Filed pursuant to Rule 424(b)(3)
Registration No. 333-255205

Prospectus Supplement No. 2
(To Prospectus dated September 14, 2021)

4,800,000 Units Each Consisting of
One Share of Common Stock and
One Warrant to Purchase One Share of Common Stock

Pasithea Therapeutics Corp.

This is a supplement ("Prospectus Supplement No. 2") to the prospectus, dated September 14, 2021 (the "Prospectus") of Pasithea Therapeutics Corp. (the "Company"), which forms a part of the Company's Registration Statement on Form S-1 (Registration Nos. 333-255205). Pursuant to the Prospectus, this prospectus supplement relates to the offering 4,800,000 units ("Units"), each Unit consisting of one share of our common stock ("Common Stock"), par value $0.0001 per share, and one warrant ("Warrant") to purchase one share of our Common Stock (and the shares issuable from time to time upon exercise of the Warrants) pursuant to the Prospectus.

This Prospectus Supplement updates and should be read in conjunction with, and delivered with, the Prospectus, and the Prospectus Supplement No. 1, filed with the SEC on December 22, 2021 ("Prospectus Supplement No. 1"). To the extent there is a discrepancy between the information contained herein and the information in the Prospectus and Prospectus Supplement No. 1, the information contained herein supersedes and replaces such conflicting information.

This prospectus supplement consists of the Company's Annual Report on Form 10-K, which was filed with the SEC on March 30, 2022 (the "Annual Report") as set forth below.

This Prospectus Supplement No. 2 is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, including any amendments or supplements to it.

Investing in our Common Stock involves a high degree of risk. Before buying any of our Common Stock, you should carefully read the discussion of the material risks of investing in our securities under the heading "Risk Factors" beginning on page 15 of the prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 2 is April 18, 2022.

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, 2021**

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, exercisable for one share of Common Stock	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 ☐	Accelerated filer ☐
Non-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. ☐

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

The registrant had 22,858,371 shares of common stock outstanding as of March 23, 2022. The aggregate market value of the 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, 2021) was $0, as the registrant had not been publicly-traded as of that such date.

PASITHEA THERAPEUTICS CORP.
2021 FORM 10-K ANNUAL REPORT
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "10-K") contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this 10-K include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our future product candidates, and other positive results;
- 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 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;

- the need to hire additional personnel and our ability to attract and retain such personnel;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our dependence on third parties;
- our financial performance;
- 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 ability to generate revenue and profit margin under our anticipated contracts which is subject to certain risks;
- difficulties in our and our partners' ability to recruit and retain qualified physicians and other healthcare professionals, and enforce our non-compete agreements with our physicians; and
- our ability to restructure our operations to comply with future changes in government regulation.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this 10-K and are subject to a number of risks, uncertainties and assumptions

described in the section titled “Risk Factors” and elsewhere in this 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, 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. 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 or otherwise.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

PART I

ITEM 1. BUSINESS

Overview

We are a biotechnology company focused on the research and discovery of new and effective treatments for psychiatric and neurological disorders. Epidemiological data indicate neuropsychiatric disorders as being some of the most prevalent, devastating, and yet poorly treated illnesses.

Our biotech operations focus on developing drugs that target the pathophysiology underlying such disorders rather than symptomatic treatments, with the goal of developing new pharmacological agents that display significant advantages over conventional therapies with respect to efficacy and tolerability. We particularly focus on the cross-talk between the immune system and brain disorders and how immune dysregulation affects CNS function.

For many years the brain was considered an “immune-privileged” organ. The anatomical and physiological characteristics of the central nervous system, in addition to the presence of the blood brain barrier, were thought to underlie slow immune reactions in the brain. However, according to a 2020 article published by Frontiers in Neuroanatomy, a 2020 article published by Nature Reviews Immunology, a 2019 article published by Frontiers in Immunology, and a 2020 article published by Frontiers Pharmacology, recent studies have shown substantial progress in the understanding of neuroimmune interactions, and there is now strong evidence for a close and bi-directional communication between nerve and immune cells. Altered communication between the immune and nervous system is emerging as a common hallmark in neuro-developmental, neurodegenerative, and neuro-immunological diseases. On the one hand, the brain is able to modulate the immune response through the connections between the autonomic nervous system (parasympathetic and sympathetic nerves) and lymphoid organs. Furthermore, brain hormones such as corticotrophin-releasing hormone and substance P can regulate cytokine levels. On the other hand, the immune system regulates the brain through its modulation of microglia cells and the release of peripheral cytokines, a phenomenon referred to as “cross talk” due to the close, reciprocal relationship of these two systems. Our drug discovery efforts focus on neuropsychiatric disorders that, although phenotypically distinct, are pathogenically related. We focus on mechanism-based immune treatments for the treatment of these disorders.

The first new chemical entity drug development program is focused on schizophrenia. Schizophrenia is an inherited brain disease and an incurable chronic mental disorder. With treatment, most recover from the first episode but then relapse. The pathogenetic mechanisms are unknown, while the loss of grey matter and a reduced number of synaptic structures on neurons are evident. Converging lines of genetic, epidemiological and clinical evidence indicate that inflammatory pathways are altered in schizophrenia. Studies in numerous scientific journals, including a 2013 study from the Journal of Psychiatric Research, a 1998, 2005 and a 2014 study from the Schizophrenia Research, a 2015 study from the Journal of Psychiatry & Neuro Science, a 2009 study from Molecular Psychiatry and a 2004 study from the Journal of Clinical Psychiatry have repeatedly shown that patients with schizophrenia have increased serum and cerebrospinal fluid concentrations of pro-inflammatory cytokines. Several other studies in scientific journals, including a 1997 study from Psychiatry Research, a 2016 study from Nature and a 2012 study from Revista Brasileira de Psiquiatria, have also reported increased complement gene expression, protein concentration, and overall activity in the serum or plasma of schizophrenia cases compared to controls. Taken together, this evidence has led to the hypothesis that schizophrenia is a neuroimmune disorder mediated by alterations in pro- and anti-inflammatory processes in the central nervous system (CNS). We are currently developing a brain-penetrant small molecules able to down regulate a novel neuroinflammatory pathway for the systemic treatment of schizophrenia. The work is currently being conducted by Evotec, utilizing Evotec’s integrated research and development expertise and state-of-the-art structure-based drug design techniques.

The second new chemical entity drug development program is focusing in a tolerizing vaccine in Multiple Sclerosis. Infection with the Epstein-Barr virus (EBV) has long been postulated to trigger multiple sclerosis (MS) and recent data, according to a 2022 article published by Science, in a cohort of >10 million people have provided compelling evidence to show that EBV is the trigger for the development of MS. Furthermore, in a 2022 article published by Nature, the mechanism through which EBV mediate MS development was elucidated. Through a process of molecular mimicry, antibodies targeting EBNA-1 residues 386–405 that cross-react with the CNS cell adhesion molecule, glialCAM, Preclinical work is currently being conducted at Hooke Laboratories, a full-service Contract Research Organization (“CRO”) with deep experience in experimental autoimmune encephalomyelitis (“EAE”), the standard animal model of MS.

Our secondary operations are focused on providing business support services to anti-depression clinics in the U.K. and in the United States.

We believe that the current treatments for mental health disorders, such as depression, are inadequate and that conventional medicines have low success rates in long-term treatment. According to an article published by PLOS One, randomized, double-blind, placebo-controlled clinical trials of antidepressants were only effective for 42-51% of patients with MDD. For example, current pharmacotherapies for MDD and BDep have a distinct lag of onset that can generate further distress and impairment in patients. According to an article published in 2000 by The Journal of Clinical Psychiatry, and an article published in 2010 by Pharmaceuticals (Basel), available antidepressant medications usually take several weeks before patients display significant therapeutic benefit. This delayed onset of treatment can result in increased morbidity and increased risk for suicidal behavior. This has been reported in a base population study including 159,810 users of 4 antidepressant drugs showing that the risk of suicidal behavior increased in the first month after starting antidepressants, and in particular during the first 1 to 9 days, regardless of the chemical class of antidepressant. This study was published in a 2004 article published by The Journal of the American Medical Association. Similarly, other studies including a 2006 article published by The American Journal of Psychiatry have shown a significantly higher risk of suicide attempts during the first week of antidepressant treatment compared to subsequent weeks. Furthermore, depressive symptoms are commonly known to affect the ability of patients to function across multiple domains, impacting self-esteem, motivation and cognitive function. Delayed onset of antidepressants contributes to ongoing functional impairment and may interfere with integration back into daily life, in turn delaying full functional recovery. Furthermore, according to a 2012 article published by Biological Psychiatry and a 2013 article published by Brain Stimulation, the continued presence of depressive symptoms may promote chronic neuronal loss and suppress neurogenesis in the hippocampus. Traditional psychiatric drugs can also cause side effects. Furthermore, the approval of psychotropic drugs with novel mechanisms of action has been rare in recent years.

Our operations in the U.K. involve providing business support services to registered healthcare providers who assess patients, and if appropriate, administer intravenous infusions of ketamine, and our operations in the United States involve providing business support services to entities that furnish similar services to patients who

personally pay for those services. Operations currently take place in several districts of London in the United Kingdom. We intend to commence operations in the United States, with operations in New York, Los Angeles, San Diego and San Francisco. In addition, we intend to expand our coverage to other jurisdictions in the United States, including Florida and Nevada. We operate through partnerships with healthcare companies, including with Zen Healthcare and The IV Doc. Our operations in the U.K., and our future operations in the United States, are limited to providing business support services to healthcare companies. In the United States, certain of these business support services are subcontracted to The IV Doc through a Business Support Services Subcontract. We do not provide professional medical services, establish or own anti-depression clinics, provide psychiatric assessments, or are responsible for the administration of intravenous infusions of ketamine in the United States. Furthermore, we do not obtain or administer ketamine, nor will we maintain any license or registration to own, maintain or dispense controlled substances in the U.K. or in the United States. We provide business support services to properly authorized companies that provide clinical services of the type described above to self-pay patients, and we subcontract certain of these business support services to The IV Doc.

Ketamine was first introduced to the medical community as a surgical anesthetic more than 50 years ago. According to a 2015 article published by Therapeutic Advances in Chronic Disease, and a 2019 article published on the Harvard Medical School's website, as of the date of this 10-K, ketamine is gaining grounds as a promising treatment for some cases of major depression. It works differently than traditional antidepressants, which target the brain's serotonin and noradrenalin systems. Ketamine blocks NMDA, a receptor in the brain that is activated by glutamate, a neurotransmitter. A single subanesthetic dose infusion of the NMDA receptor antagonist ketamine has been shown to have potentially rapid and potent antidepressant effects in treatment-resistant MDD as well as for the treatment of post-traumatic stress disorder.

While not approved by the FDA or the MHRA to treat depression, and while recreational use remains prohibited, ketamine has been repurposed for the treatment of MDD. As detailed below, the use of ketamine has been subject to consensus statements by the APA Council of Research Task Force on Novel Biomarkers and Treatments, the Royal College of Psychiatrists Committee on Electroconvulsive Therapy and Related Treatments, the Royal Australian and New Zealand College of Psychiatrists Committee for Evidence-Based Practice, and by an international expert opinion paper published in the American Journal of Psychiatry that was written by an international group of mood disorder experts:

- APA Council of Research Task Force on Novel Biomarkers and Treatments - *A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders Council of Research Task Force on Novel Biomarkers and Treatments* (April 2017)
    - The report highlights the current state of the field and the critical issues to be considered when contemplating the use of ketamine for treatment-resistant depression but has not been endorsed or promulgated as policy by the APA. Pursuant to the report, it is recommended that each patient undergo a thorough pre-treatment evaluation process and that the strongest data supporting ketamine's clinical benefit in psychiatric disorders are in the treatment of major depressive episodes without psychotic features. The report states that most clinical trials and case reports available have used the ketamine hydrochloride dose of 0.5 mg/kg per 40 minutes IV. It has also been noted that at this dose, ketamine does not appear to have any significant effects on the respiratory status of healthy individuals or patients with depression who are otherwise generally healthy. However, ketamine treatment can have meaningful effects on blood pressure and heart rate, and it is recommended that clinicians delivering ketamine treatment be prepared to manage potential cardiovascular events should they occur. It is further recommended that clinicians be familiar with behavioral management of patients with marked mental status changes and be prepared to treat any emergency behavioral situations. Additionally, it is recommended that clinicians develop some level of experience before performing the procedure independently. Furthermore, it is recommended that site-specific standard operating procedures be developed and followed for the delivery of ketamine treatments. The report highlights that the existing data surrounding the benefits of repeated infusions of ketamine remain limited. The report notes that most other articles describing the effects of repeated ketamine treatments show the largest benefits occurring early in the course of treatment, but some reports have shown cumulative benefit of continued treatment. Finally, the report suggests that assessments of cognitive function, urinary discomfort, and substance use should be considered if repeated administrations are provided.
- Royal College of Psychiatrists Committee on Electroconvulsive Therapy and Related Treatments - *Statement on Ketamine to Treat Depression* (February 2017)
    - In this statement, the authors indicate that ketamine for the treatment of depression is a novel treatment. Pursuant to the statement, it is recommended that the treating psychiatrist should consider this treatment as novel or innovative, which should include discussion with peers (preferably including a second opinion). Additionally, the statements notes that individuals considering ketamine as a treatment and their caregivers should be provided with clear information and an explanation that this is a novel treatment. This information should include a detailed explanation of the current evidence and potential risks, and be documented in the clinical notes. The statement recommends that ketamine treatment for depression occurring outside formal research studies should be coordinated across centers using a regular mood monitoring framework.
- Royal Australian and New Zealand College of Psychiatrists Committee for Evidence-Based Practice - *Use of ketamine for treatment-resistant depression* (November 2019)
    - In this clinical memorandum, the authors highlight that there is currently limited evidence to recommend ketamine as a viable treatment option for treatment-resistant depression. Short-term efficacy has been demonstrated after a single treatment, but benefits are not lasting for most patients. The memorandum recommends that psychiatrists considering prescribing ketamine for a patient with treatment-resistant depression (outside of a research trial) should ensure the patient is willing and able to consent and should discuss this treatment with peers, preferably including a second opinion, and/or institutional review by a medicines advisory committee or medicines assessment advisory committee.
- American Journal of Psychiatry - *Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation* (March 2021)
    - This report provides practitioners with a synthesis of the current knowledge as it relates to ketamine's pharmacology, efficacy, tolerability, and safety and reviews the clinical aspects related to administration of ketamine at point of care. In their consensus statement, the authors note that evidence supports the rapid-onset (i.e., within 1–2 days) efficacy of ketamine in treatment-resistant depression and that efficacy is best established for intravenous ketamine with insufficient evidence for oral, subcutaneous, or intramuscular administration. Additionally, the article indicates that evidence for long-term efficacy, safety, and tolerability of intravenous ketamine in treatment-resistant depression is insufficient. The statement identifies safety concerns with respect to ketamine, which include but are not limited to, psychiatric (e.g., dissociation, psychotomimetic), neurologic/cognitive, genitourinary, and hemodynamic effects. Pursuant to the article, it is recommended that ketamine be administered only in settings with multi-disciplinary personnel, including those with expertise in the assessment of mood disorders.

The following randomized-clinical trials have reported a response after IV ketamine infusions in patients with treatment-resistant MDD and BDep:

- In 2006, a randomized, placebo-controlled, double-blind clinical trial on treatment-resistant MDD was published by Zarate CA Jr, Singh JB, Carlson PJ, Brutsche NE, Ameli R, Luckenbaugh DA, Charney DS, Manji HK. The study lasted 1 week and included 18 patients, who received 0.5mg/kg IV infusion or placebo. The clinical response was defined as 50% or greater decrease in the HDRS score from baseline. The results of the study showed that the day (24h) following ketamine infusion 71% of patients who received ketamine responded to treatment and 29% met remission criteria. No serious adverse events occurred during the study.

- In 2010, a randomized, placebo-controlled, double-blind, crossover, add-on study on treatment-resistant BDep was published by Diazgranados N, Ibrahim L, Brutsche NE, Newberg A, Kronstein P, Khalife S, Kammerer WA, Quezado Z, Luckenbaugh DA, Salvadore G, Machado-Vieira R, Manji HK, Zarate CA Jr. The trial lasted 2 weeks and included 18 patients, who received 0.5mg/kg IV infusion or placebo. The clinical response was defined as greater than 50% improvement from baseline on MADRS. The results of the study showed that 71% patients responded to ketamine and 1 of 16 (or 6%) responded to placebo at some point during the trial. The median time to initial response was 40 minutes. No serious adverse events occurred during the study.

- In 2012, a double-blind, randomized, crossover, placebo-controlled trial on Bipolar I or II depression was published by Zarate CA Jr, Brutsche NE, Ibrahim L, Franco-Chaves J, Diazgranados N, Cravchik A, Selter J, Marquardt CA, Liberty V, Luckenbaugh DA. The trial lasted 2 weeks and included 15 patients, who received 0.5mg/kg IV infusion or placebo. The clinical response was defined as greater than 50% improvement from baseline on MADRS. The results of the study showed that 79% percent of subjects responded to ketamine at some point during the trial (64% of patients receiving ketamine responded at 40 minutes) and 0% responded to placebo. No serious adverse events occurred during the study.

- In 2013, a randomized, controlled trial of a single infusion of ketamine compared to an active placebo control condition, the anesthetic midazolam on treatment-resistant MDD was performed by Murrough JW, Iosifescu DV, Chang LC, Al Jurdi RK, Green CE, Perez AM, Iqbal S, Pillemer S, Foulkes A, Shah A, Charney DS, Mathew SJ. The study lasted 4 weeks and included 72 patients, who received 0.5mg/kg IV infusion or active placebo (midazolam). The clinical response was defined as greater than 50% improvement from baseline in the score on the MADRS. The results of the study showed response rates at 24h were 64% in the ketamine group and 28% in the placebo group. There were 2 serious adverse events that occurred during the study. Patient 1's adverse event occurred on the day of infusion and consisted of hypotension (BP=73/40 for 1 min)/bradycardia (HR <30 bpm for 30 sec, followed by spontaneous recovery). This occurred while the subject was undergoing venipuncture at the 30 min time point and was considered a vaso-vagal episode. According to the study physician, there was a possible relation to study drug. Patient 2's adverse event occurred during the washout phase and consisted of a suicide attempt while tapering off of psychotropic medication. The patient was hospitalized following the attempted overdose. According to the study physician, there was no relation to study drug.

- In 2016, a randomized, double-blind, placebo-controlled trial of ketamine on treatment-resistant MDD was performed by Singh JB, Fedgchin M, Daly EJ, De Boer P, Cooper K, Lim P, Pinter C, Murrough JW, Sanacora G, Shelton RC, Kurian B, Winokur A, Fava M, Manji H, Drevets WC, Van Nueten L. The study lasted 2 weeks and included 67 patients, who received 0.5mg/kg IV infusion or placebo. The clinical response was defined as greater than 50% improvement from baseline in the score on the MADRS. The results of the study showed that at day 15, 68.8% of patients in the ketamine group responded to treatment as compared to 15.4% receiving placebo. There were 2 serious adverse events that occurred during the study, which consisted of anxiety leading to hospitalization on day 12 in one patient and suicide attempt on day 40 (i.e., more than 4 weeks after last dose) in another patient. Neither of these adverse events was considered by the study's responsible physician to be related to ketamine.

- In 2016, a randomized, double-blind, placebo-controlled trial of a single IV ketamine infusion on treatment-resistant MDD was performed by Hu YD, Xiang YT, Fang JX, Zu S, Sha S, Shi H, Ungvari GS, Correll CU, Chiu HF, Xue Y, Tian TF, Wu AS, Ma X, Wang G. The study lasted 4 weeks and included 30 patients, who received a single 0.5mg/kg IV infusion or placebo. The clinical response was defined as greater than 50% improvement from baseline in the score on the MADRS. The results of the study showed that by 4 weeks, 92.3% of patients in the ketamine group responded to treatment as compared to 57.1% in the placebo group. No serious adverse events occurred during the study.

- In 2017, a double-blind, randomized, parallel-group, placebo-controlled trial of a single ketamine infusion on treatment-resistant MDD was performed by Su TP, Chen MH, Li CT, Lin WC, Hong CJ, Gueorguieva R, Tu PC, Bai YM, Cheng CM, Krystal JH. The study lasted 2 weeks and included 71 patients who received 0.5mg/kg IV infusion or placebo. The clinical response was defined as greater than 50% reduction from baseline in the score on the HAMD on at least 2 days between days 2 and 5 after infusion. The results of the study showed that 45.8% of patients in the ketamine group responded as compared to 12.5% in the placebo group. No serious adverse events occurred during the study.

- In 2019, a randomized, double-blind, placebo-controlled trial of a single IV ketamine infusion on treatment-resistant MDD was performed by Fava M, Freeman MP, Flynn M, Judge H, Hoeppner BB, Cusin C, Ionescu DF, Mathew SJ, Chang LC, Iosifescu DV, Murrough J, Debattista C, Schatzberg AF, Trivedi MH, Jha MK, Sanacora G, Wilkinson ST, Papakostas GI. The study lasted 4 weeks and included 99 patients who received different IV ketamine infusion doses or active placebo (midazolam). Out of the 99 patients, 22 received 0.5mg/kg IV infusion and 19 received placebo The clinical response was defined as 50% or greater reduction from baseline on the HAM-D6. The results of the study showed that 59% of patients in the 0.5mg/kg ketamine group responded to treatment as compared to 11% in the active placebo group at the 24h endpoint assessment. There was one serious adverse event that occurred during the trial. The participant attempted suicide by overdosing on Day 11 and was subsequently evaluated by the study team and sent to the emergency room.

- In 2021, a randomized, double-blind, placebo-controlled trial of a single IV ketamine infusion on treatment-resistant MDD was performed by Dwyer JB, Landeros-Weisenberger A, Johnson JA, Londono Tobon A, Flores JM, Nasir M, Coulours K, Sanacora G, Bloch MH. The study lasted 2 weeks and included 17 patients, who received 0.5mg/kg IV infusion or placebo. The clinical response was defined as greater than or equal to 50% decrease in MADRS total score 24 hours after treatment. The results of the study showed that 76% of patients on the ketamine group responded to treatment as compared to 35% in the active placebo group at the 24h endpoint assessment. No serious adverse events occurred during the study.

The antidepressant effects of ketamine on treatment-resistant MDD even when administered in one single subanesthetic dose has been demonstrated in multiple studies, as set forth in a 2000 article published by Biological Psychiatry, a 2012 article published in PLOS One, a 2017 article published by Neuropsychopharmacology, a 2015 article published by Psychological Medicine, a 2018 article published by Journal of Affective Disorders.

In 2014, a randomized, double-blind, placebo-controlled trial of ketamine infusion on 41 chronic PTSD patients published by JAMA Psychiatry showed that 0.5mg/kg IV ketamine infusion produced a significant and rapid reduction in PTSD symptom severity within 24 hours of infusion when compared to placebo.

Our Strategy

Our core strategy is to become a leader in solving psychiatric and neurological disorders, one of the world's biggest clinical problems, through research, development, and commercialization of novel CNS drugs. Key elements of our business strategy are as follows:

- Research new drugs or the treatment of CNS disorders targeting the pathophysiology underlying the disease and with different mechanisms of action than conventional psychiatric and neurological drugs. Research is conducted under the leadership of Professor Lawrence Steinman, a renowned neurologist and immunologist based at Stanford University, and Dr. Tiago Reis Marques, a psychiatrist and neuroscientist at Imperial College and King's College London;

- Partner with reputable and successful healthcare companies and clinics to support the intravenous administration of ketamine to treat treatment-resistant depression and PTSD;

    - Create a capital efficient revenue stream with significant client bases across the United States and the U.K., including in Los Angeles, New York City, and London; and

    - Create a diversified revenue stream by establishing and supporting clinics to provide greater visibility of revenue and EBITDA.

Development Plan

We are currently focusing in two drug development programs in the following indications:

1. *Schizophrenia*: We are currently developing a brain-penetrant small molecules able to down regulate a novel neuroinflammatory pathway for the systemic treatment of schizophrenia. The work is currently being conducted by Evotec, utilizing Evotec's integrated research and development expertise and state-of-the-art structure-based drug design techniques.
2. *Multiple Sclerosis*: We are developing a tolerizing vaccine in Multiple Sclerosis and starting preclinical work. Preclinical work is currently being conducted at Hooke Laboratories, a full-service Contract Research Organization ("CRO") with deep experience in experimental autoimmune encephalomyelitis ("EAE"), the standard animal model of MS.

About Our Target Market

According to the National Institute of Mental Health, mental illnesses are common in the United States. Mental illnesses include many different conditions that vary in degree of severity, ranging from mild to moderate to severe. Two broad categories can be used to describe these conditions: AMI and SMI. AMI encompasses all recognized mental illnesses, whereas SMI is a smaller and more severe subset of AMI.

In 2019, there were an estimated 51.5 million adults aged 18 or older in the United States with AMI. Among the 51.5 million adults with AMI, 23.0 million (44.8%) received mental health services in the past year. In 2019, there were an estimated 13.1 million adults aged 18 or older in the United States with SMI, which represented 5.2% of all U.S. adults. Out of the 13.1 million adults with SMI, 8.6 million (65.5%) received mental health treatment in the past year.

A 2004 article published in the bulletin of the WHO suggests that many people with depression do not receive treatment, and that the "treatment gap" for major depression was 45.4% in the WHO European Region and 56.9% in the Americas. A comprehensive study of such undertreatment published in the British Journal of Psychiatry in 2017 showed that 1 in 5 patients with MDD in high-income countries and 1 in 27 in low-income countries received minimally adequate treatment and that only a minority of those with MDD, generally, receive either minimally adequate counseling, psychotherapy or antidepressant therapy. In addition, according to an article published by Cambridge University Press in 2018, the overall drop-out rate, or percentage of drop-outs from out-patient mental healthcare in WHO's Mental Health Survey initiative, sits at 31.7%.

According to BlueCross BlueShield, diagnosis of major depression in the US increased 33% between 2013 and 2016, and the rate is rising even faster among millennials (up to 47%) and adolescents (up to 47% for boys and 65% for girls). Further, a 2020 report published by Reports and Data indicates that the global anxiety and depression treatment market is anticipated to grow at a rate of 2.4% from $15.85 billion in 2019 to $19.21 billion in 2027, and that the market is mainly driven by the increasing prevalence of mental health issues like anxiety disorder and depression. According to the Harvard School of Public Health, mental health conditions alone will account for the loss of $16.1 trillion over a span of 20 years, from 2010 to 2030, with dramatic impact on productivity and quality of life.

According to the Mayo Clinic, treatment for mental illness largely depends on the type of mental illness and its severity. Currently, treatment can include psychiatric medication (such as anti-depressants, anti-anxiety medications, mood stabilizers, and antipsychotic drugs), psychotherapy, brain-stimulation treatments, hospitalization, substance misuse treatment, or any combination of the foregoing.

Recent Business Developments

On September 17, 2021, we sold 4,800,000 Units in our Initial Public Offering at a price of $5.00 per Unit for a total of $24,000,000. We incurred offering costs of $3,445,200, consisting of $2,137,800 of underwriting fees and expenses and $1,307,400 of costs related to the Initial Public Offering.

In October 2021, services commenced under the terms of an agreement entered into between our wholly owned UK subsidiary, Pasithea Therapeutics Limited ("Pasithea UK") and Purecare Limited (operating as Zen Knightsbridge Clinic) on 31 December 2020 and amended and re-stated on 4 August 2021 (the "Amended and Restated Zen Knightsbridge Collaboration Agreement").

In December 2021, services commenced under the terms of an agreement entered into between Pasithea UK and Portman Limited (operating as Zen Baker Street Clinic) on 31 December 2020 and amended and re-stated on 4 August 2021 (the "Amended and Restated Zen Baker Street Collaboration Agreement").

On November 17, 2021, we announced that Pasithea Clinics Corp. ("Pasithea Clinics"), our wholly owned Delaware subsidiary, intends to begin operations providing business support services to registered healthcare providers who assess patients and, if appropriate, administer intravenous infusions of ketamine in New York, Los Angeles, San Diego and San Francisco, offering in-home IV ketamine therapy to patients in those cities. On December 1, 2021, Pasithea Clinics announced its intention to expand its business support services to clinics in Nevada, and to offer, through registered healthcare providers, in-home IV ketamine therapy in the United States to patients in Florida, and Pasithea Clinics is exploring potential licensure necessary for the provision of such services. On January 26, 2022, Pasithea Clinics announced it intends to provide business support services at in-person clinics operated by registered healthcare providers in the United States, in the Los Angeles area during the second quarter of 2022.

On November 29, 2021, we consummated the November 2021 Private Placement, pursuant to which we issued 8,680,000 PIPE Shares and 8,680,000 Warrants to 21 institutional investors. The offering price per PIPE Share and accompanying Warrant was $3.50, resulting in aggregate proceeds of $30,380,000.

On February 3, 2022, we announced a new chemical entity ("NCE") development program aimed at developing a tolerizing vaccine for multiple sclerosis ("MS"). As part of this NCE development program, we named Hooke Laboratories as our research partner.

On March 8, 2022, we announced a partnership with The Glimpse Group, Inc. (Nasdaq: VRAR), a virtual reality ("VR") and augmented reality platform company. Pursuant to this partnership, we will co-develop with The Glimpse Group, Inc. (and its subsidiary Foretell Reality) VR-environments that will assist in our treatment of patients

with psychiatric disorders.

Services

Our secondary operations in the U.K., and our intended secondary operations in the United States, are focused on providing business support services to anti-depression clinics. Our operations in the U.K. involve providing business support services to registered healthcare providers who assess patients, and if appropriate, administer intravenous infusions of ketamine, and our intended operations in the United States involve providing business support services to entities that furnish similar services to patients who personally pay for those services. Operations initially take place across the United States and the U.K. through partnerships with healthcare companies, including Zen Healthcare and The IV Doc. Our operations in the U.K. are, and our intended operations in the United States will be, limited to providing business support services to healthcare companies. In the United States, certain of these business support services will be subcontracted to The IV Doc through a Business Support Services Subcontract. (See "Business – License Agreements and Strategic Collaboration") We do not provide professional medical services, establish or own anti-depression clinics, provide psychiatric assessments, or be responsible for the administration of intravenous infusions of ketamine in the United States. Furthermore, we do not obtain or administer ketamine, nor do we maintain any license or registration to own, maintain or dispense controlled substances in the U.K. or in the United States. We provide business support services to properly authorized companies that provide clinical services of the type described above to self-pay patients, and we subcontract certain of these business support services to The IV Doc.

United Kingdom. In the U.K., we have established Pasithea Therapeutics Limited as a wholly owned subsidiary to provide business support to ketamine services providers. As of December 31, 2021, Pasithea Therapeutics Limited had hired one employee who is responsible for marketing. Our U.K. branch has already partnered with Purecare Limited and Portman Health Ltd, which own Zen Healthcare, a general practice group with two locations in London: Knightsbridge and Baker Street. Zen Healthcare clinics treat patients, including providing psychiatric consultations, and have pharmacies that procure, handle, and administer ketamine in treatment rooms, providing all pharmaceuticals and equipment necessary for the assessment of patients and the provision of the Treatments. Zen Healthcare has been operating for five years and has approximately 30,000 patients. Its practices give us immediate exposure in the U.K.. Other advantages include gaining access to an existing management structure and qualified general practitioners, pharmacists, therapists, and psychotherapists.

During the year ended December 31, 2020, we entered into the Amended and Restated Zen Knightsbridge Collaboration Agreement with Purecare, as amended and restated on August 4, 2021, and the Amended and Restated Zen Baker Street Collaboration Agreement with Portman, as amended and restated on August 4, 2021. Under the Amended and Restated Zen Knightsbridge Collaboration Agreement and the Amended and Restated Zen Baker Street Collaboration Agreement, Purecare and Portman provide consulting and treatment rooms, apply for and maintain CQC registrations, employ or engage licensed and qualified staff, assess patients and, if appropriate, administer the Treatments, maintain equipment and provide all ketamine and other pharmaceuticals necessary for the Treatments at the Zen Knightsbridge Clinic and the Zen Baker Street Clinic, respectively. Under the Amended and Restated Zen Knightsbridge Collaboration Agreement and the Amended and Restated Zen Baker Street Collaboration Agreement, we, among other things, market the Treatments to the extent permitted under law, arrange and pay for the fit-out of the consulting room, provide equipment necessary for the Treatments, develop, operate and maintain a booking website for the Treatments, make bookings and take payments, and employ or engage customer services advisers to liaise with clinical staff and pay certain staff costs. Under both the Amended and Restated Zen Knightsbridge Collaboration Agreement and the Amended and Restated Zen Baker Street Collaboration Agreement, we receive 30% of all revenues less certain clinical staff costs which results from the provision of the Treatments provided at the Zen Knightsbridge Clinic and the Zen Baker Street Clinic. Services commenced in October 2021 and December 2021 under the Amended and Restated Zen Knightsbridge Collaboration Agreement and the Amended and Restated Zen Baker Street Collaboration Agreement respectively. (See "Business – License Agreements and Strategic Collaborations).

Our Chief Operating Officer, Head of U.K. Clinics and Director, Dr. Yassine Bendiabdallah, is a co-founder, current managing director, and 25% shareholder of Purecare. Dr. Bendiabdallah is also a co-founder and 16.25% shareholder of Portman. (See "Certain Relationships and Related Party Transactions.")

Our risks are mostly related to our reliance on ketamine as a key aspect of treatment because (i) ketamine is a controlled substance, (ii) ketamine would be prescribed for an unlicensed therapeutic indication, (iii) ketamine requires specific manufacture, storing, promotion and administration compliance, and (iv) ketamine poses certain clinical risks to patients.

First, in the U.K., 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. Possession of ketamine requires Home Office licensing and may only be stored on premises complying with professional strictures of the GPhC. As a controlled substance, ketamine requires production and supply from a manufacturer possessing MHRA manufacturing authorization which ensures the production of GMP quality ketamine. Additionally, like in the US, because IV ketamine has not yet been granted marketing authorization for the psychotherapy indication in the U.K., it must be regarded as an unlicensed medicine that is being used off label without its authorized indications for anesthesia and/or chronic pain. The GMC code of good practice allows a physician to prescribe an unlicensed medicine under his own responsibility and they will be required to abide by their professional regulatory requirements.

Moreover, English laws restrict the offering of inducements to persons qualified to prescribe medicinal products. The Human Medicines Regulations 2012, at Regulation 300(1), make it a criminal offence for a person, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, to supply, offer or promise to such persons any gift, pecuniary advantage or benefit unless it is inexpensive and relevant to the practice of medicine or pharmacy. It is also an offence for any person qualified to prescribe or supply medicines to solicit or accept any gift, pecuniary advantage or benefit in kind (Regulation 300(4)). The Bribery Act 2010, which provides a legal framework to combat bribery in the public and private sectors, includes criminal offenses covering the offering, promising or giving of an advantage, and requesting, agreeing to receive or accepting of an advantage; bribing a foreign public official and the corporate offense of failing to prevent bribery. A company will be found liable of committing this offence if an "associated person" performing services on its behalf bribes another person to obtain or retain business or a business advantage. The definition of associated persons is broad and will capture many business relationships, including joint venture partners, introducers and other intermediaries. The associated individual or entity that carries out the act of bribery on behalf of the organization need not have any connection to the U.K.. The SFO, which enforces the Bribery Act, will typically not seek to prosecute unless it considers that to do so is in the public interest; and in reaching that decision it would have regard to any relevant action already taken by the MHRA and the PMCPA. Further, the Human Medicines Regulations 2012, at Regulation 284, prohibit the publishing of any advertisement that is likely to lead to the use of a prescription only medicine such as ketamine.

Under English law, the provision of health and care services is a regulated activity and requires registration with the Care Quality Commission. The provision of regulated activities without registration is an offence .

Specifically, in the UK, we currently operate under Zen Healthcare's CQC registration and regulatory approvals and will have no independent employees providing health services.

Therefore, the associated risk factors relating to our ownership and operation of outpatient clinics dispensing and prescribing intravenous infusions of ketamine in the U.K. include that the MHRA may not approve manufacturing authorization for the production site responsible for production of ketamine; product defects may cause liabilities under civil law for negligence and products liability under the Consumer Protection Act 1987; clinics or the medical staff operating the clinics may not be able to comply with regulatory requirements and standards of performance demanded by the CQC and the GMC code of practice; similarly the operation of the clinics themselves may not comply with CQC rules on hygiene and safety; we may be found not to comply 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 promotion and marketing of medicinal products; we and/or associated persons

may be found to not be compliant with the Bribery Act 2010; and the prescription of ketamine for the unlicensed indication of acute depressive illness may increase prevalence of serious adverse events during the post marketing vigilance of the new formulation, damaging the commercial reputation of our potential products.

United States (including New York and California). In New York and California, we have established business support services agreements (BSSAs) with a California independent professional services company and an independent professional services company in New York that is organized and established under the laws of the state of New York. The independent professional services companies, through their employed or contracted medical providers (i.e., physicians and nurses), will provide clinical services. Individual clinicians, including psychiatrists, anesthesiologists, and nurses, all licensed and qualified to provide clinical services, will contract with the independent professional services companies to provide their services. Through our business support services agreements, we, in conjunction with The IV Doc, will provide non-clinical business support services necessary for the professional services companies to operate, including administrative services, information technology services and marketing services, online advertising, and other channels, in exchange for a flat fee.

Pasithea Clinics, an affiliate of the Company, has entered into a BSSA with the following professional corporations: Nadelson Medical PLLC and Nadelson Medical of CA, P.C. Elliot J. Nadelson, MD, is the sole owner of Nadelson Medical PLLC and Nadelson Medical of CA, P.C. These professional corporations are separate and independent entities from Pasithea Clinics, and have been organized consistent with the state professional licensing laws, including fee-splitting prohibitions, and all requirements for establishment of professional corporations in their respective states. The BSSA sets forth the details of the support services which will include non-medical administrative, financial, human resources, technology, and legal services to the professional corporations. Any service fees will be based on fair market value for the services Pasithea Clinics provides and no professional fees will be shared with Pasithea Clinics by the professional corporations.

As noted above, we have partnered with The IV Doc, a leading provider of administrative and support services to affiliated clinical practices providing intravenous infusions. Adam J. Nadelson, MD, serves as the Chief Executive Officer of The IV Doc and also holds voting power over the Living Trust of Adam Nadelson, a minority stockholder in the Company. (See "Certain Relationships and Related Party Transactions.") The IV Doc itself and through clinical affiliates has treated over 50,000 patients over the past seven years and has developed significant business support resources. The IV Doc has established relationships with over 800 clinicians in the intravenous infusion space. Through these efforts, The IV Doc has developed a national reputation for the provision of in-home infusion services, testing, and outpatient medical care. Pursuant to the Business Support Services Subcontract, we have access to The IV Doc's business support resources, which will allow us to provide superior business support services to the professional services companies with which we contract. We expect The IV Doc's business support resources will facilitate the efficient expansion of our intended operations in New York and Los Angeles to other locations utilizing The IV Doc business support services to assist their patient service delivery model, including The IV Doc software and technology and clinical services management resources.

We provide business support services to one or more professional services companies that utilize psychiatrists to perform diagnostic services and anesthesiologists to administer IV ketamine. Our business support services agreements require all independent practices receiving our business support services to ensure all clinicians possess and maintain all applicable state and local licenses during the course of their employment or contractual obligations. At this time, we do not plan on entering into business support services agreements with professional services companies that receive third-party reimbursement for their services.

In the United States, the FDA, the DEA and state agencies regulate the use, maintenance and distribution of ketamine. At the federal level, the FDA has approved ketamine for use as an anesthetic but not for subanesthetic intravenous administration for psychotherapy. However, in general, physicians may prescribe FDA-approved drugs for conditions other than what the drugs have been explicitly approved for (off-label use). Once a drug such as ketamine is approved for any use, physicians may prescribe those drugs for off-label uses consistent with applicable state medical practice requirements (see below). The DEA, under the federal Controlled Substance Act, oversees the maintenance and distribution of all controlled substances, including ketamine. Depending on the specific clinical protocols and standards established by the independent professional services company and the contracted or employed physicians prescribing and administering ketamine, the entity and/or the contracted or employed physicians will be required to comply with all DEA requirements. Our business support services agreements require all independent practices receiving our business support services to ensure the entity and/or the contracted or employed physicians comply with all DEA requirements.

Our business support services arrangements are subject to state laws, including those in certain of the states where we operate, which prohibit the practice of medicine by, and/or the splitting of professional fees with, non-professional persons or entities such as general business corporations. Corporate practice of medicine and fee-splitting prohibitions vary widely from state to state. In addition, such prohibitions are subject to broad powers of interpretation and enforcement by state regulators. Our failure to comply with state regulations could lead to adverse action against us and/or our providers by courts or state agencies, civil or criminal penalties, loss of provider licenses, or the need to restructure our business model and/or physician relationships, any of which could harm our business.

Under our BSSAs we provide various administrative and operations support services in exchange for scheduled fees at the fair market value of our services provided to each professional services company. As a result, our ability to receive cash fees from the professional services companies is limited to the fair market value of the services provided under the BSSAs. To the extent our ability to receive cash fees from the professional services companies is limited, our ability to use that cash for growth, debt service or other uses may be impaired and, as a result, our results of operations and financial condition may be adversely affected.

Our ability to perform business support services in a particular U.S. state is directly dependent upon the applicable laws governing the practice of medicine, healthcare delivery and fee splitting in such locations, which are subject to changing political, regulatory and other influences. The extent to which a U.S. state considers particular actions or contractual relationships to constitute the practice of medicine is subject to change and to evolving interpretations by medical boards and state attorneys general, among others, each of which has broad discretion. There is a risk that U.S. state authorities in some jurisdictions may find that our relationships with professional services companies violate laws prohibiting the corporate practice of medicine and fee splitting. Accordingly, we must monitor our compliance with laws in every jurisdiction in which we operate on an ongoing basis, and we cannot provide assurance that our activities and arrangements, if challenged, will be found to be in compliance with the law. Additionally, it is possible that the laws and rules governing the practice of medicine and fee splitting in one or more jurisdictions may change in a manner adverse to our business. While our BSSAs prohibit us from controlling, influencing or otherwise interfering with the practice of medicine at each professional services company, and provide that licensed physicians retain exclusive control and responsibility for all aspects of the practice of medicine and the delivery of medical services, we cannot assure you that our contractual arrangements and activities with the professional services companies are free from scrutiny from U.S. state authorities, including the possibility that a U.S. state regulatory authority would find that the BSSAs create an impermissible delegation of clinical control by a physician practice to an unlicensed person. We further cannot guarantee that subsequent interpretation of the corporate practice of medicine and fee splitting laws will not circumscribe our business operations. Further, notwithstanding our belief that the professional corporations have been organized and operate consistent with all applicable laws, these risks may be heightened due to the immediate familial relationship between Adam J. Nadelson, MD, the Chief Executive Officer of The IV Doc and the individual with voting power of the Living Trust of Adam Nadelson, a minority stockholder in the Company, and Elliot J. Nadelson, MD, the sole shareholder of each of Nadelson Medical PLLC and Nadelson Medical of CA, P.C. State corporate practice of medicine doctrines also often impose penalties on physicians themselves for aiding the corporate practice of medicine, which could discourage providers from participating in our network of physicians. If a successful legal challenge or an adverse change in relevant laws were to occur, and we were unable to adapt our business model accordingly, our operations in affected jurisdictions would be disrupted, which could harm our business.

Any material changes in our relationship with or among the professional services companies, whether resulting from a dispute among the entities, a challenge from a

governmental regulator, a change in government regulation, or the loss of these relationships or contracts with the professional services companies, could impair our ability to provide services to the professional services companies and could harm our business. Any scrutiny, investigation or litigation with regard to our arrangements with professional services companies, and any resulting penalties, including monetary fines and restrictions on or mandated changes to our current business and operating arrangements, could harm our business.

Moreover, identifying professional services companies, and negotiating and documenting relationships with them, requires significant time and resources. Our competitors may be more effective in executing such relationships and performing against them. If we are unsuccessful in establishing or maintaining our relationships with professional services companies, our ability to compete in the marketplace or to grow our net revenue could be impaired and our results of operations may suffer.

Financial Overview

We have experienced losses since inception and, at December 31, 2021, had an accumulated deficit of approximately $2.2 million. We expect to incur additional losses in the future and expect cumulative losses to increase. In January 2021, we received approximately $1.2 million in equity financing in connection with which we issued 635,594 shares of Common Stock to 29 accredited investors through a series of financings conducted pursuant to the Rule 506(b) Regulation D "safe harbor" for the private offering exemption of Section 4(a)(2) of the Securities Act completed in January 2021. On September 17, 2021, we sold 4,800,000 Units in our Initial Public Offering at a price of $5.00 per Unit for a total of $24,000,000. We incurred offering costs of $3,445,200, consisting of $2,137,800 of underwriting fees and expenses and $1,307,400 of costs related to the Initial Public Offering. On November 29, 2021, we consummated the November 2021 Private Placement, pursuant to which we issued 8,680,000 PIPE Shares and 8,680,000 Warrants to 21 institutional investors. The offering price per PIPE Share and accompanying Warrant was $3.50, resulting in aggregate proceeds of $30,380,000.

Competition in our Pharmaceutical Model

The pharmaceutical market for the treatment of major depressive disorder (MDD) includes selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors and atypical antipsychotics. A number of these marketed antidepressants will be generic, and would be key competitors to our future drug candidates. These products include Janssen Pharmaceuticals, Inc.'s Spravato (esketamine), Forest Laboratory's Lexapro/Cipralex (escitalopram) and Viibryd (vilazodone), Pfizer, Inc.'s Zoloft (sertraline), Effexor (venlafaxine) and Pristiq (desvenlafaxine), GlaxoSmithKline plc's Paxil/Seroxat (paroxetine), Eli Lilly and Company's Prozac (fluoxetine) and Cymbalta (duloxetine), AstraZeneca plc's Seroquel (quetiapine) and Bristol-Myers Squibb Company's Abilify (aripiprazole), among others.

We anticipate that competition in our industry will increase. In addition, the health care industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render future product candidates, or any products manufactured or marketed by us, non-competitive or otherwise obsolete.

Intellectual Property

We currently do not hold any intellectual property, but intend to develop product candidates that may be the subject of future patent applications.

TraDigital Services Agreement

On September 18, 2021, the Company entered into a services agreement with TraDigital Marketing Group ("TraDigital") pursuant to which TraDigital provide consulting services from September 18, 2021 through December 17, 2021 (the "Services Agreement"). The Services Agreement included a prepaid cash consulting fee of $394,000, payable and paid upon the agreement date; the Company expensed the total amount over the term of the agreement as selling, general and administrative expense as of December 31, 2021. The Services Agreement also includes 150,000 common shares of the Company due and earned upon the agreement date of September 18, 2021.

License Agreements and Strategic Collaborations

Zen Clinics

During the year ended December 31, 2020, we entered into the Amended and Restated Zen Knightsbridge Collaboration Agreement, as amended and restated on August 4, 2021, with Purecare, a company that operates the Zen Knightsbridge Clinic, whereby both parties have agreed to collaborate on the provision of Treatments at Purecare's London based clinic. During the year ended December 31, 2020, we entered into the Amended and Restated Zen Baker Street Collaboration Agreement, as amended and restated on August 4, 2021, with Portman, a company that operates the Zen Baker Street Clinic, whereby both parties have agreed to collaborate on the provision of Treatments at Portman's London based clinic.

Under the Amended and Restated Zen Knightsbridge Collaboration Agreement and the Amended and Restated Zen Baker Street Collaboration Agreement, Purecare and Portman provide consulting and treatment rooms, apply for and maintain CQC registrations, employ or engage licensed and qualified staff, assess patients and, if appropriate, administer the Treatments, maintain equipment and provide all ketamine and other pharmaceuticals necessary for the Treatments at the Zen Knightsbridge Clinic and the Zen Baker Street Clinic, respectively. Under the Amended and Restated Zen Knightsbridge Collaboration Agreement and the Amended and Restated Zen Baker Street Collaboration Agreement, we, among other things, market the Treatments to the extent permitted under law, arrange and pay for the fit-out of the consulting room, provide equipment necessary for the Treatments, develop, operate and maintain a booking website for the Treatments, make bookings and take payments, and employ or engage customer services advisers to liaise with clinical staff and pay certain staff costs. Under both the Amended and Restated Zen Knightsbridge Collaboration Agreement and the Amended and Restated Zen Baker Street Collaboration Agreement, we receive 30% of all revenues less certain clinical staff costs which results from the provision of the Treatments provided at the Zen Knightsbridge Clinic and the Zen Baker Street Clinic. The initial term of the Amended and Restated Zen Knightsbridge Collaboration Agreement and the Amended and Restated Zen Baker Street Collaboration Agreement commenced during the year ended December 31, 2020 and continues in effect for an initial term of two years and thereafter continues unless terminated on three months' notice by either party provided that this notice of termination may not be given during the initial term. Each party may terminate the Amended and Restated Zen Knightsbridge Collaboration Agreement and the Amended and Restated Zen Baker Street Collaboration Agreement, as applicable, immediately at any time by giving written notice to the other party upon the occurrence of certain conditions, including, but not limited to, the other party committing any default, breach or fraud, or the other party suspending or ceasing to carry on all or a substantial part of its business.

The IV Doc

On April 9, 2021, Pasithea Clinics, entered into a Business Support Services Subcontract (the "Subcontract") with The IV Doc, pursuant to which The IV Doc provides certain non-clinical administrative, back office, and other business support services to one or more professional medical practices in the State of New York provided under a BSSA with Pasithea Clinics. During the term of the Subcontract, Pasithea Clinics will pay The IV Doc monthly subcontract fees in consideration of the subcontract services rendered by The IV Doc. The subcontract fees, which are equal to $22,500 per month, which represents fair market value for the subcontract services and are commensurate with

the subcontract services to be provided, and do not constitute an illegal fee-splitting or impermissible profit-sharing arrangement in violation of any applicable laws. In addition to the subcontract fees, Pasithea Clinics reimburses The IV Doc for all reasonable expenses, including travel, meals and lodging expenses, incurred by The IV Doc in connection with the services provided pursuant to such agreement, provided that such expenses are otherwise commercially reasonable and necessary. The initial term of the Subcontract is 15 years, and will automatically renew for successive five-year terms unless either party delivers written notice to the other party of its intent not to renew at least 180 days before the end of the initial term or unless the Subcontract is earlier terminated pursuant to the terms thereof. The Subcontract may be terminated during the term by (a) mutual agreement of the parties, (b) by Pasithea Clinics immediately and without notice upon termination of the BSSA, (c) by Pasithea Clinics immediately upon written notice if The IV Doc breaches the Subcontract and fails to cure such breach within 45 days after receiving written notice from Pasithea Clinics or if The IV Doc admits in writing that it is unable to pay its debts generally when due, or (d) by The IV Doc immediately upon written notice if Pasithea Clinics breaches the Subcontract and fails to cure such breach within 45 days after receiving written notice from The IV Doc or if Pasithea Clinics admits in writing that it is unable to pay its debts generally when due.

Government Regulation and Drug Approval

Governmental Regulations

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 drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The FDA's Center for Drug Evaluation and Research would have primary jurisdiction over the premarket development, review and approval of our future product candidates. Accordingly, we have and plan to continue to investigate our products through the IND framework and seek approval through the NDA pathway. 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 after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA 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 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 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 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 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 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 does not satisfy the criteria for approval. The FDA could also approve the NDA 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 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, 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 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.

Controlled Substances

The federal Controlled Substances Act of 1970, or CSA, and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the DEA. The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence.

To conduct clinical trials with controlled substances in the United States prior to approval, each of the research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense the products and to obtain the product from a supplier. If the DEA delays or denies the grant of a research registration to one or more research sites, the clinical trial could be significantly delayed, and the clinical trial sites could be lost. The supplier for the clinical trials must also obtain a Schedule I registration.

If any proposed products developed receive FDA approval, the DEA will make a scheduling determination and place it in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. Consequently, its manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use may be subject to a significant degree of regulation by the DEA. Our failure to comply with these regulations could result in the loss of our DEA registration, civil penalties or criminal prosecution. In addition, the scheduling process may take one or more years, thereby delaying the launch of any product in the United States. Furthermore, if the FDA, DEA, or any foreign regulatory authority determines that any product may have potential for abuse, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of any proposed product.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s).

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary, to ensure that the United States complies with its obligations under international drug control treaties.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

The DEA, and some states, also conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

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 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, auto-immune 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 licence 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 31 December 2022, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorisation 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 licences 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.

Zen Healthcare has established consultants and advisors to ensure it operates in accordance with the CQC. Zen Healthcare also has responsibility under our agreements to obtain all the regulatory approvals and licenses to operate from the aforementioned bodies and complies with the MHRA, CQC and GPhC.

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.

Facilities and Operational Regulation

U.S.

Federal, state and local regulations (implemented by CMS, FDA, the Occupational Health and Safety Administration ("OSHA"), the DEA, and state departments or boards of public health, public welfare, medicine, nursing, pharmacy, and medical assistance, among others) would require us to meet various standards relating to, among other things, the management, licensing, safety, security and operation of facilities (including, e.g., laboratories, pharmacies, and clinics), personnel qualifications and licensing, the maintenance of proper records, equipment, and quality assurance programs, and the dispensing, storage, and administration of controlled substances. All of our clinics and facilities in the U.S. would be subject to periodic inspection by federal, state and local agencies to determine if the operations, premises, equipment, personnel and patient care meet applicable standards.

Our operations are subject to various federal, state and local hazardous and medical waste disposal laws. As currently in effect, laws governing the disposal of hazardous waste do not classify most of the waste produced in connection with the provision of our health care services as hazardous, although disposal of non-hazardous medical waste is subject to specific state regulation. Our operations are also subject to various air emission and wastewater discharge regulations.

Non-U.S.

We would be subject to a broad spectrum of regulation in other countries. Our operations must comply with various environmental and transportation regulations in the countries in which we operate. Our facilities and clinics are also subject to various standards relating to, among other things, facilities, management, personnel qualifications and licensing, maintenance of proper records, equipment, quality assurance programs, the operation of pharmacies, the protection of workers from blood-borne diseases and the dispensing of controlled substances. All of our operations may be subject to periodic inspection by various governmental authorities to determine if the operations, premises, equipment, personnel and patient care meet applicable standards. Our clinic operations and our related activities generally require licenses, which may be subject to periodic renewal and may be revoked for violation of applicable regulatory requirements.

In addition, many countries impose various investment restrictions on foreign companies. For instance, government approval may be required to enter into a joint venture with a local partner. Some countries do not permit foreign investors to own a majority interest in local companies or require that companies organized under their laws have at least one local stockholder. Investment restrictions therefore affect the corporate structure, operating procedures and other characteristics of our subsidiaries and joint ventures in these and other countries.

Human Capital Management

As of December 31, 2021, we had three full time employees, two part time employees and 7 contractors/consultants, in addition to Zen Healthcare's staff of over 60 team members across three clinics.] 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 device, biotechnology, 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 plan, pension, healthcare and insurance benefits, paid time off, family leave, and on-site services, 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. This includes having employees work from home, while implementing additional safety measures for employees continuing critical on-site work.

We consider our relations with our employees to be good.]

Environmental, Social and Governance Efforts

Environmental Commitment

We are committed to protecting the environment and attempt to mitigate any negative impact of our operations. We monitor resource use, improve efficiency, and at the same time reduce our emissions and waste.

We are systematically addressing the environmental impacts of the buildings we own as we make improvements, including adding energy control systems and other energy efficiency measures. Waste in our own operation is minimized by our commitment to reduce both single-use plastics and operating paper-free, primarily in a digital environment. We have safety protocols in place for handling biohazardous waste in our labs, and we use third-party vendors for biohazardous waste and chemical disposal.

Social Responsibility

For third-party vendor selection and oversight, we have standard operating procedures that apply to employees and subcontractors who on our behalf, oversee and conduct research regulated by the FDA. We retain ultimate authority and responsibility for the conduct of regulated research, manufacturing, and testing and we must ensure that contracted services are conducted in accordance with Good Practice Guidelines and all applicable regulations.

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 and research and development operations.

Legal Proceedings

We are not currently subject to any material legal proceedings.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.

Summary Risk Factors

The principal factors and uncertainties that make investing in our ordinary shares risky, include, among others:

Risks Relating to our Business

- 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.

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

- If the potential of our future product candidates to treat diseases is not realized, the value of our technology and our development programs could be significantly reduced.

- Our future product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations.

- If we are not able to recruit and retain qualified management and scientific personnel, we may fail in developing our technologies and our future product candidates.

- A member of our board of directors will be working for us on a part-time basis resulting in a potential lack of availability due to other commitments.

- Our future product candidates will represent new classes of therapy that the marketplace may not understand or accept.

- We have ongoing challenges with respect to our liquidity and access to capital.

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

- Public health threats, including those related to the novel strain of coronavirus, SARS-CoV-2 (which causes the disease now called COVID-19), could have an adverse effect on our operations.

- If we are unable to effectively adapt to changes in the health care industry, our revenue, profitability or liquidity could be adversely affected.

- 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.

- A variety of risks associated with marketing our future product candidates internationally could materially adversely affect our business.

- We plan to operate in a highly regulated sector and may not always succeed in complying fully with applicable regulatory requirements in all jurisdictions where we carry on business.

- Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any of our future therapeutic candidates and could have a material adverse effect on our business.

Risks Relating to Intellectual Property

- If our trade secret and patent position does not adequately protect our future product candidates and uses, others could compete against us more directly, which could harm our business and have a material adverse effect on our business, financial condition and results of operations.

- If we are unable to protect the confidentiality of our proprietary information, trade secrets, and know-how, our competitive position could be impaired and our business, financial condition, results of operations, and prospects could be adversely affected.

- Third-party claims of intellectual property infringement may prevent or delay our product development efforts.

- Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of any future patent applications and the enforcement or defense of any future patents.

- Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our future product candidates.

- Patent terms may be inadequate to protect our competitive position on our future product candidates for an adequate amount of time.

Risks Related to Regulatory Approval and Other Government Regulations

- Any product candidates we may develop in the future may be subject to controlled substance laws and regulations in the territories where the product may be marketed, such as the U.S. and the U.K., and failure to comply with these laws and regulations, or the cost of compliance, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition. In addition, during the review process of our future product candidates, and prior to approval, the FDA and/or other regulatory bodies may require additional data, including with respect to whether our future product candidates have abuse potential, which may delay approval and any potential rescheduling process.

- We cannot market and sell our future product candidates in the United States or in other countries if we fail to obtain the necessary regulatory approvals.

- Final marketing approval of our future product candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which could adversely affect our ability to generate operating revenues.

- We may not be able to secure and maintain research institutions to conduct our clinical trials.

- Producing and marketing an approved drug or other medical product is subject to significant and costly post-approval regulation.

- Clinical services in the U.K. include 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. Further, registration is required with the CQC for the provision of certain health and care services. If certain of our clinics and providers fail 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.

Risks Related to Our Dependence on Third Parties

- We may rely on third parties to provide us with supplies to produce our future product candidates. Any problems experienced by these third parties could result in a delay or interruption in the supply of our future product candidates for our clinical trials and future approved products to our customers, which could have a material negative effect on our business.

- We may become dependent upon third parties for services and raw materials needed for the manufacture of our future product candidates, and if these products are successfully commercialized, may become dependent upon third parties for product distribution. If any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver could be compromised.

- If we decide to use third-party manufacturers in the future, they will likely be dependent upon their own third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

- We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our future product candidates.

- We will depend on third-party distributors in the future to market and sell our future product candidates which will subject us to a number of risks.

- The successful commercialization of our future product candidates will depend on obtaining reimbursement from government and third-party payors.

- We may enter into arrangements with third-party collaborators to help us develop our product candidates and commercialize our products, and our ability to commercialize such products may be impaired or delayed if collaborations are unsuccessful.

Risks Related to the Discovery, Development and Commercialization of Our Future Product Candidates

- Interim, "topline" and preliminary data from our future clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

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

- 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.

- Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

- Inadequate funding for the FDA and other government agencies, or future government shutdown and or furlough of government employees, or public health emergencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being reviewed or approved in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

- Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

General Risk Factors

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

- 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.

- 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.

- 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.

- 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.

- 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 of directors.

Risks Relating to our Business

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.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage biotechnology companies in rapidly evolving fields, including, but not limited to, changes in FDA or foreign body regulatory oversight of such products. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. Such a transition may involve substantial additional capital requirements in order to launch and market a product, changes in the use of proceeds, and significant adjustment to personnel, compared to a clinical-stage development company. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

Clinical services in the US include 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 furnish business support services fail 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 providers who prescribe, dispense and administer ketamine are 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.

If the potential of our future product candidates to treat diseases is not realized, the value of our technology and our development programs could be significantly reduced.

Our team is currently exploring the potential of our future product candidates to treat psychiatric and neurological disorders. We have not yet proven in clinical trials that our future product candidates will be a safe and effective treatment for any disease or condition. Our future product candidates are susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their marketing approval or commercial use. We have not yet completed all of the testing necessary to allow us to make a determination that serious unintended consequences will not occur. If the potential of our future product candidates to treat disease is not realized, the value of our technology and our development programs could be significantly reduced.

Our future product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations.

Undesirable side effects observed in clinical trials or in supportive preclinical studies with our future product candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA or comparable foreign authorities for any or all targeted indications or adversely affect the marketability of any such product candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our future product candidates.

Our future product candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. There are also risks associated with additional requirements the FDA or comparable foreign authorities may impose for marketing approval with regard to a particular disease.

Our future product candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study, and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug, or could be limited to a more restricted patient population. Any risk management program required for approval of our future product candidates could potentially have an adverse effect on our business, financial condition and results of operations.

Undesirable side effects involving our future product candidates may have other significant adverse implications on our business, financial condition and results of operations. For example:

- we may be unable to obtain additional financing on acceptable terms, if at all;

- our collaborators may terminate any development agreements covering these product candidates;

- if any development agreements are terminated, we may determine not to further develop the affected product candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all;

- if we were to later continue the development of these product candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization;

- we may be subject to product liability or stockholder litigation; and

- we may be unable to attract and retain key employees.

In addition, if any of our future product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may withdraw their approval of the product, or we or our partners may decide to cease marketing and sale of the product voluntarily;

- we may be required to change the way the product is administered, conduct additional clinical trials or preclinical studies regarding the product, change the labeling of the product, or change the product's manufacturing facilities; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

If we are not able to recruit and retain qualified management and scientific personnel, we may fail in developing our technologies and our future product candidates.

Our future success depends to a significant extent on the skills, experience, and efforts of the principal members of our scientific and management personnel. These members include Professor Lawrence Steinman, Dr. Tiago Reis Marques and our staff of scientific consultants. The loss of any or all of these individuals could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. Competition for regulatory, clinical manufacturing and management personnel in the pharmaceutical industry is intense. We may be unable to recruit or retain personnel with sufficient management skills or attract or integrate other qualified management and scientific personnel in the future.

A member of our board of directors is working for us on a part-time basis resulting in a potential lack of availability due to other commitments.

Professor Steinman our director, is devoting his time in the performance of his duties to our board on a part-time basis, dedicating approximately 10 hours per week to this role. Professor Steinman also has other obligations, which may result in a lack of availability when needed due to responsibilities at his other jobs.

Our future product candidates will represent new classes of therapy that the marketplace may not understand or accept.

Even if we successfully develop and obtain regulatory approval for our product candidates, the market may not understand or accept them. We anticipate developing product candidates that represent novel treatment approaches and will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. The degree of market acceptance of any of our developed and potential products will depend on a number of factors, including:

- the clinical safety and effectiveness of our products and their perceived advantage over alternative treatment methods;

- our ability to demonstrate that our products can have a clinically significant effect in the treatment of depression and mental illness for which we may seek marketing approval;

- our ability to develop drugs that show efficacy for the treatment of psychiatric and neurological disorders;

- our ability to supply a sufficient amount of our products to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and

- the cost of our products and the reimbursement policies of government and third-party payors.

If the health care community does not accept our future product candidates or future approved products for any of the foregoing reasons, or for any other reason, it could affect our sales or have a material adverse effect on our business, financial condition, results of operations, and prospects.

We expect to function as a HIPAA "business associate" as defined under HIPAA and, as such, we expect to be subject to strict privacy and data security requirements. If we fail to comply with any of these requirements, we could be subject to significant liability, all of which can adversely affect our business.

The Health Insurance Portability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations ("HIPAA"), imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates." We expect to function as a business associate of HIPAA covered entities and service providers, and in that context, we are regulated as a business associate for the purposes of HIPAA.

HIPAA applies national privacy and security standards for protected health information ("PHI") to covered entities, including certain types of health care entities and their service providers that access PHI, known as business associates. HIPAA requires covered entities and business associates to maintain policies and procedures governing PHI that is used or disclosed, and to implement administrative, physical and technical safeguards to protect PHI, including PHI maintained, used and disclosed in electronic form. These safeguards include, by way of example, employee training and identifying third party service providers that are "business associates" or "subcontractors" with whom covered entities and business associates need to enter into HIPAA-compliant contractual arrangements. While we intend to undertake efforts to secure the PHI we create, receive, maintain, transmit, use and disclose in electronic form, a cyber-attack or other intrusion that bypasses our information security systems could cause an information security breach, loss of PHI or other data subject to privacy laws or a material disruption of our operational systems. This could result in a material adverse impact on our

business, along with potentially substantial fines and penalties. Ongoing implementation and oversight of these security measures involves significant time, effort and expense. HIPAA requires covered entities to report breaches of unsecured PHI to affected individuals without unreasonable delay and in no case later than 60 days after the discovery of the breach by the covered entity or its agents. Covered entities must also notify the U.S. Department of Health and Human Services ("HHS") and, in certain situations involving breaches that affect more than 500 individuals in a single state or jurisdiction, the media. Business associates are similarly required to report breaches of unsecured PHI to covered entities without unreasonable delay and in no case later than 60 days after discovery of the breach by the business associate or its agents. The HIPAA rules created a presumption that all non-permitted uses or disclosures of unsecured PHI are breaches unless the covered entity establishes that there is a low probability the information has been compromised. A data breach affecting sensitive personal information, including health information, could therefore result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. If we are unable to comply with our obligations as a HIPAA business associate, we could face substantial civil and even criminal liability. HITECH created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing such civil actions. Certain federal and state laws protect types of personal information that may be viewed as particularly sensitive. For example, the Confidentiality of Substance Use Disorder Patient Records (42 C.F.R. Part 2) is a federal law that protects information that would reveal if an individual has or had a substance abuse disorder. Similarly, many states have laws that protect other sensitive, individually identifiable information, including but not limited to, HIV-related information, genetic test results, and substance use disorder treatment. Some states have enacted laws that require health care providers to obtain consent before disclosing health information – even for treatment or payment purposes for which HIPAA does not typically require consent. HIPAA does not pre-empt federal or state laws that are more stringent than HIPAA, and therefore if we fail to comply with one or more of these more stringent federal or state laws, we could be subject to significant penalties and/or reputational harm.

The HIPAA covered entities and service providers to which we provide services require us to enter into HIPAA-compliant business associate agreements. These agreements impose stringent privacy and data security obligations on us. If we are unable to meet the requirements of any of these business associate agreements, we could face contractual liability under the applicable business associate agreement as well as possible civil and criminal liability under HIPAA, all of which can have an adverse impact on our business and generate negative publicity.

Even when HIPAA does not apply to the information we collect, according to the Federal Trade Commission, or the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair and/or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Enforcement actions by the FTC can result in corrective action plans and civil monetary penalties.

We may eventually compete for product sales with other companies, many of which will have greater resources or capabilities than we have, or may succeed in developing better products or in developing products more quickly than we do, and we may not compete successfully with them. Other companies and research institutions may obtain licenses or authorizations for drugs or for drugs with similar pharmacologies before we do which may affect our commercialization.

We compete or may eventually compete with other companies and organizations that are marketing or developing therapies for our targeted disease indications, based on traditional pharmaceutical, medical device, or other technologies. In addition, we have other potential competitors developing a variety of therapeutics, and in some cases, there may be tens or hundreds of companies seeking to commercialize therapeutics. The pharmaceutical market for the treatment of MDD includes selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors and atypical antipsychotics. A number of these marketed antidepressants will be generic, and would be key competitors to our future drug candidates. These products include Janssen Pharmaceuticals, Inc.'s Spravato (esketamine), Forest Laboratory's Lexapro/Cipralex (escitalopram) and Viibryd (vilazodone), Pfizer, Inc.'s Zoloft (sertraline), Effexor (venlafaxine) and Pristiq (desvenlafaxine), GlaxoSmithKline plc's Paxil/Seroxat (paroxetine), Eli Lilly and Company's Prozac (fluoxetine) and Cymbalta (duloxetine), AstraZeneca plc's Seroquel (quetiapine) and Bristol-Myers Squibb Company's Abilify (aripiprazole), among others.

We anticipate that competition in our industry will increase. In addition, the health care industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render future product candidates, or any products manufactured or marketed by us, non-competitive or otherwise obsolete.

We have ongoing challenges with respect to our liquidity and access to capital.

As we advance the development of our programs, we expect to continue to incur significant expenses and operating losses, for which we do not have offsetting revenue. We expect that our sales, research and development and general and administrative costs will increase in connection with conducting preclinical studies and clinical trials for our future programs and product candidates, contracting with contract research organizations (CROs) to support preclinical studies and clinical trials, establishing, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

Since May 2020, we have received approximately $55.9 million, net, in equity financing. As of December 31, 2021, we had approximately $53 million in cash and cash equivalents and working capital of approximately $52.9 million. There are no assurances that we will be able to continue to finance operations through these means, and our inability to generate sufficient revenue in the near term may have an adverse impact on our business, operations and prospects.

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

We have experienced losses since inception and, as of December 31, 2021, had an accumulated deficit of approximately $2.2 million. We expect to incur additional losses in the future and expect the cumulative losses to increase. There is no assurance that operating expenses will remain at current levels, nor that any potential grant revenue will fund our clinical programs. In such event, we will not have sufficient cash flow to meet our obligations or make progress in our clinical programs, and will need to raise additional capital to provide sufficient funding.

Public health threats, including those related to the novel strain of coronavirus, SARS-CoV-2 (which causes the disease now called COVID-19), could have an adverse effect on our operations.

Public health threats could adversely affect our planned research and development activities. In particular, SARS-CoV-2, which causes the disease now called COVID-19, was first reported to have surfaced in Wuhan, China in December 2019, and has since spread globally, including to every state in the United States. On January 31, 2020, the Secretary of HHS issued a Public Health Emergency determination in response to the spread of COVID-19. Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Starting in mid-March 2020, the governor of New York issued "shelter-in-place" or "stay at home" orders restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Similar orders and restrictions have been imposed in California and Massachusetts. Even after the "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19 are lifted, we may continue to experience disruptions to our business. The outbreak of COVID-19 has severely impacted global economic activity and caused significant volatility and negative pressure in financial markets. The global impact of the outbreak has been rapidly evolving and many countries, including the United States, have reacted by instituting quarantines, mandating business and school closures and restricting travel. As a result, the COVID-19 pandemic is negatively impacting almost every industry directly or indirectly.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage,

including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain the coronavirus or treat its impact, among others.

If we are unable to effectively adapt to changes in the health care industry, our revenue, profitability or liquidity could be adversely affected.

The health care industry continues to experience significant change driven by efforts to reduce costs and improve standards of care. In addition to reduction in Medicare, Medicaid and third-party reimbursement, these efforts include potential national health care reform, increased and restrictive pharmacy benefit management and horizontal and vertical consolidation within the health care industry. The results of these efforts may put additional downward pressure on pricing for our products and services, which may adversely affect our revenue, profitability or liquidity. Our inability to react effectively to these and other changes in the health care industry could adversely affect our business.

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 compete for nurses with hospitals and other healthcare providers, and we face increasing labor costs generally, and in particular, we continue to face increased labor costs and difficulties in hiring nurses due to a nationwide shortage of skilled clinical personnel that has been exacerbated by the ongoing COVID-19 pandemic. We have incurred and expect to continue to incur increased labor costs and experience staffing challenges related to COVID-19 while the pandemic persists, the extent of which will depend on the severity and duration of the pandemic, among other things. 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.

Our internal computer systems, or those of any of our future CROs, manufacturers, other contractors, consultants, or collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants, collaborators and third-party service providers, are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as HIPAA, EU Regulation 2016/679, the General Data Protection Regulation (GDPR) and the United Kingdom GDPR), it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions.

In addition, some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Mandated notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture our future product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our future product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

We currently do not have insurance policies to compensate us for the potential losses arising from any such disruption, failure or security breach, and we may not be able to obtain insurance policies on favorable terms. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

A variety of risks associated with marketing our future product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our future product candidates outside of the United States, and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

- difficulties staffing and managing foreign operations;

- workforce uncertainty in countries where labor unrest is more common than in the United States;

- potential liability under the FCPA or comparable foreign regulations;

- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We may face limitations on ownership of controlled substances licenses.

In certain states, the controlled substances laws and regulations limit not only the number of licenses issued, but also the number of licenses that one person or entity may own. Such limitations on the ownership of additional licenses within certain states may limit our ability to expand in such states.

We operate in a highly regulated sector and may not always succeed in complying fully with applicable regulatory requirements in all jurisdictions where we carry on business.

Our business and activities are heavily regulated in all jurisdictions where we plan to carry on business. Our operations are subject to various laws, regulations and guidelines by state and local governmental authorities relating to the manufacture, marketing, management, transportation, storage, and also including laws and regulations relating to health and safety, insurance coverage, the conduct of operations and the protection of the environment. Laws and regulations, applied generally, grant government agencies and self-regulatory bodies broad administrative discretion over our activities, including the power to limit or restrict business activities as well as impose additional disclosure requirements on our products and services. Achievement of our business objectives is contingent, in part, upon compliance with regulatory requirements enacted by these governmental authorities and obtaining all necessary regulatory approvals for the manufacture, production, storage, transportation, sale, import and export, as applicable, of our products. The industry is still a new industry at the state and local level. The effect of relevant governmental authorities' administration, application and enforcement of their respective regulatory regimes and delays in obtaining, or failure to obtain, applicable regulatory approvals which may be required may significantly delay or impact the development of markets, products and sales initiatives and could have a material adverse effect on our business, prospects, revenue, results of operation and financial condition.

While we endeavor to comply with all relevant laws, regulations and guidelines and, to our knowledge, we are in compliance or are in the process of being assessed for compliance with all such laws, regulations and guidelines, any failure to comply with the regulatory requirements applicable to our operations may lead to possible sanctions including the revocation or imposition of additional conditions on licenses to operate our business; the suspension or expulsion from a particular market or jurisdiction or of our key personnel; the imposition of additional or more stringent inspection, testing and reporting requirements; and the imposition of fines and censures. In addition, changes in regulations, more vigorous enforcement thereof or other unanticipated events could require extensive changes to our operations, increase compliance costs or give rise to material liabilities and/or revocation of our licenses and other permits, which could have a material adverse effect on our business, results of operations and financial condition. Furthermore, governmental authorities may change their administration, application or enforcement procedures at any time, which may adversely impact our ongoing costs relating to regulatory compliance.

We may not be able to successfully engage physicians and other healthcare professionals in need of our services.

Our ability to engage physicians and other healthcare professionals will affect our performance. Our support services related to the infusion of ketamine are furnished to physicians with a greater degree of specialized skills, training and experience than in other areas of practice. This decreases the number of healthcare professionals who may be recipients of our services. Moreover, we compete with other entities to furnish business support services to physician practices. Our future success depends in part on our ability to engage physicians and other healthcare professionals to maintain and expand our operations.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any of our future therapeutic candidates and could have a material adverse effect on our business.

In the United States, the EU and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. Highlighting the U.S. in particular by way of example, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "ACA"), substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry.

Among the provisions of the ACA of importance to our potential therapeutic candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs, a Federal and state program which extends healthcare to low-income individuals and other groups, by, among other things, allowing states to offer Medicaid coverage to certain individuals and adding new eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program, which requires that drug manufacturers provide rebates to states in exchange for state Medicaid coverage for most of the manufacturers' drugs by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans (i.e., a type of Medicare healthcare plan offered by private companies);

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;

- expansion of the types of entities eligible for the 340B drug discount program, which requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations and covered entities at significantly reduced prices;

- establishment of the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% point-of-sale-discount (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 1, 2019) off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;

- creation of a new non-profit, nongovernmental institute, called the Patient-Centered Outcomes Research Institute, to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and

- establishment of the Center for Medicare and Medicaid Innovation within Centers for Medicare & Medicaid to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business. Additionally, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the tax penalty on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the "individual mandate." Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On June 17 2021, the U.S. Supreme Court held in a 7–2 opinion that the states and individuals that brought the lawsuit challenging the ACA's individual mandate did not have standing to challenge the law. The Supreme Court did not reach the merits of the challenge, but the decision ends the case.

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 the ACA. Instead, it is possible that legislation will be pursued to enhance or reform the ACA. We are not able to state with certainty what the impact of potential legislation will be on our business. This uncertainty is heightened by President Biden's January 28, 2021 Executive Order on Strengthening Medicaid and the Affordable Care Act which indicates that the incoming Biden Administration may significantly modify the ACA and potentially revoke any changes implemented by the Trump Administration. It is also possible that President Biden will further reform the ACA and other federal programs in manner that may impact our operations. The Biden Administration has indicated that a goal of its administration is to expand and support Medicaid and the ACA and to make high-quality healthcare accessible and affordable. The potential increase in patients covered by government funded insurance may impact our pricing. Further, it is possible that the Biden Administration may further increase the scrutiny on drug pricing. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product or product candidates to be medically necessary or cost-effective compared to other available therapies.

Additionally, the containment of healthcare costs (including drug prices) has become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. For example, the Biden Administration, including his nominee for Secretary of DHHS, has indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take or whether such steps will be successful. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products or product candidates if approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition. In addition, state and federal healthcare reform measures have been and 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 products or product candidates once approved or additional pricing pressures.

Risks Relating to Intellectual Property

If our trade secret and patent position does not adequately protect our future product candidates and uses, others could compete against us more directly, which could harm our business and have a material adverse effect on our business, financial condition and results of operations.

Our success depends, in large part, on our ability to obtain and maintain intellectual property protection for our future product candidates. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions, and continues to be the subject of much litigation. Our trade secrets will remain valid and enforceable without regard to limitations such as term restrictions that are imposed on patents. Our trade secrets and know-how are the subject of various license agreements and confidentiality agreements as further discussed below.

The claims of U.S. and foreign patent applications and patents that may in the future be owned by the Company or under an obligation of assignment to the Company, or those to be licensed to us, may not confer on us significant commercial protection against competing products. Furthermore, to the extent that the Company owns or is assigned or licenses patent rights covering its business, third parties may challenge or design around those patent rights, such as by asserting that the patents are invalid or arguing that the patent claims should be narrowly construed, and thereby avoid infringement actions. The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. To the extent our future product candidates based on that technology are not commercialized ahead of this patent expiration, to the extent we have no other patent protection on such products, or to the extent that regulatory or patent extensions are not granted, those products might not have the robust protection we currently expect to enjoy. The background technologies used in the development of our future product candidates are known in the scientific community, and it may be possible to duplicate the methods we use to create our future product candidates, which makes us vulnerable to competition, without the ability to exclude others from potentially commercializing a similar product.

If we are unable to protect the confidentiality of our proprietary information, trade secrets, and know-how, our competitive position could be impaired and our business, financial condition, results of operations, and prospects could be adversely affected.

As disclosed above, some aspects of our technology, especially regarding manufacturing processes, will be unpatented and maintained by us as trade secrets. In an effort to protect these trade secrets, we will require our employees, consultants, collaborators, and advisors to execute confidential disclosure agreements before the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators, or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets could impair our competitive position and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement may prevent or delay our product development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we will develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our future product candidates, methods of making product candidates, and methods of using product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we infringe their patents or are otherwise employing their proprietary technology without authorization and may sue us. Generally, conducting clinical trials and other acts relating to FDA approval are not considered acts of infringement in the United States.

Additionally, there may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our future product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our future product candidates may infringe. Some of those patent applications may not yet be available for public inspection. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our future product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held not infringed, unpatentable, invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held not infringed, unpatentable, invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our future product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our future product candidates. They might seek an exclusion order from the International Trade Commission to prevent import of our future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our future product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our future product candidates, which could harm our business significantly.

We may become involved in lawsuits to protect or enforce our future patents or the patents of our collaborators or licensors, which could be expensive and time consuming.

Litigation may be necessary to enforce future patents we own or that are licensed to us, to protect trade secrets or know-how, or to determine the scope and validity of the proprietary rights. Litigation, opposition, or other patent office proceedings could result in substantial additional costs and diversion of management focus. If we are ultimately unable to protect our technology, trade secrets, or know-how, we may be unable to operate profitably. Competitors may infringe any future patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to protect our proprietary rights, which can be expensive and time-consuming, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or is unenforceable, or may refuse to enjoin the other party from using the technology at issue. An adverse determination of any litigation or defense proceedings could put any future patents at risk of being invalidated or interpreted narrowly. Litigation or other patent office proceedings may fail and, even if successful, may result in substantial costs and distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, though we would seek protective orders where appropriate, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our Common Stock could be significantly harmed.

The biotechnology industry, including our fields of therapeutic interest, is highly competitive and subject to significant and rapid technological change. Accordingly, our success may depend, in part, on our ability to respond quickly to such change through the development and introduction of new products. Our ability to compete successfully against currently existing and future alternatives to our future product candidates and systems and competitors who compete directly with us in the biopharmaceutical industry may depend, in part, on our ability to attract and retain skilled scientific and research personnel, develop technologically superior products, develop competitively priced products, obtain patents direct to our products or any required regulatory approvals for our products, and be early entrants to the market and manufacture, market, and sell our products, independently or through collaborations. If a third party were to commercialize a competitive product, there is no assurance that we would have a basis for initiating patent infringement proceedings or that, if initiated, we would prevail in such proceedings.

If our future product candidates are approved by the FDA, then potential competitors who seek to introduce generic versions of our product candidates may seek to take advantage of the abbreviated approval pathway for products shown to be similar to or interchangeable with our product candidates. The Biologics Price Competition and Innovation Act of 2009 might permit these potential competitors to enter the market using a shorter and less costly development program for a biosimilar product that competes with our future products.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our Common Stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property at that time could be diminished. Accordingly, the market price of shares of our Common Stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of any future patent applications and the enforcement or defense of any future patents.

In September 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the United States Patent and Trademark Office (USPTO) after March 2013 but before us could therefore be awarded a patent covering an invention of that we also made even if we had made the invention before the invention was made independently by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we will be the first to either (1) file any patent application related to our future product candidates or (2) invent any of the inventions claimed in any future patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, any future patents rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a patent claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate any future patents claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or licensors' patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our future product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in any future patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

Patent terms may be inadequate to protect our competitive position on our future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, are limited. Even if patents directed to our product candidates are obtained, once the patent term has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of future product candidates, patents directed to our future product candidates might expire before or shortly after such candidates are commercialized.

If we or our licensors do not obtain patent term extension for our future product candidates and/or methods of their use, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our future product candidates and their methods of use, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, or the Biologics Price Competition and Innovation Act of 2009. These laws 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. A maximum of one patent may be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended.

Patent term extension may also be available in certain foreign countries upon regulatory approval of our future product candidates. However, we or our licensors may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Patent term extension may also not be granted because the product candidates and/or methods of use are determined not to be the first permitted marketing or use of those drug candidates in the jurisdiction in question, or patent term extension may not be granted because the product candidates and/or methods of use are determined not to constitute an "active ingredient" or use of an "active ingredient" that is eligible for patent term extension. Moreover, even if patent term extension is granted, the additional time period or the scope of patent protection afforded could be less than we request. If we or our licensors are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following any future patent expiration, and our revenue

could be reduced, possibly materially. Further, if this occurs, our competitors may be able to take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their products earlier than might otherwise be the case.

Risks Related to Regulatory Approval and Other Government Regulations

If we are not able to successfully develop and commercialize our product candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations.

To generate sales revenue from our future product candidates, we must successfully develop and commercialize our product candidates, which includes conducting extensive preclinical studies and clinical trials to demonstrate that our future product candidates are safe and effective and obtaining required regulatory approvals. Our early-stage product candidates may fail to perform as we expect. Moreover, our future product candidates in later stages of development may fail to show the required safety and effectiveness for approval despite having progressed successfully through preclinical or initial clinical testing. We may need to devote significant additional research and development, financial resources, and personnel to develop commercially viable products. If our future product candidates do not prove to be safe and efficacious in clinical trials, we will not obtain the required regulatory approvals. If we fail to obtain such approvals, we may not generate sufficient revenues to continue our business operations.

Even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers, and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market or a withdrawal of the approved application by the FDA. Furthermore, FDA may require post-approval studies or other commitments from us, and failure to comply with or meet those commitments could result in withdrawal of the approved application by FDA. Regulatory agencies may also establish additional regulations, policies, or guidance that could prevent or delay regulatory approval of our future product candidates.

Any product candidates we may develop in the future may be subject to controlled substance laws and regulations in the territories where the product may be marketed, such as the U.S. and the U.K., and failure to comply with these laws and regulations, or the cost of compliance, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition. In addition, during the review process of our future product candidates, and prior to approval, the FDA and/or other regulatory bodies may require additional data, including with respect to whether our future product candidates have abuse potential, which may delay approval and any potential rescheduling process.

In the U.S., certain substances are classified by the Drug Enforcement Administration (the "DEA") as "Controlled Substances" or scheduled substances, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act, or CSA. The DEA regulates chemical compounds, including by means of manufacturing and procurement quotas, security requirements criteria for importation, dispensing restrictions and commercial marketing restrictions.

Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. During the review process, and prior to approval, the FDA may determine that it requires additional data, either from non-clinical or clinical studies, including with respect to whether, or to what extent, the substance has abuse potential. This may introduce a delay into the approval and any potential rescheduling process. That delay would be dependent on the quantity of additional data required by the FDA. This scheduling determination will require DEA to conduct notice and comment rule making including issuing an interim final rule. Such action will be subject to public comment and requests for hearing which could affect the scheduling of these substances. There can be no assurance that the DEA will make a favorable scheduling decision. Even assuming adequate categorization at the federal level, such substances would also require scheduling determinations under state laws and regulations.

Similarly, the MHRA considers that all Schedule 1 drugs under the U.K.'s Misuse of Drugs Regulations 2001 have no therapeutic benefit, and can only be imported, exported, produced, supplied and the like under a license issued by the U.K. Government's Home Office. Our future product candidates and their compounds may never be rescheduled under the Misuse of Drugs Regulations 2001, or reclassified under the U.K.'s Misuse of Drugs Act 1971.

In the U.K., entities in our supply chain, including third party collaborators in research or research sites, may be required to hold Home Office licenses and comply with necessary control measures. Import and export licenses may be required if sites are not located in the U.K.

In England, the provision of healthcare services requires registration with the CQC.

We cannot market and sell our future product candidates in the United States or in other countries if we fail to obtain the necessary regulatory approvals.

We cannot sell our future product candidates until regulatory agencies grant marketing approval. We have not previously submitted a New Drug Application, or NDA, to the FDA, or a Marketing Authorization Application, or MAA, to the EMA or the MHRA. Before obtaining regulatory approvals for the commercial sale of our product candidates or any future therapeutic candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our future product candidates are safe and effective for use in each target indication. 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, and there is a high risk of failure and we may never succeed in developing marketable products.

The regulatory approval process of the FDA, the EMA, the MHRA, and comparable foreign authorities are lengthy, time-consuming, expensive, inherently unpredictable, and uncertain, and the legal requirements for obtaining approval may change. It is likely to take several years to obtain the required regulatory approvals for our future product candidates, or we may never gain the necessary approvals. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our operations.

We may encounter delays or rejections if changes occur in regulatory agency regulations, policies or guidance during the period in which we develop a product candidate or during the period required for review of any application for regulatory agency approval. If we are not able to obtain regulatory approvals for use of our future product candidates under development, we will not be able to commercialize such products, and therefore may not be able to generate sufficient revenues to support our business.

Our future product candidates could fail to receive regulatory approval from the FDA, the EMA, the MHRA or comparable foreign regulatory authorities or be precluded from commercial marketing for many reasons, including the following:

- the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may disagree with, question or request changes in the design or implementation of our clinical trials;

- the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective, or have undesirable or unintended side effects, toxicities, or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;

- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA, the MHRA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that our future product candidates or any future therapeutic candidate's clinical and other benefits outweigh its safety risks;

- the FDA, the EMA, the MHRA 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 sufficient to support the submission of an NDA or other submission, or to obtain regulatory approval in the United States or elsewhere;

- the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the approval policies or regulations of the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and

- the potential risk of our novel therapy and delivery method, including the use of third-party clinical trial sites and therapists.

The FDA, the EMA, the MHRA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for our future product candidates or any future therapeutic candidates. Even if we believe the data collected from clinical trials of our future product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA, the MHRA or any other regulatory authority. If our future product candidates fail to obtain approval on the basis of any applicable condensed regulatory approval process, this will prevent such therapeutic candidate from obtaining approval on a shortened time frame, or at all, resulting in increased expenses which would materially harm our business.

In addition, even if we were to obtain approval, regulatory or pricing authorities may approve our future product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products or therapies, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a therapeutic candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that therapeutic candidate.

Even if our future product candidates receive regulatory approval in the U.S., we may never receive approval or commercialize our future product candidates outside of the U.S.

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to develop foreign markets for our future product candidates.

Our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate, or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval may be delayed or denied by the FDA.

Final marketing approval of our future product candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which could adversely affect our ability to generate operating revenues.

Final marketing approval for our future product candidates may be delayed, limited, or denied if, among other factors:

- we are unable to satisfy the significant clinical testing required to demonstrate safety and effectiveness of our future product candidates before marketing applications can be filed with the FDA;

- FDA does not agree with our interpretation of data obtained from preclinical and nonclinical animal testing and clinical trials, even though the data can be interpreted in different ways;

- we fail at any stage of the development and testing of our future product candidates, which may take years to complete;

- we receive negative or inconclusive results or reports of adverse side effects during a clinical trial; or

- the FDA requires us to expand the size and scope of the clinical trials.

If marketing approval for our future product candidates is delayed, limited, or denied, our ability to market products, and our ability to generate product sales, could be adversely affected.

We may not be able to secure and maintain research institutions to conduct our clinical trials.

We rely on research institutions to conduct our 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.

Producing and marketing an approved drug or other medical product is subject to significant and costly post-approval regulation.

Even if approved for commercial sale, we may be required to conduct Phase IV clinical trials or comply with other post-marketing requirements for our future product candidates. Even if we obtain approval of our future product candidates, we can only market the product for the approved indications. After granting marketing approval, the

FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers, and manufacturing facilities, creating additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions on the product or manufacturer, including a withdrawal of the future product candidates from the market. Further, regulatory agencies may establish different or additional regulations that could impact the post-marketing status of our products.

We face exposure to the risk that employees, independent contractors or consultants may engage in fraudulent or illegal activity.

We face exposure to the risk that employees, independent contractors or consultants may engage in fraudulent or other illegal activities. Misconduct by these parties could be intentional, reckless and/or negligent conduct. There may be disclosure of unauthorized activities that violate government regulations, manufacturing standards, healthcare laws, abuse laws and other financial reporting laws. Further, it may not always be possible for us to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not always be effective. As a result, we could face potential penalties and litigation.

If current or future laws or regulations force us to restructure our arrangements with physician practices, we may incur additional costs, lose contracts and suffer a reduction in net revenue under existing contracts.

A number of laws bear on our relationships with our physicians. Our business support services arrangements will be subject to state laws, including those in certain of the states where we operate, which prohibit the practice of medicine by, and/or the splitting of professional fees with, non-professional persons or entities such as general business corporations. Corporate practice of medicine and fee-splitting prohibitions vary widely from state to state. In addition, such prohibitions are subject to broad powers of interpretation and enforcement by state regulators. Our failure to comply could lead to adverse action against us and/or our providers by courts or state agencies, civil or criminal penalties, loss of provider licenses, or the need to restructure our business model and/or physician relationships, any of which could harm our business.

Under our BSSAs we provide various administrative and operations support services in exchange for scheduled fees at the fair market value of our services provided to each professional services company. As a result, our ability to receive cash fees from the professional services companies is limited to the fair market value of the services provided under the BSSAs. To the extent our ability to receive cash fees from the professional services companies is limited, our ability to use that cash for growth, debt service or other uses may be impaired and, as a result, our results of operations and financial condition may be adversely affected.

Furthermore, our ability to perform business support services in a particular U.S. state is directly dependent upon the applicable laws governing the practice of medicine, healthcare delivery and fee splitting in such locations, which are subject to changing political, regulatory and other influences. The extent to which a U.S. state considers particular actions or contractual relationships to constitute the practice of medicine is subject to change and to evolving interpretations by medical boards and state attorneys general, among others, each of which has broad discretion. There is a risk that U.S. state authorities in some jurisdictions may find that our relationships with professional services companies violate laws prohibiting the corporate practice of medicine and fee splitting. Accordingly, we must monitor our compliance with laws in every jurisdiction in which we operate on an ongoing basis, and we cannot provide assurance that our activities and arrangements, if challenged, will be found to be in compliance with the law. Additionally, it is possible that the laws and rules governing the practice of medicine and fee splitting in one or more jurisdictions may change in a manner adverse to our business. While our BSSAs prohibit us from controlling, influencing or otherwise interfering with the practice of medicine at each professional services company, and provide that licensed physicians retain exclusive control and responsibility for all aspects of the practice of medicine and the delivery of medical services, we cannot assure you that our contractual arrangements and activities with the professional services companies are free from scrutiny from U.S. state authorities, including the possibility that a U.S. state regulatory authority would find that the BSSAs create an impermissible delegation of clinical control by a physician practice to an unlicensed person. We further cannot guarantee that subsequent interpretation of the corporate practice of medicine and fee splitting laws do not circumscribe our business operations. Further, notwithstanding our belief that the professional corporations have been organized and operate consistent with all applicable laws, these risks may be heightened due to the immediate familial relationship between Adam J. Nadelson, MD, the Chief Executive Officer of The IV Doc and the individual with voting power of the Living Trust of Adam Nadelson, a minority stockholder in the Company, and Elliot J. Nadelson, MD, the sole shareholder of each of Nadelson Medical PLLC and Nadelson Medical of CA, P.C. State corporate practice of medicine doctrines also often impose penalties on physicians themselves for aiding the corporate practice of medicine, which could discourage providers from participating in our network of physicians. If a successful legal challenge or an adverse change in relevant laws were to occur, and we were unable to adapt our business model accordingly, our operations in affected jurisdictions would be disrupted, which could harm our business.

Any material changes in our relationship with or among the professional services companies, whether resulting from a dispute among the entities, a challenge from a governmental regulator, a change in government regulation, or the loss of these relationships or contracts with the professional services companies, could impair our ability to provide services to the professional services companies and could harm our business. Any scrutiny, investigation or litigation with regard to our arrangements with professional services companies, and any resulting penalties, including monetary fines and restrictions on or mandated changes to our current business and operating arrangements, could harm our business.

Moreover, identifying professional services companies, and negotiating and documenting relationships with them, requires significant time and resources. Our competitors may be more effective in executing such relationships and performing against them. If we are unsuccessful in establishing or maintaining our relationships with professional services companies, our ability to compete in the marketplace or to grow our net revenue could be impaired and our results of operations may suffer.

Antitrust laws may deem each such physician/entity to be separate, both from us and from each other and, accordingly, each such physician/practice is subject to a wide range of laws that prohibit anti-competitive conduct between or among separate legal entities or individuals. A review or action by regulatory authorities or the courts could force us to terminate or modify our contractual relationships with affiliated medical groups or revise them in a manner that could be materially adverse to our business.

Various licensing laws, regulations and standards apply to our affiliated physicians and our relationships with our affiliated physicians. Failure to comply with these laws and regulations could result in our services being found to be non-reimbursable or prior payments being subject to recoupment, and can give rise to civil or criminal penalties. While we have made reasonable efforts to ensure our affiliated physician practices and our relationships with our affiliated physician practices substantially comply with licensing laws and regulations and standards, we cannot assure you that agencies that administer these programs will not find that the affiliated practices or our relationships with our affiliated practices have failed to comply in some material respects.

Adverse judicial or administrative interpretations could result in a finding that we are not in compliance with one or more of these laws and rules that affect our relationships with our physicians.

These laws and rules, and their interpretations, may also change in the future. Any adverse interpretations or changes could force us to restructure our relationships with physicians or professional corporations, or to restructure our operations. This could cause our operating costs to increase significantly. A restructuring could also result in a loss of contracts or a reduction in revenue under existing contracts.

Clinical services in the U.K. include 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 clinics and providers fail 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 ownership and operation of outpatient clinics dispensing and prescribing intravenous infusions of ketamine in the U.K. include that the MHRA may not approve manufacturing authorization for the production site responsible for production of ketamine; product defects 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 be able to comply with standards of performance demanded by the CQC and the GMC code of practice; similarly the operation of the clinics themselves may not comply with CQC rules on hygiene and safety; we may be found not to comply 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 promotion and marketing of medicinal products; and the prescription of ketamine for the unlicensed indication of acute depressive illness may increase prevalence of serious adverse events during the post marketing vigilance of the new formulation, damaging the commercial reputation of our potential products. Additionally, we and/or associated persons may be found to not be compliant with the Bribery Act 2010, which includes criminal liability.

Risks Related to Our Dependence on Third Parties

We may rely on third parties to provide us with supplies to produce our future product candidates. Any problems experienced by these third parties could result in a delay or interruption in the supply of our future product candidates for our clinical trials and future approved products to our customers, which could have a material negative effect on our business.

We rely on third parties to provide us with supplies to produce our future product candidates. If the operations of these third parties are interrupted or if they are unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill our supply and product candidate needs. Any prolonged disruption in the operations of third parties could have a significant negative impact on our ability to produce our future product candidates for pre-clinical and clinical trials or sell our future approved products, could harm our reputation and could cause us to seek other third-party contracts, thereby increasing our anticipated development and commercialization costs. In addition, if we are required to change third parties for any reason, we are required to verify that the new third parties maintain facilities and procedures that comply with quality standards required by the FDA and with all applicable regulations and guidelines. The delays associated with the verification of a new third party could negatively affect our ability to develop product candidates or receive approval for any future product candidates in a timely manner.

We may become dependent upon third parties for services and raw materials needed for the manufacture of our future product candidates, and if these products are successfully commercialized, may become dependent upon third parties for product distribution. If any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver could be compromised.

As we proceed with our clinical trial efforts, we must be able to demonstrate to the FDA that we can manufacture our future product candidates with consistent characteristics. While we plan to produce our future product candidates in our own facility, scaling up the manufacturing process would require us to develop a larger facility, which could require significant time and capital investments to conform to applicable manufacturing standards, or outsource manufacturing, which would cause us to be materially dependent on these suppliers for supply of GMP-grade components of consistent quality. Our ability to complete our future clinical trials may be negatively affected in the event that we are forced to seek and validate a replacement source for any of these critical components. If we are not able to obtain adequate supplies of these items of consistent quality from our third-party suppliers, it will also be more difficult to manufacture commercial quantities of our future product candidates that are approved for commercial sale.

In addition, if one or more of our future product candidates is approved for commercial sale, we intend to rely on third parties for their distribution. Proper shipping and distribution require compliance with specific storage and shipment procedures (e.g., prevention of damage to shipping materials and prevention of temperature excursions during shipment). Failure to comply with such procedures will necessitate return and replacement, potentially resulting in additional cost and causing us to fail to meet supply requirements.

Use of third-party manufacturers may increase the risk that we will not have adequate quantities of our future product candidates.

We may use a third-party manufacturer to supply our future product candidates for clinical trials or other uses at some point. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured such components ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;

- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Future contract manufacturers are or will be subject to all of the risks and uncertainties that we would have if we manufactured the product candidates on our own. Similar to us, they are subject to ongoing, periodic, and unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with GMP regulations and other governmental regulations and corresponding foreign standards. Although we do not control compliance by our contract manufacturers with these regulations and standards, we—as the manufacturer—assume the liabilities for our contract manufacturers' non-compliance. Our future contract manufacturers might not be able to comply with these regulatory requirements. If our third-party manufacturers fail to comply with applicable regulations, the FDA or other regulatory authorities could impose penalties on us, including fines, injunctions, civil penalties, consent decrees, compliance with FDA's Application Integrity Policy, issuance of warning or untitled letters, denial of marketing approval of our future product candidates, delays, suspensions, or withdrawals of approvals, license revocation, seizures or recalls of product candidates or our other products, operating restrictions, and criminal prosecutions. Any of these actions could significantly and adversely affect supplies of our future product candidates or other products and could have a material adverse effect on our business, financial condition, and results of operations.

If we decide to use third-party manufacturers in the future, they will likely be dependent upon their own third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

The operations of any future third-party manufacturers will likely be dependent upon their own third-party suppliers. A supply interruption or an increase in demand beyond a supplier's capabilities could harm the ability of any future manufacturers to manufacture our future product candidates or intended products until the manufacturer identifies and qualifies new sources of supply. Reliance on these third-party manufacturers and their suppliers could subject us to a number of risks that could harm our business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- failure of third-party manufacturers or suppliers to comply with their own legal and regulatory requirements;

- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to suppliers prioritizing other customer orders over ours or those of our third-party manufacturers;
- damage to our brand reputation caused by defective components produced by the suppliers; and
- fluctuation in delivery by the suppliers due to changes in demand from us, our third-party manufacturers or their other customers.

Any interruption in the supply of components of our future product candidates, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demands of our clinical trials or of our future customers, which would have an adverse effect on our business.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our future product candidates.

The process of manufacturing our future product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our future product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our future product candidates could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our future product candidates or in the manufacturing facilities in which our future product candidates will be made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our future product candidates will be made could be adversely affected by equipment failures, labor shortages, natural disasters, public health crises, pandemics and epidemics, such as the recent coronavirus disease 2019 (COVID-19), power failures and numerous other factors.

In addition, any adverse developments affecting manufacturing operations for our future product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our future product candidates. We also may need to take inventory write-offs and incur other charges and expenses for future product candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

We will depend on third-party distributors in the future to market and sell our future product candidates which will subject us to a number of risks.

We will depend on third-party distributors to sell, market, and service our future product candidates in our intended markets. We are subject to a number of risks associated with reliance upon third-party distributors including:

- lack of day-to-day control over the activities of third-party distributors;
- failure of the third-party distributors to comply with their own legal and regulatory requirements;
- third-party distributors may not commit the necessary resources to market and sell our future product candidates to our level of expectations;
- third-party distributors may terminate their arrangements with us on limited or no notice or may change the terms of these arrangements in a manner unfavorable to us; and
- disagreements with our future distributors could result in costly and time-consuming litigation or arbitration which we could be required to conduct in jurisdictions with which we are not familiar.

If we fail to establish and maintain satisfactory relationships with our future third-party distributors, our revenues and market share may not grow as anticipated, and we could be subject to unexpected costs which could harm our results of operations and financial condition.

The successful commercialization of our future product candidates will depend on obtaining reimbursement from government and third-party payors.

If we successfully develop and obtain necessary regulatory approvals, we intend to sell our product candidates in countries such as the United States. In the United States, the market for any pharmaceutical product is affected by the availability of reimbursement from government and third-party payors, such as government health administration authorities, private health insurers, health maintenance organizations, and pharmacy benefit management companies. This, in turn, may make it more difficult for us to obtain adequate reimbursement from government and third-party payors, particularly if we cannot demonstrate a favorable cost-benefit relationship. Government and third-party payors may also deny coverage or offer inadequate levels of reimbursement for our potential products if they determine that the product has not received appropriate clearances from the FDA or other government regulators or is experimental, unnecessary or inappropriate.

In some other countries where we may seek to market our products, the pricing of prescription pharmaceutical products and services and the level of government reimbursement are subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our potential future collaborators may be required to conduct one or more clinical trials that compare the cost effectiveness of our product candidates or products to other available therapies. Conducting one or more additional clinical trials would be expensive and could result in delays in commercialization of our product candidates.

Managing and reducing health care costs has been a general concern of federal and state governments in the United States and various foreign governments. Although we do not believe that any recently enacted or presently proposed legislation in any jurisdictions in which we currently operate should impact our business based on our current model, we might be subject to future regulations or other cost-control initiatives that materially restrict the price we would receive for our products. In addition, government and third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and many limit reimbursement for newly approved health care products. In particular, government and third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price for products that we may develop, which could result in lower product revenues to us.

We may enter into arrangements with third-party collaborators to help us develop our product candidates and commercialize our products, and our ability to commercialize such products may be impaired or delayed if collaborations are unsuccessful.

We are parties to various collaborations with third parties, and may enter into additional collaborations in the future. We are dependent upon the success of our current and any future collaborators in performing their responsibilities in connection with the relevant collaboration. If we fail to maintain these collaborative relationships for any reason, we would need to perform the activities that we currently anticipate would be performed by our collaborators on our own at our sole expense. This could substantially increase our capital needs, and we may not have the capability or financial capacity to undertake these activities on our own, or we may not be able to find other collaborators on acceptable terms, or at all. This may limit the programs we are able to pursue and result in significant delays in the development, sale, and manufacture of our future product candidates and products, and may have a material adverse effect on our business, financial condition, and results of operations.

Our dependence upon our current and potential future collaborations exposes us to a number of risks, including that our collaborators (i) may fail to cooperate or perform their contractual obligations, including financial obligations, (ii) may choose to undertake differing business strategies or pursue alternative technologies, or (iii) may take an opposing view regarding ownership of clinical trial results or intellectual property.

Due to these factors and other possible events, we could suffer delays in the research, development, or commercialization of our future product candidates or we may become involved in litigation or arbitration, which could be time consuming and expensive. We additionally may be compelled to split revenue with our collaborators, which could have a material adverse effect on our business, financial condition, and results of operations.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products or product candidates, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products or product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party to receive marketing approvals for their existing products or product candidates; and
- our inability to generate revenue from acquired technology, product candidates and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

A shortage of qualified registered nursing staff and other caregivers could adversely affect our partners' ability to attract, train and retain qualified personnel and could increase operating costs.

Our clinics rely significantly on our partners' ability to attract and retain caregivers who possess the skills, experience and licenses necessary to meet the requirements of our patients. We compete for personnel with other providers for qualified staff and caregivers. Our partners' ability to attract and retain caregivers depends on several factors, including our partners' ability to provide these caregivers with attractive assignments and competitive benefits and salaries. We cannot assure you that we will succeed in any of these areas. In addition, there are occasional shortages of qualified health care personnel in some of the markets in which we operate. As a result, we may face higher costs to attract caregivers and we may have to provide them with more attractive benefit packages than we originally anticipated, either of which could cause our profitability to decline. Finally, if we expand our operations into geographic areas where health care providers historically have unionized, we cannot assure you that negotiating collective bargaining agreements will not have a negative effect on our partners' ability to timely and successfully recruit qualified personnel. Generally, if we are unable to attract and retain caregivers, the quality of our services may decline and we could lose patients and referral sources.

We anticipate generating revenue and profit margin under contracts with medical professional entities, and will face risks related to entering and retaining such contracts.

In our arrangements with separate legal professional entities (*e.g.*, professional medical corporations) for providing business support services related to the infusion of ketamine, it is expected that our affiliated physicians will collect the fees for physician services provided. We cannot assure you that we will be successful in entering such contracts in a timely manner or at all due to issues related to the formation of such entities, which is currently completed in California and New York, or in retaining such contracts or that we will retain them on terms that are as favorable as present terms.

Any non-compete agreements and other restrictive covenants involving physicians may not be enforceable.

We have entered into contracts with physicians and professional corporations in New York and California, and later in other states. Some of these contracts will include provisions preventing these physicians and professional corporations from engaging other business support services organizations both during and after the term of our relationship with them. The law governing non-compete agreements and other forms of restrictive covenants varies from state to state. Some states are reluctant to strictly enforce non-compete agreements and restrictive covenants applicable to physicians. There can be no assurance that our non-compete agreements will not be successfully challenged as unenforceable in certain states. In such event, we would be unable to prevent former affiliated physicians and professional corporations from engaging other business support services organizations that compete with us.

Failure of our affiliated physicians and other medical practitioners to comply with laws and regulations could result in suspension or revocation of our affiliated physicians' licenses and termination of our service agreements with such affiliated physicians.

Our affiliated physicians are subject to various licensing laws and regulations relating to, among other things, the practice of medicine, adequacy of medical care, equipment, personnel and operating policies and procedures. Our affiliated physician practices may be subject to inspection by governmental and other authorities to assure

continued compliance with the various standards necessary for licensing. Failure of our affiliated physicians and other medical practitioners to comply with these laws and regulations could result in suspension or revocation of our affiliated physicians' licenses and termination of our service agreements with such affiliated physicians. While we have made reasonable efforts to ensure our affiliated physician practices substantially comply with licensing laws and regulations and standards, we cannot assure you that agencies that administer these programs will not find that the affiliated practices have failed to comply in some material respects. See "Business – Clinics" for further discussion regarding certain regulatory matters regarding the clinical infusion of ketamine to treat depression.

Risks Related to the Discovery, Development and Commercialization of Our Future Product Candidates

Interim, "topline" and preliminary data from our future clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data. These results and related findings and conclusions are based on assumptions, estimations, calculations and conclusions, and are subject to change following the generation of additional data or a more comprehensive review of the data related to the particular study or trial. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data become available or as subjects from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Common Stock after the date of this 10-K.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our future product candidates may be harmed, which could have a material adverse effect on our business, financial condition, and results of operations.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

The FDA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate means. The FDA may accept the use of some foreign data to support a marketing approval if the clinical trial meets certain requirements. Additionally, the FDA's clinical trial requirements, including the adequacy of the subject population studied and statistical powering, must be met. Furthermore, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign regulatory authority will accept data from trials conducted outside of its respective jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our future product candidates not receiving approval for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of a product in one jurisdiction does not mean that we will be successful in obtaining or maintaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of a product in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Moreover, product types or regulatory classifications, as well as approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including different or additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fails to comply with the regulatory requirements in international markets or fails to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our future product candidates will be harmed.

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.

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 face difficulties from changes to current regulations and future legislation, both in the U.S. as well as in other foreign jurisdictions where we may be operating.

Existing regulations and regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our future product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

There have been judicial and congressional challenges to 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. On December 14, 2018, a federal district court in Texas ruled that the ACA is unconstitutional as a result of the Tax Cuts and Jobs Act, the federal income tax reform legislation previously passed by Congress and signed by President Trump on December 22, 2017, that eliminated the individual mandate portion of the ACA. The case, Texas, et al, v. United States of America, et al., (N.D. Texas), is an outlier, and the ruling has been stayed by the ruling judge, but in 2019, the Fifth Circuit Court of Appeals subsequently upheld the lower court decision which was then appealed to the United States Supreme Court. The U.S. Supreme Court declined to hear the appeal on an expedited basis and so no decision is expected until the next Supreme Court term in early 2021. We are not able to state with any certainty what will be the impact of this court decision on our business pending further court action and possible appeals. 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 in the United States that could impact our future business and operations, including those that may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our future product candidates, if approved, and accordingly, our business, financial condition, and results of operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. Although future measures will require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our future product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our future product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security

laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any future product candidates for which we obtain future marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable US federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback 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 U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS starting in 2022 information regarding payments and other transfers of value to physicians, certain other healthcare providers and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the U.K. and the European Union is governed by the GDPR . From January 1, 2021, companies that offer goods or services to U.K. residents have to comply with the United Kingdom GDPR (the "U.K. GDPR") when receiving personal data from the U.K.. The U.K. GDPR and the amended U.K. Data Protection Act 2018 retain the GDPR in United Kingdom national law extend the geographical scope of the data protection law to non-European Union entities under certain conditions, tighten existing data protection principles, and create new obligations for companies and new rights for individuals. The relationship between the U.K. and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how U.K. data protection laws and regulations will develop in the medium to longer term. Failure to comply with the GDPR or U.K. GDPR may result in substantial fines and other administrative penalties. In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Additionally, California voters approved a new privacy law, the CPRA, in the November 3, 2020 election. Effective in most material respects on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The CCPA and CPRA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and passed in other states, such as Nevada, Virginia and Colorado. The Nevada Privacy Law took effect on October 1, 2019, while the Virginia and Colorado laws will become effective on January 1, 2023 and July 1, 2023 respectively.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, temporary or permanent debarment, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Inadequate funding for the FDA and other government agencies, or future government shutdown and or furlough of government employees, or public health emergencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being reviewed or approved in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, the availability of industry-paid user fees, and statutory, regulatory, and policy changes. Average review times for product approvals at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including those resulting from the current COVID-19 global pandemic, may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, if a prolonged government shutdown and/or government employee furloughs were to occur, or if FDA's response to a global pandemic such as COVID-19 diverts FDA resources and attention to other regulatory efforts, then the ability of the FDA to timely review and process our regulatory submissions could be significantly impacted, which could have a material adverse effect on our business, financial condition, and results of operations. Further, in our operations as a public company, future government shutdowns, furloughs or public health emergencies could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations will require us to test our future product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, or if the laws and regulations regarding animal testing otherwise change, our research and development activities may be interrupted, delayed or become more expensive.

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.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities, nor do any of our current employees have any experience in commercializing a regulated product. To achieve commercial success for our future product candidates, which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our future approved products on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our products and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our future approved products. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our future approved products, we may not generate revenues from them or be able to reach or sustain profitability.

In order to successfully implement our plans and strategies, we will need to grow our organization, and we may experience difficulties in managing this growth.

As of December 31, 2021, we had two part time employees and one full time employee, in addition to Zen Health's staff of over 60 team members across three clinics.

In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including preclinical and clinical studies and investigations, as well as FDA and other comparable foreign regulatory agencies' review process for any current or future product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize, any current or future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our current and future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize our current and future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

General Risk Factors

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

The trading price of our Common Stock can be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to operating performance.

Broad market and industry factors may negatively affect the market price of our Common Stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this 10-K, these factors include:

- 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 by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our future product candidates on

unfavorable terms to us.

In order to meet our operational goals, we will need to obtain additional capital, which we will likely obtain through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our future product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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, our stock price and trading volume could decline.

The trading market for our Common Stock 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 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 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 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 could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our Common Stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

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

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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 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 Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price 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 $1.07 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 of directors, particularly to serve on our audit committee and 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 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 certificate of incorporation and 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 of directors 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 of directors.

As of March 23, 2022, our officers, directors and principal stockholders, beneficially own, in the aggregate, approximately 6.5% 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 of directors;
- 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.

The ongoing conflict in Ukraine may result in market volatility that could adversely affect our stock price.

In late February 2022, Russia invaded Ukraine, significantly amplifying already existing geopolitical tensions among Russia and other countries in the region and in the west, including the U.S. Russia's invasion, the responses of countries and political bodies to Russia's actions, the larger overarching tensions, and Ukraine's military response and the potential for wider conflict may increase financial market volatility and could have severe adverse effects on regional and global economic markets.

Following Russia's actions, various countries, including the U.S., Canada, the United Kingdom, Germany and France, as well as the European Union, issued broad-ranging economic sanctions against Russia. Such sanctions included, among other things, a prohibition on doing business with certain Russian companies, officials and oligarchs; a commitment by certain countries and the European Union to remove selected Russian banks from the Society for Worldwide Interbank Financial Telecommunications (SWIFT) electronic banking network that connects banks globally; and restrictive measures to prevent the Russian Central Bank from undermining the impact of the sanctions. The current sanctions (and potential further sanctions in response to continued Russian military activity) and other actions may have adverse effects on regional and global economic markets, and may result in increased volatility in the price of our Common Stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

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 and research and development operations.

We believe that our facilities are generally in good condition and suitable to carry on 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

We are not involved in any pending legal proceedings that we anticipate would result in a material adverse effect on our business or operations.

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

General

We are authorized to issue an aggregate of 500,000,000 shares. The authorized capital stock is divided into 495,000,000 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. As of March 23, 2022, there were 22,858,371 shares of our Common Stock outstanding held by approximately 46 stockholders of record and no shares of our preferred stock outstanding.

Listing

We have listed our Common Stock on The Nasdaq Capital Market under the symbol “KTTA”.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is VStock Transfer, LLC.

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 for by resolution of the board of directors, the holders of outstanding shares of Common Stock have the exclusive right to vote on all matters requiring stockholder action. 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 holders of any series of outstanding preferred stock, holders of shares of Common Stock have equal rights of participation in the dividends and other distributions in cash, stock or property of the Company when, as and if declared thereon by the board of directors from time to time out of assets or funds of the Company legally available therefor and shall have equal rights to receive the assets and funds of the Company available for distribution to stockholders in the event of any liquidation, dissolution or winding up of the affairs of the Company, whether voluntary or involuntary.

Liquidation. Subject to the rights of holders of any series of outstanding preferred stock, holders of shares of Common Stock have equal rights to receive the assets and funds of the Company available for distribution to stockholders 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 have no preemptive, conversion or subscription rights, and there are no redemption or sinking funds provisions applicable to our Common Stock. The rights, preferences and privileges of the holders of our Common Stock are 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 fully paid and nonassessable.

Preferred Stock

Shares of preferred stock of the Company may be issued from time to time in one or more series, the shares of each series to have such voting powers, full or limited, if any, and such designations, preferences and relative, participating, optional or other special rights, and qualifications, limitations or restrictions thereof, as are stated and expressed in the resolution or resolutions providing for the issue of such series, adopted by the board of directors. The resolutions providing for issuance of any series of preferred stock may provide that such series shall be superior to, rank equally with or be junior to any other series of preferred stock to the extent permitted by law and the terms of any other series of preferred stock.

Anti-Takeover Provisions

Some provisions of Delaware law could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interests or in our best interests, including transactions that provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock. The ability of our board of directors, without action by our stockholders, to issue up to 5,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to effect a change in control of our company. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors of a committee of our board of directors.

Unregistered Sales of Equity Securities

During the fiscal year ended December 31, 2021, our financing activities consisted of the following:

Subscription Agreements

The Company entered into various subscription agreements in connection with a private placement seeking to raise up to $1 million through the sale of 625,000 shares of the Company’s common stock, at a price of $1.60 per share, with a closing date for accepted subscriptions of January 31, 2021. The Company issued a total of 395,625 shares for aggregate proceeds received of approximately $633,000 related to such private placement.

The Company entered into various subscription agreements in connection with a second private placement seeking to raise up to $5 million through the sale of 2,083,333 shares of the Company’s common stock, at a price of $2.40 per share, with a closing date for accepted subscriptions of March 31, 2021. The Company issued a total of 239,969 shares for aggregate proceeds received of approximately $576,000 related to such second private placement.

The Company issued an additional 153,652 shares of common stock to existing investors related to an administrative correction, with no significant effect on the Company’s financial statements.

All of the securities issued in the transactions described above were issued without registration under the Securities Act in reliance upon the exemptions provided in Section 4(2) or Regulation S of the Securities Act. Except with respect to securities sold pursuant to Regulation S, the recipients of securities in each such transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof. Appropriate legends were affixed to the share certificates issued in all of the above transactions. Each of the recipients also represented that they were “accredited investors” within the meaning of Rule 501(a) of Regulation D under the Securities Act or had such knowledge and experience in financial and business matters as to be able to evaluate the merits and risks of an investment in its common stock. All

recipients had adequate access, through their relationships with the Company and its officers and directors, to information about the Company. None of the transactions described above involved general solicitation or advertising.

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, 2021 and December 31, 2020 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, 2021, as compared to the fiscal year ended December 31, 2020. This discussion should be read in conjunction with our consolidated financial statements for the fiscal years ended December 31, 2021 and December 31, 2020 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."

The full extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. We have made estimates of the impact of COVID-19 within our financial statements, and although there is currently no major impact, there may be changes to those estimates in future periods. Actual results may differ from these estimates.

Company Summary

We are a biotechnology company focused on the research and discovery of new and effective treatments for psychiatric and neurological disorders. Epidemiological data indicate neuropsychiatric disorders as being some of the most prevalent, devastating, and yet poorly treated illnesses. We believe that the current treatments for these disorders, such as depression, are inadequate and that conventional medicines have low success rates in long-term treatment. According to an article published by PLOS One, randomized, double-blind, placebo-controlled clinical trials of antidepressants were only effective for 42-51% of patients with MDD. For example, current pharmacotherapies for MDD and bipolar depression (BDep) have a distinct lag of onset that can generate further distress and impairment in patients. According to an article published in 2000 by The Journal of Clinical Psychiatry and an article published in 2010 by Pharmaceuticals (Basel), available antidepressant medications usually take several weeks before patients display significant therapeutic benefit. This delayed onset of treatment can result in increased morbidity and increased risk for suicidal behavior. This has been reported in a base population study including 159,810 users of 4 antidepressant drugs showing that the risk of suicidal behavior increased in the first month after starting antidepressants, and in particular during the first 1 to 9 days, regardless of the chemical class of antidepressant. This study was published in a 2004 article published by The Journal of the American Medical Association. Similarly, other studies including a 2006 article published by The American Journal of Psychiatry have shown a significantly higher risk of suicide attempts during the first week of antidepressant treatment compared to subsequent weeks. Furthermore, depressive symptoms are commonly known to affect the ability of patients to function across multiple domains, impacting self-esteem, motivation and cognitive function. Delayed onset of antidepressants contributes to ongoing functional impairment and may interfere with integration back into daily life, in turn delaying full functional recovery. Furthermore, according to a 2012 article published by Biological Psychiatry and a 2013 article published by Brain Stimulation, the continued presence of depressive symptoms may promote chronic neuronal loss and suppress neurogenesis in the hippocampus.

Traditional psychiatric drugs can also cause side effects. Furthermore, the approval of psychotropic drugs with novel mechanisms of action has been rare in recent years. Our biotech operations focus on developing drugs that target the pathophysiology underlying such disorders rather than symptomatic treatments, with the goal of developing new pharmacological agents that display significant advantages over conventional therapies with respect to efficacy and tolerability. We particularly focus on the cross-talk between the immune system and brain disorders and how immune dysregulation affects CNS function.

Company Strategy

Our core strategy is to become a leader in solving psychiatric and neurological disorders, one of the world's biggest clinical problems, through research, development, and commercialization of novel CNS drugs. Key elements of our business strategy are as follows:

- Research new drugs or the treatment of CNS disorders targeting the pathophysiology underlying the disease and with different mechanisms of action than conventional psychiatric and neurological drugs. Research will be conducted under the leadership of Professor Lawrence Steinman, a renowned neurologist and immunologist based at Stanford University, and Dr. Tiago Reis Marques, a psychiatrist and neuroscientist at Imperial College and King's College London;
- Partner with reputable and successful healthcare companies and clinics to support the intravenous administration of ketamine to treat treatment-resistant depression and PTSD;
    - o Create a capital efficient revenue stream with significant client bases across the United States and the U.K., including in Los Angeles, New York City, London; and
    - o Create a diversified revenue stream by establishing and supporting clinics to provide greater visibility of revenue and EBITDA.

Private Placements

November 2021 Private Placement

On November 24, 2021, the Company entered into a purchase agreement with institutional investors to issue 8,680,000 common shares (the "PIPE Shares") and 8,680,000 warrants to purchase up to 8,680,000 shares of common stock in a private placement ("November 2021 Private Placement"). The combined purchase price for one PIPE Share and warrant was $3.50. The warrants are immediately exercisable, expire five years from the date of issuance and have an exercise price of $3.50 per share of common stock, subject to adjustment as set forth in the warrants.

The investors may exercise the warrants on a cashless basis if the warrant shares are not then registered pursuant to an effective registration statement. The investors

have contractually agreed to restrict their ability to exercise the warrants such that the number of shares of common stock held by the investors and any of their affiliates after such exercise does not exceed either 4.99% or 9.99% of the Company's then issued and outstanding shares of common stock, at the investor's election.

In connection with the Purchase Agreement, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the investors. Pursuant to the Registration Rights Agreement, the Company are be required to file a resale registration statement with the Securities and Exchange Commission (the "SEC") to register for resale the shares and the warrant shares and to have such Registration Statement declared effective within 60 days after the date of the Purchase Agreement, or 90 days of the date of the Purchase Agreement in the event the Registration Statement is subject to a "full review" by the SEC. The Company are obligated to pay certain liquidated damages to the investor if it fails to file the resale registration statement when required, fail to cause the Registration Statement to be declared effective by the SEC when required, or if it fails to maintain the effectiveness of the Registration Statement.

Pursuant to a Placement Agent Agreement (the "Placement Agent Agreement"), dated as of November 24, 2021, by and between us and EF Hutton, division of Benchmark Investments, LLC ("EF Hutton"), the Company engaged EF Hutton to act as its exclusive placement agent in connection with the November 2021 Private Placement. Pursuant to the Placement Agent Agreement, the Company paid EF Hutton a cash fee of 9.0% of the gross proceeds raised in the November 2021 Private Placement, and a cash fee equal to 1.0% of the gross proceeds raised in the November 2021 Private Placement for non-accountable expenses, and also reimbursed EF Hutton $70,000 for accountable expenses, including "road show", diligence, and reasonable legal fees and disbursements for EF Hutton's counsel. Additionally, the Company granted EF Hutton a right of first refusal following the closing of the November 2021 Private Placement, whereby EF Hutton shall have an irrevocable right of first refusal (the "Right of First Refusal") until November 29, 2022, to act as sole investment banker, sole book-runner, and/or sole placement agent, at EF Hutton's sole discretion, for each and every future public and private equity and debt offering, including all equity linked financing.

On November 29, 2021, the Company consummated the November 2021 Private Placement, pursuant to which it issued 8,680,000 PIPE Shares and 8,680,000 warrants to institutional investors. The offering price per PIPE Share and accompanying warrant was $3.50, resulting in aggregate gross proceeds of $30,380,000 and net proceeds to the Company, net of underwriter discounts and fees, of approximately $27 million. We bear all fees and expenses incidental to our obligation to register the shares of common stock. Brokerage fees, commissions and similar expenses, if any, attributable to the sale of shares offered will be assumed by the selling stockholder. The Company intends to use such proceeds from the November 2021 Private Placement for general corporate and working capital purposes.

A total of 8,680,000 warrants remain outstanding as of December 31, 2021. No liability accounting or valuation is deemed necessary for these warrants.

Results of Operations

Comparison of the Year Ended December 31, 2021 to the Year Ended December 31, 2020.

Our financial results for the year ended December 31, 2021 are summarized as follows in comparison to the year ended December 31, 2020:

	Year Ended December 31,	
	2021	**2020**
Revenues	$ 15,062	$ -
Cost of goods sold	17,275	
Selling, general and administrative expenses	4,505,200	40,984
Loss from operations	(4,507,413)	(40,984)
Other income (expense), net	2,333,892	-
Loss before income taxes	$ (2,173,521)	$ (40,984)

The increase is mainly attributable to an increase in selling, general and administrative expenses as a result of the proceeds received from the sale of equity and further expansion of operations, offset partially by the change in fair value of warrant liabilities of $2,334,400.

Working Capital

	December 31,	
	2021	**2020**
Current assets	$ 53,300,457	$ 247,958
Current liabilities	$ 447,280	$ 6,603
Working capital	$ 52,853,177	$ 241,355

Current assets increased by $53,052,499 between December 31, 2020 and December 31, 2021, which was primarily attributable to an increase in cash and cash equivalents due to the Company's sale of its Units, common stock and warrants during the period.

Current liabilities increased by $440,677 between December 31, 2020 and December 31, 2021, which was primarily attributable to an increase in accounts payable and accrued expenses due to expansion of operations.

Liquidity and Capital Resources

	Year Ended December 31,	
	2021	**2020**
Net loss	$ (2,173,521)	$ (40,984)
Net cash used in operating activities	(3,174,058)	(38,689)
Net cash provided by (used in) investing activities	(21,503)	-

Net cash provided by financing activities	55,929,178	282,339
Effect of foreign currency translation	(10,561)	-
Net change in cash and cash equivalents	$ 52,723,056	$ 243,650

Cash and cash equivalents increased by $52,723,056 between December 31, 2020 and December 31, 2021, which was primarily attributable to the Company's sale of its Units, common stock and warrants during the period.

November 2021 Private Placement

On November 24, 2021, the Company entered into a purchase agreement with institutional investors to issue 8,680,000 common shares (the "PIPE Shares") and 8,680,000 warrants to purchase up to 8,680,000 shares of common stock in a private placement ("November 2021 Private Placement"). The combined purchase price for one PIPE Share and warrant was $3.50. The warrants are immediately exercisable, expire five years from the date of issuance and have an exercise price of $3.50 per share of common stock, subject to adjustment as set forth in the warrants.

The investors may exercise the warrants on a cashless basis if the warrant shares are not then registered pursuant to an effective registration statement. The investors have contractually agreed to restrict their ability to exercise the warrants such that the number of shares of common stock held by the investors and any of their affiliates after such exercise does not exceed either 4.99% or 9.99% of the Company's then issued and outstanding shares of common stock, at the investor's election.

In connection with the Purchase Agreement, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the investors. Pursuant to the Registration Rights Agreement, the Company are be required to file a resale registration statement with the Securities and Exchange Commission (the "SEC") to register for resale the shares and the warrant shares and to have such Registration Statement declared effective within 60 days after the date of the Purchase Agreement, or 90 days of the date of the Purchase Agreement in the event the Registration Statement is subject to a "full review" by the SEC. The Company are obligated to pay certain liquidated damages to the investor if it fails to file the resale registration statement when required, fail to cause the Registration Statement to be declared effective by the SEC when required, or if it fails to maintain the effectiveness of the Registration Statement.

Pursuant to a Placement Agent Agreement (the "Placement Agent Agreement"), dated as of November 24, 2021, by and between us and EF Hutton, division of Benchmark Investments, LLC ("EF Hutton"), the Company engaged EF Hutton to act as its exclusive placement agent in connection with the November 2021 Private Placement. Pursuant to the Placement Agent Agreement, the Company paid EF Hutton a cash fee of 9.0% of the gross proceeds raised in the November 2021 Private Placement, and a cash fee equal to 1.0% of the gross proceeds raised in the November 2021 Private Placement for non-accountable expenses, and also reimbursed EF Hutton $70,000 for accountable expenses, including "road show", diligence, and reasonable legal fees and disbursements for EF Hutton's counsel. Additionally, the Company granted EF Hutton a right of first refusal following the closing of the November 2021 Private Placement, whereby EF Hutton shall have an irrevocable right of first refusal (the "Right of First Refusal") until November 29, 2022, to act as sole investment banker, sole book-runner, and/or sole placement agent, at EF Hutton's sole discretion, for each and every future public and private equity and debt offering, including all equity linked financing.

On November 29, 2021, the Company consummated the November 2021 Private Placement, pursuant to which it issued 8,680,000 PIPE Shares and 8,680,000 warrants to institutional investors. The offering price per PIPE Share and accompanying warrant was $3.50, resulting in aggregate gross proceeds of $30,380,000. We bear all fees and expenses incidental to our obligation to register the shares of common stock. Brokerage fees, commissions and similar expenses, if any, attributable to the sale of shares offered will be assumed by the selling stockholder. The Company intends to use such proceeds from the November 2021 Private Placement for general corporate and working capital purposes. As of March 23, 2022, no warrants have been exercised.

The consummation of the private placement offering resulted in gross proceeds of $30,380,000 and net proceeds to the Company, net of underwriter discounts and fees, of approximately $27 million.

Liquidity and Capital Resources Outlook

As of December 31, 2021, the Company had $52,966,706 in its operating bank account and working capital of $52,853,177. The Company's liquidity needs prior to the consummation of the Initial Public Offering had been satisfied through proceeds from the issuance of common stock in private placements. Subsequent to the consummation of the Initial Public Offering and the November 2021 Private Placement (Note 5), the Company's liquidity will be satisfied through the net proceeds from the consummation of the Initial Public Offering and the November 2021 Private Placement. Based on the foregoing, management believes that the Company will have sufficient working capital to meet its needs through twelve months from the date of these financial statements.

Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in the notes to our financial statements included in this 10-K for the fiscal year ended December 31, 2021. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

None.

Subsequent Events

Amendment to Business Support Services Subcontract – The IV Doc

On January 19, 2022, the Pasithea Clinics, an affiliate of the Company, entered into an Amended Business Support Services Subcontract (the "Amended Subcontract") with The IV Doc, pursuant to which The IV Doc will provide certain non-clinical administrative, back office, and other business support services to one or more professional medical practices in the State of New York. The Amended Subcontract was modified with the start date effective January 1, 2022.

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 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, 2021, or the Evaluation Date. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective.

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 company's board of directors, 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, 2021. In making this evaluation, our management used the criteria set forth in the Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2021 based on those criteria.

This 10-K does not include an attestation report of our registered public accounting firm on internal control over financial reporting because we are a smaller reporting company and non-accelerated filer.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers, Non-executive employees and Directors

The following table sets forth the name, age as of March 23, 2022, and 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	45	Chief Executive Officer and Director
Stanley M. Gloss	63	Chief Financial Officer
Dr. Yassine Bendiabdallah	37	Chief Operating Officer, Head of U.K. Clinics and Director
Non-Employee Directors		
Prof. Lawrence Steinman	74	Executive Chairman and Co-Founder
Simon Dumesnil	44	Director
Dr. Emer Leahy	56	Director

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 of directors 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 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 of directors due to his medical and scientific background.

Stanley M. Gloss (Chief Financial Officer) has served as our Chief Financial Officer since April 2021. He has been self-employed for the past year doing financial consulting in the areas of accounting and financial reporting. From 2017 to 2020, Mr. Gloss was Controller at Ace Universe, establishing and maintaining the budgets and financial reporting systems and sourcing and maintaining the company insurance. From 2009 to 2016, Mr. Gloss was Controller and Vice President of Finance of Wizard World Inc., where he established and maintained the budgets and financial reporting systems, sourced and maintained the company contracts and insurance, and coordinated public filings. He received his Bachelor of Science in Accounting from Fairfield University.

Dr. Yassine Bendiabdallah (Chief Operating Officer, Head of U.K. Clinics and Director) has served on our board of directors and as Chief Operating Officer since March 2021. He also co-founded Pasithea Therapeutics Corp. and is currently Head of U.K. Clinics. Dr. Bendiabdallah is an expert in functional medicine and bio-identical hormone therapy. He completed a Masters in Pharmacy at King's College London in 2006. He was then awarded a PhD scholarship within Cancer Research U.K. group at University Colleges London which was completed with honours in 2010. He then went on to work for a number of pharmaceutical companies and held research position at University College London. He has been involved in several startups including HelloDr (HelloDr Ltd, Proximal Health Ltd) an online tech in healthcare, Androgenix Pharmaceuticals Ltd, and Purecare Ltd (Zen Healthcare) which he is the co-founder and current managing director. Zen Healthcare now comprises several clinics and pharmacies in the U.K.. He also co-founded Pasithea Therapeutics Corp. and is currently Head of U.K. Clinics. He holds a number of scientific publications in peer-reviewed literature the anticancer research industry. Dr. Bendiabdallah has also attended and presented at several seminars and conferences globally. His current clinical expertise includes age reversal therapies, functional approaches to medicines and intravenous micronutrient therapies. We believe that Dr. Bendiabdallah is qualified to serve on our board of directors due to his significant scientific and industry knowledge.

Non-Employee Directors

Prof. Lawrence Steinman has served on our board of directors since August 2020. Prior to joining Pasithea, he served on the board of directors of Centocor from 1989 to 1998, the board of directors of Neurocine Biosciences from 1997 to 2005, the board of directors of Atreca from 2010 to 2019, the board of directors of BioAtla from 2016 to the present, and the board of directors of Tolerion from 2013 to the present. 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 a 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. 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. We believe that Prof. Steinman is qualified to serve on our board of directors 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 of directors 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 of directors due to his management and investment experience.

Dr. Emer Leahy has served on our board of directors 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 is currently serving as a member of both the compensation committee and the audit committee of Bright Minds Biosciences, a biotech company. 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 directors 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 directors of PsychoGenics Inc, the board of directors of Intensity Therapeutics, and the Board of Trustees of BIONJ. We believe that Dr. Leahy is qualified to serve on our board of directors due to her extensive pharmaceutical, biotechnology and business background.

Scientific Advisory Board

Professor Charles B. Nemeroff, M.D., Ph.D.

Prof. Charles B. Nemeroff, M.D., Ph.D., is a pProfessor and Chair of the Department of Psychiatry and Behavioral Sciences at the University of Texas Dell Medical School and Matthew P. Nemeroff Endowed Chair. His research is focused on the pathophysiology of mood and anxiety disorders, and he has published more than 1,100 research reports and reviews. Prof. Nemroff has received numerous research and education awards, including the Kempf Award in Psychobiology, the Samuel Hibbs Award, Research Mentoring Award, Judson Marmot Award and the Vestermark Award from the American Psychiatric Association (APA), the Mood Disorders Award, Bowis Award and Dean Award from the American College of Psychiatrists (ACP) and the Julius Axelrod Award for mentoring from the ACNP. He currently sits on the Scientific Advisory

Board of the Brain and Behavioral Research Foundation. Prof. Nemeroff is a member of the National Academy of Medicine. Prof. Nemeroff received his medical degree and doctorate at the University of North Carolina School of Medicine.

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 Natiomal Academy of Medicine, The International Neuroscience Prize of the Gertrud Reemtsma Foundation of the Max Planck Society, the NIH Directors Award, The Roche-Nature Medicine Neuroscience Award, The William K. Warren Medical Research Institute Award, the Adolf Meyer Prize of the American Psychiatric Association, , the Foundation's Fund Prize from the American Psychiatric Association, and the Lieber Prize of the Brain and Behavior Research Foundation. He is past president of the Society of Biological Psychiatry, past President of the American College of Neuropsychopharmacology and has been elected to the National Academy of Medicine of the National Academy of Sciences.

Board Composition and Election of Directors

Our board of directors currently consists of five members. Under our bylaws, the number of directors who shall constitute the Board shall equal not less than 1 nor more than 10, as the Board or majority stockholders may determine by resolution from time to time.

Director Independence

Our board has determined that Prof. Lawrence Steinman, Simon Dumesnil and Dr. Emer Leahy are all "independent" as that term is defined under the Nasdaq rules. Our board has determined that Dr. Tiago Reis Marques and Dr. Yassine Bendiabdallah currently have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, such that neither of them is "independent" as that term is defined under the rules of The Nasdaq Stock Market LLC, or the Nasdaq rules.

As permitted by Nasdaq, we intend to phase in compliance with Nasdaq's director independence requirements within the schedule outlined in Nasdaq's rules. That schedule requires a majority of the members of our Board to be independent within one year of listing. It also requires one member of each Board committee be independent at the time of listing, a majority of Board committee members to be independent within 90 days of listing, and all Board committee members to be independent within one year from listing.

Board Elections

In accordance with our bylaws, our stockholders shall elect the directors at our annual meeting of stockholders (except as otherwise provided therein for the filling of vacancies). Each director shall hold office until his death, resignation, retirement, removal, or disqualification, or until his successor shall have been elected and qualified.

Board 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 not limited to: presiding over all meetings of the board of directors 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 of directors 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 of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors 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 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 of directors is regularly informed through committee reports about such risks.

Board Committees

After the consummation of the Initial Public Offering, we established three board committees and 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 of directors. 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 of directors' 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 Lawrence Steinman. 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. However, a minority of the members of the audit committee may be exempt from the heightened audit committee independence standards for one year from the date of effectiveness of the registration statement filed in connection with our initial public offering. Our board of directors has determined that Simon Dumesnil (chairperson) and Dr. Emer Leahy are independent under the heightened audit committee independence standards of the SEC and Nasdaq.

As allowed under the applicable rules and regulations of the SEC and Nasdaq, we intend to phase in compliance with the heightened audit committee independence requirements prior to the end of the one-year transition period. 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 of directors, 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 of directors 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 (chair), Professor Lawrence Steinman and Simon Dumesnil. Each of the members of our compensation committee is independent under the applicable rules and regulations of Nasdaq and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. The compensation committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Nominating and Corporate Governance Committee. The nominating and corporate governance committee's responsibilities include:

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

The members of our nominating and corporate governance committee are Professor Lawrence Steinman (chairperson), Dr. Emer Leahy and Simon Dumesnil. Each of the members of our nominating and corporate governance committee is an independent director under the applicable rules and regulations of Nasdaq relating to nominating and corporate governance committee independence. The nominating and corporate governance committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

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.

DELINQUENT SECTION 16(a) REPORTS

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires officers and directors of the Company and persons who beneficially own more than ten percent (10%) of the Common Stock outstanding to file initial statements of beneficial ownership of Common Stock (Form 3) and statements of changes in beneficial ownership of Common Stock (Forms 4 or 5) with the SEC. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all such forms they file.

Our records reflect that all reports which were required to be filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, were filed on a timely basis.

Corporate Code of Conduct and Ethics

Our Board of Directors 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

The following table shows the total compensation paid or accrued during the last two fiscal years ended December 31, 2021 to our Chief Executive Officer and Chief Financial Officer. As of December 31, 2021, there were no other executive officers who earned more than $100,000 during the fiscal year ended December 31, 2021 and were serving as executive officers as of such date (the "named executive officers").

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 ($) [2]	Total ($)
Tiago Reis Marques,	2021	243,750	-	-	-	-	-	-	243,750
Chief Executive Officer	2020	-	-	-	-	-	-	-	-
Stanley M. Gloss,	2021	67,500	-	60,000	284,665	-	-	-	412,165
Chief Financial Officer	2020	-	-	-	-	-	-	-	-

(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 4 to this 10-K for the year ended December 31, 2021.

(2) For 2021 and 2020, represents the compensation as described under the caption "All Other Compensation" below.

Outstanding Equity Awards at December 31, 2021

The following table summarizes the outstanding equity awards held by each named executive officer of our company as of December 31, 2021.

Name	Grant Date	Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Shares Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Tiago Reis Marques, *Chief Executive Officer*	-(1)	-	-	-	-
Stanley M. Gloss, *Chief Financial Officer*	April 13, 2021 (2)	100,000	-	$ 6.00	April 13, 2031

(1) No options granted as of December 31, 2021.

(2) The options were fully vested as of December 31, 2021.

There were no option exercises by our named executive officers during our fiscal year ended December 31, 2020 and 2021.

Summary Compensation

Dr. Tiago Reis Marques (the "NEO") was paid $243,750 for services rendered during the year ended December 31, 2021. Yassine Bendiabdallah was paid $20,000 by our U.K. subsidiary for services rendered during the year ended December 31, 2021.

Employment Agreements

Employment Agreement – Dr. Tiago Reis Marques

On July 13, 2020, we entered into an employment agreement with Dr. Tiago Reis Marques to serve as our Chief Executive Officer. The initial term of Dr. Marques' employment will commence on the closing of our initial business combination and end on the first anniversary of the commencement date. After the initial term, the employment agreement will automatically renew for additional one-year periods, unless we or Dr. Marques provide the other party with at least 60 days' prior written notice of its desire not to renew. The employment agreement shall automatically terminate without any action on the part of any person and be *void ab initio* if a business combination agreement to be entered into between us and a prospective target is terminated in accordance with its terms, and neither we nor any other person shall have any liability to Dr. Marques under the employment agreement if the closing does not occur. Pursuant to the employment agreement, we agreed to pay Dr. Marques an annual base salary of $120,000. Upon the completion of our financing of over $5,000,000, the terms of the employment agreement will be renegotiated. Dr. Marques will also be eligible to receive equity awards, benefits including but not limited to health insurance, retirement, and fringe benefits, and 20 days of vacation per year. We have also agreed to reimburse Dr. Marques for all expenses associated with our business.

In December 2021, we entered into a new executive employment agreement (the "2021 Employment Agreement") with Dr. Marques to serve as our Chief Executive

Officer, effective January 1, 2022. The agreement includes a base salary of $450,000 per year, Sign-on bonus of $100,000, paid in a lump sum after January 1, 2022, and eligibility for an annual discretionary bonus of up to 75% of the base salary. The 2021 Employment Agreement also includes an option to purchase 200,000 shares of the Company's common stock, subject to approval by the Board, which include a three year vesting schedule, under which 33% of the total shares subject to the Option will vest 12 months after the vesting commencement date (which will be grant date), and the remainder shall vest in equal tranches quarterly thereinafter until either the Option is fully vested or Executive's Continuous Service (as defined in the Plan) terminates, whichever occurs first.

Subject to the approval by the Board, Dr. Marques shall be eligible to receive an equity grant of 200,000 Restricted Stock Units (the "RSU"s) of the Parent, all in accordance with the terms and conditions set forth in the Plan. The RSU's shall vest over 3 years with 33 and 1/3% vesting on the employees first anniversary and then quarterly then after over the remaining vesting period. The anticipated RSUs will be governed by the terms and conditions of the Plan and Executive's grant agreement (the "RSU Agreement"), and will include a three year vesting schedule, under which 33% of the RSUs will vest 12 months after the vesting commencement date (which will be grant date), and the remainder shall vest in equal tranches quarterly thereinafter until either the RSUs are fully vested or Executive's Continuous Service (as defined in the Plan) terminates, whichever occurs first.

We may terminate Dr. Marques' employment under the employment agreement for Cause. "Cause" means any of the following: (i) Dr. Marques engaging in any acts of fraud, theft, or embezzlement involving the Company; (ii) Dr. Marques' conviction, including any plea of guilty or nolo contendere, of any felony crime which is relevant to Dr. Marques' position with our Company; and (iii) Dr. Marques' material violation of the employment agreement which is materially damaging to our reputation or business; provided, however, our board of directors must first provide notice to Dr. Marques specifying in reasonable detail the condition giving rise to Cause for termination no later than the 60th day following the occurrence of that condition; provide Dr. Marques a period of 30 days to remedy the condition, if subject to remedy, and so specify in the notice; and terminate his employment for Cause within 30 days following the expiration of the period to remedy if Dr. Marques fails to remedy the condition. We may also terminate Dr. Marques without Cause by giving Dr. Marques 60 days' prior written notice.

Dr. Marques may terminate his employment with us for Good Reason (as defined below) by providing notice to us specifying in reasonable detail the condition giving rise to the Good Reason no later than the 60th day following the occurrence of that condition, providing us a period of 30 days to remedy the condition if subject to remedy, and so specifying in the notice, and terminating his employment for Good Reason within 30 days following the expiration of the period to remedy if we fail to remedy the condition. The following, if occurring without Dr. Marques' consent, shall constitute "Good Reason" for termination by the Mr. Marques: (i) a material diminution in the nature or scope of Dr. Marques' title, authority or responsibilities; (ii) a material adverse change in the Dr. Marques' duties; (iii) a requirement that Dr. Marques report to any person other than the board of directors; (iv) a material reduction in base salary or target bonus opportunity; or (v) our breach of a material provision of the employment agreement.

On December 20, 2021, the Company entered into a new Executive Employment Agreement with Tiago Reis Marques, the Company's Chief Executive Officer.

Pursuant to an Executive Employment Agreement, which is to be effective January 1, 2022, Dr. Marques will receive the following compensation:

- A base salary of $450,000;
- Sign-on bonus of $100,000, paid in a lump sum after January 1, 2022;
- Eligibility to receive an annual discretionary bonus of up to seventy-five percent (75%) of Dr. Marques's base salary actually received in any such year;
- Subject to the approval of the Board and pursuant to the Company's Equity Compensation Plan, an equity grant of 200,000 restricted stock unit ("RSU"), which shall vest into common stock of the Company over three years, subject to Dr. Marques remaining employed and in good standing, one-third vesting 12 months after the grant date, and the remainder vesting in equal tranches quarterly for thereinafter;
- Subject to the approval of the Board and pursuant to the Company's Equity Compensation Plan, an option to purchase 200,000 shares ("Options") of the Company's common stock, which shall vest over three years, subject to Dr. Marques remaining employed and in good standing, one-third vesting 12 months after the grant date, and the remainder vesting in equal tranches quarterly thereinafter;
- Eligibility to participate in all employee benefit programs for which Dr. Marques is eligible under the terms and conditions of the benefit plans, including, at minimum, medical & dental for Dr. Marques and his spouse and dependents and paid time off including twenty-one (21) days of paid vacation as well as other benefits; and
- Severance benefits in the event that the Company terminates Dr. Marques's employment for any reason other than for "cause", as defined in the Executive Employment Agreement, equal to the equivalent of twelve (12) months of Dr. Marques's base salary in effect as of the date of Dr. Marques's employment termination, subject to standard payroll deductions and withholdings and subject to Dr. Marques signing, not revoking, and complying with a separation agreement and release of claims in a form reasonably satisfactory to the Company.

The Executive Employment Agreement defines "cause" as: (a) commission of any felony or crime involving dishonesty or moral turpitude (whether or not a felony); (b) any action by Executive involving fraud, breach of the duty of loyalty, malfeasance, willful misconduct, or negligence, (ii) the failure or refusal by Executive u to perform any material duties hereunder or to follow any lawful and reasonable direction of the Company; (c) intentional damage to any property of the Company; (d) chronic neglect or absenteeism in the performance of Executive's duties; (e) willful misconduct, or other material violation of Company policy or code of conduct that causes an adverse effect upon the Company; (f) breach of any written agreement with the Company (including the Employment Agreement); or (g) any action that in the reasonable belief of the Company shall or potentially shall subject the Company to negative adverse publicity or effects.

In accordance with the provisions of the Executive Employment Agreement, on December 20, 2021, the Board approved equity grants of 200,000 RSUs and Options to purchase 200,000 shares, with an exercise price equal to the closing price of the Company's common stock on December 20, 2021, and that each grant will vest over three years, subject to Dr. Marques remaining employed and in good standing, one-third vesting 12 months after the grant date, and the remainder vesting in equal tranches quarterly thereinafter.

Consulting Agreement with U.K. Subsidiary – Yassine Bendiabdallah

Effective November 1, 2021, the Company entered into a Consulting Agreement with Yassine Bendiabdallah to act as the Head of Pasithea Therapeutic U.K., manage all Pasithea U.K. clinics and aid in E.U. expansion. The Consulting Agreement provides an annual salary of $120,000 to be paid on a monthly basis, includes three weeks of vacation for each year and provides for reimbursement for all reasonable out-of-pocket expenses incurred in connection with the services provided. The Consulting Agreement continues indefinitely until either party decides to terminate the contract.

Outstanding Equity Awards at Fiscal Year-End

No equity awards were awarded to our NEO during the year ended December 31, 2021.

Incentive Award Plans

2021 Incentive Plan

On July 15, 2021, our board of directors adopted the 2021 Incentive Plan, which plan was approved by our stockholders on July 15, 2021. Under the 2021 Incentive Plan, we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2021 Incentive Plan are summarized below.

Types of Awards. The 2021 Incentive Plan provides for the grant of non-qualified stock options ("NQSOs"), incentive stock options ("ISOs"), restricted stock awards, restricted stock units ("RSUs"), unrestricted stock awards, stock appreciation rights and other forms of stock-based compensation.

Eligibility and Administration. Employees, officers, consultants, directors, and other service providers of the Company and its affiliates are eligible to receive awards under the 2021 Incentive Plan. The 2021 Incentive Plan is administered by the board with respect to awards to non-employee directors and by the Compensation Committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of the company's directors and/or officers (all such bodies and delegates referred to collectively as the plan administrator), subject to certain limitations that may be imposed under Section 16 of the Exchange Act, and/or other applicable law or stock exchange rules, as applicable. The plan administrator has the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2021 Incentive Plan, subject to its express terms and conditions. The plan administrator also sets the terms and conditions of all awards under the 2021 Incentive Plan, including any vesting and vesting acceleration conditions.

Share Reserve. Pursuant to the 2021 Incentive Plan, we have reserved 1,280,732 shares of the Common Stock for issuance thereunder, which reserve shall be increased annually beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (A) 3% of the aggregate 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 our board. The share reserve is subject to the following adjustments:

- The share limit is increased by the number of shares subject to awards granted that later are forfeited, expire or otherwise terminate without issuance of shares, or that are settled for cash or otherwise do not result in the issuance of shares.

- Shares that are withheld upon exercise to pay the exercise price of a stock option or satisfy any tax withholding requirements are added back to the share reserve and again are available for issuance under the 2021 Incentive Plan.

Awards issued in substitution for awards previously granted by a company that merges with, or is acquired by, the Company do not reduce the share reserve limit under the 2021 Incentive Plan.

Director Compensation. The 2021 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 of directors of the Company. 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.

Stock Options. ISOs may be granted only to employees of the Company, or to employees of a parent or subsidiary of the Company, determined as of the date of grant of such options. An ISO granted to a prospective employee upon the condition that such person becomes an employee shall be deemed granted effective on the date such person commences employment. The exercise price of an ISO shall not be less than 100% of the fair market value of the shares covered by the awards on the date of grant of such option or such other price as may be determined pursuant to the Internal Revenue Code of 1986, as amended from time to time (the "Code"). Notwithstanding the foregoing, an ISO may be granted with an exercise price lower than the minimum exercise price set forth above if such award is granted pursuant to an assumption or substitution for another option in a manner that complies with the provisions of Section 424(a) of the Code. Notwithstanding any other provision of the 2021 Incentive Plan to the contrary, no ISO may be granted under the 2021 Incentive Plan after 10 years from the date that the 2021 Incentive Plan was adopted. No ISO shall be exercisable after the expiration of 10 years after the effective date of grant of such award, subject to the following sentence. In the case of an ISO granted to a ten percent stockholder, (i) the exercise price shall not be less than 110% of the fair market value of a share on the date of grant of such ISO, and (ii) the exercise period shall not exceed 5 years from the effective date of grant of such ISO.

Restricted Stock and Restricted Stock Units. The committee may award restricted stock and RSUs under the 2021 Incentive Plan. Restricted stock awards consist of shares of stock that are transferred to the participant subject to restrictions that may result in forfeiture if specified vesting conditions are not satisfied. RSU awards result in the transfer of shares of stock to the participant only after specified vesting conditions are satisfied. A holder of restricted stock is treated as a current stockholder and shall be entitled to dividend and voting rights, whereas the holder of a restricted stock unit is treated as a stockholder with respect to the award only when the shares are delivered in the future. RSUs may include dividend equivalents. Specified vesting conditions may include performance goals to be achieved during any performance period and the length of the performance period. The committee may, in its discretion, make adjustments to performance goals based on certain changes in the Company's business operations, corporate or capital structure or other circumstances. When the participant satisfies the conditions of an RSU award, the Company may settle the award (including any related dividend equivalent rights) in shares, cash or other property, as determined by the committee, in its sole discretion.

Other Shares or Share-Based Awards. The committee may grant other forms of equity-based or equity-related awards other than stock options, restricted stock or restricted stock units. The terms and conditions of each stock-based award shall be determined by the committee.

Clawback Rights. Awards granted under the 2021 Incentive Plan will be subject to recoupment or clawback under the Company's clawback policy or applicable law, both as in effect from time to time.

Sale of the Company. Awards granted under the 2021 Incentive Plan do not automatically accelerate and vest, become exercisable (with respect to stock options), or have performance targets deemed earned at target level if there is a sale of the Company. The Company does not use a "liberal" definition of change in control as defined in Institutional Shareholder Services' proxy voting guidelines. The 2021 Incentive Plan provides flexibility to the committee to determine how to adjust awards at the time of a sale of the Company.

No Repricing. The 2021 Incentive Plan prohibits the amendment of the terms of any outstanding award, and any other action taken in a manner to achieve (i) the reduction of the exercise price of NQSOs, ISOs or stock appreciation rights (collectively, "Stock Rights"); (ii) the cancellation of outstanding Stock Rights in exchange for cash or other awards with an exercise price that is less than the exercise price or base price of the original award; (iii) the cancellation of outstanding Stock Rights with an exercise price or base price that is less than the then current fair market value of a share of Common Stock in exchange for other awards, cash or other property; or (iv) otherwise effect a transaction that would be considered a "repricing" for the purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation system on

which the Common Stock is listed or quoted without stockholder approval.

Transferability of Awards. Except as described below, awards under the 2021 Incentive Plan generally are not transferable by the recipient other than by will or the laws of descent and distribution. Any amounts payable or shares issuable pursuant to an award generally will be paid only to the recipient or the recipient's beneficiary or representative. The committee has discretion, however, to permit certain transfer of awards to other persons or entities.

Adjustments. As is customary in incentive plans of this nature, each share limit and the number and kind of shares available under the 2021 Incentive Plan and any outstanding awards, as well as the exercise price or base price of awards, and performance targets under certain types of performance-based awards, are subject to adjustment in the event of certain reorganizations, mergers, combinations, recapitalizations, stock splits, stock dividends, or other similar events that change the number or kind of shares outstanding, and extraordinary dividends or distributions of property to the stockholders.

Amendment and Termination. The board of directors may amend, modify or terminate the 2021 Incentive Plan without stockholder approval, except that stockholder approval must be obtained for any amendment that, in the reasonable opinion of the board or the committee, constitute a material change requiring stockholder approval under applicable laws, policies or regulations or the applicable listing or other requirements of a stock exchange on which shares of Common Stock are then listed. The 2021 Incentive Plan will terminate upon the earliest of (1) termination of the 2021 Incentive Plan by the board of directors, or (2) the tenth anniversary of the board adoption of the 2021 Incentive Plan. Awards outstanding upon expiration of the 2021 Incentive Plan shall remain in effect until they have been exercised or terminated, or have expired.

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 will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved 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, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

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 executive officers, in addition to indemnification provided for in our bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, 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 executive 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 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, 2021 certain information concerning his or her compensation for the year ended December 31, 2021 and the December 2018 transition period:

Year Ended December 31, 2021

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 ($)
Professor Lawrence Steinman	72,917	-	47,195(2)	-	-	-	120,112
Simon Dumesnil	60,000	-	47,195(2)	-	-	-	107,195
Dr. Emer Leahy	60,000	-	47,195(2)	-	-	-	107,195

(1) In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this column is a non-cash expense for the Company that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance. The fair value of the stock options will likely vary from the actual value the holder receives because the actual value depends on the number of options exercised and the market price of our common stock on the date of exercise. For a discussion of the assumptions made in the valuation of the stock options, see Note 5 (Stockholders' Equity) to our financial statements, which are included in this 10-K.

(2) Includes the fair value through December 31, 2021 of stock options to purchase 100,000 shares of common stock granted on August 2, 2021 and which vest as to 50% on the first anniversary of the grant date and 50% on the second anniversary of the grant date, exercisable at a $5.00 per share.

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

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

Compensation Policy for Non-Employee Directors.

No compensation was paid to our non-employee directors for services rendered during the year ended December 31, 2021.

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 receives 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 receives an additional annual retainer of $100,000. The non-employee directors also receives stock options to purchase 100,000 shares of Common Stock of the Company, with 50% vesting after the first year and 50% vesting after the second year. In addition to the compensation above, Professor Lawrence Steinman also receives an annual retainer of $90,000 for consulting services.

Compensation under our non-employee director compensation policy is subject to the annual limits on non-employee director compensation set forth in the 2021 Incentive Plan, as described above. Our board of directors or its 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 2021 Incentive Plan. As provided in the 2021 Incentive Plan, our board of directors or its authorized committee may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the board of directors or its authorized committee may determine in its discretion.

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 December 31, 2021 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 22,858,371 shares of Common Stock outstanding as of March 23, 2022. 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, 2022 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**	**%**
Named Executive Officers and Directors:		
Dr. Tiago Reis Marques (1)	600,000	2.6%
Dr. Yassine Bendiabdallah	300,000	1.3%
Prof. Lawrence Steinman	600,000	2.6%
Simon Dumesnil	-	-
Stanley M. Gloss	-	-
Dr. Emer Leahy	-	-
All officers and directors as a group (6 persons)	1,500,000	6.5%

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table summarizes certain information regarding our equity compensation plans as of December 31, 2021:

Plan Category	**Number of Securities to be Issued Upon Exercise of Outstanding Options**	**Weighted-Average Exercise Price of Outstanding Options**	**Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))**
	(a)	**(b)**	**(c)**
Equity compensation plans approved by security holders[(1)]	400,000	$ 5.00	880,732
Equity compensation plans not approved by security holders	-	$ -	-
Total	400,000	$ 5.00	880,732

(1) Consists of the 2021 Equity Incentive Plan. For a short description of this plan, see Note 4 to our Consolidated Financial Statements included in this 10-K for the year ended December 31, 2021.

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

Transactions with Related Persons

Except as set out below, as of December 31, 2021, 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 May 12, 2020 (inception) 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

Zen Healthcare – Purecare Ltd.

We entered into the Amended and Restated Zen Knightsbridge Collaboration Agreement with Purecare during the year ended December 31, 2020, and amended and

restated as of August 4, 2021, whereby both parties have agreed to collaborate on the provision of Treatments at Purecare's London based clinic. The Company has agreed, among other things, market the Treatments to the extent permitted under law, arrange and pay for the fit-out of the consulting room, provide equipment necessary for the Treatments, develop, operate and maintain a booking website for the Treatments, make bookings and take payments, and employ or engage customer services advisers to liaise with clinical staff and pay certain staff costs. Purecare has agreed provide consulting and treatment rooms, apply for and maintain CQC registrations, employ or engage licensed and qualified staff, assess patients and, if appropriate, administer the Treatments, maintain equipment and provide all ketamine and other pharmaceuticals necessary for the Treatments. All revenues from such Treatments (less certain staff costs) shall be allocated 30% to the Company and 70% to Purecare.

Our Chief Operating Officer, Head of U.K. Clinics and Director, Dr. Yassine Bendiabdallah, is a co-founder, current managing director, and 25% shareholder of Purecare. As of December 31, 2021, no payments have been made pursuant to the Amended and Restated Zen Knightsbridge Collaboration Agreement.

Zen Healthcare – Portman Health Ltd

We entered into the Amended and Restated Zen Baker Street Collaboration Agreement with Portman on during the year ended December 31, 2020, and amended and restated as of August 4, 2021, whereby both parties have agreed to collaborate on the provision of Treatments at Portman's London based clinic. The Company has agreed, among other things, market the Treatments to the extent permitted under law, arrange and pay for the fit-out of the consulting room, provide equipment, develop, operate and maintain a booking website for the Treatments, make bookings and take payments, and employ or engage customer services advisers to liaise with clinical staff and pay certain staff costs. Portman has agreed provide consulting and treatment rooms, apply for and maintain CQC registrations, employ or engage licensed and qualified staff, assess patient and, if appropriate, administer the Treatments, maintain equipment and provide all ketamine and other pharmaceuticals necessary for the Treatments. All revenues from such Treatments (less certain staff costs) shall be allocated 30% to the Company and 70% to Portman.

Dr. Bendiabdallah is a co-founder and 16.25% shareholder of Portman. As of December 31, 2021, no payments have been made pursuant to the Amended and Restated Zen Baker Street Collaboration Agreement.

Brio Financial Group

On April 13, 2021, the Company entered into an agreement with Brio Financial Group, LLC ("Brio") pursuant to which Brio provided Stanley M. Gloss to serve as the Chief Financial Officer of the Company and also provided certain other specified financial and accounting services typically provided by a chief financial officer (the "Brio Agreement"), which are described more fully in the Brio Agreement (the "CFO Services"). The term of the Brio Agreement runs through March 31, 2022, unless terminated by either party upon 10 days prior written notice to the other party, pursuant to the terms of the Brio Agreement. The Company pays a monthly fixed fee of $7,500 for the CFO Services during the term of the Brio Agreement. In addition, 25,000 restricted shares of Common Stock were issued to Brio which vests over the 1-year term of the Brio Agreement. Furthermore, the Company issued Stanley M. Gloss stock options to purchase up to 100,000 shares of the Company's Common Stock, which options vested fully upon execution of the Brio Agreement and shall be exercisable at a price equal to the public price of the Company's Common Stock sold in our initial public offering.

Named Executive Officers and Current Directors

For information regarding compensation for our named executive officers and current directors, see "Executive Compensation."

Director Independence

See "Directors, Executive Officers and Corporate Governance – Director Independence" and "Directors, Executive Officers and Corporate Governance – Board Committees" in Item 10 above.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Board of Directors of the Company has appointed Marcum LLP as our independent registered public accounting firm (the "Independent Auditor") for the fiscal year ended December 31, 2021. The following table sets forth the fees billed to the Company for professional services rendered by Marcum LLP for the years ended December 31, 2021 and December 31, 2020:

	Year Ended December 31,	
Services:	**2021**	**2020**
Audit Fees (1)	$ 179,347	$ -
Audit-Related Fees (2)	16,480	-
Tax Fees (3)	-	-
All Other Fees	-	-
Total fees	$ 195,827	$ -

(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 2021.

(3) The tax fees were paid for reviewing various tax related matters.

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.

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
3.1	Amended & Restated Certificate of Incorporation of Pasithea Therapeutics Corp. (incorporated by reference to exhibit 3.1 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
3.2	Bylaws of Pasithea Therapeutics Corp. (incorporated by reference to exhibit 3.2 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
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	Description of Securities Registered Under Section 12*
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).

10.5+	Employment Agreement between Pasithea Therapeutics Corp. and Dr. Tiago Reis Marques (incorporated by reference to exhibit 10.5 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
10.6	Brio Financial Group Consulting Agreement (incorporated by reference to exhibit 10.6 of the Company's Form S-1 (File No. 333-255205), filed with the Commission on April 13, 2021, as amended).
10.7+	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).
10.8	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).
10.9	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).
10.10	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).
10.11	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).

10.12	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).
10.13	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).
10.14+*	Yassine Bendiabdallah Consulting Agreement with Pasithea Therapeutics Limited
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
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 30, 2022

By: */s/ Stanley M. Gloss*
Stanley Gloss
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 30, 2022

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

Signature	Title	Date
/s/ Dr. Tiago Reis Marques Dr. Tiago Reis Marques	Chief Executive Officer and Director (Principal executive officer)	March 30, 2022
/s/ Stanley M. Gloss Stanley M. Gloss	Chief Financial Officer (Principal financial and accounting officer)	March 30, 2022
/s/ Dr. Yassine Bendiabdallah Dr. Yassine Bendiabdallah	Chief Operating Officer, Head of U.K. Clinics and Director (Principal operating officer)	March 30, 2022
/s/ Prof. Lawrence Steinman Prof. Lawrence Steinman	Director	March 30, 2022
/s/ Simon Dumesnil Simon Dumesnil	Director	March 30, 2022
/s/ Dr. Emer Leahy Dr. Emer Leahy	Director	March 30, 2022

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 Shareholders and Board of Directors of

Pasithea Therapeutics Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pasithea Therapeutics Corp. (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, changes in stockholders' equity and cash flows for the year ended December 31, 2021 and for the period from May 12, 2020 (inception) through December 30, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the year ended December 31, 2021 and for the period from May 12, 2020 (inception) through December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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 30, 2022

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED BALANCE SHEETS

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,966,706	$ 243,650

Prepaid expenses	333,751	4,308
Total current assets	53,300,457	247,958
Property and equipment	20,124	-
Total assets	$ 53,320,581	$ 247,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 447,280	$ 6,603
Total current liabilities	447,280	6,603
Non-current liabilities		
Warrant liabilities	1,452,800	-
Total non-current liabilities	1,452,800	-
Total liabilities	1,900,080	6,603
Commitments and Contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, par value $0.0001, 5,000,000 shares authorized; 0 issued and outstanding	-	-
Common stock, par value $0.0001, 495,000,000 shares authorized; 23,008,371 and 7,469,125 shares issued and outstanding as of December 31, 2021 and 2020, respectively	17,684	14,938
Additional paid-in capital	53,627,883	267,401
Accumulated other comprehensive loss	(10,561)	-
Accumulated deficit	(2,214,505)	(40,984)
Total stockholders' equity	51,420,501	241,355
Total liabilities and stockholders' equity	$ 53,320,581	$ 247,958

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

PASITHEA THERAPEUTICS CORP.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2021	For the Period from May 12, 2020 (Inception) to December 31, 2020
Sales	$ 15,062	$ -
Cost of good sold	17,275	-
Gross margin	(2,213)	-
Operating expenses:		
Selling, general and administrative	$ 4,505,200	$ 40,984
Loss from operations	(4,507,413)	(40,984)
Other income (expense)		
Change in fair value of warrant liabilities	2,334,400	-
Interest expense	(508)	-
Other income (expense)	2,333,892	-
Loss before income taxes	(2,173,521)	(40,984)
Provision for income taxes	-	-
Net loss	$ (2,173,521)	$ (40,984)
Weighted-average common shares outstanding, basic and diluted	10,404,668	7,364,166
Basic and diluted net loss per common share	$ (0.21)	$ (0.00)
Comprehensive loss:		
Net loss	$ (2,173,521)	$ (40,984)
Foreign currency translation	(10,561)	-
Comprehensive loss:	$ (2,184,082)	$ (40,984)

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 Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at May 12, 2020 (Inception)	-	$ -	$ -	$ -	$ -	$ -
Issuance of common stock for cash	7,300,000	14,600	-	-	-	14,600
Issuance of common stock for cash	156,250	313	246,826	-	-	247,139
Issuance of common stock for cash				-	-	-
Issuance of common stock for advances	12,875	25	20,575	-	-	20,600
Net loss	-	-	-	-	(40,984)	(40,984)
Balance at December 31, 2020	7,469,125	$ 14,938	$ 267,401	$ -	$ (40,984)	$ 241,355
Stock-based compensation expense	-	-	471,250	-	-	471,250
Issuance of shares for cash	635,594	1,271	1,207,655	-	-	1,208,926
Issuance of shares for services	150,000	15	749,985	-	-	750,000
Share adjustment (Note 5)	153,652	-	-	-	-	-
Issuance of public warrants	-	-	(3,600,000)	-	-	(3,600,000)
Issuance of representatives' warrants	-	-	(187,200)	-	-	(187,200)
Sale of Units, net of underwriting discounts and offering costs	4,800,000	480	20,554,320	-	-	20,554,800
Sale of common stock and warrants, net of fees and costs	8,680,000	868	27,164,584	-	-	27,165,452
Exercise of warrants for cash	1,120,000	112	6,999,888	-	-	7,000,000
Foreign currency translation	-	-	-	(10,561)	-	(10,561)
Net loss	-	-	-	-	(2,173,521)	(2,173,521)
Balance at December 31, 2021	23,008,371	$ 17,684	$ 53,627,883	$ (10,561)	$ (2,214,505)	$ 51,420,501

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, 2021	For the Period from May 12, 2020 (Inception) to December 31, 2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,173,521)	$ (40,984)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,379	-
Stock-based compensation	471,250	-
Shares issued for services	750,000	-
Change in fair value of warrant liabilities	(2,334,400)	-
Changes in operating assets and liabilities:		
Changes in prepaid expenses	(329,443)	(4,308)
Changes in accounts payable and accrued liabilities	440,677	6,603
Net cash used in operating activities	(3,174,058)	(38,689)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(21,503)	-
Net cash used in investing activities	(21,503)	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Cash proceeds from sale of 4,800,000 Units	21,862,200	-
Cash proceeds from issuance of common stock	1,208,926	282,339
Sale of common stock and warrants, net of fees and costs	27,165,452	-
Cash proceeds received from exercise of warrants	7,000,000	-
Payment of offering costs	(1,307,400)	-
Net cash probided by financing activities	55,929,178	282,339
Effect of foreign currency translation	(10,561)	-
NET CHANGE IN CASH	52,723,056	243,650
Cash - Beginning of period	243,650	-

Cash - End of period	$ 52,966,706	$ 243,650
SUPPLEMENTAL CASH FLOW INFORMATION:		
Non-cash investing and financing activities:		
Initial recording of warrant liabilities	$ 3,787,200	$ -

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

PASITHEA THERAPEUTICS CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – NATURE OF THE ORGANIZATION AND BUSINESS

Pasithea Therapeutics Corp. ("Pasithea" or the "Company") was incorporated in the State of Delaware on May 12, 2020. The Company is a biotechnology company focused on the research and discovery of new and effective treatments for psychiatric and neurological disorders. The Company's primary biotech operations focus on developing drugs that target the pathophysiology underlying such disorders rather than symptomatic treatments, with the goal of developing new pharmacological agents that display significant advantages over conventional therapies with respect to efficacy and tolerability.

The Company's secondary operations are focused on providing business support services to anti-depression clinics in the U.K. and in the United States. Its operations in the U.K. involve providing business support services to registered healthcare providers who assess patients and, if appropriate, administer intravenous infusions of ketamine. Its operations in the United States involve providing business support services to entities that furnish similar services to patients who personally pay for those services. Operations are expected to initially take place across the United States and the U.K. through partnerships with healthcare companies.

The Company is located in Miami Beach, Florida, USA.

On September 17, 2021, the Company sold 4,800,000 Units in an Initial Public Offering (the "Initial Public Offering") at a price of $5.00 per Unit for a total of $24,000,000. The Company incurred offering costs of $3,445,200, consisting of $2,137,800 of underwriting fees and expenses and $1,307,400 of costs related to the Initial Public Offering.

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 and Pasithea Clinics Corp. 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 Corp. is incorporated in Delaware.

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 (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) 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 which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's consolidated financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

COVID-19 Pandemic

In March 2020, the World Health Organization (the "WHO") characterized the outbreak of the novel strain of coronavirus, specifically identified as COVID-19, as a global pandemic. This has resulted in governments enacting emergency measures to combat the spread of the virus. These measures, which include the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to business, resulting in a global economic slowdown. Equity markets have experienced significant volatility and weakness and the governments and central banks have reacted with significant monetary and fiscal interventions designed to stabilize economic conditions.

The current challenging economic climate may lead to adverse changes in cash flows, working capital levels and/or debt balances, which may also have a direct impact on the Company's operating results and financial position in the future. The ultimate duration and magnitude of the impact and the efficacy of government interventions on the economy and the financial effect on the Company is not known at this time. The extent of such impact will depend on future developments, which are highly uncertain and not in the Company's control, including new information which may emerge concerning the spread and severity of COVID-19, or any of its variants, and actions taken to address its impact, among others. The repercussions of this health crisis could have a material adverse effect on the Company's business, financial condition, liquidity and operating results.

In response to COVID-19, the Company has implemented working practices to address potential impacts to its operations, employees and customers, and will take further measures in the future if and as required. At present, we do not believe there has been any appreciable impact on the Company specifically associated with COVID-19.

Liquidity and Capital Resources

As of December 31, 2021, the Company had $52,966,706 in its operating bank account and working capital of $52,853,177. The Company's liquidity needs prior to the consummation of the Initial Public Offering had been satisfied through proceeds from the issuance of common stock in private placements. Subsequent to the consummation of the Initial Public Offering and the November 2021 Private Placement (Note 5), the Company's liquidity was and will continue to be satisfied through the net proceeds from the consummation of the Initial Public Offering and the November 2021 Private Placement. Based on the foregoing, management believes that the Company will have sufficient working capital to meet its needs through twelve months from the date of these financial statements.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The Company evaluates the need to consolidate affiliates based on standards set forth in ASC 810, "Consolidation," ("ASC 810"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Pasithea Therapeutics Limited (U.K.) and Pasithea Clinics Corp. ("Pasithea Clinics"). All significant consolidated 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. One of the more significant accounting estimates included in these consolidated financial statements is the determination of fair value of the warrant liabilities. Accordingly, the actual results could differ significantly from those estimates.

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. The Company has no cash equivalents as of December 31, 2021 and 2020.

Property and Equipment

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. 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. As of December 31, 2021 and 2020, the Company had capitalized total property and equipment costs of $21,503 and $0, respectively, with accumulated depreciation of $1,379 and $0, respectively. Depreciation expense was $1,379 and $0 for the year ended December 31, 2021 and for the period from May 12, 2020 (inception) through December 31, 2020, respectively.

Offering Costs

Offering costs consist of professional fees, filing, regulatory and other costs incurred through the balance sheet date that are directly related to the Initial Public Offering. In September 2021, the Company recognized offering costs of $3,445,200, consisting of $2,137,800 of underwriting fees and expenses and $1,307,400 of costs related to the Initial Public Offering. Offering costs are allocated to the separable financial instruments issued in the Initial Public Offering based on the relative fair value basis compared to total proceeds received.

Warrant Liability

The Company accounts for its Public and Representative Warrants (each, the "Public Warrants" and "Representative Warrants" and, collectively, the "Warrants") in accordance with the guidance contained in ASC 815 under which the Warrants do not meet the criteria for equity treatment and must be recorded as derivative liabilities. Accordingly, the Company classifies the Warrants as liabilities at their fair value and adjusts the Warrants to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until the Warrants are exercised or expire, and any change in fair value is recognized in the Company's statement of operations. The fair value of the Public and Representative Warrants was initially and subsequently measured at the end of each reporting period, using a Black-Scholes option pricing model.

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.

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, 2021. 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, 2021, 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

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 assets and 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 and cash equivalents, December 31, 2021	$ 52,966,706	$ 52,966,706	$ -	$ -
Liabilities:				
Warrant liabilities, December 31, 2021	$ 1,452,800	$ -	$ -	$ 1,452,800

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 similar to 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. There are no outstanding dilutive or potentially dilutive instruments.

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.

The relevant translation rates are as follows:

	December 31, 2021
Closing rate, British Pound (GBP) to US$ as of December 31, 2021	1.348
Average rate, GBP to US$ for the period ended December 31, 2021	1.371

Closing rate, Euro (EUR) to US$ as of December 31, 2021	1.132
Average rate, EUR to US$ for the period ended December 31, 2021	1.143

Comprehensive Income (Loss)

FASB Topic No. 220, "Comprehensive Income," establishes standards for reporting and display of comprehensive income and its components in a full set of general-purpose financial statements. As of December 31, 2021, the Company had no material items of other comprehensive income except for the foreign currency translation adjustment.

Recent Accounting Pronouncements

Management 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.

NOTE 3 – INITIAL PUBLIC OFFERING

Pursuant to the Initial Public Offering, on September 17, 2021, the Company sold 4,800,000 Units at a price of $5.00 per Unit for a total of $24,000,000. The Company incurred offering costs of $3,445,200, consisting of $2,137,800 of underwriting fees and expenses and $1,307,400 of costs related to the Initial Public Offering.

Each Unit consisted of one share of common stock and one Public Warrant. Each redeemable Public Warrant entitles the holder to purchase one share of common stock at a price of $6.25 per share, will be exercisable upon issuance and will expire five years from issuance.

The Company classifies each warrant as a liability at its fair value and the warrants were allocated a portion of the proceeds from the issuance of the Units equal to its fair value determined by the Black-Scholes model.

In connection with the Initial Public Offering, the Company granted the underwriters an option for a period of 45 days to purchase up to an additional 720,000 shares of common stock and/or warrants to purchase up to 720,000 shares of common stock at $5.00 per unit less the underwriting discounts and commissions. On October 29, 2021, the underwriters' option lapsed without exercise.

NOTE 4 – COMMITMENTS AND CONTINGENCIES

Consulting Agreement – Yassine Bendiabdallah

Effective November 1, 2021, the Company entered into a Consulting Agreement with Yassine Bendiabdallah to act as the Head of Pasithea Therapeutic U.K., manage all Pasithea U.K. clinics and aid in E.U. expansion. The Consulting Agreement provides an annual salary of $120,000 to be paid on a monthly basis, includes three weeks of vacation for each year and provides for reimbursement for all reasonable out-of-pocket expenses incurred in connection with the services provided. The Consulting Agreement continues indefinitely until either party decides to terminate the contract.

Service Agreement – The University of Texas at Austin

On September 21, 2021, the Company entered into a Service Agreement with the University of Texas at Austin ("UTA"), a university of higher education in the State of Texas, to act as the Chair of the Scientific Advisory Board, holding three scientific advisory board meetings per year and providing incidental monthly consults. The Company pays UTA $50,000 annually for services billed on a quarterly basis and any costs incurred by UTA are reimbursed only after prior written consent of the Company. The Service Agreement will terminate on September 21, 2024 unless terminated earlier or extended by mutual agreement.

Collaboration Agreement – Zen Baker Street Clinic (U.K.)

On August 4, 2021, the Company entered into an Amended and Restated Collaboration Agreement with Portman Health Ltd ("Portman"), whereby both parties have agreed to collaborate on the provision of ketamine infusion treatments and any other treatments agreed to by the parties from time to time (the "Treatments") at Portman's London based clinic. The Company has agreed, among other things, market the Treatments to the extent permitted under law, arrange and pay for the fit-out of the consulting room, provide equipment necessary for the Treatments, develop, operate and maintain a booking website for the Treatments, make bookings and take payments, and employ or engage customer services advisers to liaise with clinical staff and pay certain staff costs. Portman has agreed provide consulting and treatment rooms, apply for and maintain CQC registrations, employ or engage licensed and qualified staff, assess patient and, if appropriate, administer the Treatments, maintain equipment and provide all ketamine and other pharmaceuticals necessary for the Treatments. All revenues from such Treatments (less certain staff costs) shall be allocated 30% to the Company and 70% to Portman.

Collaboration Agreement – Zen Knightsbridge Clinic (U.K.)

On August 4, 2021, the Company entered into an Amended and Restated Collaboration Agreement with Purecare Limited ("Purecare"), whereby both parties have agreed to collaborate on the provision of Treatments at Purecare's London based clinic. The Company has agreed, among other things, market the Treatments to the extent permitted under law, arrange and pay for the fit-out of the consulting room, provide equipment necessary for the Treatments, develop, operate and maintain a booking website for the Treatments, make bookings and take payments, and employ or engage customer services advisers to liaise with clinical staff and pay certain staff costs. Purecare has agreed provide consulting and treatment rooms, apply for and maintain CQC registrations, employ or engage licensed and qualified staff, assess patient and, if appropriate, administer the Treatments, maintain equipment and provide all ketamine and other pharmaceuticals necessary for the Treatments. All revenues from such Treatments (less certain staff costs) shall be allocated 30% to the Company and 70% to Purecare.

Business Support Services Subcontract – The IV Doc

On April 9, 2021, Pasithea Clinics, an affiliate of the Company, entered into a Business Support Services Subcontract (the "Subcontract") with The IV Doc, pursuant to which The IV Doc provides certain non-clinical administrative, back office, and other business support services to one or more professional medical practices in the State of New York provided under a BSSA with Pasithea Clinics. During the term of the Subcontract, which shall be effective for 15 years from the effective date, Pasithea Clinics pays The IV Doc monthly subcontract fees in consideration of the subcontract services rendered by The IV Doc. The subcontract fees, which are equal to $22,500 per month, represents fair market value for the subcontract services and are commensurate with the subcontract services to be provided, and does not constitute an illegal fee-splitting or

impermissible profit-sharing arrangement in violation of any applicable laws. In addition to the subcontract fees, Pasithea Clinics reimburses The IV Doc for all reasonable expenses, including travel, meals and lodging expenses, incurred by The IV Doc in connection with the provision of the subcontract services, provided that such expenses are otherwise commercially reasonable and necessary. See Note 7 for details of the Amendment to this Subcontract.

Employment Agreement – Dr. Tiago Reis Marques

On July 13, 2020, we entered into an employment agreement with Dr. Tiago Reis Marques to serve as our Chief Executive Officer. The initial term of Dr. Marques' employment commenced on the closing of our initial business combination and ends on the first anniversary of the commencement date. After the initial term, the employment agreement will automatically renew for additional one-year periods, unless the Company or Dr. Marques provides the other party with at least 60 days' prior written notice of its desire not to renew. The employment agreement shall automatically terminate without any action on the part of any person and be *void ab initio* if a business combination agreement to be entered into between us and a prospective target Agreement is terminated in accordance with its terms, and neither the Company nor any other person shall have any liability to Dr. Marques under the employment agreement if the closing does not occur. Pursuant to the employment agreement, we agreed to pay Dr. Marques an annual base salary of $120,000. Upon the completion of the next qualified financing of over $5,000,000, the terms of the employment agreement will be renegotiated. Dr. Marques will also be eligible to receive equity awards, benefits including but not limited to health insurance, retirement, and fringe benefits of the Company, and 20 vacation days per year. We have also agreed to reimburse Dr. Marques for all expenses associated with the Company's business.

In December 2021, we entered into a new executive employment agreement (the "2021 Employment Agreement") with Dr. Marques to serve as our Chief Executive Officer, effective January 1, 2022. The agreement includes a base salary of $450,000 per year, Sign-on bonus of $100,000, paid in a lump sum after January 1, 2022, and eligibility for an annual discretionary bonus of up to 75% of the base salary. The 2021 Employment Agreement also includes an option to purchase 200,000 shares of the Company's common stock, subject to approval by the Board, which include a three year vesting schedule, under which 33% of the total shares subject to the Option will vest 12 months after the vesting commencement date (which will be grant date), and the remainder shall vest in equal tranches quarterly thereinafter until either the Option is fully vested or Executive's Continuous Service (as defined in the Plan) terminates, whichever occurs first.

Subject to the approval by the Board, Dr. Marques shall be eligible to receive an equity grant of 200,000 Restricted Stock Units (the "RSU"s) of the Parent, all in accordance with the terms and conditions set forth in the Plan. The RSU's shall vest over 3 years with 33 and 1/3% vesting on the employees first anniversary and then quarterly then after over the remaining vesting period. The anticipated RSUs will be governed by the terms and conditions of the Plan and Executive's grant agreement (the "RSU Agreement"), and will include a three year vesting schedule, under which 33% of the RSUs will vest 12 months after the vesting commencement date (which will be grant date), and the remainder shall vest in equal tranches quarterly thereinafter until either the RSUs are fully vested or Executive's Continuous Service (as defined in the Plan) terminates, whichever occurs first.

2021 Incentive Plan

On July 15, 2021, our board of directors adopted the 2021 Incentive Plan, which plan was approved by our stockholders on July 15, 2021. Under the 2021 Incentive Plan, we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2021 Incentive Plan are summarized below.

Types of Awards. The 2021 Incentive Plan provides for the grant of non-qualified stock options ("NQSOs"), incentive stock options ("ISOs"), restricted stock awards, restricted stock units ("RSUs"), unrestricted stock awards, stock appreciation rights and other forms of stock-based compensation.

Eligibility and Administration. Employees, officers, consultants, directors, and other service providers of the Company and its affiliates are eligible to receive awards under the 2021 Incentive Plan. The 2021 Incentive Plan is administered by the board with respect to awards to non-employee directors and by the Compensation Committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of the company's directors and/or officers (all such bodies and delegates referred to collectively as the plan administrator), subject to certain limitations that may be imposed under Section 16 of the Exchange Act, and/or other applicable law or stock exchange rules, as applicable. The plan administrator has the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2021 Incentive Plan, subject to its express terms and conditions. The plan administrator also sets the terms and conditions of all awards under the 2021 Incentive Plan, including any vesting and vesting acceleration conditions.

Share Reserve. Pursuant to the 2021 Incentive Plan, we have reserved 1,280,732 shares of the Common Stock for issuance thereunder, which reserve shall be increased annually beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (A) 3% of the aggregate 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 our board. The share reserve is subject to the following adjustments:

- The share limit is increased by the number of shares subject to awards granted that later are forfeited, expire or otherwise terminate without issuance of shares, or that are settled for cash or otherwise do not result in the issuance of shares.

- Shares that are withheld upon exercise to pay the exercise price of a stock option or satisfy any tax withholding requirements are added back to the share reserve and again are available for issuance under the 2021 Incentive Plan.

Awards issued in substitution for awards previously granted by a company that merges with, or is acquired by, the Company do not reduce the share reserve limit under the 2021 Incentive Plan.

Director Compensation. The 2021 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 of directors of the Company. 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.

Stock Options. ISOs may be granted only to employees of the Company, or to employees of a parent or subsidiary of the Company, determined as of the date of grant of such options. An ISO granted to a prospective employee upon the condition that such person becomes an employee shall be deemed granted effective on the date such person commences employment. The exercise price of an ISO shall not be less than 100% of the fair market value of the shares covered by the awards on the date of grant of such option or such other price as may be determined pursuant to the Internal Revenue Code of 1986, as amended from time to time (the "Code"). Notwithstanding the foregoing, an ISO may be granted with an exercise price lower than the minimum exercise price set forth above if such award is granted pursuant to an assumption or substitution for another option in a manner that complies with the provisions of Section 424(a) of the Code. Notwithstanding any other provision of the 2021 Incentive Plan to the contrary, no ISO may be granted under the 2021 Incentive Plan after 10 years from the date that the 2021 Incentive Plan was adopted. No ISO shall be exercisable after the expiration of 10 years after the effective date of grant of such award, subject to the following sentence. In the case of an ISO granted to a ten percent stockholder, (i) the exercise price shall not be less than 110% of the fair market value of a share on the date of grant of such ISO, and (ii) the exercise period shall not exceed 5 years from the effective date of grant of such ISO.

Restricted Stock and Restricted Stock Units. The committee may award restricted stock and RSUs under the 2021 Incentive Plan. Restricted stock awards consist of shares of stock that are transferred to the participant subject to restrictions that may result in forfeiture if specified vesting conditions are not satisfied. RSU awards result in the transfer of shares of stock to the participant only after specified vesting conditions are satisfied. A holder of restricted stock is treated as a current stockholder and shall be entitled to dividend and voting rights, whereas the holder of a restricted stock unit is treated as a stockholder with respect to the award only when the shares are delivered in the future. RSUs may include dividend equivalents. Specified vesting conditions may include performance goals to be achieved during any performance period and the length of the performance period. The committee may, in its discretion, make adjustments to performance goals based on certain changes in the Company's business operations, corporate or capital structure or other circumstances. When the participant satisfies the conditions of an RSU award, the Company may settle the award (including any related dividend equivalent rights) in shares, cash or other property, as determined by the committee, in its sole discretion.

Other Shares or Share-Based Awards. The committee may grant other forms of equity-based or equity-related awards other than stock options, restricted stock or restricted stock units. The terms and conditions of each stock-based award shall be determined by the committee.

Clawback Rights. Awards granted under the 2021 Incentive Plan are subject to recoupment or clawback under the Company's clawback policy or applicable law, both as in effect from time to time.

Sale of the Company. Awards granted under the 2021 Incentive Plan do not automatically accelerate and vest, become exercisable (with respect to stock options), or have performance targets deemed earned at target level if there is a sale of the Company. The Company does not use a "liberal" definition of change in control as defined in Institutional Shareholder Services' proxy voting guidelines. The 2021 Incentive Plan provides flexibility to the committee to determine how to adjust awards at the time of a sale of the Company.

No Repricing. The 2021 Incentive Plan prohibits the amendment of the terms of any outstanding award, and any other action taken in a manner to achieve (i) the reduction of the exercise price of NQSOs, ISOs or stock appreciation rights (collectively, "Stock Rights"); (ii) the cancellation of outstanding Stock Rights in exchange for cash or other awards with an exercise price that is less than the exercise price or base price of the original award; (iii) the cancellation of outstanding Stock Rights with an exercise price or base price that is less than the then current fair market value of a share of Common Stock in exchange for other awards, cash or other property; or (iv) otherwise effect a transaction that would be considered a "repricing" for the purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation system on which the Common Stock is listed or quoted without stockholder approval.

Transferability of Awards. Except as described below, awards under the 2021 Incentive Plan generally are not transferable by the recipient other than by will or the laws of descent and distribution. Any amounts payable or shares issuable pursuant to an award generally will be paid only to the recipient or the recipient's beneficiary or representative. The committee has discretion, however, to permit certain transfer of awards to other persons or entities.

Adjustments. As is customary in incentive plans of this nature, each share limit and the number and kind of shares available under the 2021 Incentive Plan and any outstanding awards, as well as the exercise price or base price of awards, and performance targets under certain types of performance-based awards, are subject to adjustment in the event of certain reorganizations, mergers, combinations, recapitalizations, stock splits, stock dividends, or other similar events that change the number or kind of shares outstanding, and extraordinary dividends or distributions of property to the stockholders.

Amendment and Termination. The board of directors may amend, modify or terminate the 2021 Incentive Plan without stockholder approval, except that stockholder approval must be obtained for any amendment that, in the reasonable opinion of the board or the committee, constitute a material change requiring stockholder approval under applicable laws, policies or regulations or the applicable listing or other requirements of a stock exchange on which shares of Common Stock are then listed. The 2021 Incentive Plan terminates upon the earliest of (1) termination of the 2021 Incentive Plan by the board of directors, or (2) the tenth anniversary of the board adoption of the 2021 Incentive Plan. Awards outstanding upon expiration of the 2021 Incentive Plan shall remain in effect until they have been exercised or terminated, or have expired.

Stock Options

As of December 31, 2021, there are 400,000 stock options granted, with 100,000 stock options vesting in full as of December 31, 2021, and vesting primarily as follows: 50% of the shares underlying the options shall vest on the first and second anniversary of the option grant.

Stock options outstanding at December 31, 2021 are as follows:

	Number of Options	Weighted-average Exercise Price per Share
Outstanding, January 1, 2021	-	$ -
Granted	400,000	5.00
Expired	-	-
Exercised	-	-
Outstanding, December 31, 2021	400,000	$ 5.00
Exercisable, December 31, 2021	100,000	$ 5.00

These options had a weighted average remaining life of 9.6 years and an aggregate intrinsic value of $0 as of December 31, 2021.

The fair value of the 400,000 stock options granted was $964,287, of which $426,250 was expensed during the period from inception through December 31, 2021, with unamortized stock compensation remaining as of December 31, 2021 of $538,037. The fair value was determined by the Black-Scholes Option Pricing Model with the following assumptions: stock price of $5.00, exercise price of $5.00 per share, dividend yield of 0%, term of 10 years, volatility of 45.20% to 47.07%, and risk-free rate of 0.96 to 1.29%.

NOTE 5 – STOCKHOLDERS' EQUITY

The Company is authorized to issue an aggregate of 500,000,000 shares. The authorized capital stock is divided into: (i) 495,000,000 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.

Effective April 8, 2021, we amended our certificate of incorporation to effect a 1-for-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. All share information presented in these financial statements has been retroactively adjusted to reflect the reduced number of shares outstanding.

From inception, May 12, 2020, through December 31, 2020, the Company issued 7,300,000 shares of common stock at a price of $0.002 per share for cash proceeds of $14,600. Additionally, the Company issued 156,250 shares of common stock at a price of $1.60 per share for cash proceeds of $247,139, net of share issuance costs of $2,861, as of December 31, 2020.

In 2020, several investors advanced funds totaling approximately $20,600 to the Company with no specific terms of repayment, interest or maturity, subsequent to which the parties executed conversion documents to convert the funds into common shares. As the fair value of the equity instruments was equal to the funds advanced, there was no gain or loss on the transaction when on December 30, 2020, the Company issued 12,875 shares of common stock at a price of $0.08 per share to the respective investors.

During 2021, the Company entered into various subscription agreements in connection with a private placement seeking to raise up to $1 million through the sale of 625,000 shares of the Company's common stock, at a price of $1.60 per share, with a closing date for accepted subscriptions of January 31, 2021. The Company issued a total of 395,625 shares for aggregate proceeds received of approximately $633,000 related to such private placement.

During 2021, the Company entered into various subscription agreements in connection with a second private placement seeking to raise up to $5 million through the sale of 2,083,333 shares of the Company's common stock, at a price of $2.40 per share, with a closing date for accepted subscriptions of March 31, 2021. The Company issued a total of 239,969 shares for aggregate proceeds received of approximately $576,000 related to such second private placement.

During 2021, the Company issued an additional 153,652 shares of common stock to existing investors related to an administrative correction, with no significant effect on the Company's financial statements.

Brio Financial Group

On April 13, 2021, the Company entered into an agreement with Brio Financial Group, LLC ("Brio") pursuant to which Brio provided Stanley M. Gloss to serve as the Chief Financial Officer of the Company and also provided certain other specified financial and accounting services typically provided by a Chief Financial Officer (the "Brio Agreement"), which are described more fully in the Brio Agreement (the "CFO Services"). The term of the Brio Agreement runs through March 31, 2022, unless terminated by either party upon 10 days prior written notice to the other party, pursuant to the terms of the Brio Agreement. The Company pays a monthly fixed fee of $7,500 for the CFO Services during the term of the Brio Agreement. In addition, 25,000 restricted shares of the Company's common stock were issued to Brio fully vesting over the 1-year term of the Brio Agreement. Furthermore, the Company issued Stanley M. Gloss stock options to purchase up to 100,000 shares of the Company's Common Stock, which options vested fully upon execution of the Brio Agreement and shall be exercisable at a price of $5.00 per share.

The fair value of the 25,000 restricted shares of common stock granted of approximately $60,000 is being amortized over the 1-year term of the Brio Agreement. The total compensation expense was $45,000 as of December 31, 2021, with unamortized expense remaining of $15,000 as of December 31, 2021.

The fair value of the 100,000 fully-vested stock options granted of approximately $284,665 was expensed in full as of December 31, 2021. The fair value was determined by the Black-Scholes Pricing Model with the following assumptions: dividend yield of 0%, term of 10 years, volatility of 47.07%, and risk-free rate of 1.29%.

Director Options

On August, 2, 2021, the Company granted 100,000 stock options each to three directors to purchase the Company's common stock to serve as directors of the Company for director services. The options vest at 50% on the first anniversary of the grant date and 50% on the second anniversary of the grant date, and shall be exercisable at a price of $5.00 per share.

The fair value of the aggregate 300,000 options to purchase shares of common stock granted of approximately $679,622 is being amortized over the 2-year term of the grant. The total compensation expense was $141,585 as of December 31, 2021, with unamortized expense remaining of $538,037 as of December 31, 2021.

The fair value of the 300,000 stock options granted of approximately $679,822 was determined by the Black-Scholes Pricing Model with the following assumptions: stock price of $5.00, dividend yield of 0%, term of 10 years, volatility of 45.20%, and risk-free rate of 0.96%.

Services Agreement

On September 18, 2021, the Company entered into a services agreement with TraDigital Marketing Group ("TraDigital") pursuant to which TraDigital provided consulting services from September 18, 2021 through December 17, 2021 (the "Services Agreement"). The Services Agreement included a prepaid cash consulting fee of $394,000, payable and paid upon the agreement date; the Company expensed the total amount over the term of the agreement as selling, general and administrative expense as of December 31, 2021.

The Services Agreement also includes 150,000 common shares of the Company due and earned upon the agreement date of September 18, 2021. The aggregate fair value of the 150,000 common shares of $750,000 and was recorded as shares issued for services, which is included in selling, general and administrative expense as of December 31, 2021.

November 2021 Private Placement

On November 24, 2021, the Company entered into a purchase agreement with institutional investors to issue 8,680,000 common shares (the "PIPE Shares") and 8,680,000 warrants to purchase up to 8,680,000 shares of common stock in a private placement ("November 2021 Private Placement"). The combined purchase price for one PIPE Share and warrant was $3.50. The warrants are immediately exercisable, expire five years from the date of issuance and have an exercise price of $3.50 per share of common stock, subject to adjustment as set forth in the warrants.

The investors may exercise the warrants on a cashless basis if the warrant shares are not then registered pursuant to an effective registration statement. The investors have contractually agreed to restrict their ability to exercise the warrants such that the number of shares of common stock held by the investors and any of their affiliates after such exercise does not exceed either 4.99% or 9.99% of the Company's then issued and outstanding shares of common stock, at the investor's election.

In connection with the Purchase Agreement, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the investors. Pursuant to the Registration Rights Agreement, the Company is required to file a resale registration statement with the Securities and Exchange Commission (the "SEC") to register for resale the shares and the warrant shares and to have such Registration Statement declared effective within 60 days after the date of the Purchase Agreement, or 90 days of the date of the Purchase Agreement in the event the Registration Statement is subject to a "full review" by the SEC. The Company is obligated to pay certain liquidated damages to the investor if it fails to file the resale registration statement when required, fail to cause the Registration Statement to be declared effective by the SEC when required, or if it fails to maintain the effectiveness of the Registration Statement.

Pursuant to a Placement Agent Agreement (the "Placement Agent Agreement"), dated as of November 24, 2021, by and between us and EF Hutton, division of Benchmark Investments, LLC ("EF Hutton"), the Company engaged EF Hutton to act as its exclusive placement agent in connection with the November 2021 Private Placement. Pursuant to the Placement Agent Agreement, the Company paid EF Hutton a cash fee of 9.0% of the gross proceeds raised in the November 2021 Private Placement, and a cash fee equal to 1.0% of the gross proceeds raised in the November 2021 Private Placement for non-accountable expenses, and also reimbursed EF Hutton $70,000 for accountable expenses, including "road show", diligence, and reasonable legal fees and disbursements for EF Hutton's counsel. Additionally, the Company granted EF Hutton a right of first refusal following the closing of the November 2021 Private Placement, whereby EF Hutton shall have an irrevocable right of first refusal (the "Right of First Refusal") until November 29, 2022, to act as sole investment banker, sole book-runner, and/or sole placement agent, at EF Hutton's sole discretion, for each and every future public and private equity and debt offering, including all equity linked financing.

On November 29, 2021, the Company consummated the November 2021 Private Placement, pursuant to which it issued 8,680,000 PIPE Shares and 8,680,000 warrants to institutional investors. The offering price per PIPE Share and accompanying warrant was $3.50, resulting in aggregate gross proceeds of $30,380,000 and net proceeds to the Company, net of underwriter discounts and fees, or approximately $27 million. We bear all fees and expenses incidental to our obligation to register the shares of common stock. Brokerage fees, commissions and similar expenses, if any, attributable to the sale of shares offered will be assumed by the selling stockholder. The Company intends to use such proceeds from the November 2021 Private Placement for general corporate and working capital purposes. As of March 3, 2022, no warrants have been exercised.

A total of 8,680,000 warrants remain outstanding as of December 31, 2021. No liability accounting or valuation is deemed necessary for these warrants.

NOTE 6 – WARRANT LIABILITIES

On September 17, 2021, the Company consummated its Initial Public Offering of 4,800,000 Units at a price of $5.00 per Unit, generating gross proceeds of $24,000,000, with each Unit consisting of one share of common stock, $0.0001 par value, and one redeemable Public Warrant. Each redeemable Public Warrant entitles the holder to purchase one share of common stock at a price of $6.25 per share which will expire five years from issuance.

Simultaneously with the consummation of the closing of the Initial Public Offering, the Company issued the underwriters a total of 240,000 Representative Warrants that are exercisable for six months from the date of its Initial Public Offering at an exercise price of $6.25 with a five-year expiration term.

The Company evaluated the Public and Representative Warrants (collectively, the "Warrants") as either equity-classified or liability-classified instruments based on an assessment of the warrants' specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock, among other conditions for equity classification. Pursuant to such evaluation, the Company further evaluated the Warrants under *ASC 815-40, Derivatives and Hedging — Contracts in Entity's Own Equity*, and concluded that the Warrants do not meet the criteria to be classified in stockholders' equity.

Certain adjustments to the settlement amount of the Warrants are based on a variable that is not an input to the fair value of an option as defined under ASC 815 — 40, and thus the Warrants are not considered indexed to the Company's own stock and not eligible for an exception from derivative accounting. The accounting treatment of derivative financial instruments requires that the Company record a derivative liability upon issuance of the Warrants at the closing of the Initial Public Offering. Accordingly, the Company classifies each Warrant as a liability at its fair value, with subsequent changes in their respective fair values recognized in the statement of operations and comprehensive income (loss) at each reporting date.

During November 2021, 1,120,000 public warrants were exercised at a price of $6.25 per share for total proceeds of $7,000,000. As of December 31, 2021, the fair value of the Public Warrants was approximately $0.37 per Public Warrant which was determined using the Black-Scholes option pricing model with the following assumptions: exercise price of $6.25, dividend yield of 0%, term of 5 years, volatility of 61.1%, and risk-free rate of 1.22%. The fair value of the Representatives' Warrants was approximately $0.38 per Representative Warrant which was determined using the Black-Scholes option pricing model with the following assumptions: exercise price of $6.00, dividend yield of 0%, term of 5 years, volatility of 61.1%, and risk-free rate of 1.22%.

NOTE 7 – 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, 2021 are summarized below.

	December 31, 2021
Deferred tax assets:	
Amortization	$ 11,000
Net operation loss carryforwards	920,000
Total deferred tax asset	931,000
Valuation allowance	(931,000)
	$ -

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 due to taxable loss for the year ended December 31, 2021. The Company has no history of generating taxable income. Therefore, a valuation allowance of $931,000 was recorded as of December 31, 2021. Deferred tax assets were calculated using the Company's combined effective tax rate, which it estimated to be 28%.

A reconciliation of the federal income tax rate to the Company's effective tax rate at December 31, 2021 is as follows:

	December 31, 2021
Statutory federal income tax rate	21.0%
State taxes, net of federal tax benefit	7.0%
Stock-based compensation	(6.1)%
Shares issued for services	(9.7)%
Change in fair value of warrant liabilities	30.1%
Change in valuation allowance	(42.3)%
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, 2021, the Company had federal net operating loss carryforwards available to offset future taxable income in the amounts of approximately $3,300,000 which do not expire, and state net operating loss carryovers of approximately $3,300,000 which expire in 20 years.

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 8 – SUBSEQUENT EVENTS

The Company has evaluated events and transactions subsequent to December 31, 2021, through the date these consolidated financial statements were included in this Annual Report on Form 10-K and filed with the SEC. Other than the below, there are no subsequent events identified that would require disclosure in these consolidated financial statements.

Amendment to Business Support Services Subcontract – The IV Doc

On January 19, 2022, Pasithea Clinics, an affiliate of the Company, entered into an Amended Business Support Services Subcontract (the "Amended Subcontract") with The IV Doc, pursuant to which The IV Doc will provide certain non-clinical administrative, back office, and other business support services to one or more professional medical practices in the State of New York. The Amended Subcontract was modified with the start date effective January 1, 2022.