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, 2023**

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: **(702) 514-4174**

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 checkmark 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, 2023) was $10.5 million.

As of March 23, 2024, there were 1,042,415 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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 lack of 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 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;
- disruptions to the development of our product candidates due to public health crises, such as epidemics and pandemics, including the COVID-19 global pandemic;
- the timing and focus of our future preclinical 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;
- 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 in the reports we will file from time to time with the SEC.

EXPLANATORY NOTE

On December 28, 2023, our board of directors (“Board”) approved a 1:20 reverse stock split (the “Reverse Stock Split”) of our outstanding shares of common stock, par value $0.0001 per share (“Common Stock”), which became effective on January 2, 2024. In connection with the Reverse Stock Split, there was corresponding reduction in the number of authorized shares of Common Stock to 100,000,000.

Unless otherwise noted, the share and per share information in this Annual Report on Form 10-K reflects the Reverse Stock Split.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage biotechnology company primarily focused on the discovery, research and development of innovative treatments for Central Nervous System ("CNS") disorders and other diseases, including RASopathies. We are leveraging our expertise in the fields of neuroscience, translational medicine, and drug development to bring life-changing therapies to patients where we believe there are suboptimal treatment options.

During the year ended December 31, 2023, we discontinued our support services to anti-depression clinics in the U.K. and related at-home services in New York, NY. In addition, we discontinued our clinical operations in Los Angeles, CA and disposed of the related property. Accordingly, as of December 31, 2023, we have discontinued the operations of our "Clinics" segment provided by our subsidiaries, and currently have one reportable segment, "Therapeutics," related to the research and development of our therapeutic product candidates.

Our Therapeutic Pipeline

We are advancing a pipeline of three therapeutic product candidates, with a focus on our lead product candidate, PAS-004, a next-generation macrocyclic (as defined below) mitogen-activated protein kinase, or 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") and a number of oncology indications, among others.

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 certain cancers and NF1-associated plexiform neurofibromas ("NF1-PN") in pediatric patients. We believe these MEK inhibitors suffer from certain limitations, including known toxicities. Unlike current FDA approved MEK inhibitors, PAS-004 is macrocyclic, which we believe may lead to improved pharmacokinetics ("PK"), tolerability and potency. Macrocycles are large cyclic molecules that can bring increased potency, metabolic stability, and oral bioavailability. Cyclization also offers rigidity for stronger binding with drug target receptors. PAS-004 was designed to provide a lower Cmax (the maximum (or peak) serum concentration that a drug achieves in a specified compartment or test area of the body after the drug has been administered) and a longer half-life that may lead to a better therapeutic window. 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. We are currently conducting the Phase 1 clinical trial at four clinical sites in the U.S. and plan to open three additional sites in Eastern Europe. The objective of the Phase 1 study is to assess the safety, tolerability, PK, and pharmacodynamics ("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(s).

PAS-004 has received orphan-drug designation from the FDA for the treatment of NF1. Our clinical development plan for PAS-004 following the ongoing Phase 1 trial is to advance PAS-004 into a Phase 1b/2 clinical trial in adult NF1-PN patients followed by adolescent and pediatric NF1-PN patients.

Our remaining two programs, PAS-001 and PAS-003, are in the earlier stages of development and are based on novel targets for the treatment of CNS disorders that we believe address limitations in the treatment paradigm of the indications we plan to address, which are currently amyotrophic lateral sclerosis ("ALS") for our PAS-003 program, and schizophrenia for our PAS-001 program.

Our PAS-003 program aims to develop a proprietary humanized monoclonal antibody ("mAb") with a mechanism-of-action targeting a5b1 integrin for the treatment of ALS and potentially address other CNS disorders, such as MS and stroke. We believe targeting a5b1 integrin may have a beneficial impact on disease due to modulation of multiple cell types and mechanisms involved in neuroinflammation, which occurs in ALS. We acquired PAS-003 in connection with our acquisition of Alpha-5 Integrin, LLC, a privately held biotechnology company, in June 2022.

On November 9, 2023, we announced that we selected our PAS-003 lead development candidate, a humanized monoclonal antibody with optimal properties that targets α5β1 integrin for the treatment of both sporadic and familial ALS. PAS-003 is now ready for manufacturing and IND-enabling studies.

Our PAS-001 discovery program 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) are an important genetic risk factor for schizophrenia.

During the year ended December 31, 2023, we determined to cease further development of our PAS-002 program for multiple sclerosis ("MS") due to several factors including the significant capital, resources and time required to develop the program, and the current and projected availability of effective treatment options for MS patients, among others.

Our Strategy

Our mission is to develop innovative therapies to address areas of high unmet medical need, initially in RASopathies and CNS disorders. To

achieve our mission, we are executing a near-term strategy with the following key elements:

- ***Initiate a first-in-human clinical trial of PAS-004.*** In December 2023 we received a study may proceed letter from the FDA for our IND and in February 2024 we opened the first clinical site of our first-in-human clinical trial of PAS-004 in patients with MAPK pathway driven advanced solid tumors with a documented RAS, NF1 and RAF mutation or patients who have failed BRAF/MEK inhibition. The objective of the Phase 1 dose escalation 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. The Phase 1 trial will also evaluate the levels of inhibition of ERK phosphorylation, or pERK. We will utilize this data to help determine PAS-004 dosing for the treatment of NF1-PN patients. We expect to release initial preliminary data as early as the second half of 2024 and expect to complete the trial in the second half of 2025.

- ***Advance clinical development of PAS-004 for NF1-PN.*** The initial indication we plan to seek PAS-004 marketing approval for is the treatment of NF1-PN. Assuming a successful Phase 1 dose escalation study, we plan to advance PAS-004 in 2025 into a Phase 1b/2 clinical trial in adult patients with NF1-PN followed by adolescent and then pediatric NF1-PN patients.

- ***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 cutaneous neurofibromas, ALS, Noonan syndrome, LMNA cardiomyopathy and other MAPK-mutation driven cancers. We plan to test PAS-004 in various preclinical models to further demonstrate the potential utility of PAS-004 in additional indications.

- ***Expand formulation development for PAS-004.*** PAS-004 is currently being administered orally in capsule formulation in the ongoing Phase 1 clinical trial. We are currently evaluating additional formulations of PAS-004 including tablets, and liquids in the treatment of adult and pediatric NF1-PN patients respectively. Additionally, we may pursue topical formulation development for other indications where a topical formulation to treat a localized pathology may be indicated, including cutaneous neurofibromas.

- ***Maximize the potential of our discovery product candidates with selective use of business development and commercial collaborations.*** In order to maximize potential value of each of our discovery programs with our limited resources, following lead candidate selection for each of our discovery programs, we plan to seek business development, non-dilutive funding and collaborative opportunities for continued preclinical and clinical development of our discovery product candidates. We plan to continue evaluating opportunities to work with partners that meaningfully enhance our capabilities with respect to the development and commercialization of our product candidates, which may entail the potential out-licensing of the development and commercialization of our product candidates to larger pharmaceutical organizations, including our lead product candidate PAS-004. Additionally, we plan to establish research collaborations for the continued preclinical and clinical development of our discovery programs. Further, we intend to commercialize our product candidates in key markets either alone or with partners in order to maximize the worldwide commercial potential of our programs.

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-PN), 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. Three of them are approved by the FDA for various oncological indications, and only one approved for the treatment of children aged two and older with NF1-PN. These MEK inhibitors are selective towards MEK 1/2, as they bind to non-ATP-competitive allosteric sites. We believe a limitation of current FDA approved MEK inhibitors are their high rates of serious drug-related adverse events, reported to occur in many treated patients, which may result in drug intolerability. These MEK inhibitors often require multiple doses per day which provides high maximum concentrations which may result in a higher rate of adverse events.

Our rationale in developing PAS-004 is to address these shortcomings to potentially provide patients with better outcomes and improved safety.

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, 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.

Neurofibramatosis 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 is one of the most common genetic disorders, affecting both children and adults. NF1 affects approximately one in 3,000 newborns throughout the world, with approximately 100,000 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 ("PN"), 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 15% 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 NF1-PN.

Limitations of Current Standard of Care

Koselugo (selumetinib), a MEK inhibitor, was approved by the FDA in 2020 for NF1 pediatric patients two years of age and older who have symptomatic, inoperable plexiform neurofibromas. Koselugo is the only FDA approved drug for the treatment of NF1. Koselugo is also being evaluated in an ongoing Phase 3 clinical trial for the treatment of adult patients with NF1-PN. In addition to Koselugo, we are aware of several 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 and other earlier generation MEK inhibitors approved for indications other than NFI suffer from limitations, such as a challenging dosing schedule, which requires dosing twice a day on an empty stomach, at least one hour before or two hours after a meal. We believe that this creates a significant market opportunity for a next-generation MEK inhibitor that addresses these shortcomings, has a pharmacokinetic and tolerability profile suitable for long-term dosing and that can arrest or reverse tumor growth.

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. We believe PAS-004's PK profile and extended half-life compared to other MEK inhibitors allows durable suppression of ERK phosphorylation, critical for clinical responses.

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 pharmacokinetic profile, potency and dose-dependent inhibitory activity against cellular proliferation in NF1 deficient Schwann cells and appears similar to selumetinib, an FDA approved MEK inhibitor.

In vivo Preclinical Studies

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 treatment with superior efficacy by allowing better sustained MEK/ERK signaling inhibition, in addition allowing for greater intervals between dosing such as single daily dose as compared to the required twice daily dosing 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, or 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 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. We are currently conducting long-term toxicological studies in rats and dogs to support chronic dosing of PAS-004.

Completion of GMP-Compliant Manufacturing

In June 29, 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 Phase I clinical trial.

Clinical Development Overview

In December 2023 we received a study may proceed letter from the FDA for our IND and in February 2024 we opened the first clinical site of our first-in-human clinical trial of PAS-004 in patients with MAPK pathway driven advanced solid tumors with a documented RAS, NF1 and RAF mutation or

patients who have failed BRAF/MEK inhibition. The Phase 1 clinical trial 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. Approximately 30 to 36 patients will be enrolled across four clinical sites in the U.S. and three clinical sites in Eastern Europe. Patients will be enrolled into dosing cohorts under a modified 3+3 dose escalation study design framework and will sequentially receive one of seven planned dose levels of PAS-004 (2 mg, 4 mg, 6 mg, 9 mg, 12 mg, 15 mg, and 18 mg) to be taken orally. We currently expect to provide initial interim data as early as the second half of 2024 and to complete the Phase 1 trial in 2025.

The Company's clinical development plan for PAS-004 following the ongoing Phase 1 study is to bridge to a Phase 1b/2 clinical trial in adult and then pediatric patients with NF1-PN and ultimately seek FDA marketing approval of PAS-004 for adult and pediatric NF1-PN patients.

Overview of Our Discovery Programs

PAS-003 Program

Amyotrophic Lateral Sclerosis Overview

ALS, or Lou Gehrig's disease, is a fatal, progressive motor neuron disease that targets nerve cells in the spinal cord and brain. ALS most commonly affects people between the ages of 40 and 70, with an average age of 55 at the time of diagnosis. It affects as many as 30,000 patients in the United States, with 5,000 new cases diagnosed each year.

While approximately 10% of cases are hereditary, which is known as familial ALS, the large majority of cases (90-95%) are not, which is known as sporadic ALS. While the pathogenesis of ALS is not fully understood, studies have shown that the disease is multifactorial, with several interlinked mechanisms, such as neuroinflammation and neurodegeneration.

ALS often begins with muscle twitching and/or weakness in a limb, however, as the disease progresses, ALS affects control of the muscles needed to move, speak, eat and breathe. As a result, ALS patients develop extensive muscle wasting and atrophy leading to paralysis and ultimately death. The life expectancy is low, with patients living on average three to five years after symptom onset, and the patient´s quality of life is typically poor.

There are currently four FDA approved medications to treat ALS and its symptoms. However, they have been shown to only have modest clinical efficacy. Therefore, despite these therapies, the medical need for new treatments for ALS patients is very high.

Scientific Background and Rationale for Targeting a5b1 integrin for the treatment of ALS

Integrins are the principal receptors used by animal cells to bind to the extracellular matrix as well as other cells. Integrins activate intracellular signaling pathways and can cooperate with other conventional signaling receptors. Integrins are involved in a wide range of biological processes including cell growth, migration, survival, and proliferation as well as cytokine activation and release. As a result, integrins play a significant role in many physiological processes, including embryogenesis, organogenesis, and tissue development, but also in pathogenic ones, including inflammation, infection, and allergic and neoplastic diseases.

Integrins are composed by two non-covalently linked alpha and beta subunits. a5b1 integrin, also known as the fibronectin receptor, is a heterodimer consisting of the a5 and b1 subunits. Integrins can be broadly grouped based on ligand specificity. In this classification, integrin a5b1 falls under RGD-recognizing integrins and is known to bind fibronectin, osteopontin, fibrillin, thrombospondin, among others. a5b1 integrin has been shown to play a role in cancer, angiogenesis and in a variety of neurological disorders. a5b1 integrin is a validated drug target supported by the clinical development of anti-a5b1 mAbs by several pharmaceutical companies, including PDL Biopharma, Inc. jointly with Biogen Inc., and Pfizer, Inc., for the treatment of cancer indications.

In a 2018 *Nature Neuroscience* publication, scientists at the Steinman Laboratory at Stanford University, headed by our Chairman, Prof. Lawrence Steinman, used mass cytometry to identify an upregulation of a5b1 integrin (CD49e) on brain myeloid cells in the mutant SOD1-G93A mouse model of ALS and demonstrated that a5b1 integrin is upregulated on microglia in the CNS as the disease progresses. Additional preclinical studies have shown that a5b1 integrin is also elevated on macrophages in the periphery and suggest a role for mast cells which also express high level of a5b1 integrin.

In August 2023, we announced the publication of a study in the peer-reviewed journal *Proceedings of the National Academy of Sciences* (PNAS) that presented new findings related to PAS-003 from an interdisciplinary collaboration of scientific teams from the Company, the Mayo Clinic, and Oregon Health & Science University, combining results from human post-mortem tissues from ALS patients and tissue samples from the SOD1-G93A mouse model of ALS ("SOD1-G93A"), the most phenotypically relevant preclinical model for ALS.

We have shown an upregulation of a5b1 integrin in the human brain motor regions but not in sensory regions in ALS and that a5b1 expression increases with disease progression in both mouse models of ALS and human ALS patients. Furthermore, we shown that treatment with a monoclonal antibody targeting a5b1 leads to increase survival and improved motor function in SOD1-G93A mouse model of ALS.

We believe these findings suggest that a5b1 integrin in implicated in the pathophysiology of ALS and that targeting a5b1 integrin may provide a treatment for ALS. We have repeated preclinical studies in over 250 animals, using the SOD1-G93A and TDP-43rNLS8 ALS models, and have consistently demonstrated that anti-a5b1 mAb treatment improved motor function on behavioral testing and increased survival in SOD-G93A transgenic mice, as compared to an isotype control.

We believe these preclinical results demonstrate that targeting a5b1 integrin has the potential to be a new therapy that could improve outcomes for all ALS patients. In November 2023, we announced that we selected our PAS-003 lead development candidate, a humanized mAb with optimal properties that targets α5β1 integrin for the treatment of both sporadic and familial ALS. PAS-003 is now ready for manufacturing and IND enabling studies.

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. The initial development work and screening is currently being conducted by Evotec, utilizing Evotec's integrated research and development expertise and state-of-the-art structure-based drug design techniques. 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 preclinical studies.

Tender Offer

On July 20, 2023, we announced that our Board authorized the repurchase of up to approximately 285,000 shares of our outstanding Common Stock at a cash purchase price of $14.00 per share, through a $4.0 million tender offer (the "Tender Offer"). We launched the Tender Offer on August 9, 2023 and it was completed on September 8, 2023.

On September 14, 2023, we disclosed that a total of 266,171 shares of Common Stock (the "Tender Offer Shares") were validly tendered and not properly withdrawn at a purchase price of $14.00 per share for an aggregate purchase price of $3,726,416, including fees and expenses of $150,000 relating to the Tender Offer. As a result of the Tender Offer, we had 1,040,749 shares of Common Stock outstanding immediately following the closing of the Tender Offer. The Tender Offer Shares were retired and cancelled following the closing of the Tender Offer.

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 our board of directors (the "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.

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, "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.

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); and AstraZeneca PLC and Merck & Co., Inc., which received FDA approval for Koselugo (selumetinib).

Koselugo (selumetinib) marketed by AstraZeneca PLC is currently the only FDA approved therapy for the treatment of pediatric NF1-PN patients, while Mekinist, Mektovi, and Cotellic 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, Springworks Therapeutics, Inc., Array BioPharma Inc. (a subsidiary of Pfizer), Chia Tai Tianqing Pharmaceutical Group Co., LTD, Infixion Bioscience, Inc., NFlection Therapeutics, Inc., Novartis International AG, and Shanghai Fosun Pharmaceutical (Group) Co., Ltd. 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.

In March 2024, Springworks Therapeutics, Inc. announced that it initiated a rolling submission of a New Drug Application ("NDA") to the FDA for mirdametinib, an investigational MEK inhibitor, in pediatric and adult patients with NF1-PN.

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. 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 issue in these families will have a statutory expiration date of 2045 (without consideration of PTA and PTE).

PAS-003

For PAS-003, we have pending patent applications in two patent families. The first patent family has claims directed to monoclonal antibodies. The second patent family has claims directed to humanized monoclonal antibodies. Patents that may issue worldwide in these families will have a statutory expiration date in May of 2042 to November 2043 (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. During the year ended December 31, 2023, there was no grant income.

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 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 plan to utilize Wuxi for the manufacture of 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 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 ingredient 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’’ basis based on the needs of our current development plans.

Employees & Human Capital

As of December 31, 2023, we had 8 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 research 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. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations.

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 research and development facility is located at 458 Carlton Court, South San Francisco, CA. We rent approximately 1,900 square feet of space, which includes our laboratory and offices.

Website

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 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, as appropriate, as well as manufacturing information, analytical data and any 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 trials 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, 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 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 a 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 to the satisfaction of the FDA.

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 is often 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 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 contraindications, 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 studies 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 generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product marketing exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA or NDA application user fee.

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. In addition, 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, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

The Rare Pediatric Disease Designation and Priority Review Voucher Program

Under the FD&C Act, the FDA incentivizes the development of drugs and biologics that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making such product for such disease or condition will be received from sales in the United States. To be eligible for the incentives, a sponsor must first request and receive from FDA, prior to or with an NDA or BLA submission, a rare pediatric disease designation. The FDA must deem the application eligible for priority review (i.e., the product treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness). If the rare pediatric product is approved, the sponsor may be eligible for a voucher that can be used to obtain a priority review for a subsequent, different NDA or BLA for any use, pediatric or not. Rare pediatric disease designation does not guarantee that a sponsor will receive a priority review voucher (PRV) upon approval of its NDA or BLA. If a PRV is received, it may be sold or transferred an unlimited number of times. Under current law, PRVs can be granted only for products that receive rare disease designation by September 30, 2024, and that are approved by September 30, 2026.

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 after completion. 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. 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 any non-patent exclusivity for a drug or biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug or biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications 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 the 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 a 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 each country's national health authority 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, 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.

U.K. Regulation

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care in the U.K. which is responsible for ensuring that medicines and medical devices work and are acceptably safe.

The MHRA has the following roles:

- Operate post-marketing surveillance - in particular the Yellow Card Scheme - for reporting, investigating and monitoring of adverse drug reactions to medicines and incidents with medical devices.

- Assess and authorize medicinal products for sale and supply in the U.K.

- Oversee the Notified Bodies that ensure medical device manufacturers comply with regulatory requirements before putting devices on the market.

- Operate a quality surveillance system to sample and test medicines to address quality defects and to monitor the safety and quality of unlicensed products.

- Investigate internet sales and potential counterfeiting of medicines, and prosecute where necessary.
- Regulate clinical trials of medicines and medical devices.
- Monitor and ensure compliance with statutory obligations relating to medicines and medical devices.
- Promote safe use of medicines and devices.

In the United Kingdom and following the United Kingdom's exit from the European Union, EU medicines regulation has been adopted as standalone United Kingdom legislation with some amendments to reflect procedural and other requirements with respect to marketing authorizations and other regulatory provisions.

In order to market a medicinal product in the United Kingdom, a license or marketing authorization must be obtained from the MHRA The United Kingdom legislation includes multiple assessment routes for applications for medicinal products, including a 150-day national assessment or a rolling review application. Further, and for a transitional period until December 31, 2022, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure. In addition, the MHRA has the power to have regard to marketing authorizations approved in EU member states.

The United Kingdom has adopted new legislation, the Medicines and Medical Devices Act 2021 and may make changes to the licensing or authorization of medicines in the future. The separate UK authorization system, albeit with transitional recognition procedures in the UK, may lead to additional regulatory costs. In addition, further regulatory costs will be incurred with respect to the lack of mutual recognition of batch testing and related regulatory measures between the European Union and the United Kingdom.

The CQC is an executive non-departmental public body of the Department of Health and Social Care of the U.K. It regulates and inspects health and social care services in England and registration is required prior to the provision of health and care services. Further, certain drug and pharmaceutical licenses and registrations may be required for the possession and/or supply of certain drugs.

The GPhC is the body responsible for the independent regulation of the pharmacy profession within Great Britain (England, Scotland and Wales) regulation and enforcement by, responsible for the regulation of pharmacists, pharmacy technicians and pharmacy premises.

Other Health Care Laws

We may also be subject to healthcare regulation and enforcement by the US federal government and the states and foreign governments where we may market our product candidates, if approved. The US 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-US countries.

The US 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 US 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 government and private payers our business could be adversely impacted. In November 2020, Joseph Biden was elected President and, in January 2021, the Democratic Party obtained control of the Senate. As a result of these electoral developments, it is unlikely that continued legislative efforts will be pursued to repeal ACA. Instead, it is possible that legislation will be pursued to enhance or reform ACA. We are not able to state with certainty what the impact of potential legislation will be 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 impair our business operations in these circumstances, 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 "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 biopharmaceutical 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, such as COVID-19, 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 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.

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 development, especially preclinical stage pharmaceutical companies such as ours. 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 $16.0 million and $13.9 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of approximately $35.3 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 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 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, as well as to support our transition to a public reporting company; 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 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.

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, 2023, we had cash and cash equivalents of approximately $16.3 million. We have incurred continuing losses including a net loss of $16.0 million for the year ended December 31, 2023. 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;
- 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 and other collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate 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 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 remains unclear in many respects and 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. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

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

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. We continue to work with our tax advisors and auditors to determine the full impact TCJA and the CARES Act will have on us. We urge our investors to consult with their legal and tax advisors with respect to both TCJA and the CARES Act 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, 2023, we had approximately $24.3 million of federal and $11.6 million of state net operating loss carryforwards (“NOLs”), available to offset future taxable income. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or 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.

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, 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 conflict between Israel and Hamas, 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. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. 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, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining Institutional Review Board (“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 in “Risks Related to Our Dependence on Third Parties”.

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 may 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 will be influenced by a variety of factors, including but not limited to:

- the amount of capital 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.

Approval may be delated or denied because we cannot satisfy 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 FDA's current Good Manufacturing Practices ("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 cannot be sure that submission of an IND or, in the case of the European Medicines Agency (the "EMA"), a clinical trial application (a "CTA"), will result in the FDA or EMA allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our 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;
- 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, including the COVID-19 pandemic;
- 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 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 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 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.

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, and 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 pre-clinical 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.

We may not identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our Treg Modalities. We are seeking to do so through our internal research programs, and may also explore strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, targets for different neurodegenerative and auto immune diseases may require changes to our cell manufacturing platform, which may slow down development or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology modality used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- we may choose to cease development if we determine that clinical results do not show promise;
- product candidates we develop may nevertheless be covered by third-party patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, and we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

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 of 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 damages 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 in 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.

Risks Related to Our Dependence on Third Parties

We rely completely on third parties 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 for the production of PAS-004 drug substance and we plan to 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, such as the COVID-19 pandemic or the conflict between Russia and Ukraine and the conflict between Israel and Hamas, 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 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. Foreign CMOs may be subject to U.S. legislation, including the proposed BIOSECURE bill, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

For example, 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 UK, 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 that 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.

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 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 may lead to potential 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 Trump administration announced the imposition of tariffs on steel and aluminum entering the United States and in June 2018, the 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. It is unknown whether and to what extent new tariffs, export controls, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry, and it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Most recently, in February 2024, U.S. lawmakers have called for investigations into and the imposition of possible economic sanctions against Chinese biotechnology companies WuXi AppTec and WuXi Biologics, or collectively WuXi, over alleged ties to the Chinese military. 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 candidate 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 price of our Common Stock and Warrants may be volatile, and you could lose all or part of your investment.

The market price of our Common Stock and Warrants are highly volatile and for the year ended December 31, 2023, the market price of our Common Stock ranged from $5.60 to $14.62 per share and the market price of our Warrants ranged from $0.08 to $1.31. 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 price 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 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 shareholders.

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 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 future product candidates 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 future product candidates receive regulatory approval, the terms of such approval and market acceptance and demand for such approved products;
- regulatory developments affecting our 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.

In connection with the preparation of our financial statements for the fiscal year ended December 31, 2023, we identified a material weakness in our internal control over financial reporting. 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 price 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. 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 to our financial statements, as set forth in Item 9A of this Annual Report on Form 10-K. As of the date hereof, we have commenced procedures to remediate the material weakness. We will continue to monitor the design and effectiveness of these procedures and controls and make any further changes we determine appropriate. However, this material weakness will not be considered remediated until the applicable remedial actions have been fully implemented and we have concluded that these controls are operating effectively for a sufficient period of time.

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 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 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 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, result 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 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 price 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 ("Certificate of Incorporation"), and our 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; and
- 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.

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 23, 2024, our officers, directors and principal stockholders, beneficially own, in the aggregate, approximately 30.4% 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 conditions.

In light of the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar, the British pound and the Euro, may adversely affect us. Although we are based in the United States, we had operations in the United Kingdom. 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 Global Market continued listing requirements may result in our Common Stock and/or Warrants being delisted from The Nasdaq Global Market.

On January 19, 2023, we received a letter (the "Notice") from the Listing Qualifications Staff (the "Staff) of the Nasdaq Stock Market, LLC ("Nasdaq") indicating that, based upon the closing bid price of our Common Stock for the last 30 consecutive business days, we are not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). We were provided a compliance period of 180 calendar days from the date of the Notice, or until July 18, 2023, to regain compliance with the Minimum Bid Price Requirement. On July 19, 2023, we received a letter from Nasdaq advising that we had been granted a 180-day extension to January 15, 2024, to regain compliance with the Minimum Bid Price Requirement.

On December 19, 2023, we held our 2023 Annual Meeting at which our stockholders approved the adoption and approval of an amendment to our Charter to effect the Reverse Stock Split which became effective on January 2, 2024.

On January 17, 2024, we received a letter from Nasdaq stating that our Common Stock had maintained a closing bid price at or above $1.00 per share for a sufficient number of consecutive business days to regain compliance with the Minimum Bid Price Requirement, and that the matter was closed.

There can be no assurance that we will continue to maintain compliance with the Minimum Bid Price Requirement or maintain compliance with the other Nasdaq listing requirements. If the price of our Common Stock were to again decline to a price whereby we are in violation of the Minimum Bid Price Requirement, the market may perceive a decision to effect an additional reverse stock split as a negative indicator of our future prospects, and as a result, the price of our Common Stock may fail to regain compliance with the Minimum Bid Price Requirement after any such additional reverse stock split. 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 price of our Common Stock and/or Warrants may decline further, and stockholders may lose some or all of their investment.

Risks Related to Our Discontinued Clinics Segment

Past clinical services in the US included prescribing, dispensing and administering ketamine, which as a Schedule III controlled substance under US law requires proper authorization and federal and state registration. If the clinical providers to whom we furnished business support services failed to comply with any of these requirements, we could be subject to liability and harm to our brand that would affect our business.

Ketamine is a Schedule III controlled substance under the Controlled Substances Act ("CSA"). Under the CSA, controlled substances in Schedule III have an accepted medical use in the United States and have a lower dependence and abuse potential than Schedule II substances. In order to prescribe, dispense and administer a controlled substance in Schedule III, a provider must be authorized to prescribe controlled substances by the state in which the provider is licensed and have a DEA registration.

Ketamine has been approved by the FDA for anesthetic purposes generally and, in 2019, esketamine nasal spray was approved by the FDA for treatment of treatment-resistant depression used in conjunction with an oral antidepressant. Once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient and within scope of their authority to practice. Therefore, as long as properly licensed providers are authorized to prescribe ketamine under state licensing laws, they may prescribe ketamine for "off label" uses, including for psychotherapy purposes, when deemed medically appropriate by the provider.

To be eligible for a DEA registration, practitioners must be licensed or otherwise authorized by the state in which they practice to carry out the specific activity for which they seek a DEA registration. Importantly, a physician who is registered with DEA to dispense controlled substances at a particular location in a state may travel to other unregistered locations, such as a patient's home, in the same state to dispense controlled substances on an "as-needed and random basis," so long as the physician does not maintain a principal place of professional practice at any of those unregistered locations. In certain states, authorized providers must also have a state specific controlled substances registration. DEA registrants may also be required to keep and submit certain records of inventory.

Moreover, ketamine has been identified by the DEA as a drug that has been used illegally by predators of sexual assault because it causes individuals to feel detached from their bodies and surroundings. Therefore, if our past providers who prescribed, dispensed and administered ketamine were not properly authorized and registered to do so, we could face substantial civil penalties, suffer significant reputational damage, and expose our business to other liability.

As of December 31, 2023, we have discontinued all operations of our Clinics segment.

Past clinical services in the U.K. included prescribing, dispensing and administering ketamine, which as a Schedule II controlled substance under English laws requires specific manufacture, storing, and administration compliance, for an unlicensed therapeutic indication that poses certain clinical risks to patients. If certain of our past clinics and providers failed to comply with any of these requirements, we could be subject to liability and harm to our brand that may have a material adverse effect on our business.

Ketamine is a Schedule II controlled substance under the Misuse of Drugs Regulations 2001 and is controlled with regard to synthesis, storage and distribution as a Class B substance under the Misuse of Drugs Act 1971, as amended. Therefore, the associated risk factors relating to our past ownership and operation of outpatient clinics dispensing and prescribing intravenous infusions of ketamine in the U.K. include product defects that may cause liabilities under civil law for negligence and products liability under the Consumer Protection Act 1987; the medical staff operating the clinics may not have complied with standards of performance demanded by the Care Quality Commission ("CQC") and the General Medical Council ("GMC") code of practice; similarly the operation of the clinics themselves may not have complied with CQC rules on hygiene and safety; we may be found to not have complied with the Human Medicines Regulations 2012 with respect to advertising requirements (including the prohibition of any advertisement that is likely to lead to the use of a prescription only medicine) or the Advertising Standards Authority standards and rules (The MHRA Blue Guide on Advertising and Promotion of Medicines in the U.K. Third Edition 2020) with regard to the promotion and marketing of medicinal products; and the prescription of ketamine for the unlicensed indication of acute depressive illness may have increased the prevalence of serious adverse events, damaging the commercial reputation of our brand and future products. Additionally, we and/or associated persons may be found to not have been compliant with the Bribery Act 2010, which includes criminal liability.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We have certain processes for assessing, identifying and managing cybersecurity risks, which are built into our overall information technology function and are designed to help protect our information assets and operations from internal and external cyber threats, and protect employee, collaborator and patient information from unauthorized access or attack, as well as secure our networks and systems. Such processes include physical, procedural and technical safeguards and routine review of our policies and procedures to identify risks and refine our practices. We consider the internal risk oversight programs of third-party service providers before engaging them in order to help protect us from any related vulnerabilities.

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

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. Management provides periodic updates to the Audit Committee regarding cybersecurity matters including significant new cybersecurity threats or incidents, when and if appropriate.

We use technology-based tools that are designed to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

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. Our research and development facility is located at 458 Carlton Court, South San Francisco, CA. We rent approximately 1,900 square feet of space, which includes our laboratory and 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 23, 2024, we had 40 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.

Issuer Repurchases of Equity Securities

On July 20, 2023, we announced that our Board authorized the repurchase of up to approximately 285,000 shares of our outstanding Common Stock at a cash purchase price of $14.00 per share, through a $4.0 million tender offer (the "Tender Offer"). We launched the Tender Offer on August 9, 2023 and it was completed on September 8, 2023.

On September 14, 2023, we disclosed that a total of 266,171 shares of Common Stock (the "Tender Offer Shares") were validly tendered and not properly withdrawn at a purchase price of $14.00 per share for an aggregate purchase price of $3,726,416, including fees and expenses of $150,000 relating to the Tender Offer. As a result of the Tender Offer, we had 1,040,749 shares of Common Stock outstanding immediately following the closing of the Tender Offer. The Tender Offer Shares were retired and cancelled following the closing of the Tender Offer.

Recent Sales of Unregistered Securities

None.

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, 2023 and December 31, 2022 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, 2023, as compared to the fiscal year ended December 31, 2022. This discussion should be read in conjunction with our consolidated financial statements for the fiscal years ended December 31, 2023 and December 31, 2022 and related notes included elsewhere in this 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 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 (UK), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, Pasithea Clinics Inc., Alpha-5 Integrin, LLC, and AlloMek Therapeutics, LLC. Pasithea Therapeutics Limited (UK) is a private limited Company, registered in the United Kingdom (UK). Pasithea Clinics Inc. is 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.

Overview

We are a biotechnology company primarily focused on the discovery, research and development of innovative treatments for central nervous system (CNS) disorders and RASopathies. Our primary operations are focused on developing our lead therapeutic candidate, PAS-004, a next-generation macrocyclic MEK inhibitor for potential use in a range of indications, including neurofibromatosis type 1--associated plexiform neurofibromas and certain oncology indications that we acquired from AlloMek Therapeutics, LLC ("AlloMek") in October 2022.

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 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 Company is currently conducting the Phase 1 clinical trial. Our clinical development plan for PAS-004 following the Phase 1 study is to begin a Phase 1b/2 clinical trial in neurofibromatosis type 1 (NF1)-associated plexiform neurofibroma pediatric and adult patients.

We are also focused on the development of our discovery programs through lead identification of drug candidates, including PAS-003, a monoclonal antibody targeting a5b1 integrin for the treatment of ALS and PAS-001, a small molecule targeting the complement component 4A(C4A) gene for the treatment of schizophrenia.

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 as 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.

During the year ended December 31, 2023, we discontinued our support services to anti-depression clinics in the U.K. and related at-home services in New York, NY. We also discontinued our clinical operations in Los Angeles, CA and disposed of the related property. Accordingly, as of December 31, 2023, we have discontinued the operations of our support services to clinics provided by our subsidiaries and remain focused on the research and development of our therapeutic product candidates.

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 2024, we expect inflation to continue to have a negative impact throughout 2024, 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 Amended and Restated Certificate of Incorporation reflecting a one-for-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 to 100,000,000. 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 data herein that relates to our Common Stock prior to the effective date has been retroactively restated to reflect the Reverse Stock Split.

Results of Operations

Years Ended December 31, 2023 and 2022

Our financial results for the years ended December 31, 2023 and 2022 are summarized as follows:

	For the years ended December 31,			
	2023	**2022**	**Change**	**% Change**
General and administrative	$ 7,878,596	$ 9,923,544	$ (2,044,948)	(20.6)%
Research and development	8,100,765	2,665,427	5,435,338	203.9%
Loss from operations	(15,979,361)	(12,588,971)	(3,390,390)	26.9%
Other income, net	471,613	861,086	(389,473)	(45.2)%
Net loss from continuing operations	(15,507,748)	(11,727,885)	(3,779,863)	32.2%
Net loss from discontinued operations, net of tax	(453,910)	(2,208,567)	1,754,657	(79.4)%
Net loss	$ (15,961,658)	$ (13,936,452)	$ (2,025,206)	14.5%

General and Administrative

General and administrative expenses decreased by approximately $2.0 million, or 21%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The decrease was primarily driven by (i) a decrease of $1.6 million in professional fees associated with being a public company and non-recurring corporate communication costs associated with a dissident shareholder campaign that were incurred in 2022, of which approximately $1.2 million was related to public relations and communications, approximately $236,000 was related to investor relations, research, and other professional fees, and approximately $171,000 was related to the transfer agent and proxy fees (ii) a decrease in consulting and legal fees of approximately $1.6 million due to the non-recurring costs of a dissident shareholder campaign, litigation settlements, hiring of contractors, and the acquisition of Alpha-5 during 2022, (iii) a decrease in accounting and valuation fees of approximately $159,000 due to higher fees related to the acquisition in 2022, offset by (iv) an increase of approximately $655,000 in personnel expenses related to the hiring of employees, (v) an increase of approximately $278,000 in non-cash expenses, primarily related to the amortization of intangible assets, (vi) an increase of approximately $388,000 in office and other expenses related to director fees, insurance, IT administration, utilities, travel, and (business development.

We expect general and administrative expenses to decrease in fiscal year 2024 as compared to fiscal year 2023 due to the non-recurring expenses that were incurred in 2023 related to the unsolicited, non-binding proposal to acquire all outstanding shares of the Company from a third party and the tender offer we completed in September 2023.

Research and Development

Research and development expenses for the years ended December 31, 2023 and 2022 relates to activities primarily focused on the development of PAS-001, PAS-003 and PAS-004.

Research and development expenses increased by approximately $5.4 million, or 204%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase is due to the expansion of our drug development activities related to the research of our product candidates, the manufacturing and clinical development of PAS-004, and increased consulting fees.

We expect research and development expenses to increase in fiscal year 2024 as compared to fiscal year 2023 primarily due to the clinical development of PAS-004 as well as PAS-004 CMC activities.

Other Income, Net

For the year ended December 31, 2023, other income, net decreased by approximately $389,000, or 45%, as compared to the year ended December 31, 2022. The decrease was primarily driven by a $1.8 million decrease in gains associated with changes in the fair value of our warrant liabilities, offset by interest and dividends of approximately $415,000 during the year ended December 31, 2023 that did not occur in the prior year and non-recurring litigation settlements of $1.0 million paid during the year ended December 31, 2022.

Discontinued Operations

During the year ended December 31, 2023, we discontinued our support services to anti-depression clinics in the U.K. and related at-home services in New York, NY. We also discontinued our clinical operations in Los Angeles, CA and disposed of the related property. Accordingly, as of December 31, 2023, all activity related to our discontinued subsidiaries is included in Net loss from discontinued operations, net of tax in the statements of operations.

Working Capital

	As of December 31,	
	2023	2022
Current assets	$ 16,692,154	$ 33,913,231
Current liabilities	2,634,040	1,641,755
Working capital	$ 14,058,114	$ 32,271,476

Working capital decreased by $18.2 million between December 31, 2023 and December 31, 2022 due primarily to cash used to repurchase shares of our Common Stock in the Tender Offer and to fund operations for the year ended December 31, 2023.

Liquidity and Capital Resources

	Year Ended December 31,	
	2023	2022
Net loss	$ (15,961,658)	$ (13,936,452)
Net cash used in operating activities	(12,814,133)	(11,894,567)
Net cash provided by (used in) investing activities	75,199	(2,299,699)
Net cash used in financing activities	(3,726,416)	(3,206,244)
Effect of foreign currency translation	(3,991)	9,900
Net cash used in discontinued operations	(287,471)	(2,423,489)
Decrease in cash and cash equivalents	$ (16,756,812)	$ (19,814,099)

Cash and cash equivalents decreased by approximately $16.8 million for the year ended December 31, 2023 compared to a decrease of approximately $19.8 million for the year ended December 31, 2022, which was primarily attributable to cash used to repurchase shares of our common shares in the Tender Offer during the year and cash used to fund operations, partially offset by a decrease of approximately $287,000 in net cash used in discontinued operations, compared to a decrease of approximately $2.4 million during the year ended December 31, 2022.

Liquidity & Capital Resources Outlook

As of December 31, 2023, we had approximately $16.3 million in operating bank accounts and money market funds, with working capital of approximately $14.1 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. Subsequent to the consummation of the Initial Public Offering, our liquidity was and continues to be satisfied through the net proceeds from the Initial Public Offering, the private placement we consummated in November 2021 and the receipt of cash upon the prior exercise of our outstanding warrants. Based on the foregoing, management believes that we will not have sufficient working capital to meet our needs through twelve months from the issuance date of the financial statements included in this annual report, without raising additional capital.

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 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 13 – Commitments and Contingencies in the Notes to the Consolidated Financial Statements in Item 8 of this Form 10-K for a summary of our contractual obligations.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements 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 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.

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.

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.

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act and regulations promulgated thereunder) as of December 31, 2023, or the Evaluation Date.

Based upon their evaluation and due to the material weakness cited below, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were ineffective as of the Evaluation Date.

Management's 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, 2023. 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 not effective at a reasonable assurance

level as of December 31, 2023, due primarily to the material weakness described below.

Notwithstanding the material weakness described below, our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that the financial statements included in this Annual Report present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in accordance with U.S. Generally Accepted Accounting Principles. The material weakness did not result in any restatements of consolidated financial statements previously reported by us, nor were there any changes to previously released financial results.

This annual report does not include an attestation report of our registered public accounting firm on our internal control over financial reporting due to an exemption established by the JOBS Act for “emerging growth companies.” In addition, we are currently a non-accelerated filer and are therefore not required to provide an attestation report on our internal control over financial reporting until such time as we are an accelerated filer or large accelerated filer.

Material Weakness in Internal Control Over Tax Provision Disclosure

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

During the audit process related to our fiscal year ended December 31, 2023, management, in connection with our independent auditors, identified a material weakness in our controls related to the review of the annual income tax provision prepared by a third-party firm. Specifically, we did not maintain effective controls to sufficiently review the completeness and accuracy of the annual tax provision in Note 10 to our financial statements (the “Tax Provision Disclosure”). Based on our review, we failed to identify an error in our disclosures of our net operating losses carryover of approximately $6.5 million in federal and $3.8 million in state net operating losses. Our independent auditors identified, and we corrected the error prior to the inclusion of the Tax Provision Disclosure in the financial statements included in this Annual Report on Form 10-K. We did not record an audit adjustment, the error did not impact any balance sheet items, and there was no need to change our income tax position as we continue to maintain a full valuation allowance against our net operating losses. This material weakness was isolated to the review and confirmation of the Tax Provision Disclosure.

Remediation of Material Weakness

As disclosed above, we utilized a third-party firm to prepare the Tax Provision Disclosure. However, due to the size of our operations and resource constraints, we did not perform a sufficient review of third-party materials prepared with respect to the Tax Provision Disclosure. Management believes that the best remediation plan for the material weakness is creating processes to ensure a thorough review of all materials and schedules prepared by third parties with respect to the Tax Provision Disclosure. Further, management intends to engage a tax professional to prepare and review any Tax Provision Disclosures. Remediation efforts have begun, as management has retained a tax professional who will prepare and review the Company’s Tax Provision Disclosure going forward. Management believes the involvement of the tax professional will provide sufficient remediation in future periods and management will continue to evaluate the appropriate level of staffing to ensure adherence to the controls over Tax Provision Disclosures.

We will continue to monitor the design and effectiveness of these procedures and controls and make any further changes we determine appropriate. However, this material weakness will not be considered remediated until the applicable remedial actions have been fully implemented and we have concluded that these controls are operating effectively for a sufficient period of time.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected, despite our efforts.

Changes in Internal Control Over Financial Reporting

Except as discussed above, there were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

(a) None.

(b) During the fiscal quarter ended December 31, 2023, 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 23, 2024, 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	47	Chief Executive Officer and Director
Daniel Schneiderman	46	Chief Financial Officer
Dr. Graeme Currie	57	Chief Development Officer
Non-Employee Directors		
Prof. Lawrence Steinman	76	Executive Chairman and Co-Founder
Simon Dumesnil [(1)(2)(3)]	47	Director
Dr. Emer Leahy [(1)(2)(3)]	58	Director
Alfred Novak [(1)(2)(3)]	76	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 on our Board and as Chief Executive Officer since August 2020. He is a senior clinical fellow at Imperial College London and a lecturer at the IoPPN, King's College London. IoPPN is ranked second in the world for psychology and psychiatry by US News and Best Global Universities, and is home to one of the world's largest centers for neuroscience research. Dr. Marques is also a psychiatrist at Maudsley Hospital. His research focuses on topics including the mechanism of action of psychiatric medication and novel treatment targets. During his career, he has obtained multiple awards for his research. Dr. Marques is an author or co-author of more than 100 scientific publications in peer-reviewed journals in psychiatry and neuroscience, has an h-index above 40 and has co-authored international treatment guidelines and written book chapters, including in the leading book in the field, "Neurobiology of Mental Illness." We believe that Dr. Marques is qualified to serve on our Board due to his medical and scientific background.

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.

Dr. Graeme Currie, Ph.D. (Chief Development Officer) is a highly experienced drug development executive with over 30 years of experience in pharmaceutical and biotechnology companies. Dr. Currie has served as our Chief Development Officer since June 22, 2022. During his tenure with Pasithea, he also has served as a part-time consulting Chief Development Officer for Lytix Biopharma, a Norwegian based clinical stage biopharma company from January 2021 to June 2023. Prior to joining the Company, from January 2021 through June 2022, Dr. Currie served as Chief Executive Officer of Alpha 5 Integrin LLC (also known as Tegrigen Therapeutics LLC), a pre-clinical stage biopharmaceutical company specializing in the development of integrin targeting agents for life threatening diseases. Prior to joining Alpha 5 Integrin, from March 2019 to January 2021, Dr. Currie served as Chief Development Officer of Tolerion Inc., a privately held clinical-stage biotechnology company focused on the development of drug candidates for autoimmune diseases. From October 2017 to March 2019, Dr. Currie served as Chief Operating Officer for Bioclin Therapeutics (also known as Rainer Therapeutics Inc). Dr. Currie has held senior management roles at a number of biotechnology companies, including Dynavax Technologies (DVAX), Regeneron Pharmaceuticals (REGN), PDL Biopharma (PDL) and Gilead Sciences (GILD). Dr Currie holds a bachelor's degree from the University of Salford and a PhD from Aston University in the UK.

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 Neurocine 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. whose investments are predominately in Eastern European corporate distressed credits and structured products. From 2013 to 2018, Mr. Dumesnil was Managing Director and Head of Structured Financing Group Americas of UBS Securities LLC, where he was responsible for the structured financing trading book in the USA and LATAM and managed a book of financing positions across fixed income products (corporate syndicated and middle-market loans, corporate bonds, real estate loans, CMBS/RMBS/CLO/ABS, LATAM Sovereign). From 2010 to 2013, he was Managing Director and Co-Head Private-Side Structuring Group EMEA of UBS AG., where he was responsible for arranging structured solution transactions and acquisitions for FIG and Special Situation Group (SSG) and also co-headed the illiquid financing business. From 2009 to 2010, Mr. Dumesnil was the Chief Investment Officer Bluestone Capital Management and responsible for investments in distressed assets across Europe. From 2008 to 2009, Mr. Dumesnil was Director of Lehman Brother Holding Inc. and responsible for restructuring and unwinding Lehman Brothers Special Financing Inc. derivative book post-bankruptcy. From 2003 to 2008, Mr. Dumesnil was Director of Lehman Brothers International (Europe). Throughout his career at Dunraven Capital Management, UBS Securities, UBS AG, Bluestone Capital Management and Lehman Brothers, Mr. Dumesnil advised and underwritten corporate risk related to companies across industries or jurisdictions. He has an in-depth knowledge on corporate restructuring and capital structure optimization for companies across their business life cycle. His experience as Chief Investment Officer during the launch and growth phases of a financial services and technology company represents valuable insights for our Company. Mr. Dumesnil attended Cass Business School, where he received his Master of Science in Banking and International Finance and École des Hautes-Études-Commerciales HEC, where he received his Bachelor in Business and Administration, Finance. We believe that Mr. Dumesnil is qualified to serve on our Board due to his management and investment experience.

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, 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, and she has served as a member of the Board of Intensity Therapeutics, Inc. since 2016. Dr. Leahy has more than 30 years of experience in drug discovery, clinical development and business development for pharmaceutical and biotechnology companies, including extensive knowledge of technology assessment, licensing, mergers and acquisitions, and strategic planning. She also holds an Adjunct Associate Professor of Neuroscience position at Mount Sinai School of Medicine. Dr. Leahy 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.

Alfred Novak has served on our Board since September 2022. Mr. Novak has broad operating experience as a Chief Executive Officer and Chief Financial Officer and has served on the boards of several pharmaceutical and medical device companies. Mr. Novak brings financial acumen and extensive expertise in product development, regulatory approval, commercial activities, and a track record of delivering substantial value for stockholders. Between October 2015 to June 2022, Mr. Novak served as a director of LivaNova Plc (NASDAQ: LIVN), which is a medical device company. From May 2017 to November 2019, Mr. Novak served as a director of Dova Pharmaceuticals, which was sold to Swedish Orphan Biovitrum AB or Sobi™, a company focused on rare diseases, for over $900 million; a director and CEO of Biosense, which was sold to Johnson & Johnson for $427 million; and CFO of Cordis Corporation, which was acquired by Johnson & Johnson for $1.8 billion. He received his MBA from the Wharton School of the University of Pennsylvania with a concentration in Healthcare Administration and 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 in product development, the regulatory approval process and commercialization in the pharmaceutical and medical device industries.

Scientific Advisory Board

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.

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. His 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.

Merit Cudkowicz, M.D.

Dr. Cudkowicz is the Chief of Neurology at Massachusetts General Hospital, Director of the Sean M. Healey & AMG Center for ALS, and the Julieanne Dorn Professor of Neurology at Harvard Medical School. A member of the National Academy of Medicine, Dr. Cudkowicz has been a pioneer in promoting and devising more efficient methods for the development of new therapies for people with neurological disorders such as ALS and is one of the founders and co-directors of the Northeast ALS (NEALS) Consortium, a group of over 130 clinical sites in the United States and Canada dedicated to performing collaborative academic-led clinical trials in ALS. Dr. Cudkowicz is also the Study Chair and Principal Investigator of the HEALEY ALS Platform Trial, a perpetual multi-center, multi-regimen clinical trial evaluating the safety and efficacy of investigational products for the treatment of ALS. Dr. Cudkowicz received the American Academy of Neurology 2009 Sheila Essay ALS award, the 2017 Forbes Norris Award from the International MND Alliance, the 2017 Pinnacle Award from the Boston Chamber of Commerce and the 2019 Ray Adams American Neurological Association Award. She received a B.S. in Chemical Engineering from Massachusetts Institute of Technology, an M.D. from Harvard Medical School and a MSc. in Clinical Epidemiology from Harvard School of Public Health.

Board Composition

Our Board currently consists of five members. Under our Bylaws, the number of directors who shall constitute the Board shall equal not less than one nor more than ten, as the Board may determine by resolution from time to time.

Board Elections

In accordance with the terms of our 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 2024 Annual Meeting;
- The Class II directors are Alfred Novak and Simon Dumesnil; their terms will expire at the 2025 Annual Meeting; and
- The Class III directors are Dr. Tiago Reis Marques and Prof. Lawrence Steinman; their terms will expire at the 2026 Annual Meeting.

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 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 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 Corporate 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 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 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. Prof. Lawrence Steinman served as a member of the Compensation Committee until March 2023 and Mr. Novak joined the Compensation Committee in March 2023.

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, 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. Prof. Lawrence Steinman was a member of our Nominating and Corporate Governance Committee until March 2023 and Mr. Novak joined the Compensation Committee in March 2023.

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. 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 rules of The Nasdaq Stock Market LLC, or 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 10-K does not include or incorporate by reference the information on our website into this 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.

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, 2023 and December 31, 2022, 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)	Non-Equity Incentive Plan Compensation ($)	Non-qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($) (6)
Tiago Reis Marques[(2)]	2023	450,000	30,000	57,347	-	-	-	-	537,347
Chief Executive Officer	2022	450,000	89,250	-	-	-	-	-	539,250
Daniel Schneiderman[(3)]	2023	330,000	15,939	-	-	-	-	-	345,939
Chief Financial Officer	2022	135,205	57,500	-	174,498	-	-	-	367,203
Graeme Currie[(4)]	2023	330,647	15,970	-	98,247	-	-	-	444,864
Chief Development Officer	2022	143,870	55,000	-	-	-	-	-	198,870
Stanley Gloss[(5)] *Former Chief Financial Officer*	2022	60,000	-	-	-	-	-	-	60,000

(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 8 to this Form 10-K for the year ended December 31, 2023.

(2) Total compensation for 2023 for Dr. Marques includes $57,347 for stock awards representing the grant date fair value of the issuance of 5,832 shares of Common Stock pursuant to the vesting of RSUs.

(3) Mr. Schneiderman was hired as Chief Financial Officer of the Company on October 11, 2022. Salary for Mr. Schneiderman includes $66,667 paid to Mr. Schneiderman as a consultant to the Company from July 1, 2022 through October 10, 2022.

(4) Dr. Currie was hired as our Chief Development Officer on June 22, 2022 and became an Executive Officer on July 3, 2023. From June 22, 2022 to June 21, 2023 Dr. Currie was paid an annual salary of $281,250 for his part time service as Chief Development Officer and commencing on June 22, 2023, Dr. Currie was paid an annual salary of $375,000 per year for his full-time service.

(5) Mr. Gloss passed away on June 7, 2022.

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 $450,000 annually. In addition, Dr. Marques is eligible to receive an annual bonus, with a target amount equal to seventy-five percent (75%) 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 thereinafter. 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 Mr. 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 $330,000 annually. In addition, Mr. Schneiderman is eligible to receive an annual bonus, with a target amount equal to thirty-five percent (35%) 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.

Employment Agreement with Dr. Graeme Currie

On June 21, 2022, we entered into an employment agreement with Dr. Currie. Under the terms of Dr. Currie's employment agreement, he holds the position of Chief Development Officer and receives an annual base salary of $375,000. In addition, Dr. Currie is eligible to receive an annual bonus, with a target amount equal to thirty-five percent (35%) of Dr. Currie'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 Dr. Currie's individual performance. Pursuant to the terms of his employment agreement, Dr. Currie 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. Currie's employment agreement, Dr. Currie was paid $30,000 as a sign on bonus. We also issued to Dr. Currie 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 Dr. Currie's employment at any time with or without Cause (as that term is defined in Dr. Currie's employment agreement) and with or without advance notice to Dr. Currie, and Dr. Currie may terminate his employment at any time for any reason upon providing 60 days' written notice to the Company.

In the event we terminate Dr. Currie's employment without Cause, we will pay Dr. Currie 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 Dr. Currie'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 Dr. Currie's employment for any other reason, Dr. Currie 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, 2023:

	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 (3)(4)
Tiago Reis Marques, *Chief Executive Officer* (1)	12/20/2021	6,667	3,333	$ 28.80	12/20/2031	3,335	$ 30,833
Daniel Schneiderman, *Chief Financial Officer* (2)	10/11/2021	5,000	10,000	$ 25.20	10/11/2031	-	$ -
Graeme Currie, *Chief Development Officer*	2/24/2023	7,500	7,500	$ 9.82	2/24/2033	-	$ -

(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 vest 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 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 each vest 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.

(3) Under the terms of Dr. Currie's Executive Employment Agreement, on February 24, 2023, 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. 5,000 of Mr. Currie's stock options vested on June 30, 2023 and the remaining 10,000 stock options vest in equal quarterly tranches over each of the next two years.

(4) The market value of unvested RSUs is based on the closing market price of our Common Stock of $7.40 per share on December 29, 2023.

There were no option exercises by our Named Executive Officers during our fiscal years ended December 31, 2023 or 2022.

Incentive Award Plans

2023 Incentive Plan

On October 6, 2023, our Board adopted the 2023 Incentive Plan, and our stockholders approved the 2023 Incentive Plan at our 2023 Annual Meeting. 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 will 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.

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 is filed as an exhibit 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 Board approval of this 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 ISO grants. As of October 12, 2023, the Company and its subsidiaries had a total of eight employees, including three 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 October 12, 2023, 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, plus (ii) such number of unused shares of Common Stock reserved under the 2021 Incentive Plan as of the date of stockholder approval of this 2023 Incentive Plan, which unused reserve shall be rolled in to the 2023 Incentive Plan (subsections (i) and (ii) 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 of stockholder approval of this 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).

The number of shares of Common Stock available for issuance under the 2023 Incentive Plan will automatically increase on January 1 st of each year commencing with January 1, 2024 and on each January 1st thereafter 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 this paragraph 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 the additional compensation.

Terms and Conditions of 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 October 12, 2023, the closing sale price of a share of our Common Stock on The Nasdaq Capital Market, adjusted for the Reverse Stock Split, was $8.668.

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 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 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 "Description of Capital Stock-Limitations on Liability and Indemnification Matters."

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 assets 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 following table sets forth for each non-employee director that served as a director during the year ended December 31, 2023 certain information concerning his or her compensation for the year ended December 31, 2023:

Year Ended December 31, 2023

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)
Prof. Lawrence Steinman	250,000[3][4]	-	-	-	-	-	250,000
Simon Dumesnil	60,000[5]	-	-	-	-	-	60,000
Dr. Emer Leahy	60,000[5]	-	-	-	-	-	60,000
Alfred Novak	50,000[6]	-	-	-	-	-	50,000

(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 7 (Stockholders' Equity) to our financial statements, which are included in this 10-K. The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2023 held by each of Prof. Lawrence Steinman, Simon Dumesnil, Dr. Emer Leahy and Alfred Novak was 5,000.

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

(3) Consists of (i) $100,000 for services as Chairman of the Board, (ii) $50,000 annual retainer as a non-employee director, and (iii) $100,000 pursuant to a consulting agreement between the Company and Prof. Lawrence Steinman (the "Steinman Consulting Agreement"). Under the Steinman Consulting Agreement, Prof. Lawrence Steinman receives $25,000 per quarter for his services to the Company.

(4) $62,500 in fees earned for services rendered during fiscal year 2023 were paid in fiscal year 2024.

(5) $15,000 in fees earned for services rendered during fiscal year 2023 were paid in fiscal year 2024.

(6) $12,500 in fees earned for services rendered during fiscal year 2023 were paid in fiscal year 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 $10,000 for each Board committee that he or

she chairs. A non-employee director serving as Chairman of the Board is eligible to receive an additional annual retainer of $100,000. 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

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 $25,000 per quarter for his services.

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 23, 2024 by:

- each of our Named Executive Officers;
- each of our directors; and
- all of our 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 1,042,415 shares of Common Stock outstanding as of March 23, 2024. 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 23, 2024 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, and 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		
PD Joint Holdings, LLC (3)	170,434	15.8%
Named Executive Officers and Directors:		
Dr. Tiago Reis Marques (4)	57,168	5.4%
Daniel Schneiderman (5)	12,177	1.2%
Graeme Currie (6)	14,688	1.4%
Prof. Lawrence Steinman (7)	81,358	7.7%
Dr. Emer Leahy (8)	5,000	*
Simon Dumesnil (9)	7,500	*
Alfred Novak (10)	2,500	*
All Directors and Officers as a group (7 persons)	180,391	16.2%

* 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 nearest tenth of a percent. Percentages are based on 1,042,415 shares of Common Stock outstanding as of March 23, 2024. Warrants, stock options or other derivative securities that are presently exercisable or exercisable within 60 days 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) Consists of (i) 130,434 shares of Common Stock and (ii) 40,000 shares of Common Stock issuable upon the exercise of a warrant held directly by PD Joint Holdings, LLC Series 2016-A. All share information is based on information disclosed in a statement on Schedule 13G filed with the SEC on February 15, 2023 on behalf of Paul B. Manning, Bradford Manning, PD Joint Holdings, LLC, Series 2016-A, and Tiger Lily Capital, LLC. The business address for each person and entity named in this footnote is 200 Garrett Street, Suite S, Charlottesville, Virginia 22902.

(4) Includes (i) 37,999 shares of Common Stock and (ii) 19,169 shares of Common Stock issuable upon exercise of vested stock options. Excludes (i) 17,500 unvested options and (ii) 2,502 unvested restricted stock units.

(5) Includes 12,177 shares of Common Stock issuable upon exercise of vested stock options. Excludes 18,750 unvested stock options.

(6) Includes 14,688 shares of Common Stock issuable upon exercise of vested stock options. Excludes 6,250 unvested stock options.

(7) Includes (i) 66,358 shares of Common Stock, (ii) 10,000 shares of Common Stock issuable upon exercise of warrants; and (iii) 5,000 shares of Common Stock issuable upon exercise of vested stock options. Excludes 7,500 unvested stock options.

(8) Includes 5,000 shares of Common Stock issuable upon exercise of vested stock options. Excludes 7,500 unvested stock options.

(9) Includes (i) 2,500 shares of Common Stock and (ii) 5,000 shares of Common Stock issuable upon exercise of vested stock options. Excludes 7,500 unvested stock options.

(10) Includes 2,500 shares of Common Stock issuable upon exercise of vested stock options. Excludes 7,500 unvested stock options.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2023, including our 2021 Incentive Plan and our 2023 Incentive Plan. Upon the adoption by our stockholders of the 2023 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 (a)	Weighted-Average Exercise Price of Outstanding Options (2) (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (3) (c)
Equity compensation plans approved by security holders (1)	99,000	$ 32.38	153,389
Equity compensation plans not approved by security holders	-	$ -	-
Total	99,000	$ 32.38	153,389

(1) Consists of stock options exercisable for 99,000 shares of Common Stock and excludes 10,000 restricted stock units issued and outstanding under the 2021 Incentive Plan. Excludes 153,389 shares available under the 2023 Incentive Plan. For a description of the 2021 Incentive Plan and 2023 Incentive Plan, see Note 8 to our Consolidated Financial Statements included in this 10-K for the year ended December 31, 2023.

(2) The weighted average exercise price does not take into account outstanding restricted stock units, which have no exercise price.

(3) 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, 2022, 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 adopted in 2021, 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, 2022 to which we have been a party in which the amount involved will be the lesser of $120,000 or 1% of our assets, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Related Party Transactions

PsychoGenics, Inc.

In April 2023 we entered into a contract with PsychoGenics, Inc. ("PsychoGenics") for the conduct of one of our preclinical studies. PsychoGenics is a contract manufacturing organization with extensive experience running preclinical and clinical. Pursuant to the contract, we made aggregate payments to PsychoGenics totaling approximately $0.3 million over the term of the contract. The contract was completed in September 2023.

Dr. Emer Leahy, a member of our Board, is the current Chief Executive Officer and a less than 5% owner of PsychoGenics.

Alpha-5 Integrin, LLC

On June 21, 2022, we entered into the Alpha-5 Agreement with the Alpha-5 Sellers, pursuant to which the Alpha-5 Sellers sold all of the issued and outstanding equity of Alpha-5 to the Company. Alpha-5 is a preclinical-stage company developing a monoclonal antibody (mAbs) for the treatment of ALS and other neuroinflammatory disorders, such as Multiple Sclerosis. In connection with the transaction, we issued to the Alpha-5 Sellers 163,044 shares of our Common Stock, which had a market value of $1.01 million on the date of the transaction, and warrants exercisable for 50,000 shares of Common Stock at an exercise price of $37.60 per share, expiring five years from the acquisition date, the aggregate fair value of which was $0.4 million at the date of acquisition.

Prof. Lawrence Steinman, our Executive Chairman and Co-Founder, was a 20% owner of Alpha-5 at the time of the transaction.

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 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 $25,000 per quarter for his services.

Brio Financial Group

On April 13, 2021, we entered into the Brio Agreement pursuant to which Brio provided Stanley M. Gloss to serve as our Chief Financial Officer and also provided certain other specified financial and accounting services typically provided by a chief financial officer. The initial term of the Brio Agreement ran through March 31, 2022. The Company paid a monthly fixed fee of $7,500 during the term of the Brio Agreement. In addition, 1,250 restricted shares of Common Stock were issued to Brio which vested over the 1-year term of the Brio Agreement. Further, the Company issued Stanley M. Gloss stock options to purchase up to 5,000 shares of Common Stock, which options vested fully upon execution of the Brio Agreement and had an exercise price of $100.00 per share.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Board of the Company has appointed Marcum LLP as our independent registered public accounting firm (the "Independent Auditor") for the fiscal year ended December 31, 2023. The following table sets forth the fees billed to the Company for professional services rendered by Marcum LLP for the years ended December 31, 2023 and December 31, 2022:

	Year Ended December 31,	
Services:	**2023**	**2022**
Audit Fees (1)	$ 252,173	$ 295,546
Audit-Related Fees (2)	70,695	51,034
Tax Fees	-	-
All Other Fees	-	-
Total fees	$ 322,868	$ 346,580

(1) Audit fees consisted of audit work performed in the preparation of financial statements, as well as work generally only the independent registered public accounting firm can reasonably be expected to provide, such as statutory audits.

(2) Audit related fees consisted principally of procedures related to regulatory filings in 2023 and 2022.

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 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 Marcum in our fiscal years ended December 31, 2023 and 2022 were pre-approved by our Audit Committee.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

a) Financial Statements

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

b) Financial Statement Schedules

No financial statement schedules have been filed as part of this 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
2.01	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).
2.02	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).
2.03	Form of Lock-up Agreement dated October 11, 2022 (incorporated by reference to exhibit 2.2 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	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*	Description of Securities.
10.1	Amended and Restated Zen Knightsbridge Collaboration Agreement (incorporated by reference to exhibit 10.1 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
10.2	Amended and Restated Zen Baker Street Collaboration Agreement (incorporated by reference to exhibit 10.2 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 Professional Corporation Agreement (incorporated by reference to exhibit 10.3 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
10.4	IV Docs Subcontract Agreement (incorporated by reference to exhibit 10.4 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).

10.6+	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).
10.7	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).
10.8	Stock Option Grant Notice and Agreement between Pasithea Therapeutics Corp. and Stanley M. Gloss (incorporated by reference to exhibit 10.9 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
10.9	Placement Agent Agreement, dated November 24, 2021 (incorporated by reference to exhibit 10.1 of the Company's Form 8-K, filed with the Commission on November 29, 2021).
10.10	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).
10.11	Form of Warrants (incorporated by reference to exhibit 10.3 of the Company's Form 8-K, filed with the Commission on November 29, 2021).
10.12	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).
10.13+	Offer of Employment, dated as of June 21, 2022, between Pasithea Therapeutics Corp. and Dr. Graeme Currie (incorporated by reference to exhibit 10.1 to the Company's Form 10-Q, filed with the Commission on August 11, 2023).
10.14+	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).
10.15+	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).
10.16+	Restricted Stock Unit Agreement, dated December 20, 2021, between Pasithea Therapeutics Corp. and Dr. Tiago Reis Marques (incorporated by reference to exhibit 10.17 of the Company's Form 10-K/A, filed with the Commission on May 12, 2022).
10.17+	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).
10.18	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).
10.19+	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).
10.20*+	Consulting Agreement between Pasithea Therapeutics Corp. and Dr. Lawrence Steinman, dated November 13, 2023.
21.1*	Subsidiaries of the Registrant.
23.1*	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.
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 Res Marques
Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 28, 2024

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

Date: March 28, 2024

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 28, 2024
/s/ Daniel Schneiderman Daniel Schneiderman	Chief Financial Officer (Principal financial and accounting officer)	March 28, 2024
/s/ Prof. Lawrence Steinman Prof. Lawrence Steinman	Director	March 28, 2024
/s/ Simon Dumesnil Simon Dumesnil	Director	March 28, 2024
/s/ Dr. Emer Leahy Dr. Emer Leahy	Director	March 28, 2024
/s/ Alfred Novak Alfred Novak	Director	March 28, 2024

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED FINANCIAL STATEMENTS

TABLE OF CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Pasithea Therapeutics Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pasithea Therapeutics Corporation (the “Company”) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 accumulated deficit, 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**s**. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ Marcum LLP
Marcum LLP

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

New Haven, CT
March 28, 2024

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,331,052	$ 33,087,864
Amount due from sale of assets	40,500	-
Prepaid expenses	215,895	562,375
Other current assets	104,707	262,992
Current assets of discontinued operations	-	163,462
Total current assets	16,692,154	34,076,693
Property and equipment, net	141,208	125,197
Right of use asset- operating lease	79,271	500,428
Intangibles, net	7,941,314	8,571,478
Goodwill	1,262,911	1,262,911
Non-current assets of discontinued operations	-	643,382
Total assets	$ 26,116,858	$ 45,180,089
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,552,360	$ 1,481,393
Lease liability- short term portion	81,680	160,362
Current liabilities of discontinued operations	-	235,879
Total current liabilities	2,634,040	1,877,634
Non-current liabilities		
Lease liability	-	344,021
Warrant liabilities	84,366	140,611
Non-current liabilities of discontinued operations	-	319,575
Total non-current liabilities	84,366	804,207
Total liabilities	2,718,406	2,681,841
Commitments and Contingencies (Note 13)	-	-
Stockholders' equity:		
Preferred stock, par value $0.0001, 5,000,000 shares authorized; 0 issued and outstanding	-	-
Common stock, par value $0.0001, 100,000,000 shares authorized; 1,041,582 and 1,301,921 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	104	130
Additional paid-in capital	58,721,538	61,855,659
Accumulated other comprehensive loss	(4,652)	(661)
Accumulated deficit	(35,318,538)	(19,356,880)
Total stockholders' equity	23,398,452	42,498,248
Total liabilities and stockholders' equity	$ 26,116,858	$ 45,180,089

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

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Years Ended December 31,

	2023	2022
Operating expenses:		
General and administrative	$ 7,878,596	$ 9,923,544
Research and development	8,100,765	2,665,427
Loss from operations	(15,979,361)	(12,588,971)
Other income (expense):		
Change in fair value of warrant liabilities	56,245	1,852,189
Interest and dividends, net	415,368	-
Gain on forgiveness of accounts payable	-	10,633
Litigation settlements	-	(1,001,736)
Other income, net	471,613	861,086
Loss before income taxes	(15,507,748)	(11,727,885)
Provision for income taxes	-	-
Net loss from continuing operations	$ (15,507,748)	$ (11,727,885)
Net loss from discontinued operations, net of tax	(453,910)	(2,208,567)
Net loss	$ (15,961,658)	$ (13,936,452)
Weighted-average common shares outstanding, basic and diluted	1,226,600	1,262,339
Basic and diluted net loss per share from continuing operations	$ (12.64)	$ (9.29)
Basic and diluted net loss per share from discontinuing operations	$ (0.37)	$ (1.74)
Comprehensive loss:		
Net loss	$ (15,961,658)	$ (13,936,452)
Foreign currency translation	(3,991)	9,900
Comprehensive loss	$ (15,965,649)	$ (13,926,552)

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

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

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at January 1, 2022	1,150,170	$ 115	$ 53,645,452	$ (10,561)	$ (2,214,505)	$ 51,420,501
Stock-based compensation expense:						
-restricted share units	-	-	95,912	-	-	95,912
-stock options	-	-	439,979	-	-	439,979
-restricted stock	-	-	16,932	-	-	16,932
Common shares issued for services	13,972	1	282,240	-	-	282,241
Warrants issued for acquisition	-	-	680,000	-	-	680,000
Common shares issued for acquisition	163,044	16	3,293,463	-	-	3,293,479
Warrants issued for acquisition of intangible assets	-	-	522,358	-	-	522,358
Common shares issued for acquisition of intangible assets	135,000	14	2,879,629	-	-	2,879,642
Common shares repurchased in litigation settlement	(160,264)	(16)	(305)	-	(3,205,923)	(3,206,244)
Foreign currency translation	-	-	-	9,900	-	9,900
Net loss	-	-	-	-	(13,936,452)	(13,936,452)
Balance at December 31, 2022	1,301,921	$ 130	$ 61,855,659	$ (661)	$ (19,356,880)	$ 42,498,248
Stock-based compensation expense:						
-restricted share units	5,832	1	71,735	-	-	71,736
-stock options	-	-	520,533	-	-	520,533
Common shares repurchased in tender offer	(266,171)	(27)	(3,726,389)	-	-	(3,726,416)
Foreign currency translation	-	-	-	(3,991)	-	(3,991)
Net loss	-	-	-	-	(15,961,658)	(15,961,658)
Balance at December 31, 2023	1,041,582	$ 104	$ 58,721,538	$ (4,652)	$ (35,318,538)	$ 23,398,452

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

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss from continuing operations	$ (15,507,748)	$ (11,727,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	18,290	5,094
Amortization expense	630,164	-
Stock-based compensation	592,269	835,064
Change in fair value of warrant liabilities	(56,245)	(1,852,189)
Gain on sale of assets	(65,048)	-
Changes in operating assets and liabilities:		
Prepaid expenses	346,480	(181,374)
Other assets	158,285	(262,992)
Accounts payable and accrued liabilities	1,070,967	745,759
Lease liabilities	(1,547)	543,956
Net cash used in operating activities	(12,814,133)	(11,894,567)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(34,301)	(107,101)
Net cash proceeds from sale of assets	109,500	-
Acquisition of business, net of cash acquired	-	(2,192,598)
Net cash provided by (used in) investing activities	75,199	(2,299,699)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Note payable proceeds	392,354	-
Principal payments on note payable	(392,354)	-
Repurchase of common stock	(3,726,416)	-
Shares repurchased in litigation settlement	-	(3,206,244)
Net cash used in financing activities	(3,726,416)	(3,206,244)
Effect of foreign currency translation on cash	(3,991)	9,900
Net cash used in operating activities of discontinued operations	(611,278)	(1,796,591)
Net cash provided by (used in) investing activities of discontinued operations	323,807	(626,898)
Net cash provided by (used in) financing activities of discontinued operations	-	-
NET CHANGE IN CASH	$ (16,756,812)	$ (19,814,099)
Cash and cash equivalents - Beginning of period	33,087,864	52,901,962
Cash and cash equivalents - End of period	$ 16,331,052	$ 33,087,864
Supplemental disclosure of cash flow information:		
Lease liabilities arising from obtaining right-of-use assets	$ -	$ 504,383
Amount due from sale of assets	40,500	-

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

PASITHEA THERAPEUTICS CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

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 biotechnology company focused on the discovery, research and development of innovative treatments for central nervous system (CNS) disorders and other diseases, including RASopathies. The Company is leveraging its expertise in the fields of neuroscience, translational medicine, and drug development to bring life-changing therapies to patients.

The Company’s lead product candidate, PAS-004, is 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 our Investigational New Drug application (the “IND”) for PAS-004 and the Company received a study may proceed letter from the FDA for the Company’s 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 Company is currently conducting the Phase 1 clinical trial. The Company’s clinical development plan for PAS-004 following the Phase 1 study is to begin a Phase 1b/2 clinical trial in neurofibromatosis type 1 (NF1)-associated plexiform neurofibroma pediatric and adult patients.

Additionally, the Company has two programs that are in the discovery stage, which the Company believes address limitations in the treatment paradigm of the indications the Company plans to address with these programs, which are currently amyotrophic lateral sclerosis (“ALS”) for PAS-003 and schizophrenia for PAS-001.

During the year ended December 31, 2023, the Company discontinued providing business support services to anti-depression clinics 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”) (See Note 6), and AlloMek Therapeutics, LLC (“AlloMek”) (See Note 6). Pasithea Therapeutics Limited (U.K.) is 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. is

incorporated in Delaware. Alpha-5 Integrin, LLC is Delaware limited liability company. AlloMek Therapeutics, LLC is Delaware limited liability company. The operations of Pasithea Therapeutics Limited (U.K.), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, and Pasithea Clinics Inc. have been discontinued (see Note 14).

Basis of Presentation

The accompanying audited 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, 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, 2023, the Company had approximately $ 16.3 million of cash and cash equivalents and working capital of approximately $ 14.1 million. The Company's major sources of cash have been comprised of proceeds from various private offerings, the Initial Public Offering 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. Based on the foregoing, management believes that the Company will not have sufficient working capital to meet its needs through twelve months from the date of these financial statements if additional funding cannot be obtained.

Going Concern Uncertainty

The accompanying audited 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, 2023, the Company had cash and cash equivalents of approximately $16.3 million and an accumulated deficit of approximately $ 35.3 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. Without additional funding, there is substantial doubt about the Company's ability to continue as a going concern through twelve months from the date of these 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.) and Pasithea Clinics Inc. ("Pasithea Clinics"). 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 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.

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 & patents. Research and development costs consist principally of compensation of employees and consultants that perform the Company's research activities, payments to third parties for preclinical and non-clinical activities, costs to acquire drug product from contract development and manufacturing organizations and third-party contractors relating to chemistry, manufacturing and controls ("CMC") efforts, the fees paid for and to maintain the Company's intellectual property, 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, 2023 and 2022, the Company recorded zero and $0.2 million of grant income 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.

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. There was no grant income recognized for the year ended December 31, 2023. For the year ended December 31, 2022, the Company recorded $0.2 million of grant income related to this grant as a contra expense within research and development.

Cash and Cash Equivalents

The Company considers all short-term investments 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 $13.4 million as of December 31, 2023, and did not have any cash equivalents as of December 31, 2022.

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.

Warrant Liability

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, "Derivatives and Hedging," 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 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.

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, 2023, 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, 2023 and 2022.

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, 2023 and December 31, 2022. 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, 2023, the Company has not experienced losses on this account and management believes the Company is not exposed to significant risks on such account.

Fair Value of Financial Instruments

With the exception of liabilities related to the IPO Warrants, 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 represented 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. 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:		
Description	**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, 2023	$ 13,419,860	$ 13,419,860	$ -	$ -
Liabilities:				
Public Warrant liabilities, December 31, 2023	$ 79,200	$ 79,200	$ -	$ -
Representative Warrant liabilities, December 31, 2023	$ 5,166	$	$ -	$ 5,166
Liabilities:				
Public Warrant liabilities, December 31, 2022	$ 132,000	$ 132,000	$ -	$ -
Representative Warrant liabilities, December 31, 2022	$ 8,611	$ -	$ -	$ 8,611

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

	Year ended December 31,	
	2023	**2022**
Representative warrant liabilities, January 1	$ 8,611	$ 91,200
Issuances	-	-
Exercises	-	-
Change in fair value	(3,445)	(82,589)
Representative warrant liabilities, December 31	$ 5,166	$ 8,611

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 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, 2023 and 2022, 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, 2023 and 2022, 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,	
	2023	**2022**
Stock options	99,000	50,000

Warrants	767,800	767,800
Restricted stock units	4,168	10,000

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.

The relevant translation rates are as follows:

	As of December 31, 2023	As of December 31, 2022
Closing rate, British Pound (GBP) to $USD at period end	1.2747	1.2039
Average rate, GBP to $USD for the period ended	1.2434	1.2362
Closing rate, Euro (EUR) to $USD at period end	0.9052	0.9367
Average rate, EUR to $USD for the period ended	0.9251	0.9517

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, 2023 and December 31, 2022, the Company had no material items of other comprehensive income (loss) except for the 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 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. There were no charges related to impairments of long-lived assets for all periods presented.

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. There were no charges related to goodwill impairment for all periods presented.

Leases

The Company's has leases 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 concurrent 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.

Recent Accounting Pronouncements

The Company does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company's financial statements.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses,* which requires entities to estimate all expected credit losses for financial assets measured at amortized cost basis, including trade receivables, held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The Company adopted this guidance on January 1, 2023. The adoption of this accounting standard did not have a material impact to the Company's condensed consolidated financial statements.

NOTE 3 – PROPERTY AND EQUIPMENT

Property and equipment, net consists of the following:

	As of December 31,	
	2023	**2022**
Leasehold improvements	$ 3,193	$ 3,193
Medical equipment	155,363	99,220
Office equipment	6,140	26,343
Property and equipment, gross	164,696	128,756
Less: accumulated depreciation	(23,488)	(3,559)
Property and equipment, net	$ 141,208	$ 125,197

Depreciation expense was $18,290 and $5,094 for the years ended December 31, 2023 and 2022, respectively.

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 will increase to $ 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 December 31, 2023, the Company recognized total ROU assets and lease liabilities of as follows:

	As of December 31, 2023	**As of December 31, 2022**
Non-current leases - right of use assets	$ 79,271	$ 500,428
Current liabilities - operating lease liabilities	$ 81,680	$ 160,362
Non-current liabilities - operating lease liabilities	$ -	$ 344,021
Operating lease expense	$ 243,230	$ 168,812
Cash paid for amounts included in the measurement of operating lease liabilities	$ -	$ 169,695

The following table summarizes the maturity of the Company's operating lease payments as of December 31, 2023:

2024	$ 83,280
Total future minimum lease payments	$ 83,280
Amount representing interest	(1,600)
Present value of net future minimum lease payments	$ 81,680

NOTE 5 – ACQUISITIONS

Business Combination with Alpha-5 Integrin LLC

On June 21, 2022, the Company entered into a membership purchase agreement (the "Alpha-5 Agreement") with Alpha-5 to purchase 100% of Alpha-5's outstanding membership interests. One of the sellers of Alpha-5, Lawrence Steinman, is the Company's Chairman, and as such is considered a related party to the Company. Alpha-5 was a preclinical-stage company developing a monoclonal antibody (mAbs) for the treatment of amyotrophic lateral sclerosis ("ALS") and other neuroinflammatory disorders, such as Multiple Sclerosis. In connection with the transaction, the Company issued to the Alpha-5 sellers 163,044 shares of Common Stock, which had a market value of $ 20.20 on the date of the transaction, and warrants to acquire 50,000 shares of Common Stock at an exercise price of $37.60 per share, for a period of five years from the acquisition date, the aggregate fair value of which was $ 0.7 million at the date of acquisition.

In addition, the Alpha-5 Agreement allows for an earnout to be paid as part of the consideration due to the sellers. As any future sales are predicated upon FDA approval, no amounts will be due the sellers in the absence of that approval. Should FDA approval be obtained the amount of the earnout payment is dependent on the attainment of certain financial targets. The terms of the earnout contain three performance target thresholds that trigger three different payout amounts depending on which of the three targets is achieved. Sales generated after the drug is no longer subject to any patent protection or regulatory exclusivity are excluded from the earnout calculation. Purchase consideration consisted of the following:

Equity consideration	$ 3,293,479
Warrants issued as consideration	680,000
Total purchase consideration	$ 3,973,479

The Alpha-5 acquisition was accounted for as a business combination in accordance with ASC 805, Business Combinations. The fair values of the acquired assets and liabilities as of the acquisition date were:

Cash	$ 77,060
Prepaid assets	49,380
Fixed assets	19,551
In-process research and development	2,900,000
Accounts payable & accrued expenses	(335,423)
Net assets acquired, excluding Goodwill	2,710,568
Goodwill	1,262,911

The goodwill recognized is largely attributable to the potential leveraging of Alpha-5's scientific expertise in the integrin space. The Company believes the acquisition of Alpha-5 will help in its efforts to move the treatment forward and increase its potential to have a positive impact on the treatment of ALS. This goodwill is expected to be deductible for income tax purposes. Expenses incurred in relation to this acquisition totaled approximately $311,000.

Asset Acquisition of AlloMek Therapeutics, LLC

On October 11, 2022, the Company entered into a membership interest purchase agreement, whereby the Company acquired 100% of the issued and outstanding equity interests of AlloMeK Therapeutics, LLC ("AlloMek") from the holders thereof on a cash free, debt-free basis (the "AlloMek Acquisition"). AlloMek was a pre-clinical biotechnology company focused on developing PAS-004, a macrocyclic MEK Inhibitor with a unique potency, safety and pharmacokinetic profile. The Company acquired all issued and outstanding equity interests of AlloMek in exchange for: (i) an aggregate of 135,000 shares of Common Stock, (ii) an aggregate of 50,000 warrants to purchase shares of Common Stock 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 $1,050,000, (iv) the right to certain milestone payments in an amount up to $5,000,000, and (v) the right to contingent earn-out payments ranging from 3% to 5% of net sales of the drug depending on the amount of such net sales in the applicable measurement period. In connection with the closing, each of the sellers entered into a two-year Lock-up Agreement with the Company regarding the shares of Common Stock received by the sellers pursuant. On the one-year anniversary of the closing date, the restrictions contained in the Lock-Up Agreements will terminate for 67,500 shares of Common Stock, and then in each subsequent month, the restrictions will cease for an additional 5,625 shares of Common Stock.

The AlloMek acquisition was accounted for as an asset acquisition as substantially all of the fair value of the gross assets acquired is attributable to PAS-004. The cost of the asset acquisition included the purchase consideration as well as transaction expenses, as follows:

135,000 shares of Pasithea common stock	$ 3,402,000
Warrants to acquire 50,000 shares of common stock at exercise price of $ 37.60	522,358
Cash	1,000,000
Non-refundable payment for AlloMek transaction expenses	50,000
Pasithea transaction expenses	697,121
Total cost of asset acquisition	$ 5,671,479

The Company capitalized the cost of the asset acquisition as intellectual property within Intangibles on the consolidated balance sheet as of December 31, 2023 and 2022.

NOTE 6 – INTANGIBLE ASSETS AND GOODWILL

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

	December 31, 2023	December 31, 2022

	Gross Carrying Amount	Accumulated Amortization	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	(630,164)	5,041,314	5,671,478	-	5,671,478
Intangible assets, net	$ 8,571,478	$ (630,164)	$ 7,941,314	$ 8,571,478	$ -	$ 8,571,478

As of December 31, 2023, future expected amortization expense of Intangible assets was as follows:

2024	630,134
2025	630,134
2026	630,134
2027	630,134
2028	630,134
Thereafter	1,890,644
Remaining future amortization expense	$ 5,041,314

There were no changes to goodwill for the year ended December 31, 2023. During the year ended December 31, 2022, the Company acquired $ 1.3 million of goodwill in connection with the acquisition of Alpha-5.

NOTE 7 – STOCKHOLDERS' EQUITY

The Company is authorized to issue an aggregate of 105,000,000 shares. The authorized capital stock is 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 1,041,582 and 1,301,921 shares of its Common Stock issued and outstanding at December 31, 2023 and 2022, 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 Charter and 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 certificate of incorporation to effect a one-for-twenty (1:20) reverse stock split of our 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. See Note 16 for additional information.

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.

As of January 1, 2023, the number of shares of Common Stock available for issuance under the 2021 Plan automatically increased by 39,065 to 137,389. The Company issued an aggregate of 44,000 and 40,000 stock options under the 2021 Plan during the years ended December 31, 2023 and 2022, respectively. Stock options issued under the 2021 Plan vest over a period of three years. Stock-based compensation related to stock options was $520,533 and $439,979, respectively, for the years ended December 31, 2023 and 2022. 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.

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 restricted stock units ("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.

As of December 31, 2023, 153,389 total shares were available under the 2023 Plan, of which no shares were issued and outstanding and 153,389 shares were available for potential issuances.

2022 Common Stock Transactions

During the year ended December 31, 2022, the Company issued 163,044 shares of Common Stock in connection with the business combination with Alpha-5 as referenced in Note 5.

During the year ended December 31, 2022, the Company issued 135,000 shares of Common Stock in connection with the acquisition of AlloMek as referenced in Note 5.

During the year ended December 31, 2022, the Company entered into a comprehensive Settlement and Cooperation Agreement ("the Settlement and Cooperation Agreement") with certain shareholders (collectively, the "Camac Group") resolving all outstanding issues between the parties. Pursuant to the Settlement and Cooperation Agreement, the Camac Group agreed to a three-year standstill provision and the parties agreed to dismiss with prejudice the pending Delaware litigation against the Company and the Board filed by the Camac Group. The Company purchased all 160,264 shares of Common Stock held by the Camac Group at a price of $20.006 per share, the equivalent to the 5-day volume-weighted average price of the Common Stock. Additionally, the Company reimbursed approximately $698,000 of certain fees and expenses of the Camac Group, which are included as litigation settlements in the statements of operations.

All repurchased shares were cancelled and recorded within Accumulated Deficit on the Company's consolidated balance sheet as of December 31, 2022. The Company recorded the reimbursed fees and expenses within Litigation settlements on the consolidated statement of operations for the year ended December 31, 2022.

During the year ended December 31, 2022, the Company entered into settlement agreements with certain shareholders for approximately $ 300,000, which are included as litigation settlements in the statements of operations.

2023 Common Stock Transactions

On July 20, 2023, the Company announced that its Board authorized the repurchase, through a $ 4.0 million tender offer of up to approximately 285,000 shares of the Company's outstanding common stock at a cash purchase price of $14.00 per share (the "Tender Offer"). The Company launched the Tender Offer on August 9, 2023 and it was completed on September 8, 2023.

On September 14, 2023, the Company disclosed the results of the Tender Offer. A total of 266,171 shares of Common Stock (the "Tender Offer Shares") were validly tendered and not properly withdrawn at a purchase price of $14.00 per share for an aggregate purchase price of $3,726,416, including fees and expenses of $150,000 relating to the Tender Offer. The Company had 1,040,749 shares of Common Stock outstanding following payment for the Tender Offer Shares purchased in the Tender Offer. The Tender Offer Shares were retired and cancelled following the closing of the Tender Offer.

Restricted Stock Units

During the year ended December 31, 2021, the Company issued its chief executive officer, Dr. Marques, 10,000 RSUs with a grant date fair value of $288,000. As of December 31, 2023, 5,832 RSUs were vested. The Company recognized approximately $ 72,000 and $96,000 of stock-based compensation expense for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the remaining unamortized RSU compensation expense was approximately $117,000, and will be expensed quarterly through the year ended December 31, 2024.

Restricted Stock

There was no restricted stock issued during the year ended December 31, 2023.

During the year ended December 31, 2022, the Company issued an aggregate of 13,972 shares of restricted Common Stock to certain consultants for services provided. These 13,972 shares of restricted Common Stock had a total grant date fair value of approximately $ 282,000 and vested immediately. The Company recognized approximately $282,000 of stock-based compensation expense for these restricted stock issuances for year ended December 31, 2022.

NOTE 8 – STOCK OPTIONS

Stock Options Issued, Vested and Cancelled

During the year ended December 31, 2023, the Company issued stock options under the 2021 Plan to employees to purchase an aggregate of 44,000 shares of Common Stock with a strike price of $9.82 per share and a term of ten years. One-third of these options vest within one year of the issuance date and then the remaining stock options vest in equal quarterly installments over the remaining two years. These options had a total fair value of approximately $288,000, as calculated using the Black-Scholes model.

During the year ended December 31, 2023, stock options to purchase an aggregate of 10,000 shares of Common Stock under our 2021 Plan were cancelled with a strike price of $19.20 per share.

During the year ended December 31, 2023, stock options to purchase an aggregate of 44,667 shares of Common Stock, subject to time-based milestone vesting conditions, vested.

During the year ended December 31, 2022, the Company issued stock options under the 2021 Plan to employees to purchase an aggregate of 20,000 shares of Common Stock with strike prices ranging from $19.20 to $25.20 per share and a term of ten years. One-third of these options vest on the one-year anniversary of the issuance date and then the remaining stock options vest in equal quarterly installments over the remaining two years. These options had a total fair value of approximately $180,000, as calculated using the Black-Scholes model.

During the year ended December 31, 2022, the Company issued stock options under the 2021 Plan to its current chief financial officer, to purchase an aggregate of 15,000 shares of Common Stock with a strike price of $ 25.20 per share and a term of ten years. One-third of these options vest on the one-year anniversary of the issuance date, one-third of these options vest on the two-year anniversary of the issuance date and one-third of these options vest on the three-year anniversary of the issuance date. These options had a total fair value of approximately $174,000, as calculated using the Black-Scholes model.

During the year ended December 31, 2022, the Company issued stock options under the 2021 Plan to a non-executive Board member, to purchase an aggregate of 5,000 shares of Common Stock with a strike price of $ 21.20 per share and a term of ten years. One-half of these options vest on the one-year anniversary of the issuance date and one-half of these options vest on the two-year anniversary of the issuance date. These options had a total fair value of approximately $49,000, as calculated using the Black-Scholes model.

During the year ended December 31, 2022, stock options to purchase an aggregate of 5,000 shares of Common Stock under our 2021 Plan were cancelled with a strike price of $100.00 per share.

During the year ended December 31, 2022, stock options to purchase an aggregate of 10,833 shares of Common Stock, subject to time-based milestone

vesting conditions, vested.

During the year ended December 31, 2022, the Company recorded approximately $ 22,000 of stock-based compensation which was included as part of general and administrative expense.

Stock-Based Compensation

For the years ended December 31, 2023 and 2022, total stock-based compensation expense related to the Company's stock options was approximately $520,000 and approximately $440,000, respectively. For the year ended December 31, 2023, the Company recognized approximately $ 398,000 of stock-based compensation related to its options within general and administrative expense, and approximately $122,000 within research and development expense. For the year ended December 31, 2022, all stock-based compensation expense was recorded within general and administrative expense.

Stock option activity for the years ended December 31, 2023 and 2022 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, 2023	65,000	$ 45.63	9.12	$ -
Granted	44,000	$ 9.82	-	$ -
Expired/Cancelled	(10,000)	$ -	-	$ -
Exercised	-	$ -	-	$ -
Outstanding, December 31, 2023	99,000	$ 32.38	8.55	$ -
Exercisable, December 31, 2023	55,500	$ 44.71	8.39	$ -
Outstanding, January 1, 2022	30,000	$ 86.20	9.74	$ -
Granted	40,000	$ 22.00	-	$ -
Expired/Cancelled	(5,000)	$ 100.00	-	$ -
Exercised	-	$ -	-	$ -
Outstanding, December 31, 2022	65,000	$ 45.63	9.12	$ -
Exercisable, December 31, 2022	10,833	$ 92.00	8.71	$ -

As of December 31, 2023, remaining unamortized stock-based compensation expense related to the stock options was $ 408,844.

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,	
	2023	2022
Expected volatility	68.6%	40.5%
Expected term (in years)	6.5	6.5
Weighted-average risk-free interest rate	4.1%	3.3%
Weighted average fair value of underlying interest	$ 0.49	$ 1.10
Expected dividends	-	-

The weighted average grant date fair value of options granted during the years ended December 31, 2023 and 2022 was $ 6.67 per option and $10.00 per option, respectively.

NOTE 9 – WARRANTS

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, 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, 2023 and 2022, 50,000 AlloMek Warrants were outstanding.

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, 2023 and 2022, 50,000 Alpha-5 Warrants were outstanding.

PIPE Warrants

During the year ended December 31, 2021, the Company issued PIPE Warrants to purchase an aggregate of 434,000 shares of Common Stock to certain investors in connection with the November 2021 Private Placement. The PIPE Warrants were issued on November 24, 2021, are immediately exercisable at $70.00 per share and expire five years from the date of issuance.

As of December 31, 2023 and 2022, 434,000 PIPE Warrants were outstanding.

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, 2023 and 2022, 220,000 Public Warrants and 13,800 Representative Warrants were outstanding.

As of December 31, 2023, the fair value of the Public Warrants was approximately $ 0.36 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.

Warrant activity for the years ended December 31, 2023 and 2022 was as follows:

	Number of Warrants	Exercise price per share	Weighted average exercise price
Outstanding and exercisable on January 1, 2023	767,800	$37.60 - $125.00	$ 82.44
Granted	-	-	-
Expired/Cancelled	-	-	-
Exercised	-	-	-
Outstanding and exercisable on December 31, 2023	767,800	$37.60 - $125.00	$ 82.44
Outstanding and exercisable on January 1, 2022	667,800	$70.00 - $125.00	$ 89.20
Granted	100,000	$ 37.60	$ 37.60
Expired/Cancelled	-	-	-
Exercised	-	-	-
Outstanding and exercisable on December 31, 2022	767,800	$37.60 - $125.00	$ 82.44

Warrants exercisable at December 31, 2023 were as follows:

Exercise Price	Number of Warrants	Weighted-average remaining contractual term (years)	Weighted-average exercise price
$ 37.60	100,000	3.63	
$ 70.00	434,000	2.90	
$ 120.00	13.800	2.71	
$ 125.00	220,000	2.71	
	767,800	2.94	$ 82.44

No warrants were granted, expired/cancelled, or exercised during the year ended Dec ember 31, 2023.

NOTE 10 – 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, 2023 and 2022 are summarized below.

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Amortization	$ 7,000	$ 8,000
Research & development costs	1,977,000	592,000
ROU asset	1,000	6,000
Warrant liabilities	19,000	33,000
Stock-based compensation	430,000	303,000
Net operation loss carryforwards	5,146,000	3,213,000

Federal R&D tax credit	59,000	-
Total deferred tax asset	7,639,000	4,155,000
Deferred tax liabilities:		
Depreciation	(25,000)	(12,000)
Net deferred tax asset	7,614,000	4,143,000
Valuation allowance	(7,614,000)	(4,143,000)
	$ -	$ -

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 $3,471,000 and $3,212,000 for the years ended December 31, 2023 and 2022, respectively.

A reconciliation of the federal income tax rate to the Company's effective tax rate at December 31, 2023 and 2022 is as follows:

	December 31, 2023	December 31, 2022
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal tax benefit	1.7%	0.1%
Stock-based compensation	(0.9)%	0.8%
Return to provision adjustment	6.6%	-%
Permanent items	-%	(1.6)%
Other	(6.0)%	4.2%
Change in valuation allowance	(22.4)%	(24.4)%
Income tax provision	__%	__%

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, 2023, the Company had federal and state net operating loss carryforwards available to offset future taxable income in the amounts of approximately $24,300,000 and $11,600,000, 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 positions through its income tax expense.

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

NOTE 11 – 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, 2023, diluted net loss per share did not include the effect of 767,800 shares of Common Stock issuable upon the exercise of outstanding warrants, and 99,000 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, 2022, diluted net loss per share did not include the effect of 767,800 shares of Common Stock issuable upon the exercise of outstanding warrants, and 50,000 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 12 – RELATED PARTY TRANSACTIONS

PsychoGenics, Inc.

In April 2023 we entered into a contract with PsychoGenics, Inc. ("PsychoGenics") for the conduct of one of our preclinical studies. PsychoGenics is a contract manufacturing organization with extensive experience running preclinical and clinical. Pursuant to the contract, we made aggregate payments to PsychoGenics totaling approximately $0.3 million over the term of the contract. The contract was completed in September 2023.

Dr. Emer Leahy, a member of our Board, is the current Chief Executive Officer and a less than 5% owner of PsychoGenics.

Alpha-5 Integrin, LLC

On June 21, 2022, we entered into the Alpha-5 Agreement with PD Joint Holdings, LLC Series 2016-A and Lawrence Steinman (collectively, the "Sellers"), pursuant to which the Sellers sold all of the issued and outstanding equity of Alpha-5 to the Company. Lawrence Steinman, our Executive Chairman and Co-Founder, was a 20% owner of Alpha-5 at the time of the transaction. Alpha-5 is a preclinical-stage company developing a mAbs for the treatment of ALS and other neuroinflammatory disorders, such as Multiple Sclerosis. In connection with the transaction, we issued to the Sellers 163,044 shares of our Common Stock, which had a market value of $1.01 million on the date of the transaction and warrants exercisable for 50,000 shares of Common Stock at an exercise price of $37.60 per share, expiring five years from the acquisition date, the aggregate fair value of which was $ 0.4 million at the date of acquisition.

In addition, the Alpha-5 Agreement allows for an earnout payment to be paid as part of the consideration due to the Sellers (the "Earnout Amount"). The Earnout Amount is dependent upon FDA approval of a monoclonal antibody targeting alpha5 beta1 integrin that was in development by Alpha-5 at the time of the execution of the Alpha-5 Agreement. Should such FDA approval be obtained, the Earnout Amount will depend on the attainment of certain net sales targets. The terms of the earnout contain three net sales target thresholds that trigger three different Earnout Amounts depending on which of the three net sales targets is achieved. Net sales generated after the drug is no longer subject to any patent protection or regulatory exclusivity are excluded from the Earnout Amount calculation. The earnout is deemed part of the consideration paid for the acquisition, in the form of contingent consideration. As of December 31, 2023, this amount has been determined by the Company to hold no value.

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 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 $25,000 per quarter for his services.

NOTE 13 – 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 14 – DISCONTINUED OPERATIONS

During the year ended December 31, 2023, we sold and disposed of our assets associated with the Clinics operations in Los Angeles, CA and disposed of our services in the U.K. The lease associated with the related property in Los Angeles was assumed by the buyer in the transaction.

As of December 31, 2023, the carrying amounts of the classes of assets and liabilities related to the discontinued operations of the Clinics operations were $0.

The results of operations from discontinued operations for the years ended December 31, 2023 and 2022, have been reflected in the consolidated statements of operations and consist of the following:

	Years Ended December 31,	
	2023	**2022**
Revenues	$ -	$ 486,559
Cost of services	-	113,195
Gross margin	-	373,364
General and administrative	518,958	2,601,074
Research and Development	-	-
Loss from discontinued operations	(518,958)	(2,227,710)
Gain on sale of accounts payable	-	34,090
Litigation settlement		(14,947)
Gain on sale of assets	65,048	-
Loss from discontinued operations, before income tax	(453,910)	(2,208,567)
Income tax expense	-	-
Net loss from discontinued operations, net of tax	$ (453,910)	$ (2,208,567)
Weighted-average common shares outstanding, basic and diluted	1,226,600	1,262,339
Basic and diluted loss per share from discontinued operations	$ (0.42)	$ (1.76)

The following table presents the gain on the sale of assets in Los Angeles, CA:

	As of December 31, 2023
Cash proceeds	$ 109,500
Proceeds to receive in installments	40,500
Total	$ 150,000
Less transaction costs	(11,250)
Less book value of assets	(73,702)
Gain on sale, before income tax	$ 65,048
Income tax expense	-
Gain on sale, net of tax	$ 65,048

The following table presents non-cash items related to discontinued operations, which are included in the Company's consolidated statement of cash flows:

	Year ended December 31, 2023
Cash Flows From Operating Activities:	
Gain on sale of assets	$ (65,048)
Supplemental disclosure of cash flow information:	
Amount due from sale of assets	$ 40,500

NOTE 15 – SUBSEQUENT EVENTS

The Company has evaluated events and transactions subsequent to December 31, 2023 through the date these consolidated financial statements were included 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.

Reverse Stock Split

On January 2, 2024, the Company implemented a one-for-twenty reverse stock split ("Reverse Stock Split") of the Company's issued and outstanding shares of common stock, par value $0.0001.

As a result of the Reverse Stock Split, every twenty shares of Common Stock issued and outstanding was converted into one share of Common Stock, with a corresponding reduction in the number of authorized shares of Common Stock from 495,000,000 to 100,000,000. 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 would have otherwise been 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 being adjusted to give effect to the Reverse Stock Split).

The Reverse Stock Split did not change the par value of the Common Stock. 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, have been adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

On January 17, 2024, after effecting the Reverse Stock Split, the Company received a letter from the Listing Qualifications Department of The Nasdaq Stock Market stating that the Common Stock had maintained a closing bid price at or above $1.00 per share for a sufficient number of consecutive business days to regain compliance with the minimum bid price requirement, and that the matter is now closed.

As of March 23, 2024, there were 1,042,415 common shares outstanding.

Issuance of Stock Options

On March 1, 2024, the Company issued stock options under the 2023 Plan to purchase an aggregate of 104,433 shares of Common Stock to certain employees and directors of the Company. These stock options had a strike price of $8.13 per share. Of the shares granted, 37,433 shares were fully vested at issuance and the remaining options vest over a term of one to three years.

Exhibit 4.7

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

Pasithea is authorized to issue an aggregate of 105,000,000 shares. The authorized capital stock is divided into 100,000,000 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 the holders of preferred stock, holders of shares of Common Stock are entitled to receive such dividends and distributions and other distributions in cash, stock or property of the Company when, as and if declared by the Board.

Liquidation. Subject to the rights of the 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 share 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 4.4 is a part. We encourage you to review the terms and provisions set forth in the Warrant Agency 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 (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 more than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of 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 of directors 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 of directors 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 of directors 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 ("Amended Charter") and Second Amended and Restated Bylaws ("Amended Bylaws") and Certain Provisions of Delaware Law

Our Amended Charter, Amended Bylaws and the DGCL contain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors. 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 of directors 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 of directors 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 of directors 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 Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors 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 stockholder, 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 10.20

CONSULTING AGREEMENT

Effective November 13, 2023, Lawrence Steinman ("**Consultant**") and Pasithea Therapeutics Corp. (the " **Company**") agree as follows:

1. Services; Payment; No Violation of Rights or Obligations . Consultant agrees to undertake and complete the services set forth and described in Exhibit A in accordance with and on the schedule specified in Exhibit A and other such matters as the Company may reasonably require (the foregoing, collectively, the "**Services**"). As the only consideration due to Consultant regarding the subject matter of this Consulting Agreement (the " **Agreement**"), the Company will compensate Consultant in accordance with Exhibit A. Consultant shall personally perform the Services. Consultant agrees that Consultant will (i) not (and will not permit others to) violate any agreement with or rights of any third party or, except as expressly authorized by the Company in writing hereafter, use or disclose at any time Consultant's own or any third party's confidential information or intellectual property in connection with the Services or otherwise for or on behalf of the Company; (ii) render the Services as are requested from time to time by the Company in such manner as it and the Company mutually shall agree; (iii) render the Services ethically and conscientiously and devote its best efforts and abilities to the Company; and (iv) observe all policies and directives in place from time to time by the Company for independent contractors. The Services shall be non-exclusive to the Company, provided that any such other services do not interfere with or conflict with the Services to be provided by Consultant under this Agreement. Furthermore, Consultant shall not be authorized to incur on behalf of the Company any expenses incurred in connection with rendering the Services and will be responsible for all expenses incurred unless otherwise agreed to in advance by the Company's Chief Executive Officer, which consent shall be evidenced in writing.

2. Ownership; Rights; Publicity.

a. The Company shall own all right, title and interest (including patent rights, copyrights, trade secret rights, mask work rights, trademark rights, *sui generis* database rights and all other intellectual property rights of any sort throughout the world) relating to any and all inventions (whether or not patentable), works of authorship, mask works, designations, designs, know-how, ideas and information made or conceived or reduced to practice, in whole or in part, by or for or on behalf of Consultant during the term of this Agreement that relate to the subject matter of or arise out of or in connection with the Services or any Confidential Information (as defined below) (collectively, "**Inventions**") and Consultant will promptly disclose and provide all Inventions to the Company and hereby assigns such Inventions to the Company. Consultant will not disclose any Invention to anyone other than persons authorized by the Company, without the Company's express prior written instruction to do so. All Inventions shall belong solely to the Company from conception. Consultant hereby expressly disclaims all interest in all Inventions. Consultant hereby irrevocably assigns to the Company all of Consultant's right, title and interest to that Invention. Consultant shall assist the Company, at the Company's expense, to further evidence, record and perfect such assignments, and to perfect, obtain, maintain, enforce and defend any rights assigned. Consultant hereby irrevocably designates and appoints the Company as its agents and attorneys-in-fact, coupled with an interest, to act for and on Consultant's behalf to execute and file any document and to do all other lawfully permitted acts to further the foregoing with the same legal force and effect as if executed by Consultant and all other creators or owners of the applicable Invention.

b. Upon termination or as otherwise requested by the Company, Consultant will promptly provide to the Company all items and copies containing or embodying Confidential Information (defined below), except that Consultant may keep its personal copies of its compensation records and this Agreement. Consultant also recognizes and agrees that Consultant has no expectation of privacy with respect to the Company's telecommunications, networking or information processing systems (including, without limitation, stored computer files, email messages and voice messages) and that Consultant's activity, and any files or messages, on or using any of those systems may be monitored at any time without notice.

c. To the extent allowed by law, Section 2.a and any license granted to the Company hereunder includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as "moral rights," "artist's rights," "droit moral," or the like. Furthermore, Consultant agrees that notwithstanding any rights of publicity, privacy or otherwise (whether or not statutory) anywhere in the world, and without any further compensation, Company may and is hereby authorized to (and to allow others to) use Consultant's name in connection with promotion of its business, products or Services. To the extent any of the foregoing is ineffective under applicable law, Consultant hereby provides any and all ratifications and consents necessary to accomplish the purposes of the foregoing to the extent possible. Consultant will confirm any such ratifications and consents from time to time as requested by the Company. If any other person is in any way involved in any Services, Consultant will obtain the foregoing ratifications, consents and authorizations from such person for the Company's exclusive benefit.

d. If any part of the Services or Inventions or information provided hereunder is based on, incorporates, or is an improvement or derivative of, or cannot be reasonably and fully made, used, reproduced, distributed and otherwise exploited without using or violating technology or intellectual property rights owned by or licensed to Consultant (or any person involved in the Services) and not assigned hereunder, Consultant hereby grants the Company and its successors a perpetual, irrevocable, worldwide royalty-free, non-exclusive, sublicensable right and license to exploit and exercise all such technology and intellectual property rights in support of the Company's exercise or exploitation of the Services, Inventions, other work or information performed or provided hereunder, or any assigned rights (including any modifications, improvements and derivatives of any of them).

e. Nothing herein shall be construed to restrict, impair or deprive Consultant of any of its rights or proprietary interest in technology or products that existed prior to and independent of the performance of Services.

3. Warranties and Other Obligations. Consultant represents, warrants and covenants that: (i) the Services will be performed in a professional and workmanlike manner and that none of such Services nor any part of this Agreement is or will be inconsistent with any obligation Consultant may have to others; (ii) all work under this Agreement shall be Consultant's original work and none of the Services or Inventions nor any development, use, production, distribution or exploitation thereof will infringe, misappropriate or violate any intellectual property or other right of any person or entity (including, without limitation, Consultant); (iii) Consultant has the full right to allow it to provide the Company with the assignments and rights provided for herein (and has written enforceable agreements with all persons necessary to give it the rights to do the foregoing and otherwise fully perform this Agreement); (iv) Consultant shall comply with all applicable laws and the Company's safety rules in the course of performing the Services; and (v) if Consultant's work requires a license, Consultant has obtained that license and the license is in full force and effect.

4. Consulting Period; Termination; Survival. This Agreement may be terminated by the Consultant upon thirty (30) days prior notice to the Company. The Company may terminate this Agreement at any time upon notice to the Consultant. In the event of such termination by the Company, the

Consultant shall be entitled to payment for any Services rendered and undisputed expenses incurred prior to the date of termination.

5. Competitive Employment and No Solicitation .

a. Except and to the extent prohibited by law, during the Term, and for a period of one (1) year following termination of this Agreement, the Consultant shall not, directly or indirectly, (a) engage in or be connected with any business competing with the business engaged in or proposed to be engaged in by the Company, whether as an officer, director, stockholder, owner, employee, partner, affiliate or consultant, or assist others engaging in any such business, except with the prior approval of the Company, or (b) induce, solicit, persuade, entice or attempt to induce, solicit, persuade or entice, any person or entity associated with the Company as an employee, consultant, agent or customer to terminate or leave his, her or its association with the Company.

b. The Consultant acknowledges that the provisions of this Section 5 contain limitations and restrictions that are reasonable and do not impose a greater restraint than is necessary to protect the goodwill or other business interests of the Company, such as the Company's need to protect its Confidential Information and Inventions.

c. The Consultant further acknowledges that money damages would not be a sufficient remedy for any breach by the Consultant of this Section 5 and that the Company shall be entitled to equitable relief, including an injunction and specific performance without the necessity of posting a bond, as a remedy for any such breach. Such remedy shall not be deemed to be the exclusive remedy for a breach of this Section 5, but shall be in addition to all other remedies available to the Company at law or in equity.

6 . Relationship of the Parties; Independent Contractor; No Employee Benefits . Notwithstanding any provision hereof, Consultant is an independent contractor and is not an employee, agent, partner or joint venturer of the Company and shall not bind nor attempt to bind the Company to any contract. Consultant shall accept any directions issued by the Company pertaining to the goals to be attained and the results to be achieved by Consultant, but Consultant shall be solely responsible for the manner and hours in which the Services are performed under this Agreement. Consultant shall not be eligible to participate in any of the Company's employee benefit plans, fringe benefit programs, group insurance arrangements or similar programs. The Company shall not provide workers' compensation, disability insurance, Social Security or unemployment compensation coverage or any other statutory benefit to Consultant. Consultant shall comply at Consultant's expense with all applicable provisions of workers' compensation laws, unemployment compensation laws, federal Social Security law, the Fair Labor Standards Act, federal, state and local income tax laws, and all other applicable federal, state and local laws, regulations and codes relating to terms and conditions of employment required to be fulfilled by employers or independent contractors. Consultant will ensure that its employees, contractors and others involved in the Services, if any, are bound in writing to the foregoing, and to all of Consultant's obligations under any provision of this Agreement, for the Company's benefit and Consultant will be responsible for any noncompliance by them.

7. Confidentiality.

a . For the purposes of this Agreement, "**Confidential Information**" means any and all information disclosed by or on behalf of the Company to Consultant or any of Consultant's employees, agents or other representatives (collectively, "**Representatives**"), prior to or during the term of this Agreement, regardless of whether the information is received in written, oral, visual or other form, including, but not limited to, any and all: (i) information regarding any products and proposed products of the Company or any of its affiliates, including, but not limited to, marketing plans, specifications and advertiser lists; (ii) any other business, technical, financial or other information of the Company or any of its affiliates and (iii) any information with respect to which the Company or any of its affiliates is under an obligation of confidentiality to a third party.

b . Notwithstanding the foregoing, "**Confidential Information**" does not include any information which: (i) is publicly known prior to disclosure hereunder by the Company, or subsequent to such disclosure without breach of this Agreement, (ii) is known, as evidenced by documentation, to Consultant prior to disclosure hereunder by the Company, provided that any source of such information was not known by Consultant to be under an obligation of confidentiality with respect to such information, (iii) is disclosed to Consultant, without any obligation of confidentiality, by a third party having a bona fide right to do so or (iv) is independently developed, as evidenced by documentation, by Consultant without use of or access to any Confidential Information.

c. Consultant will store the Confidential Information in a secure location, and will handle and protect the Confidential Information with no less care than that with which Consultant handles and protects Consultant's own highly confidential and proprietary information (but in no event less than a reasonable degree of care).

d . Consultant will use the Confidential Information only in connection with the provision of Services to the Company (the "**Purpose**"). Consultant will not directly or indirectly disclose the Confidential Information to any person or company, other than its Representatives who have a need to know the Confidential Information in connection with the Purpose. Consultant will be responsible for its Representatives' compliance with the provisions of this Agreement.

e. If Consultant is requested to disclose any Confidential Information pursuant to any judicial or governmental order, Consultant will not disclose such Confidential Information without first giving the Company written notice of the request and sufficient opportunity to contest the order and/or obtain confidential treatment for such disclosure.

f. At the request of the Company, Consultant will, at the Company's option, either promptly return to the Company, or destroy and certify that it has destroyed, all copies, in its or any of its Representatives' possession or control, of any and all documents, computer files and other materials that contain or are derived from any Confidential Information.

g. Consultant agrees during the term of this Agreement not to accept work or enter into a contract or accept an obligation, inconsistent or incompatible with Consultant's obligations under this Agreement or the scope of services rendered for the Company. Consultant warrants that there is no existing contract or duty on Consultant's part inconsistent with this Agreement, unless a copy of such contract or a description of such duty is attached to this Agreement as Exhibit B. Consultant further agrees not to disclose to the Company, or bring onto the Company's premises, or induce the Company to use any confidential information that belongs to anyone other than the Company or Consultant.

h . Defend Trade Secrets Act Notice. Consultant acknowledges receipt of notice of the following immunities under 18 USC Section 1833(b): An individual shall not be held criminally or civilly liable under any U.S. federal or state trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney and (B) solely for the purpose of

reporting or investigating a suspected violation of law or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the employer's trade secrets to its attorney and use the trade secret information in the court proceeding if the individual: (x) files any document containing the trade secret under seal and (y) does not disclose the trade secret, except pursuant to court order.

i. This Confidentiality Section shall survive any expiration or termination of this Agreement with respect to any Confidential Information that was received prior to the date of such expiration or termination, for a period of five (5) years following the date of such expiration or termination (or, if longer, for as long as the Company maintains the Confidential Information as a trade secret).

8. Assignment. This Agreement and the services contemplated hereunder are personal to Consultant and Consultant shall not have the right or ability to assign, transfer or subcontract any rights or obligations under this Agreement without the written consent of the Company. Any attempt to do so shall be void. The Company may fully assign and transfer this Agreement in whole or part.

9. Governing Law; Venue. This Agreement shall be governed by and construed in accordance with the laws of the State of [Delaware], notwithstanding any rules regarding choice of law to the contrary. Any legal action or proceeding with respect to this Agreement shall be brought only in the state or federal courts located in the State of [Delaware], and by execution and delivery of this Agreement, each party hereby accepts the jurisdiction of the aforesaid courts with respect to any such action or proceeding.

10. Non-Disparagement. Consultant and the Company agree that during the term and at all times thereafter, Consultant shall not disparage the reputation of the Company, its products or services, or any of its officers, directors, employees or representatives. Notwithstanding the foregoing, nothing in this section will be deemed to prohibit (a) truthful communications in response to a request by a regulator or self-regulatory organization; (b) truthful responses to a subpoena or other legal process; or (c) any truthful testimony or pleadings in any administrative, legislative, judicial, or other legal proceeding.

11. Miscellaneous. The failure of either party to enforce its rights under this Agreement at any time for any period shall not be construed as a waiver of such rights. No changes or modifications or waivers to this Agreement will be effective unless in writing and signed by both parties. In the event that any provision of this Agreement shall be determined to be illegal or unenforceable, that provision will be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable. Headings herein are for convenience of reference only and shall in no way affect interpretation of the Agreement.

[*Signature Page Follows*]

CONSULTANT:

/s/ Lawrence Steinman
Lawrence Steinman

COMPANY:

PASITHEA THERAPEUTICS CORP.:

/s/ Tiago Reis Marques
By: Tiago Reis Marques
Title: CEO

Exhibit A

Consultant shall perform Services that are normally associated with a consultant. The duties and responsibilities, will include, but are not limited to the following:

- ☐ Fulfill the Company's mission and strategic objectives by advancing assets through pre-clinical and early clinical development,
- ☐ Formulate and supervise the overall research & development strategy of the Company including all phases of discovery and preclinical development, including setting research priorities,
- ☐ Supervise research projects and oversee the technological development of processes,
- ☐ Be responsible for keeping the Company up to date with industry trends and advancements,
- ☐ Recommending future research projects and opportunities,
- ☐ Identify potential partners for the Company's pre-clinical assets, and assist in business development efforts related to the Company's pre-clinical assets, and
- ☐ Represent the scientific interests of the Company.

Compensation for performing the Services shall be $25,000 per quarter.

Exhibit B

Exhibit 21.1

Subsidiaries of Pasithea Therapeutics Corp.

Legal Name	Jurisdiction
Alpha 5 Integrin, LLC	Delaware
AlloMek Therapeutics, LLC	Delaware

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Pasithea Therapeutics Corp. on Form S-8 [FILE NO. 333-267535 and 333-271011] and Form S-3 [FILE NO. 333-271010 and 333-271896] of our report dated March 28, 2024, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Pasithea Therapeutics Corp. as of December 31, 2023 and 2022 and for the years ended December 31, 2023 and 2022, which report is included in this Annual Report on Form 10-K of Pasithea Therapeutics Corp. for the year ended December 31, 2023.

/s/ Marcum LLP

New Haven, CT
March 28, 2024

Exhibit 31.1

PASITHEA THERAPEUTICS CORP.
CEO CERTIFICATE
PURSUANT TO SECTION 302

I, Dr. Tiago Res Marques, certify that:

1. I have reviewed the Annual Report on Form 10-K for the year ended December 31, 2023 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. [Reserved];

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 28, 2024

By: /s/ Dr. Tiago Res Marques
Name: Dr. Tiago Res 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, 2023 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. [Reserved];

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 28, 2024

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, 2023 (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 28, 2024

By: /s/ Dr. Tiago Res Marques
Name: Dr. Tiago Res 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, 2023 (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 28, 2024

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.

Exhibit 97.1

PASITHEA THERAPEUTICS CORP.

COMPENSATION RECOVERY POLICY

(Adopted and approved on October 6, 2023, and effective as of December 1, 2023)

1. Purpose

Pasithea Therapeutics Corp. (the "**Company**") is committed to promoting high standards of honest and ethical business conduct and compliance with applicable laws, rules and regulations. As part of this commitment, the Company has adopted this Compensation Recovery Policy (this "**Policy**"). This Policy is designed to comply with the requirements of Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), Rule 10D-1 promulgated thereunder and the rules of the national securities exchange on which the Company's securities are traded and explains when the Company will pursue recovery of Incentive Compensation awarded or paid to a Covered Person. Please refer to Exhibit A attached hereto (the "**Definitions Exhibit**") for the definitions of capitalized terms used throughout this Policy.

2. Recovery of Recoverable Incentive Compensation

In the event of a Restatement, the Company will pursue, reasonably promptly, recovery of all Recoverable Incentive Compensation from a Covered Person without regard to such Covered Person's individual knowledge or responsibility related to the Restatement. Notwithstanding the foregoing, if the Company is otherwise required by this Policy to undertake a Restatement, the Company will not be required to recover the Recoverable Incentive Compensation if the Compensation Committee determines, after exercising a normal due process review of all the relevant facts and circumstances, that (a) a Recovery Exception exists and (b) it would be impracticable to seek such recovery under such facts and circumstances.

If such Recoverable Incentive Compensation was not awarded or paid on a formulaic basis, the Company will pursue recovery of the amount that the Compensation Committee determines in good faith should be recovered.

3. Other Actions

The Compensation Committee may, subject to applicable law, pursue recovery of Recoverable Incentive Compensation in the manner it chooses, including by pursuing reimbursement from the Covered Person of all or part of the compensation awarded or paid, by electing to withhold unpaid compensation, by set-off, or by rescinding or canceling unvested stock or option awards.

In the reasonable exercise of its business judgment under this Policy, the Compensation Committee may in its sole discretion determine whether and to what extent additional action is appropriate to address the circumstances surrounding a Restatement to minimize the likelihood of any recurrence and to impose such other discipline as it deems appropriate.

4. No Indemnification or Reimbursement

As required by applicable law, notwithstanding the terms of any other policy, program, agreement or arrangement, in no event will the Company or any of its affiliates indemnify or reimburse a Covered Person for any loss of Recoverable Incentive Compensation under this Policy and, to the extent prohibited by law, neither the Company nor any of its affiliates will pay premiums on any insurance policy that would cover a Covered Person's potential obligations with respect to Recoverable Incentive Compensation under this Policy.

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5. Administration of Policy

The Compensation Committee will have full authority to administer this Policy. The Compensation Committee will, subject to the provisions of this Policy and Rule 10D-1 of the Exchange Act, and the Company's applicable exchange listing standards, make such determinations and interpretations and take such actions in connection with this Policy as it deems necessary, appropriate or advisable. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, Rule 10D-1 thereunder and any applicable rules or standards adopted by the Securities and Exchange Commission or any national securities exchange on which the Company's securities are listed. All determinations and interpretations made by the Compensation Committee will be final, binding and conclusive.

6. Other Claims and Rights

The requirements of this Policy are in addition to, and not in lieu of, any legal and equitable claims the Company or any of its affiliates may have or any actions that may be imposed by law enforcement agencies, regulators, administrative bodies, or other authorities. Further, the exercise by the Compensation Committee of any rights pursuant to this Policy will not impact any other rights that the Company or any of its affiliates may have with respect to any Covered Person subject to this Policy.

7. Acknowledgement by Covered Persons; Condition to Eligibility for Incentive Compensation

The Company will provide notice and seek acknowledgement of this Policy from each Covered Person, provided that the failure to provide such notice or obtain such acknowledgement will have no impact on the applicability or enforceability of this Policy. After the Effective Date (and also with respect to any Incentive Compensation Received on or after October 2, 2023 pursuant to a preexisting contract or arrangement), any grant of Incentive Compensation to a Covered Person will be deemed to have been made subject to the terms of this Policy, whether or not such Policy is specifically referenced in the documentation relating to such grant and this Policy shall be deemed to constitute an integral part of the terms of any such grant. All Incentive Compensation subject to this Policy will remain subject to this policy, even if already paid, until the Policy ceases to apply to such Incentive Compensation and any other vesting conditions applicable to such Incentive Compensation are satisfied.

8. Amendment; Termination

The Board or the Compensation Committee may amend or terminate this Policy at any time. In the event that Section 10D of the Exchange Act, Rule 10D-1 thereunder or the rules of the national securities exchange on which the Company's securities are traded are modified or supplemented, whether by law, regulation or legal interpretation, such modification or supplement shall be deemed to modify or supplement this Policy to the maximum extent permitted by applicable law.

9. Effectiveness

Except as otherwise determined in writing by the Compensation Committee, this Policy will apply to any Incentive Compensation that is Received by a Covered Person on or after the Effective Date. This Policy will survive and continue notwithstanding any termination of a Covered Person's employment with the Company and its affiliates.

10. Successors

This Policy shall be binding and enforceable against all Covered Persons and their successors, beneficiaries, heirs, executors, administrators, or other legal representatives.

Exhibit A

PASITHEA THERAPEUTICS CORP.

COMPENSATION RECOVERY POLICY

DEFINITIONS EXHIBIT

"**Applicable Period**" means the three completed fiscal years of the Company immediately preceding the earlier of (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes (or reasonably should have concluded) that a Restatement is required or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare a Restatement. The "Applicable Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence.

"**Board**" means the Board of Directors of the Company.

"**Compensation Committee**" means the Company's committee of independent directors responsible for executive compensation decisions, or in the absence of such a committee, a majority of the independent directors serving on the Board.

"**Covered Person**" means any person who is, or was at any time, during the Applicable Period, an Executive Officer of the Company. For the avoidance of doubt, a Covered Person may include a former Executive Officer that left the Company, retired, or transitioned to an employee role (including after serving as an Executive Officer in an interim capacity) during the Applicable Period.

"**Effective Date**" means December 1, 2023.

"**Executive Officer**" means the Company's president, principal executive officer, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person (including an officer of the Company's parent(s) or subsidiaries) who performs similar policy-making functions for the Company.

"**Financial Reporting Measure**" means a measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measure (including but not limited to, "non-GAAP" financial measures, such as those appearing in the Company's earnings releases or Management Discussion and Analysis). Stock price and total shareholder return (and any measures derived wholly or in part therefrom) shall be considered Financial Reporting Measures.

"**Recovery Exception**" A recovery of Recoverable Incentive Compensation shall be subject to a "Recovery Exception" if the Compensation Committee determines in good faith that: (i) pursuing such recovery would violate the home country law of the jurisdiction of incorporation of the Company where that law was adopted prior to November 28, 2022 and the Company provides an opinion of home country counsel to that effect acceptable to the Company's applicable listing exchange; (ii) the direct expense paid to a third party to assist in enforcing this Policy would exceed the Recoverable Incentive Compensation and the Company has (A) made a reasonable attempt to recover such amounts and (B) provided documentation of such attempts to recover to the Company's applicable listing exchange; or (iii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and regulations thereunder.

"**Incentive Compensation**" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive Compensation does not include any base salaries (except with respect to any salary increases earned wholly or in part based on the attainment of a Financial Reporting Measure performance goal); bonuses paid solely at the discretion of the Compensation Committee or Board that are not paid from a "bonus pool" that is determined by satisfying a Financial Reporting Measure performance goal; bonuses paid solely upon satisfying one or more subjective standards and/or completion of a specified employment period; non-equity incentive plan awards earned solely upon satisfying one or more strategic measures or operational measures; and equity awards that vest solely based on the passage of time and/or attaining one or more non-Financial Reporting Measures. Incentive Compensation includes any Incentive Compensation Received on or after October 2, 2023 pursuant to a preexisting contract or arrangement.

"**Received**" Incentive Compensation is deemed "Received" in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of the Incentive Compensation occurs after the end of that period.

"**Recoverable Incentive Compensation**" means the amount of any Incentive Compensation (calculated on a pre-tax basis) Received by a Covered Person during the Applicable Period that is in excess of the amount that otherwise would have been Received if the calculation were based on the Restatement. For Incentive Compensation based on (or derived from) stock price or total shareholder return where the amount of Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in the applicable Restatement, the amount will be determined by the Compensation Committee based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive Compensation was Received (in which case, the Company will maintain documentation of such determination of that reasonable estimate and provide such documentation to the Company's applicable listing exchange).

"**Restatement**" means an accounting restatement of any of the Company's financial statements filed with the Securities and Exchange Commission under the Exchange Act, or the Securities Act of 1933, as amended, due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, regardless of whether the Company or Covered Person misconduct was the cause for such restatement. "Restatement" includes any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (commonly referred to as "Big R" restatements), or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (commonly referred to as "little r" restatements).