular entities within ten months of the filing date or, if the application relates to a serious or life-threatening indication and demonstrates the potential to provide a significant improvement in safety or effectiveness over currently marketed therapies, six months from the filing date. The review process can be significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the drug product and/or its active pharmaceutical ingredient will be produced, it may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A complete response letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA may grant accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, and requiring the company to conduct confirmatory trials. If the confirmatory trials fail to verify clinical benefit, then FDA may withdraw the approval. The FDA could also approve the NDA or BLA with a risk evaluation and mitigation strategy (REMS) to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug.

After regulatory approval of a drug product is obtained, manufacturers are required to comply with a number of post-approval requirements. The holder of an approved NDA or BLA must report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for the approved product. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long-term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. 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 regulatory compliance.

We expect to rely on third parties for the production of clinical and commercial quantities of our future product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and precautions, contraindications and other use restrictions, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Expedited Development and Review Programs for Drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients more quickly than standard FDA review timelines typically permit.

A drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the agency may review portions of the marketing application before the sponsor submits the complete application. In addition, a drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review designation, once an NDA or a biologics license application, or BLA, is submitted, if the drug that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. Products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies that are usually required to be underway prior to approval or within a specified timeframe after the date of approval to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug, or an indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA or NDA. 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.

The first NDA applicant to receive FDA approval for a particular active moiety to treat a rare disease for which the FDA has granted orphan designation is entitled to a seven-year exclusivity period in the United States for the specific product and the specific indication for which orphan designation was granted. During the seven-year exclusivity period, the FDA may not approve any other sponsor's application to market the same drug for the same indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues or consent by the exclusivity holder. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same indication, or the same drug for a different indication. Other benefits of orphan drug designation include tax credits for certain research and an exemption from the user fee required to submit an NDA, as long as the NDA does not seek approval of an indication that has not received orphan drug designation.

The Rare Pediatric Disease Designation and Priority Review Voucher Program

Under the Rare Pediatric Disease Priority Review Voucher Program, the FDA may award a priority review voucher to the sponsor of an approved marketing application for a product that treats or prevents a rare pediatric disease. A rare pediatric disease is a serious or life-threatening disease or condition that affects less than 200,000 persons in the United States; affects more than 200,000 persons in the United States with no reasonable expectation of recovering the cost of developing and making the drug available in the United States; or is an orphan subset of a disease or condition that otherwise affects 200,000 or more persons in the United States. A voucher may be awarded only upon approval of a rare pediatric disease product application. A rare pediatric disease product application is a marketing application that meets the following criteria: the application is for a product that treats or prevents a rare pediatric disease; the application must be deemed eligible for priority review; the application must not seek approval for an adult indication; the product must not contain an active moiety or ingredient (as applicable) that has been previously approved by the FDA; the application must be submitted under section 505(b)(1) of the FDCA; and the application must rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population such that the approved product can be adequately labeled for the pediatric population. At a sponsor's request, the FDA may designate a product as a product for a rare pediatric disease and the application for the new product as a rare pediatric disease product application.

A sponsor must notify the FDA, upon submission of the rare pediatric disease application, of its intent to request a voucher. The FDA may revoke a rare pediatric disease priority review voucher if the product for which it was awarded is not marketed in the United States within 365 days of the product's approval. The voucher, which is transferable to another sponsor, may be submitted with a subsequent application and entitles the holder to priority review of that application. The sponsor using a rare pediatric disease priority review voucher must notify FDA of its intent to submit the voucher with the NDA at least 90 days prior to submission of the application and must pay a priority review user fee determined by the FDA in addition to any other required user fee. Under the FDA's current performance goals, the FDA's goal is to take action on a priority review application within six months.

The rare pediatric disease priority review voucher program began to sunset on December 20, 2024, and, under current law, the FDA may not award rare pediatric disease priority review vouchers after September 30, 2026. Renewal of the PRV Voucher Program is subject to approval by Congress and it is currently uncertain whether the program will be renewed and whether any such renewal will be retroactively effective.

U.S. Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our current and potential product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit 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's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of a BLA or NDA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated drugs and biologics are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials no later than one year after the primary completion date of the trial. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Extensions may be available for good cause. Extensions may be available for good cause. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), NDAs and BLAs must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to an NDA or BLA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act ("BPCA") provides a six-month extension of unexpired exclusivity if certain conditions are met. For NDAs, pediatric exclusivity will attach to unexpired nonpatent and patent exclusivity listed in the Approved Drug Products With Therapeutic Equivalence Evaluations for any drug containing same active moiety as the drug studied. Conditions for earning pediatric exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, the applicant agreeing to perform and completing those studies, and the applicant reporting on the requested studies within the statutory timeframe for pediatric exclusivity to be granted. Applications and supplements proposing a labeling change as a result of a pediatric study conducted under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements

Once an NDA or BLA is approved, maintaining post-approval compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register establishments where the approved products are made with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP and other laws. Rigorous and extensive FDA regulation of products continues after approval, particularly with respect to GMP. We rely, and expect to continue to rely, on third parties for the production and distribution of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After an NDA or BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Hatch-Waxman Amendments and Exclusivity

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA 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. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve.

The FDA also cannot approve an ANDA or 505(b)(2) application until all applicable non-patent exclusivities listed in the Orange Book for the branded reference drug have expired. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug containing an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule responsible for the drug substance's physiological or pharmacologic action. During that five-year exclusivity period, the FDA cannot accept for filing (and therefore cannot approve) any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA that relies on the FDA's approval of the drug, provided that that the FDA may accept an ANDA four years into the NCE exclusivity period if the ANDA applicant also files a Paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular 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 studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 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.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be highly similar to, or interchangeable with, an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

The BPCIA includes, among other provisions:

- A 12-year exclusivity period from the date of first licensure, or BLA approval, of the reference product, during which approval of a 351(k) application referencing that product may not be made effective;

- A four-year exclusivity period from the date of first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted; and

- An exclusivity period for certain biological products that have been approved through the 351(k) pathway as interchangeable biosimilars.

The BPCIA also establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHSA.

The BPCIA is complex and its interpretation and implementation by the FDA remains unpredictable. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate effect, implementation, and meaning of the BPCIA is subject to uncertainty.

Failure to comply with the applicable U.S. requirements after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our future product candidates.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application ("CTA"), must be submitted to national health authorities and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

Following the U.K.'s exit from the European Union, a separate regulatory regime applies in the U.K. to clinical trials and licensing of medicines.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under EU regulatory systems, we must submit a marketing authorization application. The EMA is responsible for the scientific evaluation of centralized MAA. Once granted by the European Commission, the centralized marketing authorization is valid in all EU Member States, Iceland, Norway and Liechtenstein. The application used to file the NDA or BLA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe that are not part of the EU, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Authorization Procedures in the European Union

In all cases, the application for marketing approval requires the completion of clinical trials. Clinical trials are currently regulated under Directive 2001/20/EC. EU directives are not directly applicable in the Member States. They have to be transposed into national law. National law transposing EU directives often varies to a great extent. However, in April 2014 a new regulation on clinical trials on medicinal products for human use was adopted. Regulations are directly applicable in the Member States, so they generally lead to greater harmonization. Regulation 536/2014 ("CTR"), entered into force on in June 2014. The CTR will harmonize the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, or CTIS, which will contain a centralized EU portal and database for clinical trials. The exact timing of the Regulation's application depends on confirmation of full functionality of CTIS through an independent audit.

Medicines can be authorized in the EU by using either the centralized authorization procedure or national authorization procedures.

- Centralized Procedure (regulated in Regulation (EC) 726/2004). Under the Centralized Procedure a so-called Community Marketing Authorization is issued by the European Commission, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency ("EMA"). The Community Marketing Authorization is valid throughout the entire territory of the European Economic Area ("EEA") (which includes the 27 Member States of the EU plus Norway, Liechtenstein and Iceland). The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

- Cooperative Authorization Procedures (regulated in Directive 2001/83/EC and implemented into Member States' national law). There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:

- Decentralized Procedure. Using the Decentralized Procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the Decentralized Procedure the applicant chooses one country as Reference Member State. The regulatory authority of the Reference Member State will then be in charge of leading the assessment of the marketing authorization application.

- Mutual Recognition Procedure. In the Mutual Recognition Procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

- Furthermore, there is the option to obtain a national authorization in just one Member State.

In the EU, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and there is a risk that products may not qualify for data exclusivity.

Australia Regulation

In Australia, the relevant regulatory body responsible for the pharmaceutical industry is the Therapeutics Goods Administration, or TGA. The TGA has a Clinical Trial Notification (CTN) scheme and a Clinical Trial Approval (CTA) scheme to allow for clinical trials to proceed in Australia with an investigational product. Most clinical trials require Clinical Trial Notification via an electronic submission prior to commencing the clinical trial.

In addition to the above-mentioned competent authority there are local competent authorities, human research ethic committee (HREC), ethics committees (ECs), IRBs and other regulatory authorities at federal, state or local levels who may need to be consulted based on the applicable laws and regulations.

After we have completed our clinical trials, we must obtain marketing authorization before we can market our product in Australia. The approval process ensures that the product is safe, performs as intended and meets the appropriate standards for use in Australia. Just like with the FDA and EMA, quality, preclinical and clinical data is submitted to gain marketing authorization. Once the TGA reviews the application it aims to make a decision within 255 working days. The registration process is designed to take, on average, 330 calendar days (11 months), including the time for applicant activities. Once approval is granted, the product will be added to the Australian Register of Therapeutic goods, or the ARTG, the electronic register of therapeutic goods that are available for use in Australia.

A five-year data exclusivity period commences on the day marketing approval is granted in Australia for any new active component. During this time period a third party may seek regulatory approval for a biosimilar product, however the third party must submit their own data package and may not rely on any submissions to the TGA that is under the data exclusivity period.

Other Health Care Laws

We may also be subject to healthcare regulation and enforcement by the U.S. federal government and the states and foreign governments where we may market our product candidates, if approved. The U.S. laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician sunshine and privacy and security laws and regulations with corresponding laws in non-U.S. countries.

The U.S. 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 Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the 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 federal False Claims Act. The majority of states also have anti-kickback laws which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the U.S. Civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the United States government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the United States, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion-dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

HIPAA also created new federal criminal statutes 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.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, "the Affordable Care Act"), among other things, imposed new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information may result in civil monetary penalties of up to an aggregate of approximately $0.2 million per year (or up to an aggregate of $1.2 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of marketing expenditures and pricing information as well as gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes 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 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 such civil actions. In addition, state laws 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.

Coverage and Reimbursement

Sales of our product candidates, once approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, private health insurers and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our products and product candidates, if approved, will therefore depend substantially on the extent to which the costs of products and our product candidates will be paid by third-party payors. Additionally, the market for our products and future product candidates will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

In addition, the United States government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic 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 future net revenue and results. Decreases in third-party reimbursement for our products and future product candidates or a decision by a third-party payor to not cover our products or future product candidates could reduce physician usage of our products and future product candidates, if approved, and have a material adverse effect on our sales, results of operations and financial condition.

Health Care Reform

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. There have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs.

In particular, in the United States, the Affordable Care Act has had, and is expected to continue to have, a significant impact on the healthcare industry. The Affordable Care Act was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. The Affordable Care Act, 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 and taxes on manufacturers of certain branded prescription drugs, and established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which, through subsequent legislative amendments, was increased to 70%, 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. Substantial new provisions affecting compliance were also enacted, which may require us to modify our business practices with healthcare providers and entities.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. If a law is enacted, many if not all of the provisions of the ACA may no longer apply to prescription drugs. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how any future products are paid for and reimbursed by the government and private payers our business could be adversely impacted. During his first term in office, President Trump supported the repeal of all or portions of the ACA. President Trump also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the ACA and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of, the provisions of the ACA to the maximum extent permitted by law. As a result of recent electoral developments, it is likely that continued legislative efforts will be pursued to repeal the ACA. We are not able to state with certainty what the impact of potential legislation will have on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. Recently 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 bills designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in implementing 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 expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our future product candidates or additional pricing pressures.

ITEM 1A. RISK FACTORS

Our future operating results could differ materially from the results described in this annual report due to the risks and uncertainties described below. You should consider carefully the following information about risks in evaluating our business. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may affect our business, financial condition, results of operations and future growth prospects. If any of these risks actually materialize, the market price of our securities would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements" for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Summary Risk Factors

The following summarizes key risks and uncertainties that could materially adversely affect us. You should read this summary together with the more detailed description of each risk factor contained below.

- We are a clinical-stage biotechnology company with a limited operating history.
- We have incurred a history of operating losses and expect to continue to incur substantial costs for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability.
- We will need to raise additional capital to complete the development and commercialization efforts for PAS-004 and our other product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- A pandemic, epidemic, or outbreak of an infectious disease, could cause a disruption to the development of our product candidates.
- We are dependent primarily on the successful development and commercialization of our lead product candidate, PAS-004, which is not yet approved. Our business could be materially adversely affected if one or more of our key product candidates do not perform as well as expected and do not receive regulatory approval. We cannot give any assurance that we will receive regulatory approval for such a product candidate or any other product candidates which is necessary before any of our product candidates can be commercialized.
- Even if we obtain regulatory approval for PAS-004, or any of our other product candidates, such approval may be limited, and we will be subject to stringent, ongoing government regulation The commercial success of our product candidates, if approved, depends partially upon attaining market acceptance by physicians, patients, third-party payors, and the medical community.
- Our business is subject to extensive regulatory requirements, and our product candidates that obtain approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.
- We rely on third parties to conduct our clinical trials and our regulatory submissions for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials and/or regulatory submissions.

- We may rely on third parties to perform many essential services for any products that we commercialize, including distribution, customer service, accounts receivable management, cash collection and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize PAS-004 or our other product candidates will be significantly impacted and we may be subject to regulatory sanctions.

- We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.

- Our research and development is focused on discovering and developing product candidates which may not make it to the market.

- We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

- If our intellectual property related to our products or product candidates is not adequate, we may not be able to compete effectively in our market.

- An active trading market for our Common Stock or warrants to purchase shares of our Common Stock that were issued in our Initial Public Offering and are listed on Nasdaq (the "Warrants") may not be sustained.

- Impacts of increased trade tariffs, import quotas or other trade restrictions or measures taken by the United States and other countries, including the recent and potential changes in U.S. trade policies that have been and may continue to be made by the federal administration, may adversely affect our operations.

- Failure to comply with The Nasdaq Capital Market continued listing requirements may result in our Common Stock and/or Warrants being delisted from The Nasdaq Capital Market.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have no products or services approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We have a limited operating history upon which you can evaluate our business and prospects. We have no products or services approved for commercial sale and have not generated any material revenue from product sales. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, and product candidate development. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of clinical development. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to, among other things:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound;

- successfully manufacture our clinical product candidates and establish commercial supply;

- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of our product candidates;

- secure market exclusivity and/or adequate intellectual property protection for our product candidates;

- attract and retain an experienced management and advisory team;
- secure acceptance of our product candidates in the medical community and with third-party payors and consumers;
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan; and
- utilize the funds that we do have and/or raise in the future to efficiently execute our business strategy.

If we cannot successfully execute any one of the foregoing, our business may fail and your investment will be adversely affected.

We have a history of losses and may not be able to achieve profitability going forward.

We are a clinical-stage biotechnology company with a limited operating history and have incurred losses since our formation. We incurred net losses of approximately $20.4 million and $13.9 million for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of approximately $70.0 million. We have not commercialized any product candidates 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, general and administrative expenses, as well as to intellectual property.

We expect to incur significant additional operating losses for the next several years, at least, as we advance our product candidates through preclinical and non-clinical development, complete clinical trials, seek regulatory approval and commercialization, if any our product candidates are approved. The costs of advancing product 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 product 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:

- establish a sales, marketing and distribution infrastructure to commercialize our drugs, if approved, and for any other product 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 product development and planned future commercialization efforts; and
- acquire or in-license or invent other product candidates or technologies.

Furthermore, our ability to successfully develop, commercialize and license any product candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described below under "*–Risks Related to Development, Clinical Testing, Manufacturing, Regulatory Approval and 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 and Warrants will be materially and adversely affected.

As of December 31, 2025, our cash and cash equivalents were approximately $55.2 million. We expect our existing cash and cash equivalents to enable us to fund our operating expenses and capital expenditure requirements through at least the first half of 2028. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities.

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 our drugs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of and launch and commercialize our product candidates if we receive regulatory approval. We will require additional capital for the further development and potential commercialization of our product candidates and may also need to raise additional funds sooner to pursue a more accelerated development of our product candidates, if available to us. 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.

At December 31, 2025, we had cash and cash equivalents of approximately $55.2 million. We have incurred continuing losses including a net loss of $20.4 million for the year ended December 31, 2025. 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 our product candidates or any other future product candidates;
- clinical development plans we establish for our product candidates and any other future product 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 product 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;
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and
- cost associated with being a public company.

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, collaborations, strategic alliances and licensing arrangements, government or private party grants, or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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

Changes in U.S. tax law may materially adversely affect our financial condition, results of operations and cash flows.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was signed into law to address the COVID-19 crisis. The CARES Act is an approximately $2 trillion emergency economic stimulus package that includes numerous U.S. federal income tax provisions, including the modification of: (i) net operating loss rules (as discussed below), (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of the U.S. Internal Revenue Code of 1986, as amended, or the Code.

On December 22, 2017, President Trump signed into law federal tax legislation commonly referred to as the TCJA (defined below), which also significantly changed the U.S. federal income taxation of U.S. corporations. TCJA has been, and may continue to be, subject to 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 TCJA.

The Tax Cuts and Jobs Act ("TCJA") (P.L. 115-97) modified the section 174 rules and beginning in 2022, taxpayers may no longer currently deduct research and development expenditures but instead must amortize specified research and development expenditures ratably over five years (or 15 years for foreign expenditures).

On August 16, 2022, the Inflation Reduction Act ("IRA") was signed into law and, among other things, imposed a 1% U.S. federal excise tax on certain stock repurchases by publicly traded companies. The 1% excise tax generally applies to any acquisition by the publicly traded company (or certain of its affiliates) of stock of the publicly traded corporation in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases.

The One Big Beautiful Bill Act, or the OBBBA, was signed into law on July 4, 2025, and includes the permanent extension of certain expiring provisions of the TCJA, modifications to the international tax framework, changes to the business interest deduction limitation, the restoration of expensing for domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures over 15 years), and changes to the bonus depreciation deduction rules. The OBBBA has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. We continue to examine the impact this tax reform legislation may have, including the OBBBA, on our business.

Regulatory guidance under the TCJA, the CARES Act, the IRA, the OBBBA, and such additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition.

While some of these U.S. federal income tax changes may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going-forward basis. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the CARES Act, the IRA, the OBBBA, and additional tax legislation. We continue to work with our tax advisors and auditors to determine the full impact of the TCJA, the CARES Act, the IRA and the OBBBA on us. We urge our investors to consult with their legal and tax advisors with respect to the TCJA, the CARES Act, the IRA and the OBBBA and the potential tax consequences of investing in our Common Stock and Warrants.

Our ability to use our net operating losses and other tax attributes may be limited.

As of December 31, 2025, we had approximately $11.0 million of federal and $34.6 million of state net operating loss carryforwards ("NOLs"), available to offset future taxable income. Under current law, our federal NOLs generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of its taxable income annually for tax years beginning after December 31, 2020. Under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period is subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes such as research tax credits to offset future taxable income. We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in other ownership changes. If it is determined that we have in the past experienced other ownership changes, or if we undergo one or more ownership changes as a result of future transactions in our stock, which may be outside our control, then our ability to utilize NOLs and other pre-change tax attributes could be further limited by Sections 382 and 383 of the Code, and certain of our NOLs and other pre-change tax attributes may expire unused. As a result, if or when we earn net taxable income, our ability to use our pre-change NOLs or other tax attributes to offset such taxable income or otherwise reduce any liability for income taxes may be subject to limitations, which could adversely affect our future cash flows. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes.

Unfavorable global economic conditions and adverse developments with respect to financial institutions and associated liquidity risk could adversely affect our business, financial condition and stock price.

The global credit and financial markets are currently experiencing, and have from time-to-time experienced, extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine, the ongoing conflicts in the Middle East, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability.

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 or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair our ability to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers, and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

In addition, any further deterioration in the macroeconomic economy or financial services industry, could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition.

If our labor costs continue to rise, including due to shortages, changes in certification requirements and/or higher than normal turnover rates in skilled clinical personnel; or currently pending or future governmental laws, rules, regulations or initiatives impose additional requirements or limitations on our operations or profitability; or, if we are unable to attract and retain key leadership talent, we may experience disruptions in our business operations and increases in operating expenses, among other things, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We have incurred and expect to continue to incur increased labor costs and experience staffing challenges. Furthermore, changes in certification requirements can impact our ability to maintain sufficient staff levels, including to the extent our teammates are not able to meet new requirements, among other things. In addition, if we experience a higher-than-normal turnover rate for our skilled clinical personnel, our operations and treatment growth may be negatively impacted, which could adversely affect our business, results of operations, financial condition and cash flows. We also face competition in attracting and retaining talent for key leadership positions. If we are unable to attract and retain qualified individuals, we may experience disruptions in our business operations, including, without limitation, our ability to achieve strategic goals, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

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, our product candidates 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 a trial;
- reaching an agreement on acceptable terms with prospective CROs (as defined below), 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 IRB approval at each site, or Independent Ethics Committee ("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, 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 or dropping out of a trial;
- 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 product candidate 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 ("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 below in "*–Risks Related to Our Dependence on Third Parties*."

Furthermore, we conduct clinical trials in various countries outside the United States, including Bulgaria, Romania, Australia and South Korea. The FDA may not accept data from these trials if they do not comply with U.S. regulatory requirements, including GCP standards. Differences in regulatory standards, clinical practices, and patient populations between the U.S. and foreign countries may result in the FDA requiring additional data or information, which could delay our approval process. Moreover, the FDA may conduct inspections of foreign clinical trial sites, and any findings of non-compliance could compromise the acceptance of our data to support our commercialization efforts. See the risk factor below, entitled "*–We may conduct certain of our clinical trials for our product candidates outside of the U.S. which, among other risks, exposes us to the possibility that the FDA and other comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.*"

Our industry is subject to extensive regulatory obligations and policies that may be subject to change, including due to judicial challenges.

The U.S. pharmaceutical industry is highly regulated and subject to frequent and substantial changes, including as a result of new judicial or governmental actions. Legislative and regulatory agendas as they relate to the pharmaceutical industry are currently uncertain. Changes in the regulatory approval process, or substantial reductions in the personnel who oversee that process, could affect our ability to obtain regulatory approval for our product candidates or the timeline in which we can obtain that approval. We and/or our current and future third-party collaborators may rely on government programs or agencies, such as the National Institutes for Health ("NIH"), as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as the NIH can fluctuate and is subject to the political process, which is often unpredictable. Reductions in NIH grants to us or our third-party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates. In addition, on June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision could have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the pharmaceutical industry. The new framework may increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies could be subject to increased litigation and judicial scrutiny. We cannot predict how other future federal or state legislative or administrative changes relating to healthcare reform or the pharmaceutical industry, or the regulatory agencies that oversee the pharmaceutical industry, will affect our business.

Our choice of product candidates and our development plans for our product candidates are subject to change based on a variety of factors, some of which may be out of our control, and if we abandon development of a product candidate we may not be able to develop or acquire a replacement product candidate.

We have determined and may in the future determine to abandon the development of one or more of our product candidates, or we may change the prioritization of the development of certain product candidates, or we may select or acquire and prioritize the development of new product candidates. Our choice and prioritization of product candidates for development have been and will in the future be influenced by a variety of factors, including but not limited to:

- the amount of capital that we will have for our development programs and our projected costs for those programs;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- product candidates may not be effective in treating their targeted indications;
- product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and/or achieve market acceptance;
- our analysis of market demand and market prices for the products we plan to develop could lead us to conclude that market conditions are not favorable for receiving an adequate return on our investment in product development and commercialization;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is too complex and difficult to navigate successfully or economically.

Furthermore, given the nature of our business, the biopharmaceutical industry in general and the uncertainty and costs associated with developing and commercializing our product candidates within a complicated and costly regulatory environment, our goals, plans and assumptions with respect to our product candidates may evolve or change. For example, we may not continue to emphasize, focus our research and development efforts on or direct resources to certain of our product candidates, and we may shift our focus and resources to our other current or future product candidates. Any such change in our business strategy could harm our business, cause uncertainty or confusion in the marketplace or harm the clinical prospects of our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product 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 regulatory approval may change during the course of a product 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 our product candidates. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA. Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product 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 product candidates, or other products containing the active ingredient in our product 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 product 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 product 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 product 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; 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 product 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 product 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 product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities, or we may decide to abandon the development or commercialization of a product candidate altogether.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product 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 design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with our safety interpretation of our product candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our efficacy interpretation of our product candidate;
- the FDA or comparable foreign regulatory authorities may regard our CMC package as inadequate.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are 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 our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, the FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable 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. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Moreover, the development of our product candidates may be delayed by other events beyond our control. For example, actions by the federal administration to limit federal agency budgets or personnel, may result in reductions to the FDA's (or other agencies with which we interact) budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. See the below risk factor entitled, "*–Reductions in staffing and funding at the FDA and other federal agencies could cause delays in the development and approval of our products*."

Changes in funding for the FDA, the SEC, other government agencies or comparable foreign regulatory authorities and other disruptions caused by leadership changes, staffing cuts or other staffing shortages, along with uncertainty regarding the potential for new initiatives, laws, regulations, policies and guidance affecting our product candidates or other aspects of our business, could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent these agencies or authorities from performing normal business functions on which the operations of our business may rely, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, leadership changes and the ability to hire and retain key leadership and other personnel, the sufficiency of user fees, the availability of personnel and other resources, and statutory, regulatory, and policy changes that affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and comparable foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, other government agencies or comparable foreign regulatory authorities may also slow the time necessary for new products to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times – including the most recent shutdown, which began October 1, 2025, and ended November 12, 2025 – and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. In addition, there have recently been terminations of large numbers of federal employees at various federal agencies, including the FDA. Changes and cuts in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion, or at all. A prolonged government shutdown and/or employee terminations or resignations could significantly impact the ability of the FDA or other federal agencies to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns and/or employee terminations or resignations at the SEC could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

There is substantial uncertainty as to whether and how the current administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval, if any. This uncertainty could present new challenges as we navigate development and approval of our product candidates. Some of these efforts have manifested to date in the form of personnel cuts and measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. There is uncertainty as to whether we will be materially and negatively impacted by governmental orders, regulations, policies or guidance, or disruptions to the normal operations of government agencies.

Approval may be delayed or denied because we cannot satisfy the FDA's Chemistry, Manufacturing and Control Requirements.

Formulation and manufacturing of biologic products such as ours is complex and expensive. Our BLAs must include information about the chemistry and physical characteristics of our products, and we must demonstrate that we have a reliable process for manufacturing the products in commercial quantities in accordance with the FDA's cGMP requirements. The manufacturing process must consistently produce quality batches of the biologic, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life. If we are unable to successfully complete any of these complex steps, approval of our biologic may be delayed or denied.

We may encounter substantial delays in our planned clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Our planned clinical trials are expected to be expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We are currently conducting the FIH Phase 1 Advanced Cancer Study at four clinical sites in the U.S. and three sites in Eastern Europe and expect to complete the FIH Phase 1 Advanced Cancer Study in 2028. We are currently conducting the Phase 1/1b Adult NF1 Trial at five clinical sites in the U.S., Australia and South Korea and expect to complete the Phase 1/1b Adult NF1 Trial in 2028. We cannot be sure that submission of an IND or, in the case of the EMA, a CTA, will result in the FDA or EMA allowing future clinical trials to begin in a timely manner, if at all. Moreover, even if additional trials begin, issues may arise that could suspend or terminate such clinical trials, which may also be true for our current clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our current or future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required IRB approval at each clinical trial site (or IEC approval at sites outside the United States);
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including, but not limited to, after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites; developments in trials conducted by competitors that raise FDA or EMA concerns about risk to patients broadly; or if the FDA or EMA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays or difficulties resulting from public health crises;
- delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's current good clinical practices, requirements, or applicable EMA or other regulatory guidelines in other countries;
- occurrence of adverse events associated with a product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or to abandon product development programs; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete current or future clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA or any other regulatory authority, or if the IRBs or IECs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial 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, EMA 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 product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

We conduct certain of our clinical trials for our product candidates outside of the U.S. which, among other risks, exposes us to the possibility that the FDA and other comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We are currently conducting clinical trials in Bulgaria, Romania, Australia and South Korea and we may continue to conduct future clinical trials outside of the United States. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice. Therefore, later stage clinical trials designed to determine that our product candidates are safe and effective for the purposes of FDA approval will be conducted in part in the U.S. For studies that are conducted only at sites outside of the U.S. and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCPs and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such studies not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates conducted outside of the United States, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

Conducting clinical trials outside the United States also exposes us to additional risks including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

By extension, clinical trials that are predominantly conducted in the U.S. or primarily based on feedback from the FDA may not result in sufficiently diverse patient populations to warrant approval in other countries (for example, Japan) or those other comparable foreign regulatory authorities may have differences of opinion on appropriateness of trial design or differences in interpretation of some data. In those situations, approvals in other countries outside the U.S. may be delayed or never approved, which would materially detract from the commercial success of any impacted product candidates.

Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

In order to obtain FDA or other regulatory authority approval to market a new biological product we must demonstrate proof of safety, purity, potency, and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Any delays in preclinical testing and studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on study design; and
- the FDA not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, because standards for preclinical assessment are evolving and may change rapidly, even if we reach an agreement with the FDA on a pre-IND proposal, the FDA may not accept the IND submission as presented, in which case patient enrollment would be placed on partial or complete hold and treatment of enrolled patients could be discontinued while the product candidate is re-evaluated. Even if clinical trials do begin for our preclinical programs, our clinical trials or development efforts may not be successful.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through an expedited review program, and if we are unable to do so, then we could face increased expense to obtain, and delays in the receipt of necessary marketing approvals.

We may in the future seek approval for one or more of our future product candidates under one of the FDA's expedited review programs for serious conditions. These programs are available to sponsors of therapies that address an unmet medical need to treat a serious condition. The qualifying criteria and requirements vary for each expedited program. Prior to seeking review under one of these expedited programs for any of our future product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive marketing approval through an expedited review program.

There can be no assurance that, after our evaluation of the FDA's feedback and other factors, we will decide to pursue one or more of these expedited review programs. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue one or more of these expedited programs, even if we initially decide to do so. Furthermore, FDA could decide not to grant our request to use one or more of the expedited review programs for a product candidate, even if the FDA's initial feedback is that the product candidate would qualify for such program(s). Moreover, FDA can decide to stop reviewing a product candidate under one or more of these expedited review programs if, for example, the conditions that warranted expedited review no longer apply to that product candidate.

Some of these expedited programs (e.g., accelerated approval) also require post-marketing clinical trials to be completed and, if any such required trial fails, the FDA could withdraw the approval of the product. If one of our future product candidates does not qualify for any expedited review program, then this could result in a longer time period to approval and commercialization of such product candidate, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace.

We may seek Orphan Drug Designation for our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

We have received Orphan Drug Designation for our PAS-004 product candidate for the treatment of NF1. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation may entitle a party to financial incentives such as grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation may entitle a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for our product candidates, that exclusivity may not effectively protect those product candidates from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek Orphan Drug Designation for applicable indications for our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

If any of our product candidates are approved for marketing and commercialization and we have not developed or secured third-party marketing, sales and distribution capabilities, we will be unable to successfully commercialize such products and may not be able to generate product revenue.

We currently have no sales, marketing or distribution organizational experience or capabilities. We will need to develop internal sales, marketing and distribution capabilities to commercialize any product candidate that gains FDA or other regulatory authority approval, which would be expensive and time-consuming, or enter into partnerships with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties to market products or decide to co-promote products with partners, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all.

We will face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations 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. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition, and results of operations.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting pre-approval promotion and the promotion of off-label uses.

The FDA prohibits the pre-approval promotion of drugs as safe and effective for the purposes for which they are under investigation. Similarly, the FDA prohibits the promotion of approved drugs for new or unapproved indications. If the FDA finds that we have engaged in pre-approval promotion of our future product candidates, or if any of our future product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our future product candidates, if approved. In particular, an approved product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label, which is within their purview as part of their practice of medicine. If we are found to have promoted such off-label uses, however, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. The FDA may also issue a public warning letter or untitled letter to the company. If we cannot successfully manage the promotion of our future approved products, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the Securities and Exchange Commission ("SEC") and Department of Justice ("DOJ") have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our products and technology may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products and technology, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely adversely affect our business.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal.

We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers and suppliers for handling and disposing these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damage and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Any contamination by such hazardous materials could therefore materially adversely affect our business, financial condition, results of operations and growth prospects.

Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations.

The disruptions to the global economy which began in 2020 have impeded global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have taken and may have to take steps to minimize the impact of these disruptions on lead times and increased costs by working closely with our suppliers and other third parties on whom we rely for the conduct of our business. Despite the actions we may have to undertake to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain will not have a material adverse effect on our business, financial condition and results of operations.

Furthermore, inflation can adversely affect us by increasing the costs of clinical trials, the research and development of our product candidates, as well as administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

Pursuant to the AlloMek Agreement, the AlloMek Sellers have a right to repurchase certain assets and specified intellectual property from us in the event of a change of control and if we fail to meet certain obligations regarding development and commercialization.

Pursuant to the AlloMek Agreement, the AlloMek Sellers have a right to repurchase certain specified assets and intellectual property that we purchased from the AlloMek Sellers pursuant to the AlloMek Agreement. This right is triggered if (1) we undergo a change of control, and (2) if we fail to meet our obligations regarding the development and commercialization of PAS-004 (formerly CIP-137401) (the "Drug"), including actions such as winding up, liquidating, or exiting the biotechnology business. If these conditions are met, we must offer to sell the Drug and all related intellectual property back to the AlloMek Sellers at a specified price. The exercise of this repurchase right could result in the loss of key assets upon which a substantial portion of our business and strategy is based.

Risks Related to Our Dependence on Third Parties

We rely completely on third parties, including WuXi, to supply drug substance and manufacture drug product for our clinical trials and preclinical studies. We intend to rely on other third parties to produce commercial supplies of product candidates, and our dependence on third parties could adversely impact our business.

We are completely dependent on third-party suppliers of the drug substance and drug product for our product candidates. If third-party suppliers do not supply sufficient quantities of materials to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there could be a significant interruption of our supplies, which would adversely affect clinical development and commercialization. Furthermore, if any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications within regulatory requirements, we will not be able to secure and/or maintain regulatory approval, if any, for our product candidates.

We currently only use one CMO, WuXi, for the production of PAS-004 drug substance and we utilize the same manufacturer for the production of drug product for our clinical trials. The termination of this relationship would result in a disruption to our product development and our business may be harmed.

We also rely on our contract manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. We do not have any control over the process or timing of the acquisition of raw materials by our contract manufacturers. Moreover, we currently do not have agreements in place for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial, including as a result of public health crises, the ongoing conflict between Russia and Ukraine and the ongoing conflicts in the Middle East, increased U.S. trade tariffs and trade disputes with other countries and any resulting trade wars, could considerably delay completion of that clinical trial, product candidate testing, and potential regulatory approval of that product candidate.

We do not expect to have the resources or capacity to commercially manufacture any of our proposed product candidates if approved and will likely continue to be dependent on third-party manufacturers. Our dependence on third parties to manufacture and supply clinical trial materials and any approved product candidates may adversely affect our ability to develop and commercialize our product candidates on a timely basis.

If, for any reason, our CMOs are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our ingredients or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Our inability to coordinate the efforts of our third-party manufacturing partner(s), or the lack of capacity available at our third-party manufacturing partner(s), could impair our ability to supply any of our product candidates at the required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partner(s), we could experience significant interruptions in the supply of any of our product candidates if we decide to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer, including WuXi, could be disruptive to our operations and delay development of our product candidates. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of any of our product candidates and, if approved, products.

In addition, we currently rely on foreign CROs and CMOs, including WuXi, and will likely continue to rely on foreign CROs and CMOs in the future. There has been increased governmental focus in the United States on the role of Chinese companies in the life sciences industry. For example, the BIOSECURE Act was recently enacted, which prohibits U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of that contract. It would also prohibit loans or grant funding from U.S. federal agencies to entities that use any biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of the government grant or loan. The BIOSECURE Act restricts the ability of pharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing services or equipment from certain Chinese biotechnology companies. The BIOSECURE Act does not specifically name WuXi Biologics and WuXi AppTec as "biotechnology companies of concern." However, the BIOSECURE Act provides a mechanism for Chinese companies to be designated as a "biotechnology company of concern" in the future, and it is possible that WuXi Biologics and/or WuXi AppTec could receive that designation in the future, which means we could be potentially restricted from pursuing U.S. federal government business or government reimbursement for our products in the future if we continue to use WuXi Biologics, WuXi AppTec or other suppliers or partners identified as "biotechnology companies of concern." In addition to the BIOSECURE Act, any additional executive action, legislative action, or potential sanctions with China could materially impact our work with WuXi. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. Our reliance on Chinese-based contract research organizations, such as WuXi, may also cause us to face additional risks due to geopolitical tensions between the U.S. and China and related legal and regulatory restrictions and requirements, including measures directly affecting WuXi.

In addition, these entities or materials sourced from these entities may be subject to other U.S. legislation, sanctions, investigations, regulations, trade restrictions, tariffs, regulatory actions, or ex-U.S. legislation, regulatory actions or requirements that could increase the cost or reduce the supply of material available to us, delay or prevent the procurement or supply of such material, delay or impact the availability of our product candidates, delay or impact clinical trials, availability of commercial supply or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Any of the foregoing outcomes could adversely affect our financial condition and business prospects.

Furthermore, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the U.K., could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs.

We have in the past relied and expect to continue to rely on third-party CROs and other third parties to conduct and oversee our research programs, preclinical studies, planned clinical trials and other aspects of product development. If these third parties do not meet our requirements or otherwise operate as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates when expected or at all.

We have in the past relied and expect to continue to rely on third-party CROs to conduct and oversee our research programs, preclinical studies, clinical trials and other aspects of product development. We will also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and GCPs, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties will play a significant role in the conduct of these trials and the subsequent collection and analysis of data from our planned clinical trials. We will rely heavily on these parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP, GLP, and GACP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP, GLP and GACP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP, GLP and GACP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authority may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine whether any of our clinical or preclinical trials complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us 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 preclinical or 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 may develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If any of our CROs or clinical trial sites terminate their involvement in one of our preclinical studies or clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

We also rely on research institutions to conduct our research programs, preclinical studies and planned clinical trials. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. Even if we do replace the institution, we may incur additional costs to conduct the trial at the new institution. We may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

Moreover, we also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. We are required to post information related to the intervention (e.g., drug product), patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial, which is then made public as part of the registration. Sponsors are also required to submit the results of their clinical trials no later than one year after the primary completion date of the trial. Disclosure of the results of these trials can be delayed in certain circumstances upon timely submission of a certification, but results must be submitted not later than two years after the certification's submission. Extensions may be available for good cause. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

If we enter into collaborations with third parties to develop or commercialize our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

If we enter into future collaboration with third parties, we could face the following risks:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

If conflicts arise between our collaborators and us, our collaborators may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates. Our collaborators may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such a transaction.

Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that has led and may continue to lead to changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China. In March 2018, the first Trump administration announced the imposition of tariffs on steel and aluminum entering the United States and in June 2018, the first Trump administration announced further tariffs targeting goods imported from China. Recently both China and the United States have each imposed tariffs indicating the potential for further trade barriers, including the U.S. Commerce Department adding numerous Chinese entities to its "unverified list," which requires U.S. exporters to go through more procedures before exporting goods to such entities. Further, with rising international trade tensions and sanctions following the change of administrations, our business may be adversely affected following new or increased tariffs implemented during the second Trump administration. Throughout 2025, the United States announced tariffs on all foreign goods and individualized higher reciprocal tariffs on goods imported from certain countries. Tariffs could result in increased global clinical trial costs as a result of international transportation of clinical drug supplies, as well as the costs of materials and products imported into the U.S. Tariffs, trade restrictions or sanctions imposed by the U.S. or other countries could increase the prices of our and our collaboration partners' drug products, if any, affect our and our collaboration partners' ability to commercialize such drug products, if any, or create adverse tax consequences in the U.S. or other countries. As a result, changes in international trade policy, changes in trade agreements and the imposition of new or increased tariffs or sanctions, including any retaliatory measures, by the U.S. or other countries could materially adversely affect our results of operations and financial condition.

Further, our primary manufacturer and supplier, WuXi, is located in China and the subject of increased U.S. government scrutiny. Trade tensions and conflicts between the United States and China have been escalating in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. If any such laws or regulations are passed, they would have the potential to severely restrict the ability of companies to contract with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise received funding from, the U.S. government. Such disruptions could have adverse effects on the development of our product candidates and our business operations.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect the demand for our drug products (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidates used in our and our collaborators' preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China, including pursuant to our manufacturing service arrangements with WuXi. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

Risks Related to Our Securities

The prices of our Common Stock and Warrants may be volatile, and you could lose all or part of your investment.

The market prices of our Common Stock and Warrants are highly volatile and for the year ended December 31, 2025, the market price of our Common Stock ranged from $0.29 to $3.12 per share and the market price of our Warrants ranged from less than $0.01 to $0.06 per Warrant. The recent fluctuations in our trading price and future trading in our Common Stock and Warrants may be subject to wide fluctuations in response to a variety of factors, including the following:

- the timing and results of preclinical studies and clinical trials of our future product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our or our competitors' product candidates or products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- price and volume fluctuations attributable to inconsistent trading volume levels of our securities;
- announcement or expectation of additional financing efforts;
- sales of our Common Stock and Warrants by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

These and other market and industry factors may cause the market prices and demand for our Common Stock and Warrants to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of Common Stock or Warrants and may otherwise negatively affect the liquidity of our Common Stock and Warrants. In addition, the stock market in general, and Nasdaq Capital Markets and emerging growth companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a security has been volatile, holders of that security have instituted securities class action litigation against the company that issued the security. If any of our stockholders brought a lawsuit against us, we could incur substantial costs by defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

We could be negatively affected as a result of the actions of activists or hostile stockholders.

Our business could be negatively affected as a result of stockholder activism, which could cause us to incur significant expense, hinder execution of our business strategy, and impact the trading value of our securities. Stockholder activism requires significant time and attention by management and the Board of Directors, potentially interfering with our ability to execute our strategic plan. Stockholder activism could give rise to perceived uncertainties as to our future direction, adversely affect our relationships with key executives and business partners, and make it more difficult to attract and retain qualified personnel. Also, we may be required to incur significant legal fees and other expenses related to activist stockholder matters. Any of these impacts could materially and adversely affect our business and operating results. Further, the market price of our Common Stock could be subject to significant fluctuation or otherwise be adversely affected by stockholder activism.

Our Warrants may not have any value.

There can be no assurance that the market price of our Common Stock will ever equal or exceed the exercise price of our outstanding Warrants. In the event that our Common Stock price does not exceed the exercise price of the Warrants during the period when the Warrants are exercisable, the Warrants may not have any value.

A Warrant does not entitle the holder to any rights as common stockholders until the holder exercises the Warrant for a share of our Common Stock.

Until you acquire shares of our Common Stock upon exercise of your Warrants, your Warrants will not provide you any rights as a common stockholder. Upon the exercise of your Warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, the price and trading volume of our Common Stock and Warrants could decline.

The trading market for our Common Stock and Warrants is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our future intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, the price of our Common Stock and Warrants would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause the price of our Common Stock and Warrants or trading volume to decline.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our operating results are subject to quarterly fluctuations. Our net loss and other operating results are affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our current or future product candidates or current or future development programs;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;

- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our current or future product candidates receive regulatory approval, the terms of such approval and market acceptance and demand for such approved products;
- regulatory developments affecting our current or future product candidates, or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our Common Stock and Warrants could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our Common Stock and Warrants to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading prices of our Common Stock and Warrants.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

During the year ended December 31, 2023, we identified a material weakness in our financial reporting related to certain tax disclosures in Note 10 of our financial statements for such year. As of the date hereof, after designing and conducting procedures designed to remediate the material weakness, and testing such procedures, we have concluded that these controls are operating effectively, and the prior material weakness has been remediated.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our Common Stock and Warrants less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report on Form 10-K;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Pursuant to the JOBS Act, as an emerging growth company, we have elected to use the extended transition period for complying with any new or revised financial accounting standards to delay adopting new or revised accounting standards until such time as those standards apply to private companies.

The requirements of being a public company may strain our resources, resulting in more litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations increases legal and financial compliance costs, makes some activities more difficult, time consuming or costly and increases demand on our systems and resources, including management. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board, particularly to serve on our Audit Committee and compensation committee ("Compensation Committee"), and qualified executive officers.

By disclosing information in this Annual Report on Form 10-K and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market prices of our Common Stock and Warrants may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We do not currently intend to pay dividends on our Common Stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our Common Stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our Common Stock, which is not certain.

Provisions in our Certificate of Incorporation and Bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our securities.

Our second amended and restated certificate of incorporation, as amended ("Certificate of Incorporation"), and our second amended and restated bylaws ("Bylaws") contain provisions that could depress the market price of our securities by acting to discourage, delay or prevent a change in control of our Company or changes in our management that the stockholders of our Company may deem advantageous. These provisions, among other things:

- prohibit cumulative voting;
- authorize our Board to amend the Bylaws;
- provide that our Board be divided into three classes of directors serving staggered three-year terms and removal of directors can only be for cause;
- provide that our stockholders may only adopt, amend, alter or repeal the Bylaws by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66.67%) in voting power of the outstanding shares of Common Stock;
- eliminate the ability of our stockholders to act by written consent without a meeting, requiring all stockholder action to be taken at an annual or special meeting of stockholders;
- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- state that a stockholders meeting, special or annual, may be adjourned by the Board, the chairman of the meeting or, if directed to be voted on by the chairman of the meeting, by the Company's stockholders present or represented at the meeting, although less than a quorum.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our Certificate of Incorporation, Bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our securities.

Certain beneficial owners might have control over us which could delay or prevent a change in corporate control or result in the entrenchment of management and/or the Board.

As of March 24, 2026, our officers, directors and principal stockholders, beneficially own, in the aggregate, approximately 1.9% of our outstanding Common Stock. Accordingly, these stockholders, if acting together, may have the ability to impact the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. In addition, these persons may have the ability to influence the management and affairs of our Company. Accordingly, this concentration of ownership may harm the market price of our securities by:

- delaying, deferring, or preventing a change in control;
- entrenching our management and/or the Board;
- impeding a merger, consolidation, takeover, or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

In light of the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar, the British pound, the Euro, and the Australian Dollar, may adversely affect us. Although we are based in the United States, we currently have research and development operations through our Australian subsidiary, Pasithea MacroMEK Pty Ltd. As a result, our business may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period and the price of our Common Stock and Warrants. Currently, we do not have any exchange rate hedging arrangements in place.

Failure to comply with The Nasdaq Capital Market continued listing requirements may result in our Common Stock and/or Warrants being delisted from The Nasdaq Capital Market.

On February 20, 2026, we received a written notice (the "Notice") from the Listing Qualifications Department of Nasdaq indicating that, based upon the closing bid price of our Common Stock for 30 consecutive business days prior to the delivery of the Notice, we are not in compliance with $1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market (the "Bid Price Requirement"). The Notice does not result in the immediate delisting of our Common Stock from The Nasdaq Capital Market. We were provided a compliance period of 180 calendar days from the date of the Notice, or until August 19, 2026, to regain compliance with the Bid Price Requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

We will continue to monitor the closing bid price of our Common Stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods and may, if appropriate, consider available options, including implementation of a reverse stock split of our Common Stock, to regain compliance with the Bid Price Requirement. If we seek to implement a reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our Common Stock and/or Warrants. If we do not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our Common Stock and/or Warrants will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that we will regain compliance with the Bid Price Requirement during the 180-day compliance period or maintain compliance with the other Nasdaq listing requirements. A delisting could substantially decrease trading in our Common Stock and/or Warrants, adversely affect the market liquidity of our Common Stock and/or Warrants as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws, adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Additionally, the market prices of our Common Stock and/or our Warrants may decline further, and stockholders may lose some or all of their investment.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We, like other companies in our industry, face several cybersecurity risks in connection with our business. Our business strategy, results of operations, and financial condition have not, to date, been affected by risks from cybersecurity threats. During the reporting period, we have not experienced any material cyber incidents, nor have we experienced a series of immaterial incidents, which would require disclosure.

In the ordinary course of our business, we may use, store and process sensitive data. To effectively prevent, detect, and respond to cybersecurity threats, we maintain a cyber risk management program, which is comprised of data segregation, physical, procedural, and technical safeguards along with documented policies and procedures. By fully outsourcing our IT environment and placing it within expert third party software-as-a-service, human resource, and clinical providers, our primary means of avoiding cyber risk is minimizing sensitive data within our enterprise.

The cyber risk management program falls under the responsibility of our Chief Financial Officer ("CFO") who manages the overall security through constant communication and supervision of our third-party vendors. Under the guidance of our CFO who reports to the Audit Committee, we seek to minimize our data footprint to keep our cyber risk low. We use technology-based tools that are designed to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

Governance; Board Oversight

Under the ultimate direction of our CFO, with oversight from our board of directors, we maintain a security governance structure to evaluate and address cyber risk. Our CFO regularly consults with our third-party IT consultant who has expertise in cybersecurity to develop strategies to assess, address and align cybersecurity efforts with our business objectives and operational requirements.

The Audit Committee of our Board provides direct oversight over cybersecurity risk, and provides updates to the Board of Directors regarding such oversight, when and if appropriate. Our CFO provides periodic updates to the Audit Committee regarding cybersecurity matters including significant new cybersecurity threats or incidents, when and if appropriate.

ITEM 2. PROPERTIES

We do not own any real property.

Our principal executive office is located at 1111 Lincoln Road, Suite 500, Miami Beach, FL 33139. We rent approximately 300 square feet of space, which includes our executive offices.

We believe that our facilities are generally in good condition and suitable to operate our business. We also believe that, if required, suitable alternative or additional space will be available to us on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

None.

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

Our Common Stock trades on the Nasdaq Capital Market under the symbol "KTTA."

Holders of Record

As of March 24, 2026, we had 37 holders of record of our Common Stock. The actual number of holders of our Common Stock 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 or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any dividends on our Common Stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our Board.

ITEM 6. [RESERVED]

[Reserved]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the fiscal years ended December 31, 2025 and December 31, 2024 and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the year ended December 31, 2025, as compared to the fiscal year ended December 31, 2024. This discussion should be read in conjunction with our consolidated financial statements for the fiscal years ended December 31, 2025 and December 31, 2024 and related notes included elsewhere in this Annual Report on Form 10-K. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains numerous forward-looking statements, all of which are based on our current expectations (as described in the section entitled "Cautionary Note Regarding Forward-Looking Statements"), and could be affected by the uncertainties and risks described throughout this filing, particularly in "Item 1A. Risk Factors."

Throughout this report, the terms "our," "we," "us," and the "Company" refer to Pasithea Therapeutics Corp. and its subsidiaries, Pasithea Therapeutics Limited (U.K.), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, Pasithea Clinics Inc., Alpha-5 Integrin, LLC, AlloMek Therapeutics, LLC and Pasithea MacroMEK Pty Ltd. Pasithea Therapeutics Limited (U.K.), legally dissolved as of January 2, 2024, was a private limited company, registered in the United Kingdom (U.K.). Pasithea Clinics Inc., legally dissolved as of September 3, 2025, was incorporated in Delaware. Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, a private limited company, registered in Portugal, and Alpha-5 Integrin, LLC and AlloMek Therapeutics, LLC, are both Delaware limited liability companies. Pasithea MacroMEK Pty Ltd is registered in Australia. The operations of Pasithea Therapeutics Limited (U.K.), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, and Pasithea Clinics Inc. have been discontinued.

Overview

We are a clinical-stage biotechnology company focused on the discovery, research and development of innovative treatments for RASopathies, MAPK pathway-driven tumors, and other diseases, including central nervous system (CNS) disorders.

Our primary operations (the "Therapeutics" segment) are focused on developing our lead product candidate, PAS-004, a next-generation macrocyclic mitogen-activated protein kinase, or MEK inhibitor that we believe may address the limitations and liabilities associated with existing drugs targeting a similar mechanism of action. In December 2023, the U.S. Food and Drug Administration (the "FDA") cleared our Investigational New Drug application (the "IND") for PAS-004 and we received a study may proceed letter from the FDA for our Phase 1 multicenter, open-label, dose escalation trial of PAS-004 in patients with MAPK pathway-driven advanced tumors with a documented RAS, NF1 or RAF mutation or patients who have failed BRAF/MEK inhibition (the "FIH Phase 1 Advanced Cancer Study"). We are currently conducting the FIH Phase 1 Advanced Cancer Study at four clinical sites in the United States and three additional sites in Eastern Europe. We have completed the initial eight cohorts through 45 mg capsule and have not reached the maximum tolerated dose. We plan to file a protocol amendment to continue dose escalation in the FIH Phase 1 Advanced Cancer Study using our tablet formulation of PAS-004 in an effort to continue to explore the safety, PK, and early signals of efficacy at higher dose levels of PAS-004. Simultaneously, a pilot food effect assessment is planned in a subset of patients who agree to participate in this optional component of the study. As such, we expect to complete the trial in 2028.

In May 2025, we initiated our Phase 1/1b multicenter, open-label, dose escalation trial of PAS-004 in adult patients with neurofibromatosis type 1 ("NF1") with symptomatic and inoperable, incompletely resected, or recurrent plexiform neurofibromas ("PN"). We are currently conducting the trial at a total of five sites in the United States, Australia, and South Korea.

The initial indication we plan to seek FDA marketing approval for PAS-004 is the treatment of symptomatic PNs in both adult and pediatric patients with NF1. As such, we aim to conduct a Phase 1 trial for pediatric NF1-PN patients and ultimately complete registrational clinical trials in both adult and pediatric NF1-PN populations.

Additionally, we have one program, PAS-001, in the discovery stage, which we believe addresses limitations in the treatment paradigm for schizophrenia. During the year ended December 31, 2025, we determined to cease further development of our PAS-003 program for ALS due to several factors including the significant capital, resources and time required to develop the program.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- establish a sales, marketing and distribution infrastructure to commercialize our drugs, if approved, and for any other product 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 product development and planned future commercialization efforts; and
- acquire or in-license or invent other product candidates or technologies.

Impact of Inflation

We have recently experienced higher costs across our business as a result of inflation, including higher costs related to employee compensation and outside services. Although we anticipate a decline in the rate of inflation in 2026, we expect inflation to continue to have a negative impact throughout 2026, and it is uncertain whether we will be able to offset the impact of inflationary pressures in the near term.

Reverse Stock Split

On December 28, 2023, we filed a Certificate of Amendment to our Second Amended and Restated Certificate of Incorporation reflecting a one-for-twenty (1:20) Reverse Stock Split of our issued and outstanding shares of Common Stock which became effective at 12:01 a.m. Eastern Time on January 2, 2024. As a result of the Reverse Stock Split, every 20 shares of Common Stock issued and outstanding were converted into one share of Common Stock, with a corresponding reduction in the number of authorized shares of Common Stock from 495,000,000 shares to 100,000,000 shares (which was subsequently increased to 500,000,000 authorized shares of Common Stock on January 28, 2026 after we filed another Certificate of Amendment to our Second Amended and Restated Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to increase such number of authorized shares of Common Stock). The Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the Reverse Stock Split resulted in some stockholders owning a fractional share. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who were otherwise entitled to receive a fractional share instead received a cash payment (without interest) equal to such fraction multiplied by the average of the closing sales prices of Common Stock on The Nasdaq Capital Market for the five consecutive trading days immediately preceding the effective date of the Reverse Stock Split (with such average closing sales prices adjusted to give effect to the Reverse Stock Split). All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, convertible debt and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

The accompanying consolidated financial statements reflect the Reverse Stock Split. All share and per share information presented herein that relate to our Common Stock prior to the effective date of the Reverse Stock Split have been retroactively restated to reflect the Reverse Stock Split.

Results of Operations

Years Ended December 31, 2025, and 2024

Our financial results for the years ended December 31, 2025, and 2024 are summarized as follows:

	For the Twelve Months Ended December 31,	
	2025	**2024**
General and administrative	$ 12,876,175	$ 7,051,468
Research and development	7,981,120	7,198,494
Loss from operations	(20,857,295)	(14,249,962)
Other income, net	429,612	345,378
Net loss	$ (20,427,683)	$ (13,904,584)

General and Administrative

General and administrative expenses increased by approximately $5,825,000, or 82.6%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase was primarily driven by (i) an increase in impairment expense of intangible assets and goodwill totaling approximately $4,163,000, (ii) an increase of approximately $1,652,000 in personnel costs, (iii) an increase in office expenses of approximately $313,000, (iv) an increase in accounting and business development expenses of approximately $144,000, (v) an increase in public company and corporate communication costs of approximately $136,000, (vi) an increase in consulting costs of approximately $77,000, offset by (vii) a decrease in stock-based compensation expense of approximately $328,000, (viii) a decrease in legal expenses of approximately $264,000, (ix) a decrease in insurance costs of approximately $62,000 and (x) a decrease in board fees of approximately $6,000.

We expect general and administrative expenses to decrease in fiscal year 2026 as compared to fiscal year 2025 primarily due to a decrease in impairment expenses offset by a ramp up in operational activity, public company and corporate communications expenses, and non-cash stock-based compensation.

Research and Development

Research and development expenses relate to activities primarily focused on the development of PAS-004 and PAS-001 for the year ended December 31, 2025, and PAS-004, PAS-003, and PAS-001 for the year ended December 31, 2024.

Research and development expenses increased by approximately $783,000, or 10.9%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase was primarily due to (i) an increase in clinical trial and regulatory expenses of approximately $2,397,000, (ii) an increase in CMC expenses of approximately $564,000, offset by (iii) a decrease in preclinical research expense of approximately $1,811,000, (iv) a decrease in stock-based compensation expense of approximately $148,000, (v) a decrease in consulting expense of approximately $140,000 and (vi) a decrease in other expenses of approximately $79,000.

We expect research and development expenses to increase in fiscal year 2026 as compared to fiscal year 2025 primarily due to (i) an increase in clinical trial and regulatory expenses related to our ongoing clinical trials for PAS-004, (ii) an increase in CMC costs related to PAS-004 drug product and drug supply for our clinical trials, as well as the development of a liquid formation of PAS-004, (iii) the initiation of non-clinical absorption, distribution, metabolism and excretion (“ADME”) studies, non-clinical developmental and reproductive toxicology studies, and clinical human ADME studies, (iv) an increase in preclinical research for PAS-004 and PAS-001, and (v) an increase in personnel costs related to anticipated new workforce hires to support our research and development activities.

Other Income, Net

For the year ended December 31, 2025, other income, net increased by approximately $84,000, or 24.4%, as compared to the year ended December 31, 2024. The increase was primarily driven by (i) an approximate $193,000 increase in the fair value of our Initial Public Offering (“IPO”) warrant liabilities during the year ended December 31, 2025, (ii) a decrease in interest and dividends, net of approximately $96,000, (iii) an increase in foreign currency gain of approximately $30,000, (iv) an decrease in loss on change in fair value of derivative warrant liability of approximately $417,000, (v) an increase in other income of approximately $381,000, which included recognition of a research and development tax credit of approximately $337,000, and (vi) a decrease in realized foreign currency translation loss from dissolution of subsidiaries of approximately $7,000 during the year ended December 31, 2025.

Working Capital

	As of December 31,	
	2025	2024
Current assets	$ 56,459,084	$ 7,368,315
Current liabilities	4,973,961	1,119,871
Working capital	$ 51,485,123	$ 6,248,444

Working capital increased by $45.2 million from December 31, 2024, to December 31, 2025, due primarily to net cash provided by financing activities of $63.5 million which was partially offset by cash used to fund operations.

Liquidity and Capital Resources

	For the Twelve Months Ended December 31,	
	2025	2024
Net loss	$ (20,427,683)	$ (13,904,584)
Net cash used in operating activities	$ (15,211,490)	$ (13,923,438)
Net cash provided by investing activities	11,000	-
Net cash provided by financing activities	63,518,800	4,517,634
Effect of foreign currency translation on cash	18,766	(2,519)
Increase (decrease) in cash, cash equivalents and restricted cash	$ 48,337,076	$ (9,408,323)

Cash, cash equivalents and restricted cash increased by approximately $48.3 million for the year ended December 31, 2025. The increase was primarily attributable to net cash provided by financing activities of $63.5 million which was partially offset by cash used to fund operations.

Liquidity & Capital Resources Outlook

As of December 31, 2025, we had approximately $55.2 million in operating bank accounts and money market funds, with working capital of approximately $51.5 million. We are dependent on obtaining additional working capital funding from the sale of equity and/or debt securities in order to continue to execute our development plans and continue operations. During the year ended December 31, 2025, we completed two separate significant capital raises, the May 2025 and December 2025 offerings, which resulted in net proceeds of approximately $59.6 million in the aggregate. Additionally, during the year ended December 31, 2025, we received (i) net proceeds of approximately $2.1 million from the sale of shares of Common Stock under an "at-the-market" ("ATM") offering program, and (ii) net proceeds of approximately $2.2 million from the exercise of warrants. Such ATM offering program is no longer active and we will not make any additional sales of shares of Common Stock under such ATM offering program.

During the year ended December 31, 2024, we completed a private placement (the "September 2024 Private Placement") of (i) pre-funded warrants (the "September Pre-Funded Warrants") to purchase up to 1,219,513 shares of our Common Stock, at an exercise price of $0.001 per share, (ii) Series A warrants (the "Series A Warrants") to purchase up to 1,219,513 shares of Common Stock, at an exercise price of $3.85 per share, and (iii) Series B warrants (the "Series B Warrants" and together with the Series A Warrants, the "September 2024 Warrants") to purchase up to 1,219,513 shares of Common Stock with an exercise price of $3.85 per share. The combined purchase price per September Pre-Funded Warrant and accompanying September 2024 Warrants was $4.099. The net proceeds to us from the September 2024 Private Placement were approximately $4.5 million, after deducting placement agent fees and estimated offering expenses.

Our primary use of cash is to fund operating expenses, primarily general and administrative and research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with third parties in order to further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- expenses needed to attract and retain skilled personnel;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

We believe that our current available cash and cash equivalents will be sufficient to meet our working capital needs for at least the next twelve months and beyond. However, we will need significant additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Contractual Obligations

See Note 12 – *Commitments and Contingencies* in the Notes to the consolidated financial statements in Item 8 of this Annual Report on Form 10-K for a summary of our contractual obligations.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2025, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated under the Exchange Act.

Critical Accounting Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events.

We believe that the following critical accounting estimates are particularly subject to management's judgment and could materially affect our financial condition and results of operations:

- Assumptions used in the Black-Scholes pricing model for valuation of stock option awards, such as expected volatility, risk-free interest rate, expected term and expected dividends.

- Valuation of the liability for Representative Warrants, for which there is no active market, based on the relative fair value to the quoted market price of the Public Warrants, accounting for a small difference in the exercise price.

- Assumptions used in the Black-Scholes pricing model for valuation of the derivative warrant liability, such as expected volatility, risk-free interest rate, expected term and expected dividends.

Management also regularly makes estimates related to the recoverability of long-lived assets; the fair values and useful lives of intangible assets acquired in business combinations; the potential impairment of goodwill; and income taxes. The Company bases its estimates on historical experience and on various assumptions that are believed to be reasonable, the results of which form the basis for the amounts recorded in the consolidated financial statements. As appropriate, the Company obtains reports from third-party valuation experts to inform and support estimates related to fair value measurements.

For additional information on critical accounting estimates, see Note 2 to the consolidated financial statements, "*Summary of Significant Accounting Policies and New Accounting Standards*," in Part II, Item 8, of this Annual Report on Form 10-K.

New Accounting Standards

For discussion of new accounting standards, see Note 2 to the consolidated financial statements, "*Summary of Significant Accounting Policies and New Accounting Standards*," in Part II, Item 8, of this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable. As a smaller reporting company, we are not required to provide the information required by this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information called for by Item 8 is included following the "Index to Financial Statements" on page F-1 contained in this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing disclosure controls and procedures, our management was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures 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. Any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we are required to perform an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Exchange Act, as of December 31, 2025.

Management has completed such an evaluation and has concluded that our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is appropriate to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control Over Financial Reporting

Our management, under the supervision of the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Board, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our company's assets that could have a material effect on the financial statements.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this evaluation, our management used the criteria set forth in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this evaluation, management concluded that our internal control over financial reporting was effective at a reasonable assurance level as of December 31, 2025, based on those criteria.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended December 31, 2025, that has materially affected, or is 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 our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to an exemption for nonaccelerated filers and emerging growth companies from the internal control audit requirements of Section 404(b) of the Sarbanes-Oxley Act.

ITEM 9B. OTHER INFORMATION

(a) None.

(b) During the fiscal quarter ended December 31, 2025, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(c) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers, Non-Executive Employees and Directors

The following table sets forth the name, age as of March 24, 2026, and current position of the individuals who serve as directors and executive officers of the Company. The following also includes certain information regarding the individual experience, qualifications, attributes and skills of our directors and executive officers as well as brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors.

Name	Age	Position
Executive Officers		
Dr. Tiago Reis Marques	49	Chief Executive Officer and Director
Daniel Schneiderman	48	Chief Financial Officer
Non-Employee Directors		
Prof. Lawrence Steinman	78	Executive Chairman and Co-Founder
Simon Dumesnil (1)(2)(3)	49	Director
Dr. Emer Leahy (1)(2)(3)	60	Director
Alfred Novak (1)(2)(3)	78	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

Executive Officers

Each executive officer serves at the discretion of our Board and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal.

Dr. Tiago Reis Marques (Chief Executive Officer and Director) has served as our Chief Executive Officer and member of our Board since August 2020. Dr. Marques is also a senior clinical fellow at Imperial College London and a lecturer at the Institute of Psychiatry, Psychology and Neuroscience (IoPPN) at King's College London. The IoPPN is renowned globally, being ranked second in the world for psychology and psychiatry by US News and Best Global Universities and is home to one of the largest centers for neuroscience research worldwide. Dr. Marques also practices as a psychiatrist at Maudsley Hospital. His research is primarily focused on the mechanism of action of psychiatric medications and novel treatment targets. During his career, he has obtained multiple awards for his research. Dr. Marques has authored or co-authored over 100 scientific publications in peer-reviewed journals within the fields of psychiatry and neuroscience, has an h-index exceeding 45 and over 10,000 citations, and has co-authored international treatment guidelines and written book chapters, including the seminal, "Neurobiology of Mental Illness." We believe that Dr. Marques's extensive medical and scientific background coupled with his significant research and development achievements and clinical experience, makes him qualified to serve as our Chief Executive Officer and a member of our Board.

Daniel Schneiderman (Chief Financial Officer) is an experienced finance executive with over 24 years of experience in the areas of capital markets and finance operations. Mr. Schneiderman has served as our Chief Financial Officer since October 11, 2022, and as a consultant to the Company from July 1, 2022, through October 10, 2022. Prior to joining the Company, from January 2020 through February 2022 Mr. Schneiderman served as Chief Financial Officer of First Wave BioPharma, Inc. (Nasdaq: FWBI), a clinical stage biopharmaceutical company specializing in the development of targeted, non-systemic therapies for gastrointestinal (GI) diseases. Prior to joining First Wave, from November 2018 through December 2019, Mr. Schneiderman served as Chief Financial Officer of Biophytis SA, (ENXTPA: ALBPS; Nasdaq: BPTS) and its U.S. subsidiary, Biophytis, Inc., a European-based, clinical-stage biotechnology company focused on the development of drug candidates for age-related diseases, with a primary focus on neuromuscular diseases. From February 2012 through August 2018, Mr. Schneiderman served as Vice President of Finance, Controller and Secretary of MetaStat, Inc. (OTCQB: MTST), a publicly traded biotechnology company with a focus on Rx/Dx precision medicine solutions to treat patients with aggressive (metastatic) cancer. From 2008 through February 2012, Mr. Schneiderman was Vice President of Investment Banking at Burnham Hill Partners LLC, a boutique investment bank providing capital raising, advisory and merchant banking services primarily in the healthcare and biotechnology industries. From 2004 through 2008, Mr. Schneiderman served in various roles and increasing responsibilities, including as Vice President of Investment Banking at Burnham Hill Partners, a division of Pali Capital, Inc. Previously, Mr. Schneiderman worked at H.C. Wainwright & Co., Inc. in 2004 as an investment banking analyst. Mr. Schneiderman holds a bachelor's degree in economics from Tulane University.

Non-Employee Directors

Prof. Lawrence Steinman has served on our Board since August 2020. Prior to joining Pasithea, he served on the Board of Centocor from 1989 to 1998, the Board of Neurocrine Biosciences from 1997 to 2005, the Board of Atreca from 2010 to 2019, the Board of BioAtla from 2016 to the present, and the Board of Tolerion from 2013 to 2021. He is currently the George A. Zimmermann Endowed Chair in the Neurology Department at Stanford University and previously served as the Chair of the Interdepartmental Program in Immunology at Stanford University Medical School from 2003 to 2011. He is an elected member of the National Academy of Medicine and the National Academy of Sciences. He also founded the Steinman Laboratory at Stanford University, which is dedicated to understanding the pathogenesis of autoimmune diseases, particularly multiple sclerosis and neuromyelitis optica. He received the Frederic Sasse Award from the Free University of Berlin in 1994, the Sen. Jacob Javits Award from the U.S. Congress in 1988 and 2002, the John Dystel Prize in 2004 from the National MS Society in the U.S., the Charcot Prize for Lifetime Achievement in Multiple Sclerosis Research in 2011 from the International Federation of MS Societies and the Anthony Cerami Award in Translational Medicine by the Feinstein Institute of Molecular Medicine in 2015. He also received an honorary Ph.D. at the Hasselt University in 2008 and from the University of Buenos Aires in 2022. He received his BA (physics) from Dartmouth College in 1968 and his MD from Harvard University in 1973. He also completed a fellowship in chemical immunology at the Weizmann Institute (1974 - 1977) and was an intern and resident at Stanford University Medical School (1973-1974; 1977-1980). We believe that Prof. Steinman is qualified to serve on our Board due to his extensive background in medicine and his experience as a board member in the life sciences industry.

Simon Dumesnil has served on our Board since April 2021. He is currently a Managing Partner and Director of Dunraven Capital Partners Limited, an investment management advisory company incorporated in the U.K. that focuses on investments in Eastern European corporate distressed credits and structured products. From 2013 to 2018, Mr. Dumesnil served as Managing Director and Head of the Structured Financing Group Americas at UBS Securities LLC. In this role, he was responsible for managing the structured financing trading book in the USA and LATAM, overseeing a portfolio of financing positions across various fixed income products including corporate syndicated and middle-market loans, corporate bonds, real estate loans, and CMBS/RMBS/CLO/ABS, as well as LATAM Sovereign. Prior to this, Mr. Dumesnil was the Managing Director and Co-Head of the Private-Side Structuring Group EMEA at UBS AG from 2010 to 2013. In these roles, he was responsible for arranging structured solution transactions and acquisitions for the Financial Institutions Group (FIG) and Special Situation Group (SSG) and co-headed the illiquid financing business. From 2009 to 2010, Mr. Dumesnil served as the Chief Investment Officer at Bluestone Capital Management, where he managed investments in distressed assets across Europe. Between 2008 and 2009, Mr. Dumesnil was a Director at Lehman Brothers Holding Inc., where he was responsible for restructuring and unwinding Lehman Brothers Special Financing Inc.'s derivative book post-bankruptcy. From 2003 to 2008, Mr. Dumesnil was a Director at Lehman Brothers International (Europe). Mr. Dumesnil holds a Master of Science in Banking and International Finance from Cass Business School and a Bachelor in Business and Administration from École des Hautes Études Commerciales (HEC). Throughout his career, Mr. Dumesnil has advised on and underwritten corporate risk related to companies across various industries and jurisdictions. He possesses extensive knowledge in corporate restructuring and capital structure optimization for companies at different stages of their business life cycle. His experience as Chief Investment Officer during the launch and growth phases of a financial services and technology company provides valuable insights for our Company. We believe that Mr. Dumesnil is qualified to serve on our Board due to his extensive management and investment experience, as well as his expertise in corporate restructuring and capital structure optimization.

Dr. Emer Leahy has served on our Board since June 2021. Dr. Leahy received her Ph.D. in neuropharmacology from University College Dublin, Ireland in 1990, and her MBA from Columbia University in 2000. She has been with PsychoGenics Inc., a preclinical CNS service company, since 1999 and is currently serving as its chief executive officer and is responsible for compensation recommendations companywide. Prior to her appointment as the chief executive officer, where she is responsible for compensation recommendations companywide. Prior to her appointment as chief executive officer, she was the vice president of business development. Dr. Leahy is also the chief executive officer of PGI Drug Discovery LLC, a company engaged in psychiatric drug discovery with five partnered clinical programs including one in Phase III. Additionally, Dr. Leahy served as a member of both the compensation committee and the audit committee of Bright Minds Biosciences Inc. (NASDAQ: DRUG), a biotech company, until April 2022. Since 2016, Dr. Leahy has served as a member of the board of directors of Intensity Therapeutics, Inc. With more than 30 years of experience in drug discovery, clinical development and business development for pharmaceutical and biotechnology companies, Dr. Leahy possesses extensive knowledge of technology assessment, licensing, mergers and acquisitions, and strategic planning. She is also an Adjunct Associate Professor of Neuroscience at Mount Sinai School of Medicine. Dr. Leahy has also served on the Emerging Companies Section Governing Board for the Board of the Biotechnology Industry Organization, the Business Review Board for the Alzheimer's Drug Discovery Foundation, and the Scientific Advisory Board of the International Rett Syndrome Foundation. She also currently serves on the Board of PsychoGenics Inc, the Board of Intensity Therapeutics, and is the Chair of the Board of Trustees of BioNJ. We believe that Dr. Leahy is qualified to serve on our Board due to her extensive pharmaceutical, biotechnology and business background, which provides valuable insights and expertise to the Company.

Alfred Novak has been a member of our Board since September 2022, bringing financial acumen and expertise in the pharmaceutical and medical device industries. He has held leadership positions as a Chief Executive Officer and Chief Financial Officer of public and private companies and has served on several boards of directors. Between October 2007 and June 2022, Mr. Novak served as a director, Audit Committee Chair, and Compensation Committee member of LivaNova Plc (NASDAQ: LIVN) (and its predecessor company, Cyberonics, Inc.), a publicly held, medical device company. Mr. Novak was actively involved in several acquisitions, disposals and start-up companies during his career. Mr. Novak has an MBA from the Wharton School of the University of Pennsylvania with a concentration in Healthcare and Finance. He holds a BS from the United States Merchant Marine Academy. We believe Mr. Novak is qualified to serve on our Board due to his extensive experience as a Chief Executive Officer, in financial management, strategic planning, international operations, product development, regulatory process and commercialization in the pharmaceutical and medical device industries.

Scientific Advisory Board

Rebecca Brown, M.D., Ph.D.

Dr. Rebecca Brown is a board-certified adult neuro-oncologist who specializes in Neurofibromatosis (NF) and Schwannomatosis (SWN) genetic nerve tumor predisposition syndromes. She earned her Ph.D. from The University of Texas at Austin (UT Austin) in Neuroscience studying the molecular genomics and behavioral outcomes of endocrine-disrupting pollutants on females across multiple generations. Dr. Brown completed a post-doctoral fellowship at the Center for Strategic and Innovative Technologies at UT Austin in human performance research and then earned her M.D. from UT Southwestern in 2013. She completed her intern year at East Tennessee State University in 2014 and her neurology residency at Mount Sinai Hospital in NYC in 2017. She specialized in neuro-oncology during a fellowship at Memorial Sloan Kettering Cancer Center (MSKCC) completed in 2019. She worked as an instructor at MSKCC for 18 months prior to accepting a position as Assistant Professor and Director of the all-ages NF and SWN Clinic at The Mount Sinai Health System in January 2021. In November 2024, Dr. Brown joined the University of Alabama (UAB) Department of Neurology as an associate professor and is the Director of the adult NF and SWN clinic at UAB. Dr. Brown has experience on both sides of the bench in NF laboratory research involving the RAS-RAF-MEK-ERK (MAPK) pathway, including genome editing, cell culture, xenografts, and clinical trials. Her particular interest is in developing treatments for NF1-associated dermal tumors called cutaneous neurofibromas.

Luca Rastelli, Ph.D.

Dr. Rastelli is the Chief Scientific Officer of Deepcure, an emerging biotech that uses AI-driven discovery to create better molecules and faster cures for every disease-relevant protein target. Dr. Rastelli brings more than 25 years of oncology drug discovery and development experience, as well as business development experience ranging from startups to large pharmaceutical companies. Most recently, Dr. Rastelli was Chief Scientific Officer at Jubilant Therapeutics where he led all aspects of R&D for the company and was instrumental in bringing 2 compounds to the clinic. Previously Dr. Rastelli was Chief Scientific Officer at Kleo Pharmaceuticals where he led the team that brough a CD38 targeting compound based on Kleo's novel ARM technology to the clinic for multiple myeloma. At BioXcel Therapeutics he was Vice President, Oncology at where he helped bring the company to a successful IPO and he led a project focused on Neurofibromatosis type 2. Dr. Rastelli has held multiple preclinical and clinical project leadership positions at Boston Scientifics, CuraGen, Sopherion and EMD Serono (Merck Serono). Dr. Rastelli led the initial development of c-MET inhibitor TEPMETKO, approved for the treatment of METex14 positive NSCLC patients. Dr. Rastelli was also part of the initial development of the immuno-oncology antibody BAVENCIO, a PDL-1 inhibitor approved for several type of cancers. Dr. Rastelli received the American Brain Tumor Association's 25th Anniversary Translational grant for his work on Medulloblastoma tumors at the Department of Neuro-Oncology, MD Anderson Cancer Center. Dr. Rastelli is a named inventor on more than 10 issued patents and holds a Ph.D. in Molecular Biology from the University of Geneva.

James Lee Ph.D.

Dr. Lee is a Clinician Scientist Group Leader at the Francis Crick Institute (London, UK) and an Honorary Consultant Gastroenterologist at the Royal Free Hospital. Dr. Lee is a clinician-scientist with a longstanding focus on better understanding the biology of immune-mediated disease, and the translation of that knowledge for patient benefit. He has clinical expertise in inflammatory bowel disease (IBD) and is also an active member of the UK and International IBD Genetics Consortia. Dr. Lee completed medical training at the University of Oxford (2004) and undertook his Ph.D. at the University of Cambridge as part of the inaugural Wellcome Trust Clinical PhD Programme (2008-2011). Following his Ph.D. in Ken Smith's lab, Dr. Lee completed clinical training in gastroenterology as a clinical lecturer (University of Cambridge), before being awarded a Wellcome Trust Intermediate Clinical Fellowship in 2015. Dr. Lee spent 2 years of this award at Harvard University before returning to the University of Cambridge in 2018 to establish a research group at the newly-opened Cambridge Institute for Therapeutic Immunology and Infectious Disease. He joined the Francis Crick Institute as a Clinician Scientist Group Leader in 2021. Dr Lee has published over 50 research papers, including first / senior author papers in Cell, Nature Genetics, Journal of Clinical Investigation, Gut and EMBO Molecular Medicine, and co-authored papers in journals including Nature, Cell, Nature Immunology and Journal of Experimental Medicine. In 2014, Dr. Lee was named as the inaugural "Young Gastroenterologist of the Year - Clinical and Translational Science" by the British Society of Gastroenterology and has since been awarded the Julia Bodmer Award (European Federation of Immunogenetics, 2017), the Sir Francis Avery-Jones Medal (British Society of Gastroenterology, 2018), and the United European Gastroenterology Society Rising Star Award (2018). He is an editorial board member at Gut and Research Awards Panel member for Crohn's and Colitis UK.

Daniel R. Weinberger, M.D.

Dr. Weinberger is Director and CEO of the Lieber Institute for Brain Development at the Johns Hopkins Medical Center and Professor of Psychiatry, Neurology, Neuroscience and Human Genetics at the Johns Hopkins School of Medicine. He was formally Director of the Genes, Cognition, and Psychosis Program of the Intramural Research Program, National Institute of Mental Health, National Institutes of Health in Bethesda, Maryland. He attended college at the Johns Hopkins University and medical school at the University of Pennsylvanian and did residencies in psychiatry at Harvard Medical School and in neurology at George Washington University. He is board certified in both psychiatry and neurology. Dr. Weinberger's research has focused on brain and genetic mechanisms involved in the pathogenesis and treatment of neuropsychiatric disorders, especially schizophrenia. He was instrumental in focusing research on the role of abnormal brain development as a risk factor for schizophrenia. He has identified a number of specific neural and molecular mechanisms of genetic risk for schizophrenia, and genetic effects that account for variation in specific human cognitive functions and in human temperament. His recent work has focused on genetic and epigenetic regulation of expression in human brain of genes associated with developmental brain disorders. In 2003, *Science* magazine highlighted the genetic research of his lab as the second biggest scientific breakthrough of the year, second to the origins of the cosmos. He is the recipient of many honors and awards, including the Sarnat International Prize of the National Academy of Medicine, The International Neuroscience Prize of the Gertrud Reemtsma Foundation of the Max Planck Society, the NIH Directors Award, The Roche-Nature Medicine Neuroscience Award, The William K. Warren Medical Research Institute Award, the Adolf Meyer Prize of the American Psychiatric Association, the Foundation's Fund Prize from the American Psychiatric Association, and the Lieber Prize of the Brain and Behavior Research Foundation. He is past president of the Society of Biological Psychiatry, past President of the American College of Neuropsychopharmacology and has been elected to the National Academy of Medicine of the National Academy of Sciences.

Board Composition

Our Board currently consists of five members. Under our Second Amended and Restated Bylaws (the "Bylaws"), the number of directors who shall constitute the Board shall equal not less than one or more than ten, as the Board may determine by resolution from time to time.

Board Elections

In accordance with the terms of our Second Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), and Bylaws, our Board is divided into three classes; Class I, Class II and Class III, with each class serving staggered three-year terms. Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires. Our directors are divided among the three classes as follows:

- The Class I director is Dr. Emer Leahy; her term will expire at the 2027 Annual Meeting of Stockholders;
- The Class II directors are Alfred Novak and Simon Dumesnil; their terms will expire at the 2028 Annual Meeting of Stockholders; and
- The Class III directors are Dr. Tiago Reis Marques and Prof. Lawrence Steinman; their terms will expire at the 2026 Annual Meeting of Stockholders.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the total number of directors. The division of our Board into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Our Certificate of Incorporation and Bylaws provide that the authorized number of directors may be changed only by resolution of our Board. Our Certificate of Incorporation and Bylaws also provide that our directors may be removed only for cause, and that any vacancy on our Board, including a vacancy resulting from an enlargement of our Board, may be filled only by vote of a majority of our directors then in office, even if less than a quorum, or by a sole remaining director.

Board Leadership Structure

The positions of our Chairman of the Board and Chief Executive Officer are separated. Separating these positions allows our Chief Executive Officer to focus on our day-to-day business, while allowing the Chairman of the Board to lead our Board in its fundamental role of providing advice to and independent oversight of management. Our Board recognizes the time, effort and energy that the Chief Executive Officer must devote to his position in the current business environment, as well as the commitment required to serve as our Chairman, particularly as our Board's oversight responsibilities continue to grow. Our Board also believes that this structure ensures a greater role for the independent directors in the oversight of our Company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our Board. Our Board believes its administration of its risk oversight function has not affected its leadership structure.

Our corporate governance guidelines provide that, if the Chairman of the Board is a member of management or does not otherwise qualify as independent, the independent directors of the Board may elect a lead director. The lead director's responsibilities include, but are not limited to: presiding over all meetings of the Board at which the chairman is not present, including any executive sessions of the independent directors; approving Board meeting schedules and agendas; and acting as the liaison between the independent directors and the Chief Executive Officer and Chairman of the Board. Our corporate governance guidelines further provide the flexibility for our Board to modify our leadership structure in the future as it deems appropriate.

Role of the Board in Risk Oversight

One of the key functions of our Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee but rather administers this oversight function directly through our Board as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure and our audit committee ("Audit Committee") has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our Audit Committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee ("Nominating and Corporate Governance Committee") monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee ("Compensation Committee") assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire Board is regularly informed through committee reports about such risks.

Board Committees

We currently have three committees of the Board and have adopted charters for such committees: an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. The composition and responsibilities of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Each committee's charter is available under the Governance section of our website at *www.pasithea.com*. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report on Form 10-K.

Audit Committee. The Audit Committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our Board's oversight of our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the Audit Committee report required by SEC rules.

The members of our Audit Committee are Simon Dumesnil (chairperson), Dr. Emer Leahy and Alfred Novak. All members of our Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our Board has determined that Simon Dumesnil is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of Nasdaq. Under the rules of the SEC, members of the Audit Committee must also meet heightened independence standards. Our Board has determined that Simon Dumesnil (chairperson), Dr. Emer Leahy and Alfred Novak are independent within the meaning of the rules and regulations of Nasdaq and Rule 10A-3 under the Exchange Act.

The Audit Committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Compensation Committee. The Compensation Committee's responsibilities include:

- reviewing and approving, or recommending for approval by the Board, the compensation of our Chief Executive Officer and our other executive officers;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our Board with respect to director's compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required; and
- preparing the annual Compensation Committee report required by SEC rules, to the extent required.

The members of our Compensation Committee are Dr. Emer Leahy (chairperson), Alfred Novak and Simon Dumesnil. Each of the members of our Compensation Committee is independent under the applicable rules and regulations of Nasdaq and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. The Compensation Committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee's responsibilities include:

- identifying individuals qualified to become Board members;
- recommending to our Board the persons to be nominated for election as directors and to each Board committee;
- developing and recommending to our Board corporate governance guidelines, and reviewing and recommending to our Board proposed changes to our corporate governance guidelines from time to time; and
- overseeing a periodic evaluation of our Board.

The members of our Nominating and Corporate Governance Committee are Alfred Novak (chairperson), Dr. Emer Leahy and Simon Dumesnil. Each of the members of our Nominating and Corporate Governance Committee is an independent director under the applicable rules and regulations of Nasdaq relating to Nominating and Corporate Governance Committee independence. The Nominating and Corporate Governance Committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Director Independence

Our Board has determined that Simon Dumesnil, Dr. Emer Leahy and Alfred Novak are all "independent" as that term is defined under the rules of The Nasdaq Stock Market LLC, or the Nasdaq rules. Our Board has determined that due to Dr. Tiago Reis Marques' employment as an executive officer of the Company, he currently has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, such that he is not "independent" as that term is defined under the Nasdaq rules. Our Board has also determined that beginning as of June 21, 2022, due to the Company's transaction with Alpha-5, Prof. Lawrence Steinman has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, such that he is not "independent" as that term is defined under the Nasdaq rules.

Compensation Committee Interlocks and Insider Participation

No member of our Compensation Committee is a current or former officer or employee. None of our executive officers served as a director or a member of a Compensation Committee (or other committee serving an equivalent function) of any other entity, one of whose executive officers served as a director or member of our Compensation Committee during the last completed fiscal year.

Corporate Code of Conduct and Ethics

Our Board has adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Copies of our corporate code of conduct and ethics are available, without charge, upon request in writing to Pasithea Therapeutics Corp., 1111 Lincoln Road, Suite 500, Miami Beach, FL 33139, Attn: Secretary and are posted on the investor relations section of our website, which is located at *www.pasithea.com*. The inclusion of our website address in this Annual Report on Form 10-K does not include or incorporate by reference the information on our website into this Annual Report on Form 10-K. We also intend to disclose any amendments to the Corporate Code of Conduct and Ethics, or any waivers of its requirements, on our website.

Insider Trading Policies

We have adopted an insider trading policy that governs the purchase, sale, and/or other transactions of our securities by our directors, officers and employees. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K. In addition, with regard to the Company's trading in its own securities, it is our policy to comply with the federal securities laws and the applicable exchange listing requirements in all respects.

ITEM 11. EXECUTIVE COMPENSATION

As an emerging growth company under the JOBS Act, we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," which require compensation disclosure for our principal executive officer and the two most highly compensated executive officers (other than our principal executive officer) serving as executive officers at the end of our most recently completed fiscal year (collectively, our "Named Executive Officers"). This section describes the executive compensation program in place for our Named Executive Officers during the years ended December 31, 2025 and December 31, 2024, who are the individuals who served as our principal executive officer and two most highly compensated executive officers.

This section discusses the material components of the executive compensation program for our executive officers who are named in the "Summary Compensation Table" below and the non-employee members of our Board.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
Tiago Reis Marques (2)	2025	533,610	493,150	-	277,258	23,500	**1,327,518**
Chief Executive Officer	2024	450,000	-	22,241	167,818	-	**640,059**
Daniel Schneiderman (3)	2025	386,984	306,400	-	178,303	23,500	**895,187**
Chief Financial Officer	2024	330,000	-	-	100,223	-	**430,223**
Graeme Currie (4)	2025	-	-	-	-	-	**-**
Chief Development Officer	2024	386,535	-	-	48,276	-	**434,811**

(1) In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this column is a non-cash expense for the Company that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance.

(2) Dr. Marques has served as a Director and Chief Executive Officer since August 2020. Total compensation for 2025 for Dr. Marques includes i) $277,258 for the issuance of stock options to purchase 493,341 shares of Common Stock in October 2025, and ii) $23,500 relating to the Company 401(k) matching contributions. Total compensation for 2024 for Dr. Marques includes i) $22,241 for stock awards representing the grant date fair value of the issuance of 4,168 shares of common stock pursuant to the vesting of RSUs originally issued in December 2021 and ii) $167,818 for the issuance of stock options to purchase 26,669 shares of Common Stock in March 2024.

(3) Mr. Schneiderman was hired as Chief Financial Officer of the Company on October 11, 2022. Total compensation for 2025 for Mr. Schneiderman includes i) $178,303 for the issuance of stock options to purchase 317,266 shares of Common Stock in October 2025, and ii) $23,500 relating to the Company 401(k) matching contributions. Total compensation for 2024 for Mr. Schneiderman includes $100,223 for the issuance of stock options to purchase 15,927 shares of Common Stock in March 2024.

(4) Dr. Currie resigned as Chief Development Officer effective as of November 15, 2024.

Employment Agreements with our Named Executive Officers

Employment Agreement with Dr. Tiago Reis Marques

On January 1, 2022, we entered into an employment agreement with Dr. Marques. Under the terms of Dr. Marques' employment agreement, he holds the position of Chief Executive Officer and receives a base salary of $621,000 annually (effective January 1, 2026). In addition, Dr. Marques is eligible to receive an annual bonus, with a target amount equal to fifty-five percent (55%) of Dr. Marques' annual base salary. The actual amount of each bonus will be determined by the sole discretion of our Compensation Committee and will be based upon both the Company's performance and Dr. Marques' individual performance. Pursuant to the terms of his employment agreement, Dr. Marques is also eligible to participate in all incentive and deferred compensation programs available to other executives or officers of the Company, and will be eligible to participate in any employee benefit plans and equity plans that we may adopt, which plans may be amended by the Company from time to time in its sole discretion.

Pursuant to Dr. Marques' employment agreement, Dr. Marques was paid $100,000 as a sign on bonus. We also issued to Dr. Marques stock options to purchase 10,000 shares of Common Stock under our 2021 Incentive Plan, with one-third of the total shares vesting on the 12-month anniversary of the grant date, and the remainder vesting in equal quarterly installments thereafter. Further, we issued to Dr. Marques Restricted Stock Units exercisable for 10,000 shares of Common Stock, with one-third of the total shares underlying the RSUs vesting upon the 12-month anniversary of the grant date, with the remainder vesting in equal quarterly installments thereafter.

We may terminate Dr. Marques' employment at any time with or without Cause (as that term is defined in Dr. Marques' employment agreement) and with or without advance notice to Dr. Marques, and Dr. Marques may terminate his employment at any time for any reason upon providing 90 days' written notice to the Company.

In the event we terminate Dr. Marques' employment without Cause, we will pay Dr. Marques the equivalent of 12 months of his base annual salary in effect as of the date of termination, subject to standard payroll deductions and withholdings and Dr. Marques' executing a release of claims against the Company. If we terminate Dr. Marques' employment for any other reason, Dr. Marques will receive no compensation other than what he has earned at the time of the termination, and he will not be entitled to any severance benefits.

Employment Agreement with Daniel Schneiderman

On October 11, 2022, we entered into an employment agreement with Mr. Schneiderman. Under the terms of Mr. Schneiderman' employment agreement, he holds the position of Chief Financial Officer and receives a base salary of $456,000 annually (effective January 1, 2026). In addition, Mr. Schneiderman is eligible to receive an annual bonus, with a target amount equal to forty percent (40%) of Mr. Schneiderman's annual base salary. The actual amount of each bonus will be determined by the sole discretion of our Compensation Committee and will be based upon both the Company's performance and Mr. Schneiderman's individual performance. Pursuant to the terms of his employment agreement, Mr. Schneiderman is also eligible to participate in all incentive and deferred compensation programs available to other executives or officers of the Company, and will be eligible to participate in any employee benefit plans and equity plans that we may adopt, which plans may be amended by the Company from time to time in its sole discretion.

Pursuant to Mr. Schneiderman's employment agreement, Mr. Schneiderman was paid $30,000 as a sign on bonus. We also issued to Mr. Schneiderman stock options to purchase 15,000 shares of Common Stock under our 2021 Incentive Plan, with one-third of the total shares vesting on the one year anniversary of the grant date, one-third of the total shares vesting on the two year anniversary of the grant date, and one-third of the total shares vesting on the three year anniversary of the grant date.

We may terminate Mr. Schneiderman's employment at any time with or without Cause (as that term is defined in Mr. Schneiderman's employment agreement) and with or without advance notice to Mr. Schneiderman, and Mr. Schneiderman may terminate his employment at any time for any reason upon providing 60 days' written notice to the Company.

In the event we terminate Mr. Schneiderman's employment without Cause, we will pay Mr. Schneiderman the equivalent of six months of his base annual salary in effect as of the date of termination, subject to standard payroll deductions and withholdings and Mr. Schneiderman's executing a release of claims against the Company. His stock options will also accelerate and fully vest on his termination date. If we terminate Mr. Schneiderman's employment for any other reason, Mr. Schneiderman will receive no compensation other than what he has earned at the time of the termination and he will not be entitled to any severance benefits.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes, for each of our Named Executive Officers, the number of shares of our Common Stock underlying outstanding stock options held as of December 31, 2025:

		Option Awards					Stock Awards	
Name		Grant Date	Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Shares Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Units of Stock That Have Not Vested	Market Value of Units of Stock That Have Not Vested
Tiago Reis Marques,	(1)	12/20/2021	10,000	-	$ 28.80	12/20/2031	-	$ -
Chief Executive Officer	(2)	03/01/2024	20,419	6,250	$ 8.13	03/01/2034	-	$ -
	(3)	10/24/2025	-	493,341	$ 0.72	10/24/2035	-	$ -
Daniel Schneiderman,	(4)	10/11/2021	15,000	-	$ 25.20	10/11/2031	-	$ -
Chief Financial Officer	(5)	03/01/2024	11,760	4,167	$ 8.13	03/01/2034	-	$ -
	(6)	10/24/2025	-	317,266	$ 0.72	10/24/2035	-	$ -
Graeme Currie,		-	-	-	$ -	-	-	$ -
Chief Development Officer		-	-	-	$ -	-	-	$ -

(1) Under the terms of Dr. Marques' Executive Employment Agreement, on December 20, 2021, he received (i) a grant of 10,000 stock options at an exercise price equal to the closing price of the Company's Common Stock on the grant date and (ii) a grant of 10,000 restricted stock units ("RSUs"). Dr. Marques' stock options and RSUs each vested over three years, with one-third vesting 12 months after the grant date, and the remainder vesting in equal tranches quarterly for two years thereafter.

(2) Under the terms of the Company's 2023 Incentive Plan (as defined below), Dr. Marques received a grant of 26,669 stock options at an exercise price equal to the closing price of the Company's Common Stock on the grant date. 11,669 shares vested immediately, 5,000 shares vested on February 28, 2025, and then 10,000 shares vest in equal quarterly tranches for each of the two years thereafter.

(3) Under the terms of the Company's 2023 Incentive Plan, Dr. Marques received a grant of 493,341 stock options at an exercise price equal to the closing price of the Company's Common Stock on the grant date. One-third of the shares will vest on the one-year anniversary of the grant date, and the remaining shares will vest in equal quarterly installments thereafter for the next two years.

(4) Under the terms of Mr. Schneiderman's Executive Employment Agreement, on October 11, 2022, he received a grant of 15,000 stock options at an exercise price equal to the closing price of the Company's Common Stock on the grant date. Mr. Schneiderman's stock options vested over three years, with one-third vesting one year after the grant date, one-third vesting two years after the grant date and the one-third vesting three years after the grant date.

(5) Under the terms of the Company's 2023 Incentive Plan, Mr. Schneiderman received a grant of 15,927 stock options at an exercise price equal to the closing price of the Company's Common Stock on the grant date. 5,927 shares vested immediately, 3,334 shares vested on February 28, 2025, and then 6,666 shares vest in equal quarterly tranches for each of the two years thereafter.

(6) Under the terms of the Company's 2023 Incentive Plan, Mr. Schneiderman received a grant of 317,266 stock options at an exercise price equal to the closing price of the Company's Common Stock on the grant date. One-third of the shares will vest on the one-year anniversary of the grant date, and the remaining shares will vest in equal quarterly installments thereafter for the next two years.

There were no option exercises by our Named Executive Officers during our fiscal years ended December 31, 2025, or 2024.

Incentive Award Plans

2023 Incentive Plan

On October 6, 2023, our Board adopted the Company's 2023 Stock Incentive Plan (as amended, the "2023 Incentive Plan"), and our stockholders approved the 2023 Stock Incentive Plan at our 2023 Annual Meeting of Stockholders. As of stockholder approval of the 2023 Incentive Plan, no new grants of awards were made under the Pasithea Therapeutics Corp. 2021 Stock Incentive Plan (the "2021 Incentive Plan") and all new grants of awards have been and will continue to be made under the 2023 Incentive Plan. All unused shares of Common Stock reserved under our 2021 Incentive Plan and shares from outstanding awards that are canceled or forfeited under the 2021 Incentive Plan will be rolled over for issuance under the 2023 Incentive Plan.

On September 3, 2025, at our 2025 Annual Meeting of Stockholders, our stockholders approved an amendment (the "First Plan Amendment") to our 2023 Stock Incentive Plan increasing the number of shares of Common Stock authorized for issuance under the 2023 Stock Incentive Plan by 1,750,000 shares to 2,014,221 shares. The First Plan Amendment became effective following its approval by our stockholders. Further, on January 28, 2026, at a Special Meeting of Stockholders, our stockholders approved an additional amendment (the "Second Plan Amendment") to our 2023 Stock Incentive Plan, as amended by the First Plan Amendment, increasing the number of shares of Common Stock authorized for issuance under the 2023 Stock Incentive Plan, as amended by the First Plan Amendment, by 11,985,779 shares to 14,000,000 shares. The Second Plan Amendment became effective following its approval by our stockholders. No other modifications were made to the 2023 Incentive Plan.

The following description of the material terms of the 2023 Incentive Plan is intended to be a summary only. This summary is qualified in its entirety by the full text of the 2023 Incentive Plan, a copy of which, along with the amendments thereto, are filed as exhibits to this Annual Report on Form 10-K and incorporated herein by reference.

Administration. The 2023 Incentive Plan is administered by the Compensation Committee. However, the entire Board may act in lieu of the Compensation Committee on any manner. The Compensation Committee has authority, in its discretion, to approve the persons to whom awards may be granted, to make any combination of awards to participants, to accelerate the exercisability or vesting of an award and to determine the specific terms and conditions of each award, subject to the provisions of the 2023 Incentive Plan. The Compensation Committee may also approve rules and regulations for the administration of the 2023 Incentive Plan and amendments or modifications of outstanding awards (except that options and Stock Appreciation Rights ("SARs") cannot be repriced without shareholder approval). The Compensation Committee may delegate authority to the Chief Executive Officer and/or other officers to grant awards to employees (other than themselves), subject to applicable law and the 2023 Incentive Plan. No awards may be made under the 2023 Incentive Plan on or after the tenth anniversary of the date of original Board approval of the 2023 Incentive Plan (the "Expiration Date"), but the 2023 Incentive Plan will continue thereafter while previously granted awards remain outstanding.

Eligibility. Persons eligible to receive awards under the 2023 Incentive Plan are all employees, officers, directors, consultants, other advisors and other individual service providers of our Company and our subsidiaries, who, in the opinion of the Compensation Committee, are in a position to contribute to the success and growth of the Company, or any person who is determined by the Compensation Committee to be a prospective employee, officer, director, consultant, advisor or other individual service provider of our Company or any subsidiary. Notwithstanding the foregoing, only Company employees are eligible to receive grants of "incentive stock options" ("ISOs") that meet the requirements of Section 422 of the Code. As of December 31, 2025, the Company and its subsidiaries had a total of five employees (including two officers) and four non-employee directors. In accordance with our Bylaws, directors who are serving the Company as employees and who receive compensation for their services as such, shall not be eligible to receive any other compensation under the 2023 Incentive Plan for their services as directors of the Company. None of our subsidiaries have employees and none of the officers and directors of our subsidiaries are eligible for awards under the 2023 Incentive Plan other than those who are eligible as officers or directors of the Company. As of December 31, 2025, no person is eligible to participate as a result of a determination by the Compensation Committee that that person is a prospective employee, officer, director, consultant, advisor or other individual service provider of the Company or any subsidiary. As awards under the 2023 Incentive Plan are within the discretion of the Compensation Committee, the Company cannot determine how many individuals in each of the categories described above will receive awards.

Shares Subject to the 2023 Incentive Plan. The Board has reserved for issuance under the 2023 Incentive Plan (i) 125,000 shares of Common Stock (after adjustment for the reverse stock split we effected on January 2, 2024), (ii) such number of unused shares of Common Stock reserved under the 2021 Incentive Plan as of the date stockholders initially approved the 2023 Incentive Plan, (iii) a total of 73,082 shares of Common Stock that were added pursuant to the 2023 Incentive Plan's "evergreen" provision described below, (iv) a total of 1,750,000 shares of Common Stock that were added pursuant to the First Plan Amendment and (v) a total of 11,985,779 shares of Common Stock that were added pursuant to the Second Plan Amendment (subsections (i), (ii), (iii), (iv) and (v) together, the "Share Reserve"). All such shares of Common Stock reserved for issuance under the 2023 Incentive Plan may, but need not, be issued in respect of ISOs. In addition, shares of our Common Stock that relate to any outstanding grants or awards under the 2021 Incentive Plan as of the date stockholders initially approved the 2023 Incentive Plan that are forfeited, cancelled or otherwise lapse in accordance with applicable plan terms or are surrendered in payment of the exercise price and/or withholding taxes shall be rolled into the 2023 Incentive Plan and added to the Share Reserve (but not issued in respect of ISOs).

Under the 2023 Incentive Plan's "evergreen" provision, the number of shares of Common Stock available for issuance under the 2023 Incentive Plan will automatically increase on January 1st of each year until the Expiration Date, in an amount equal to three percent (3%) of the total number of shares of our Common Stock outstanding on the December 31st of the preceding calendar year, unless the Board takes action prior thereto to provide that there will not be an increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be of a lesser number of shares of Common Stock than would otherwise occur. None of the additional shares of Common Stock available for issuance pursuant to the 2023 Incentive Plan's "evergreen" provision for years beginning in 2027 and after, if any, shall be issued in respect of ISOs.

If any option or SAR granted under the 2023 Incentive Plan terminates without having been exercised in full or if any award is forfeited, or if shares of Common Stock are withheld to cover withholding taxes on options or other awards or applied to the payment of the exercise price of an option or purchase price of an award, the number of shares of Common Stock as to which such option or award was forfeited, withheld or paid, will be available for future grants under the 2023 Incentive Plan. Awards settled in cash will not count against the number of shares available for issuance under the 2023 Incentive Plan.

The number of shares of Common Stock authorized for issuance under the 2023 Incentive Plan and the foregoing share limitations are subject to customary adjustment for stock splits, stock dividends or similar transactions.

Director Compensation. The 2023 Incentive Plan provides for an annual limit on non-employee director compensation of $500,000, increased to $750,000 in the fiscal year of a non-employee director's initial service as a non-employee member of the Board. This limit applies to the sum of both equity grants that could be awarded to non-employee directors during a fiscal year (based on their value under ASC Topic 718 on the grant date) and cash compensation, such as cash retainers and meeting fees earned during a fiscal year. Notwithstanding the foregoing, the Board reserves the right to make an exception to these limits due to extraordinary circumstances without the participation of the affected director receiving additional compensation.

Terms and Conditions of Stock Options. Options granted under the 2023 Incentive Plan may be either ISOs or "nonstatutory stock options" that do not meet the requirements of Section 422 of the Code. The Compensation Committee will determine the exercise price of options granted under the 2023 Incentive Plan. The exercise price of stock options may not be less than the fair market value per share of our Common Stock on the date of grant (or 110% of fair market value in the case of ISOs granted to a ten-percent stockholder).

If on the date of grant the Common Stock is listed on a stock exchange or is quoted on the automated quotation system of Nasdaq, the fair market value will generally be the closing sale price on the date of grant (or the last trading day before the date of grant if no trades occurred on the date of grant). If no such prices are available, the fair market value will be determined in good faith by the Compensation Committee based on the reasonable application of a reasonable valuation method. On December 31, 2025, the closing sale price of a share of our Common Stock on The Nasdaq Capital Market was $1.29.

No option may be exercisable for more than ten years (five years in the case of an ISO granted to a ten-percent stockholder) from the date of grant. Options granted under the 2023 Incentive Plan will be exercisable at such time or times as the Compensation Committee prescribes at the time of grant. Unless otherwise provided by the Compensation Committee, no option will provide for vesting or exercise earlier than one year after the date of grant. No employee may receive ISOs that first become exercisable in any calendar year in an amount exceeding $100,000. The Compensation Committee may, in its discretion, permit a holder of a nonstatutory option to exercise the option before it has otherwise become exercisable, in which case the shares of our Common Stock issued to the recipient will continue to be subject to the vesting requirements that applied to the option before exercise.

Generally, the option price may be paid in cash or by certified check, bank draft or money order. The Compensation Committee may permit other methods of payment, including (a) through delivery of shares of our Common Stock having a fair market value equal to the purchase price, (b) by a full recourse, interest bearing promissory note having such terms as the Compensation Committee may permit, or (c) a combination of these methods, as set forth in an award agreement or as otherwise determined by the Compensation Committee. The Compensation Committee is authorized to establish a cashless exercise program and to permit the exercise price (or tax withholding obligations) to be satisfied by reducing from the shares otherwise issuable upon exercise a number of shares having a fair market value equal to the exercise price.

No option may be transferred other than by will or by the laws of descent and distribution, and during a recipient's lifetime an option may be exercised only by the recipient. However, the Compensation Committee may permit the holder of a nonstatutory option to transfer the award to immediate family members or a family trust for estate planning purposes. The Compensation Committee will determine the extent to which a holder of a stock option may exercise the option following termination of service with us.

Stock Appreciation Rights. The Compensation Committee may grant SARs independent of or in connection with an option. The Compensation Committee will determine the other terms applicable to SARs. Unless otherwise provided by the Compensation Committee, no SAR will provide for vesting or exercise earlier than one year after the date of grant. The exercise price per share of a SAR will not be less than 100% of the fair market value of a share of our Common Stock on the date of grant, as determined by the Compensation Committee. The maximum term of any SAR granted under the 2023 Incentive Plan is ten years from the date of grant. Generally, each SAR will entitle a participant upon exercise to an amount equal to:

- the excess of the fair market value on the exercise date of one share of our Common Stock over the exercise price, *multiplied by*
- the number of shares of Common Stock covered by the SAR.

Payment may be made in shares of our Common Stock, in cash, or partly in Common Stock and partly in cash, all as determined by the Compensation Committee.

Restricted Stock and Restricted Stock Units. The Compensation Committee may award restricted Common Stock and/or restricted stock units under the 2023 Incentive Plan. Restricted stock awards consist of shares of Common Stock that are transferred to a participant subject to restrictions that may result in forfeiture if specified conditions are not satisfied. Restricted stock units confer the right to receive shares of our Common Stock, cash, or a combination of shares of Common Stock and cash, at a future date upon or following the attainment of certain conditions specified by the Compensation Committee. The restrictions and conditions applicable to each award of restricted stock or restricted stock units may include performance-based conditions. Unless otherwise provided by the Compensation Committee, no award of restricted stock or restricted stock units will provide for vesting earlier than one year after the date of grant. Dividends or distributions with respect to restricted stock may be paid to the holder of the shares as and when dividends are paid to stockholders or at the time that the restricted stock vests, as determined by the Compensation Committee. If any dividends or distributions are paid in stock before the restricted stock vests, they will be subject to the same restrictions. Dividend equivalent amounts may be deemed reinvested in additional restricted stock units or paid with respect to restricted stock units either when cash dividends are paid to stockholders or when the units vest. Unless the Compensation Committee determines otherwise, holders of restricted stock will have the right to vote on the shares.

Performance Shares and Performance Units. The Compensation Committee may award performance shares and/or performance units under the 2023 Incentive Plan to any eligible employee or other individual service provider other than a non-employee director of the Board. Performance shares and performance units are awards, denominated in either shares of Common Stock or U.S. dollars, which are earned during a specified performance period subject to the attainment of performance criteria, as established by the Compensation Committee. The Compensation Committee will determine the restrictions and conditions applicable to each award of performance shares and performance units.

Incentive Bonus Awards. The Compensation Committee may grant incentive bonus awards under the 2023 Incentive Plan from time to time. The terms of incentive bonus awards will be set forth in award agreements. Each award agreement will have such terms and conditions as the Compensation Committee determines, including performance goals and the amount of payment based on achievement of such goals. Incentive bonus awards are payable in cash and/or shares of our Common Stock.

Other Stock-Based and Cash-Based Awards. The Compensation Committee may award other types of equity-based or cash-based awards under the 2023 Incentive Plan, including the grant or offer for sale of shares of our Common Stock that do not have vesting requirements and the right to receive one or more cash payments subject to satisfaction of such conditions as the Compensation Committee may impose.

Effect of Certain Corporate Transactions. The Compensation Committee may, at the time of the grant of an award provide for the effect of a Change in Control (as defined in the 2023 Incentive Plan) on any award, including (i) accelerating or extending the time periods for exercising, vesting in, or realizing gain from any award, (ii) eliminating or modifying the performance or other conditions of an award, or (iii) providing for the cash settlement of an award for an equivalent cash value, as determined by the Compensation Committee. The Compensation Committee may, in its discretion and without the need for the consent of any recipient of an award, also take one or more of the following actions contingent upon the occurrence of a Change in Control: (a) cause any or all outstanding options and SARs to become immediately exercisable, in whole or in part; (b) cause any other awards to become non-forfeitable, in whole or in part; (c) cancel any option or SAR in exchange for a substitute option; (d) cancel any award of restricted stock, restricted stock units, performance shares or performance units in exchange for a similar award of the capital stock of any successor corporation; (e) redeem any restricted stock for cash and/or other substitute consideration with a value equal to the fair market value of an unrestricted share of our Common Stock on the date of the change in control; (f) cancel any awards in exchange for cash and/or other property equal to the amount, if any, that would have been attained upon the exercise of such award or realization of rights upon a change in control, but if the change in control consideration with respect to any option or SAR does not exceed its exercise price, the option or SAR may be canceled without payment of any consideration; or (g) take any other action the Compensation Committee deems necessary or appropriate to carry out the terms of any definitive agreement controlling the terms and conditions of the Change in Control.

Clawback/Recoupment. Awards granted under the 2023 Incentive Plan will be subject to the requirement that the awards be forfeited or amounts repaid to the Company after they have been distributed to the participant (i) to the extent set forth in an award agreement or (ii) to the extent covered by any clawback or recapture policy adopted by the Company from time to time, or any applicable laws that impose mandatory forfeiture or recoupment, under circumstances set forth in such applicable laws.

Amendment, Termination. Our Board may at any time amend, suspend or terminate the 2023 Incentive Plan for the purpose of satisfying the requirements of the Code, or other applicable law or regulation or for any other legal purpose, provided that, without the consent of our stockholders, the Board may not (i) increase the number of shares of Common Stock available under the 2023 Incentive Plan, (ii) change the group of individuals eligible to receive awards, or (iii) extend the term of the 2023 Incentive Plan.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer. For further information, see "*–Limitations on Liability and Indemnification Matters*" below.

Policies and Procedures for Related Person Transactions

Our Board has adopted a written related person transaction policy, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions as set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved will be the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our Audit Committee is tasked to consider all relevant facts and circumstances, including, but not limited to (i) whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated party; (ii) the extent of the related person's interest in the transaction; (iii) the benefits to the Company; (iv) the impact on a director's independence in the event the related person is a director, an immediately family member of a director or an entity in which a director is a partner, stockholder or executive officer; (v) the availability of other sources for comparable products or services; (vi) the terms of the transaction; and (vii) the terms available to unrelated third parties.

All related-party transactions may only be consummated if our Audit Committee has approved or ratified such transaction in accordance with the guidelines set forth in the policy. Any member of the Audit Committee who is a related person with respect to a transaction under review will not be permitted to participate in the deliberations or vote respecting approval or ratification of the transaction. However, such director may be counted in determining the presence of a quorum at a meeting of the Audit Committee that considers the transaction.

Limitations on Liability and Indemnification Matters

Our Certificate of Incorporation limits our directors' liability to the fullest extent permitted under Delaware law, which prohibits our Certificate of Incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended.

Our Bylaws provide that we indemnify our directors and officers to the fullest extent permitted under Delaware law and that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our Bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether we would have the power to indemnify such person against such expense, liability or loss under the DGCL.

We have entered into indemnification agreements with our directors and officers, in addition to indemnification provided for in our Bylaws. These agreements, among other things, provide for indemnification of our directors and officers for expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by such persons in any action or proceeding arising out of this person's services as a director or officer or at our request. We believe that these provisions in our Certificate of Incorporation and Bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the limitation of liability and indemnification provisions of our Certificate of Incorporation, our Bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to this Annual Report on Form 10-K.

The limitation of liability and indemnification provisions in our Certificate of Incorporation and Bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Director Compensation

The below table sets forth for each non-employee director that served as a director during the year ended December 31, 2025, certain information concerning his or her compensation for the year ended December 31, 2025. Directors who are also our employees, namely Dr. Marques, are not compensated for serving on the Board. Dr. Marques' compensation is set forth in the Summary Compensation Table above and he will not receive any additional compensation for his service as a director.

Year Ended December 31, 2025

Name		Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($) (1)	Non-equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($) (2)
Professor Lawrence Steinman	(3)	208,751	-	136,517	-	-	-	345,268
Simon Dumesnil	(4)	65,000	-	24,117	-	-	-	89,117
Dr. Emer Leahy	(5)	60,000	-	24,117	-	-	-	84,117
Alfred Novak	(6)	80,000	-	24,117	-	-	-	104,117

(1) In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this column is a non-cash expense for the Company that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance. The fair value of the stock options will likely vary from the actual value the holder receives because the actual value depends on the number of options exercised and the market price of our Common Stock on the date of exercise. For a discussion of the assumptions made in the valuation of the stock options, see Note 5 (Stockholders' Equity) to our financial statements, which are included in this Annual Report on Form 10-K. The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2025, held by each of Prof. Lawrence Steinman, Simon Dumesnil, Dr. Emer Leahy and Alfred Novak was 255,413, 55,413, 55,413 and 52,913, respectively.

(2) All directors receive reimbursement for reasonable out of pocket expenses in attending Board meetings and for participating in our business.

(3) Under the terms of the Company's 2023 Incentive Plan, Prof Steinman received a grant of 242,913 stock options at an exercise price of $0.715 per share, equal to the closing price of the Company's Common Stock on the grant date.

(4) Under the terms of the Company's 2023 Incentive Plan, Mr. Dumesnil received a grant of 42,913 stock options at an exercise price of $0.715 per share, equal to the closing price of the Company's Common Stock on the grant date.

(5) Under the terms of the Company's 2023 Incentive Plan, Dr. Leahy received a grant of 42,913 stock options at an exercise price of $0.715 per share, equal to the closing price of the Company's Common Stock on the grant date.

(6) Under the terms of the Company's 2023 Incentive Plan, Mr. Novak received a grant of 42,913 stock options at an exercise price of $0.715 per share, equal to the closing price of the Company's Common Stock on the grant date. $20,000 of cash fees paid in 2025 were from accrued and unpaid fees earned in 2024.

Compensation Policy for Non-Employee Directors.

The material terms of the non-employee director compensation program, as it is currently contemplated, are summarized below.

The non-employee director compensation program provides for annual retainer fees and/or long-term equity awards for our non-employee directors. Each non-employee director is eligible to receive an annual retainer of $50,000 plus an additional (i) $10,000 for serving as Chair of the Compensation Committee or the Nominating and Corporate Governance Committee or (ii) $15,000 (effective as of January 1, 2025) for serving as Chair of the Audit Committee. A non-employee director serving as Chairman of the Board is eligible to receive an additional annual retainer of $35,000 (effective as of October 1, 2025). Additionally, upon joining the Board, non-employee directors are eligible to receive stock options to purchase 5,000 shares of Common Stock, with 50% of the shares subject to the options vesting after the first year of service and 50% vesting after the second year.

Compensation under our non-employee director compensation policy is subject to the annual limits on non-employee director compensation set forth in the 2023 Incentive Plan, as described above. Our Board or an authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, subject to the annual limit on non-employee director compensation set forth in the 2023 Incentive Plan. As provided in the 2023 Incentive Plan, our Board or its authorized committee may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the Board or its authorized committee may determine in its discretion.

Consulting Agreement with Prof. Lawrence Steinman

A consulting agreement between us and Prof. Lawrence Steinman (as amended effective as of October 1, 2025, the "Steinman Consulting Agreement") memorializes the compensation arrangements pursuant to which Prof. Steinman has been compensated for his services to our Company, as previously disclosed in our public filings. Pursuant to the Steinman Consulting Agreement, Prof. Steinman provides a variety of consulting and advisory services relating principally to the clinical and commercial development of our product candidates, including our research and development strategy through all phases of discovery and preclinical development, identifying potential partners for our pre-clinical assets, and business development efforts related to our pre-clinical assets, among other things. Pursuant to the Steinman Consulting Agreement, Prof. Steinman receives $1.00 per quarter for his services (effective as of October 1, 2025).

The Company's Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of nonpublic Information

We do not have any formal policy that requires us to grant, or avoid granting, equity-based compensation to our executive officers at certain times. Consistent with our annual compensation cycle, the Compensation Committee has for several years granted annual equity awards to our executive officers and directors at the start of the new fiscal year. The timing of any equity grants to executive officers in connection with new hires, promotions, or other non-routine grants is tied to the event giving rise to the award (such as an executive officer's commencement of employment or promotion effective date). As a result, in all cases, the timing of grants of equity awards, including stock options, occurs independent of the release of any material nonpublic information, and we do not time the disclosure of material nonpublic information for the purpose of affecting the value of equity-based compensation.

No stock options were issued to executive officers in fiscal year 2025 during any period beginning four business days before the filing of a periodic report or current report disclosing material non-public information and ending one business day after the filing or furnishing of such report with the SEC.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Security Ownership of Certain Beneficial Holders and Management

The following table sets forth information with respect to the beneficial ownership of our Common Stock as of March 24, 2026, by:

- each person known by us to be the beneficial owner of more than 5% of our issued and outstanding Common Stock;
- each of our Named Executive Officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined in accordance with the rules issued by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of Common Stock beneficially owned by them, subject to any community property laws.

Percentage ownership of our Common Stock is based on 24,939,948 shares of Common Stock outstanding as of March 24, 2026. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of Common Stock subject to options, restricted units, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of March 24, 2026 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

To calculate a stockholder's percentage of beneficial ownership of Common Stock, we must include in the numerator and denominator those shares of Common Stock, as well as those shares of Common Stock underlying options, warrants and convertible securities, that such stockholder is considered to beneficially own. Shares of Common Stock underlying options, warrants and convertible securities, held by other stockholders, however, are disregarded in this calculation. Therefore, the denominator used in calculating beneficial ownership of each of the stockholders may be different.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Pasithea Therapeutics Corp., 1111 Lincoln Road, Suite 500, Miami Beach, FL 33139. To our knowledge, there is no arrangement, including any pledge by any person of securities of the Company, the operation of which may at a subsequent date result in a change in control of the Company.

	Beneficial Ownership Common Stock	
Name of Beneficial Owner	**Shares [1]**	**% [2]**
5% or Greater Stockholders		
Vivo Opportunity Fund Holdings, L.P. [3]	17,560,467	9.9%
Janus Henderson Group plc [4]	10,229,652	9.9%
Coastlands Capital LP [5]	2,394,765	9.9%
Adage Capital Management, L.P. [6]	2,329,749	9.9%
Squadron Capital Management, LLC [7]	2,329,749	9.9%
Ameriprise Financial, Inc. [8]	1,930,128	8.4%
Named Executive Officers and Directors:		
Dr. Tiago Reis Marques [9]	105,003	*
Daniel Schneiderman [10]	54,260	*
Prof. Lawrence Steinman [11]	219,691	*
Dr. Emer Leahy [12]	43,333	*
Simon Dumesnil [13]	45,833	*
Alfred Novak [14]	11,834	*
Dr. Graeme Currie [15]	-	*
All Current Directors and Executive Officers as a group (6 persons) [16]	**479,954**	**1.9%**

* Less than 1%.

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. All entries exclude beneficial ownership of shares issuable pursuant to warrants, options or other derivative securities that have not vested or that are not otherwise exercisable as of the date hereof or which will not become vested or exercisable within 60 days.

(2) Percentages are rounded to the nearest tenth of a percent. Percentages are based on 24,939,948 shares of Common Stock outstanding as of March 24, 2026. Warrants, stock options or other derivative securities that are presently exercisable or exercisable within 60 days of March 24, 2026 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage of any other person.

(3) Percentage ownership information is based on information disclosed in a statement on Schedule 13G filed with the SEC on December 5, 2025, on behalf of Vivo Opportunity Fund Holdings, L.P., Vivo Opportunity, LLC, Vivo Opportunity Cayman Fund, L.P. and Vivo Opportunity Cayman, LLC. The business address for Vivo Opportunity Fund Holdings, L.P., Vivo Opportunity, LLC, Vivo Opportunity Cayman Fund, L.P. and Vivo Opportunity Cayman, LLC is 192 Lytton Avenue, Palo Alto, California 94301.

(4) Percentage ownership information is based on information disclosed in a statement on Schedule 13G filed with the SEC on December 8, 2025, on behalf of Janus Henderson Group plc. The business address for Janus Henderson Group plc is 201 Bishopsgate, EC2M 3AE, United Kingdom.

(5) Percentage ownership information is based on information disclosed in a statement on Schedule 13G filed with the SEC on February 27, 2026, on behalf of Coastlands Capital LP, Coastlands Capital Partners LP, Coastlands Capital GP LLC, Coastlands Capital LLC and Matthew D. Perry. The business address for Coastlands Capital LP, Coastlands Capital Partners LP, Coastlands Capital GP LLC, Coastlands Capital LLC and Matthew D. Perry is 601 California Street, Suite 1210, San Francisco, CA 94108.

(6) Percentage ownership information is based on information disclosed in a statement on Schedule 13G filed with the SEC on February 12, 2026, on behalf of Adage Capital Management, L.P., Robert Atchinson and Phillip Gross. The business address for Adage Capital Management, L.P., Robert Atchinson and Phillip Gross is 200 Clarendon Street, 52nd Floor, Boston, Massachusetts 02116.

(7) Percentage ownership information is based on information disclosed in a statement on Schedule 13G/A filed with the SEC on February 17, 2026, on behalf of Squadron Master Fund LP, Squadron Capital Management, LLC, Matthew Sesterhenn and William Blank. The business address for Squadron Master Fund LP, Squadron Capital Management, LLC, Matthew Sesterhenn and William Blank is c/o Squadron Capital Management, LLC, 999 Oakmont Plaza Drive, Suite 600, Westmont, Illinois 60559.

(8) Percentage ownership information is based on information disclosed in a statement on Schedule 13G filed with the SEC on February 17, 2026, on behalf of Ameriprise Financial, Inc. and Columbia Management Investment Advisers, LLC. The business address for Ameriprise Financial, Inc. is 145 Ameriprise Financial Center, Minneapolis, MN 55474 and the business address for Columbia Management Investment Advisers, LLC is 290 Congress Street, Boston, MA 02210.

(9) Includes (i) 73,334 shares of Common Stock and (ii) 31,669 shares of Common Stock issuable upon exercise of vested stock options. Excludes 498,341 unvested options.

(10) Includes (i) 26,667 shares of Common Stock and (ii) 27,593 shares of Common Stock issuable upon exercise of vested stock options. Excludes 320,600 unvested stock options.

(11) Includes (i) 199,691 shares of Common Stock, (ii) 10,000 shares of Common Stock issuable upon exercise of warrants and (iii) 10,000 shares of Common Stock issuable upon exercise of vested stock options. Excludes 245,413 unvested stock options.

(12) Includes (i) 33,333 shares of Common Stock and (ii) 10,000 shares of Common Stock issuable upon exercise of vested stock options. Excludes 45,413 unvested stock options.

(13) Includes (i) 35,833 shares of Common Stock and (ii) 10,000 shares of Common Stock issuable upon exercise of vested stock options. Excludes 45,413 unvested stock options.

(14) Includes (i) 3,500 shares of Common Stock and (ii) 8,334 shares of Common Stock issuable upon exercise of vested stock options. Excludes 44,579 unvested stock options.

(15) Dr. Currie resigned from his position as Chief Development Officer effective as of November 15, 2024. As of the date of his resignation, he held no shares of Common Stock and all vested stock options held by Dr. Currie have been cancelled as of March 24, 2026.

(16) Excludes Dr. Graeme Currie.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2025, including our 2021 Incentive Plan and our 2023 Incentive Plan. Upon the adoption by our stockholders of the original 2023 Incentive Plan on December 19, 2023, all unused shares of Common Stock reserved under our 2021 Incentive Plan, and shares from outstanding awards that are canceled or forfeited under the 2021 Incentive Plan, are available for issuance under the 2023 Incentive Plan:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options (2)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (2)
	(a)	(b)	(c)
Equity compensation plans approved by security holders (1)	1,685,843	$ 9.60	389,628
Equity compensation plans not approved by security holders	-	$ -	-
Total	1,685,843	$ 9.60	389,628

(1) Consists of stock options exercisable for 61,250 shares of Common Stock outstanding under the 2021 Incentive Plan and 1,624,593 shares of Common Stock outstanding under the 2023 Incentive Plan as of December 31, 2025. Excludes 389,628 shares available under the 2023 Incentive Plan as of December 31, 2025. Also excludes 11,985,779 additional shares that became available under the 2023 Incentive Plan after the Company's stockholders approved the Second Plan Amendment in January 2026. For a description of the 2021 Incentive Plan and 2023 Incentive Plan, see Note 8 to our consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2025.

(2) The number of shares of Common Stock available for grant and issuance under the 2023 Incentive Plan is subject to an automatic annual increase on January 1 of each year beginning on January 1, 2024, by an amount equal to 3% of the total number of shares of Common Stock outstanding on December 31 of the preceding calendar year.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Persons

Except as set out below, as of January 1, 2024, there have been no transactions, or currently proposed transactions, in which we were or are to be a participant and the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of the following persons had or will have a direct or indirect material interest:

- any director or executive officer of our company;
- any person who beneficially owns, directly or indirectly, shares carrying more than 5% of the voting rights attached to our outstanding shares of Common Stock;
- any promoters and control persons; and
- any member of the immediate family (including spouse, parents, children, siblings and in laws) of any of the foregoing persons.

Pursuant to our Audit Committee charter, the Audit Committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us have or will have a direct or indirect material interest.

The following includes a summary of transactions since January 1, 2024 to which we have been a party in which the amount involved will be the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Item 11. Executive Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Related Party Transactions

Consulting Agreement with Prof. Lawrence Steinman

The Steinman Consulting Agreement memorializes the compensation arrangements pursuant to which Prof. Steinman has been compensated for his services to the Company, as previously disclosed in our public filings. Pursuant to the Steinman Consulting Agreement, Prof. Steinman provides a variety of consulting and advisory services relating principally to the clinical and commercial development of our product candidates, including our research and development strategy through all phases of discovery and preclinical development, identifying potential partners for our pre-clinical assets, and business development efforts related to our pre-clinical assets, among other things. Pursuant to the Steinman Consulting Agreement, as of September 30, 2025, Prof. Steinman received $25,000 per quarter for his services, which was subsequently reduced to $1.00 per quarter, effective as of October 1, 2025 (see Note 11 to our consolidated financial statements).

Director Independence

Nasdaq rules require that a majority of our Board be independent. An "independent director" is defined generally as a person other than an officer or employee of a company or its subsidiaries or any other individual having a relationship with such company which in the opinion of such company's board of directors, could interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director. Our Board has determined that Simon Dumesnil, Dr. Emer Leahy and Alfred Novak are all "independent" as that term is defined under the Nasdaq rules. Our Board has determined that due to Dr. Tiago Reis Marques' employment as an executive officer of the Company, he currently has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, such that he is not "independent" as that term is defined under the Nasdaq rules. Our Board has also determined that beginning as of June 21, 2022, due to the Company's transaction with Alpha-5, Prof. Lawrence Steinman has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, such that he is not "independent" as that term is defined under the Nasdaq rules.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Board of the Company has appointed CBIZ CPAs P.C. ("CBIZ") as our independent registered public accounting firm for the fiscal year ended December 31, 2025. On November 1, 2024, CBIZ acquired the attest business of Marcum LLP, our prior independent registered public accounting firm. The following table sets forth the aggregate fees billed to the Company for professional services rendered by CBIZ for the year ended December 31, 2025, and Marcum LLP for the year ended December 31, 2024:

	Year Ended December 31,	
Services:	**2025**	**2024**
Audit Fees (1)	$ 498,475	$ 271,048
Audit-Related Fees (2)	-	-
Tax Fees (3)	-	-
All Other Fees	-	-
Total fees	$ 498,475	$ 271,048

(1) Audit Fees represent the aggregate fees and expenses for professional services rendered for the audit of our consolidated financial statements included in our Annual Report on Form 10-K, our registration statements on Form S-1, Form S-3 and Form S-8, the review of the unaudited interim financial statements included in our quarterly reports on Form 10-Q, other professional services related to our SEC filings and various accounting consultations. This category also includes fees for comfort letters and consents issued in connection with SEC filings.

(2) Audit Related Fees represent the aggregate fees billed in each of the last two fiscal years for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under "Audit Fees" above.

(3) Tax Fees consist of fees related to tax compliance, tax planning and tax advice.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to the engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. ***Audit*** services include audit work performed in the preparation of financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

2. ***Audit-Related*** services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. ***Tax*** services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. ***Other Fees*** are those associated with services not captured in the other categories. The Company generally does not request such services from our independent registered public accounting firm.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires our independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging our independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

All services rendered by CBIZ and Marcum LLP in our fiscal years ended December 31, 2025, and 2024 were pre-approved by our Audit Committee.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

a) Financial Statements

Our consolidated financial statements are set forth in Part II, Item 8 of this Annual Report on Form 10-K and are incorporated herein by reference.

b) Financial Statement Schedules

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable or are not required or because the information is otherwise included herein.

c) Exhibits required by Regulation S-K

Exhibit Number	Description of Exhibit
2.1	Membership Interest Purchase Agreement entered into June 21, 2022, by and among Pasithea Therapeutics Corp., Alpha-5 integrin, LLC, and certain Sellers (as defined in the agreement) (incorporated by reference to exhibit 2.01 of the Company's Form 10-Q, filed with the Commission on August 15, 2022).
2.2	Membership Interest Purchase Agreement dated October 11, 2022 by and among Pasithea Therapeutics Corp., AlloMek Therapeutics, LLC, the Persons listed on Schedule 1.1 thereto, and Uday Khire, not individually but in his capacity as the representative of the Persons listed on Schedule 1.1 thereto (incorporated by reference to exhibit 2.1 of the Company's Form 8-K, filed with the Commission on October 12, 2022).
3.1	Second Amended & Restated Certificate of Incorporation of Pasithea Therapeutics Corp. (incorporated by reference to exhibit 3.1 of the Company's Form 8-K, filed with the Commission on January 2, 2024).
3.2	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of Pasithea Therapeutics Corp., dated December 29, 2023 (incorporated by reference to exhibit 3.4 of the Company's Form 8-K, filed with the Commission on January 2, 2024).
3.3	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of Pasithea Therapeutics Corp., as amended, dated January 28, 2026 (incorporated by reference to exhibit 3.1 of the Company's Form 8-K, filed with the Commission on January 28, 2026).
3.4	Second Amended & Restated Bylaws of Pasithea Therapeutics Corp. (incorporated by reference to exhibit 3.2 of the Company's Form 8-K, filed with the Commission on January 2, 2024).
4.1	Specimen Common Stock Certificate evidencing the shares of Common Stock (incorporated by reference to exhibit 4.1 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
4.2	Form of Warrant Agent Agreement, including Form of Warrant Certificate (incorporated by reference to exhibit 4.2 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
4.3	Form of Representative Warrant (incorporated by reference to exhibit 4.3 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
4.4	Form of Warrants issued in private placement (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the Commission on November 29, 2021).
4.5	Form of Warrants issued in acquisition of AlloMek Therapeutics, LLC (incorporated by reference to Exhibit 4.3 of the Company's Form S-3 (File No. 333-271896) filed with the Commission on May 12, 2023).
4.6	Form of Warrant issued in acquisition of Alpha-5 integrin, LLC (incorporated by reference to Exhibit 4.4 of the Company's Form S-3 (File No. 333-271896) filed with the Commission on May 12, 2023).
4.7	Form of Pre-Funded Common Stock Purchase Warrant issued in private placement (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K, filed with the Commission on September 30, 2024).
4.8	Form of Common Stock Purchase Warrant issued in private placement (incorporated by reference to Exhibit 4.2 of the Company's Form 8-K, filed with the Commission on September 30, 2024).
4.9	Form of Placement Agent Common Stock Purchase Warrant issued in private placement (incorporated by reference to Exhibit 4.3 of the Company's Form 8-K, filed with the Commission on September 30, 2024).
4.10	Form of Pre-Funded Warrant issued in May 2025 public offering (incorporated by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-1 (File No. 333-286889) filed on May 1, 2025).
4.11	Form of Series C/D Common Warrant issued in May 2025 public offering (incorporated by reference to Exhibit 4.2 of the Company's Form 8-K, filed with the Commission on May 7, 2025).
4.12	Form of Placement Agent Warrant issued in May 2025 public offering (incorporated by reference to Exhibit 4.3 of the Company's Form 8-K, filed with the Commission on May 7, 2025).
4.13	Form of Pre-Funded Warrant issued in December 2025 public offering (incorporated by reference to Exhibit 4.14 to the Company's Registration Statement on Form S-1 (File No. 333-291611), filed on November 18, 2025).

4.14	Form of Placement Agent Warrant issued in December 2025 offering (incorporated by reference to Exhibit 4.15 to the Company's Registration Statement on Form S-1, as amended (File No. 333-291611), filed on November 26, 2025).
4.15*	Description of Securities
10.1+	2021 Incentive Plan (incorporated by reference to exhibit 10.7 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
10.2	Form of Indemnification Agreement for Officers and Directors (incorporated by reference to exhibit 10.8 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
10.3	Form of Securities Purchase Agreement (incorporated by reference to exhibit 10.2 of the Company's Form 8-K, filed with the Commission on November 29, 2021).
10.4	Form of Registration Rights Agreement (incorporated by reference to exhibit 10.4 of the Company's Form 8-K, filed with the Commission on November 29, 2021).
10.5+	Executive Employment Agreement, dated as of January 1, 2022, between Pasithea Therapeutics Corp. and Dr. Tiago Reis Marques (incorporated by reference to exhibit 10.15 of the Company's Form 10-K/A, filed with the Commission on May 12, 2022).
10.6+	Stock Option Agreement, dated December 20, 2021, between Pasithea Therapeutics Corp. and Dr. Tiago Reis Marques (incorporated by reference to exhibit 10.16 of the Company's Form 10-K/A, filed with the Commission on May 12, 2022).
10.7+	Employment Agreement with Daniel Schneiderman (incorporated by reference to exhibit 10.1 of the Company's Form 10-Q, filed with the Commission on November 14, 2022).
10.8	Settlement and Cooperation Agreement dated December 9, 2022, by and between Pasithea Therapeutics Corp. and Camac Fund, LP and its affiliates (incorporated by reference to exhibit 10.1 of the Company's Form 8-K, filed with the Commission on December 14, 2022).
10.9+	Pasithea Therapeutics Corp. 2023 Stock Incentive Plan (incorporated by reference to exhibit 10.1 of the Company's Form 8-K filed with the Commission on December 19, 2023).
10.10+	Amendment to Pasithea Therapeutics Corp. 2023 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, filed with the Commission on September 3, 2025).
10.11+	Second Amendment to Pasithea Therapeutics Corp. 2023 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, filed with the Commission on January 28, 2026).
10.12+	Consulting Agreement between Pasithea Therapeutics Corp. and Dr. Lawrence Steinman, dated November 13, 2023 (incorporated by reference to Exhibit 10.20 of the Company's Form 10-K filed with the Commission on March 29, 2024).
10.13+	Amendment, effective as of October 1, 2025, to Consulting Agreement between Pasithea Therapeutics Corp. and Dr. Lawrence Steinman, dated November 13, 2023 (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q filed with the Commission on November 13, 2025).
10.14	Securities Purchase Agreement, dated September 26, 2024, by and between Pasithea Therapeutics Corp. and purchaser parties thereto (incorporated by reference to exhibit 10.1 of the Company's Form 8-K filed with the Commission on September 30, 2024).
10.15	Registration Rights Agreement, dated September 26, 2024, by and between Pasithea Therapeutics Corp. and purchaser parties thereto (incorporated by reference to exhibit 10.2 of the Company's Form 8-K filed with the Commission on September 30, 2024).
10.16	Form of May 2025 Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, filed with the Commission on May 7, 2025).
10.17	Form of December 2025 Securities Purchase Agreement (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1, as amended (File No. 333-291611), filed on November 26, 2025).
16.1	Letter from Marcum dated April 23, 2025 (incorporated by reference to Exhibit 16.1 to the Company's Form 8-K, filed with the Commission on April 25, 2025).
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Company's Form 10-K, filed with the Commission on March 24, 2025).
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Company's Form 10-K, filed with the Commission on March 24, 2025).
23.1*	Consent of Independent Registered Public Accounting Firm (CBIZ CPAs P.C.).
23.2*	Consent of Independent Registered Public Accounting Firm (Marcum LLP).
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended.
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 (incorporated by reference to Exhibit 97.1 of the Company's Form 10-K, filed with the Commission on March 29, 2024).
101.INS*	Inline XBRL Instance 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 (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
** Furnished herewith.
\+ Indicates a management contract or any compensatory plan, contract or arrangement.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PASITHEA THERAPEUTICS CORP.

By: */s/ Dr. Tiago Reis Marques*
Dr. Tiago Reis Marques
Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 30, 2026

By: */s/ Daniel Schneiderman*
Daniel Schneiderman
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 30, 2026

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.

Signature	Title	Date
/s/ Dr. Tiago Reis Marques Dr. Tiago Reis Marques	Chief Executive Officer and Director (Principal executive officer)	March 30, 2026
/s/ Daniel Schneiderman Daniel Schneiderman	Chief Financial Officer (Principal financial and accounting officer)	March 30, 2026
/s/ Prof. Lawrence Steinman Prof. Lawrence Steinman	Director	March 30, 2026
/s/ Simon Dumesnil Simon Dumesnil	Director	March 30, 2026
/s/ Dr. Emer Leahy Dr. Emer Leahy	Director	March 30, 2026
/s/ Alfred Novak Alfred Novak	Director	March 30, 2026

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED FINANCIAL STATEMENTS

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Pasithea Therapeutics Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Pasithea Therapeutics Corp. (the "Company") as of December 31, 2025, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows the year ended December 31, 2025, (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2021 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Hartford, Connecticut
March 30, 2026

PCAOB Firm ID #199

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Pasithea Therapeutics Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Pasithea Therapeutics Corp. (the "Company") as of December 31, 2024, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024 in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Marcum LLP

We have served as the Company's auditor from 2021 through 2025.

Marcum LLP
New Haven, CT
March 24, 2025

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,158,939	$ 6,922,729
Restricted cash	100,866	-
Prepaid expenses	811,456	302,641
Other current assets	387,823	142,945
Total current assets	56,459,084	7,368,315
Property and equipment, net	-	122,343
Intangibles, net	3,780,986	7,311,150
Goodwill	-	1,262,911
Total assets	$ 60,240,070	$ 16,064,719
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 1,131,104	$ 1,119,871
Warrant liabilities – Placement Agent Warrants	3,842,857	-
Total current liabilities	4,973,961	1,119,871
Non-current liabilities		
Warrant liabilities	46,871	162,172
Total non-current liabilities	46,871	162,172
Total liabilities	5,020,832	1,282,043
Stockholders' equity:		
Preferred stock, par value $0.0001 per share, 5,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2025 and December 31, 2024	-	-
Common stock, par value $0.0001 per share, 100,000,000 shares authorized; 23,091,062 shares and 1,394,263 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	2,309	139
Additional paid-in capital	125,208,624	64,372,486
Accumulated other comprehensive income (loss)	18,766	(7,171)
Accumulated deficit	(70,010,461)	(49,582,778)
Total stockholders' equity	55,219,238	14,782,676
Total liabilities and stockholders' equity	$ 60,240,070	$ 16,064,719

The accompanying notes are an integral part of these consolidated financial statements.

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Twelve Months Ended December 31,	
	2025	**2024**
Operating expenses:		
General and administrative	$ 12,876,175	$ 7,051,468
Research and development	7,981,120	7,198,494
Loss from operations	(20,857,295)	(14,249,962)
Other income (expense):		
Change in fair value of warrant liabilities	115,301	(77,806)
Realized foreign currency translation loss from dissolution of subsidiaries	(7,171)	-
Foreign currency gain	30,376	-
Other income	380,532	-
Change in fair value of derivative warrant liability	(416,619)	-
Interest and dividends, net	327,193	423,184
Other income, net	429,612	345,378
Loss before income taxes	(20,427,683)	(13,904,584)
Provision for income taxes	-	-
Net loss	$ (20,427,683)	$ (13,904,584)
Weighted-average common shares outstanding, basic and diluted	7,031,050	1,096,082
Basic and diluted loss per share	$ (2.91)	$ (12.69)
Comprehensive loss:		
Net loss	$ (20,427,683)	$ (13,904,584)
Foreign currency translation	18,766	(2,519)
Comprehensive loss	$ (20,408,917)	$ (13,907,103)

The accompanying notes are an integral part of these consolidated financial statements.

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	POST-SPLIT					
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at January 1, 2024	1,041,582	$ 104	$ 58,721,538	$ (4,652)	$ (35,318,538)	$ 23,398,452
Stock-based compensation:						
-restricted stock units	4,168	-	117,460	-	-	117,460
-stock options	-	-	648,367	-	-	648,367
-warrants	-	-	7,866	-	-	7,866
Proceeds from September 2024 offering of pre-funded and common warrants, net	-	-	4,517,285	-	-	4,517,285
Issuance of common stock from the exercise of pre-funded warrants, net	348,513	35	314	-	-	349
Deemed dividend - warrant modification	-	-	359,656	-	(359,656)	-
Foreign currency translation	-	-	-	(2,519)	-	(2,519)
Net loss	-	-	-	-	(13,904,584)	(13,904,584)
Balance at December 31, 2024	1,394,263	$ 139	$ 64,372,486	$ (7,171)	$ (49,582,778)	$ 14,782,676
Stock-based compensation:						
-stock options	-	-	295,894	-	-	295,894
-warrants	-	-	1,573	-	-	1,573
Issuance of common stock under ATM agreement, net	801,278	80	2,078,268	-	-	2,078,348
Issuance of common stock from the exercise of pre-funded warrants, net	871,000	87	784	-	-	871
Realized foreign currency translation loss from dissolution of subsidiaries	-	-	-	7,171	-	7,171
Proceeds from May 2025 public offering of common stock, pre-funded warrants and warrants, net	3,571,428	357	4,214,149	-	-	4,214,506
Proceeds from December 2025 public offering of common stock and pre-funded warrants, net	14,846,665	1,485	51,996,631	-	-	51,998,116
Issuance of common stock from the exercise of warrants, net	1,606,428	161	2,248,839	-	-	2,249,000
Foreign currency translation	-	-	-	18,766	-	18,766
Net loss	-	-	-	-	(20,427,683)	(20,427,683)
Balance at December 31, 2025	23,091,062	$ 2,309	$ 125,208,624	$ 18,766	$ (70,010,461)	$ 55,219,238

The accompanying notes are an integral part of these consolidated financial statements.

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Twelve Months Ended December 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (20,427,683)	$ (13,904,584)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	32,421	18,865
Amortization expense	630,164	630,164
Stock-based compensation	297,467	773,693
Change in fair value of warrant liabilities	(115,301)	77,806
Impairment expense	4,162,911	-
Realized foreign currency translation loss from dissolution of subsidiaries	7,171	-
Change in fair value of derivative warrant liability	416,619	-
Loss on asset disposal	103,322	-
Changes in operating assets and liabilities:		
Prepaid expenses	(60,536)	(86,746)
Other current assets	(269,278)	2,262
Accounts payable and accrued liabilities	11,233	(1,432,489)
Lease liabilities	-	(2,409)
Net cash used in operating activities	(15,211,490)	(13,923,438)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of equipment	11,000	-
Net cash provided by investing activities	11,000	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on financed director and officer insurance	(448,279)	-
Proceeds from issuance of common stock under ATM agreement, net of fees and offering costs	2,078,348	-
Proceeds from issuance of common stock from the exercise of pre-funded warrants, net	871	349
Proceeds from May 2025 public offering of common stock, net	4,214,506	-
Proceeds from December 2025 public offering of common stock, net	55,424,354	-
Issuance of common stock from the exercise of warrants, net	2,249,000	-
Proceeds from September 2024 offering of pre-funded and common warrants, net	-	4,517,285
Net cash provided by financing activities	63,518,800	4,517,634
Effect of foreign currency translation on cash	18,766	(2,519)
NET CHANGE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	$ 48,337,076	$ (9,408,323)
Cash, cash equivalents, and restricted cash - Beginning of period	6,922,729	16,331,052
Cash, cash equivalents, and restricted cash - End of period	$ 55,259,805	$ 6,922,729
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	55,158,939	6,922,729
Restricted cash	100,866	-
Total cash, cash equivalents and restricted cash	$ 55,259,805	$ 6,922,729
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 13,212	$ -
Cash paid for taxes	$ -	$ -
Supplemental disclosures of non-cash activity:		
Dividend - warrant modification	$ -	$ (359,656)

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 – NATURE OF THE ORGANIZATION AND BUSINESS

Pasithea Therapeutics Corp. ("Pasithea" or the "Company") was incorporated in the State of Delaware on May 12, 2020 and completed an initial public offering (the "Initial Public Offering") on September 17, 2021. The Company is a clinical-stage biotechnology company focused on the discovery, research and development of innovative treatments for RASopathies, MAPK pathway-driven tumors, and other diseases, including central nervous system (CNS) disorders.

The Company's primary operations (the "Therapeutics" segment) are focused on developing the Company's lead product candidate, PAS-004, a next-generation macrocyclic mitogen-activated protein kinase, or MEK inhibitor that the Company believes may address the limitations and liabilities associated with existing drugs targeting a similar mechanism of action. In December 2023, the U.S. Food and Drug Administration (the "FDA") cleared the Company's Investigational New Drug application (the "IND") for PAS-004 and the Company received a study may proceed letter from the FDA for its Phase 1 multicenter, open-label, dose escalation trial of PAS-004 in patients with MAPK pathway-driven advanced tumors with a documented RAS, NF1 or RAF mutation or patients who have failed BRAF/MEK inhibition (the "FIH Phase 1 Advanced Cancer Study"). The Company is currently conducting the FIH Phase 1 Advanced Cancer Study at four clinical sites in the United States and three additional sites in Eastern Europe. The Company has completed the initial eight cohorts through 45 mg capsule and has not reached the maximum tolerated dose. The Company plans to file a protocol amendment to continue dose escalation in the FIH Phase 1 Advanced Cancer Study using its tablet formulation of PAS-004 in an effort to continue exploring the safety, PK, and early signals of efficacy at higher dose levels of PAS-004. Simultaneously, a pilot food effect assessment is planned in a subset of patients who agree to participate in this optional component of the study. As such, the Company expects to complete the trial in 2028.

In May 2025, the Company initiated its Phase 1/1b multicenter, open-label, dose escalation trial of PAS-004 in adult patients with neurofibromatosis type 1 ("NF1") with symptomatic and inoperable, incompletely resected, or recurrent plexiform neurofibromas ("PN"). The Company is currently conducting the trial at a total of five sites in the United States, Australia, and South Korea.

The initial indication the Company plans to seek FDA marketing approval for PAS-004 is the treatment of symptomatic PNs in both adult and pediatric patients with NF1. As such, the Company aims to conduct a Phase 1 trial for pediatric NF1-PN patients and ultimately complete registrational clinical trials in both adult and pediatric NF1-PN populations.

Additionally, the Company has one program, PAS-001, in the discovery stage, which the Company believes addresses limitations in the treatment paradigm for schizophrenia.

During the year ended December 31, 2023, the Company through its subsidiaries discontinued providing business support services to anti-depression clinics (the "Clinics" segment) in the U.K. and in the United States, previously conducted through partnerships with healthcare providers. During the year ended December 31, 2023, the at home services in New York, NY as well as in the U.K were discontinued and the Company sold and disposed of the assets associated with the Clinics operations in Los Angeles, CA. The lease associated with the related property in Los Angeles was assumed by the buyer in the transaction.

Throughout this report, the terms "our," "we," "us," and the "Company" refer to Pasithea Therapeutics Corp. and its subsidiaries, Pasithea Therapeutics Limited (U.K.), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, Pasithea Clinics Inc., Alpha-5 Integrin, LLC ("Alpha-5"), AlloMek Therapeutics, LLC ("AlloMek") and Pasithea MacroMEK Pty Ltd. Pasithea Therapeutics Limited (U.K.), legally dissolved as of January 2, 2024, was a private limited company, registered in the United Kingdom (U.K.). Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda is a private limited company registered in Portugal. Pasithea Clinics Inc., legally dissolved as of September 3, 2025, was incorporated in Delaware. Alpha-5 and AlloMek are both Delaware limited liability companies. Pasithea MacroMEK Pty Ltd is registered in Australia. The operations of Pasithea Therapeutics Limited (U.K.), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, and Pasithea Clinics Inc. have been discontinued.

Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Emerging Growth Company

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and it may 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, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and approval of any golden parachute payments not previously approved. Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period.

Liquidity and Capital Resources

As of December 31, 2025, the Company had approximately $55.2 million in operating bank accounts and money market funds, and working capital of approximately $51.5 million. The Company's major sources of cash have been comprised of proceeds from various private and public offerings, the Initial Public Offering, ATM sales and the exercise of warrants. The Company is dependent on obtaining additional working capital funding from the sale of equity and/or debt securities in order to continue to execute its development plans and continue operations.

The accompanying consolidated financial statements have been prepared as if the Company will continue as a going concern. The Company has incurred significant operating losses and negative cash flows from operations since inception. On December 31, 2025, the Company had cash and cash equivalents of approximately $55.2 million and an accumulated deficit of approximately $70.0 million. The Company has incurred recurring losses, has experienced recurring negative operating cash flows, and requires significant cash resources to execute its business plans. Historically, the Company's major sources of cash have been comprised of proceeds from various public and private offerings of its capital stock. The Company is dependent on obtaining additional working capital funding from the sale of equity and/or debt securities in order to continue to execute its development plans and continue operations. Management considered whether or not there are conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern, and concluded that there are none as it estimates that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these consolidated financial statements.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND NEW ACCOUNTING STANDARDS

Principles of Consolidation

The Company evaluates the need to consolidate affiliates based on standards set forth in Accounting Standards Codification ("ASC") 810, "Consolidation," ("ASC 810"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Alpha-5 Integrin, LLC, AlloMek Therapeutics, LLC, Pasithea Therapeutics Limited (U.K.), Pasithea Clinics Inc. ("Pasithea Clinics") and Pasithea MacroMEK Pty Ltd. All significant intercompany transactions and balances have been eliminated in consolidation.

These consolidated financial statements are presented in U.S. Dollars.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statement and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events. Management regularly makes estimates related to the fair value of warrant liabilities; the recoverability of long-lived assets; the fair values and useful lives of intangible assets acquired in business combinations; the potential impairment of goodwill; and prepaid expenses and accrued expenses related to our CROs. The Company bases its estimates on historical experience and on various assumptions that are believed to be reasonable, the results of which form the basis for the amounts recorded in the consolidated financial statements. As appropriate, the Company obtains reports from third-party valuation experts to inform and support estimates related to fair value measurements.

Research and Development

Research and development costs are charged to operations when incurred and are included in operating expense, except for goodwill related to intellectual property and patents. Research and development costs consist principally of compensation of employees and consultants that perform the Company's research and development activities, payments to third parties for pre-clinical, non-clinical and clinical activities, costs to acquire drug products from contract development and manufacturing organizations and third-party contractors relating to chemistry, manufacturing and controls ("CMC") efforts and research and development costs related to our discovery programs. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Research and development also includes contra expense related to costs reimbursed under the Company's grant agreement. For the years ended December 31, 2025 and 2024, the Company recorded grant income of $43,000 and $0, respectively, as a contra expense within research and development.

General and Administrative

Our general and administrative expenses primarily consist of personnel and related costs, including stock-based compensation, legal fees relating to both intellectual property and corporate matters, accounting and audit related costs, insurance, corporate communications and public company expenses, information technology, office and facility rents and related expenses, including depreciation, amortization and maintenance, and fees for consulting, business development and other professional services.

Defined-Contribution Savings Plan

In the United States, the Company maintains a defined-contribution savings plan pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan is available to employees who meet the minimum age and length of service requirements. The contributions made during the twelve months ended December 31, 2025, and 2024 were approximately $91,000 and $44,000, respectively.

Grants

In connection with the acquisition of Alpha-5, the Company legally assumed rights under a grant agreement with FightMND, which was entered into by Alpha-5 on September 23, 2021. FightMND supports pre-clinical research, development and assessment of therapeutics for motor neuron disease, including ALS. Under the grant agreement, the Company is entitled to reimbursements for costs incurred for research related to its monoclonal antibody targeting a5b1 integrin as a potential treatment for ALS.

Cash and Cash Equivalents

The Company considers all money market funds with an original maturity of three months or less when purchased to be cash equivalents, classified as trading securities. The Company had cash equivalents of $53.4 million and $6.1 million as of December 31, 2025, and 2024, respectively.

Property and Equipment and Depreciation

Property and equipment is recorded at cost. Depreciation is computed using straight-line and accelerated methods over the estimated useful lives of the related assets which range from three to ten years. Expenditures that enhance the useful lives of the assets are capitalized and depreciated. Maintenance and repairs are expensed as incurred. When properties are retired or otherwise disposed of, related costs and related accumulated depreciation are removed from the accounts. Leasehold improvements are amortized over the shorter of the estimated useful life of those leasehold improvements and the remaining lease term. Gains or losses on the disposal of property and equipment are determined by comparing the net proceeds from the sale, if any, with the carrying amount of the assets at the time of disposal. These gains or losses are recognized in the consolidated statements of operations and comprehensive loss within other income (expense).

Common Stock Warrants

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

For issued warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance, or when the conditions for equity classification are met, and are not remeasured. Issued warrants that do not meet all the criteria for equity classification are classified as liabilities. Liability-classified warrants are recorded at their fair value, and the Company adjusts such warrants to fair value at each reporting period. Until the warrants are exercised, expire or are reclassified as an equity instrument, any change in fair value is recognized in the Company's consolidated statements of operations.

The Company accounts for the publicly traded warrants issued in its Initial Public Offering (the "Public Warrants") and the warrants issued as compensation to the underwriters in its Initial Public Offering (the "Representative Warrants" and together with the Public Warrants, the "IPO Warrants") in accordance with the guidance contained in ASC 815, under which the IPO Warrants do not meet the criteria for equity treatment and must be recorded as derivative liabilities. Accordingly, the Company classifies the IPO Warrants as liabilities at their fair value. This liability is subject to re-measurement at each balance sheet date until the IPO Warrants are exercised or expire, and any change in fair value is recognized in the Company's condensed consolidated statements of operations and comprehensive loss. The fair value of the IPO Warrants was initially measured using a Black-Scholes pricing model. Currently, the fair value of the Public Warrants is measured using quoted market prices, and the fair value of the Representative Warrants is based on an estimate of the relative fair value to the Public Warrants, accounting for a small difference in the exercise price.

Derivative Financial Instruments

The Company accounts for their derivative financial instruments in accordance with ASC 815, therefore any embedded conversion options and warrants accounted for as derivatives are to be recorded at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification.

The Black-Scholes option valuation model was used to estimate the fair value of the embedded conversion options and warrants. The model includes subjective input assumptions that can materially affect the fair value estimates.

Income Taxes

The Company follows the asset and liability method of accounting for income taxes under ASC 740, "Income Taxes." Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. As of December 31, 2025, and 2024, respectively, the Company had deferred tax assets related to certain net operating losses. A valuation allowance was established against these deferred tax assets at their full amount, resulting in a zero balance of deferred tax assets on the consolidated balance sheets as of December 31, 2025, and 2024.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of December 31, 2025, and 2024. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The Company is subject to income tax examinations by major taxing authorities since inception.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of a cash account in a financial institution, which, at times, may exceed the Federal Depository Insurance Coverage of $250,000. As of December 31, 2025, the Company has not experienced losses on this account and management believes the Company is not exposed to significant risks on such account.

Warrant Liability

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

The Company uses Level 3 inputs for its valuation methodology for the derivative liabilities as their fair values were determined by using a Black-Scholes pricing model. The Company's derivative liabilities are adjusted to reflect fair value at each reporting date, with any increase or decrease in the fair value being recorded in the statement of operations.

Fair Value of Financial Instruments

With the exception of liabilities related to the IPO Warrants and derivative warrant liability, described in the table below, the fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC 820, "Fair Value Measurements and Disclosures," approximates the carrying amounts presented in the accompanying balance sheet, primarily due to their short-term nature.

Fair Value Measurements

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices (unadjusted) for identical instruments in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The following table presents information about the Company's liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

		Fair value measurements at reporting date using:		
	Fair value	Quoted prices in active markets for identical liabilities (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents, December 31, 2025	$ 53,436,440	$ 53,436,440	$ -	$ -
Cash equivalents, December 31, 2024	$ 6,093,044	$ 6,093,044	$ -	$ -
Liabilities:				
Public warrant liabilities, December 31, 2025	$ 44,000	$ 44,000	$ -	$ -
Representative warrant liabilities, December 31, 2025	$ 2,871	$ -	$ -	$ 2,871
Warrant derivative liability, December 3, 2025	$ 3,842,857	$ -	$ -	$ 3,842,857
Liabilities:				
Public warrant liabilities, December 31, 2024	$ 152,240	$ 152,240	$ -	$ -
Representative warrant liabilities, December 31, 2024	$ 9,932	$ -	$ -	$ 9,932

The following table presents a reconciliation of the Level 3 Representative Warrant liabilities:

	Twelve Months Ended December 31,	
	2025	2024
Representative warrant liabilities, January 1	$ 9,932	$ 5,166
Issuances	-	-
Exercises	-	-
Change in fair value	(7,061)	4,766
Representative warrant liabilities, December 31	$ 2,871	$ 9,932

The change in fair value of the Representative Warrants liabilities is recorded in change in fair value of warrant liabilities on the consolidated statements of operations and comprehensive loss.

The following table presents a reconciliation of the Level 3 Derivative Warrant liabilities:

	Twelve Months Ended December 31,	
	2025	2024
Derivative warrant liabilities, January 1	$ -	$ -
Issuances	3,426,239	-
Exercises	-	-
Change in fair value	416,619	-
Derivative warrant liabilities, December 31	$ 3,842,857	$ -

The change in fair value of the derivative warrant liabilities is recorded in change in fair value of derivative warrant liabilities on the consolidated statements of operations and comprehensive loss.

The fair value of the cash equivalents is based on the fair value of marketable securities invested in U.S. government money market funds.

The fair value of the liability associated with the Public Warrants as of December 31, 2025, and 2024, was based on the quoted closing price on The Nasdaq Capital Market and is classified as Level 1. The fair value of the liability associated with the Representative Warrants as of December 31, 2025, and 2024, was based on an estimate of the relative fair value to the Public Warrants, accounting for a small difference in the exercise price, and is classified as Level 3.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

Net Loss Per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted earnings per share is computed similarly to the basic earnings per share, except the weighted average number of common shares outstanding are increased to include additional shares from the assumed exercise of share options, if dilutive. The following outstanding shares issuable upon exercise of stock options and warrants and vesting of restricted stock units were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2025	2024
Stock options	1,685,843	182,034
Warrants	9,080,120	3,293,692
Restricted stock units	-	-

Foreign Currency Translations

The Company's functional and reporting currency is the U.S. dollar. All transactions initiated in other currencies are translated into U.S. dollars using the exchange rate prevailing on the date of transaction. Monetary assets and liabilities denominated in foreign currencies are translated into the U.S. dollar at the rate of exchange in effect at the balance sheet date. Unrealized exchange gains and losses arising from such transactions are deferred until realization and are included as a separate component of stockholders' equity (deficit) as a component of comprehensive income or loss. Upon realization, the amount deferred is recognized in income in the period when it is realized.

Translation of Foreign Operations

The financial results and position of foreign operations whose functional currency is different from the Company's presentation currency are translated as follows:

- assets and liabilities are translated at period-end exchange rates prevailing at that reporting date;
- equity is translated at historical exchange rates; and
- income and expenses are translated at average exchange rates for the period.

Exchange differences arising on translation of foreign operations are transferred directly to the Company's accumulated other comprehensive loss in the consolidated financial statements. Transaction gains and losses arising from exchange rate fluctuation on transactions denominated in a currency other than the functional currency are included in the consolidated statements of operations and comprehensive loss. During the twelve months ended December 31, 2025, the Company had one operating subsidiary with a functional currency other than the U.S. dollar, which experienced a foreign currency translation gain of approximately $19,000. During the twelve months ended December 31, 2024, the Company had one operating subsidiary with a functional currency other than the U.S. dollar, which experienced a foreign currency translation loss of approximately $0. Additionally, losses related to the now dissolved subsidiaries which were previously operating in functional currencies not that of the U.S. dollar as the parent were realized in the consolidated statements of operations within other income (expense) in the amount of approximately $7,000 for the twelve months ended December 31, 2025.

The relevant translation rates are as follows:

	As of December 31,	
	2025	**2024**
Closing rate, British Pound (GBP) to $USD at period end	N/A	1.2529
Average rate, GBP to $USD for the period ended	N/A	1.2783
Closing rate, Euro (EUR) to $USD at period end	N/A	1.0355
Average rate, EUR to $USD for the period ended	N/A	1.0818
Closing rate, Australian Dollar (AUD) to $USD at period end	0.6669	N/A
Average rate, AUD to $USD for the period of subsidiary inception to period end	0.6450	N/A

N/A - Not applicable due to the Company having no operating subsidiaries with functional currencies other than that of the parent company U.S. Dollar.

Comprehensive Loss

ASC 220, "Comprehensive Income," establishes standards for reporting and display of comprehensive income (loss) and its components in a full set of general-purpose financial statements. As of December 31, 2025, and 2024, the Company had no material items of other comprehensive income (loss) except for the unrealized foreign currency translation adjustment.

Acquisitions, Intangible Assets and Goodwill

The consolidated financial statements reflect the operations of an acquired business beginning as of the date of acquisition. Assets acquired and liabilities assumed are recorded at their fair values at the date of acquisition; goodwill is recorded for any excess of the purchase price over the fair value of the net assets acquired. Significant judgment is required to determine the fair value of certain tangible and intangible assets and in assigning their respective useful lives. Accordingly, we typically obtain the assistance of third-party valuation specialists for significant tangible and intangible assets. The fair values are based on available historical information and on future expectations and assumptions deemed reasonable by management but are inherently uncertain and could affect the accuracy or validity of the estimates and assumptions. Determining the useful life of an intangible asset also requires judgment. Intangible assets are amortized over their estimated lives. Any intangible assets associated with acquired in-process research and development activities ("IPR&D") are not amortized until a product is available for sale.

Impairment of Long-Lived Assets, Intangibles and Goodwill

Long-lived and amortizable intangible assets are assessed annually for impairment or sooner should impairment indicators exist. Significant events or changes in business circumstances indicate that the carrying value of the assets may not be recoverable. Such circumstances may include a significant decrease in the market price of an asset, a significant adverse change in the manner in which the asset is being used or in its physical condition or a history of operating or cash flow losses associated with the use of an asset. An impairment loss is recognized when the carrying amount of an asset exceeds the anticipated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition. The amount of the impairment loss is the excess of the asset's carrying value over its fair value.

Goodwill is assessed for impairment annually during the fourth quarter, or more frequently if impairment indicators exist. Impairment exists when the carrying amount of goodwill exceeds its implied fair value. The Company may elect to assess goodwill for impairment using a qualitative or a quantitative approach, to determine whether it is more likely than not that the fair value of goodwill is greater than its carrying value.

Leases

The Company's previous leases were related to office space. The Company determines whether a contract is or contains a lease at the time of the contract's inception based on the presence of identified assets and the Company's right to obtain substantially all the economic benefit from or to direct the use of such assets. When the Company determines a lease exists, it records a right-of-use ("ROU") asset and corresponding lease liability on its balance sheet. ROU assets represent the Company's right to use an underlying asset for the lease term. Lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets are recognized at the lease commencement date at the present value of the remaining future lease payments the Company is obligated for under the terms of the lease. Lease liabilities are recognized concurrently with the recognition of the ROU asset and represent the present value of lease payments to be made under the lease. These ROU assets and liabilities are adjusted for any prepayments, lease incentives received, and initial direct costs incurred. As the discount rate implicit in the lease is not readily determinable in most of the Company's leases, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. If the Company's lease terms include an option to extend the lease for a set period, the Company evaluates the renewal option and should it be reasonably certain that the Company will exercise that option, adjusts the ROU asset and liability accordingly.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards to employees and members of its Board of Directors (the "Board") in accordance with ASC Topic 718, Compensation—Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees and Board members, including grants of employee stock options, to be recognized in the statements of operations by measuring the fair value of the award on the date of grant and recognizing this fair value as stock-based compensation using a straight-line method over the requisite service period, generally the vesting period.

The Company estimates the grant date fair value of stock option awards using the Black-Scholes option-pricing model. The use of the Black-Scholes 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.

Segment Information

Operating segments are defined as components of an enterprise for which separate discrete information is available for evaluation by the Chief Operating Decision Maker ("CODM") or decision-making group in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business as one operating and reporting segment, which is the business of research and development of innovative treatments for RASopathies, MAPK pathway-driven tumors and other diseases, including central nervous system (CNS) disorders. See Note 13 Segment Information for further information.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*. The standard requires public business entities to disaggregate specific expense captions on the income statement into required natural expense categories within the footnotes to the financial statements. This guidance is effective for the Company for annual reporting periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027. The Company is currently evaluating the impact of the adoption of this standard on our financial statement disclosures.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires public business entities on an annual basis to disclose specific categories in the income-tax rate reconciliation, provide information for reconciling items that meet a quantitative threshold, and disclose certain information about income taxes paid. The standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The amendment has been applied on a prospective basis.

NOTE 3 – PROPERTY AND EQUIPMENT

Property and equipment, net consists of the following:

	As of December 31,	
	2025	2024
Leasehold improvements	$ -	$ 3,193
Medical equipment	-	155,363
Office equipment	-	6,140
Property and equipment, gross	-	164,696
Less: accumulated depreciation	-	(42,353)
Property and equipment, net	$ -	$ 122,343

Depreciation expense was approximately $32,000 and $19,000 for the twelve months ended December 31, 2025, and 2024, respectively. During the twelve months ended December 31, 2025, the Company wrote off gross leasehold improvements of approximately $3,200 and related accumulated amortization of approximately $2,500, resulting in a loss of approximately $700 recorded in general and administrative expense in the consolidated statements of operations and comprehensive loss. Additionally, during the twelve months ended December 31, 2025, the Company sold medical and office equipment for approximately $11,000. The gross book value of the assets sold was approximately $162,000 with approximately $49,000 of accumulated depreciation, resulting in a loss of approximately $102,000 and is recorded other income (expense) on the consolidated statements of operations and comprehensive loss.

NOTE 4 – LEASES

Laboratory Lease – South San Francisco, California

In August 2022, the Company, as a lessee, entered into an amended sublease agreement to sublease laboratory and office space in South San Francisco, California. The lease commenced on August 15, 2022. The term of this sublease is for a period of thirty-nine and one-fourth (39.25) months commencing on the effective date, until May 15, 2024. The lease had a gross monthly rent of $15,700 per month to December 31, 2022. Starting January 1, 2023, the monthly rent increased by 3% annually, to $16,171 per month in 2023, and $16,656 in 2024.

This lease was accounted for as an operating lease under ASC 842, Leases, which resulted in the recognition of a right of use asset (“ROU asset”) and liability of approximately $332,000 at inception. The ROU asset is separately presented as a non-current asset, and the liability is recorded as a component of current and non-current liabilities on the Company’s Consolidated Balance Sheets. The Company discounted the future lease payments of this lease using the prevailing collateralized lending rate which would be extended to the Company based on its credit profile relative to the period of inception, and the duration of the lease from inception. The interest rate used in calculating the fair value listed above was 7.8%.

As of and for the years ended December 31, 2025, and 2024, the Company had the following balances and activity related to ROU assets and lease liabilities:

	As of December 31,	
	2025	2024
Non-current leases - right of use assets	$ -	$ -
Current liabilities - operating lease liabilities	$ -	$ -
Non-current liabilities - operating lease liabilities	$ -	$ -

	Twelve Months Ended December 31,	
	2025	2024
Operating lease expense	$ -	$ 156,041
Cash paid for amounts included in the measurement of operating lease liabilities	$ -	$ -

There are no additional lease payments as of December 31, 2025.

NOTE 5 – INTANGIBLE ASSETS AND GOODWILL

Intangible assets, net consists of the following (in thousands):

	December 31, 2025				December 31, 2024		
	Gross Carrying Amount	Accumulated Amortization	Impairment	Net	Gross Carrying Amount	Accumulated Amortization	Net
In-process research and development	$ 2,900,000	$ -	$ (2,900,000)	$ -	$ 2,900,000	$ -	$ 2,900,000
Patents and intellectual property	5,671,478	(1,890,492)	-	3,780,986	5,671,478	(1,260,328)	4,411,150
Intangible assets, net	$ 8,571,478	$ (1,890,492)	$ (2,900,000)	$ 3,780,986	$ 8,571,478	$ (1,260,328)	$ 7,311,150

As of December 31, 2025, future expected amortization expense of Intangible assets was as follows:

2026	$ 630,164
2027	630,164
2028	630,164
2029	630,164
2030	630,164
Thereafter	630,166
Remaining future amortization expense	$ 3,780,986

During the year ended December 31, 2025, the Company performed its annual impairment test and determined that a triggering event occurred due to the Company strategically determining to abandon its PAS-003 program which represented a significant adverse change in the expected use and future cash flows of the associated assets. Therefore, the Company impaired the entirety of its intangible assets and goodwill related to the PAS-003 program in the amounts of approximately $2.9 million and $1.3 million, respectively, during the year ended December 31, 2025. These expenses were recorded in general and administrative expenses on the consolidated statements of operations and comprehensive loss.

There were no changes to goodwill for the year ended December 31, 2024.

NOTE 6 – STOCKHOLDERS' EQUITY

As of December 31, 2025, the Company was authorized to issue an aggregate of 105,000,000 shares. The authorized capital stock, as of such date, was divided into: (i) 100,000,000 shares of Common Stock having a par value of $0.0001 per share and (ii) 5,000,000 shares of preferred stock having a par value of $0.0001 per share.

Common Stock

The Company had 23,091,062 and 1,394,263 shares of its Common Stock issued and outstanding at December 31, 2025, and 2024, respectively.

Each holder of Common Stock is entitled to one vote for each share of Common Stock held on all matters submitted to a vote of the stockholders. Our Second Amended and Restated Certificate of Incorporation, as amended (the "Charter") and Second Amended and Restated Bylaws (the "Bylaws") do not provide for cumulative voting rights.

In addition, the holders of our Common Stock will be entitled to receive ratably such dividends, if any, as may be declared by the Board out of legally available funds; however, the current policy of our Board is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our Common Stock will be entitled to share ratably in all assets that are legally available for distribution.

Holders of our Common Stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the Common Stock. The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Effective January 2, 2024, the Company amended its Charter to effect a one-for-twenty (1:20) reverse stock split of its outstanding shares of Common Stock. No fractional shares were issued as a result of the reverse stock split. Any fractional shares resulting from the reverse stock split were paid in cash. The reverse stock split did not otherwise affect any of the rights currently accruing to holders of our Common Stock.

2021 Stock Incentive Plan

The Company's Board and stockholders adopted and approved the 2021 Stock Incentive Plan (the "2021 Plan") which took effect on July 15, 2021. The 2021 Plan allows for the issuance of securities, including stock options, restricted stock, and restricted stock units ("RSUs") to employees, Board members and consultants. On December 19, 2023, the remaining shares available under the 2021 Plan were added to the Company's 2023 Stock Incentive Plan (the "2023 Incentive Plan", or "2023 Plan"). There will be no new issuances under the 2021 Plan.

As of December 31, 2025, there were a total of 61,250 stock options outstanding under the 2021 Plan, which are all fully vested.

2023 Stock Incentive Plan

The Board and stockholders have adopted and approved the 2023 Plan which took effect on December 19, 2023. The 2023 Plan allows for the issuance of securities, including stock options, restricted stock, and RSUs to employees, Board members and consultants. The initial number of shares of Common Stock available for issuance under the 2023 Plan was 125,000 shares plus 28,389 unused shares reserved under the 2021 Plan, which will, on January 1 of each calendar year, beginning on January 1, 2024 and ending on and including January 1, 2033, unless the Board decides otherwise, automatically increase to equal to the lessor of (A) three percent (3%) of the number of shares of Common Stock outstanding on the final day of the immediately preceding calendar year or (B) such smaller number of shares as is determined by the Board.

On September 3, 2025, at our 2025 Annual Meeting of Stockholders, our stockholders approved an amendment (the "First Plan Amendment") to our 2023 Plan increasing the number of shares of Common Stock authorized for issuance under the 2023 Plan by 1,750,000 shares to 2,014,221 shares. The First Plan Amendment became effective following its approval by our stockholders.

As of December 31, 2025, 2,014,221 total shares were available under the 2023 Plan, of which 1,624,593 shares were issued and outstanding and 389,628 shares were available for potential issuances.

On January 28, 2026, at a Special Meeting of Stockholders, our stockholders approved an additional amendment (the "Second Plan Amendment") to our 2023 Plan, as amended by the First Plan Amendment, increasing the number of shares of Common Stock authorized for issuance under the 2023 Plan, as amended by the First Plan Amendment, by 11,985,779 shares to 14,000,000 shares. The Second Plan Amendment became effective following its approval by our stockholders. See Note 14 Subsequent Events.

September 2024 Private Offering

On September 26, 2024, the Company entered into a securities purchase agreement (the "September 2024 Offering") with an institutional investor, pursuant to which the Company agreed to sell shares of Common Stock or pre-funded warrants in lieu thereof ("September 2024 Pre-Funded Warrants") to purchase up to an aggregate of 1,219,513 shares of Common Stock at an exercise price of $0.001 per share, Series A warrants ("Series A Warrants") to purchase up to an aggregate of 1,219,513 shares of common stock at an exercise price of $3.85 per share, and Series B warrants ("Series B Warrants" together with the Series A Warrants, the "September 2024 PIPE Warrants") to purchase up to an aggregate of 1,219,513 shares of common Stock with an exercise price of $3.85 per share. The combined purchase price per September 2024 Pre-Funded Warrant and accompanying September 2024 PIPE Warrants was $4.099. Aggregate gross proceeds from the September 2024 Offering were approximately $4.5 million and the September 2024 Offering closed on September 30, 2024.

The September 2024 Pre-Funded Warrants are exercisable immediately upon issuance and expire when exercised in full. The Series A Warrants are exercisable immediately upon issuance and have a term of exercise equal to five (5) years from the date of issuance. The Series B Warrants are exercisable immediately upon issuance and have a term of exercise equal to eighteen (18) months from the date of issuance.

A holder of the September 2024 Pre-Funded Warrants and the September 2024 PIPE Warrants may not exercise any portion of such holder's September 2024 Pre-Funded Warrants or September 2024 PIPE Warrants to the extent that the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the Company's outstanding shares of Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to the Company, the holder may increase the beneficial ownership limitation to up to 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise. In the event of certain fundamental transactions, holders of the September 2024 PIPE Warrants will have the right to receive the Black Scholes Value of their September 2024 PIPE Warrant calculated pursuant to a formula set forth in the September 2024 PIPE Warrant, payable either in cash or in the same type or form of consideration that is being offered and being paid to the holders of Common Stock.

In connection with the September 2024 Offering, the Company entered into a registration rights agreement (the "Registration Rights Agreement"), dated as of September 26, 2024, with the investor, pursuant to which the Company agreed to prepare and file a registration statement with the Securities and Exchange Commission (the "SEC") registering the resale of the shares of Common Stock underlying the September 2024 Pre-Funded Warrants and the September 2024 PIPE Warrants no later than fifteen (15) days after the date of the Registration Rights Agreement (the "Registration Statement"), and to use its best efforts to have the registration statement declared effective as promptly as practical thereafter, and in any event no later than forty-five (45) days following the date of the Registration Rights Agreement (or ninety (90) days following the date of the Registration Rights Agreement in the event of a "full review" by the SEC). The Registration Statement was declared effective by the SEC on October 11, 2024.

The net proceeds to the Company from the September 2024 Offering were approximately $4.5 million, after deducting placement agent fees and offering expenses payable by the Company. In addition, the Company issued to the placement agent or its designees warrants (the "Placement Agent Warrants") to purchase up to an aggregate of 85,366 shares of Common Stock at an exercise price equal to $5.125 per share. The Placement Agent Warrants have substantially the same terms as the September 2024 PIPE Warrants, are exercisable immediately upon issuance and have a term of exercise equal to five (5) years from the date of issuance. The Company intends to use the net proceeds received from the September 2024 Offering for working capital and general corporate purposes.

The September 2024 PIPE Warrants met the requirement for equity classification. The Company computes the fair value of warrants and options using a Black-Scholes model. The expected term used for warrants is the contractual life. The Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

During the year ended December 31, 2024, 348,513 September 2024 Pre-Funded Warrants were exercised. As of December 31, 2024, 871,000 September 2024 Pre-Funded Warrants are paid and issued but unexercised. During the year ended December 31, 2025, 871,000 September 2024 Pre-Funded Warrants were exercised, and no September 2024 Pre-Funded Warrants were outstanding as of December 31, 2025. In addition, the September 2024 PIPE Warrants have not been exercised as of December 31, 2025.

At The Market Agreement with H.C. Wainwright

On November 26, 2024, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), as sales agent, pursuant to which the Company was able to issue and sell, from time to time, through Wainwright, shares of its Common Stock, and pursuant to which Wainwright was able to sell its Common Stock by any method permitted by law deemed to be an "at the market offering" as defined by Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company was obligated to pay Wainwright a commission of 3.0% of the aggregate gross proceeds from each sale of Common Stock. As of December 31, 2024, the Company was authorized to offer and sell up to $2,076,000 of its Common Stock pursuant to the ATM Agreement.

On June 20, 2025, the Company increased the maximum aggregate offering price of the shares of Common Stock issuable under the ATM Agreement, from $2,076,000 to $4,227,000 and filed a prospectus supplement to register an aggregate of $2,151,000 of additional shares of Common Stock available to be sold under the ATM Agreement.

During the twelve months ended December 31, 2025, the Company sold an aggregate of 801,278 shares of Common Stock under the ATM Agreement at a weighted average price of $2.68 per share for net proceeds of $2,078,348. During the twelve months ended December 31, 2024, the Company did not utilize the ATM Agreement.

On January 26, 2026, the Company filed a Post-Effective Amendment No. 1 (the "Amendment") to its Registration Statement on Form S-3 (File No. 333-271010) (the "Registration Statement"), to deregister any and all securities of the Company registered but unsold or otherwise unissued under the Registration Statement as of the date thereof. As a result of such Amendment, the Company is not able to sell any additional shares of its Common Stock under the ATM Agreement. See Note 14 Subsequent Events.

May 2025 Public Offering

On May 6, 2025, the Company entered into securities purchase agreements with investors (the "May 2025 Purchase Agreements") pursuant to which the Company agreed to sell an aggregate of (i) 3,094,284 shares (the "May 2025 Shares") of Common Stock, (ii) 477,144 pre-funded warrants (the "May 2025 Pre-Funded Warrants") to purchase up to an aggregate of 477,144 shares of Common Stock (the "May 2025 Pre-Funded Warrant Shares"), (iii) 3,571,428 Series C Common Warrants (the "Series C Common Warrants") to purchase up to an aggregate of 3,571,428 shares of Common Stock, and (iv) 3,571,428 Series D Common Warrants (the "Series D Common Warrants" and, together with the Series C Common Warrants, the "May 2025 Common Warrants") to purchase up to an aggregate of 3,571,428 shares of Common Stock. Each May 2025 Share, or May 2025 Pre-Funded Warrant in lieu thereof, was sold together with a Series C Common Warrant to purchase one share of Common Stock and a Series D Common Warrant to purchase one share of Common Stock in a best-efforts public offering (the "May 2025 Public Offering").

The public offering price for each May 2025 Share and accompanying May 2025 Common Warrants was $1.40, and the public offering price for each May 2025 Pre-Funded Warrant and accompanying May 2025 Common Warrants was $1.399. The May 2025 Pre-Funded Warrants have an exercise price of $0.001 per share, are exercisable immediately and will expire when exercised in full. The Series C Common Warrants have an exercise price of $1.40 per share, became exercisable upon issuance and will expire five years thereafter. The Series D Common Warrants have an exercise price of $1.40 per share, became exercisable upon issuance and will expire 18 months thereafter. Simultaneously with the closing of the May 2025 Public Offering, certain investors exercised Series D Common Warrants to purchase an aggregate of 914,286 shares of Common Stock, resulting in additional gross proceeds of approximately $1.3 million. In addition, all May 2025 Pre-Funded Warrants were exercised simultaneously with the closing of the May 2025 Public Offering, resulting in the issuance of 477,144 May 2025 Pre-Funded Warrant Shares.

A holder will not have the right to exercise any portion of the May 2025 Common Warrants if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the May 2025 Common Warrants. However, upon notice from the holder to the Company, the holder may increase the beneficial ownership limitation, which may not exceed 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the May 2025 Common Warrants, provided that any increase in the beneficial ownership limitation will not take effect until 61 days following notice to the Company.

The net proceeds of the May 2025 Public Offering, after deducting the placement agent fees and estimated offering expenses payable by the Company and excluding the net proceeds from the exercise of the May 2025 Common Warrants, were approximately $4.2 million. The aggregate gross proceeds from the May 2025 Public Offering and the exercise of the Series D Common Warrants were approximately $6.3 million.

In addition, the Company issued to the placement agent or its designees warrants (the "May 2025 Placement Agent Warrants") to purchase up to an aggregate of 250,000 shares of Common Stock at an exercise price equal to $1.75 per share. The May 2025 Placement Agent Warrants have substantially the same terms as the Series C Common Warrants, became exercisable immediately upon issuance and have a term of five (5) years from the date of the May 2025 Purchase Agreements.

The warrants issued in connection with the May 2025 Public Offering met the requirement for equity classification. The Company computes the fair value of warrants and options using a Black-Scholes model. The expected term used for warrants is the contractual life. The Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

December 2025 Public Offering

On November 28, 2025, the Company agreed to sell to investors an aggregate of (i) 14,846,665 shares (the "December 2025 Shares") of Common Stock and (ii) 65,153,335 pre-funded warrants (the "December 2025 Pre-Funded Warrants") to purchase up to an aggregate of 65,153,335 shares of Common Stock (the "December 2025 Pre-Funded Warrant Shares") in a best efforts public offering (the "December 2025 Offering").

The public offering price for each December 2025 Share was $0.75, and the public offering price for each December 2025 Pre-Funded Warrant was $0.749. The December 2025 Pre-Funded Warrants have an exercise price of $0.001 per share, became exercisable immediately and will expire when exercised in full.

The net proceeds of the December 2025 Offering, after deducting the placement agent fees and estimated offering expenses payable by the Company, were approximately $54.9 million. The December 2025 Offering closed on December 1, 2025.

A holder will not have the right to exercise any portion of the December 2025 Pre-Funded Warrants if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the December 2025 Pre-Funded Warrants. However, upon notice from the holder to the Company, the holder may increase the beneficial ownership limitation, which may not exceed 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the December 2025 Pre-Funded Warrants, provided that any increase in the beneficial ownership limitation will not take effect until 61 days following notice to the Company.

In addition, the Company issued to the placement agent or its designees warrants (the "December 2025 Placement Agent Warrants") to purchase up to an aggregate of 4,000,000 shares of Common Stock at an exercise price equal to $0.9375 per share. The December 2025 Placement Agent Warrants expire on November 28, 2030, and become exercisable upon a shareholder approval to increase the authorized and unissued shares of Common Stock of the Company to satisfy the exercise of the December 2025 Placement Agent Warrants. As such, the December 2025 Placement Agent Warrants were not exercisable upon consummation of the offering. The Company concluded that the December 2025 Placement Agent Warrants do not meet the criteria for equity classification under the guidance of ASC 815 as the Company did not have sufficient authorized and unissued shares to satisfy the December 2025 Placement Agent Warrants as of the closing date of the December 2025 Offering or December 31, 2025. The Company recorded the December 2025 Placement Agent Warrants as liabilities at their fair value. This liability is subject to remeasurement at each balance sheet date and any change in fair value is recognized in the Company's condensed consolidated statement of operations and comprehensive income. The Company incurred $3,426,238 of placement agent warrant issuance costs in connection with the December 2025 Offering. During the twelve months ended December 31, 2025, the Company recorded a loss on derivative warrant liability related to the December 2025 Placement Agent Warrants of $416,619 and the fair value of the December 2025 Placement Agent Warrants as of December 31, 2025, was $3,842,857.

Restricted Stock Units

During the twelve months ended December 31, 2025, and 2024, the Company issued a total of 0 and 4,168 shares of Common Stock, respectively, pursuant to the vesting of RSUs. The Company recognized approximately $0 and $117,000 of stock-based compensation expense for the twelve months ended December 31, 2025, and 2024, respectively, in relation to the vesting of historically granted RSUs.

During the twelve months ended December 31, 2025, and 2024, the Company did not grant any RSUs or restricted stock awards. As of December 31, 2025, there were no outstanding RSUs and no remaining unamortized RSU compensation expense.

NOTE 7 – STOCK OPTIONS

Stock Options Issued, Vested and Cancelled

During the twelve months ended December 31, 2024, the Company issued stock options under the 2023 Plan to employees to purchase an aggregate of 104,433 shares of Common Stock with a strike price equal to $8.13 per share and a term of ten years. Of the stock options granted, stock options to purchase an aggregate of 37,433 shares of Common Stock were fully vested at issuance and the remaining stock options are subject to time-based vesting over a term ranging between one to three years. These stock options had a total fair value of approximately $849,000, as calculated using the Black-Scholes pricing model with the following assumptions: volatility of 88.41%, discount rate of 4.20%, expected term of 6.5 years, and an exercise price of $8.13. Additionally, during the twelve months ended December 31, 2024, the Company experienced forfeitures of 21,399 stock options and stock options to purchase an aggregate of 63,331 shares of Common Stock, subject to time-based milestone vesting conditions, vested.

During the twelve months ended December 31, 2025, the Company issued stock options under the 2023 Plan to employees and Board members to purchase an aggregate of 1,534,525 shares of Common Stock with a strike price equal to $0.715 per share and a term of ten years. The stock options granted are subject to time-based vesting over a term ranging between one to three years. These stock options had a total fair value of approximately $862,000, as calculated using the Black-Scholes pricing model with the following assumptions: volatility of 105.36%, discount rate of 3.61%, expected term of 5.0 years, and an exercise price of $0.715. Additionally, during the twelve months ended December 31, 2025, the Company experienced forfeitures of 30,716 stock options, and stock options to purchase an aggregate of 40,079 shares of Common Stock, subject to time-based milestone vesting conditions, vested.

Stock-Based Compensation

Total stock-based compensation related to the Company's stock options was approximately $296,000 and $648,000 for the twelve months ended December 31, 2025, and 2024, respectively. For the twelve months ended December 31, 2025, the Company recognized approximately $287,000 of stock-based compensation related to its stock options within general and administrative expense, and approximately $9,000 within research and development expense on the consolidated statements of operations and comprehensive loss. For the twelve months ended December 31, 2024, the Company recognized approximately $490,000 of stock-based compensation related to its stock options within general and administrative expense, and approximately $158,000 within research and development expense on the consolidated statements of operations and comprehensive loss.

Stock option activity for the years ended December 31, 2025, and 2024 was as follows:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding, January 1, 2024	99,000	$ 32.38	8.55	
Granted	104,433	$ 8.13	9.16	
Expired/Cancelled	(21,399)	$ 9.43	-	
Outstanding, December 31, 2024	182,034	$ 21.17	8.98	$ -
Exercisable, December 31, 2024	106,536	$ 29.35	8.05	
Outstanding, January 1, 2025	182,034	$ 21.17	8.98	
Granted	1,534,525	$ 0.72	9.81	$ -
Expired/Cancelled	(30,716)	$ 9.30	-	
Outstanding, December 31, 2025	1,685,843	$ 9.60	7.68	$ 882,352
Exercisable, December 31, 2025	117,566	$ 28.01	7.22	

As of December 31, 2025, remaining unamortized stock-based compensation expense related to the stock options was $860,000.

The Company estimates the fair value of each stock option on the date of grant using the Black-Scholes option pricing model, which requires various assumptions including fair value of the underlying share, volatility, expected option life, risk-free interest rate and expected dividends. The fair value of the underlying share was based on the fair value on the grant date. The expected term was based on the expected exercise behavior of grantees. Expected volatility was calculated based on the volatilities of a peer group of companies. The risk-free rate of the option is based on the U.S. Treasury rate for the expected term of the option. The following weighted-average assumptions were used in the Black-Scholes calculations:

	Year ended December 31,	
	2025	2024
Expected volatility	105.36%	88.41%
Expected term	5.0	6.5
Weighted-average risk-free interest rate	3.61%	4.2%
Weighted average fair value of underlying interest	$ 0.72	$ 8.13
Expected dividends	-	-

The weighted average grant date fair value of options granted during the years ended December 31, 2025, and 2024 was $0.56 per option and $6.29 per option, respectively.

NOTE 8 – WARRANTS

For the years ended December 31, 2025, and 2024, total stock-based compensation expense related to the Company's warrants was approximately $1,600 and $8,000, respectively, and is recognized within general and administrative expense on the consolidated statements of operations and comprehensive loss.

Additionally, as of December 31, 2025, 10,000 warrants issued in October 2025, to a consultant were outstanding and not exercisable at an exercise price of $0.715. One third of these consulting warrants vest on the one year anniversary of issuance and the remainder vest in equal quarterly tranches for two years thereafter.

AlloMek Warrants

During the year ended December 31, 2022, the Company issued warrants to purchase an aggregate of 50,000 shares of Common Stock (the "AlloMek Warrants") to certain sellers in connection with the acquisition of AlloMek. The AlloMek Warrants were issued on October 11, 2022, and were immediately exercisable at $37.60 per share and expire five years from the date of issuance. The total grant date fair value of the AlloMek Warrants was determined to be approximately $0.5 million, as calculated using the Black-Scholes model and were capitalized and included in intangible assets. The assumptions used in the Black-Scholes calculation were as follows: volatility 55.7%; duration five years; and a risk-free rate of 4.14%.

As of December 31, 2025, and 2024, 50,000 AlloMek Warrants were outstanding, respectively.

Alpha-5 Warrants

During the year ended December 31, 2022, the Company issued warrants to purchase an aggregate of 50,000 shares of Common Stock (the "Alpha-5 Warrants") to certain sellers in connection with the acquisition of Alpha-5. The Alpha-5 Warrants were issued on June 21, 2022, were immediately exercisable at $37.60 per share and expire five years from the date of issuance. The total grant date fair value of the Alpha-5 Warrants was determined to be approximately $0.4 million, as calculated using the Black-Scholes model and were recorded as an increase to additional paid-in capital. This amount was included as part of the consideration paid for the Alpha-5 acquisition and were included as part of the purchase price allocation accordingly. The assumptions used in the Black-Scholes calculation were as follows: volatility 55.7%; duration five years; and a risk-free rate of 3.38%.

As of December 31, 2025, and 2024, 50,000 Alpha-5 Warrants were outstanding, respectively.

PIPE Warrants

During the year ended December 31, 2021, the Company issued PIPE Warrants to purchase an aggregate of 433,999 shares of Common Stock to certain investors in connection with the November 2021 Private Placement. The PIPE Warrants were issued on November 24, 2021, were immediately exercisable, and expire five years from the date of issuance at $70.00 per share, subject to adjustment as set forth in the PIPE Warrants. Due to a certain anti-dilution provision, the exercise price of each 2021 PIPE Warrant was reduced to $20.00 per share (the "Warrant Modification") as a result of the September 2024 Offering. The Company recognized the effect of the Warrant Modification as a deemed dividend of $359,656.

As of December 31, 2025, and 2024, 433,999 PIPE Warrants were outstanding, respectively.

IPO Warrants

During the year ended December 31, 2021, the Company issued Public Warrants to purchase an aggregate of 276,000 shares of Common Stock in its Initial Public Offering. Simultaneously with the consummation of the closing of the Initial Public Offering, the Company issued the underwriters a total of 13,800 Representative Warrants that became exercisable commencing six (6) months following issuance at an exercise price of $120.00 per share and expire five years from issuance.

The Company evaluated the IPO Warrants based on an assessment of the IPO Warrants' specific terms and applicable authoritative guidance in ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480") and ASC 815, "Derivatives and Hedging" ("ASC 815"). The IPO warrants are classified as liabilities and remeasured at each reporting period.

As of December 31, 2025, and 2024, 220,000 Public Warrants and 13,800 Representative Warrants were outstanding, respectively.

As of December 31, 2025, the fair value of the Public Warrants was approximately $0.10 per Public Warrant based on the closing price of the Public Warrants on The Nasdaq Capital Market. The fair value of the Representative Warrants was approximately $0.374 per Representative Warrant which was based on the relative fair value to the Public Warrants.

May 2025 Warrants

During the year ended December 31, 2025, the Company issued warrants to purchase an aggregate of 7,392,856 shares of Common Stock in connection with the May 2025 Public Offering as described in Note 6 above. This consisted of (i) Series C Common Warrants to purchase 3,571,428 shares of Common Stock, (ii) Series D Common Warrants to purchase 3,571,428 shares of Common Stock, and (iii) May 2025 Placement Agent Warrants to purchase 250,000 shares of Common Stock.

As of December 31, 2025, 3,553,428 Series C Common warrants, 1,983,000 Series D Common Warrants and 250,000 Placement Agent Warrants were outstanding.

December 2025 Warrants

During the year ended December 31, 2025, the Company issued December 2025 Placement Agent Warrants to purchase an aggregate of 4,000,000 shares of Common Stock in connection with the December 2025 Public Offering as described in Note 6 above.

As of December 31, 2025, 4,000,000 December 2025 Placement Agent Warrants were outstanding, but not exercisable.

Warrant activity for the years ended December 31, 2025, and 2024 was as follows:

	Number of Warrants	Exercise price per share	Weighted average exercise price
Outstanding and exercisable on January 1, 2025	3,293,692	$3.85 - $125.00	$ 15.62
Granted	11,402,856	$0.72 - $1.75	$ 1.24
Expired / Cancelled	-	-	-
Exercised	(1,606,428)	-	$ 1.40
Outstanding on December 31, 2025	13,090,120	$0.72 - $125.00	$ 4.84
Outstanding and exercisable on January 1, 2024	767,800	$37.60 - $125.00	$ 15.62
Granted	2,525,892	$3.85 - $8.13	3.90
Expired / Cancelled	-	-	-
Exercised	-	-	-
Outstanding and exercisable on December 31, 2024	3,293,692	$3.85 - $125.00	$ 15.62

As of December 31, 2025, 4,000,000 December 2025 Placement Agent Warrants were outstanding and not exercisable at an exercise price of $0.9375. A proxy vote for an increase in authorized shares allowing these warrants to become exercisable was completed on January 28, 2026. The proposal was approved by shareholders. See Note 14 for more information regarding the proxy vote. Additionally, as of December 31, 2025, 10,000 warrants issued in October 2025, to a consultant were outstanding and not exercisable at an exercise price of $0.9375. one third of these warrants vest on the one year anniversary of issuance and the remainder vest in equal tranches for two years thereafter.

Warrants exercisable at December 31, 2025, were as follows:

Exercise Price	Number of warrants	Weighted-average remaining contractual term (years)	Weighted average exercise price
$1.40	5,536,428	-	
$1.75	250,000	-	
$3.85	2,439,026	-	
$5.13	85,366	-	
$8.13	1,500	-	
$20.00	433,999	-	
$37.60	100,001	-	
$120.00	13,800	-	
$125.00	220,000	-	
	9,080,120	2.79	$ 6.57

No warrants expired/cancelled during the year ended December 31, 2025. A total of 1,606,428 warrants were exercised during the year ended December 31, 2025.

NOTE 9 – INCOME TAXES

The Company accounts for income taxes under ASC 740 - Income Taxes (“ASC 740”), which provides for an asset and liability approach of accounting for income taxes. Under this approach, deferred tax assets and liabilities are recognized based on anticipated future tax consequences, using currently enacted tax laws, attributed to temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts calculated for income tax purposes.

Significant components of the Company's deferred tax assets as of December 31, 2025, and 2024 are summarized below.

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Amortization	$ 148,000	$ -
Research & development costs	4,286,000	2,917,000
Warrant liabilities	11,000	40,000
Stock-based compensation	345,000	307,000
Net operating loss carryforwards	11,025,000	8,126,000
Federal R&D tax credit	368,000	419,000
Total deferred tax assets	16,183,000	11,809,000
Deferred tax liabilities:		
Amortization	-	(83,000)
Depreciation	-	(28,000)
Net deferred tax assets	16,183,000	11,698,000
Valuation allowance	(16,183,000)	(11,698,000)
	$ -	$ -

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. The Company assessed the need for a valuation allowance against its net deferred tax assets and determined a full valuation allowance is required since the Company has no history of generating taxable income. Our deferred tax asset and valuation allowance increased by $4,485,000 and $4,084,000 for the years ended December 31, 2025, and 2024, respectively.

A reconciliation of the federal income tax rate to the Company's effective tax rate at December 31, 2025, and 2024 is as follows:

	December 31,	
	2025	2024
Statutory federal income tax rate	21.00%	21.00%
State taxes, net of federal tax benefit	0.00%	-0.10%
Stock-based compensation	-0.10%	-0.60%
Return to provision adjustment	0.20%	0.20%
Permanent items	0.00%	0.00%
R&D credit generated	-0.30%	1.70%
Other	0.50%	0.00%
Change in valuation allowance	-19.80%	-22.30%
Income tax provision	1.50%	-0.10%

The Company's ability to utilize net operating loss carryforwards will depend on its ability to generate adequate future taxable income. Future utilization of the net operating loss carry forwards is subject to certain limitations under Section 382 of the Internal Revenue Code. As of December 31, 2025, the Company had federal and state net operating loss carryforwards available to offset future taxable income in the amounts of approximately $11,025,000 and $34,610,000, respectively, which do not expire.

The Company has evaluated its income tax positions and has determined that it does not have any uncertain tax positions. The Company will recognize interest and penalties related to any uncertain tax position through its income tax expense.

The Company is subject to franchise tax filing requirements in the State of Delaware.

NOTE 10 – NET LOSS PER COMMON SHARE

Basic net loss per share is computed by dividing net loss available to Common Stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share reflect, in periods in which they have a dilutive effect, the impact of common shares issuable upon exercise of stock options and warrants that are not deemed to be anti-dilutive. The dilutive effect of the outstanding stock options and warrants is computed using the treasury stock method.

At December 31, 2025, diluted net loss per share did not include the effect of 13,090,120 shares of Common Stock issuable upon the exercise of outstanding warrants, and 1,685,843 shares of Common Stock issuable upon the exercise of outstanding stock options as their effect would be antidilutive during the periods prior to conversion.

At December 31, 2024, diluted net loss per share did not include the effect of 3,293,692 shares of Common Stock issuable upon the exercise of outstanding warrants, and 182,034 shares of Common Stock issuable upon the exercise of outstanding stock options as their effect would be antidilutive during the periods prior to conversion.

NOTE 11 – RELATED PARTY TRANSACTIONS

Consulting Agreement with Prof. Lawrence Steinman

The Steinman Consulting Agreement memorializes the compensation arrangements pursuant to which Prof. Steinman has been compensated for his services to the Company, as previously disclosed in our public filings. Pursuant to the Steinman Consulting Agreement, Prof. Steinman provides a variety of consulting and advisory services relating principally to the clinical and commercial development of our product candidates, including our research and development strategy through all phases of discovery and preclinical development, identifying potential partners for our pre-clinical assets, and business development efforts related to our pre-clinical assets, among other things. Pursuant to the Steinman Consulting Agreement, effective as of September 30, 2025, Prof. Steinman received $25,000 per quarter for his services, which was subsequently reduced to $1.00 per quarter, effective as of October 1, 2025.

NOTE 12 – COMMITMENTS AND CONTINGENCIES

Legal and Regulatory Environment

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not limited to, matters such as licensure, accreditation, government healthcare program participation requirement, reimbursement for patient services and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers.

Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well as other applicable government laws and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation, as well as regulatory actions unknown or unasserted at this time.

NOTE 13 – SEGMENT INFORMATION

The Company views its operations and manages its business as one operating and reportable segment, which is the business of research and development of innovative treatments for central nervous system (CNS) disorders and other diseases, including RASopathies and certain cancers. The determination of a single operating segment is consistent with the consolidated financial information regularly provided to the CODM. Consistent with the operational structure, the Chief Executive Officer, as the CODM, reviews and evaluates net loss for purposes of assessing performance, making operating decisions, allocating resources available and how to best deploy these resources across functions, therapeutic areas and research and development projects, and planning and forecasting for future periods on a consolidated basis. Operating expenses are used to monitor budget versus actual results in assessing performance of the segment. Total assets are monitored by the CODM on a consolidated basis which is reported on the face of the consolidated balance sheets. All the Company's long-lived assets are held in the United States.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment. A reconciliation to the consolidated net loss for the years ended December 31, 2025, and 2024 is included at the bottom of the table below.

	Twelve Months Ended December 31,	
Significant segment expenses	**2025**	**2024**
General and administrative [1]	$ 7,778,869	$ 5,786,293
Pre-clinical research	378,343	1,479,896
CMC	1,887,466	1,463,530
Clinical development [1]	5,685,715	4,097,521
Depreciation and amortization	662,585	-
Share based compensation expense	297,467	649,029
Impairment expense	4,162,911	-
Other segment items [2]	3,939	773,693
Total operating and segment expenses	20,857,295	14,249,962
Reconciliation of net loss		
Change in fair value of warrant liabilities	115,301	(77,806)
Realized foreign currency translation loss from dissolution of subsidiaries	(7,171)	-
Foreign currency gain/(loss)	30,376	-
Other income	380,532	-
Change in fair value of derivative warrant liability	(416,619)	
Interest and dividends, net	327,193	423,184
Segment and consolidated net loss	$ 20,427,683	$ 13,904,584

(1) includes personnel costs and excludes share-based compensation expense and impairment expense

(2) includes litigation settlements, loss from sale of assets, and loss on asset write offs

NOTE 14 – SUBSEQUENT EVENTS

The Company has evaluated events and transactions subsequent to December 31, 2025, through the date these consolidated financial statements were included on this Annual Report on Form 10-K and filed with the SEC. Other than the below, there are no subsequent events identified that would require disclosure in these consolidated financial statements.

Share Increases

On January 28, 2026, at a Special Meeting of Stockholders of the Company (the "Special Meeting"), the Company's stockholders approved the Second Plan Amendment to the 2023 Plan, as amended, increasing the number of shares of Common Stock authorized for issuance under the 2023 Plan, as amended, by 11,985,779 shares to 14,000,000 shares. The Second Plan Amendment became effective following its approval by the Company's stockholders.

Additionally, on January 28, 2026, the Company filed a Certificate of Amendment (the "Certificate of Amendment") to the Charter with the Secretary of State of the State of Delaware to increase the number of the Company's authorized shares of Common Stock from 100,000,000 shares to 500,000,000 shares. The Certificate of Amendment was approved by the Company's stockholders at the Special Meeting and became effective upon filing.

Post-Effective Amendment

On January 26, 2026, the Company filed the Amendment to the Registration Statement to deregister any and all securities of the Company registered but unsold or otherwise unissued under the Registration Statement as of the date thereof. As a result of such Amendment, any and all offerings of the Company's securities pursuant to the Registration Statement were terminated and the Company terminated the effectiveness of the Registration Statement.

Exercise of the Pre-funded Warrants

From January 1, 2026, through March 24, 2026, a total of 1,850,000 December 2025 Pre-Funded Warrants were exercised by holders thereof, and the Company issued an aggregate of 1,848,886 shares of Common Stock upon such exercises.

Exhibit 4.15

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

Pasithea Therapeutics Corp. (the "Company", "we" or "our") has common stock, par value $0.0001 per share ("Common Stock"), and warrants issued in connection with our initial public offering exercisable to purchase shares of Common Stock ("Warrants"), registered under Section 12 of the Securities Exchange Act of 1934, as amended.

General

The Company is authorized to issue an aggregate of 505,000,000 shares. The authorized capital stock is divided into 500,000,000 shares of Common Stock having a par value of $0.0001 per share and 5,000,000 shares of preferred stock having a par value of $0.0001 per share.

Common Stock

All shares of Common Stock of the Company are one and the same class, identical in all respects and have equal rights, powers and privileges.

Voting. Except as otherwise provided by law or by the resolution or resolutions providing for the issue of any series of preferred stock, the holders of outstanding shares of Common Stock have the exclusive right to vote for the election and removal of directors and for all other purposes. On each matter on which holders of Common Stock are entitled to vote, each outstanding share of such Common Stock is entitled to one vote.

Dividends. Subject to the rights of any holders of preferred stock, holders of shares of Common Stock are entitled to receive such dividends and other distributions in cash, stock or property of the Company when, as and if declared by the Board of Directors of the Company (the "Board").

Liquidation. Subject to the rights of any holders of preferred stock, shares of Common Stock are entitled to receive the assets and funds of the Company available for distribution in the event of any liquidation, dissolution or winding up of the affairs of the Company, whether voluntary or involuntary.

Rights and Preferences. Holders of our Common Stock will have no preemptive, conversion or subscription rights, and there will be no redemption or sinking funds provisions applicable to our Common Stock. The rights, preferences and privileges of the holders of our Common Stock will be subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable. All of our outstanding shares of Common Stock are, and the shares of Common Stock to be issued upon exercise of the Warrants will be, fully paid and nonassessable.

Warrants

The following summary of certain terms and provisions of the Warrants is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrant Agent Agreement between us and VStock Transfer, LLC, as warrant agent, and the form of Warrant, both of which are filed as exhibits to this Annual Report on Form 10-K of which this Exhibit 4.7 is a part. We encourage you to review the terms and provisions set forth in the Warrant Agent Agreement and form of Warrant.

Exercisability. The Warrants are exercisable at any time up to the date that is five years after their original issuance. The Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of Common Stock underlying the Warrants under the Securities Act of 1933, as amended (the "Securities Act"), is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the issuance of the shares of Common Stock underlying the Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the Warrant. No fractional shares of Common Stock will be issued in connection with the exercise of a Warrant. In lieu of fractional shares, we will round up or down, as applicable, to the nearest whole number the number of shares of Common Stock to be issued to such holder.

Exercise Limitation. A holder will not have the right to exercise any portion of the Warrant if the holder (together with its affiliates) would beneficially own more than 4.99% of the outstanding Common Stock after exercise, as such percentage ownership is determined in accordance with the terms of the Warrants, except that upon notice from the holder to us, the holder may waive such limitation up to a percentage, not in excess of 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants.

Exercise Price. The exercise price per whole share of Common Stock purchasable upon exercise of the Warrants is $125 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the Warrants may be offered for sale, sold, transferred or assigned without our consent.

Warrant Agent. The Warrants were issued in registered form under a Warrant Agent Agreement between VStock Transfer, LLC, as warrant agent, and us. The Warrants were initially represented only by one or more global Warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company ("DTC") and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Fundamental Transactions. In the event of a fundamental transaction, as described in the Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of 50% or more of our outstanding Common Stock, or any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding Common Stock, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of a Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the Warrant.

Governing Law. The Warrants and the Warrant Agent Agreement are governed by New York law.

Preferred Stock

Our Board has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more classes or series. Our Board is able to determine, with respect to any series of preferred stock, the powers (including voting powers), preferences and relative, participating, optional or other special rights, and the qualifications, limitations or restrictions thereof, including, without limitation:

- the designation of the series;
- the number of shares of the series, which our Board may, except where otherwise provided in the preferred stock designation, increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares then outstanding);
- whether dividends, if any, will be cumulative or non-cumulative and the dividend rate of the series;

- the dates at which dividends, if any, will be payable;
- the redemption or repurchase rights and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;
- the amounts payable on, and the preferences, if any, of shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding-up of our affairs;
- whether the shares of the series will be convertible into shares of any other class or series, or any other security, of us or any other entity, and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates, any rate adjustments, the date or dates as of which the shares will be convertible and all other terms and conditions upon which the conversion may be made;
- restrictions on the issuance of shares of the same series or of any other class or series;
- the voting rights, if any, of the holders of the series; and
- any other powers, preferences and relative, participating, optional or other special rights of each series of preferred stock, and any qualifications, limitations or restrictions thereof, all as may be determined from time to time by the Board and stated in the resolution or resolutions providing for the issuance of such preferred stock.

We could issue a series of preferred stock that could, depending on the terms of the series, impede or discourage an acquisition attempt or other transaction that some, or a majority, of the holders of our Common Stock might believe to be in their best interests or in which the holders of our Common Stock might receive a premium over the market price of the shares of our Common Stock. Additionally, the issuance of preferred stock may adversely affect the rights of holders of our Common Stock by restricting dividends on the Common Stock, diluting the voting power of the Common Stock or subordinating the liquidation rights of the Common Stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of our Common Stock.

Anti-Takeover Effects of Our Second Amended and Restated Certificate of Incorporation, as amended ("Amended Charter"), and Second Amended and Restated Bylaws ("Amended Bylaws") and Certain Provisions of Delaware Law

Our Amended Charter, Amended Bylaws and the Delaware General Corporation Law (the "DGCL") contain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our Board. These provisions are intended to avoid costly takeover battles, reduce our vulnerability to a hostile or abusive change of control and enhance the ability of our Board to maximize stockholder value in connection with any unsolicited offer to acquire us. However, these provisions may have an anti-takeover effect and may delay, deter or prevent a merger or acquisition of our company by means of a tender offer, a proxy contest or other takeover attempt that a stockholder might consider in its best interest, including those attempts that might result in a premium over the prevailing market price for the shares of Common Stock held by stockholders.

Potential Effects of Authorized but Unissued Stock

Pursuant to our Amended Charter, we have shares of Common Stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved Common Stock and preferred stock may enable our Board to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the Board has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the DGCL and subject to any limitations set forth in our Amended Charter. The purpose of authorizing the Board to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

Section 203 of the Delaware General Corporation Law. We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Listing

We have listed our Common Stock and Warrants on The Nasdaq Capital Market under the symbols "KTTA" and "KTTAW," respectively, since September 15, 2021.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock and Warrants is VStock Transfer, LLC.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-3 File No. 333-271896 and 333-282532, on Forms S-8 File No. 333-267535, 333-271011, 333-278386, 333-290135 and 333-293086, and on Forms S-1 File No. 333-286889 and 333-291611 of our report dated March 30, 2026, with respect to the consolidated financial statements of Pasithea Therapeutics Corp. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.
Hartford, CT
March 30, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-271896 and 333-282532), on Forms S-8 (File Nos. 333-267535, 333-271011, 333-278386, 333-290135, and 333-293086), and on Form S-1 (File Nos. 333-286889 and 333-291611) of our report dated March 24, 2025, with respect to the consolidated financial statements of Pasithea Therapeutics Corp. as of December 31, 2024, included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

Marcum LLP
Hartford, CT
March 30, 2026

Exhibit 31.1

PASITHEA THERAPEUTICS CORP.
CEO CERTIFICATE
PURSUANT TO SECTION 302

I, Dr. Tiago Reis Marques, certify that:

1. I have reviewed the Annual Report on Form 10-K for the year ended December 31, 2025 for Pasithea Therapeutics Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 30, 2026

By: /s/ Dr. Tiago Reis Marques
Name: Dr. Tiago Reis Marques
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

PASITHEA THERAPEUTICS CORP.
CFO CERTIFICATE
PURSUANT TO SECTION 302

I, Daniel Schneiderman, certify that:

1. I have reviewed the Annual Report on Form 10-K for the year ended December 31, 2025 of Pasithea Therapeutics Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 30, 2026

By: /s/ Daniel Schneiderman
Name: Daniel Schneiderman
Title: Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

PASITHEA THERAPEUTICS CORP.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Annual Report on Form 10-K of Pasithea Therapeutics Corp. (the "Company") for the year ended December 31, 2025 (the "Annual Report"), the undersigned hereby certifies in his capacity as an officer of the Company that to such officer's knowledge:

1. The Annual Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2026

By: /s/ Dr. Tiago Reis Marques
Name: Dr. Tiago Reis Marques
Title: Chief Executive Officer
(Principal Executive Officer)

This certification shall not be deemed "filed" for any purpose, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act.

Exhibit 32.2

PASITHEA THERAPEUTICS CORP.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Annual Report on Form 10-K of Pasithea Therapeutics Corp. (the "Company") for the year ended December 31, 2025 (the "Annual Report"), the undersigned hereby certifies in his capacity as an officer of the Company that to such officer's knowledge:

1. The Annual Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2026

By: /s/ Daniel Schneiderman
Name: Daniel Schneiderman
Title: Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

This certification shall not be deemed "filed" for any purpose, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act.