

PROSPECTUS



## Up to 10,774,596 Shares of Common Stock

This prospectus relates to up to an aggregate of 10,774,596 shares of common stock, par value \$0.001, of Plus Therapeutics, Inc., a Delaware corporation ("Plus Therapeutics," "Plus," "we," "us" or "our"), which may be offered for sale from time to time by selling stockholders named herein. The shares of common stock covered in this prospectus consist of:

- up to 1,439,988 shares of common stock;
- up to 2,151,544 shares of common stock issuable upon exercise of pre-funded warrants ("Pre-Funded Warrants");
- up to 3,591,532 shares of common stock issuable upon exercise of Series A common stock warrants ("Series A Common Stock Warrants"); and
- up to 3,591,532 shares of common stock issuable upon exercise of Series B common stock warrants ("Series B Common Stock Warrants", and together with the Series A Common Stock Warrants, the "Common Warrants").

The shares of common stock being registered were issued pursuant to the Securities Purchase Agreement, dated May 5, 2024 (the "Securities Purchase Agreement"), among us and certain accredited investors and Company insiders named therein (the "Purchasers," or "selling stockholders"), which was subsequently amended by the First Amendment to Securities Purchase Agreement, dated May 8, 2024 (the "Amendment to Securities Purchase Agreement", and together with the "Securities Purchase Agreement", the "Purchase Agreement").

We are registering the resale of the shares of common stock pursuant to the Registration Rights Agreement, dated May 5, 2024 (the "Registration Rights Agreement"), that we entered into with the Purchasers in connection with the Purchase Agreement. See the section entitled "Selling Stockholders" for additional information regarding the Purchasers. Our registration of the resale of the shares of common stock covered by this prospectus does not mean that the selling stockholders will offer or sell all or any of the shares of common stock. The selling stockholders may offer, sell or distribute all or portion of their shares of common stock from time to time directly or indirectly through one or more underwriters, broker-dealers or agents, and in one or more public or private transactions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. See the section entitled "[Plan of Distribution](#)" for more information.

We are not selling any shares under this prospectus and will not receive any proceeds from the sale shares by the selling stockholders or their donees, pledgees, assignees, transferees or other successors-in-interest, except with respect to amounts received by us upon exercise of the Pre-Funded Warrants, the Series A Common Stock Warrants and the Series B Common Stock Warrants (collectively, the "Warrants"), to the extent the Warrants are exercised for cash. We will bear all expenses of any offering of shares of the common stock, except that the selling stockholders will pay any applicable underwriting fees, discounts or commissions and transfer taxes.

Our common stock is listed on The Nasdaq Capital Market under the trading symbol "PSTV." On June 21, 2024, the closing sale price of our Common Stock was \$1.79 per share.

**Investing in our common stock involves a high degree of risk that are described in the section entitled "[Risk Factors](#)" beginning on page 13 of this prospectus. You should also review carefully any risk factors included in any applicable prospectus supplement for a discussion of additional risks that you should consider before investing in our common stock.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**The date of this prospectus is June 24, 2024.**

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You should rely only on the information provided in this prospectus, as well as the information incorporated by reference to exhibits to the registration statement of which this prospectus forms a part and any applicable prospectus supplement or amendment. Neither we nor the selling stockholders have authorized anyone to provide you with different information. Neither we nor the selling stockholders are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date of the applicable document. Since the date of this prospectus and the documents filed as exhibits to the registration statement of which this prospectus forms a part, our business, financial condition, results of operations and prospects may have changed.

## ABOUT THIS PROSPECTUS

This prospectus relates to the resale by the selling stockholders identified in this prospectus under the section entitled “[Selling Stockholders](#),” from time to time, of up to an aggregate up to 10,774,596 shares of our common stock, consisting of: (i) 1,439,988 are shares of common stock, (ii) 2,151,544 shares are issuable upon the exercise of Pre-Funded Warrants, (iii) 3,591,532 shares are issuable upon the exercise of Series A Common Stock Warrants, and (iv) 3,591,532 shares are issuable upon the exercise of Series B Common Stock Warrants. We are not selling any shares of common stock under this prospectus, and we will not receive any proceeds from the sale of shares of common stock offered hereby by the selling stockholders, although we may receive cash from the exercise of the Warrants.

You should rely only on the information provided in this prospectus, including any information incorporated by reference. We have not authorized anyone to provide you with any other information and we take no responsibility for, and can provide no assurances as to the reliability of, any other information that others may give you. The information contained in this prospectus speaks only as of the date set forth on the cover page and may not reflect subsequent changes in our business, financial condition, results of operations and prospects.

We are not, and the selling stockholders are not, making offers to sell these securities in any jurisdiction in which an offer or solicitation is not authorized or permitted or in which the person making such offer or solicitation is not qualified to do so or to any person to whom it is unlawful to make such an offer or solicitation. You should read this prospectus, including any information incorporated by reference, in its entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled “[Where You Can Find Additional Information](#)” as well as any post-effective amendments to the registration statement of which this prospectus is a part, before you make any investment decision. To the extent there is a conflict between the information contained in this prospectus and any applicable prospectus supplement, including the information incorporated by reference, you should rely on the information in the applicable prospectus supplement.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains “forward-looking statements” for purposes of the federal securities laws. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Words such as “anticipate,” “believe,” “can,” “continue,” “could,” “designed,” “estimate,” “expect,” “intend,” “likely,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will” and “would,” as well as similar expressions which predict or indicate future events and trends or which do not relate to historical matters, are intended to identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. For example, we may use forward-looking statements when addressing topics such as:

- our ability to enter into strategic arrangements and/or collaborations and to realize the potential benefits of such arrangements, including license agreements;
- U.S. Food and Drug Administration and European Medicines Agency approvals and interactions;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our product candidates, if approved;
- our ability to enroll patients in our clinical trials;
- our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- our estimates regarding the potential market size and market opportunity for our product candidates, if approved;
- our research and development efforts;
- the timing of the initiation, progress, and expected results of our nonclinical studies, our pre-clinical and clinical trials, and our research and development programs;
- our ability to advance product candidates into, and successfully complete, nonclinical studies and clinical trials;
- results from our pre-clinical and clinical studies and the implications of such results regarding the efficacy or safety of our product candidates;
- the safety profile, pathways, and efficacy of our product candidates and formulations;
- the anticipated advantages of our product candidates over other products available in the market and being developed;
- the populations that will most benefit from our product candidates and indications that will be pursued with each product candidate;
- the anticipated progress in our current and future clinical trials; plans and strategies to create novel technologies;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our technology platforms and product candidates, and the defense of such intellectual property rights;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- future development and/or expansion of our product candidates and therapies in our markets;
- sources of competition for any of our product candidates;
- our ability to generate product or development revenue and the sources of such revenue;
- our ability to effectively manage our gross profit margins;

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- our potential need for additional financing and the availability thereof;
- our ability to continue as a going concern;
- our ability to remain listed on the Nasdaq Capital Market (“Nasdaq”);
- our estimates regarding expenses, capital requirements, and needs for additional financing and our ability to obtain additional capital;
- our ability to transfer the drug product manufacturing to a contract drug manufacturing organization;
- the potential enhancement of our cash position through development, marketing, and licensing arrangements;
- the implementation of our business model, strategic plans for our business, and product candidates;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; and
- other factors detailed under the section entitled “[Risk Factors](#)” in this prospectus.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Forward-looking statements are not guarantees of future performance, conditions or results, and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those anticipated in any forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. 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.

Important factors that could cause or contribute to such differences include, but are not limited to, those discussed under the “[Management’s Discussion and Analysis of Financial Condition and Results of Operations](#)” and “[Risk Factors](#)” sections of this prospectus, in our press releases and in our other filings with the U.S. Securities and Exchange Commission (“SEC”). Except as required by applicable law, we undertake no obligation to update or revise any forward-looking statements contained in this prospectus, whether as a result of new information, future events or otherwise.

## PROSPECTUS SUMMARY

*This summary highlights selected information from this prospectus and may not contain all of the information that is important to you in making your investment decision. Before investing in our common stock, you should carefully read the entire prospectus, including our financial statements and the related notes included in this prospectus and the information set forth under the “[Risk Factors](#)” and “[Management’s Discussion and Analysis of Financial Condition and Results of Operations](#)” sections of this prospectus. Also see the “[Where You Can Find Additional Information](#)” section of this prospectus.*

### Our Company

#### Overview

Plus Therapeutics is a U.S. pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system (“CNS”) cancers. Our novel radioactive drug formulations and therapeutic candidates are designed to deliver safe and effective doses of radiation to tumors. To achieve this, we have developed innovative approaches to drug formulation, including encapsulating radionuclides such as rhenium isotopes with nanoliposomes and microspheres. Our formulations are intended to achieve elevated patient absorbed radiation doses and extend retention times such that the clearance of the isotope occurs after significant and essentially complete radiation decay, which will contribute and provide less normal tissue/organ exposure and improved safety margins.

Our lead radiotherapeutic candidate, rhenium ( $^{186}\text{Re}$ ) obisbameda, is designed specifically for CNS cancers including recurrent glioblastoma (“GBM”), leptomeningeal metastases (“LM”), and pediatric brain cancers (“PBC”) by direct localized delivery utilizing approved standard-of-care tissue access such as with convection-enhanced delivery (“CED”) and intraventricular brain (Ommaya reservoir) catheters. Our acquired radiotherapeutic candidate, Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere (“ $^{188}\text{RNL-BAM}$ ”) is designed to treat many solid organ cancers including primary and secondary liver cancers by intra-arterial injection.

We have an established, good manufacturing practice validated research and development and manufacturing facility in San Antonio, Texas, tailored to produce Current Good Manufacturing Practice (“cGMP”) rhenium ( $^{186}\text{Re}$ ) obisbameda. We have built a robust supply chain through strategic partnerships that enable the development, manufacturing and future potential commercialization of our products. Our current supply chain and key partners are positioned to supply cGMP rhenium ( $^{186}\text{Re}$ ) obisbameda for ongoing and planned Phase 2 and Phase 3 clinical trials in patients with GBM, LM and PBC.

#### Pipeline

Our most advanced investigational drug, rhenium ( $^{186}\text{Re}$ ) obisbameda, is a patented radiotherapy potentially useful for patients with CNS and other cancers. Preclinical study data describing the use of rhenium ( $^{186}\text{Re}$ ) obisbameda for several cancer targets have been published in peer-reviewed journals and reported at a variety of medical society peer-reviewed meetings. Besides GBM, LM and PBC, rhenium ( $^{186}\text{Re}$ ) obisbameda has been reported to have potential applications for head and neck cancer, ovarian cancer, breast cancer and peritoneal metastases.

Our rhenium ( $^{186}\text{Re}$ ) obisbameda technology has been evaluated in preclinical studies for several cancer targets. We have an active \$3.0 million award from U.S. National Institutes of Health/National Cancer Institute, which is expected to provide financial support for the continued clinical development of rhenium ( $^{186}\text{Re}$ ) obisbameda for recurrent GBM through the completion of a Phase 2 clinical trial, including enrollment of up to 55 patients.

On August 29, 2022, we announced feedback from a Type C meeting with the FDA regarding Chemistry, Manufacturing and Controls (“CMC”) practices. The meeting focused on our cGMP clinical and commercial manufacturing process for our lead investigational targeted radiotherapeutic, BMEDA-chelated rhenium (<sup>186</sup>Re) obisbameda, for recurrent GBM.

The FDA indicated agreement with our proposed application of cGMP guidance for radiotherapeutics, small molecule drug products and liposome drug products for our novel rhenium (<sup>186</sup>Re) obisbameda in support of ongoing and future GBM clinical trials, manufacturing scale up, and commercialization. Alignment with the FDA includes support of our proposed controls and release strategy for new drug substance and new drug product. Because this product is identical for recurrent GBM, LM, and PBC, we believe alignment will be consistent for rhenium (<sup>186</sup>Re) obisbameda used in other clinical development programs, including LM and PBC.

*Rhenium (<sup>186</sup>Re) obisbameda versus External Beam Radiation Therapy for Recurrent GBM*

Rhenium (<sup>186</sup>Re) obisbameda is a novel injectable radiotherapy designed to deliver targeted, high dose radiation directly into GBM tumors in a safe, effective, and convenient manner that may ultimately prolong patient survival. Rhenium (<sup>186</sup>Re) obisbameda is composed of the radionuclide Rhenium-186 and a nanoliposomal carrier, and is infused in a highly targeted, controlled fashion, directly into the tumor via precision brain mapping and CED catheters. Potential benefits of rhenium (<sup>186</sup>Re) obisbameda compared to standard external beam radiotherapy or external beam radiation therapy (“EBRT”) include:

- The rhenium (<sup>186</sup>Re) obisbameda radiation dose delivered to patients may be up to 20 times greater than what is possible with commonly used EBRT, which, unlike EBRT and proton beam devices, spares normal tissue and the brain from radiation exposure.
- Rhenium (<sup>186</sup>Re) obisbameda can be visualized in real-time during administration, possibly giving clinicians better control of radiation dosing, distribution and retention.
- Rhenium (<sup>186</sup>Re) obisbameda potentially more effectively treats a bulk tumor and microscopic disease that has already invaded healthy tissue.
- Rhenium (<sup>186</sup>Re) obisbameda is infused directly into the targeted tumor by CED catheter insertion using MRI guided software to avoid critical patient neurological structures and neural pathways and also bypasses the blood brain barrier, which delivers the therapeutic product where it is needed. Importantly, it reduces radiation exposure to healthy cells, in contrast to EBRT, which passes through normal tissue to reach the tumor, continuing its path through the tumor, hence being less targeted and selective.
- Rhenium (<sup>186</sup>Re) obisbameda is given during a single, short, in-patient hospital visit, and is available in all hospitals with nuclear medicine and neurosurgery, while EBRT requires out-patient visits five days a week for approximately four to six weeks.

*ReSPECT-GBM Trial for Recurrent GBM*

Recurrent GBM is the most common, complex, and aggressive primary brain cancer in adults. In the U.S., there are approximately 13,000 GBM cases diagnosed and approximately 10,000 patients succumb to the disease each year. The average length of overall survival (“OS”) for GBM patients is eight months, with a one-year survival rate of 40.8% and a five-year survival rate of only 6.8% and these estimates vary and are lower in some publications. GBM routinely presents with headaches, seizures, vision changes and other significant neurological complications, with a significant compromise in quality of life. Despite the best available medical treatments, the disease remains incurable. Even after efforts to manage the presenting signs and symptoms and completely resect the initial brain tumor, some microscopic disease almost always remains and tumor regrowth occurs within

months. Approximately 90% or more of patients with primary GBM experience tumor recurrence. Complete surgical removal of GBM is usually not possible and GBM is often resistant or quickly develops resistance to most available current and investigational therapies. Even today, the treatment of GBM remains a significant challenge and it has been nearly a decade since the FDA approved a new therapy for this disease, and these more recent approvals have not improved GBM patients OS over past decades, and a significant unmet medical need persists.

For recurrent GBM, there are few currently approved treatments, which in the aggregate, provide only marginal survival benefit. Furthermore, these therapies are associated with significant side effects, which limit dosing and prolonged use.

While EBRT has been shown to be safe and has temporary efficacy in many malignancies including GBM, typically at absorbed, fractionated radiation dose of ~30 Gray in GBM, this maximum possible administered dose is always limited by toxicity to the normal tissues surrounding the malignancy and because EBRT requires fractionation to manage toxicity and maximum EBRT limits are typically reached before long-term efficacy reached. Because of this limitation, EBRT cannot provide a cure or long term control of GBM and GBM always recurs within months after EBRT. In contrast, locally delivered and targeted radiopharmaceuticals that precisely deliver radiation in the form of beta particles such as Iodine-131 for thyroid cancer, are known to be safe and effective and minimize exposure to normal cells and tissues especially with optimal administered dose and minimizing exposure to normal tissue. The locally delivered rhenium ( $^{186}\text{Re}$ ) obisbameda is designed for and provides patient tolerability and safety. Though no rhenium ( $^{186}\text{Re}$ ) obisbameda head-to-head trial with chemo, immune, EBRT or systemic radiopharmaceutical products have been conducted, patient tolerability and safety considerations have been reported as expected.

Interim results from our ongoing Phase 1/2a ReSPECT-GBM trial (ClinicalTrials.gov NCT01906385) show that the beta particle energy from our lead investigational drug rhenium ( $^{186}\text{Re}$ ) obisbameda has provided preliminary positive data and utility in treating GBM and potential other malignancies. More specifically, the preliminary data from our Phase 1/2a ReSPECT-GBM trial suggests that radiation, in the form of high energy beta particles or electrons, can be effective against GBM. Thus far, we have been able to deliver up to 740 Gy of absorbed radiation to tumor tissue in humans, without significant or dose limiting toxicities and with what we believe has the capability to go higher if required. In comparison, current EBRT protocols for recurrent GBM typically recommend a total maximum radiation dose of about ~30-35 Gray.

In September 2020, the FDA granted both Orphan Drug designation and Fast Track designations to rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of patients with GBM.

Rhenium ( $^{186}\text{Re}$ ) obisbameda is under clinical investigation in a multicenter, sequential cohort, open-label, volume and dose escalation study of the safety, tolerability, and distribution of rhenium ( $^{186}\text{Re}$ ) obisbameda given by CED catheters to patients with recurrent or progressive malignant glioma after standard surgical, radiation, and/or chemotherapy treatment (NCT01906385). The study uses a standard, modified 3x3 Fibonacci dose escalation, followed by a planned Phase 2 expansion trial at the maximum tolerated dose (“MTD”) / maximum feasible dose (“MFD”) or non-dose limiting toxicity (“DLT”) if MTD is not reached, to determine efficacy. The trial is funded through Phase 2 in large part by a National Institute of Health/National Cancer Institute (“NIH/NCI”) grant. These investigations have not reached DLT or MTD/MFD and the study is in its eighth dosing administration cohort. Due to the observation of a preliminary efficacy signal, we have initiated in parallel a Phase 2, non-DLT dose trial pursuant to the currently funded NIH/NCI grant. This trial will begin at the current non-DLT rhenium ( $^{186}\text{Re}$ ) obisbameda dose and will expand exploring higher radiation doses in larger volumes to treat larger tumors. Additionally, two or more rhenium ( $^{186}\text{Re}$ ) obisbameda administrations, if indicated, will be evaluated, and reviewed with the FDA, as well as expanded safety, imaging and efficacy data to support a planned future registrational trial. On September 6, 2022, we announced a summary of our Type C clinical



meeting with the FDA that focused on the ReSPECT-GBM trial. The FDA agreed with us that the ReSPECT-GBM clinical trial should proceed to the planned Phase 2. The key focus areas of clinical investigation of the Phase 2 trial will be (1) further dose exploration, including both increased dosing and multiple doses, and (2) collecting additional safety and efficacy data to inform the design of a future registrational trial. Because no DLT administered doses were observed, the FDA and we also agreed to continue to dose cohort eight. There was further agreement with the FDA that in a planned future registrational trial, overall survival should be used as the primary endpoint. We agreed with the FDA to hold future meeting(s) to consider the use of external data to augment the use of a control arm in the registrational trial. On January 18, 2023, we announced that the first patient has been dosed in the ReSPECT-GBM Phase 2b dose expansion clinical trial evaluating rhenium obisbameda for the treatment of recurrent GBM. The Phase 2b trial is expected to enroll up to 31 total patients with small- to medium-sized tumors and is targeted for full enrollment by the end of 2024. We currently have four clinical sites, with the plan to add additional sites to support the trial, and expect an initial data read-out by the end of 2024.

In June 2023, we presented data regarding the safety and feasibility results from our Phase 1/2 Clinical Trial of  $^{186}\text{RnL}$  (Rhenium-186 Nanoliposome) ( $^{186}\text{Re}$ ) Obisbameda in Recurrent Glioma: The ReSPECT-GBM Trial at the Society of Nuclear Medicine & Molecular Imaging Annual Meeting.

On November 20, 2023, we announced positive data from the ongoing ReSPECT-GBM Phase 2 trial evaluating rhenium ( $^{186}\text{Re}$ ) obisbameda, for the treatment of recurrent glioblastoma at the Society for NeuroOncology 28th Annual Meeting, which was held November 15-19, 2023 in Vancouver, Canada. Key findings included:

- Median overall survival (“mOS”) in 15 patients with recurrent glioblastoma (“rGBM”) from the Phase 2 study is 13 months, which is 63% better than current standard of care (bevacizumab monotherapy) of 8 months; 9 of the 15 patients remain alive.
- Median progression free survival (“mPFS”) is 11 months, compared to SOC at 4 months.
- Rhenium ( $^{186}\text{Re}$ ) obisbameda continues to demonstrate a favorable safety profile, despite delivering up to 20x the dose of radiation (up to 740 Gy) typically delivered by EBRT for rGBM patients (up to 35 Gy).
- Imaging data presented by Andrew Brenner, MD, PhD is consistent with the efficacy signal of Rhenium ( $^{186}\text{Re}$ ) obisbameda in rGBM.

On March 31, 2022, we entered into a Sales Order (the “Sales Order”) with Medidata Solutions, Inc. (“Medidata”), pursuant to which Medidata built a Synthetic Control Arm<sup>®</sup> platform that facilitates the use of historical clinical data to incorporate into our Phase 2 clinical trial of rhenium ( $^{186}\text{Re}$ ) obisbameda in GBM. The Sales Order had a term of six (6) months. Work under this Sales Order has been completed. As part of this collaboration, we jointly submitted with Medidata a historical clinical trials control arm methodology abstract (“HCA”) to American Society of Clinical Oncology (“ASCO”) which was accepted for publication, further strengthening this collaboration and allowing applications to advance GBM development. We plan to use the HCA for breakthrough therapy designation and Phase 2 and/or a pivotal or registrational Phase 3 trial.

#### *ReSPECT-LM Clinical Trial for LM*

LM is a rare complication of cancer in which the disease spreads to the membranes (meninges) surrounding the brain and spinal cord. The incidence of LM is growing and occurs in approximately 5%, or more, of people with late-stage cancer, or 110,000 people in the U.S. each year. It is highly lethal with an average one-year survival of just 7%. All solid cancers, particularly breast, lung, GI, and melanoma, have the potential to spread to the leptomeninges.

The ReSPECT-LM Phase 1 clinical trial (ClinicalTrials.gov NCT05034497) was preceded with preclinical studies in which tolerance to doses of rhenium ( $^{186}\text{Re}$ ) obisbameda as high as 1,075 Gy were shown in animal models with LM without significant observed toxicity. Furthermore, treatment led to a marked reduction in tumor burden in both C6 and MDA-231 LM models.

Upon receiving acceptance of our Investigational New Drug application and Fast Track designation by the FDA for rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of LM in November 2021, we initiated the trial and began screening patients for the ReSPECT-LM Phase 1 clinical trial in Q4 2021.

The ReSPECT-LM is a multi-center, sequential cohort, open-label, dose escalation study evaluating the safety, tolerability, and efficacy of a single-dose application of rhenium ( $^{186}\text{Re}$ ) obisbameda administered through intrathecal infusion to the ventricle of patients with LM after standard surgical, radiation, and/or chemotherapy treatment. The primary endpoint of the study is the incidence and severity of adverse events and dose limiting toxicities, together with determining the maximum tolerated and recommended Phase 2 dose. Full enrollment in the Phase 1 trial is expected by the end of 2024, with the plan to add additional clinical sites to support the trial.

On September 19, 2022, we entered into a Cancer Research Grant Contract (the “CPRIT Contract”), effective as of August 31, 2022, with Cancer Prevention and Research Institute of Texas (“CPRIT”), pursuant to which CPRIT will provide us a grant of up to \$17.6 million (the “CPRIT Grant”) over a three-year period to fund the continued development of rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of patients with LM through Phase 2 of the ReSPECT LM clinical trial. The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar from us for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of rhenium ( $^{186}\text{Re}$ ) obisbameda based on specific dollar thresholds until CPRIT receives the aggregate amount of 400% of the proceeds awarded under the CPRIT Grant, and certain reporting requirements. To date, we have received approximately \$7 million in milestone payments under the CPRIT Contract. We anticipate a continuing flow of milestone payments that throughout 2024 will include \$6.9 million upon the continued progression of the Phase 2 of the ReSPECT LM clinical trial.

Interim results showed that a single treatment with rhenium ( $^{186}\text{Re}$ ) obisbameda resulted in a consistent decreased cerebrospinal fluid (“CSF”) tumor cell count/ml and was tolerated by all LM patients. Rhenium ( $^{186}\text{Re}$ ) obisbameda is an outpatient administration and treatment and is easily and safely administered through a standard intraventricular catheter (Ommaya Reservoir), distributed promptly throughout the CSF, and with durable retention in the leptomeninges at least through day seven. All patients have shown well tolerated prompt and durable rhenium ( $^{186}\text{Re}$ ) obisbameda distribution throughout the subarachnoid space. On March 11, 2024, we announced we had completed Cohort 5 of the ReSPECT-LM Phase 1/2a dose escalation trial.

A total of 18 patients have received a single-dose of rhenium ( $^{186}\text{Re}$ ) obisbameda in the ReSPECT-LM trial as of March 31, 2024. There have been no dose limiting toxicities observed to date with administered radiation doses up to 66.14 millicuries in Cohort 5, a ten-fold increase over Cohort 1. We plan to initiate dosing in Cohort 6 in the second quarter of 2024, pending Data Safety Monitoring Board (DSMB) approval. In addition, five new clinical trial sites were added to this trial over the last year, bringing the total number of sites to seven. We are planning a new multiple dosing ReSPECT-LM clinical trial in late 2024 or early 2025.

On August 10, 2023, we presented data from the ReSPECT-LM clinical trial of rhenium ( $^{186}\text{Re}$ ) obisbameda at the Society for Neuro Oncology ASCO CNS Cancer Conference.

In November 2023, the FDA granted Orphan Drug designation to rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of patients with breast cancer with LM.

On December 12, 2023, we announced our partnership with K2bio to implement novel analysis for CSF tumor and molecular biomarkers for CNS cancers. Initial clinical specimen processing and testing began in the first quarter 2024 in our ongoing Phase 1 ReSPECT-LM trial of rhenium ( $^{186}\text{Re}$ ) obisbameda in patients with LM.

*ReSPECT-PBC Clinical Trial for Pediatric Brain Cancer*

The average annual age adjusted mortality rate for children aged 0-14 for malignant brain (and other CNS) tumors is 0.71/100,000, making it the most common cause of death and cancer death in this age group. The 2021 World Health Organization Classification of CNS Tumors classifies gliomas, glioneuronal tumors, and neuronal tumors into six different families: (1) adult-type diffuse gliomas; (2) pediatric-type diffuse low-grade gliomas; (3) pediatric-type diffuse high-grade gliomas (“HGG”); (4) circumscribed astrocytic gliomas; (5) glioneuronal and neuronal tumors; and (6) ependymomas.

In August 2021, we announced plans for treating pediatric brain cancer at the 2021 American Association of Neurological Surgeons Annual Scientific Meeting. In July 2021, we reported that we had received FDA feedback pertaining to a pre-Investigational New Drug (“IND”) meeting briefing package in which the FDA stated that we are not required to perform any additional preclinical or toxicology studies.

Given the initial FDA feedback, receipt of adult GBM data and experience with rhenium ( $^{186}\text{Re}$ ) obisbameda and follow-up communications with the FDA, we plan to submit a pediatric brain tumor IND to investigate the use of rhenium ( $^{186}\text{Re}$ ) obisbameda in two pediatric brain cancers, high-grade glioma and ependymoma, by the third quarter of 2024.

Pediatric high-grade gliomas can be found almost anywhere within the CNS; however, they are most commonly found within the supratentorium. The highest incidence of supratentorial, high-grade gliomas in pediatrics appears to occur in children aged 15 to 19 years, with a median age of approximately nine years. Overall, pediatric high-grade glioma confers a three-year progression free survival (“PFS”) of  $11 \pm 3\%$  and three-year OS of  $22\% \pm 5\%$ . One-year PFS is as low as 40% in recent trials. Ependymomas are slow-growing central nervous system tumors that involve the ventricular system. Diagnosis is based on MRI and biopsy and survival rate depends on tumor grade and how much of the tumor can be removed. Grade II pathology was associated with significantly improved OS compared to Grade III (anaplastic) pathology (five-year OS =  $71 \pm 5\%$  vs.  $57 \pm 10\%$ ;  $p = 0.026$ ). Gross total resection compared to subtotal resection was associated with significantly improved OS (five-year OS =  $75 \pm 5\%$  vs.  $54 \pm 8\%$ ;  $p = 0.002$ ).

Overall, pediatric HGG and ependymoma are extremely difficult-to-treat pediatric brain tumors, frequently aggressive, and in recurrent settings, carry an extremely poor prognosis.

*Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere Technology*

In January 2022, we announced that we licensed Biodegradable Alginate Microsphere (“BAM”) patents and technology from The University of Texas Health Science Center at San Antonio (“UTHSA”) to expand our tumor targeting capabilities and precision radiotherapeutics pipeline. We intend to combine our Rhenium NanoLiposome technology with the BAM technology to create a novel radioembolization technology. Initially, we intend to utilize the Rhenium-188 isotope,  $^{188}\text{RNL}$ -BAM for the intra-arterial embolization and local delivery of a high dose of targeted radiation for a variety of solid organ cancers such as hepatocellular cancer, hepatic metastases, pancreatic cancer and many others.

Preclinical data from an ex vivo embolization experiment in which Technetium99m-BAM was intra-arterially delivered to a bovine kidney perfusion model was presented at Society of Interventional Radiology Annual Scientific Meeting. The study concluded that the technology required for radiolabeling BAM could successfully deliver, embolize and retain radiation in the target organ.  $^{188}\text{RNL}$ -BAM is a preclinical investigational drug we intend to further develop and move into clinical trials. Specifically, in 2022 we transferred the  $^{188}\text{RNL}$ -BAM technology from UTHSA, and began planning to develop the drug product and complete early preclinical studies to support a future FDA IND submission. Our intended initial clinical target is liver cancer which is the sixth most common and third deadliest cancer worldwide. It is a rare disease with increasing U.S. annual incidence (42,000) and deaths (30,000).

## Recent Developments

### *May 2024 PIPE Financing*

On May 5, 2024, the Company entered into the Securities Purchase Agreement with the Purchasers, comprising of certain of the Company's directors and executive officers ("Company Insiders"), for the sale and issuance by the Company of its securities (the "Initial Subscription"). On May 8, 2024, the Company entered into a First Amendment to the Securities Purchase Agreement for the sale and issuance by the Company of additional securities to two of the Purchasers (the "Additional Subscription", and together with the Initial Subscription, the "May 2024 PIPE Financing"). The Purchase Agreement, as amended, provides for the sale and issuance by the Company of an aggregate of 3,591,532 shares (the "Private Placement Shares") of the Company's common stock or, at the election of each Purchaser, Pre-Funded Warrants, exercisable immediately at an exercise price of \$0.001 per share, with each Private Placement Share or Pre-Funded Warrant accompanied by (i) a Series A Common Stock Warrant to purchase one share of common stock, for an aggregate of 3,591,532 Series A Common Stock Warrants, and (ii) one Series B Common Stock Warrant to purchase one share of common stock, for an aggregate of 3,591,532 Series B Common Stock Warrants.

The combined purchase price for each Private Placement Share and Pre-Funded Warrant from the Initial Subscription was \$2.022, and \$2.158 from the Additional Subscription, in each case together with one accompanying Series A Common Stock Warrant and one accompanying Series B Common Stock Warrant, provided, that the Company Insiders participated in the Initial Subscription at an offering price of \$2.04 per Private Placement Share and accompanying Series A Common Stock Warrant and Series B Common Stock Warrant.

The exercise price of each Series A Common Stock Warrant and Series B Common Stock Warrant from the Initial Subscription is \$1.772 per share and \$1.908 per share in the Additional Subscription, provided that the exercise price for the Series A Common Stock Warrants and Series B Common Stock Warrants issued to the Company Insiders is \$1.79 per share. Subject to certain ownership limitations, the Series A Common Stock Warrants are exercisable until the five-year anniversary of issuance. Subject to certain ownership limitations, the Series B Common Stock Warrants are exercisable until the one-year anniversary of the declaration of effectiveness of this prospectus. The Pre-Funded Warrant do not expire until exercised in full.

The May 2024 PIPE Financing closed on May 9, 2024. The aggregate gross proceeds at the May 2024 PIPE Financing closing were approximately \$7.25 million, before deducting certain expenses payable by the Company, and excluding the proceeds, if any, from the exercise of the Series A Common Stock Warrant, the Series B Common Stock Warrant, and Pre-Funded Warrant.

### *Departure of Former Chief Medical Officer*

On June 5, 2024, Dr. LaFrance, the Company's then-Chief Medical Officer, resigned from his position at the Company.

## Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in the "[Risk Factors](#)" section of this prospectus, that represent challenges that we face in connection with the successful implementation of our strategy and the growth of our business. In particular, the following considerations, among others, may offset our competitive strengths or have a negative effect on our business strategy, which could cause a decline in the price of our common stock and result in a loss of all or a portion of your investment:

### *Risks Related to Our Financial Position and Capital Requirements*

- We have incurred losses since inception, and we expect to incur significant net losses in the foreseeable future and we may never become profitable and our operating results have been and will likely continue to be volatile.

- Uncertainties relating to our ability to fund our operations for at least the next 12 months raises substantial doubt about our ability to continue as a going concern.
- We could be delisted from Nasdaq, which would seriously harm the liquidity of our stock and our ability to raise capital.
- We will need substantial additional funding to develop our product candidates and conduct our future operations and to repay our outstanding debt obligations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development activities or may be unable to continue our business operations.
- Borrowings under our line of credit have the effect of limiting our use of cash and marketable securities.
- We maintain our cash at financial institutions, often in balances that exceed federally insured limits.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

*Risks Related to Our Business and Industry*

- If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.
- Our future success is in large part dependent upon our ability to successfully develop our nanomedicine platform and commercialize rhenium ( $^{186}\text{Re}$ ) obisbameda and  $^{188}\text{RNL}$ -BAM and any failure to do so could significantly harm our business and prospects.
- If we are unable to successfully partner with other companies to commercialize our product candidates, our business could materially suffer.
- Our success depends in substantial part on our ability to obtain regulatory approvals for our rhenium ( $^{186}\text{Re}$ ) obisbameda and  $^{188}\text{RNL}$ -BAM product candidates. However, we cannot be certain that we will receive regulatory approval for these product candidates or our other product candidates.
- If we or any party to a key collaboration, licensing, development, acquisition or similar arrangement fail to perform material obligations, or commit a breach, under such arrangement, or any arrangement is terminated for any reason, there could be an adverse effect on our business.
- Our current business strategy is high-risk and may not be successful.
- Reliance on government funding for our programs may impose requirements that limit our ability to take certain actions, and subject it to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.
- If our competitors market or develop products that are marketed more effectively, approved more quickly than our product candidates, or demonstrated to be safer or more effective than our product candidates, our commercial opportunities could be reduced or eliminated.
- Product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Pre-clinical studies and preliminary and interim data from clinical trials of our product candidates are not necessarily predictive of the results or success of ongoing or future clinical trials of our product candidates.
- Because we have limited resources, we may decide to pursue a particular product candidate and fail to advance product candidates that later demonstrate a greater chance of clinical and commercial success.
- Clinical trial results may fail to support approval of our product candidates.

- If third parties with whom we engage are not able to successfully perform, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates and our business could be substantially harmed.
- We may have difficulty enrolling, or fail to enroll patients in our clinical trials, which could delay or prevent clinical trials of our drug candidates.
- If a particular product candidate causes significant adverse events, then we may be unable to receive regulatory approval or market acceptance for such product candidate.
- If our product candidates and technologies receive regulatory approval but do not achieve broad market acceptance, especially by physicians, the revenue that we generate will be limited.
- All potential applications of our product candidates are investigational, which subjects us to development and marketing risks.
- We and our product candidates are subject to extensive regulation, and the requirements to obtain regulatory approvals in the United States and other jurisdictions can be costly, time-consuming, and unpredictable. If we or our partners are unable to obtain timely regulatory approval for our product candidates, our business may be substantially harmed.
- We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant expense, and if we or our collaborators fail to comply with such requirements, regulatory agencies may take action against us or them, which could significantly harm our business.
- Changing, new and/or emerging government regulations, including healthcare legislative reform measures, may adversely affect us.
- Adequate coverage and reimbursement from third party payors may not be available for our products and we may be unable to successfully contract for coverage from pharmacy benefit managers and other organizations; conversely, to secure coverage from these organizations, we may be required to pay rebates or other discounts or other restrictions to reimbursement, either of which could diminish our sales or adversely affect our ability to sell our products profitably.
- Some intellectual property that we have in-licensed has been discovered through government funded programs and thus may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.
- Orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position could be harmed.
- If we experience an interruption in supply from a material sole source supplier, our business may be harmed.
- We may engage in strategic transactions that could impact our liquidity, increase our expenses, and present significant distractions to our management.
- We must maintain quality controls and compliance with manufacturing standards.
- If we are unable to identify, hire and/or retain key personnel, we may not be able to sustain or grow our business.
- We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

- A failure to adequately protect private health information could result in severe harm to our reputation and subject us to significant liabilities, each of which could have a material adverse effect on our business.
- We and our collaborators must comply with environmental laws and regulations, including those pertaining to use of hazardous and biological materials in our business, and failure to comply with these laws and regulations could expose us to significant liabilities.
- If we are unable to successfully develop the CNside technology, or successfully utilize and fully integrate CNside into our operations, we may not generate revenues from or realize the anticipated benefits of CNside, within our expected timeline or at all, and our business may be harmed as a result.

*Risks Related to Our Intellectual Property*

- Our success depends in part on our ability to protect our intellectual property. We may not be able to protect our trade secrets.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our product candidates and technology.
- If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

*Risks Related to the Securities Markets and an Investment in Our Common Stock*

- We have been notified by Nasdaq of our failure to comply with certain continued listing requirements and, if we are unable to regain compliance with all applicable continued listing requirements and standards of Nasdaq, our common stock could be delisted from Nasdaq.
- We may issue additional shares of common stock or other equity securities without our stockholder approval, and holders of warrants and other securities convertible into shares of our common stock may choose to exercise their warrants and other securities requiring us to issue shares of common stock; all of these actions would dilute your ownership interest and may depress the market price of our common stock.
- The market price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for stockholders, and future sales of our common stock may depress our share price.
- We may be or become the target of securities litigation, which is costly and time-consuming to defend.
- We may issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.
- Our organizational documents contain anti-takeover provisions.

**Company Information**

We were initially formed as a California general partnership in July 1996, and subsequently incorporated in the State of Delaware in May 1997. Our corporate offices are located at 4200 Marathon Blvd., Suite 200, Austin,

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Texas 78756. Our telephone number is (737) 255-7194. We maintain a website at [www.plustherapeutics.com](http://www.plustherapeutics.com). The contents of our website are not part of this prospectus and the references in this prospectus to our website do not constitute incorporation by reference into this prospectus of the information contained therein.



**The Offering**

Issuer	Plus Therapeutics, Inc.
Common stock Offered by the Selling Stockholders	10,774,596 shares of common stock
Use of Proceeds	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus.
Nasdaq Symbol	PSTV
Offering Price	The selling stockholders will offer the shares of common stock offered by this prospectus at the prevailing market prices or at privately negotiated prices.
Risk Factors	You should read the section entitled “ <a href="#">Risk Factors</a> ” of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

For additional information concerning the offering, see the section entitled “[Plan of Distribution](#)” beginning on page 93.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below as well as the other information in this prospectus, including our financial statements and the notes thereto, and “[Management’s Discussion and Analysis of Financial Condition and Results of Operations](#),” before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could adversely affect our business, results of operations, financial condition, reputation, and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently believe are not material may also impair our business, results of operations, financial condition, and prospects.*

### **Risks Related to our Financial Position and Capital Requirements**

*We have incurred losses since inception, we expect to incur significant net losses in the foreseeable future and we may never become profitable and our operating results have been and will likely continue to be volatile.*

We have generated negative cash flows from operations and have incurred net operating losses each year since we started business. For the year ended December 31, 2023, and quarter ended March 31, 2024, we incurred net losses of \$13.3 million and \$3.3 million, respectively, our net cash used in operating activities was \$12.9 million and \$4.5 million, respectively. As of March 31, 2024, our accumulated deficit was approximately \$483.8 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next twelve months. As our focus on development of nanomedicine and the development of therapeutic applications has increased, losses have resulted primarily from expenses associated with research and development and clinical trial-related activities, as well as general and administrative expenses. We expect to continue operating in a loss position and expect that recurring operating expenses will be at higher levels for the year ending December 31, 2024, than the year ended December 31, 2023, as we perform clinical trials and other development activities for our nanomedicine product candidates.

Our ability to generate sufficient revenue from any of our products, product candidates or technologies to achieve profitability will depend on a number of factors including, but not limited to:

- our ability to manufacture, test and validate our product candidates in compliance with applicable laws and as required for submission to applicable regulatory bodies, including manufacturing, testing and validation of our RNL candidates;
- our or our partners’ ability to successfully complete clinical trials of our product candidates;
- our ability to obtain necessary regulatory approvals for our product candidates;
- our or our partners’ ability to negotiate and receive favorable reimbursement for our product candidates, including for our product candidates that have been granted or may be granted orphan drug status or otherwise command currently anticipated pricing levels;
- our ability to negotiate favorable arrangements with third parties to help finance the development of, and market and distribute, our products and product candidates; and
- the degree to which our approved products are accepted in the marketplace.

Because of the numerous risks and uncertainties associated with our commercialization and product development efforts, we are unable to predict the extent of our future losses or when or if we will become profitable and it is possible we will never become profitable. If we do not generate significant sales from any of our product candidates that receive regulatory approval, there would be a material adverse effect on our business, results of operations, financial condition and prospects, which in turn could result in our inability to continue operations.

Our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced biotech, pharmaceutical and medical device fields. In addition, our budgeted expense levels are based in part on our

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expectations concerning future research and development activities. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events. Accordingly, unexpected events could have an immediate and material impact on our business and financial condition. From time to time, we have tried to update our investors' expectations as to our operating results. If we revise any timelines we may give with respect to our clinical trials, it could materially harm our reputation and the market's perception of us and could cause our stock price to decline.

### ***Uncertainties relating to our ability to fund our operations for at least the next 12 months raises substantial doubt about our ability to continue as a going concern.***

As of March 31, 2024, we had an accumulated stockholders' deficit of approximately \$483.8 million, a working capital deficit of approximately \$6.2 million, and approximately \$2.9 million of cash and cash equivalents to fund our operations and capital requirements. We do not currently have sufficient available liquidity to fund our operations for at least the next 12 months. Consequently, absent further actions, these matters raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements in this prospectus are issued.

We have a history of generating losses and negative cash flows from operations. Our financial statements have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our ability to continue as a going concern is dependent upon our ability to obtain additional debt, equity or other financing. Furthermore, we also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our intellectual property or product candidates or otherwise agree to terms unfavorable to us.

If we are unsuccessful in our efforts to raise any such additional capital, we would be required to take actions that could materially and adversely affect our business, including significant reductions in our research, development and administrative operations (including reduction of our employee base), possible surrender or other disposition of our rights to some technologies or product opportunities, delaying of our clinical trials or curtailing or ceasing operations.

### ***We could be delisted from Nasdaq, which would seriously harm the liquidity of our stock and our ability to raise capital.***

Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. These requirements include, among other things, maintaining a closing bid price for our common stock of \$1.00 per share (the "minimum bid price requirement") and meeting one of the following three requirements: maintaining at least \$2.5 million in stockholders' equity; maintaining \$35 million of market value of listed securities; or having \$500,000 in net income over the prior two years or two of the prior three years. In 2022, we received notice that because the closing bid price for our common stock had fallen below \$1.00 per share for 30 consecutive business days, we no longer complied with the minimum bid price requirement. While we cured this deficiency in 2023 after effecting the Reverse Stock Split (as defined below), there is no assurance that we will be able to maintain compliance with this standard. As of December 31, 2023, our stockholders' deficit was \$1.3 million. The market value of our listed securities was below \$35 million and we did not have net income in the last three years (the "Alternative Standards").

On March 8, 2024, we received a letter (the "Notice") from the Listing Qualifications staff of Nasdaq Capital Market ("Nasdaq Staff"), notifying us that we no longer complied with the requirement under Nasdaq Listing Rule 5550(b)(1) to maintain a minimum of \$2.5 million in stockholders' equity for continued listing on Nasdaq or the alternative requirements of having a market value of listed securities of \$35 million or net income from continuing operations of \$500,000 in the most recently completed fiscal year or two of the last three most recently completed fiscal years (the "Alternative Standards"). The Notice states that our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, disclosed stockholders' equity of (\$1.3 million) as of December 31, 2023, and that, as of March 8, 2024, we did not meet the Alternative Standards.

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On April 22, 2024, we provided Nasdaq with our plan to achieve and sustain compliance with the stockholders' equity requirement and requested that Nasdaq grant us an extension of time until September 4, 2024, to provide evidence of compliance with the stockholders' equity requirement. Consistent with that plan, in May 2024, we completed the May 2024 PIPE Financing, which resulted in our stockholders' equity being greater than \$2.5 million as of completion of the offering. Nasdaq has not yet responded to our plan, and there can be no assurance that Nasdaq will grant an extension or that we will be able to comply with the applicable listing standards of Nasdaq.

If, for any reason, Nasdaq were to delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders:

- the liquidity and marketability of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

In addition, if we cease to be eligible to trade on Nasdaq, we may have to pursue trading on a less recognized or accepted market, such as the over the counter markets, our stock may be traded as a "penny stock," which would make transactions in our stock more difficult and cumbersome, and we may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to decline.

***We will need substantial additional funding to develop our product candidates and conduct our future operations and to repay our outstanding debt obligations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development activities or may be unable to continue our business operations.***

We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to continue funding our operations, including our continuing substantial research and development expenses and potential commercialization activities. We do not currently believe that our cash balance will be sufficient to fund the development and marketing efforts required to reach profitability without raising additional capital from accessible sources of financing in the near future. Our future capital requirements will depend on many factors, including:

- our ability to raise capital to fund our operations on terms acceptable to us, or at all;
- our perceived capital needs with respect to our development programs, and any delays in, adverse events and excessive costs of such programs beyond what we currently anticipate;
- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our product candidates to market and the cost of such arrangements at the time;
- costs associated with operating at our San Antonio, Texas facility;
- the cost of manufacturing our product candidates, including compliance with good manufacturing practices applicable to our product candidates;
- expenses related to the establishment of sales and marketing capabilities for product candidates awaiting approval or products that have been approved;

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- competing technological and market developments; and
- our ability to introduce and sell new products.

The amount and timing of our future funding requirements will depend on many factors, including the pace and results of its clinical development efforts.

We have secured capital historically from grant revenue, collaboration proceeds, and debt and equity offerings. To obtain additional capital, we may pursue debt and/or equity offering programs, strategic corporate partnerships, state and federal development programs, licensing arrangements, and sales of assets or debt or equity securities. We cannot be certain that additional capital will be available on terms acceptable to us, or at all. If we are unsuccessful in our efforts to raise any such additional capital, we may be required to take actions that could materially and adversely harm our business, including a possible significant reduction in our research, development and administrative operations (including reduction of our employee base), the surrender of our rights to some technologies or product opportunities, delay of our clinical trials or regulatory and reimbursement efforts, or curtailment or cessation of operations.

Depending on the type and the terms of any financing we pursue, stockholders' rights and the value of their investment in our common stock could be reduced. A financing could involve one or more types of securities including common stock, convertible debt or warrants to acquire common stock. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue secured debt securities, the holders of the debt would have a claim to our assets that would be prior to the rights of stockholders until the debt is paid. Interest on these debt securities would increase costs and negatively impact operating results. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be negatively impacted.

On August 2, 2022, we entered into a purchase agreement (the "2022 Purchase Agreement") and registration rights agreement pursuant to which Lincoln Park Capital Fund ("Lincoln Park") committed to purchase up to \$50.0 million shares of our common stock. Under the terms and subject to the conditions of the 2022 Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$50.0 million shares of our common stock, provided that we cannot sell more than 57.5 million shares pursuant to the 2022 Purchase Agreement. Sales of common stock by us are subject to certain limitations, and can occur from time to time, at our sole discretion, over the 36-month period commencing on August 17, 2022, subject to the satisfaction of certain conditions. As consideration for Lincoln Park's irrevocable commitment to purchase shares of our common stock upon the terms of and subject to satisfaction of the conditions set forth in the Purchase Agreement, we paid \$0.1 million in cash as an Initial Commitment Fee and issued 492,698 Commitment Shares to Lincoln Park in consideration for its commitment to purchase shares of our common stock at our direction under the Purchase Agreement.

On August 17, 2022, a registration statement (the "First Registration Statement") was declared effective covering the resale of up to 9,500,000 shares of our common stock comprised of (i) the 492,698 Commitment Shares, and (ii) up to 9,007,302 shares that we reserved for issuance and sale to Lincoln Park under the Purchase Agreement. We cannot sell more shares under the 2022 Purchase Agreement without registering additional shares. We sold approximately 527,166 shares under the First Registration Statement.

On August 18, 2023, a second registration statement (the "Second Registration Statement") was declared effective covering the resale of up to an additional 1,500,000 shares of our common stock that we reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time. We sold 150,000 shares under the Second Registration Statement. We cannot sell more shares pursuant to the 2022 Purchase Agreement than are registered under the Second Registration Statement without registering additional shares.

Even with the arrangements described above, we will need to complete additional financing transactions in order to continue operations. These arrangements may also not be sufficient in the near-term. Given, among other things, the current status of the capital markets and our recent stock price performance and financing strategies we may pursue may not be sufficient to fund our operations in the near term, there can be no assurances that we

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will be able to secure additional financing, or if available, that it will be sufficient to meet our needs or be on favorable terms. Additionally, our cost of capital will depend upon numerous factors including, but not limited to, the strength of the financial markets, global market conditions, including inflationary pressures, interest rate fluctuations, our recovery and financial performance, the recovery and performance of our industry in general and the size, scope and timing of our financial needs. If we are unable to access current financings or secure future financings, including for any of the foregoing reasons, it will have a negative impact on our cash flows and our ability to meet our financial obligations. Failure to raise capital as and when needed, on favorable terms or at all, would have a significant negative impact on our financial condition and our ability to develop our product candidates.

### ***Borrowings under our line of credit have the effect of limiting our use of cash and marketable securities.***

We have an existing margin loan facility under a line of credit (the “Pershing Credit Facility”) with Pershing LLC (“Pershing”), an affiliate of The Bank of New York Mellon Corporation. The available credit line limit under this facility fluctuates based on our request for extensions from time to time, subject to the value of the collateralized marketable securities we hold with Pershing, provided that the amount available to draw under the facility cannot exceed 91.5% of the value of the collateralized marketable securities deposited with Pershing. Depending on the value of the marketable securities we hold with Pershing, Pershing may require us from time-to-time to deposit additional funds or marketable securities in order to restore the level of collateral to an acceptable level, and the amounts borrowed under the facility are due on demand. Volatility in the global markets could cause the interest rate to fluctuate from time to time increasing our costs, or could cause Pershing to terminate our ability to borrow funds. In addition, borrowings under the Pershing Credit Facility have the effect of limiting our use of cash and marketable securities.

### ***We maintain our cash at financial institutions, often in balances that exceed federally insured limits.***

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. The majority of our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in depository accounts may exceed the \$250,000 Federal Deposit Insurance Corporation (“FDIC”) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. By way of example, the FDIC took control of Silicon Valley Bank (“SVB”) on March 10, 2023. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although depositors at SVB received access to their funds, uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to \$25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all. Additionally, in the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. Any material loss that we may experience in the future could have a material adverse effect on our financial condition and could materially impact our ability to pay our operational expenses or make other payments.

### ***Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.***

We do not expect to make profits in the near future. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change, by

value, in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income and taxes may be limited. We have undergone "ownership changes" as a result of shifts in stock ownership in the past, which significantly limited our ability to use net operating loss carryforwards and other pre-change tax attributes. Any additional ownership change within the definition of Section 382 would further limit our ability to use net operating loss carryforwards and other tax attributes. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

### **Risks Related to Our Business and Industry**

*If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.*

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K and Form 10-Q, as required by Section 404 of the Sarbanes-Oxley Act.

During the quarter ended June 30, 2023, we recognized immaterial grant revenue related to reimbursable development costs incurred in the fourth quarter of 2022 and the first quarter of 2023 that were eligible for revenue recognition in those respective prior periods. These costs were eligible for reimbursement under our CPRIT Grant, but were not correctly recognized in prior period grant revenue due to management's view that insufficient progress had been made in the ReSPECT -LM clinical trial, despite no performance specific milestones in the grant outside of a reasonableness test for reimbursement of expenses. Management has concluded that the correction to grant revenue in the prior periods did not cause a material misstatement of our financial statements.

As a result, we concluded that we did not have adequate controls to apply appropriate accounting principles to significant and unusual grant revenue transactions. Specifically, controls over identification of significant and/or unusual transactions requiring technical analysis were not operating effectively. Management evaluated the impact of this deficiency on our disclosure controls and procedures and concluded that the control deficiency represents a material weakness. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Since the identification of the material weakness, we have taken steps to remediate the material weakness mentioned above, including strengthening our review process related to significant and unusual transactions, such as multiple level of review of categorization of the research and development expenses eligible for grant revenue and supporting evidence of such expenses.

In the quarter ended March 31, 2024, we completed the testing of the design and operating effectiveness of the controls over application of appropriate accounting principles to significant and unusual grant revenue transaction. While management determined that the controls are adequately designed and are operating effectively, and concluded that the material weakness identified in the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 had been remediated, there can be no certainty that the issue has been fully remediated or will not reoccur.

Furthermore, we may in the future discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control

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system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

***Our future success is in large part dependent upon our ability to successfully develop our nanomedicine platform and commercialize rhenium (<sup>186</sup>Re) obisbameda and <sup>188</sup>RNL-BAM and any failure to do so could significantly harm our business and prospects.***

Our ability to successfully develop and commercialize rhenium (<sup>186</sup>Re) obisbameda and <sup>188</sup>RNL-BAM is subject to a number of risks, including the following:

- we do not have substantive drug development, manufacturing, and commercialization experience, and thus we may be required to hire and rely on significant numbers of scientific, quality, regulatory and other technical personnel with the experience and expertise necessary to develop, manufacture, and commercialize our nanomedicine product candidates. We may be unable to identify, hire and retain personnel with the requisite experience to conduct the operations necessary to obtain regulatory approval and commercialize our RNL product candidates, in which case our business would be materially harmed;
- we intend to find a commercialization partner to share or assume responsibility for marketing, sales, and distribution activities and related costs and expenses for our RNL product candidates. There can be no assurance that we would obtain sufficient capital to fund the development, manufacturing, and commercialization of our nanomedicine program ourselves, or if we do obtain such capital, that our development, manufacturing, and commercialization efforts would be successful; and
- to the extent that we incur unanticipated expenses in our business, are unable to timely obtain sufficient additional capital on terms acceptable to us (or at all) to fund this business, our ability to develop our RNL product candidates could be materially and adversely impacted.

***If we are unable to successfully partner with other companies to commercialize our product candidates, our business could materially suffer.***

A key part of our business strategy is to leverage strategic partnerships and collaborations to commercialize our product candidates. We do not have the financial, human or other resources necessary to develop, commercialize, launch or sell our therapeutic offerings in all of the geographies that we are targeting, and thus it is important that we identify and partner with third parties who possess the necessary resources to bring our product candidates to market. We expect that any such partners will provide regulatory and reimbursement/pricing expertise, sales and marketing resources, and other expertise and resources vital to the success of our product offerings in their territories. We further expect, but cannot guarantee, that any such partnering arrangements will include upfront cash payments to us in return for the rights to develop, manufacture, and/or sell our product candidates in specified territories, as well as downstream revenue in the form of milestone payments and royalties. If we are unable to successfully partner with other companies to commercialize our product candidates, our business could materially suffer.

***Our success depends in substantial part on our ability to obtain regulatory approvals for our RNL product candidates. However, we cannot be certain that we will receive regulatory approval for these product candidates or our other product candidates.***

We have a limited number of product candidates in development, and our business depends substantially on their successful development and commercialization. Our product candidates will require development, regulatory



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review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from sales of our product candidates. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country.

We are not permitted to market our product candidates in the United States until we receive approval from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries (including centralized marketing authorization from EMA), and we may never receive such regulatory approvals. Obtaining regulatory approval for a product candidate is a lengthy, expensive and uncertain process, and may not be obtained. Any failure to obtain regulatory approval of any of our product candidates would limit our ability to generate future revenue (and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue), would potentially harm the development prospects of our product candidates and would have a material and adverse impact on our business.

Even if we successfully obtain regulatory approvals to market our product candidates, our revenue will be dependent, in part, on our ability to commercialize such products as well as the size of the markets in the territories for which we gain regulatory approval. If the markets for our product candidates are not as significant as we estimate, our business and prospects will be harmed.

If a product candidate is not approved in a timely fashion on commercially viable terms, or if development of any product candidate is terminated due to difficulties or delays encountered in the regulatory approval process, it could have a material adverse effect on our business, and we may become more dependent on the development of other proprietary products and/or our ability to successfully acquire other products and technologies. There can be no assurance that any product candidate will receive regulatory approval in a timely manner, or at all.

***If we or any party to a key collaboration, licensing, development, acquisition or similar arrangement fail to perform material obligations, or commit a breach, under such arrangement, or any arrangement is terminated for any reason, there could be an adverse effect on our business.***

We are currently party to certain licensing, collaboration and acquisition agreements under which we may make or receive future payments in the form of milestone payments, maintenance fees, royalties and/or minimum product purchases. Our collaborators may not devote the attention and resources to such efforts to be successful. The termination of a key collaboration agreement by one of our collaborators could materially impact our ability to enter into additional collaboration agreements with new collaborators on favorable terms.

On March 29, 2020, we entered into an exclusive license agreement with NanoTx for the global rights to develop and commercialize NanoTx's glioblastoma treatment, rhenium (<sup>186</sup>Re) obisbameda. Under the license agreement with NanoTx, we are required to use commercial reasonable efforts to develop the rhenium (<sup>186</sup>Re) obisbameda product candidate acquired under the license agreement. Further, we are subject to future milestone, earn-out and other payments to NanoTx all of which are tied to our commercialization and sale activities for product candidates. If we are unsuccessful in our efforts to develop these assets, or if NanoTx and we were to enter into a dispute over the terms of our agreement, then our business could be seriously harmed.

On December 31, 2021, we entered into an exclusive license agreement with UT Health Science Center at San Antonio for the global rights to develop and commercialize Rhenium-188 NanoLiposome biodegradable alginate microspheres (<sup>188</sup>RNL-BAM). Under the license agreement with UTHSA, we are required to use commercial reasonable efforts to develop the <sup>188</sup>RNL-BAM product candidate acquired under the license agreement. Further, we are subject to future milestone, earn-out and other payments to UTHSA all of which are tied to our commercialization and sale activities for product candidates. If we are unsuccessful in our efforts to develop these assets, or if UTHSA and we were to enter into a dispute over the terms of our agreement, then our business could be seriously harmed.

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If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties, we could lose license rights that are important to our business. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other intellectual property rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- whether and the extent to which inventors are able to contest the assignment of their rights to our licensors.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize the affected product candidates. In addition, if disputes arise as to ownership of licensed intellectual property, our ability to pursue or enforce the licensed patent rights may be jeopardized. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

### ***Our current business strategy is high-risk and may not be successful.***

Our current business strategy is to aggressively develop our nanomedicine platforms, while simultaneously controlling expenses, which is a high-risk strategy for a number of reasons including the following:

- we do not have prior experience with obtaining regulatory, reimbursement, or other approvals for product candidates such as rhenium ( $^{186}\text{Re}$ ) obisbameda and  $^{188}\text{RnL}$ -BAM;
- our nanomedicine product candidates, if commercialized, will compete against established competitive drugs that are marketed and sold by large companies with significant human, technical and financial resources;
- we are not experienced in acquiring and integrating new assets;
- there is an intense and rapidly evolving competitive landscape for our nanomedicine product candidates, including chemotherapies, targeted therapies and immuno-oncology therapies, and as such key assumptions regarding market entry, pricing, and revenue/unit share may not be realized;
- our product candidates may never become commercially viable; and
- we may not be able to prevent other companies from depriving us of market share and profit margins by selling products based on our intellectual property and developments.

### ***Reliance on government funding for our programs may impose requirements that limit our ability to take certain actions, and subject it to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.***

A significant portion of our funding will come from grants received from CPRIT. The CPRIT Grant includes provisions that reflect the government's substantial rights and remedies, many of which are not typically found in

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commercial contracts, including powers of the government to potentially require repayment of all or a portion of the grant award proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters that include any potential relocation outside of the State of Texas. After the CPRIT Grant ends, we are not permitted to retain any unused grant award proceeds without CPRIT's approval, but our obligation to pay CPRIT sales-based royalty, if and when commercialization is achieved, and other obligations, including our obligation to repay the disbursed grant proceeds under certain circumstances, to maintain certain records and documentation, to notify CPRIT of certain unexpected adverse events and our obligation to use reasonable efforts to ensure that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing related to any aspect to our CPRIT project take place in Texas, survive the termination of the agreement.

Our award from CPRIT requires us to pay CPRIT a portion of our revenues from sales of certain products by us, or received from our licensees or sublicensees, at tiered percentages of revenue in the low- to mid-single digits until the aggregate amount of such payments equals 400% of the grant award proceeds, and thereafter at a rate of 0.5% for as long as we maintain government exclusivity, subject to our right, under certain circumstances, to make a one-time payment in a specified amount to CPRIT to terminate such payment obligations. In addition, the grant contract also contains a provision that provides for repayment to CPRIT of some amount not to exceed the full amount of the grant proceeds under certain specified circumstances involving relocation of our principal place of business outside Texas.

The CPRIT Grant requires us, as a Texas-based company, to meet certain criteria, including among other things, that we maintain our headquarters in Texas and use certain vendors, consultants and employees that are located in Texas. If we fail to maintain compliance with any such requirements that may apply to us now or in the future, we may be subject to potential liability and to termination of our contracts, and potentially full repayment of the CPRIT Grant.

***If our competitors market or develop products that are marketed more effectively, approved more quickly than our product candidates, or demonstrated to be safer or more effective than our product candidates, our commercial opportunities could be reduced or eliminated.***

The life science industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products or product candidates, including small and large, domestic and multinational, medical device, biotechnology and pharmaceutical companies, academic institutions, government agencies, and private and public research institutions.

Competitors may have greater experience in developing drugs, conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercialization. It is possible that competitors may obtain patent protection, approval, or clearance from the FDA or achieve commercialization earlier than we can, any of which could have a substantial negative effect on our business. Many of our potential competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and experience;
- product development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name, brand and product recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

We expect that product candidates in our pipeline, if approved, to compete on the basis of, among other things, product efficacy and safety, time to market, price, coverage, and reimbursement by third-party payers, extent of

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adverse side effects, and convenience of treatment procedures. One or more of our competitors may develop other products that compete with ours, obtain necessary approvals for such products from the FDA, EMA, Ministry of Health, Labour and Welfare or other agencies, if required, more rapidly than we do or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us. The competition that we encounter with respect to any of our product candidates that receive the requisite regulatory approval and classification and are marketed may have an effect on our product prices, market share, and results of operations. We may not be able to differentiate any products that we are able to market from those of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors.

As a result of these factors, our competitors may obtain regulatory approval of their products more quickly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop products that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted, or less costly than ours and may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with any of our product candidates that are approved, our business, results of operations, financial condition, and prospects may be materially adversely affected.

***Product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

Clinical testing of our product candidates is a long, expensive and uncertain process, and the failure or delay of a clinical trial can occur at any stage. Many factors, currently known and unknown, can adversely affect clinical trials and the ability to evaluate a product candidate's efficacy. During the course of treatment, patients can die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Even if initial results of preclinical and nonclinical studies or clinical trial results are promising, we may obtain different results in subsequent trials or studies that fail to show the desired levels of safety and efficacy, or we may not obtain applicable regulatory approval for a variety of other reasons.

Further, with respect to the conduct and results of clinical trials generally, in the United States, Europe, Japan, and other jurisdictions, the conduct and results of clinical trials can be delayed, limited, suspended, or otherwise adversely affected for many reasons, including, among others:

- delay or failure in reaching agreement with the FDA or other regulatory authorities outside of the United States on acceptable clinical trial design, or in obtaining authorization to commence a trial;
- delay or failure in reaching agreement on acceptable terms with prospective clinical research organizations ("CRO"), and clinical trial sites;
- delay or failure in obtaining approval of an IRB or ethics committees before a clinical trial can be initiated at a prospective trial site;
- withdrawal of clinical trial sites from our clinical trials, including as a result of changing standards of care or the ineligibility of a site to participate;
- clinical results may not meet prescribed endpoints for the studies, produce negative or inconclusive results, or otherwise not provide sufficient data to support the efficacy of our product candidates;
- clinical and nonclinical test results may reveal side effects, adverse events or unexpected safety issues associated with the use of our product candidates;
- emerging of dosing issues;

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- lack of adequate funding to continue the clinical trials, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies, and increased expenses associated with the services of our CROs and other third parties;
- inability to design appropriate clinical trial protocols;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- clinical sites or investigators may deviate from trial protocol or fail to conduct the trial in accordance with applicable regulatory requirements, or drop out of a trial;
- regulatory review may not find a product safe or effective enough to merit either continued testing or final approval;
- regulatory authorities may require that we change our studies or conduct additional studies which may significantly delay or make continued pursuit of approval commercially unattractive;
- a regulatory agency may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations;
- the cost of clinical trials required for product approval may be greater than what we originally anticipate, and we may decide to not pursue regulatory approval for such a product;
- changes in the standard of care of the indication being studied;
- a regulatory agency may identify problems or other deficiencies in our existing manufacturing processes or facilities or the existing processes or facilities of our collaborators, our contract manufacturers, or our raw material suppliers;
- a regulatory agency may change its formal or informal approval requirements and policies, act contrary to previous guidance, adopt new regulations, or raise new issues or concerns late in the approval process; and
- a regulatory agency may ask us to put a clinical study on hold pending additional safety data (and there can be no assurance that we will be able to satisfy the regulator agencies' requests in a timely manner, which can lead to significant uncertainty in the completion of a clinical study).

We also face clinical trial-related risks with regard to our reliance on other third parties in the performance of many of the clinical trial functions, including CROs that help execute our clinical trials, the hospitals and clinics at which our trials are conducted, the clinical investigators at the trial sites, and other third-party service providers. Failure of any third-party service provider to adhere to applicable trial protocols, laws and regulations in the conduct of one of our clinical trials could adversely affect the conduct and results of such trial (including possible data integrity issues), which could seriously harm our business.

We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed or inhibited. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations, cash flows and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

***Pre-clinical studies and preliminary and interim data from clinical trials of our product candidates are not necessarily predictive of the results or success of ongoing or future clinical trials of our product candidates.***

Pre-clinical studies and any positive preliminary and interim data from our clinical trials of our product candidates may not necessarily be predictive of the results of ongoing or later clinical trials. A number of companies in the pharmaceutical and biotechnology industries, including us and many other companies with greater resources and experience than we, have suffered significant setbacks in clinical trials, even after seeing promising results in prior pre-clinical studies and clinical trials. Even if we are able to complete our planned clinical trials of our product candidates according to our current development timeline, initial positive results from pre-clinical studies and clinical trials of our product candidates may not be replicated in subsequent clinical trials. The design of our later stage clinical trials could differ in significant ways (e.g., inclusion and exclusion criteria, endpoints, statistical analysis plan) from our earlier stage clinical trials, which could cause the outcomes of the later stage trials to differ from those of our earlier stage clinical trials. If we fail to produce positive results in our planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, could be materially adversely affected. If we fail to produce positive results in our planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for such product candidates, and, correspondingly, our business and financial prospects, could be materially adversely affected.

***Because we have limited resources, we may decide to pursue a particular product candidate and fail to advance product candidates that later demonstrate a greater chance of clinical and commercial success.***

We are an early-stage company with limited resources and revenues. The product candidates we currently have under development will require significant development, pre-clinical and clinical testing and investment of significant funds before their commercialization. Because of this, we must make strategic decisions regarding resource allocations and which product candidates to pursue. There can be no assurance that we will be able to develop all potentially promising product candidates that we may identify. Based on preliminary results, we may choose to advance a particular product candidate that later fails to be successful, and simultaneously forgo or defer further investment in other product candidates that later are discovered to demonstrate greater promise in terms of clinical and commercial success. If we make resource allocation decisions that later are shown to be inaccurate, our business and prospects could be harmed.

***Clinical trial results may fail to support approval of our product candidates.***

Even if our clinical trials are successfully completed as planned, the results may not support approval of our product candidates under the laws and regulations of the FDA or other regulatory authorities outside the United States. The clinical trial process may fail to demonstrate that our product candidates are both safe and/or effective for their intended uses. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of our product candidates. This, in turn, would significantly adversely affect our business prospects.

***If third parties we engage are not able to successfully perform, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates and our business could be substantially harmed.***

We rely on third parties in the performance of many of the clinical trial functions, including CROs, which help execute our clinical trials, the hospitals and clinics at which our trials are conducted, the clinical investigators at the trial sites, and other third-party service providers. Failure of any third-party service provider to adhere to applicable trial protocols, laws and regulations in the conduct of one of our clinical trials could adversely affect the conduct and results of such trial (including possible data integrity issues), which could seriously harm our

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business. As a result, results from our clinical trials may be delayed, which in turn would have a material adverse impact on our clinical trial plans and timelines and impair our ability to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates. This in turn would substantially harm our business and operations.

We also rely on third-party expertise to support us in this area. We have entered into contracts with third-party manufacturers to manufacture, supply, store and distribute supplies of our product candidates for our clinical trials. If any of our product candidates receives FDA approval, we expect to rely on third-party contractors to manufacture our drugs. We have no current plans to build internal manufacturing capacity for any product candidate, and we have no long-term supply arrangements.

Our reliance on third-party manufacturers exposes us to potential risks, such as the following:

- we may be unable to contract with third-party manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited. Potential manufacturers of any product candidate that is approved will be subject to FDA compliance inspections and any new manufacturer would have to be qualified to produce our products;
- our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any;
- our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials through completion or to successfully produce, store and distribute our commercial products, if approved;
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and other government agencies to ensure compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures;
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such improvements; and
- a third-party manufacturer may gain knowledge from working with us that could be used to supply one of our competitors with a product that competes with ours.

Each of these risks could delay or have other adverse impacts on our clinical trials and the approval and commercialization of our product candidates, potentially resulting in higher costs, reduced revenues or both.

### ***We may have difficulty enrolling, or fail to enroll patients, in our clinical trials, which could delay or prevent clinical trials of our drug candidates.***

Identifying and enrolling patients to participate in clinical trials of our product candidates is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. The eligibility criteria of our planned clinical trials may further limit the available eligible trial participants as we require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical trials. We may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical trials in a timely manner because of the perceived risks and benefits of the drug candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our drug candidates may be delayed.

If we experience delays in the completion of, or termination of, any clinical trials of our drug candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue

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from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may materially and adversely harm our business, financial condition, and prospects.

***If a particular product candidate causes significant adverse events, then we may be unable to receive regulatory approval or market acceptance for such product candidate.***

We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any of our product candidates, including the occurrence of significant adverse events in clinical trials. Such significant adverse events could lead to clinical trial challenges, such as difficulties in patient recruitment, retention, and adherence, potential product liability claims, and possible trial termination by us, regulatory authorities, and/or an IRB or ethics committees. These types of clinical trial challenges could delay or prevent regulatory approval of our product candidate. Significant adverse events may also lead regulatory authorities to require additional warnings on the label for such product, require us to conduct additional costly post-marketing studies, require us to develop a risk evaluation and mitigation strategy (“REMS”), among other possible requirements. If the product candidate has already been approved, such approval may be withdrawn. Any delay in, denial, or withdrawal of marketing approval for one of our product candidates will adversely affect our financial position. Even if our product candidates receive marketing approval, undesirable side effects may limit the product’s commercial viability. Patients may not wish to use our product, physicians may not prescribe our product, and our reputation may suffer. Any of these events may significantly harm our business and financial prospects.

***If our product candidates and technologies receive regulatory approval but do not achieve broad market acceptance, especially by physicians, the revenue that we generate will be limited.***

The commercial success of any of our approved products or technologies will depend upon the acceptance of these products and technologies by physicians, patients and the medical community. The degree of market acceptance of these products and technologies will depend on a number of factors, including, among others:

- acceptance by physicians and patients of the product as a safe and effective treatment;
- any negative publicity or political action related to our or our competitors’ products or technologies;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- demonstration to authorities of the pharmacoeconomic benefits;
- demonstration to authorities of the improvement in burden of illness;
- limitations or warnings contained in a product’s approved labeling;
- payers’ level of restrictions and/or barriers to coverage;
- the clinical indications for which a product is approved;
- availability and perceived advantages of alternative treatments;
- the effectiveness of our or future collaborators’ sales, marketing and distribution strategies; and
- pricing and cost effectiveness.

We expect physicians’ inertia and skepticism to also be a significant barrier as we attempt to gain market penetration with our future products. We believe we will continue to need to finance lengthy and time-consuming clinical studies to provide evidence of the medical benefit of our products and resulting therapies in order to overcome this inertia and skepticism.



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Overall, our efforts to educate the medical community on the benefits of any of our products or technologies for which we obtain marketing approval from the FDA or other regulatory authorities and gain broad market acceptance may require significant resources and may never be successful. If our products and technologies do not achieve an adequate level of acceptance by physicians, pharmacists and patients, we may not generate sufficient revenue from these products to become or remain profitable.

***All potential applications of our product candidates are investigational, which subjects us to development and marketing risks.***

Our product candidates are at various stages of development. Successful development and market acceptance of our products is subject to developmental risks, including risk of negative clinical data from current and anticipated trials, failure of inventive imagination, ineffectiveness, lack of safety, unreliability, manufacturing hurdles, failure to receive necessary regulatory clearances or approvals, high commercial cost, preclusion or obsolescence resulting from third parties' proprietary rights or superior or equivalent products, competition from copycat products and general economic conditions affecting purchasing patterns. There can be no assurance that we or our partners will successfully develop and commercialize our product candidates, or that our competitors will not develop competing technologies that are superior or less expensive. Failure to successfully develop and market our product candidates would have a substantial negative effect on our results of operations and financial condition. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.

***We and our product candidates are subject to extensive regulation, and the requirements to obtain regulatory approvals in the United States and other jurisdictions can be costly, time-consuming and unpredictable. If we or our partners are unable to obtain timely regulatory approval for our product candidates, our business may be substantially harmed.***

The worldwide regulatory process for our nanomedicine drug candidates can be lengthy and expensive, with no guarantee of approval.

Before any new drugs may be introduced to the U.S. market, the manufacturer generally must obtain FDA approval through either an abbreviated new drug application (known as 'ANDA') process for generic drugs off patent that allow for bioequivalence to an existing reference listing drug (known as 'RLD') or the lengthier NDA process, which typically requires multiple successful and successive clinical trials to generate clinical data supportive of safety and efficacy along with extensive pharmacodynamic and pharmacokinetic preclinical testing to demonstrate safety. Our RNL product candidates are subject to the FDA's 505(b)(1) NDA process. NDA drugs can take significant time due to the preclinical and clinical trial requirements.

There are numerous risks arising out of the regulation of our nanomedicine product candidates include the following:

- we can provide no assurances that our current and future oncology drugs will meet all of the stringent government regulation in the United States under the Federal Food, Drug and Cosmetic Act, and/or in international markets such as Europe, by the EMA under its Medicinal Products Directive;
- our nanomedicine product candidates, if approved, will still be subject to post-market reporting requirements for instances where the drug may have caused or contributed to the death or serious injury, or serious adverse events;
- there are no assurances that our product candidates will not have safety or effectiveness problems occurring after the drugs reach the market;
- there are no assurances that regulatory authorities will not take steps to prevent or limit further marketing of the drug due to safety concerns; and

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- it is possible that the new legislation in our priority markets will yield additional regulatory requirements for therapeutic drugs for our nanomedicine product candidates.

***We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant expense, and if we or our collaborators fail to comply with such requirements, regulatory agencies may take action against us or them, which could significantly harm our business.***

Approved drug products are subject to ongoing regulatory requirements and oversight, including requirements related to manufacturing, quality control, conduct of post-marketing studies, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting. Regulatory authorities subject a marketed product, its manufacturer, and the manufacturing facilities to continual review and periodic inspections. We, our collaborators, and our and their respective contractors, suppliers and vendors, will be subject to ongoing regulatory requirements, including complying with regulations and laws regarding advertising, promotion and sales of products (including applicable anti-kickback, fraud and abuse and other health care laws and regulations), required submissions of safety and other post-market information and reports, registration requirements, Clinical Good Manufacturing Practices regulations (including requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation), and the requirements regarding the distribution of samples to physicians and recordkeeping requirements. Regulatory agencies may change existing requirements or adopt new requirements or policies. We, our collaborators, and our and their respective contractors, suppliers, and vendors, may be slow to adapt or may not be able to adapt to these changes or new requirements.

Failure to comply with regulatory requirements may result in any of the following:

- restrictions on the marketing of our product candidates or manufacturing processes;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- suspension or termination of any of our ongoing clinical trials;
- refusal to permit the import or export of our product candidates;
- refusal to approve pending applications or supplements to approved applications that we submit;
- product seizure;
- injunctions; or
- imposition of civil or criminal penalties.

***Changing, new and/or emerging government regulations, including healthcare legislative reform measures, may adversely affect us.***

Our nanoparticle and microparticle technologies and pipeline oncology products are being developed under existing government criteria, which are subject to change in the future. Clinical and/or pre-clinical criteria and cGMP manufacturing requirements may change and additional regulatory burdens may be imposed. Any regulatory review committees and advisory groups and any contemplated new guidelines may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we may be required to consult with these regulatory and advisory groups and comply with applicable

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guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient revenue to maintain our business. Divergence in regulatory criteria for different regulatory agencies in international jurisdictions could result in the repeat of clinical studies and/or preclinical studies to satisfy local territory requirements, resulting in the repeating of studies and/or delays in the regulatory process. Some territories may require clinical data in their indigenous population, resulting in the repeat of clinical studies in whole or in part. Some territories may object to the formulation ingredients in the final finished product and may require reformulation to modify or remove objectionable components; resulting in delays in regulatory approvals. Such objectionable reformulations include, but are not limited to, human or animal components, Bovine Spongiform Encephalopathy and/or Transmissible Spongiform Encephalopathy risks, banned packaging components, prohibited chemicals, and banned substances. There can be no assurances that the FDA or foreign regulatory authorities will accept our pre-clinical and/or clinical data.

Anticipated or unanticipated changes in the way or manner in which the FDA or other regulators regulate products or classes and groups of products can delay, further burden, or alleviate regulatory pathways that were once available to other products. There are no guarantees that such changes in the FDA's or other regulators' approach to the regulatory process will not deleteriously affect some or all of our product candidates or product applications.

In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any drug candidates for which we obtain marketing approval, if any. Further, any increased scrutiny of the FDA's approval process for drugs and biological products may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. There also are a number of state and local legislative and regulatory efforts related to drug pricing, including drug price transparency laws that apply to pharmaceutical manufacturers, which may have an impact on our business.

In addition, the Drug Supply Chain Security Act enacted in 2013 imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing. In December 2019, the Further Consolidated Appropriations Act for 2020 was signed into law (P.L. 116-94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the "CREATES Act"). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical 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, if any, of our drug candidates, may be or whether such changes will have any other impacts on our business. In addition, increased scrutiny by the U.S. 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 conditions and other requirements.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or E.U. member state level may result in significant additional requirements or obstacles that may increase our operating costs.

We expect that other legislative or healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, lower reimbursement, and additional downward pressure on the price that we will receive for any approved product. Any reduction in payments from Medicare or other government-funded 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 product candidates.

***Adequate coverage and reimbursement from third party payors may not be available for our products and we may be unable to successfully contract for coverage from pharmacy benefit managers and other organizations; conversely, to secure coverage from these organizations, we may be required to pay rebates or other discounts or other restrictions to reimbursement, either of which could diminish our sales or adversely affect our ability to sell our products profitably.***

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends in significant part on adequate financial coverage and reimbursement from third party payors, including governmental payors (such as the Medicare and Medicaid programs in the U.S.), managed care organizations and private health insurers. Without third party payor reimbursement, patients may not be able to obtain or afford prescribed medications. In addition, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness and ability to prescribe our products. The demand for, and the profitability of, our products could be materially harmed if the state Medicaid programs, Medicare program, other healthcare programs in the U.S. or elsewhere, or third party commercial payors in the U.S. or elsewhere deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms.

As part of the overall trend toward cost containment, third party payors often require prior authorization for, and require reauthorization for continuation of, prescription products or impose step edits, which require prior use of another medication, usually a generic or preferred brand, prior to approving coverage for a new or more expensive product. Such restrictive conditions for reimbursement and an increase in reimbursement-related activities can extend the time required to fill prescriptions and may discourage patients from seeking treatment. We cannot predict actions that third party payors may take, or whether they will limit the access and level of reimbursement for our products or refuse to provide any approvals or coverage. From time to time, third party payors have refused to provide reimbursement for our products, and others may do so in the future.

Third party payors increasingly examine the cost-effectiveness of pharmaceutical products, in addition to their safety and efficacy, when making coverage and reimbursement decisions. We may need to conduct expensive pharmacoeconomic and/or clinical studies in order to demonstrate the cost-effectiveness of our products. If our competitors offer their products at prices that provide purportedly lower treatment costs than our products, or otherwise suggest that their products are safer, more effective or more cost-effective than our products, this may result in a greater level of access for their products relative to our products, which would reduce our sales and harm our results of operations. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefit coverage and reimbursement and co-pay policies. Because some of our products compete in a market with both branded and generic products, obtaining and maintaining access and reimbursement coverage for our products may be more challenging than for products that are new chemical entities for which no therapeutic alternatives exist.

***Some intellectual property that we have in-licensed has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.***

Some of the intellectual property rights we have licensed are generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have

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certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation and may change in the future. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

***Orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed.***

A product candidate that receives orphan drug designation can benefit from potential commercial benefits following approval. Under the U.S. Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, defined as affecting a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA’s Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 10,000 persons in the European Union. Currently, this designation provides market exclusivity in the U.S. and the European Union for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve a drug with similar chemical structure for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs. In the European Union, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug. In September 2020, the FDA granted both Orphan Drug designation and Fast Track designation to rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with GBM. In November 2021, the FDA granted Fast Track designation to rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with LM.

***If we experience an interruption in supply from a material sole source supplier, our business may be harmed***

We acquire some of our components and other raw materials from sole source suppliers. If there is an interruption in supply of our raw materials from a sole source supplier, for any reason, there can be no assurance

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that we will be able to obtain adequate quantities of the raw materials within a reasonable time or at commercially reasonable prices. Interruptions in supplies due to pricing, timing, availability, or other issues with our sole source suppliers could have a negative impact on our ability to manufacture products and product candidates, which in turn could adversely affect the development and commercialization of our nanomedicine product candidates and cause us to potentially breach our supply or other obligations under our agreements with certain other counterparties.

We are dependent on sole source suppliers to manufacture the active pharmaceutical ingredients (“API”) and certain other components of our nanomedicine product candidates. There is no assurance that these sole source suppliers will enter into supply agreements with us to provide contractual assurance to us around supply and pricing. Regardless of whether a sole source supplier enters into a written supply arrangement with us, such supplier could still delay, suspend, or terminate supply of raw materials to us for a number of reasons, including manufacturing or quality issues, payment disputes with us, bankruptcy or insolvency, or other occurrences.

Manufacturing or quality assurance difficulties at our contractors and suppliers, the failure or refusal of a supplier or contract manufacturer to supply contracted quantities, or increases in demand on a supplier with constrained capacity could result in delays and disruptions in the manufacturing, distribution, and sale of our products and /or product candidates, leading to lost revenue or reduced market opportunities. Supply constraints may also lead to pauses, discontinuations, or other product availability issues in one or more markets, which could have a material adverse effect on our consolidated results of operations and cash flows. Further, cost inflation and global transportation and logistics challenges, as well as tight labor markets, have caused, and in the future may cause, delays in, and increase costs related to, distribution of our products, the construction or other acquisition of additional manufacturing capacity, procurement activity, and supplier or contract manufacturer arrangements. These disruptions and challenges could result from actual or perceived quality, oversight, or regulatory compliance problems; natural disasters (including increased instances or severity of natural disasters or other events that may be due to climate change), public health outbreaks, epidemics, or pandemics; periods of uneven economic growth or downturns; emergence or escalation of, and responses to international tension and conflicts; equipment, mechanical, data, or information technology system vulnerabilities, such as system inadequacies, inadequate controls or procedures, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, theft, exfiltration, ransomware or other cyber-attacks from a variety of sources; labor shortages; challenges and complexities in manufacturing new drug modalities; contractual disputes with our suppliers and contract manufacturers; vertical integration by competitors within our supply chain; or inability to obtain single-source or other raw or intermediate materials.

If a sole source supplier ceases supply of raw materials necessary, there is no guarantee that we will find an alternative supplier for the necessary raw materials on terms acceptable to us, or at all. Finding alternative suppliers if and as necessary due to geopolitical developments or otherwise may not be feasible or could take a significant amount of time and involve significant expense due to the nature of our products and product candidates. Further the qualification process for a new vendor could take months or years, and any such day in qualification could significantly harm our business.

### ***We may engage in strategic transactions that could impact our liquidity, increase our expenses, and present significant distractions to our management.***

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Growth of the nanomedicine business will require significant management time and attention. Further, the future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates or technologies. We cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and

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investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

The in-licensing and acquisition of these technologies is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. In addition, companies that perceive us to be a competitor may be unwilling to license rights to us. Furthermore, we may be unable to identify suitable product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies undertake or to successfully complete any additional transactions of the nature described above, our business, financial condition and prospects could suffer. In addition, even if we are able to successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition, and prospects.

### ***We must maintain quality controls and compliance with manufacturing standards.***

The manufacture of our product candidates is, and the manufacture of any future drug and/or cell-related therapeutic products would be, subject to periodic inspection by regulatory authorities and distribution partners. The manufacture of drug and device products for human use is subject to regulation and inspection from time to time by the FDA for compliance with the FDA's cGMP, Quality System Regulations ("QSRs"), as well as equivalent requirements and inspections by state and non-U.S. regulatory authorities. There can be no assurance that the FDA or other authorities will not, during the course of an inspection of existing or new facilities, identify what they consider to be deficiencies in our compliance with QSRs or other requirements and request, or seek remedial action.

Failure to comply with such regulations or a potential delay in attaining compliance may adversely affect our manufacturing activities and could result in, among other things, injunctions, civil penalties, FDA refusal to grant pre-market approvals or clearances of future or pending product submissions, fines, recalls or seizures of products, total or partial suspensions of production and criminal prosecution. There can be no assurance that after such occurrences that we will be able to obtain additional necessary regulatory approvals or clearances on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances, or the loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

***If we are unable to identify, hire and/or retain key personnel, we may not be able to sustain or grow our business.***

We maintain a small executive team. Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain, and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We compete for talent with numerous companies, as well as universities and non-profit research organizations. In the future, we may hire a significant number of scientists, quality and regulatory personnel, and other technical staff with the requisite expertise to support and expand our nanomedicine business. The manufacturing of our oncology drug assets is a highly complex process that requires significant experience and know-how. If we are unable to attract personnel with the necessary skills and experience to reestablish and expand our nanomedicine business, which is currently conducted out of our San Antonio, Texas facility, our business could suffer.

Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations, and maintain a cohesive and stable environment. In particular, we are highly dependent on our executive officers, especially Marc Hedrick, M.D., our Chief Executive Officer. Given his leadership, extensive technical, scientific, and financial expertise and management and operational experience, if we were unable to retain the services of Dr. Hedrick for any reason, it would materially and adversely impact our business and operations. Further, the loss of services of Dr. Hedrick or any other executive officer could result in product development delays or the failure of our collaborations with current and future collaborators, which, in turn, may hurt our ability to develop and commercialize products and generate revenue. We do not maintain key man life insurance on the lives of any of the members of our senior management. The loss of key personnel for any reason or our inability to hire, retain, and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business. The loss of services of any of our personnel, including Dr. Hedrick, particularly for an extended period, would likely result in product development delays or the failure of our collaborations with current and future collaborators, which, in turn, may impede or delay our ability to develop and commercialize products and generate revenue. In addition, it could also result in difficulty to obtain additional funding for our development of products and our future operations.

***We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.***

The clinical use of our product candidates exposes us to the risk of product liability claims. This risk exists even if a product or product candidate is approved for commercial sale by applicable regulatory authorities and manufactured in facilities regulated by such authorities. Our product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse, or abuse associated with our product candidates could result in injury to a patient or even death. For example, rhenium ( $^{186}\text{Re}$ ) obisbameda and  $^{188}\text{RnL-BAM}$  are cytotoxic, or toxic to living cells, and, if incorrectly or defectively manufactured or labeled, or incorrectly dosed or otherwise used in a manner not contemplated by its label, could result in patient harm and even death. In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury.

Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, if approved, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our product candidates;
- decreased demand for our product candidates, if approved;
- impairment of our business reputation;



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- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenue.

We have obtained product liability insurance coverage for clinical trials with a \$10 million per occurrence and annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse effect on our business, results of operations, financial condition and prospects.

***A failure to adequately protect private health information could result in severe harm to our reputation and subject us to significant liabilities, each of which could have a material adverse effect on our business.***

Throughout the clinical trial process, we may obtain the private health information of our trial subjects. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. The Healthcare Information Portability and Accountability Act (“HIPAA”) imposes privacy, security, breach reporting obligations, and mandatory contractual terms on covered entity health care providers, health plans, and health care clearinghouses, as well as their “business associates” – certain persons or covered entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. We could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Most states have laws requiring notification of affected individuals and state regulators (breach notification laws) in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Additionally, in California, the California Consumer Privacy Act (“CCPA”) establishes certain requirements for data use and sharing transparency and creates new data privacy rights for California residents. The CCPA and its implementing regulations have already been amended multiple times since their enactment. In November 2020, California voters approved the California Privacy Rights Act (“CPRA”) ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency. The amendments introduced by the CPRA went into effect on January 1, 2023. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The European Union’s General Data Protection Regulation, which imposes fines of up to EUR 20 million or 4% of the annual global revenue of a noncompliant company, whichever is greater, Canada’s Personal Information Protection and Electronic Documents Act and other data protection, privacy and similar national, state/provincial and local laws

may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers, or to alleviate problems caused by such breaches. Compliance with these laws is difficult, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. Compliance efforts will likely be an increasing and substantial cost in the future.

***We and our collaborators must comply with environmental laws and regulations, including those pertaining to use of hazardous and biological materials in our business, and failure to comply with these laws and regulations could expose us to significant liabilities.***

We and our collaborators are subject to various federal, state, and local environmental laws, rules and regulations, including those relating to discharge of materials into the air, water and ground, those relating to manufacturing, storage, use, transportation and disposal of hazardous and biological materials, and those relating to the health and safety of employees with respect to laboratory activities required for the development of our products and activities. In particular, our nanomedicine products and processes involve the controlled storage, use and disposal of certain cytotoxic, or toxic to living cells, materials. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials, or other violations of applicable environmental laws, rules or regulations cannot be completely eliminated. In the event of any violation of such laws, rules or regulations, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and could exceed our financial resources. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs in complying with environmental laws, rules and regulations.

***We recently acquired the CNSide diagnostic portfolio, and we may not be successful in our efforts to develop, fully utilize and monetize it.***

In April 2024, we completed the acquisition of substantially all of the right, title and interest in CNSide (“CNSide”), a proprietary cell enumeration test designed to detect, quantify, and monitor tumor status in LM. We are currently evaluating and developing our business plan for developing the CNSide diagnostic portfolio alongside our lead radiotherapeutic candidate, rhenium (<sup>186</sup>Re) obisbameda, and seeking partnering opportunities for CNSide but there can be no assurances that we will be able to develop the technology to allow for commercial applications, or successfully utilize and fully integrate CNSide into our operations. We may not generate revenues from or realize the anticipated benefits of CNSide within our expected timeline or at all.

#### **Risks Related to Our Intellectual Property**

***Our success depends in part on our ability to protect our intellectual property.***

Our success depends in part on our ability to obtain and maintain patent, trademark, and trade secret protection of our platform technology and current product candidates, including but not limited to our nanomedicine product candidates, including rhenium (<sup>186</sup>Re) obisbameda and <sup>188</sup>RNL-BAM, as well as successfully defending our intellectual property against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our platform technology and/or our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we, NanoTx, or UTHSA, as the case may be, might not have been the first to file patent applications for the covered inventions;

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- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are dominating patents to our product candidates of which we are not aware;
- it is possible that there are prior public disclosures that could invalidate our patents, of which we are not aware;
- it is possible that others may circumvent our patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;
- the claims of our patents or patent applications, if and when issued, may not cover our system or products, or our system or product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal administrative challenges by third parties;
- others may be able to make or use compounds that are the same or similar to the rhenium ( $^{186}\text{Re}$ ) obisbameda or 188RNL-BAM product candidates but that are not covered by the claims of our patents;
- we may not be able to detect infringement against our patents, which may be especially difficult for manufacturing processes or formulation patents, such as the patents/applications related to rhenium ( $^{186}\text{Re}$ ) obisbameda or 188 RNL-BAM;
- the API used in rhenium ( $^{186}\text{Re}$ ) obisbameda, 186-Re, is routinely produced in nuclear reactors or at a particle accelerator and is commercially available as 186-Re Sulfide for isotropic radiation synovectomy of medium sized joints and in developing countries as 186-Re-HEDP for bone pain palliation;
- we may not develop additional proprietary technologies for which we can obtain patent protection; or
- the patents of others may have an adverse effect on our business.

The patent positions of pharmaceutical, biopharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the USPTO and Congress have recently made significant changes to the patent system. There have been three U.S. Supreme Court decisions that now show a trend of the Supreme Court which is distinctly negative on patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our product candidates. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and/or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents.

Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

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Failure to obtain or maintain patent protection or protect trade secrets, for any reason (or third-party claims against our patents, trade secrets, or proprietary rights, or our involvement in disputes over our patents, trade secrets, or proprietary rights, including involvement in litigation), could have a substantial negative effect on our results of operations and financial condition.

### ***We may not be able to protect our trade secrets.***

We may rely on trade secrets to protect our technology, especially with respect to the nanomedicine products, as well as in areas where we do not believe patent protection is appropriate or obtainable. Trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, state laws in the United States vary, and their courts as well as courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

### ***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

As is common in the device, biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition.

### ***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our product candidates and technology.***

Litigation may be necessary to enforce or confirm the ownership of any patents issued or licensed to us, or to determine the scope and validity of third-party proprietary rights, which would result in substantial costs to us and diversion of effort on our part. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the USPTO or a foreign patent office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us. Any such litigation or interference proceeding, regardless of outcome, could be expensive and time-consuming.

Successful challenges to our patents through oppositions, reexamination proceedings or interference proceedings could result in a loss of patent rights in the relevant jurisdiction. If we are unsuccessful in actions we bring against the patents of other parties, and it is determined that we infringe the patents of third-parties, we may be subject to litigation, prevented from commercializing potential products in the relevant jurisdiction and/or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations or from commercializing certain products, which could adversely affect our business and results of operations.

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Competitors or third parties may infringe on or upon our patents. We may be required to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or that the third party's technology does not in fact infringe upon our patents. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing.

Litigation may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries outside the United States where patent rights may be more difficult to enforce. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or otherwise have a material adverse effect on our business, results of operations, financial condition, and prospects.

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.***

Our commercial success will also depend, in part, on our ability to avoid infringing on patents issued by others. There may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our product candidate or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents.

If a third-party's patent were found to cover our product candidates, proprietary technologies or their uses, we could be enjoined by a court and required to pay damages and could be unable to commercialize our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our product candidates, technologies or methods pending a trial on the merits, which could be years away.

## **Risks Related to the Securities Markets and an Investment in our Common Stock**

***Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock, including in connection with the sale or issuance of our common stock to Lincoln Park and the sale of the shares of common stock acquired by Lincoln Park and the sale of our common stock by Canaccord.***

Our certificate of incorporation, as amended (the “Charter”) allows us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 5,000,000 shares of preferred stock. To raise additional capital, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that are lower than the prices paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, which could result in substantial dilution to the interests of existing stockholders.

On August 2, 2022, we entered into the 2022 Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park committed to purchase up to \$50.0 million (the “Commitment Amount”) of our common stock, subject to certain limitations. As consideration for Lincoln Park’s irrevocable commitment to purchase shares of our common stock upon the terms of and subject to satisfaction of the conditions set forth in the 2022 Purchase Agreement, upon execution of the 2022 Purchase Agreement, we agreed to pay Lincoln Park an initial commitment fee equal to 1.5% of the Commitment Amount. The initial commitment fee was paid upon execution of the 2022 Purchase Agreement through the issuance of 492,698 shares of common stock and \$0.1 million in cash. An additional commitment fee equal to 2.5% of the remainder of the Commitment Amount will be paid if and when we sell over \$25.0 million of our common stock under the 2022 Purchase Agreement. The additional commitment fee may be paid in cash, common stock, or a combination of cash and common stock.

The remaining shares of our common stock that may be issued under the 2022 Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing August 17, 2022, subject to satisfaction of certain conditions. The purchase price for the shares that we may sell to Lincoln Park under the 2022 Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all or some of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sale.

***Future sales of our common stock may depress our share price.***

As of December 31, 2023, we had issued 4,522,656 shares of our common stock, of which 4,444,097 shares were outstanding. Sales of a number of shares of common stock in the public market could cause the market price of our common stock to decline. We may also sell additional common stock or securities convertible into or exercisable or exchangeable for common stock in subsequent public or private offerings or other transactions, which may adversely affect the market price of our common stock.

***The market price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for stockholders.***

The market price of our common stock has been, and may continue to be, subject to significant fluctuations. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this “Risk Factors” section and other factors, including:

- fluctuations in our operating results or the operating results of our competitors;

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- the outcome of clinical trials involving the use of our product candidates, including our sponsored trials;
- changes in estimates of our financial results or recommendations by securities analysts;
- variance in our financial performance from the expectations of securities analysts;
- changes in the estimates of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- conditions and trends in the markets we currently serve or which we intend to target with our product candidates;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- our continuing ability to list our securities on an established market or exchange;
- the timing and outcome of regulatory reviews and approvals of our product candidates;
- the commencement or outcome of litigation involving our company, our general industry or both;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of our common stock by the holders of our common stock; and
- the trading volume of our common stock.

In addition, the financial markets may experience a loss of investor confidence or otherwise experience continued volatility and deterioration. A loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, our financial condition or results of operations, which may materially harm the market price of our common stock and result in substantial losses for stockholders. Further, although our common stock is traded on the Nasdaq, there is currently a limited market for our common stock and an active market may never develop.

***We may be or become the target of securities litigation, which is costly and time-consuming to defend.***

In the past, following periods of market volatility in the price of a company's securities, the reporting of unfavorable news or continued decline in a company's stock price, security holders have often instituted class action litigation. The market value of our securities has steadily declined over the past several years for a variety of reasons discussed elsewhere in this "Risk Factors" section, which heightens our litigation risk. If we face such litigation, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, causing our business to suffer. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

***We may issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.***

In the future, we may attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated

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notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and preferred securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

### ***Our Charter documents contain anti-takeover provisions.***

Certain provisions of our Charter and amended and restated bylaws (the “Bylaws”) could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable. These provisions could also prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors (the “Board”). Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions:

- authorize our Board to issue without stockholder approval up to 5,000,000 shares of preferred stock, the rights of which will be determined at the discretion of the Board;
- require that stockholder actions must be effected at a duly called stockholder meeting and cannot be taken by written consent;
- establish advance notice requirements for stockholder nominations to our Board or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call stockholder meetings.

We are governed by the provisions of Section 203 of the Delaware General Corporation Law (“DGCL”), which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

### ***We presently do not intend to pay cash dividends on our common stock.***

We have never paid cash dividends in the past, and we currently anticipate that no cash dividends will be paid on the common stock in the foreseeable future. This could make an investment in our common stock inappropriate for some investors, and may serve to narrow our potential sources of additional capital. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business.

### ***If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely, or if our results of operations do not meet their expectations, our stock price and trading volume could decline.***

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.



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***We may issue additional shares of common stock or other equity securities without our stockholder approval, and holders of warrants and other securities convertible into shares of our common stock may choose to exercise their warrants and other securities requiring us to issue shares of common stock; all of these actions would dilute your ownership interest and may depress the market price of our common stock.***

In May 2024, we entered into the Purchase Agreement with the selling stockholders, and issued and sold in the May 2024 PIPE Financing: (i) an aggregate of 3,591,532 shares of common stock (or in lieu of shares of common stock, Pre-Funded Warrants), and (ii) Warrants to purchase up to 7,183,064 shares of common stock. If these Warrants are exercised, it will result in significant dilution to our stockholders. In the alternative, these Warrants may not be exercised, in which event we are likely to seek alternative sources of financing to continue the clinical development of our product candidates.

In addition, outstanding securities convertible into our shares of common stock may be exercised and restricted stock units may vest resulting in the issuance of additional shares of common stock, which will result in further dilution to our stockholders.

Significant additional capital may be needed in the future to continue our planned operations, including further development of our product candidates, preparing IND or equivalent filings, conducting preclinical studies and clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our shares of common stock.

We may also issue additional shares of common stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances. The issuance of additional shares or other equity securities of equal or senior rank would have the following effects:

- existing stockholders' proportionate ownership interest in us will decrease;
- the relative voting strength of each previously outstanding common stock may be diminished; and
- the market price of the common stock may decline.

### **General Risk Factors**

***Increased information technology security threats and more sophisticated and targeted computer crime could pose a risk to our systems, networks, and products.***

Increased global information technology security threats and more sophisticated and targeted computer crime pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data and communications. While we attempt to mitigate these risks by employing a number of measures, including employee refreshers, monitoring of our networks and systems, and maintenance of backup and protective systems, our systems, networks and products remain potentially vulnerable to advanced persistent threats. Depending on their nature and scope, such threats could potentially lead to the compromising of confidential information and communications, improper use of our systems and networks, manipulation and destruction of data, defective products, production downtimes and operational disruptions, which in turn could adversely affect our reputation, competitiveness and results of operations.

## USE OF PROCEEDS

We will not receive any proceeds from any sale of shares of our common stock by the selling stockholders or their permitted transferees. All proceeds from the sale of shares of common stock will be for the accounts of the selling stockholders or their permitted transferees.

We will receive approximately \$12.0 million from the exercise of all of the Common Warrants and Pre-Funded Warrants, assuming the exercise in full of all such warrants for cash. To the extent we receive proceeds from the cash exercise of the Warrants, we intend to use the proceeds for general corporate purposes.

Our expected use of proceeds described above represents our current intentions based on our present plans and business condition. The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our planned clinical trials, the results of our planned clinical trials and other factors described in "[Risk Factors](#)" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs.

## MARKET INFORMATION FOR COMMON STOCK

Our common stock is listed on Nasdaq under the symbols "PSTV".

As of June 21, 2024, there were outstanding 5,704,219 shares of our common stock, net of treasury shares, held of record by 4 holders. The actual number of stockholders of our common stock is greater than the number of record holders and includes stockholders whose common stock are held in street name by brokers and other nominees.

On June 21, 2024, the closing sale price of our common stock was \$1.79 per share.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board after considering our financial condition, results of operations, current and anticipated capital requirements, business prospects, and other factors our Board deems relevant, and subject to applicable laws and the restrictions contained in any future financing instruments.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our audited and unaudited consolidated financial statements and related notes appearing elsewhere in this prospectus. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the sections titled "[Cautionary Note Regarding Forward-Looking Statements](#)" and "Risk Factors" or in other parts of this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.*

### Overview

Plus Therapeutics is a U.S. pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for CNS cancers. Our novel radioactive drug formulations and therapeutic candidates are designed to deliver safe and effective doses of radiation to tumors. To achieve this, we have developed innovative approaches to drug formulation, including encapsulating radionuclides such as rhenium isotopes with nanoliposomes and microspheres. Our formulations are intended to achieve elevated patient absorbed radiation doses and extend retention times such that the clearance of the isotope occurs after significant and essentially complete radiation decay, which will contribute and provide less normal tissue/organ exposure and improved safety margins.

Traditional approaches to radiation therapy for cancer, such as external beam radiation, have many disadvantages including continuous treatment for four to six weeks (which is onerous for patients), that the radiation damages healthy cells and tissue, and that the amount of radiation delivered is very limited and, therefore, is frequently inadequate to fully destroy the cancer.

Our targeted radiotherapeutic platform and unique investigational drugs have the potential to overcome these disadvantages by directing higher, more powerful radiation doses at the tumor—and only the tumor—potentially in a single treatment. By minimizing radiation exposure to healthy tissues while simultaneously maximizing locoregional delivery and, thereby, efficacy, we hope to reduce the radiation toxicity for patients, improving their quality of life and life expectancy. Our radiotherapeutic platform, combined with advances in surgery, nuclear medicine, interventional radiology, and radiation oncology, affords us the opportunity to target a broad variety of cancer types.

Our lead radiotherapeutic candidate, rhenium ( $^{186}\text{Re}$ ) obisbameda, is designed specifically for CNS cancers including GBM, LM, and PBC by direct localized delivery utilizing approved standard-of-care tissue access such as with CED and intraventricular brain (Ommaya reservoir) catheters. Our acquired radiotherapeutic candidate,  $^{188}\text{RnL}$ -BAM is designed to treat many solid organ cancers including primary and secondary liver cancers by intra-arterial injection.

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Our headquarters and manufacturing facilities are in Texas and are in proximity to world-class cancer institutions and researchers. Our dedicated team of engineers, physicians, scientists, and other professionals are committed to advancing our targeted radiotherapeutic technology for the benefit of cancer patients and healthcare providers worldwide and our current pipeline is focused on treating rare and difficult-to-treat cancers with significant unmet medical needs.

In addition to our headquarters in Austin, we have an established, good manufacturing practice validated research and development and manufacturing facility in San Antonio, Texas, tailored to produce cGMP rhenium (<sup>186</sup>Re) obisbameda. We have built a robust supply chain through strategic partnerships that enable the development, manufacturing and future potential commercialization of our products. Our current supply chain and key partners are positioned to supply cGMP rhenium (<sup>186</sup>Re) obisbameda for ongoing and planned Phase 2 and Phase 3 clinical trials in patients with GBM, LM and PBC.

### **Recent Developments**

#### *Repayment of Oxford Term Loan and Use of Pershing Credit Facility*

On May 29, 2015, we entered into a Loan and Security Agreement, that was subsequently amended, with Oxford Finance, LLC (“Oxford”) (the “Oxford Term Loan”). On June 3, 2024, following the drawing of \$3.3 million on the Pershing Credit Facility on May 31, 2024, we repaid the Oxford Term Loan in full, a payment amount that totaled approximately \$3.3 million, which included both the balance of outstanding principal and interest and the final payment fee due. The repayment in full of the Oxford Term Loan terminated Oxford’s security interest in our existing and after-acquired assets, as well as all other certain restrictions and covenants under the Oxford Term Loan.

Our existing Pershing Credit Facility is a margin loan facility under a line of credit with Pershing, an affiliate of The Bank of New York Mellon Corporation. The available credit line limit under this facility fluctuates based on our request for extensions from time to time, subject to the value of the collateralized marketable securities we hold with Pershing, provided that the amount available to draw under the facility cannot exceed 91.5% of the value of the collateralized marketable securities deposited with Pershing. Depending on the value of the marketable securities we hold with Pershing, Pershing may require us from time-to-time to deposit additional funds or marketable securities in order to restore the level of collateral to an acceptable level. The amounts borrowed under the Pershing Credit Facility are due on demand.

Borrowings under the Pershing Credit Facility bear interest at the target interest rate set by the Federal Open Market Committee, subject to a floor of 5.5%, plus a spread of 1.75% and applicable fees of 0.5%, subject to a maximum interest rate of the then applicable Prime Rate as published in The Wall Street Journal plus 3.0%. Interest payments thereunder are calculated on a monthly basis and, unless paid, are added to the outstanding balance under the Pershing Credit Facility. The proceeds under the Pershing Credit Facility are available for working capital needs and other general corporate purposes. Volatility in the global markets could cause the interest rate to fluctuate from time to time increasing our costs, or could cause Pershing to terminate our ability to borrow funds. In addition, borrowings under the Pershing Credit Facility have the effect of limiting our use of cash and marketable securities.

#### *May 2024 PIPE Financing*

In May 2024, we entered into the Purchase Agreement with the selling stockholders pursuant to which we agreed to sell and issue in a private placement pursuant to the exemption in Section 4(a)(2) of the Securities Act for an aggregate of 10,774,596 shares of common stock for an aggregate purchase price of approximately \$19.25 million.

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### *Biocept Asset Purchase*

On April 26, 2024, we acquired from Biocept, for a total cash payment of \$400,000, substantially all of the right, title and interest in CNside, including (i) intellectual property, (ii) inventory and raw materials, and (iii) data, information, results and reports pertaining to the completed and on-going clinical studies involving the use of the CNside test (including, but not limited to, the FOERSEE clinical study that was being conducted by Biocept), related to the development, making, selling, and exporting or importing of CNside, after having its bid accepted by the United States Bankruptcy Court for the District of Delaware.

We are currently evaluating and developing our business plan for developing the CNside diagnostic portfolio alongside our lead radiotherapeutic candidate, rhenium (<sup>186</sup>Re) obisbameda, and seeking partnering opportunities for CNside. In May 2024, we presented topline clinical trial data from the FORESEE trial, which met its primary endpoint of clinical utility for the CNside test in 40 patients with LM due to either breast or non-small cell lung cancer; a presentation of the full analysis is planned for the August 8 through 10 SNO/ASCO Meeting in Denver, Colorado.

### *Department of Defense Grant*

On April 22, 2024, we were selected by the Department of Defense (DoD) office of the Congressionally Directed Medical Research Programs (CDMRP) to receive a \$3 million fund for research and development purposes (“DoD Award”). Transfers of funds under the DoD Award are expected to commence in the third quarter of 2024, pending execution of formal agreements, in order to support the planned expansion of our clinical trial for pediatric brain cancer.

## **Financial Overview**

### ***Operating Expenses***

#### *Research and Development Expenses*

Research and development expenses consist of costs associated with the design, development, testing, and enhancement of our product candidates, payment of regulatory fees, laboratory supplies, pre-clinical studies, and clinical studies.

The successful development of our product candidates is highly uncertain. We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of our product candidates, conduct discovery and research activities for our preclinical programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate’s commercial potential. Our clinical development costs are expected to increase significantly as we commence clinical trials. We anticipate that our expenses will increase substantially, particularly due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

the scope, rate of progress, and expenses of our ongoing research activities as well as any preclinical studies, clinical trials and other research and development activities;

- establishing an appropriate safety profile with IND enabling studies;
- successful enrollment in and completion of clinical trials;

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- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of products following any regulatory approval.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on other product candidates. For example, if the U.S. FDA, EMA, or another regulatory authority were to delay the planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any planned clinical trial, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

### *General and Administrative Expenses*

General and administrative expenses consist primarily of administrative personnel, legal and other professional expenses, and general corporate expenses. General and administrative expenses also include facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

## **Results of Operations**

### *Comparison of the Three Months Ended March 31, 2024 and 2023*

#### *Grant Revenue*

We recognized \$1.7 million and \$0.5 million of grant revenue during the three months ended March 31, 2024 and 2023, respectively, which represents CPRIT's share of the costs incurred for our rhenium ( $^{186}\text{Re}$ ) obisbameda development for the treatment of patients with LM.

#### *Research and development expenses*

Research and development expenses include costs associated with the design, development, testing, and enhancement of our product candidates, payment of regulatory fees, laboratory supplies, pre-clinical studies, and clinical studies.

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The following table summarizes the components of our research and development expenses for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	\$ 2,746	\$ 2,963
Share-based compensation	17	20
Total research and development expenses	<u>\$ 2,763</u>	<u>\$ 2,983</u>

Research and development expenses decreased by approximately \$0.2 million during the three months ended March 31, 2024 as compared to the same period in 2023. The decrease was due primarily to a reduction of \$0.8 million of licenses fee to NanoTx, offset by an increase of approximately \$0.3 million in clinical expenses related to the ReSPECT-LM trial, and an increase of approximately \$0.2 million of professional research and development service fees.

We expect aggregate research and development expenses to largely remain consistent during the remainder of 2024 as compared to the corresponding comparable period ended December 31, 2023.

### *General and administrative expenses*

General and administrative expenses include costs for administrative personnel, legal and other professional expenses, and general corporate expenses. The following table summarizes the general and administrative expenses for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
General and administrative	\$ 2,084	\$ 2,125
Share-based compensation	129	120
Total general and administrative expenses	<u>\$ 2,213</u>	<u>\$ 2,245</u>

General and administrative expenses remained consistent during the three months ended March 31, 2024, as compared to the same period in 2023.

We expect general and administrative expenditures to remain generally consistent during the remainder of 2024 as compared with the corresponding comparable period ended December 31, 2023.

### *Stock-based compensation expense*

Stock-based compensation expense includes charges related to stock options issued to employees, directors and non-employees. We measure stock-based compensation expense based on the grant-date fair value of any awards granted to our employees. Such expense is recognized over the requisite service period.

The following table summarizes the components of our stock-based compensation expenses for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	\$ 17	\$ 20
General and administrative	129	120
Total share-based compensation	<u>\$ 146</u>	<u>\$ 140</u>

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Our share-based compensation expenses, which are impacted by grants of share-based options, vesting schedule of such grants, as well as grant-date fair value of share-based awards, remained consistent for the three months ended March 31, 2024 and 2023.

### *Financing items*

The following table summarizes interest income, interest expense, and other income and expense for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended	
	March 31,	
	2024	2023
Interest income	\$ 72	\$ 51
Interest expense	(34)	(134)
Total	<u>\$ 38</u>	<u>\$ (83)</u>

The decrease in interest expense for the three months ended March 31, 2024 as compared to the same period in 2023 was primarily due to the repayment of debt principal of \$1.6 million during the year ended December 31, 2023.

We expect interest expense in 2024 to decrease as compared with 2023 due to scheduled debt payoff by June 1, 2024.

### ***Comparison of the Years Ended December 31, 2023 and 2022***

#### *Grant Revenue*

On September 19, 2022, we entered into the CPRIT Contract, effective as of August 31, 2022, with CPRIT, pursuant to which CPRIT will provide us the CPRIT Grant of up to \$17.6 million over a three-year period to fund the continued development of rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with LM through Phase 2 of the ReSPECT LM clinical trial. The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar from us for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of rhenium (<sup>186</sup>Re) obisbameda based on specific dollar thresholds until CPRIT receives the aggregate amount of 400% of the proceeds awarded under the CPRIT Grant, and certain reporting requirements. We received \$7.1 million of the available funding under the CPRIT Grant during 2022 and 2023, of which we recognized \$4.9 million and \$0.2 million of grant revenue during the years ended December 31, 2023 and 2022, respectively. The amounts recognized represents CPRIT's share of the costs incurred for our rhenium (<sup>186</sup>Re) obisbameda development for the treatment of patients with LM. As of December 31, 2023, we had \$1.9 million of deferred revenue related to the CPRIT Grant.

We expect grant revenue will increase during 2024 and the remaining term of the CPRIT Grant through August 2025, as we continue to expand the LM clinical trial to add clinical sites and enroll patients. The ability to continue to access the grant remains subject to additional FDA approval of the LM clinical trial, ability to deliver expanded drug supply and continued enrollment of patients. In addition, grant revenue amounts will vary quarter to quarter based on enrollment, mandated safety periods between cohorts and required interactions with FDA.

#### *Research and development expenses*

Research and development expenses include costs associated with the design, development, testing, and enhancement of our product candidates, payment of regulatory fees, laboratory supplies, pre-clinical studies, and clinical studies.



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The following table summarizes the components of our research and development expenses for the years ended December 31, 2023 and 2022 (in thousands):

	Years ended December 31,	
	2023	2022
Research and development	\$9,624	\$9,611
Share-based compensation	66	87
Total research and development expenses	<u>\$9,690</u>	<u>\$9,698</u>

Research and development expenses for the year ended December 31, 2023 remained consistent with the same period in 2022, due to a decrease of \$3.4 million in development of cGMP rhenium (<sup>186</sup>Re) obisbameda, a decrease of \$1.9 million of professional and legal expenses, offset by a license agreement payment of \$1.7 million to NanoTx Corp., from which we licensed our rhenium (<sup>186</sup>Re) obisbameda technology, resulting from the first patient treated in the GBM phase 2 trial and obligation to pay NanoTx 15% of CPRIT grant proceeds received (See Note 6 of the accompanying financial statements for more information), \$3.0 million from treatment of patients for LM clinical trial in 2023, and \$0.6 million increase of payroll expenses.

We expect aggregate research and development expenditures to increase significantly during 2024 as compared to the corresponding comparable period ended December 31, 2023, due to increased costs for the *ReSPECT-LM* clinical trial (for which CPRIT grant funding is available), increases in licensing payments, offset by reduced research and development spend on the cGMP development.

### General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses, and general corporate expenses. The following table summarizes the general and administrative expenses for the years ended December 31, 2023 and 2022 (in thousands):

	Years ended December 31,	
	2023	2022
General and administrative	\$8,041	\$ 9,719
Share-based compensation	503	519
Total general and administrative expenses	<u>\$8,544</u>	<u>\$10,238</u>

General and administrative expenses decreased by approximately \$1.7 million during the year ended December 31, 2023, as compared to the same period in 2022. The decrease was due primarily to a net decrease of legal and professional expenses of \$1.9 million from expenditure incurred in 2022 related to litigation that was settled in the fourth quarter of 2022, offset by an increase of \$0.1 million in personnel and related expenses, and an increase of \$0.1 million in travel, insurance and other expenses.

We expect general and administrative expenditures to remain generally consistent during 2024 as compared with the corresponding comparable period ended December 31, 2023.

### Share-based compensation expenses

Share-based compensation expenses include charges related to options and restricted stock awards issued to employees, directors and non-employees. We measure share-based compensation expenses based on the grant-date fair value of any awards granted to our employees. Such expense is recognized over the requisite service period.

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The following table summarizes the components of our share-based compensation expenses for the years ended December 31, 2023 and 2022 (in thousands):

	Years ended December 31,	
	2023	2022
Research and development	\$ 66	\$ 87
General and administrative	503	519
Total share-based compensation	<u>\$569</u>	<u>\$606</u>

Our stock-based compensation expenses, which are impacted by grants of stock-based options, vesting schedule of such grants, as well as grant-date fair value of stock-based awards, remained consistent for the year ended December 31, 2023 and 2022.

### Other Income (Expense)

The following table summarizes interest income, interest expense, and other income and expense for the years ended December 31, 2023 and 2022 (in thousands):

	Years ended December 31,	
	2023	2022
Interest income	\$ 400	\$ 147
Interest expense	(395)	(711)
Change in fair value of liability instruments	—	1
Total	<u>\$ 5</u>	<u>\$(563)</u>

The decrease in interest expense for the year ended December 31, 2023 as compared to the same period in 2022 was primarily due to reduced debt principal as the Company continued to pay down its term loan.

### ***Liquidity and Capital Resources***

#### *Short-term and long-term liquidity*

The following is a summary of our key liquidity measures at March 31, 2024 and December 31, 2023 (in thousands):

	March 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 2,901	\$ 8,554
Current assets	\$ 4,213	\$ 9,834
Current liabilities	10,399	10,727
Working capital	<u>\$ (6,186)</u>	<u>\$ (893)</u>

We incurred net losses of \$3.3 million for the three months ended March 31, 2024. We have an accumulated deficit of \$483.8 million as of March 31, 2024. Additionally, we used net cash of \$4.5 million to fund our operating activities for the three months ended March 31, 2024. These factors raise substantial doubt about our ability to continue as a going concern.

#### *May 2024 PIPE Financing*

In May 2024, we entered into the Purchase Agreement with the selling stockholders whereby we issued and sold in a private placement: (i) 3,591,532 shares of common stock (“Private Placement Shares”), or, at the election of

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each Purchaser, Pre-Funded Warrants exercisable immediately to purchase shares of common stock. Each Private Placement Share or Pre-Funded Warrant are accompanied by (i) Series A Common Stock Warrants to purchase one share of common stock, for an aggregate of 3,591,532 Series A Common Stock Warrants, and (ii) one Series B Common Warrants to purchase one share of common stock, for an aggregate of 3,591,532 Series B Common Warrants. At the closing of the May 2024 PIPE Financing, we received aggregate upfront gross proceeds of approximately \$7.25 million, before deducting fees and other expenses associated with the closing of the May 2024 PIPE Financing. If the Warrants are exercised in full we will receive additional gross proceeds of approximately \$12.0 million. None of the Warrants issued in the May 2024 PIPE Financing have been exercised as of the filing of this report.

### *CPRIT Grant*

On September 19, 2022, we entered into the CPRIT Contract, pursuant to which CPRIT will provide us with the CPRIT Grant of \$17.6 million subject to the terms of the CPRIT Contract, to fund approximately two-thirds of the continued development of rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of patients with LM. We received \$7.1 million of the available funding under the CPRIT Grant during 2022, 2023 and the three months ended March 31, 2024, of which we recognized \$1.7 million, \$4.9 million and \$0.2 million of grant revenue during the three months ended March 31, 2024, and the years ended December 31, 2023 and 2022, respectively. The amounts recognized represents CPRIT's share of the costs incurred for our rhenium ( $^{186}\text{Re}$ ) obisbameda development for the treatment of patients with LM. As of March 31, 2024, we had \$0.2 million of deferred revenue related to the CPRIT Grant.

### *Private Equity Lines*

On September 9, 2022, we entered into an Equity Distribution Agreement (the "September 2022 Distribution Agreement") with Canaccord Genuity LLC ("Canaccord"), pursuant to which we could issue and sell, from time to time, shares of our common stock in "at-the-market" offerings, having an aggregate offering price of up to \$5,000,000, depending on market demand, with Canaccord acting as an agent for sales. During the period from September 9, 2022 to December 31, 2023, we issued 68,758 shares under the September 2022 Distribution Agreement for net proceeds of approximately \$0.6 million. From January 1, 2023 through December 31, 2023, we issued 1,819,993 shares under the September 2022 Distribution Agreement for net proceeds of approximately \$4.3 million. We have reached the capacity for sales of our shares under the September 2022 Distribution Agreement.

On August 2, 2022, we entered into the 2022 Purchase Agreement and registration rights agreement pursuant to which Lincoln Park Lincoln Park committed to purchase up to \$50.0 million of shares of our common stock. Under the terms and subject to the conditions of the 2022 Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$50.0 million of shares of our common stock, provided that we cannot sell more than 57.5 million shares pursuant to the 2022 Purchase Agreement. Sales of common stock by us are subject to certain limitations, and can occur from time to time, at our sole discretion, over the 36-month period commencing on August 17, 2022, subject to the satisfaction of certain conditions. Actual sales of shares of common stock to Lincoln Park under the 2022 Purchase Agreement depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of the common stock and our determinations as to the appropriate sources of funding for the Company and its operations. As consideration for Lincoln Park's irrevocable commitment to purchase shares of our common stock upon the terms of and subject to satisfaction of the conditions set forth in the 2022 Purchase Agreement, we paid \$0.1 million in cash as an Initial Commitment Fee and issued 32,846 as the initial commitment shares to Lincoln Park in consideration for its commitment to purchase shares of our common stock at our direction under the 2022 Purchase Agreement.

On August 17, 2022, the First Registration Statement was declared effective covering the resale of up to 633,333 shares of our common stock comprised of (i) the 32,846 initial commitment shares, and (ii) up to 600,486 shares

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that we have reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement. An additional commitment fee equal to 2.5% of the remainder of the \$50 million will be paid if and when we sell over \$25.0 million of our common stock under the 2022 Purchase Agreement. The additional commitment fee may be paid in cash, common stock, or a combination thereof. We sold approximately 527,166 shares under the First Registration Statement.

On August 18, 2023, the Second Registration Statement was declared effective covering the resale of up to an additional 1,500,000 shares of our common stock that we reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time. We sold 150,000 shares under the Second Registration Statement. We cannot sell more shares than registered under the Second Registration Statement under the 2022 Purchase Agreement without registering additional shares.

During the period from August 17, 2022 to December 31, 2022, we issued 266,666 shares under the 2022 Purchase Agreement for net proceeds of approximately \$3.2 million. We issued 410,500 shares under the 2022 Purchase Agreement for net proceeds of approximately \$1.0 million from January 1, 2023 to December 31, 2023. No shares of common stock was purchased under the 2022 Purchase Agreement during the three months ended March 31, 2024.

On January 14, 2022, we entered into an Equity Distribution Agreement (the “January 2022 Distribution Agreement”) with Canaccord, pursuant to which we could issue and sell, from time to time, shares of our common stock in “at-the-market” offerings, having an aggregate offering price of up to \$5,000,000, depending on market demand, with Canaccord acting as an agent for sales. During the year ended December 31, 2023, we issued 460,151 shares under the January 2022 Distribution Agreement for net proceeds of approximately \$4.8 million. The January 2022 Distribution Agreement was terminated after all available registered shares were fully utilized.

### *Nasdaq Listing Compliance*

On March 8, 2024, we received the Notice from the Nasdaq Staff, notifying us that we no longer complied with the requirement under Nasdaq Listing Rule 5550(b)(1) to maintain a minimum of \$2.5 million in stockholders’ equity for continued listing on Nasdaq or the Alternative Requirements. The Notice states that our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, disclosed stockholders’ equity of (\$1.3 million) as of December 31, 2023, and that, as of March 8, 2024, we did not meet the Alternative Standards.

On April 22, 2024, we provided Nasdaq with our plan to achieve and sustain compliance with the stockholders’ equity requirement and requested that Nasdaq grant an extension of time until September 4, 2024, to provide evidence of our compliance with the stockholders’ equity requirement. Consistent with that plan, in May 2024, we completed the May 2024 PIPE Financing, which resulted in our stockholders’ equity being greater than \$2.5 million as of completion of the offering. Nasdaq has not yet responded to the plan we submitted, and there can be no assurance that Nasdaq will grant an extension or that we will be able to comply with the applicable listing standards of Nasdaq.

### *Funding and Material Cash Requirements*

To date, our operating losses have been funded primarily from outside sources of invested capital from issuance of our common and preferred stocks, proceeds from debt facilities and grant funding. However, the Company has had, and will continue to have, an ongoing need to raise additional cash from outside sources through a combination of equity offerings, debt financings and potential collaboration, license or development agreements to fund our future clinical development programs and other operations in the next twelve months from the filing of this report. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. There can be no assurance that the Company will be able to continue

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to raise additional capital in the future. Our inability to raise additional cash would have a material adverse impact on our operations.

Our present and future funding and cash requirements will depend on many factors, including, among other things:

- the progress, timing and completion of our ongoing and planned clinical trials and nonclinical studies;
- our ability to receive, and the timing of receipt of, future regulatory approvals for our product candidates and the costs related thereto;
- our ability to receive, and the timing of receipt of, future regulatory approvals for our product candidates and the costs related thereto;
- the scope, progress, results and costs of our ongoing and planned operations;
- the costs associated with expanding our operations and building our sales and marketing capabilities;
- our ability to establish strategic collaborations;
- the cost and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the revenue, if any, received from commercial sales of our product candidates, if approved; and
- potential new product candidates that the Company identifies and attempt to develop.

The Company's condensed financial statements have been prepared assuming that the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Cash (used in) provided by operating, investing, and financing activities for the three months ended March 31, 2024 and 2023 is summarized as follows (in thousands):

	Three Months Ended	
	March 31,	
	2024	2023
Net cash used in operating activities	<u>\$(4,513)</u>	<u>\$(5,793)</u>
Net cash used in investing activities	(364)	(97)
Net cash (used in) provided by financing activities	<u>(776)</u>	<u>493</u>
Net decrease in cash and cash equivalents	<u>\$(5,653)</u>	<u>\$(5,397)</u>

### *Material Cash Obligations*

Under the CPRIT Contract we receive matching funds for approximately two-thirds of the development costs for the development of rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with LM, subject to various funding conditions. The CPRIT contract is effective for three years, unless otherwise terminated pursuant to the terms of the contract. CPRIT may require us to repay some or all of the disbursed CPRIT grant proceeds (with interest not to exceed 5% annually) in the event of the early termination of the CPRIT Contract.

In addition, we are obligated to make operating lease payments for our office and laboratory space, and we may be required to make payments under certain of our other contractual agreements.

Other than as described above, we have no purchase commitments or long-term contractual obligations, except for lease obligations as of March 31, 2024. In addition, we have no off-balance sheet arrangements (as defined in

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the rules and regulations of the Securities and Exchange Commission) that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

### *Operating activities*

Net cash used in operating activities for the three months ended March 31, 2024 was \$4.5 million compared to \$5.8 million in the same period of 2023. Our operational cash use decreased \$1.3 million during the three months ended March 31, 2024 as compared to the same period in 2023, due primarily to increased reimbursement under the CPRIT grant agreement for research and development costs related to the ReSPECT-LM program.

### *Investing activities*

Net cash used in investing activities for the three months ended March 31, 2024 was related to purchase of short-term investments of \$0.3 million and purchases of fixed assets of \$40,000. Net cash used in investing activities for the three months ended March 31, 2023 was related to purchases of fixed assets of \$0.1 million.

### *Financing Activities*

Net cash used in financing activities for the three months ended March 31, 2024 was related to repurchase of treasury stock for approximately \$0.4 million and repayment of principle balance under the Oxford Term Loan of \$0.4 million.

Net cash provided by financing activities for the three months ended March 31, 2023 was primarily related to sales of common stock of \$0.9 million, net of offering cost through the September 2022 Distribution Agreement with Canaccord, and offset by repayment of principle balance under the Oxford Term Loan of \$0.4 million.

## **Critical Accounting Policies and Significant Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of our assets, liabilities, revenues and expenses, and that affect our recognition and disclosure of contingent assets and liabilities.

While our estimates are based on assumptions we consider reasonable at the time they were made, our actual results may differ from our estimates, perhaps significantly. If results differ materially from our estimates, we will make adjustments to our financial statements prospectively as we become aware of the necessity for an adjustment.

Goodwill is reviewed for impairment annually or more frequently if indicators of impairment exist. We perform our impairment test annually during the fourth quarter. We operate in a single operating segment and reporting unit. We monitor the fluctuations in our share price and have experienced significant volatility during the year.

We believe it is important for you to understand our most critical accounting policies. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and there have been no material changes during the three months ended March 31, 2024.

## BUSINESS

### Pipeline

Our most advanced investigational drug, rhenium ( $^{186}\text{Re}$ ) obisbameda, is a patented radiotherapy potentially useful for patients with CNS and other cancers. Preclinical study data describing the use of rhenium ( $^{186}\text{Re}$ ) obisbameda for several cancer targets have been published in peer-reviewed journals and reported at a variety of medical society peer-reviewed meetings. Besides GBM, LM and PBC, rhenium ( $^{186}\text{Re}$ ) obisbameda has been reported to have potential applications for head and neck cancer, ovarian cancer, breast cancer and peritoneal metastases.

The rhenium ( $^{186}\text{Re}$ ) obisbameda technology was part of a licensed radiotherapeutic portfolio that we acquired from NanoTx, Corp. (“NanoTx”) on May 7, 2020. The licensed radiotherapeutic has been evaluated in preclinical studies for several cancer targets and we have an active \$3.0 million award from U.S. National Institutes of Health/National Cancer Institute which is expected to provide financial support for the continued clinical development of rhenium ( $^{186}\text{Re}$ ) obisbameda for recurrent GBM through the completion of a Phase 2 clinical trial, including enrollment of up to 55 patients.

On August 29, 2022, we announced feedback from a Type C meeting with the FDA regarding CMC practices. The meeting focused on our cGMP clinical and commercial manufacturing process for our lead investigational targeted radiotherapeutic, BMEDA-chelated rhenium ( $^{186}\text{Re}$ ) obisbameda, for recurrent GBM.

The FDA indicated agreement with our proposed application of cGMP guidance for radiotherapeutics, small molecule drug products and liposome drug products for our novel rhenium ( $^{186}\text{Re}$ ) obisbameda in support of ongoing and future GBM clinical trials, manufacturing scale up, and commercialization. Alignment with the FDA includes support of our proposed controls and release strategy for new drug substance and new drug product. Because this product is identical for recurrent GBM, LM, and PBC, we believe alignment will be consistent for rhenium ( $^{186}\text{Re}$ ) obisbameda used in other clinical development programs, including LM and PBC.

#### *Rhenium ( $^{186}\text{Re}$ ) obisbameda versus External Beam Radiation Therapy for Recurrent GBM*

Rhenium ( $^{186}\text{Re}$ ) obisbameda is a novel injectable radiotherapy designed to deliver targeted, high dose radiation directly into GBM tumors in a safe, effective, and convenient manner that may ultimately prolong patient survival. Rhenium ( $^{186}\text{Re}$ ) obisbameda is composed of the radionuclide Rhenium-186 and a nanoliposomal carrier, and is infused in a highly targeted, controlled fashion, directly into the tumor via precision brain mapping and CED catheters. Potential benefits of rhenium ( $^{186}\text{Re}$ ) obisbameda compared to standard external beam radiotherapy or EBRT include:

- The rhenium ( $^{186}\text{Re}$ ) obisbameda radiation dose delivered to patients may be up to 20 times greater than what is possible with commonly used EBRT, which, unlike EBRT and proton beam devices, spares normal tissue and the brain from radiation exposure.
- Rhenium ( $^{186}\text{Re}$ ) obisbameda can be visualized in real-time during administration, possibly giving clinicians better control of radiation dosing, distribution and retention.
- Rhenium ( $^{186}\text{Re}$ ) obisbameda potentially more effectively treats a bulk tumor and microscopic disease that has already invaded healthy tissue.
- Rhenium ( $^{186}\text{Re}$ ) obisbameda is infused directly into the targeted tumor by CED catheter insertion using MRI guided software to avoid critical patient neurological structures and neural pathways and also bypasses the blood brain barrier, which delivers the therapeutic product where it is needed. Importantly, it reduces radiation exposure to healthy cells, in contrast to EBRT, which passes through normal tissue to reach the tumor, continuing its path through the tumor, hence being less targeted and selective.

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- Rhenium ( $^{186}\text{Re}$ ) obisbameda is given during a single, short, in-patient hospital visit, and is available in all hospitals with nuclear medicine and neurosurgery, while EBRT requires out-patient visits five days a week for approximately four to six weeks.

### *ReSPECT-GBM Trial for Recurrent GBM*

Recurrent GBM is the most common, complex, and aggressive primary brain cancer in adults. In the U.S., there are approximately 13,000 GBM cases diagnosed and approximately 10,000 patients succumb to the disease each year. The average length of OS for GBM patients is eight months, with a one-year survival rate of 40.8% and a five-year survival rate of only 6.8% and these estimates vary and are lower in some publications. GBM routinely presents with headaches, seizures, vision changes and other significant neurological complications, with a significant compromise in quality of life. Despite the best available medical treatments, the disease remains incurable. Even after efforts to manage the presenting signs and symptoms and completely resect the initial brain tumor, some microscopic disease almost always remains and tumor regrowth occurs within months. Approximately 90% or more of patients with primary GBM experience tumor recurrence. Complete surgical removal of GBM is usually not possible and GBM is often resistant or quickly develops resistance to most available current and investigational therapies. Even today, the treatment of GBM remains a significant challenge and it has been nearly a decade since the FDA approved a new therapy for this disease, and these more recent approvals have not improved GBM patients OS over past decades, and a significant unmet medical need persists.

For recurrent GBM, there are few currently approved treatments, which in the aggregate, provide only marginal survival benefit. Furthermore, these therapies are associated with significant side effects, which limit dosing and prolonged use.

While EBRT has been shown to be safe and has temporary efficacy in many malignancies including GBM, typically at absorbed, fractionated radiation dose of ~30 Gray in GBM, this maximum possible administered dose is always limited by toxicity to the normal tissues surrounding the malignancy and because EBRT requires fractionation to manage toxicity and maximum EBRT limits are typically reached before long-term efficacy reached. Because of this limitation, EBRT cannot provide a cure or long term control of GBM and GBM always recurs within months after EBRT. In contrast, locally delivered and targeted radiopharmaceuticals that precisely deliver radiation in the form of beta particles such as Iodine-131 for thyroid cancer, are known to be safe and effective and minimize exposure to normal cells and tissues especially with optimal administered dose and minimizing exposure to normal tissue. The locally delivered rhenium ( $^{186}\text{Re}$ ) obisbameda is designed for and provides patient tolerability and safety. Though no rhenium ( $^{186}\text{Re}$ ) obisbameda head-to-head trial with chemo, immune, EBRT or systemic radiopharmaceutical products have been conducted, patient tolerability and safety considerations have been reported as expected.

Interim results from our ongoing Phase 1/2a ReSPECT-GBM trial (ClinicalTrials.gov NCT01906385) show that the beta particle energy from our lead investigational drug rhenium ( $^{186}\text{Re}$ ) obisbameda has provided preliminary positive data and utility in treating GBM and potential other malignancies. More specifically, the preliminary data from our Phase 1/2a ReSPECT-GBM trial suggests that radiation, in the form of high energy beta particles or electrons, can be effective against GBM. Thus far, we have been able to deliver up to 740 Gy of absorbed radiation to tumor tissue in humans, without significant or dose limiting toxicities and with what we believe has the capability to go higher if required. In comparison, current EBRT protocols for recurrent GBM typically recommend a total maximum radiation dose of about ~30-35 Gray.

In September 2020, the FDA granted both Orphan Drug designation and Fast Track designations to rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of patients with GBM.

Rhenium ( $^{186}\text{Re}$ ) obisbameda is under clinical investigation in a multicenter, sequential cohort, open-label, volume and dose escalation study of the safety, tolerability, and distribution of rhenium ( $^{186}\text{Re}$ ) obisbameda given by CED catheters to patients with recurrent or progressive malignant glioma after standard surgical, radiation,



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and/or chemotherapy treatment (NCT01906385). The study uses a standard, modified 3x3 Fibonacci dose escalation, followed by a planned Phase 2 expansion trial at the MTD / MFD or non- DLT if MTD is not reached, to determine efficacy. The trial is funded through Phase 2 in large part by a NIH/NCI grant. These investigations have not reached DLT or MTD/MFD and the study is in its eighth dosing administration cohort. Due to the observation of a preliminary efficacy signal, we have initiated in parallel a Phase 2, non-DLT dose trial pursuant to the currently funded NIH/NCI grant. This trial will begin at the current non-DLT rhenium ( $^{186}\text{Re}$ ) obisbameda dose and will expand exploring higher radiation doses in larger volumes to treat larger tumors. Additionally, two or more rhenium ( $^{186}\text{Re}$ ) obisbameda administrations, if indicated, will be evaluated, and reviewed with the FDA, as well as expanded safety, imaging and efficacy data to support a planned future registrational trial.

On September 6, 2022, we announced a summary of our Type C clinical meeting with the FDA that focused on the ReSPECT-GBM trial. The FDA agreed with us that the ReSPECT-GBM clinical trial should proceed to the planned Phase 2. The key focus areas of clinical investigation of the Phase 2 trial will be (1) further dose exploration, including both increased dosing and multiple doses, and (2) collecting additional safety and efficacy data to inform the design of a future registrational trial. Because no DLT administered doses were observed, the FDA and we also agreed to continue to dose cohort eight. There was further agreement with the FDA that in a planned future registrational trial, overall survival should be used as the primary endpoint. We agreed with the FDA to hold future meeting(s) to consider the use of external data to augment the use of a control arm in the registrational trial.

On January 18, 2023, we announced that the first patient has been dosed in the ReSPECT-GBM Phase 2b dose expansion clinical trial evaluating rhenium obisbameda for the treatment of recurrent GBM. The Phase 2b trial is expected to enroll up to 31 total patients with small- to medium-sized tumors and is targeted for full enrollment by the end of 2024. We currently have four clinical sites, with the plan to add additional sites to support the trial, and expect an initial data read-out by the end of 2024.

In June 2023, we presented data regarding the safety and feasibility results from our Phase 1/2 Clinical Trial of  $^{186}\text{Re}$ RNL (Rhenium-186 Nanoliposome) ( $^{186}\text{Re}$ ) Obisbameda in Recurrent Glioma: The ReSPECT-GBM Trial at the Society of Nuclear Medicine & Molecular Imaging Annual Meeting.

On November 20, 2023, we announced positive data from the ongoing ReSPECT-GBM Phase 2 trial evaluating rhenium ( $^{186}\text{Re}$ ) obisbameda, for the treatment of recurrent glioblastoma at the Society for NeuroOncology 28th Annual Meeting, which was held November 15-19, 2023 in Vancouver, Canada. Key findings included:

- mOS in 15 patients with rGBM from the Phase 2 study is 13 months, which is 63% better than current standard of care (bevacizumab monotherapy) of 8 months; 9 of the 15 patients remain alive.
- mPFS is 11 months, compared to SOC at 4 months.
- Rhenium ( $^{186}\text{Re}$ ) obisbameda continues to demonstrate a favorable safety profile, despite delivering up to 20x the dose of radiation (up to 740 Gy) typically delivered by EBRT for rGBM patients (up to 35 Gy).
- Imaging data presented by Andrew Brenner, MD, PhD is consistent with the efficacy signal of Rhenium ( $^{186}\text{Re}$ ) obisbameda in rGBM.

On March 31, 2022, we entered into the Sales Order Medidata Solutions pursuant to which Medidata built a Synthetic Control Arm<sup>®</sup> platform that facilitates the use of historical clinical data to incorporate into our Phase 2 clinical trial of rhenium ( $^{186}\text{Re}$ ) obisbameda in GBM. The Sales Order had a term of six (6) months. Work under this Sales Order has been completed. As part of this collaboration, we jointly submitted with Medidata a HCA to ASCO which was accepted for publication, further strengthening this collaboration and allowing applications to advance GBM development. We plan to use the HCA for breakthrough therapy designation and Phase 2 and/or a pivotal or registrational Phase 3 trial.

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### *ReSPECT-LM Clinical Trial for LM*

LM is a rare complication of cancer in which the disease spreads to the membranes (meninges) surrounding the brain and spinal cord. The incidence of LM is growing and occurs in approximately 5%, or more, of people with late-stage cancer, or 110,000 people in the U.S. each year. It is highly lethal with an average one-year survival of just 7%. All solid cancers, particularly breast, lung, GI, and melanoma, have the potential to spread to the leptomeninges.

The ReSPECT-LM Phase 1 clinical trial (ClinicalTrials.gov NCT05034497) was preceded with preclinical studies in which tolerance to doses of rhenium ( $^{186}\text{Re}$ ) obisbameda as high as 1,075 Gy were shown in animal models with LM without significant observed toxicity. Furthermore, treatment led to a marked reduction in tumor burden in both C6 and MDA-231 LM models.

Upon receiving acceptance of our Investigational New Drug application and Fast Track designation by the FDA for rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of LM in November 2021, we initiated the trial and began screening patients for the ReSPECT-LM Phase 1 clinical trial in Q4 2021.

The ReSPECT-LM is a multi-center, sequential cohort, open-label, dose escalation study evaluating the safety, tolerability, and efficacy of a single-dose application of rhenium ( $^{186}\text{Re}$ ) obisbameda administered through intrathecal infusion to the ventricle of patients with LM after standard surgical, radiation, and/or chemotherapy treatment. The primary endpoint of the study is the incidence and severity of adverse events and dose limiting toxicities, together with determining the maximum tolerated and recommended Phase 2 dose. Full enrollment in the Phase 1 trial is expected by the end of 2024, with the plan to add additional clinical sites to support the trial.

On September 19, 2022, we entered into the CPRIT Contract, effective as of August 31, 2022, with CPRIT, pursuant to which CPRIT will provide us the CPRIT Grant over a three-year period to fund the continued development of rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of patients with LM through Phase 2 of the ReSPECT LM clinical trial. The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar from us for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of rhenium ( $^{186}\text{Re}$ ) obisbameda based on specific dollar thresholds until CPRIT receives the aggregate amount of 400% of the proceeds awarded under the CPRIT Grant, and certain reporting requirements. To date, we have received approximately \$7 million in milestone payments under the CPRIT Contract. We anticipate a continuing flow of milestone payments that throughout 2024 will include \$6.9 million upon the continued progression of the Phase 2 of the ReSPECT LM clinical trial.

Interim results showed that a single treatment with rhenium ( $^{186}\text{Re}$ ) obisbameda resulted in a consistent decreased CSF tumor cell count/ml and was tolerated by all LM patients. Rhenium ( $^{186}\text{Re}$ ) obisbameda is an outpatient administration and treatment and is easily and safely administered through a standard intraventricular catheter (Ommaya Reservoir), distributed promptly throughout the CSF, and with durable retention in the leptomeninges at least through day seven. All patients have shown well tolerated prompt and durable rhenium ( $^{186}\text{Re}$ ) obisbameda distribution throughout the subarachnoid space. On March 11, 2024, we announced we had completed Cohort 5 of the ReSPECT-LM Phase 1/2a dose escalation trial.

A total of 18 patients have received a single-dose of rhenium ( $^{186}\text{Re}$ ) obisbameda in the ReSPECT-LM trial as of March 31, 2024. There have been no dose limiting toxicities observed to date with administered radiation doses up to 66.14 millicuries in Cohort 5, a ten-fold increase over Cohort 1. We plan to initiate dosing in Cohort 6 in the second quarter of 2024, pending Data Safety Monitoring Board (DSMB) approval. In addition, five new clinical trial sites were added to this trial over the last year, bringing the total number of sites to seven. We are planning a new multiple dosing ReSPECT-LM clinical trial in late 2024 or early 2025.

On August 10, 2023, we presented data from the ReSPECT-LM clinical trial of rhenium ( $^{186}\text{Re}$ ) obisbameda at the Society for Neuro Oncology ASCO CNS Cancer Conference.

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In November 2023, the FDA granted Orphan Drug designation to rhenium ( $^{186}\text{Re}$ ) obisbameda for the treatment of patients with breast cancer with LM.

On December 12, 2023, we announced our partnership with K2bio to implement novel analysis for CSF tumor and molecular biomarkers for CNS cancers. Initial clinical specimen processing and testing began in the first quarter 2024 in our ongoing Phase 1 ReSPECT-LM trial of rhenium ( $^{186}\text{Re}$ ) obisbameda in patients with LM.

### *ReSPECT-PBC Clinical Trial for Pediatric Brain Cancer*

The average annual age adjusted mortality rate for children aged 0-14 for malignant brain (and other CNS) tumors is 0.71/100,000, making it the most common cause of death and cancer death in this age group. The 2021 World Health Organization Classification of CNS Tumors classifies gliomas, glioneuronal tumors, and neuronal tumors into six different families: (1) adult-type diffuse gliomas; (2) pediatric-type diffuse low-grade gliomas; (3) pediatric-type diffuse HGG; (4) circumscribed astrocytic gliomas; (5) glioneuronal and neuronal tumors; and (6) ependymomas.

In August 2021, we announced plans for treating pediatric brain cancer at the 2021 American Association of Neurological Surgeons Annual Scientific Meeting. In July 2021, we reported that we had received FDA feedback pertaining to a pre-IND meeting briefing package in which the FDA stated that we are not required to perform any additional preclinical or toxicology studies.

Given the initial FDA feedback, receipt of adult GBM data and experience with rhenium ( $^{186}\text{Re}$ ) obisbameda and follow-up communications with the FDA, we plan to submit a pediatric brain tumor IND to investigate the use of rhenium ( $^{186}\text{Re}$ ) obisbameda in two pediatric brain cancers, high-grade glioma and ependymoma, in the first or second quarter of 2024.

Pediatric high-grade gliomas can be found almost anywhere within the CNS; however, they are most commonly found within the supratentorium. The highest incidence of supratentorial, high-grade gliomas in pediatrics appears to occur in children aged 15 to 19 years, with a median age of approximately nine years. Overall, pediatric high-grade glioma confers a three-year PFS of  $11 \pm 3\%$  and three-year OS of  $22\% \pm 5\%$ . One-year PFS is as low as 40% in recent trials. Ependymomas are slow-growing central nervous system tumors that involve the ventricular system. Diagnosis is based on MRI and biopsy and survival rate depends on tumor grade and how much of the tumor can be removed. Grade II pathology was associated with significantly improved OS compared to Grade III (anaplastic) pathology (five-year OS =  $71 \pm 5\%$  vs.  $57 \pm 10\%$ ;  $p = 0.026$ ). Gross total resection compared to subtotal resection was associated with significantly improved OS (five-year OS =  $75 \pm 5\%$  vs.  $54 \pm 8\%$ ;  $p = 0.002$ ).

Overall, pediatric HGG and ependymoma are extremely difficult-to-treat pediatric brain tumors, frequently aggressive, and in recurrent settings, carry an extremely poor prognosis.

### *Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere Technology*

In January 2022, we announced that we licensed BAM patents and technology from UTHSA to expand our tumor targeting capabilities and precision radiotherapeutics pipeline. We intend to combine our Rhenium NanoLiposome technology with the BAM technology to create a novel radioembolization technology. Initially, we intend to utilize the Rhenium-188 isotope,  $^{188}\text{RnL}$ -BAM for the intra-arterial embolization and local delivery of a high dose of targeted radiation for a variety of solid organ cancers such as hepatocellular cancer, hepatic metastases, pancreatic cancer and many others.

Preclinical data from an ex vivo embolization experiment in which Technetium99m-BAM was intra-arterially delivered to a bovine kidney perfusion model was presented at Society of Interventional Radiology Annual Scientific Meeting. The study concluded that the technology required for radiolabeling BAM could successfully

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deliver, embolize and retain radiation in the target organ. <sup>188</sup>RNL-BAM is a preclinical investigational drug we intend to further develop and move into clinical trials. Specifically, in 2022 we transferred the <sup>188</sup>RNL-BAM technology from UTHSA, and began planning to develop the drug product and complete early preclinical studies to support a future FDA IND submission. Our intended initial clinical target is liver cancer which is the sixth most common and third deadliest cancer worldwide. It is a rare disease with increasing U.S. annual incidence (42,000) and deaths (30,000).

### **Facilities**

We have one lease agreement for our San Antonio, Texas locations. The lease for this property will expire in February 2025. We also lease certain office space in Austin, Texas under a month-to-month operating lease agreement. We also have a lease agreement for office space in Charlottesville. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or substitute space will be available in the future on commercially reasonable terms to accommodate any such expansion of our operations.

### **Legal Proceedings**

From time to time, we may be involved in various other claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any material legal proceedings.

## MANAGEMENT

### Officers and Directors

Set forth below are the names, ages and positions of each of the individuals who serve as our directors and officers as of June 21, 2024. There are no family relationships among any of our executive officers or directors.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Marc H. Hedrick, M.D.	62	Chief Executive Officer, President and Director
Andrew Sims	51	Chief Financial Officer
Howard Clowes	70	Director
Richard J. Hawkins	74	Chairman of the Board
An van Es-Johansson, M.D.	64	Director
Robert Lenk, PhD	76	Director
Greg Petersen	61	Director

**Marc H. Hedrick, M.D.** Dr. Hedrick joined the Company in October 2002 as Chief Scientific Officer. In May 2004, he was appointed as President of the Company and in April 2014 he was appointed as its Chief Executive Officer. Dr. Hedrick has served as a member of our Board since joining the Company in October 2002. Previously, Dr. Hedrick served in a number of executive leadership positions, including President and Chief Executive Officer of StemSource from 2001 to 2003 and Chief Scientific Officer and Medical Director of Macropore Biosurgery from 2002 to 2004. Dr. Hedrick has also served as a board member for a number of public and private companies since 2000. Prior to his corporate career, Dr. Hedrick was Associate Professor of Surgery and Pediatrics at the University of California, Los Angeles. While at the University of California, Los Angeles, Dr. Hedrick's academic research received both NIH funding as well as private and public capitalization and was widely acknowledged through scientific publications and the media. Dr. Hedrick also has first-hand experience as a physician, practicing general, vascular and craniofacial surgery. Dr. Hedrick has a medical degree from The University of Texas Southwestern Medical School and a Master of Business Administration from The UCLA Anderson School of Management and is a trained general, vascular and plastic surgeon. We believe Dr. Hedrick's qualifications to serve on our Board include his executive, financial, governance and operational leadership experience in medical and pharmaceutical product development.

**Andrew Sims.** Mr. Sims joined us as Chief Financial Officer in February 2020. Prior to his appointment as our Chief Financial Officer, Mr. Sims held roles at several private equity-backed companies. Between 2012 and 2017, Mr. Sims was Chief Financial Officer of Amplify LLC, an advisory and management consulting services firm. Following his time at Amplify, Mr. Sims served as Chief Financial Officer of Verbatim Support Services LLC, a litigation support company, from 2017 to 2019. His focus has been on mergers and acquisitions, integrations, corporate capitalization, and building out and managing teams to support global growth. Previously, Mr. Sims was Partner at Mazars, a global accounting, advisory, audit, tax and consulting firm. Working from both the Oxford, England and New York offices, Mr. Sims audited and advised global public clients, including a variety of healthcare companies, with average annual revenues in excess of \$1 billion. Further, he was the lead partner on over 50 acquisitions ranging from \$5 million to \$4 billion in purchase price. He is a Certified Public Accountant in the U.S. and a Chartered Accountant in England and Wales. Mr. Sims is a graduate of Buckingham University in the United Kingdom.

**Howard Clowes.** Mr. Clowes has served on our Board since April 1, 2020. From January 2005 until he retired as a lawyer in December 2018, Mr. Clowes was a partner in the law firm DLA Piper (US) LLC. From 1982 until the formation of DLA Piper in 2005, he was an associate and then a partner in the predecessor firms of DLA Piper, holding various management positions, including serving on its board of directors. Mr. Clowes served on the board of Equalize Health and as Chair of its Governance Committee from January 2018 to May 2022 and serves on the board of AFRAC, each of which are nonprofit corporations focused on global healthcare. Mr. Clowes served on the board of the Law Foundation of Silicon Valley, a non-profit organization located in San Jose, California, that provides free legal services to Silicon Valley residents in need, from 2008 until December 2018,

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serving during that period in various positions, including President of its board of directors, and Chair of a Strategic Planning and CEO Search Committee. From 2017 to 2021, Mr. Clowes served as a Lecturer at U.C. Berkeley's Berkeley School of Law, teaching a course in International Business Negotiations. Mr. Clowes earned his J.D. at U.C. Berkeley, his B.A. in Experimental Psychology at U.C. Santa Barbara, and in 2023, Mr. Clowes received his NACD Directorship Certification. We believe Mr. Clowes' qualifications to serve on the Board include his extensive experience as a lawyer advising boards of directors and their audit, compensation and governance committees on a wide range of matters, his experience with a wide range of transactions, and his experience serving on various boards of directors.

**Richard J. Hawkins.** Mr. Hawkins has served on our Board since December 2007 and as Chairman of our Board since January 2018. In 1982, Mr. Hawkins founded Pharmaco, a clinical research organization, or CRO, where he served as its Chairman, President and Chief Executive Officer until 1991 when it merged with the predecessor of PPD-Pharmaco. In 1992, Mr. Hawkins co-founded Sensus Drug Development Corporation, or SDDC, a privately-held company focused on the development of drugs to treat endocrine disorders, which developed and received regulatory approval for SOMAVERT, a growth hormone antagonist approved for the treatment of acromegaly, which is now marketed by Pfizer, Inc., where he served as Chairman until 2000. In 1994, Mr. Hawkins co-founded Corning Biopro, a contract protein manufacturing firm, where he served on its board until Corning BioPro's sale to Akzo-Nobel, N.V., a publicly-held producer of paints, coatings and specialty chemicals, in 2000. In September 2003, Mr. Hawkins founded LabNow, Inc., a privately held company that develops lab-on-a-chip sensor technology, where he served as the Chairman and Chief Executive Officer until October 2009. In February 2011, Mr. Hawkins became Chief Executive Officer, and is currently Chief Executive Officer, president and chairman of Lumos Pharma, Inc. (NASDAQ: LUMO). Mr. Hawkins served on the board of SciClone Pharmaceuticals, Inc. (HKD: SCLN), a publicly-held specialty pharmaceutical company, from October 2004 through December 2017. He also served on the Presidential Advisory Committee for the Center for Nano and Molecular Science and Technology at the University of Texas in Austin, and was inducted into the Hall of Honor for the College of Natural Sciences at the University of Texas. Mr. Hawkins is a member of the National Ernst & Young Entrepreneur of the Year Hall of Fame. Mr. Hawkins graduated cum laude with a B.S. in Biology from Ohio University, where he later received the Ohio University Konneker Medal, the highest award given to a faculty member or former student for entrepreneurial excellence. We believe Mr. Hawkins's qualifications to serve on our Board include his executive experience working with life sciences companies, his extensive experience in pharmaceutical research and development, his knowledge, understanding and experience in the regulatory development and approval process, and his service on other public company boards and committees.

**An van Es-Johansson, M.D.** Dr. van Es-Johansson has served on our Board since January 1, 2020. Dr. van Es-Johansson served as the Chief Medical Officer for AlzeCure Pharma, a Swedish pharmaceutical company with a primary focus on Alzheimer's disease, from September 2018 through March 1, 2021 following which she has continued to serve AlzeCure Pharma as a Senior Advisor beginning in March 2021. Since 2021 she is a Senior Advisor for Sinfonia AB, a Swedish Pharmaceutical Company with focus on neuroscience. From May 2005 to September 2018, Dr. van Es-Johansson served in a range of executive roles of increasing responsibility at Sobi, an international rare disease company headquartered in Stockholm, Sweden, including as Vice President and Head of EMENAR Medical Affairs for Specialty Care and Partner Products from March 2013 to January 2018. Prior to her time at Sobi, Dr. van Es-Johansson served in leadership positions within large pharmaceutical and smaller biotechnology companies, including Roche, Pharmacia, Eli Lilly, Active Biotech, and BioStratum. From 2004 to 2016, she was a member of the Scientific Advisory Board of Uppsala Bio and currently serves on the board of directors of Savara, Inc. (NASDAQ: SVRA), Lumos Pharma, Inc. (NASDAQ: LUMO) and privately held Agendia BV. She also served on the board of directors at BioInvent International AB (NASDAQ OMX Stockholm BINV), from June 2016 to February 2021 on the board of directors of Alzecure AB (NASDAQ OMX Stockholm ALZCUR), from 2017-2020, on the board of directors of Medivir AB (NASDAQ OMX -MVIR) from 2019-2022, and on the board of directors of IRLAB AB (NASDAQOMX Stockholm IRLAB) from May 2022 to February 2023. Dr. van Es-Johansson received a M.D. from Erasmus University, Rotterdam, The Netherlands. We believe Dr. van Es-Johansson's qualifications to serve on our Board include her extensive medical knowledge and experience in the pharmaceutical industry.

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**Robert Lenk, PhD.** Dr. Lenk has served on our Board since April 1, 2020. Since 2016, he has served as President of Lenk Pharmaceuticals, LLC, consulting to clients in the pharmaceuticals industry. Dr. Lenk co-founded the Liposome Company, in Princeton, New Jersey in 1981 until it was later acquired by Elan Pharmaceuticals. After the Liposome Company went public, he co-founded Argus Pharmaceuticals, a drug delivery company focused on cancer and infectious diseases, in 1989 as Vice President of Research & Development, until it merged with two other companies to become Aronex Pharmaceuticals. From 1995 to 2003, Dr. Lenk served as President and Chief Executive Officer of Therapeutics 2000, Inc. which was later sold to Collier Capital. Dr. Lenk joined Luna Innovations in 2004 where he served as President of its Nanoworks Division until 2010. In 2010, Dr. Lenk joined MediVector, Inc. as Chief Science Officer until 2016 when he started Lenk Pharmaceuticals, LLC, a pharmaceutical development consulting company where he currently works. He also currently serves on the board of PoP Biotechnology, a private company that develops vaccines and cancer therapies based on proprietary porphyrin liposome nanoparticle technology. Dr. Lenk received both his PhD and BSc. from the Massachusetts Institute of Technology. We believe Dr. Lenk's qualifications to serve on our Board include his broad experience in translating research candidates into products, especially in the fields of nanotechnology and liposomal drug products.

**Greg Petersen.** Mr. Petersen has served on our Board since February 14, 2020. Mr. Petersen is an accomplished executive and board member with more than 25 years of strategy, operations, finance and compliance leadership experience. His 10 years of board of directors experience includes his current role as compensation committee chair and audit committee member of PROS Holdings, Inc. (NYSE: PRO), a software company. Mr. Petersen previously served on the boards of publicly traded companies Mohawk Group Holdings (NASDAQ: MWK), a consumer product manufacturing company, from 2019 to 2022, Diligent Corporation (NZX: DIL), a software as a service company, from 2013 to 2016, and Piksel, Inc. (OTC US: PIKL), a video management software and services company, from 2012 to 2017. During his career, Mr. Petersen has served as Executive Vice Chairman of Diligent Corporation and as Chief Financial Officer of Lombardi Software (now part of IBM) and Activant Solutions (now part of Epicor). He has also held executive positions at American Airlines and other corporations. Mr. Petersen has a BA from Boston College and an MBA from Duke University's Fuqua School of Business. We believe Mr. Petersen's qualifications to serve on our Board include his extensive experience as an executive and a director, including as a director on other public company boards, as well as his strategic, operations, finance, and compliance leadership experience.

## **Corporate Governance**

### **Composition of Our Board**

Our business and affairs are managed under the direction of our Board, which is comprised of Marc H. Hedrick, Howard Clowes, Richard J. Hawkins, An van Es-Johansson, Robert Lenk, and Greg Petersen. Mr. Hawkins serves as the Chairman of our Board. Subject to the terms of our Charter, and our Bylaws, the number of directors will be fixed by our Board.

When considering whether directors and director nominees have the experience, qualifications, attributes and skills, taken as a whole, to enable our Board to satisfy its oversight responsibilities effectively in light of its business and structure, our Board expects to focus primarily on each person's character, judgment, leadership, business acumen, diversity of backgrounds and perspectives, skills, age, gender, ethnicity, and professional experience, knowledge of or experience in the pharmaceutical industry, sufficient time to devote to Plus' affairs, and commitment to represent the long-term interests of Plus' stockholders. in order to provide an appropriate mix of experience and skills relevant to the size and nature of its business.

### **Director Independence**

Our Common Stock is listed on the Nasdaq Capital Market and under the listing rules of Nasdaq, subject to specified exceptions, independent directors must comprise a majority of a listed company's board of directors, and each member of a listed company's audit, compensation, and nominating and corporate governance

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committees must be independent. Under Nasdaq listing rules, a director will only qualify as an “independent director” if, among other things, the listed company’s board of directors affirmatively determines that the director does not have a relationship which, in the opinion of the listed company’s board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our Board reviews the independence of each director. This review is based primarily on responses of the directors to questions in a directors’ and officers’ questionnaire regarding employment, business, familial, compensation and other relationships with Plus and our management. Our Board has determined that no transactions or relationships existed that would disqualify any of our directors under the Nasdaq rules or require disclosure under SEC rules, with the exception of Marc H. Hedrick, M.D., our President and Chief Executive Officer, because of his current employment relationship with Plus. Based upon that finding, the Board determined that Ms. van Es-Johansson, and Messrs. Hawkins, Clowes, Lenk and Petersen are “independent” and the composition of our Board meets the requirements for independence under Nasdaq. Each of our Audit, Compensation, and Nominating and Governance Committees is composed only of independent directors.

### **Committees of Our Board**

Our Board directs the management of its business and affairs, as provided by Delaware law, and conducts its business through meetings of our Board and its standing committees. Our Board has three standing committees: our Audit Committee, our Compensation Committee, and our Nominating and Corporate Governance Committee, each of which has the composition and the responsibilities described below, and operates under a written charter.

Copies of our standing committee charters are posted on our website, as required by applicable SEC rules and Nasdaq rules.

<u>Name</u>	<u>Age</u>	<u>Director Since</u>	<u>Board Committees</u>			
			<u>Independent</u>	<u>Audit Committee</u>	<u>Compensation Committee</u>	<u>Nominating and Corporate Governance Committee</u>
Howard Clowes	70	2020	I	M	C	M
An van Es-Johansson, MD	64	2020	I	M		C
Robert Lenk, PHD	76	2020	I			M
Greg Petersen	61	2020	I	C + FE	M	

I - Independent director under Nasdaq rules

C - Chair

M - Member

FE - Audit Committee financial expert

### **Audit Committee**

Our Audit Committee’s responsibilities include, among other things:

- review management’s and our independent auditor’s report on their assessment of the effectiveness of internal control over financial reporting as of the end of each fiscal year;
- selecting our auditors and reviewing the scope of the annual audit;
- resolving any disagreements between management and the auditor regarding financial reporting;
- approving the audit fees and non-audit fees to be paid to our auditors;



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- reviewing our financial accounting controls with the staff and the auditors;
- reviewing and monitoring management’s enterprise risk management assessment;
- reviewing and discussing with management and the auditor, our audited financial statements including our disclosures under the section entitled “[Management’s Discussion and Analysis of Financial Condition and Results of Operations](#)”;
- reviewing our earnings press releases as well as financial information and earnings guidance provided to analysts and rating agencies;
- reviewing and approving our annual budget; and
- reviewing all related person transactions which are required to be reported under applicable SEC regulations.

Our Audit Committee currently consists of Mr. Clowes, Dr. van Es-Johansson and Mr. Petersen (Chairperson). All members of our Audit Committee meet the requirements for financial literacy under the applicable Nasdaq rules and regulations. Our Board has determined that each member of our Audit Committee qualifies as “independent” under Nasdaq’s additional standards applicable to audit committee members and Rule 10A-3 of the Exchange Act. Our Board has also determined that Mr. Petersen qualifies as an “audit committee financial expert” as defined in Item 407(d)(5) of Regulation S-K.

### **Compensation Committee**

Our Compensation Committee’s responsibilities include, among other things:

- developing and implementing compensation programs for our executive officers and other employees, subject to the discretion of the full Board;
- establishing base salary rates, benefits and other compensation matters for each of our executive officers;
- administering our equity compensation plans;
- reviewing the relationship between our performance and our compensation policies and assessing any risks associated with such policies;
- reviewing and advising the Board on director compensation matters and on regional and industry-wide compensation practices and trends in order to assess the adequacy of our executive compensation programs; and
- reviewing and discussing compensation related disclosures with management and making a recommendation to the Board regarding the inclusion of such disclosures in our annual proxy statement or Form 10-K, as applicable.

Our Compensation Committee currently consists of Mr. Petersen (Chairperson) and Mr. Clowes. Our Board has determined that each of Mr. Petersen and Mr. Clowes qualifies as “independent” under Nasdaq’s additional standards applicable to compensation committee members and that each member of our Compensation Committee is a “non-employee director” as defined in Section 16b-3 of the Exchange Act.

Pursuant to our Compensation Committee’s charter, our Compensation Committee has the authority to retain or obtain the advice of compensation consultants, legal counsel and other advisors to assist in carrying out its responsibilities. Before selecting any such consultant, counsel or advisor, our Compensation Committee reviews and considers the independence of such consultant, counsel or advisor in accordance with applicable Nasdaq rules.

## **Nominating and Corporate Governance Committee**

Our Nominating and Corporate Governance Committee is responsible for, among other things:

- evaluating and make recommendations regarding the size and composition of the Board;
- making recommendations to the Board regarding the composition of committees of the Board and the chairperson for each of its committees, with consideration of the desires of individual members of the Board;
- monitoring compliance with Board and Board's committee membership criteria;
- identifying, evaluating, recruiting, recommending, and screening candidates for nomination to the Board, including those recommended by stockholders, based on criteria set forth in the Company's Corporate Governance Guidelines;
- establishing procedures for the submission and consideration of candidates for nomination to the Board recommended by stockholders;
- identifying, evaluating, recruiting, recommending to the Board for consideration and approval the individuals to constitute the nominees of the Board for election as directors at an annual meeting of stockholders or to fill vacancies on the Board;
- evaluating periodically the Company's risk management process and system in light of the nature of the material risks the Company faces and the adequacy of the Company's policies and procedures designed to address risk, and recommend to the Board any changes deemed appropriate by the Nominating and Corporate Governance Committee;
- overseeing the annual self-evaluation process of the Board and each of its committees;
- developing and recommend to the Board the qualification standards for directors and committee members, including defining specific criteria for independence, and from time to time or as necessary recommend to the Board any changes deemed appropriate by the Nominating and Corporate Governance Committee;
- reviewing periodically with the Chairman of the Board and the Chief Executive Officer the succession plan relating to the Chief Executive Officer and the management development plan, and thereafter make recommendations to the Board with respect to such plans;
- reviewing and reassess annually at its first meeting following an annual meeting of stockholders the adequacy of the Audit Committee Charter, Compensation Committee Charter, the Insider Trading and Communications Policy, and any such other charters and policies as the Board shall determine and recommend any proposed changes to the Board; and
- reviewing and discussing with management disclosure of the Company's corporate governance practices, including information regarding the operations of the Nominating and Corporate Governance Committee and other Board committees, director independence, and the director nominations process, and recommend that this disclosure be, included in the Company's proxy statement or annual report on Form 10-K, as applicable.

Our Nominating and Corporate Governance Committee currently consists of Dr. Lenk, Mr. Clowes and Dr. van Es-Johansson (Chairperson). Our Board has determined that each of Dr. Lenk, Mr. Clowes and Dr. van Es-Johansson qualifies as "independent" under Nasdaq rules applicable to nominating and corporate governance committee members.

In addition, our Board may from time to time establish other committees when it deems doing so to be necessary or advisable to address specific matters.

**Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics (the “Code of Ethics”) that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. This Code of Ethics has been posted on our website at [www.plustherapeutics.com](http://www.plustherapeutics.com). To the extent required by SEC rules, we intend to post amendments to this code, or any waivers of its requirements, on our website at <https://ir.plustherapeutics.com/governance/corporate-governance-materials>. To date, there have been no waivers under our Code of Ethics.

## EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the “Summary Compensation Table” below. In 2023, our “named executive officers” and their positions were as follows:

- Marc H. Hedrick, M.D., our President and Chief Executive Officer;
- Andrew Sims, our Chief Financial Officer; and
- Norman LaFrance, M.D., our former Chief Medical Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs.

### Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for our fiscal year ended December 31, 2023.

Name and Principal Position	Year	Salary (\$)	Option Awards (\$) (1)	Non-Equity Incentive Plan Compensation (\$) (2)	All Other Compensation (\$) (3)	Total (\$)
Marc H. Hedrick, M.D.	2023	556,400	188,692	336,622	52,313	1,134,027
<i>President and Chief Executive Officer</i>	2022	535,000	—	361,928	57,723	954,651
Andrew Sims	2023	355,000	40,722	125,803	17,706	539,231
<i>Chief Financial Officer</i>	2022	305,000	—	125,164	16,012	446,176
Norman LaFrance, M.D.	2023	440,000	29,244	161,700	44,321	675,265
<i>Former Chief Medical Officer(4)</i>	2022	440,000	—	152,460	45,351	637,811

- (1) The amounts in this column reflect the aggregate grant date fair value of stock options granted in the applicable year. In accordance with SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions computed in accordance with ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 13 to our consolidated financial statements included in Part II, Item 8 of our Annual Report on Form 10-K for fiscal year end December 31, 2023.
- (2) The amounts in this column represent annual performance-based bonuses for 2023 and 2022. See the narrative below under “Annual Bonuses and Non-Equity Incentive Plan Compensation” for additional detail.
- (3) This column includes standard benefits which are 401K match, and health and life insurance premiums.
- (4) Dr. LaFrance is included as a named executive officer in this section because he was an executive officer at the beginning of fiscal year 2024 through June 2024 and one of the three most highly compensated individuals (other than our Chief Executive Officer and Chief Financial Officer) at the end of fiscal year 2023. On June 5, Dr. LaFrance stepped down from his position as the Company’s Chief Medical Officer.

### 2023 Salaries

The named executive officers receive a base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is reviewed annually by our Compensation Committee and is intended to provide a fixed component of compensation reflecting the executive’s skill set, experience, role and responsibilities.

Name	Title	2023 Base Salary	2022 Base Salary	Percent Increase
Marc H. Hedrick, M.D.	Chief Executive Officer	\$556,400	\$535,000	4%
Andrew Sims	Chief Financial Officer	\$355,000	\$305,000	16.39%
Norman LaFrance, M.D.	Former Chief Medical Officer	\$440,000	\$440,000	—

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### 2023 Annual Bonuses and Non-Equity Incentive Plan Compensation

In 2023, each of the named executive officers was eligible to receive a cash incentive award expressed as a percentage of annual base salary.

<u>Name</u>	<u>Title</u>	<u>Target Bonus for 2023 (% of Base Salary)</u>
Marc H. Hedrick, M.D.	Chief Executive Officer	55%
Andrew Sims	Chief Financial Officer	35%
Norman LaFrance, M.D.	Former Chief Medical Officer	35%

The corporate objectives upon which the target bonus is based upon was designed by the Compensation Committee to stimulate and support a high-performance environment by tying 2023 cash incentive awards to the attainment of short-term goals related to the Company's clinical, financial and operational goals. Our Compensation Committee further determined that the award payout would be determined by measuring our actual performance as compared to corporate and/or individual objectives, and the Compensation Committee used that information, along with the overall corporate performance, to determine what percentage of each named executive officer's bonus target was achieved and would be paid out as a bonus for 2023.

For the Company's 2023 fiscal year, the corporate goals approved by the Board (upon recommendation of the Compensation Committee for purposes of executive compensation) were determined by the Compensation Committee to have been achieved at a level of 110%. Dr. Hedrick's bonus received \$336,622, or 110% of his target cash bonus. Based upon the attainment of 110% of the corporate goals, and upon an attainment of 75% of his individual goals. Mr. Sims, received \$125,803, or 101% of his target cash bonus and upon an attainment of 100% of his individual goals, and Dr. LaFrance, received \$161,700, or 105% of his target cash bonus.

### Long-Term Equity Compensation

For the year ended December 31, 2023, Dr. Hedrick was awarded stock options covering a total of 6,720 shares, Mr. Sims was awarded stock options covering a total of 1,451 shares and Dr. LaFrance was issued a stock option covering 1,047 shares.

### Personal Benefits and Perquisites

All of our executives are eligible to participate in our employee benefit plans, including medical, dental, vision, life insurance, short-term and long-term disability insurance, flexible spending accounts and 401(k). These plans are available to all full-time employees. We offer limited personal benefits and perquisites to executive officers.

### Employment Agreements

#### *Marc H. Hedrick, M.D., Chief Executive Officer*

On March 11, 2020, we entered into an employment agreement with Dr. Hedrick, providing for his position as Chief Executive Officer. Subsequently, on May 13, 2020, the employment agreement with Dr. Hedrick was amended on May 13, 2020. Dr. Hedrick's employment with us is at-will and either party may terminate the employment agreement without notice. The employment agreement generally provides for a minimum base salary, a discretionary annual cash bonus based on the achievement of Company performance goals and the ability to participate in, subject to applicable eligibility requirements, all of our benefit plans and fringe benefits and programs that may be provided to our executives from time to time.

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The employment agreement with Dr. Hedrick also provides for potential payments upon termination as described below under “Potential Payments Upon Termination or Change-in-control.”

### *Andrew Sims, Chief Financial Officer*

On March 11, 2020, we entered into an employment agreement with Mr. Sims, providing for his position as Chief Executive Officer. Subsequently, on May 13, 2020, the employment agreement with Mr. Sims was amended on May 13, 2020. Mr. Sims’s employment with us is at-will and either party may terminate the employment agreement without notice. The employment agreement generally provides for a minimum base salary, a discretionary annual cash bonus based on the achievement of Company performance goals and the ability to participate in, subject to applicable eligibility requirements, all of our benefit plans and fringe benefits and programs that may be provided to our executives from time to time.

The employment agreement with Mr. Sims also provides for potential payments upon termination as described below under “Potential Payments Upon Termination or Change-in-control.”

### **Potential Payments Upon Termination or Change-in-Control**

Pursuant to the terms of the employment agreements with Dr. Hedrick and Mr. Sims (the “Executive Employment Agreements”), if one of our named executive officers is terminated without “cause” or resigns for “good reason,” (a “Severance Termination”), then such named executive officer will be eligible to receive: (i) an amount equal to twelve months of his base salary; (ii) an amount equal to his target bonus for the year in which such Severance Termination occurs; (iii) the annual bonus earned for the prior calendar year if not yet paid as of the date of such Severance Termination; (iv) an amount equal to twelve months of the premiums such named executive officer is required to pay under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (“COBRA”) to continue coverage for him and his eligible dependents under our group health plans; and (v) the accelerated vesting of such named executive officer’s unvested equity incentive awards that would have vested during the period beginning on the date of such Severance Termination and ending on (1) in case of a Severance Termination of Dr. Hedrick, twelve months thereafter, or (ii) in the case of a Severance Termination of Mr. Sims, nine months thereafter. In order to be eligible for the benefits set forth above, such named executive officer must sign (and not revoke) a general release of claims in favor of the Company as of the date of the Severance Termination, as applicable (a “Release”).

If a Severance Termination occurs within the period beginning on the date the Company and an acquiror formally or informally agree on the terms of a transaction which, if consummated, would constitute a “change in control” and ending on the closing date of the change in control, or within twelve months following a change in control, upon signing a Release (a “CoC Termination”), such named executive officer will be eligible to receive: (i) those items listed in the above paragraph under subclauses (ii) and (iii); (ii) an amount equal to (1) in the case of a CoC Termination of Dr. Hedrick, 18 months of the greater of his base salary in effect immediately prior to the date of such CoC Termination and his base salary in effect on the date the terms of a transaction that results in a change in control are agreed to, or (2) in the case of a CoC Termination of Mr. Sims, 12 months of the greater of his base salary in effect immediately prior to the CoC Termination and his base salary in effect on the date the terms of a transaction that results in a change in control; (iii) the amounts listed in the above paragraph under subclause (iv) except that, if the CoC Termination is for Dr. Hedrick, the amount of the COBRA payment will be increased to 18 months; (iv) the acceleration of such named executive officer’s remaining unvested equity incentive awards effective on the later of the CoC Termination and the date of the change in control; and (v) the right to exercise the equity incentive awards granted to him on or after the date of his Executive Employment Agreement until the later of (1) three months after the CoC Termination, (2) three months following the change in control with respect to any equity incentive awards that become exercisable upon a change in control due to this acceleration in connection with the change in control, and (3) any period specified in such named executive officer’s award agreements (but not beyond the original expiration date of any equity incentive award). Further, even if a CoC Termination does not occur, if any of our named executive officers remain employed by the Company as of the

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closing of such change in control, all of such named executive officer's outstanding unvested incentive stock awards shall automatically accelerate on the date of such change of control.

Under the Executive Employment Agreements, the term "cause" generally refers to the occurrence of certain events including (i) the employee's extended disability, (ii) employee's repudiation of his employment or his Executive Employment Agreement, (iii) the employee's conviction of a felony or certain misdemeanors, (iv) employee's demonstrable and documented fraud, (v) intentional, reckless or grossly negligent action which causes material harm to the Company, (vi) intentional failure to substantially perform material employment duties or directives, and (vii) chronic absence from work for reasons other than illness, permitted vacation or resignation for good reason.

Under the Executive Employment Agreements, the term "good reason" generally refers to: (i) the Company's material breach of its obligation to pay employee the compensation earned for any past service (at the rate which had been stated to be in effect for such period of service); (ii) a change in employee's position with the Company which materially reduces the employee's duties or stature in the business conducted by the Company; and (iii) a reduction in the employee's level of compensation, provided, however, that a Company-wide reduction of compensation of not more than fifteen percent (15%) that is also applicable to all of the senior management team of the Company and which continues for less than three (3) months, shall not constitute Good Reason.

Under the Executive Employment Agreements, the term "change of control" generally refers to (i) a change in the composition of the Board, as a result of which fewer than one-half of the incumbent directors are directors who either: (A) had been directors of the Company; or (B) were elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the aggregate of the original directors who were still in office at the time of the election or nomination and the directors whose election or nomination was previously so approved; (ii) any "person" who by the acquisition or aggregation of securities, is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities ordinarily having the right to vote at elections of directors (the "Base Capital Stock"); except that any change in the relative beneficial ownership of the Company's securities by any person resulting solely from a reduction in the aggregate number of outstanding shares of Base Capital Stock, and any decrease thereafter in such person's ownership of securities, shall be disregarded until such person increases in any manner, directly or indirectly, such person's beneficial ownership of any securities of the Company; (iii) the consummation of a merger or consolidation of the Company with or into another entity or any other corporate reorganization, if persons who were not stockholders of the Company immediately prior to such merger, consolidation or other reorganization own immediately after such merger, consolidation or other reorganization 50% or more of the voting power of the outstanding securities of each of (A) the continuing or surviving entity and (B) any direct or indirect parent corporation of such continuing or surviving entity; or (iv) the sale, transfer or other disposition of all or substantially all of the Company's assets.

### **Resignation, Retirement, Termination for Cause, or Resignation without Good Reason Arrangements**

The Company does not have any agreements or plans other than the Executive Employment Agreements in place for the named executive officers that would provide additional compensation in connection with a retirement.

**Outstanding Equity Awards at Fiscal Year End**

The following table sets forth the information regarding each outstanding unexercised or unvested equity award held by our named executive officers as of December 31, 2023.

<u>Name</u>	<u>Option Grant Date (1)</u>	<u>Number of Securities Underlying Unexercised Options (#) Exercisable (3)</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable (2)</u>	<u>Option Exercise Price (\$)(3)</u>	<u>Option Expiration Date</u>
Marc H. Hedrick, M.D., President and Chief Executive Officer	4/11/2014	3	—	267,750	4/11/2024
	8/21/2014	1	—	157,500	8/21/2024
	1/30/2015	3	—	54,000	1/30/2025
	1/4/2016	8	—	21,060	1/4/2026
	3/8/2017	13	—	11,625	3/8/2027
	6/25/2020	8,170	1,164	32	6/25/2030
	2/16/2021	4,180	1,708	55	2/16/2031
	5/25/2021	8,649	4,736	34	5/25/2031
	2/15/2023	6,720	25,535	6	2/15/2033
Andrew Sims Chief Financial Officer	2/6/2020	2,091	576	33	2/6/2030
	2/16/2021	3,154	1,288	55	2/16/2031
	5/25/2021	4,317	2,363	34	5/25/2031
	2/15/2023	1,451	5,510	6	2/15/2033
Norman LaFrance, M.D. Former Chief Medical Officer	11/11/2021	4,168	3,832	26	11/11/2031
	2/15/2023	1,047	3,952	6	2/15/2033

- (1) For a better understanding of this table, we have included an additional column showing the grant date of the stock options.
- (2) Unless otherwise provided, unvested stock options are subject to four-year vesting (from the grant date), and all stock options have a contractual term of 10 years from the date of grant. Awards presented in this table contain one of the following two vesting provisions:
- With respect to an initial stock option grant to an employee, 1/4<sup>th</sup> of the shares subject to the award vest on the one-year anniversary of the vesting start date, while an additional 1/36<sup>th</sup> of the remaining option shares vest at the end of each month thereafter for 36 consecutive months, or
  - With respect to stock option grants made to an employee after one full year of employment, 1/48<sup>th</sup> of the shares subject to the award vest at the end of each month over a four-year period, as measured from the vesting start date.
- (3) We consummated a 1-for-15 reverse stock split in May 2016, a 1-for-10 reverse stock split in May 2018, a 1-for-50 reverse stock split in August 2019 and a 1-for-15 reverse stock split in May 2023. The amounts set forth in this column reflect these four reverse stock splits.



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### Director Compensation

The following table sets forth information concerning the compensation of our Board for the year ended December 31, 2023. Please note that Dr. Hedrick receives no compensation for his role as director, and the entirety of his compensation is reported in the Summary Compensation Table.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Option Awards (\$)(1)</u>	<u>Total (\$)</u>
Richard J. Hawkins, Chairman	95,000	7,874	102,874
Howard Clowes	67,500	7,874	75,374
An van Es-Johansson, M.D.	57,500	7,874	65,374
Robert Lenk, PhD	45,000	7,874	52,874
Greg Petersen	72,500	7,874	80,374

- (1) Amounts in this column represent awards of restricted stock options with the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. The fair value determined at the date of grant in accordance with U.S. GAAP based on the closing price of our common stock on the applicable grant date. The vesting of these stock awards are service based and subject to continued participant as Board members.

We pay each non-employee director:

- \$40,000 annual cash retainer for Board members;
- \$37,500 annual cash retainer for the Chairman of the Board;
- \$27,500 annual cash retainer for the Chairman of the Audit Committee;
- \$15,000 annual cash retainer for the Chairman of our Compensation Committee;
- \$10,000 annual cash retainer for the Chairman of our Nominating and Corporate Governance Committee;
- \$5,000 annual cash retainer for each non-Chairman committee member; and
- Additional \$2,500 annual retainer for each non-Chairman Audit Committee member.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

### May 2024 PIPE Financing

In May 2024, we entered into the Purchase Agreement whereby we issued and sold in a private placement: (i) 3,591,532 Private Placement Shares, or, at the election of each Purchaser, Pre-Funded Warrants exercisable immediately to purchase shares of common stock. Each Private Placement Share or Pre-Funded Warrant are accompanied by (i) Series A Common Stock Warrants to purchase one share of common stock, for an aggregate of 3,591,532 Series A Common Stock Warrants, and (ii) one Series B Common Warrants to purchase one share of common stock, for an aggregate of 3,591,532 Series B Common Warrants, for aggregate gross proceeds of \$19.25 million. Among the Purchasers were certain of our directors and officers, and the table below sets forth the number of shares of our common stock purchased by such holders at the closing of the May 2024 PIPE Financing:

Participant	Shares of Our Common Stock Purchase in the May 2024 PIPE Financing	Total Purchase Price (\$)
Marc H. Hedrick, MD(1)	36,765	25,000.20
Andrew Sims(2)	14,706	10,000.08
Richard J. Hawkins(3)	14,706	10,000.08
Howard Clowes(4)	29,412	20,000.16
Robert Lenk, Ph.D.(5)	12,501	8,500.68
Greg Petersen(6)	36,765	25,000.20

- (1) Dr. Hedrick is the President, Chief Executive Officer and a director of Plus Therapeutics.
- (2) Mr. Sims is the Chief Financial Officer of Plus Therapeutics.
- (3) Mr. Hawkins is the Chairman of the Board of Plus Therapeutics.
- (4) Mr. Clowes is a director Plus Therapeutics.
- (5) Dr. Lenk is a director of Plus Therapeutics.
- (6) Mr. Petersen is a director of Plus.

### PIPE Financing Registration Rights

In connection with the May 2024 PIPE Financing, in May 2024 we entered into the Registration Rights Agreement with each Purchaser in the May 2024 PIPE Financing. Pursuant to the Registration Rights Agreement, we agreed to register the “registrable securities” held by the Purchasers on a registration statement, or registration statements, if necessary, to permit resale of such securities on a continuous basis pursuant to Rule 415. The “registrable securities” include (a) all shares of our common stock issued to the purchasers at the closing of the May 2024 PIPE Financing, and (b) any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the foregoing. Under this registration rights agreement, we agreed to pay all fees and expenses incident to the performance of our obligations, including the reasonable fees of one counsel for the selling stockholders, excluding any underwriting, broker or similar fees or commissions, legal fees and other costs (except as agreed to be paid by us) of each Purchaser.

### Stock Option Grants to Executive Officers and Directors

We have entered into employment agreements with our named executive officers pursuant to which we pay our named executive officers annual salaries and bonuses as more fully described above under “[Executive Compensation](#).” Further, we have granted stock options to our executive officers and non-employee directors as more fully described above under “[Director Compensation](#).”

### **Policies for Approval of Related Party Transactions**

We have adopted a written Related Person Transactions Policy that sets forth our policies and procedures regarding the identification, review, consideration, and oversight of “related person transactions.” For purposes of our Related Person Transactions Policy only, a “related person transaction” includes, subject to certain exceptions, a transaction, arrangement, or relationship (or any series of similar transactions, arrangements or relationships) in which we or any of our subsidiaries are participants involving an amount that exceeds \$120,000, in which any “related person” has a material interest.

Transactions involving compensation for services provided to us as an employee, consultant, or director are not considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of any class of our voting securities (including our common stock), including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

The policy is administered by the Audit Committee that will approve only those transactions that are, in its judgment, appropriate or desirable under the circumstances. Under the policy, the related person in question or, in the case of transactions with a holder of more than 5% of any class of our voting securities, an officer with knowledge of the proposed transaction, must present information regarding the proposed related person transaction to our Audit Committee (or, where review by our Audit Committee would be inappropriate, to another independent body of our Board) for review. To identify related person transactions in advance, we rely on information supplied by our executive officers, directors, and certain significant stockholders. In considering related person transactions, our Audit Committee considers the relevant available facts and circumstances, which may include among other factors:

- the risks, costs, and benefits to us;
- the impact on a director’s independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products, and
- whether the terms of the transaction are fair to the Company and on terms no less favorable to the Company than terms that could have been reached with an unrelated third party.

Whether a transaction would present an improper conflict of interest for any director, director nominee or executive officer, taking into account the size of the transaction, the overall financial position of the applicable related person, the direct or indirect nature of the applicable related person, the ongoing nature of any proposed relationship and any other relevant factors.

No director may participate in the discussion or approval of a transaction in which that director, or an immediate family member, has a direct or indirect interest.

Our Audit Committee approves only those transactions that it determines are fair to us and in our and our stockholders’ best interests.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth information regarding ownership of our common stock as of June 7, 2024 by (a) each person known to us to own more than 5% of the outstanding shares of our common stock, (b) each of our directors, (c) each of our named executive officers and (d) all current directors and executive officers as a group.

We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable. The information below is based on 5,704,219 shares of common stock issued and outstanding as of June 21, 2024.

Name and Address of Beneficial Owner (1)	Number of Shares of Common Stock Owned	Number of Shares of Common Stock Subject to Awards / Warrants(2)	Total Number of Shares of Common Stock Beneficially Owned(3)	Percent Ownership
<b>Greater than 5% Stockholders</b>				
Entities associated with AIGH Capital Management, LLC(4)	568,681	1,300	569,981	9.99%
<b>Directors and Named Executive Officers</b>				
Marc H. Hedrick, M.D.(5)	12,425	70,723	83,148	1.44%
Andrew Sims(6)	5,717	25,751	31,468	*
Norman LaFrance, M.D.(7)	—	9,620	9,620	*
Howard Clowes(8)	21,497	24,981	46,478	*
An van Es-Johansson, M.D. (9)	—	5,373	5,373	*
Richard J. Hawkins(10)	4,902	17,850	22,752	*
Greg Petersen(11)	36,421	29,883	66,304	1.16%
Robert P. Lenk, PhD(12)	29,327	13,707	43,034	*
All current executive officers and directors as a group (8 persons)	110,289	188,268	298,557	5.07%

\* Less than 1%.

- (1) Unless otherwise indicated, the address of each of the persons listed above is c/o Plus Therapeutics, Inc., 4200 Marathon Blvd., Suite 200, Austin, TX 78756.
- (2) Shares of common stock subject to stock options or warrants currently exercisable or exercisable within 60 days of June 7, 2024 are deemed to be outstanding for computing the percentage ownership of the person holding such options or warrants and the percentage ownership of any group of which the holder is a member, but are not deemed outstanding for computing the percentage of any other person or group.
- (3) Reflects beneficial ownership of common stock as defined in Rule 13d-3 of the Exchange Act.
- (4) Reflects (i) AIGH Investment Partners, L.P. (“AIGH LP”) holdings of: (A) 188,537 shares of common stock, (B) 915,000 shares of common stock issuable upon exercise of Pre-Funded Warrants, (C) 1,103,537 shares of common stock issuable upon the exercise of Series A Common Stock Warrants, and (D) 1,103,537 shares of common stock issuable upon the exercise of Series B Common Stock Warrants; (ii) WVP Emerging Manager Onshore Fund, LLC – AIGH Series (“Onshore – AIGH”) holdings of: (A) 294,967 shares of common stock, (B) 294,967 shares of common stock issuable upon the exercise of Series A Common Stock Warrants, and (C) 294,967 shares of common stock issuable upon the exercise of Series B Common Stock Warrants; (iii) WVP Emerging Manager Onshore Fund, LLC – Optimized Equity Series (“Onshore – Optimized Equity”) holdings of: (A) 85,177 shares of common stock, (B) 85,177 shares of common stock issuable upon the exercise of Series A Common Stock Warrants, and (C) 85,177 shares of common stock issuable upon the exercise of Series B Common Stock Warrants; (iv) AIGH Investment Partners, LLC, a Delaware limited liability company (“AIGH LLC”) holdings of: (A) 123,640 shares of common stock issuable upon exercise of Pre-Funded Warrants, (B) 123,640 shares of common stock issuable upon the exercise of Series A Common Stock Warrants, and (C) 123,640 shares of common stock

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issuable upon the exercise of Series B Common Stock Warrants. Mr. Orin Hirschman (“Mr. Hirschman”) is the Managing Member of AIGH Capital Management, LLC, a Maryland limited liability company (“AIGH CM”), and president of AIGH LLC. AIGH CM is an advisor or sub-Advisor with respect to shares of the securities of the Company held by AIGH LP, Onshore – AIGH, Onshore – Optimized Equity and AIGH LLC. Mr. Hirschman has voting and investment control over the securities indirectly held by AIGH CM, directly held by AIGH LP and directly held by Mr. Hirschman and his family. The address of AIGH CM, AIGH LP, Onshore – AIGH, Onshore – Optimized Equity and AIGH LLC is 6006 Berkeley Avenue, Baltimore, MD 21209. The shares of common stock issuable upon exercise of the Pre-Funded Warrants, Series A Common Stock Warrants and Series B Common Stock Warrants held by AIGH LP, Onshore – AIGH, Onshore – Optimized Equity and AIGH LLC, are each subject to a beneficial ownership limitation of 9.99% and not reflected in the table above as being beneficially owned.

- (5) Reflects (i) 12,425 shares of common stock; (ii) 12,255 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; (iii) 12,255 shares of common stock issuable upon the exercise of Series B Common Stock Warrants; and (iv) 46,213 shares of common stock underlying unvested options to purchase shares of common stock held by Dr. Hedrick that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Dr. Hedrick is the President, Chief Executive Officer and a director of Plus Therapeutics.
- (6) Reflects (i) 5,717 shares of common stock; (ii) 4,902 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; (iii) 4,902 shares of common stock issuable upon the exercise of Series B Common Stock Warrants; and (iv) 15,947 shares of common stock underlying unvested options to purchase shares of common stock held by Mr. Sims that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Sims is the Chief Financial Officer of Plus Therapeutics.
- (7) Reflects 9,620 shares of Common Stock underlying unvested options to purchase shares of common stock which, if not exercised, will expire on August 11, 2024, held by our former Chief Medical Officer, Dr. LaFrance. The shares of common stock underlying unvested options to purchase shares of common stock beneficially owned by Dr. LaFrance are not included in the total of shares of common stock beneficially owned by all of our directors and officers as a group.
- (8) Reflects (i) 21,497 shares of common stock; (ii) 9,804 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 9,804 shares of common stock issuable upon the exercise of Series B Common Stock Warrants; and (iv) 5,373 shares of common stock underlying unvested options to purchase shares of common stock held by Mr. Clowes that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Clowes is a director of Plus Therapeutics.
- (9) Reflects 5,373 shares of common stock underlying unvested options to purchase shares of common stock held by Dr. van Es-Johansson that will vest within 60 days of June 7, 2024. Dr. van Es-Johansson is a director of Plus Therapeutics.
- (10) Reflects (i) 4,902 shares of common stock; (ii) 4,902 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; (iii) 4,902 shares of common stock issuable upon the exercise of Series B Common Stock Warrants; and (iv) 8,046 shares of common stock underlying unvested options to purchase shares of common stock held by Mr. Hawkins that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Hawkins is the Chairman of the Board of Plus Therapeutics.

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- (11) Reflects (i) 36,421 shares of common stock; (ii) 12,255 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; (iii) 12,255 shares of common stock issuable upon the exercise of Series B Common Stock Warrants; and (iv) 5,373 shares of common stock underlying unvested options to purchase shares of common stock held by Mr. Petersen that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Petersen is a director of Plus Therapeutics.
- (12) Reflects (i) 29,327 shares of common stock; (ii) 4,167 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; (iii) 4,167 shares of common stock issuable upon the exercise of Series B Common Stock Warrants; and (iv) 5,373 shares of common stock underlying unvested options to purchase shares of common stock held by Dr. Lenk that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Dr. Lenk is a director of Plus Therapeutics.

## DESCRIPTION OF SECURITIES

*The following summary of the material terms of our capital stock is not intended to be a complete summary of the rights and preferences of such securities, and is qualified by reference to our Charter and Bylaws described herein, which are exhibits to the registration statement of which this prospectus is a part. We urge you to read each of the documents described herein in their entirety for a complete description of the rights and preferences of our securities.*

### **Authorized and Outstanding Capital Stock**

Our Charter authorizes the issuance of 100,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock.

### **Common Stock**

#### *Voting*

Except as otherwise required by our Charter, holders of shares of common stock are generally entitled to vote.

#### *Dividends*

The holders of shares of common stock are entitled to receive dividends, as and if declared by our Board out of our assets that are by law available for such use.

#### *Liquidation or Dissolution*

Upon our liquidation, dissolution or winding up of our affairs, after payment or provision for payment of the debts and other liabilities of ours as required by law and of the preferential and other amounts, if any, to which the holders of preferred stock shall be entitled, the holders of all outstanding shares of common stock will be entitled to receive our remaining assets available for distribution ratably in proportion to the number of shares held by each such stockholder.

#### *Redemption Rights*

Holders of shares of common stock do not have preemptive, subscription, redemption, or conversion rights with respect to such shares of common stock. There are no redemption or sinking fund provisions applicable to common stock.

### **Preferred Stock**

We are authorized to issue up to 5,000,000 shares of preferred stock. Our Board is authorized, subject to limitations prescribed by law, to provide for the issuance of shares of preferred stock in one or more series, and with respect to each series, to establish the number of shares to be included in each such series, and to fix the voting powers (if any), designations, powers, preferences, and relative, participating, optional or other special rights, if any, of the shares of each such series, and any qualifications, limitations or restrictions thereof. The powers (including voting powers), preferences, and relative, participating, optional and other special rights of each series of preferred stock and the qualifications, limitations or restrictions thereof, if any, may differ from those of any other series at any time outstanding. Subject to the rights of the holders of any series of preferred stock, the number of authorized shares of preferred stock may be increased or decreased (but not below the number of shares of preferred stock then outstanding) by the approval of our Board and by the affirmative vote of the holders of a majority in voting power of the outstanding shares of our capital stock entitled to vote generally in an election of directors, without the separate vote of the holders of the preferred stock as a class, irrespective of the provisions of Section 242(b)(2) of the DGCL.

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As of June 7, 1,952 shares of preferred stock were issued and outstanding. The preferred stock consists of (i) 13,500 shares designated as Series B Convertible Preferred Stock ("Series B Preferred Stock"), out of which 1,014 of the Series B Preferred Stock are outstanding; (ii) 23,500 shares designated as Series C Convertible Preferred Stock ("Series C Preferred Stock"), out of which 938 of the Series C Preferred Stock are outstanding of Series; and (iii) 1 share designated as Series F Preferred Stock that is not outstanding.

### **Series B Preferred Stock**

#### *Voting Rights*

Except as otherwise provided in the certificate of designation for the Series B Preferred Stock or as otherwise required by law, the Series B Preferred Stock has no voting rights.

#### *Dividends*

Holders of Series B Preferred Stock are entitled to receive dividends (on an as-if-converted-to-common-stock basis) in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of common stock.

#### *Liquidation Preference*

Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series B Preferred Stock will be entitled to receive out of our assets, whether capital or surplus, an amount equal to the \$1,000 stated value per share for each share of Series B Preferred Stock before any distribution or payment is paid to the holders of our common stock.

#### *Conversion*

Each share of Series B Preferred Stock is convertible, at our option or at the option of the holder, at any time, into the number of shares of our common stock determined by dividing the \$1,000 stated value per share of the Series B Preferred Stock by a conversion price of \$2,547.74 per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications. Subject to limited exceptions, a holder of the Series B Preferred Stock will not have the right to convert any portion of the Series B Preferred Stock to the extent that, after giving effect to the conversion, the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to its conversion.

#### *Fundamental Transactions*

In the event we effect certain mergers, consolidations, sales of substantially all of our assets, tender or exchange offers, reclassifications or share exchanges in which our common stock is effectively converted into or exchanged for other securities, cash or property, we consummate a business combination in which another person acquires 50% of the outstanding shares of our common stock, or any person or group becomes the beneficial owner of 50% of the aggregate ordinary voting power represented by our issued and outstanding common stock, then, upon any subsequent conversion of the Series B Preferred Stock, a holder of the Series B Preferred Stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series B Preferred Stock.

#### *Redemption Rights*

We are not obligated to redeem or repurchase any shares of Series B Preferred Stock. Shares of Series B Preferred Stock are not otherwise entitled to any redemption rights.



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### **Series C Preferred Stock**

#### *Voting Rights*

Except as otherwise provided in the certificate of designation for the Series C Preferred Stock or as otherwise required by law, the Series C Preferred Stock has no voting rights.

#### *Dividends*

Holders of Series C Preferred Stock are entitled to receive dividends (on an as-if-converted-to-common-stock basis) in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of common stock.

#### *Liquidation Preference*

Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series C Preferred Stock will be entitled to receive out of our assets, whether capital or surplus, an amount equal to the \$1,000 stated value per share for each share of Series C Preferred Stock before any distribution or payment shall be made to the holders of any junior securities.

*Conversion.* Each share of Series C Preferred Stock is convertible, at our option at any time, subject to certain conditions, or at the option of the holder at any time, into the number of shares of our common stock determined by dividing the \$1,000 stated value per share of the Series C Preferred Stock by a conversion price of \$33.75. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications. Subject to limited exceptions, a holder of the Series C Preferred Stock does not have the right to convert any portion of the Series C Preferred Stock to the extent that, after giving effect to the conversion, the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to its conversion.

*Fundamental Transactions.* In the event we effect certain mergers, consolidations, sales of substantially all of our assets, tender or exchange offers, reclassifications or share exchanges in which our common stock is effectively converted into or exchanged for other securities, cash or property, we consummate a business combination in which another person acquires 50% of the outstanding shares of our common stock, or any person or group becomes the beneficial owner of 50% of the aggregate ordinary voting power represented by our issued and outstanding common stock, then, upon any subsequent conversion of the Series C Preferred Stock, a holder of the Series C Preferred Stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series C Preferred Stock.

#### *Anti-Dilution*

Subject to certain exceptions contained in the certificate of designation for the Series C Preferred Stock, including our ability to issue securities in connection with equity awards to service providers, strategic transactions, debt financings, research and development partnerships, an equity line of credit, our “at the market” equity offering program and other customary exceptions, if we issue or sell, or are deemed to have issued or sold, any shares of common stock or Common Stock Equivalents (as defined in the certificate of designation) for a consideration per share lower than the conversion price of the Series C Preferred Stock in effect immediately prior to such issuance or sale, or deemed issuance or sale, then the conversion price of the Series C Preferred Stock then in effect will be reduced to an amount equal to such lower price pursuant to the terms of the certificate of designation.

#### *Redemption Rights*

We are not obligated to redeem or repurchase any shares of Series C Preferred Stock. Shares of Series C Preferred Stock are not otherwise entitled to any redemption rights.

### **Anti-Takeover Effects of Delaware Law and Our Charter and Bylaws**

Certain provisions of Delaware law, our Charter and Bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to first negotiate with our Board.

*Charter and Bylaws.* Our Charter and Bylaws include provisions that:

- authorize our Board to issue, without stockholder approval, blank-check preferred stock with such designations, powers, preferences and other rights and qualifications, limitations or restrictions as our Board may authorize, which preferred stock could decrease the amount of earnings and assets available for distribution to holders of our common stock or adversely affect the rights and powers, including voting rights, of the holders of our common stock;
- establish advance notice requirements for stockholder nominations of directors and for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- provide that vacancies on our Board may be filled only by a majority of directors then in office, even if less than a quorum; and
- authorize us to indemnify officers and directors against losses that they may incur in investigations and legal proceedings resulting from their services to us, which may include services in connection with takeover defense measures.

*Anti-takeover statute.* We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the “interested stockholder” and an “interested stockholder” is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation’s outstanding voting stock.

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We expect the existence of this provision to have an anti-takeover effect with respect to transactions our Board does not approve in advance. We also anticipate that Section 203 may discourage business combinations or other attempts that might result in a premium over the market price for the shares of common stock held by our stockholders. The provisions of DGCL, our Charter and Bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

### **Exclusive Forum Selection**

Our Bylaws require, to the fullest extent permitted by law, subject to limited exceptions, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel in any action brought to enforce the exclusive forum provision. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our Bylaws.

Our Bylaws further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act and the respective rules and regulations promulgated thereunder.

### **Limitations on Liability and Indemnification of Officers and Directors**

Our Charter limits the liability of our directors to the fullest extent permitted by the DGCL and provides that we will provide them with customary indemnification and advancement of expenses. We entered into customary indemnification agreements with each of our executive officers and directors that provide them, in general, with customary indemnification in connection with their service to us or on our behalf.

### **Transfer Agent and Registrar**

The transfer agent for our common stock and preferred stock is Broadridge Corporate Issuer Solutions, Inc.

### **Listing of Common Stock**

Our common stock is listed on Nasdaq under the symbols "PSTV".

## SELLING STOCKHOLDERS

The selling stockholders listed in the table below may from time to time offer and sell up to an aggregate of 10,774,596 shares of common stock pursuant to this prospectus and the applicable prospectus supplements, which consists of:

- up to 1,439,988 shares of common stock;
- up to 2,151,544 shares of common stock issuable upon exercise of Pre-Funded Warrants;
- up to 3,591,532 shares of common stock issuable upon exercise of Series A Common Stock Warrants; and
- up to 3,591,532 shares of common stock issuable upon exercise of Series B Common Stock Warrants.

For additional information regarding the issuance of these securities, see the section entitled “Prospectus Summary—[May 2024 PIPE Financing](#).”

The selling stockholders have not had any material relationship with us within the past three years, except for the ownership of our securities, and except that Marc H. Hedrick, M.D., is our President and Chief Executive Officer, and a member of our Board, Andrew Sims is our Chief Financial Officer, Richard J. Hawkins is Chairman of our Board, Robert Lenk, Ph.D., is a member of our Board, Greg Petersen is a member of our Board, and Howard Clowes is a member of our Board.

As used in this prospectus, the term “selling stockholders” includes the selling stockholders listed in the table below, together with any additional selling stockholders listed in a subsequent amendment to this prospectus, and their respective donees, pledgees, assignees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer.

In accordance with the terms of the Registration Rights Agreement with the selling stockholders, this prospectus covers the resale of the maximum number of shares of common stock issuable upon exercise of the Pre-Funded Warrants and Common Warrants without regard to any limitations on the exercise of such warrants. Under the terms of the Pre-Funded Warrants and Common Warrants held by selling stockholders, a selling stockholder may elect to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding shares common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon exercise of such warrants that have not been exercised, to instead receive a Pre-Funded Warrant in lieu of shares of common stock. The shares reported under “Number of Shares Owned” and “Number of Shares Being Offered” in the table below do not give effect to any such beneficial ownership limitation.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of common stock by each of the selling stockholders as of June 7, 2024, assuming the full exercise of the Pre-Funded Warrants and warrants held by the selling stockholders on that date, without regard to any limitations on exercises. As of June 21, 2024, we had 5,704,219 shares of common stock issued and outstanding. The following table also provides the number of shares of common stock that may be sold by each selling stockholder under this prospectus and that each selling stockholder will beneficially own assuming all the shares of common stock that may be offered pursuant to this prospectus are sold. Because each selling stockholder may dispose of all, none or some portion of their shares of common stock, no estimate can be given as to the number of shares of common stock that will be beneficially owned by a selling stockholder upon termination of this offering. For purposes of the table below, however, we have assumed that after termination of this offering none of the shares of common stock covered by this prospectus will be beneficially owned by the selling stockholders and further assumed that the selling stockholders will not acquire beneficial ownership of any additional securities during the offering. In addition, the selling stockholders may have sold, transferred or otherwise disposed of, or may sell,

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transfer or otherwise dispose of, at any time and from time to time, our securities in transactions exempt from the registration requirements of the Securities Act after the date on which the information in the table is presented. See the section entitled “[Plan Of Distribution](#).”

Certain selling stockholders currently hold and may acquire shares of common stock, and common stock issuable upon the exercise of equity awards, in addition to those registered hereby. In accordance with the rules of the SEC, beneficial ownership includes voting or investment power with respect to securities and includes any shares issuable pursuant to stock options that are exercisable that are expected to settle within 60 days of June 7, 2024. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose.

<u>Selling Stockholder</u>	<u>Beneficial Ownership Before this Offering</u>		<u>Beneficial Ownership After this Offering</u>	
	<u>Number of Shares Owned</u>	<u>Number of Shares Being Offered</u>	<u>Number of Shares Owned</u>	<u>Percentage of Outstanding Shares</u>
AIGH Investment Partners, L.P.(1)	3,310,611	3,310,611	—	—
WVP Emerging Manager Onshore Fund, LLC – AIGH Series(2)	884,901	884,901	—	—
WVP Emerging Manager Onshore Fund, LLC - Optimized Equity Series(3)	255,531	255,531	—	—
AIGH Investment Partners, LLC(4)	370,920	370,920	—	—
Iroquois Master Fund Ltd.(5)	1,153,050	1,153,050	—	—
Iroquois Capital Investment Group LLC(6)	1,761,561	1,761,561	—	—
The Hewlett Fund LP(7)	1,706,229	1,706,229	—	—
Aramas Capital Management LLC(8)	296,733	296,733	—	—
Pinz Capital Special Opportunities Fund, L.P.(9)	296,733	296,733	—	—
Globis Capital Partners, L.P.(10)	593,472	593,472	—	—
Marc H. Hedrick, M.D.(11)	83,148	36,765	46,383	*
Andrew Sims(12)	31,468	14,706	16,762	*
Richard J. Hawkins(13)	22,753	14,706	8,047	*
Howard Clowes(14)	46,478	29,412	17,066	*
Robert Lenk, Ph.D.(15)	43,034	12,501	30,533	*
Greg Petersen(16)	66,304	36,765	29,539	*

\* Represents beneficial ownership of less than one percent (1%) of the outstanding shares of our common stock.

(1) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by AIGH LP in the May 2024 PIPE Financing: (i) 188,537 shares of common stock;

(ii) 915,000 shares of common stock issuable upon exercise of Pre-Funded Warrants; (iii) 1,103,537 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iv) 1,103,537 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Pre-Funded Warrants and Common Warrants are subject to a beneficial ownership limitation of 9.99%, which such limitation restricts the selling stockholder from exercising that portion of the Pre-Funded Warrants and Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation.

Mr. Orin Hirschman is the managing member of AIGH CM, which is an advisor with respect to the securities held by AIGH LP. Mr. Hirschman has voting and investment control over the securities indirectly held by AIGH CM, directly held by AIGH LP and directly held by Mr. Hirschman and his family. The address of Mr. Hirschman and the entities listed is 6006 Berkeley Avenue, Baltimore, Maryland 21209.

- (2) The shares reported under “Beneficial Ownership Before this Offering” include the following securities purchased by Onshore – AIGH in the May 2024 PIPE Financing: (i) 294,967 shares of common stock; (ii) 294,967 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 294,967 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Common Warrants are subject to a beneficial ownership limitation of 9.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Hirschman is the managing member of AIGH CM, which is a sub-advisor with respect to the securities held by Onshore – AIGH. Mr. Hirschman has voting and investment control over the securities indirectly held by AIGH CM and directly held by Mr. Hirschman and his family directly. The address of Mr. Hirschman and the entities listed is 6006 Berkeley Avenue, Baltimore, Maryland 21209.
- (3) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Onshore – Optimized Equity in the May 2024 PIPE Financing: (i) 85,177 shares of common stock; (ii) 85,177 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 85,177 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Common Warrants are subject to a beneficial ownership limitation of 9.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Hirschman is the managing member of AIGH CM, who is a sub-advisor with respect to the securities held by Onshore – Optimized Equity. Mr. Hirschman has voting and investment control over the securities indirectly held by AIGH CM and directly held by Mr. Hirschman and his family directly. The address of Mr. Hirschman and the entities listed is 6006 Berkeley Avenue, Baltimore, Maryland 21209.
- (4) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by AIGH Investment Partners, LLC in the May 2024 PIPE Financing: (i) 123,640 shares of common stock issuable upon exercise of Pre-Funded Warrants; (ii) 123,640 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 123,640 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Pre-Funded Warrants and Common Warrants are subject to a beneficial ownership limitation of 9.99%, which such limitation restricts the selling stockholder from exercising that portion of the Pre-Funded Warrants and Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Hirschman is the managing member of AIGH LLC. Mr. Hirschman has voting and investment control over the securities indirectly held by AIGH LLC and directly held by Mr. Hirschman and his family directly. The address of Mr. Hirschman and the entities listed is 6006 Berkeley Avenue, Baltimore, Maryland 21209.
- (5) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Iroquois Master Fund Ltd. In the May 2024 PIPE Financing: (i) 75,000 shares of common stock; (ii) 309,350 shares of common stock issuable upon exercise of Pre-Funded Warrants; (iii) 384,350 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iv) 384,350 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Pre-Funded

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Warrants and Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Pre-Funded Warrants and Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Iroquois Capital Management L.L.C. is the investment manager of Iroquois Master Fund, Ltd. Iroquois Capital Management, LLC has voting control and investment discretion over securities held by Iroquois Master Fund. As Managing Members of Iroquois Capital Management, LLC. Richard Abbe and Kimberly Page make voting and investment decisions on behalf of Iroquois Capital Management, LLC in its capacity as investment manager to Iroquois Master Fund Ltd. As a result of the foregoing, Mr. Abbe and Mrs. Page may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act) of the securities held by Iroquois Capital Management and Iroquois Master Fund. The address for Iroquois Master Fund Ltd., Mr. Abbe and Mrs. Page is c/o Iroquois Capital Management, LLC, 2 Overhill Road, Suite 400, Scarsdale, New York 10583.

- (6) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Iroquois Capital Investment Group LLC in the May 2024 PIPE Financing: (i) 139,000 shares of common stock; (ii) 448,187 shares of common stock issuable upon exercise of Pre-Funded Warrants; (iii) 587,187 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iv) 587,187 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Pre-Funded Warrants and Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Pre-Funded Warrants and Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Richard Abbe is the managing member of Iroquois Capital Investment Group LLC. Mr. Abbe has voting control and investment discretion over securities held by Iroquois Capital Investment Group LLC. The address for Iroquois Capital Investment Group LLC and Mr. Abbe is 2 Over Hill Rd., Suite 500, Scarsdale, New York 10583.
- (7) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by The Hewlett Fund LP in the May 2024 PIPE Financing: (i) 213,376 shares of common stock; (ii) 355,367 shares of common stock issuable upon exercise of Pre-Funded Warrants; (iii) 568,743 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iv) 568,743 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Pre-Funded Warrants and Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Pre-Funded Warrants and Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Martin Chopp, the general partner of the The Hewlett Fund LP, has voting and investment control over the securities held by Hewlett. The address for The Hewlett Fund LP and Mr. Chopp is 100 Merrick Road, Suite 400W, Rockville Centre, New York 11570.
- (8) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Aramas Capital Management LLC in the May 2024 PIPE Financing: (i) 98,911 shares of common stock; (ii) 98,911 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 98,911 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Sam Ginzburg has sole voting and dispositive power over the shares held by Aramas Capital Management LLC. The address for Aramas Capital Management LLC and Mr. Ginzburg is c/o Aramas Capital Holdings LLC, 19 Orchard Street, Manhasset, New York 11030.
- (9) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Pinz Capital Special Opportunities Fund, L.P. in the May 2024 PIPE Financing: (i) 98,911 shares of common stock; (ii) 98,911 shares of common stock issuable upon the exercise of Series A

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Common Stock Warrants; and (iii) 98,911 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Matthew L. Pinz has sole voting and dispositive power over the shares held by Pinz Capital Special Opportunities Fund. The address for Pinz Capital Special Opportunities Fund and Mr. Pinz is 80 Dogwood Avenue, Roslyn Harbor, New York 11576.

- (10) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Globis Capital Partners, L.P. in the May 2024 PIPE Financing: (i) 197,824 shares of common stock; (ii) 197,824 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 197,824 shares of common stock issuable upon the exercise of Series B Common Stock Warrants. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Paul Packer is the managing member of Globis Capital Partners, L.P. and has voting and investment control over the securities held by Globis Capital Partners, L.P. The address for Globis Capital Partners, L.P. and Mr. Packer is 7100 W. Camino Real, Suite 302-48, Boca Raton, FL 33433.
- (11) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Marc H. Hedrick, M.D. in the May 2024 PIPE Financing: (i) 12,255 shares of common stock; (ii) 12,255 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 12,255 shares of common stock issuable upon the exercise of Series B Common Stock Warrants, as well as 170 shares of common stock held by Dr. Hedrick and 46,213 shares of common stock underlying unvested options to purchase shares of common stock held by Dr. Hedrick that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Dr. Hedrick is the President, Chief Executive Officer and a director of Plus Therapeutics and his address is c/o Plus Therapeutics, Inc., 4200 Marathon Boulevard, Suite 200, Austin, Texas 78756.
- (12) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Mr. Andrew Sims in the May 2024 PIPE Financing: (i) 4,902 shares of common stock; (ii) 4,902 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 4,902 shares of common stock issuable upon the exercise of Series B Common Stock Warrants, as well as 815 shares of common stock held by Mr. Sims and 15,947 shares of common stock underlying unvested options to purchase shares of common stock held by Mr. Sims that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Sims is the Chief Financial Officer of Plus Therapeutics and his address is c/o Plus Therapeutics, Inc., 4200 Marathon Boulevard, Suite 200, Austin, Texas 78756.
- (13) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Mr. Richard Hawkins in the May 2024 PIPE Financing: (i) 4,902 shares of common stock; (ii) 4,902 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 4,902 shares of common stock issuable upon the exercise of Series B Common Stock Warrants, as well as 8,046 shares of common stock underlying unvested options to purchase shares of common stock held by Mr. Hawkins that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Hawkins is the Chairman of the Board of Plus Therapeutics and his address is c/o Plus Therapeutics, Inc., 4200 Marathon Boulevard, Suite 200, Austin, Texas 78756.



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- (14) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Mr. Howard Clowes in the May 2024 PIPE Financing: (i) 9,804 shares of common stock; (ii) 9,804 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 9,804 shares of common stock issuable upon the exercise of Series B Common Stock Warrants, as well as 11,693 shares of common stock held by Mr. Clowes and 5,373 shares of common stock underlying unvested options to purchase shares of common stock held by Mr. Clowes that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Clowes is a director of Plus Therapeutics and his address is c/o Plus Therapeutics, Inc., 4200 Marathon Boulevard, Suite 200, Austin, Texas 78756.
- (15) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Mr. Robert Lenk, Ph.D. in the May 2024 PIPE Financing: (i) 4,167 shares of common stock; (ii) 4,167 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 4,167 shares of common stock issuable upon the exercise of Series B Common Stock Warrants, as well as 25,160 shares of common stock held by Dr. Lenk and 5,373 shares of common stock underlying unvested options to purchase shares of common stock held by Dr. Lenk that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Dr. Lenk is a director of Plus Therapeutics and his address is c/o Plus Therapeutics, Inc., 4200 Marathon Boulevard, Suite 200, Austin, Texas 78756.
- (16) The shares reported under “Beneficial Ownership Before this Offering” consist of the following securities purchased by Mr. Greg Petersen in the May 2024 PIPE Financing: (i) 12,255 shares of common stock; (ii) 12,255 shares of common stock issuable upon the exercise of Series A Common Stock Warrants; and (iii) 12,255 shares of common stock issuable upon the exercise of Series B Common Stock Warrants, as well as 24,166 shares of common stock held by Mr. Petersen and 5,373 shares of common stock underlying unvested options to purchase shares of common stock held by Mr. Petersen that will vest within 60 days of June 7, 2024. The Common Warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the selling stockholder from exercising that portion of the Common Warrants that would result in the selling stockholder owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. Mr. Petersen is a director of Plus Therapeutics and his address is c/o Plus Therapeutics, Inc., 4200 Marathon Boulevard, Suite 200, Austin, Texas 78756.

## PLAN OF DISTRIBUTION

The selling stockholders, which as used in this prospectus includes the selling stockholders listed in the section of this prospectus entitled “[Selling Stockholders](#)”, together with any additional selling stockholders listed in a subsequent amendment to this prospectus, and their respective donees, pledgees, assignees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. The selling stockholders may use any one or more of the following methods when disposing of their securities or interests therein:

- On any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- through brokers, dealers or underwriters that may act solely as agents;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- delivery of shares in settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers, underwriters and other agents may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and the pledgee or other secured party, transferee or other successor in interest may sell shares of common stock from time to time under this prospectus, or under a supplement or amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, secured party, transferee or other successors in interest as selling

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stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances in which case the donees, pledgees, assignees, transferees or other successors-in-interest may be the selling beneficial owners for purposes of this prospectus and may sell such shares of common stock from time to time under this prospectus after an amendment or supplement has been filed under Rule 424(b)(3) under, or another applicable provision of, the Securities Act, amending, if necessary, the list of selling stockholders to include the donees, pledgees, assignees, transferees or other successors-in-interest as a selling stockholder under this prospectus.

Upon being notified in writing by the selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act will be filed, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares of common stock involved, (iii) the price at which such shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, if applicable, and (vi) other facts material to the transaction.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the donees, pledgees, assignees, transferees or other successors-in-interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short after the effective date of the registration statement of which this prospectus forms a part and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions after the effective date of the registration statement of which this prospectus forms a part with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction), including in the short sale transactions.

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities. Any compensation paid to underwriters, broker-dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers will be provided in the applicable prospectus supplement and shall comply with the rules and requirements of the Financial Industry Regulatory Authority.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities to which they may become subject, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date that such securities become eligible for resale without volume or manner-of-sale restrictions and without current public information pursuant to Rule 144

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and certain other conditions have been satisfied, or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement of which this prospectus forms a part.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

## **LEGAL MATTERS**

Hogan Lovells US LLP, Houston, Texas, will pass upon the validity of the shares of our common stock offered by this prospectus.

## **EXPERTS**

The financial statements of Plus Therapeutics, Inc. (the Company) as of December 31, 2023 and 2022 and for the years then ended included in this Prospectus and in the Registration Statement have been so included in reliance on the report of BDO USA, P.C., an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

## **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. We have also filed a registration statement on Form S-1, including exhibits, under the Securities Act with respect to the shares of Class A common stock offered by this prospectus. This prospectus is part of the registration statement, but does not contain all of the information included in the registration statement or the exhibits. Our SEC filings are available to the public on the internet at a website maintained by the SEC located at [www.sec.gov](http://www.sec.gov).

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**PLUS THERAPEUTICS, INC.**  
**CONDENSED BALANCE SHEETS**  
**(UNAUDITED)**  
**(in thousands, except share and par value data)**

	<u>March 31, 2024</u>	<u>December 31, 2023</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,901	\$ 8,554
Investments	323	—
Other current assets	989	1,280
Total current assets	4,213	9,834
Property and equipment, net	800	906
Operating lease right-use-of assets	171	202
Goodwill	372	372
Intangible assets, net	33	42
Other assets	32	32
Total assets	<u>\$ 5,621</u>	<u>\$ 11,388</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,447	\$ 6,631
Operating lease liability	115	120
Deferred grant liability	247	—
Term loan obligation, current	3,590	3,976
Total current liabilities	10,399	10,727
Noncurrent operating lease liability	59	85
Deferred grant liability	—	1,924
Total liabilities	10,458	12,736
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 4,522,656 and 4,264,231 issued and outstanding at March 31, 2024, and 4,522,656 issued and 4,444,097 outstanding as of December 31, 2023, respectively	5	5
Treasury stock (at cost, 258,425 and 78,559 shares as of March 31, 2024 and December 31, 2023, respectively)	(500)	(126)
Additional paid-in capital	479,420	479,274
Accumulated deficit	(483,762)	(480,501)
Total stockholders' deficit	(4,837)	(1,348)
Total liabilities and stockholders' deficit	<u>\$ 5,621</u>	<u>\$ 11,388</u>

See Accompanying Notes to these Condensed Financial Statements

**PLUS THERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(UNAUDITED)**  
**(in thousands, except share and per share data)**

	<b>For the Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Grant revenue	\$ 1,677	\$ 506
Operating expenses:		
Research and development	2,763	2,983
General and administrative	2,213	2,245
Total operating expenses	<u>4,976</u>	<u>5,228</u>
Operating loss	<u>(3,299)</u>	<u>(4,722)</u>
Other income (expense):		
Interest income	72	51
Interest expense	<u>(34)</u>	<u>(134)</u>
Total other expense	<u>38</u>	<u>(83)</u>
Net loss	<u>\$ (3,261)</u>	<u>\$ (4,805)</u>
Net loss per share, basic and diluted	\$ (0.75)	\$ (2.07)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	4,321,731	2,320,017

See Accompanying Notes to these Condensed Financial Statements



**PLUS THERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY/(DEFICIT)**  
**(UNAUDITED)**  
**(In thousands, except share data)**

	<u>Preferred stock</u>		<u>Convertible preferred stock</u>		<u>Common stock</u>		<u>Treasury Stock</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total stockholders' (deficit)/ equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance at December 31, 2022	—	\$ —	1,952	\$ —	2,240,092	\$ 2	—	—	\$ 473,628	\$ (467,185)	\$ 6,445
Stock-based compensation	—	—	—	—	—	—	—	—	140	—	140
Sale of common stock, net	—	—	—	—	168,164	—	—	—	895	—	895
Issuance of Series F preferred stock	1	—	—	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	—	—	—	(4,805)	(4,805)
Balance at March 31, 2023	<u>1</u>	<u>\$ —</u>	<u>1,952</u>	<u>\$ —</u>	<u>2,408,256</u>	<u>\$ 2</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 474,664</u>	<u>\$ (471,990)</u>	<u>\$ 2,676</u>
Balance at December 31, 2023	—	\$ —	1,952	\$ —	4,522,656	\$ 5	(78,559)	\$ (126)	\$ 479,274	\$ (480,501)	\$ (1,348)
Stock-based compensation	—	—	—	—	—	—	—	—	146	—	146
Purchase of treasury stock	—	—	—	—	—	—	(179,866)	(374)	—	—	(374)
Net loss	—	—	—	—	—	—	—	—	—	(3,261)	(3,261)
Balance at March 31, 2024	<u>—</u>	<u>\$ —</u>	<u>1,952</u>	<u>\$ —</u>	<u>4,522,656</u>	<u>\$ 5</u>	<u>(258,425)</u>	<u>\$ (500)</u>	<u>\$ 479,420</u>	<u>\$ (483,762)</u>	<u>\$ (4,837)</u>

See Accompanying Notes to these Condensed Financial Statements

**PLUS THERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**  
**(In thousands)**

	For the Three Months Ended	
	March 31,	
	2024	2023
<b>Cash flows used in operating activities:</b>		
Net loss	\$ (3,261)	\$ (4,805)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	155	158
Amortization of deferred financing costs and debt discount	16	66
Share-based compensation expense	146	140
Accretion of discount on short-term investments	1	—
Reduction in the carrying amount of operating lease right-of-use assets	31	29
Loss on disposal of property and equipment	—	2
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Other current assets	150	2,791
Accounts payable and accrued expenses	(43)	(3,639)
Change in operating lease liabilities	(31)	(29)
Deferred grant liability	(1,677)	(506)
Net cash used in operating activities	<u>(4,513)</u>	<u>(5,793)</u>
<b>Cash flows used in investing activities:</b>		
Purchases of property and equipment	(40)	(97)
Purchase of short-term investments	(324)	—
Net cash used in investing activities	<u>(364)</u>	<u>(97)</u>
<b>Cash flows used in/provided by financing activities:</b>		
Principal payments of term loan obligation	(402)	(402)
Purchase of treasury stock	(374)	—
Proceeds from sale of common stock, net	—	895
Net cash (used in) provided by financing activities	<u>(776)</u>	<u>493</u>
Net decrease in cash and cash equivalents	(5,653)	(5,397)
Cash and cash equivalents at beginning of period	8,554	18,120
Cash and cash equivalents at end of period	<u>\$ 2,901</u>	<u>\$ 12,723</u>
<b>Supplemental disclosure of cash flows information:</b>		
Cash paid during period for:		
Interest	\$ 23	\$ 73
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Unpaid offering cost	\$ 141	\$ 25
Right-of-use assets obtained in exchange for operating lease liability	\$ —	\$ 51

See Accompanying Notes to these Condensed Financial Statements

**PLUS THERAPEUTICS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**March 31, 2024**  
**(UNAUDITED)**

**1. Basis of Presentation and New Accounting Standards**

The accompanying unaudited condensed financial statements for the three months ended March 31, 2024 and 2023 have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for annual financial statements. The condensed balance sheet at December 31, 2023 has been derived from the audited financial statements at December 31, 2023, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of Plus Therapeutics, Inc. (the "Company") have been included. Operating results for the three months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024. These financial statements should be read in conjunction with the financial statements and notes therein included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission on March 5, 2024.

**Amendments to Certificate of Incorporation and Reverse Stock Split**

At the Annual Meeting of Stockholders of the Company held on April 20, 2023 (the "Annual Meeting"), the stockholders of the Company approved an amendment to the Company's Amended and Restated Certificate of Incorporation (the "Charter") to implement a reverse stock split of the Company's then issued and outstanding common stock, par value \$0.001 per share, with the ratio to be determined by the Board of Directors (the "Board") of the Company, within a range of not less than 1-for-3 and not greater than 1-for-15. Subsequently, on April 21, 2023, the Board determined to fix the ratio for the reverse stock split at 1-for-15, without any change to its par value (the "Reverse Stock Split").

On April 27, 2023, following stockholder and Board approval, the Company filed a Certificate of Amendment to its Charter (the "Amendment"), with the Secretary of State of the State of Delaware to effectuate the Reverse Stock Split. The Amendment became effective on May 1, 2023. Upon effectiveness of the Reverse Stock Split, the number of shares of the Company's common stock (x) issued and outstanding decreased from approximately 37.4 million shares to approximately 2.5 million shares; (y) reserved for issuance upon exercise of outstanding warrants and options decreased from approximately 2.0 million shares to approximately 0.1 million shares, and (z) reserved but unallocated under the Company's current equity incentive plans decreased from approximately 3.0 million shares of common stock to approximately 0.2 million shares of common stock. The Company's common stock began trading on the Nasdaq Capital Market ("Nasdaq") on a post-split basis on May 1, 2023. The Company's 5,000,000 shares of authorized Preferred Stock were not affected by the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split, and accordingly, the outstanding number of shares post Reverse Stock Split was adjusted down by approximately 1,310 (post-effect of the Reverse Stock Split) shares. Proportional adjustments for the Reverse Stock Split were made to the Company's outstanding stock options, warrants and equity incentive plans for the period ended March 31, 2023 as presented in the condensed financial statements in this Quarterly Report on Form 10-Q. The Company's financial statements, and all references thereto have been retroactively adjusted to reflect the Reverse Stock Split unless specifically stated otherwise.

**Grant Revenue Recognition**

In applying the provisions of Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), the Company has determined that government grants are out of the scope of ASC

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606 because the funding entities do not meet the definition of a “customer”, as defined by ASC 606, as the Company does not consider there to be a transfer of control of goods or services. With respect to each grant, the Company determines if it has a collaboration in accordance with ASC Topic 808, Collaborative Arrangements (“ASC 808”). For grants outside the scope of ASC 808, the Company applies International Accounting Standards No. 20 (“IAS 20”), Accounting for Government Grants and Disclosure of Government Assistance, by analogy, and revenue is recognized when the Company incurs expenses related to the grant for the amount the Company is entitled to under the provisions of the contract.

The Company also considers the guidance in ASC Topic 730, Research and Development, which requires an assessment, at the inception of each grant, of whether each grant agreement is a liability. If the Company is obligated to repay funds received regardless of the outcome of the related research and development activities, then the Company is required to estimate and recognize that liability. Alternatively, if the Company is not required to repay the funds, then payments received are recorded as revenue or contra-expense as the expenses are incurred.

Deferred grant liability represents grant funds received or receivable for which the allowable expenses have not yet been incurred as of the balance sheet date.

### **Available-for-Sale Securities**

The Company’s available-for-sale securities consist of U.S. government and agency securities. The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the condensed balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive income (loss) within the condensed statements of operations and comprehensive income/loss and as a separate component of stockholders’ equity. Realized gains and losses are calculated on the specific identification method and recorded as interest income (loss). At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the decline in fair value below amortized cost is a result of credit losses or other factors, whether the Company expects to recover the amortized cost of the security, the Company’s intent to sell and if it is more likely than not that the Company will be required to sell the securities before the recovery of amortized cost. The Company records changes in allowance for expected credit loss in other income (expense). As of March 31, 2024, there were no available-for-sale securities in an unrealized loss position, and there has been no allowance for expected credit losses recorded during any of the periods presented.

Any premium arising at purchase is amortized to the earliest call date and any discount arising at purchase is accreted to maturity. Accretion of discounts are recorded in interest income in the condensed statements of operations and comprehensive income/loss.

During the three months ended March 31, 2024, the unrealized gain on the Company’s available-for-sale securities was less than \$1,000, and not presented separately in the condensed statement of operations and comprehensive income/loss.

### **Recently Issued Accounting Pronouncements**

In December 2023, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (ASU) No. 2023-09 Income Taxes (Topic 740): Improvements to Income Tax Disclosure. This ASU includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. The ASU is effective for years beginning after December 15, 2024, but early adoption is permitted. This ASU should be applied on a prospective basis, although retrospective application is permitted. Management is currently evaluating the impact of the changes required by the new standard on the Company’s financial statements and related disclosures.

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In November 2023, the FASB issued Accounting Standard Update (ASU) No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The new standard is intended to improve annual and interim reportable segment disclosure requirements regardless of number of reporting units, primarily through enhanced disclosures of significant expenses. The amendment requires public entities to disclose significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit and loss. This update is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years starting after December 15, 2024. This ASU must be applied retrospectively to all prior periods presented. Management is currently evaluating the impact of the changes required by the new standard on the Company's financial statements and related disclosures.

### **2. Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. The Company's most significant estimates and critical accounting policies involve reviewing assets for impairment and determining the assumptions used in measuring stock-based compensation expense.

### **3. Liquidity and Going Concern**

The Company incurred a net loss of \$3.3 million for the three months ended March 31, 2024. The Company had an accumulated deficit of \$483.8 million as of March 31, 2024. Additionally, the Company used net cash of \$4.5 million to fund its operating activities for the three months ended March 31, 2024.

To date, the Company's operating losses have been funded primarily from outside sources of invested capital from issuance of its common and preferred stocks, proceeds from its term loan and grant funding. However, the Company has had, and will continue to have, an ongoing need to raise additional cash from outside sources to fund its future clinical development programs and other operations. There can be no assurance that the Company will be able to continue to raise additional capital in the future. The Company's inability to raise additional cash would have a material and adverse impact on its operations and could cause the Company to default on its term loan. These factors raise substantial doubt about the Company's ability to continue as a going concern.

On May 9, 2024, the Company closed a private placement of securities of the Company for aggregate gross proceeds of approximately \$7.25 million, before deducting certain expenses payable by the Company, and excluding the proceeds, if any, from the exercise of warrants issued in the private placement. See Note 12 for further information regarding the private placement.

#### *Nasdaq Listing Compliance*

On March 8, 2024, the Company received a letter (the "Notice") from the Listing Qualifications staff of Nasdaq, notifying the Company that it no longer complied with the requirement under Nasdaq Listing Rule 5550(b)(1) to maintain a minimum of \$2.5 million in stockholders' equity for continued listing on Nasdaq or the alternative requirements of having a market value of listed securities of \$35 million or net income from continuing operations of \$500,000 in the most recently completed fiscal year or two of the last three most recently completed fiscal years (the "Alternative Standards"). The Notice states that the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, disclosed stockholders' equity of (\$1,348,000) as of December 31, 2023, and that, as of March 8, 2024, the Company did not meet the Alternative Standards.

On April 22, 2024, the Company provided Nasdaq with its plan to achieve and sustain compliance with the stockholders' equity requirement and requested that Nasdaq grant the Company an extension of time until September 4, 2024, to provide evidence of compliance with the stockholders' equity requirement. Nasdaq has not yet responded to the Company's plan, and there can be no assurance that Nasdaq will grant an extension or that the Company will be able to comply with the applicable listing standards of Nasdaq.

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The Company continues to seek additional capital from other financing alternatives and other sources in order to ensure adequate funding is available to allow the Company to continue research and product development activities at their current levels. If sufficient capital is not raised, the Company will at a minimum need to significantly reduce or curtail its research and development and other operations, and this would negatively affect its ability to achieve corporate growth goals.

Should the Company fail to raise additional cash from outside sources, it would have a material adverse impact on its operations.

The accompanying condensed financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

### 4. Fair Value Measurements

Fair value measurements are market-based measurements, not entity-specific measurements. Therefore, fair value measurements are determined based on the assumptions that market participants would use in pricing the asset or liability. The Company follows a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.
- Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable in active markets.

The Company has investments in money market accounts, which are included in cash and cash equivalents on the balance sheets. Fair value inputs for these investments are considered Level 1 measurements within the fair value hierarchy since money market account fair values are known and observable through daily published floating net asset values.

The following table summarizes the Company's fair value hierarchy for its financial assets measured at fair value on a recurring basis as of March 31, 2024 and December 31, 2023, respectively (in thousands).

March 31, 2024	Fair Value	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
Money market	\$ 176	\$ 176	\$ —	\$ —
Treasury bills and government agency bonds	323	323	—	—
	<u>\$ 499</u>	<u>\$ 499</u>	<u>\$ —</u>	<u>\$ —</u>

  

December 31, 2023	Fair Value	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
Money market	\$ 5,449	\$5,449	\$ —	\$ —

### 5. Term Loan Obligations

On May 29, 2015, the Company entered into the Loan and Security Agreement (the "Loan and Security Agreement"), pursuant to which Oxford Finance, LLC ("Oxford") funded an aggregate principal amount of

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\$17.7 million (the “Term Loan”), subject to the terms and conditions set forth in the Loan and Security Agreement. The Term Loan accrues interest at a floating rate of at least 8.95% per annum, comprised of a three-month LIBOR rate with a floor of 1.00% plus 7.95%. Pursuant to the Loan and Security Agreement, as amended, the Company made interest only payments through May 1, 2021, and thereafter is required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through June 1, 2024, the maturity date. At maturity of the Term Loan, or earlier repayment in full following voluntary prepayment or upon acceleration, the Company is required to make a final payment in an aggregate amount equal to approximately \$3.2 million.

From September 2017 to March 2020, the Company entered into a total of nine amendments to the Term Loan that, among other things, extended the interest only period, required repayment of \$3.1 million using the proceeds received from sale of the Company’s former UK and Japan subsidiaries in April 2019, increased the final payment, increased the final payment fee upon maturity or early repayment of the Term Loan, increased the minimum liquidity covenant level to \$2.0 million and deferred the start date of principal repayment from May 1, 2020 to May 1, 2021 and extended the term of the Term Loan from September 1, 2021 to June 1, 2024.

On June 28, 2023, the Company and Oxford entered into a tenth amendment to the Loan and Security Agreement, and revised the interest rate of the Loan to the greater of: (1) 8.95%, or (2) the sum of 1-month Secured Overnight Financing Rate and 8.05%, effective July 1, 2023.

The Term Loan, as amended, is collateralized by a security interest in substantially all of the Company’s existing and subsequently acquired assets, including its intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement, as amended. The intellectual property asset collateral will be released upon the Company achieving a certain liquidity level when the total principal outstanding under the Loan and Security Agreement is less than \$3.0 million. As of March 31, 2024, there was \$0.4 million principal amount outstanding under the Term Loan, excluding the \$3.2 million final payment fee, and the Company was in compliance with all of the debt covenants under the Loan and Security Agreement.

The Company’s interest expense for the three ended March 31, 2024 and 2023 was \$34,000 and \$0.1 million, respectively. Interest expense is calculated using the effective interest method; therefore it is inclusive of non-cash amortization in the amount of \$21,000 and \$0.1 million for the three ended March 31, 2024 and 2023, respectively, related to the amortization of the debt discount, capitalized loan costs, and accretion of final payment.

The Loan and Security Agreement, as amended, contains customary indemnification obligations and customary events of default, including, among other things, the Company’s failure to fulfill certain obligations under the Term Loan, as amended, and the occurrence of a material adverse change, which is defined as a material adverse change in the Company’s business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan. In the event of default by the Company or a declaration of material adverse change by its lender, under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Term Loan, which could materially harm the Company’s financial condition. As of March 31, 2024, the Company has not received any notification or indication from Oxford that it intends to invoke the material adverse change clause. See Note 12 for further information regarding the repayment of the Term Loan.

## **6. Loss per Share**

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares

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that would have been outstanding as calculated using the treasury stock method. Potential common shares were related to outstanding but unexercised options, multiple series of convertible preferred stock, and warrants for all periods presented.

The following were excluded from the diluted loss per share calculation for the periods presented because their effect would be anti-dilutive:

	As of March 31,	
	2024	2023
Outstanding stock options	303,133	134,283
Preferred stock	28,190	28,190
Outstanding warrants	142,733	142,733
Total	<u>474,056</u>	<u>305,206</u>

## 7. Grant Revenue

On September 19, 2022, the Company entered into that certain CPRIT contract (“CPRIT Contract”), effective as of August 31, 2022, with CPRIT, pursuant to which CPRIT will provide the Company with a CPRIT grant (“CPRIT Grant”) over a three-year period to fund the continued development of rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with leptomeningeal metastases (“LM”). The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of rhenium (<sup>186</sup>Re) obisbameda based on specific dollar thresholds and tiered low single digit royalty rates until CPRIT receives the aggregate amount of 400% of the proceeds awarded under the CPRIT Grant, and certain reporting requirements.

The CPRIT Contract will terminate on August 30, 2025, unless terminated earlier by (a) the mutual written consent of all parties to the CPRIT Contract, (b) CPRIT for an event of default by the Company, (c) CPRIT, if the funds allocated to the CPRIT Grant become legally unavailable during the term of the CPRIT Contract and CPRIT is unable to obtain additional funds for such purposes, and (d) the Company for convenience. CPRIT may require the Company to repay some or all of the disbursed CPRIT Grant proceeds (with interest not to exceed 5% annually) in the event of the early termination of the CPRIT Contract by CPRIT for an event of default by the Company or by the Company for convenience, or if the Company relocates its principal place of business outside of the state of Texas during the CPRIT Contract term or within three years after the final payment of the grant funds.

The Company retains ownership over any intellectual property developed under the CPRIT Contract (each, a “Project Result”). With respect to non-commercial use of any Project Result, the Company granted to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license with right to sublicense any necessary additional intellectual property rights to exploit all Project Results by CPRIT, other governmental entities and agencies of the State of Texas, and private or independent institutions of higher education located in Texas, for education, research and other non-commercial purposes.

The Company recognized \$1.7 million and \$0.5 million in grant revenue from the CPRIT Contract during the three months ended March 31, 2024 and 2023, respectively.

## 8. Commitments and Contingencies

### *Leases*

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2025. The Company also leases certain office space in Austin, Texas under a month-to-month operating lease agreement and certain office space in Charlottesville, Virginia (the “Charlottesville Lease”). The Charlottesville Lease has a term of 12 months and the Company has the ability to renew for three additional one-year periods. On March 31, 2023, Company believed that it was reasonably



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certain that the Charlottesville Lease will be renewed through March 31, 2026, and as a result, it remeasured the related lease liability as of March 31, 2023 to be \$80,000 using the then-in-effect discount rate of 12.76%. Effective July 1, 2023, the Company added additional office lease premises in Charlottesville, which was accounted for as a separate operating lease contract with a lease liability and corresponding right-of-use asset of \$19,000, as a discount rate of 13.47%.

### *Piramal Master Services Agreement*

On January 8, 2021, the Company entered into a Master Services Agreement (the “MSA”) with Piramal Pharma Solutions, Inc. (“Piramal”), for Piramal to perform certain services related to the development, manufacture, and supply of the Company’s rhenium (<sup>186</sup>Re) obisbameda intermediate drug product. The MSA includes the transfer of analytical methods, development of microbiological methods, process transfer and optimization, intermediate drug product manufacturing, and stability studies for the Company, which has been initiated at Piramal’s facility located in Lexington, Kentucky.

The MSA has a term of five years and will automatically renew for successive one-year terms unless either party notifies the other no later than six months prior to the original term or any additional terms of its intention to not renew the MSA. The Company has the right to terminate the MSA for convenience upon thirty days’ prior written notice. Either party may terminate the MSA upon an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party.

### *Other commitments and contingencies*

The Company has entered into agreements with various research organizations for pre-clinical and clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, recruiting and enrolling patients, monitoring studies and data analysis. Payments under these agreements typically include fees for services and reimbursement of expenses. The timing of payments due under these agreements is estimated based on current study progress. As of March 31, 2024, the Company did not have any clinical research study obligations.

### *Legal proceedings*

From time to time, the Company is subject to legal proceedings and claims, whether asserted or unasserted, that arise in the ordinary course of business. Due to their nature, such legal proceedings involve inherent uncertainties including, but not limited to, court rulings, negotiations between affected parties and governmental actions. Management assesses the probability of loss for such contingencies and accrues a liability and/or discloses the relevant circumstances, as appropriate.

## **9. License Agreements**

### *Biocept License Agreement*

On September 7, 2023, the Company entered into a Non-Exclusive License and Services Agreement (the “Biocept Agreement”) with Biocept, Inc (“Biocept”), pursuant to which Biocept granted the Company a non-exclusive license to use the Biocept proprietary cell enumeration test, CNside™ (“CNside”). In exchange for the license, the Company issued to Biocept 53,381 unregistered shares, the fair value of which was \$75,000. The Biocept Agreement also provides that if Biocept fully transfers the technology to the Company, a tech transfer and validation fee of \$300,000 will be payable. In addition, the Company was granted an option for an exclusive worldwide license for \$1,000,000 on or before December 31, 2024, to process and perform cell enumeration testing for treatments for other patients including those on the Company’s radiotherapeutic drugs.

On October 16, 2023, Biocept filed a voluntary petition for relief under the provisions of Chapter 7 of Title 11 of the United States Bankruptcy Code. See Note 12 for further information regarding the Company’s acquisition of substantially all right, title and interest in CNside.

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### *UT Health Science Center at San Antonio (“UTHSCSA”) License Agreement*

On December 31, 2021, the Company entered into a Patent and Know-How License Agreement (the “UTHSCSA License Agreement”) with The University of Texas Health Science Center at San Antonio (“UTHSCSA”), pursuant to which UTHSCSA granted the Company an irrevocable, perpetual, exclusive, fully paid-up license, with the right to sublicense and to make, develop, commercialize and otherwise exploit certain patents, know-how and technology related to the development of biodegradable alginate microspheres (“BAM”) containing nanoliposomes loaded with imaging and/or therapeutic payloads.

### *NanoTx License Agreement*

On March 29, 2020, the Company and NanoTx, Corp. (“NanoTx”) entered into a Patent and Know-How License Agreement, pursuant to which NanoTx granted the Company an irrevocable, perpetual, exclusive, fully paid-up license, with the right to sublicense and to make, develop, commercialize and otherwise exploit certain patents, know-how and technology related to the development of radiolabeled nanoliposomes.

The transaction terms included an upfront payment of \$0.4 million in cash and \$0.3 million in the Company’s voting stock. The transaction terms also included success-based milestone and royalty payments contingent on key clinical, regulatory and sales milestones, as well as the requirement to pay 15% of any non-dilutive monetary awards or grants received from external agencies to support product development of the nanoliposome encapsulated BMEDA-chelated radioisotope, which includes grants from CPRIT. As of March 31, 2024, the Company accrued \$0.5 million of payments due to NanoTx as a result of the CPRIT grant received (see Note 7, Grant Revenue of the condensed financial statements for additional information).

## **10. Stockholders’ Equity**

### **Preferred Stock**

The Company has authorized 5,000,000 shares of preferred stock, par value \$0.001 per share. The Company’s Board is authorized to designate the terms and conditions of any preferred stock the Company issues without further action by the common stockholders.

### *Series F Preferred Stock*

On March 3, 2023, the Company filed a certificate of designation (the “Certificate of Designation”) with the Secretary of State of the State of Delaware, effective as of the time of filing, designating the rights, preferences, privileges and restrictions of the Series F Preferred Stock, with the total authorization of one (1) share of Series F Preferred Stock. The Certificate of Designation provided that the share of Series F Preferred Stock would have 50,000,000 votes per share of Series F Preferred Stock and would vote together with the Company’s common stock, as a single class exclusively with respect to any proposal to amend the Company’s Charter to effect the Reverse Stock Split. On March 3, 2023, the Company entered into a subscription and investment representation agreement with Richard J. Hawkins, chairman of the board of the Company, who is an accredited investor (the “Series F Preferred Stock Purchaser”), pursuant to which the Company agreed to issue and sell one (1) share of the Company’s Series F Preferred Stock, par value \$0.001 per share, to the Series F Preferred Stock Purchaser for \$1,000 in cash. The sale closed on March 3, 2023.

At the Company’s 2023 annual meeting, the Series F Preferred Stock was voted, without action by the holder, on the proposal to approve the Reverse Stock Split in the same proportion as shares of common stock voted to approve the Reverse Stock Split. The Series F Preferred Stock otherwise had no voting rights except as otherwise required by the General Corporation Law of the State of Delaware.

The Series F Preferred Stock was not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The Series F Preferred Stock had no rights with respect to any

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distribution of assets of the Company, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of the Company, whether voluntarily or involuntarily. The holder of the Series F Preferred Stock was not entitled to receive dividends of any kind.

The outstanding share of Series F Preferred Stock was redeemed in whole, automatically effective upon the approval by the Company's stockholders of the Reverse Stock Split. Upon such redemption, the holder of the Series F Preferred Stock received consideration of \$1,000 in cash.

### *Series B and C Preferred Stock*

As of March 31, 2024, there were 938 outstanding shares of Series C Preferred Stock that can be converted into an aggregate of 27,792 shares of common stock, and 1,014 shares of Series B Convertible Preferred Stock that can be converted into an aggregate of 398 shares of common stock.

### **Warrants**

On September 25, 2019, the Company completed an underwritten public offering. The Company issued 19,266 shares of its common stock, along with pre-funded warrants to purchase 180,733 shares of its common stock and Series U Warrants to purchase 230,000 shares of its common stock. The Series U Warrants have a term of five years from the issuance date. In addition, the Company issued warrants to H.C. Wainwright & Co., LLC, as representatives of the underwriters, to purchase 5,000 shares of its common stock with a term of five years from the issuance date, in the form of Series U Warrants (the "Representative Warrants"). As of March 31, 2024, there were 142,733 outstanding Series U Warrants and Representative Warrants which can be exercised into an aggregate of 142,733 shares of common stock at a weighted average exercise price of \$34.10 per share.

### **Common Stock**

#### *Lincoln Park Purchase Agreement*

On August 2, 2022, the Company entered into a purchase agreement (the "2022 Purchase Agreement") and registration rights agreement pursuant to which Lincoln Park Capital Fund ("Lincoln Park") committed to purchase up to \$50.0 million of the Company's common stock. Under the terms and subject to the conditions of the 2022 Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$50.0 million of the Company's common stock. Such sales of common stock by the Company are subject to certain limitations, and can occur from time to time, at the Company's sole discretion, over the 36-month period commencing on August 17, 2022, subject to the satisfaction of certain conditions.

On May 16, 2022, the Company received stockholder approval for purposes of the Nasdaq listing rules to permit issuances of up to 57.5 million shares of the Company's common stock (including the issuance of more than 19.99% of the Company's common stock) to Lincoln Park, and it was pursuant to that approval that the Company entered into the 2022 Purchase Agreement.

Upon execution of the 2022 Purchase Agreement, the Company paid \$0.1 million in cash as the initial commitment fee, and issued 32,846 shares as the initial commitment shares, to Lincoln Park as consideration for its irrevocable commitment to purchase shares of the Company's common stock at its direction under the 2022 Purchase Agreement. The Company has agreed to pay an additional commitment fee, which it may elect to pay in cash and/or shares of its common stock, upon receipt of \$25.0 million aggregate gross proceeds from sales of common stock to Lincoln Park under the 2022 Purchase Agreement.

On August 17, 2022, a registration statement (the "First Registration Statement") was declared effective to cover the resale of up to 633,333 shares of the Company's common stock comprised of (i) the 32,846 initial

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commitment shares, and (ii) up to 600,486 that the Company has reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time from and after the date of the prospectus. The Company sold approximately 527,166 shares under the First Registration Statement.

On August 18, 2023, a second registration statement (the “Second Registration Statement”) was declared effective to cover the resale of up to an additional 1,500,000 shares of the Company’s common stock that the Company reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time. The Company sold 150,000 shares under the Second Registration Statement. The Company cannot sell more shares than registered under the Second Registration Statement under the 2022 Purchase Agreement without registering additional shares.

Actual sales of shares of common stock to Lincoln Park under the 2022 Purchase Agreement depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. The net proceeds under the 2022 Purchase Agreement to the Company depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park.

During the period from August 17, 2022 to December 31, 2022, the Company issued 266,666 shares under the 2022 Purchase Agreement for net proceeds of approximately \$3.2 million. The Company issued 410,500 shares under the 2022 Purchase Agreement for net proceeds of approximately \$1.0 million from January 1, 2023 to December 31, 2023. The Company did not issue any common stock under the 2022 Purchase Agreement during the three months ended March 31, 2024.

### *At-the-market Issuances*

On September 9, 2022, the Company entered into the September 2022 Distribution Agreement with Canaccord, pursuant to which the Company could issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$5,000,000, depending on market demand, with Canaccord acting as an agent for sales. During the period from September 9, 2022 to December 31, 2022, the Company issued 68,758 shares of its common stock under the September 2022 Distribution Agreement for net proceeds of approximately \$0.6 million. From January 1, 2023 through December 31, 2023, the Company issued 1,819,993 shares under the September 2022 Distribution Agreement for net proceeds of approximately \$4.3 million. The Company has reached the capacity for sales of shares under the September 2022 Distribution Agreement and the agreement has terminated.

The Company was obligated to pay Canaccord a commission of up to 3.0% of the gross proceeds from the sale of its common stock under the September 2022 Distribution Agreement. The Company also agreed to reimburse Canaccord for its reasonable documented out-of-pocket expenses, including fees and disbursements of its counsel, in the amount of \$50,000. In addition, the Company agreed to provide customary indemnification rights to Canaccord.

On January 14, 2022, the Company entered into the January 2022 Distribution Agreement with Canaccord, pursuant to which the Company could issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$5,000,000, with Canaccord acting as an agent for sales. The Company had no obligation to sell any of the Company’s shares and it could instruct Canaccord not to sell any shares if the sales could not be effected at or above the price designated by the Company from time to time and the Company could at any time suspend sales pursuant to the January 2022 Distribution Agreement. During the year ended December 31, 2023, the Company issued 460,151 shares under the January 2022 Distribution Agreement for net proceeds of approximately \$4.8 million. The January 2022 Distribution Agreement has been terminated after all available registered shares were fully utilized.

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### *Share Repurchase Program and Treasury Stock*

On October 31, 2023, the Company announced that its Board has approved a share repurchase program (the “Share Repurchase Program”), with authorization to repurchase up to \$500,000 of the outstanding shares of the Company’s common stock. The Company funded repurchases under the Share Repurchase Program with available cash.

During the year ended December 31, 2023, the Company purchased 78,559 of its common stock for approximately \$0.1 million as treasury stock. The Company purchased 179,866 of its common shares for approximately \$0.4 million as treasury stock during the three months ended March 31, 2024. As of March 31, 2024, no amount remained authorized for repurchase.

### **11. Stock-based Compensation**

Under the Company’s 2015 New Employee Incentive Plan (the “2015 Plan”), awards may only be granted to employees who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as a material inducement to entering into employment with the Company. As of March 31, 2024, there were 6,024 shares of common stock remaining and available for future issuances under the 2015 Plan.

The Company’s 2020 Stock Incentive Plan (the “2020 Plan”), which replaced the Company’s 2014 Equity Incentive Plan, provides for the award or sale of shares of common stock (including restricted stock), the award of stock units and stock appreciation rights, and the grant of both incentive stock options to purchase common stock to directors, officers, employees and consultants of the Company. The 2020 Plan, as amended, provides for the issuance of up to 236,667 shares of common stock, plus the number of shares available for issuance is increased to the extent that awards granted under the 2020 Plan and the Company’s 2014 Equity Incentive Plan are forfeited or expire (except as otherwise provided in the 2020 Plan). As of March 31, 2024, there were 17,582 shares remaining and available for future issuances under the 2020 Plan.

Generally, options issued under the 2020 Plan are subject to a two-year or four-year vesting schedule with 25% of the options vesting on the one year anniversary of the grant date followed by equal monthly installment vesting, and have a contractual term of 10 years.

A summary of activity for the three months ended March 31, 2024 is as follows:

	<u>Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value</u>
Balance as of December 31, 2023	140,109	\$ 37.48	8.07	
Granted	163,025	\$ 2.03		
Cancelled/forfeited	(1)	\$ 289,125		
Balance as of March 31, 2024	<u>303,133</u>	<u>\$ 17.46</u>	<u>8.94</u>	<u>\$ 7,600</u>
Vested and expected to vest at March 31, 2024	<u>278,083</u>	<u>\$ 18.64</u>	<u>8.87</u>	<u>\$ 6,800</u>
Exercisable at March 31, 2024	<u>84,908</u>	<u>\$ 50.13</u>	<u>7.37</u>	<u>\$ 500</u>

As of March 31, 2024, the total compensation cost related to non-vested stock options not yet recognized for all the Company’s plans is approximately \$0.8 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 2.3 years.

## 12. Subsequent Events

### *Repayment of Term Loan and Use of Pershing Credit Facility*

On May 31, 2024, the Company drew \$3.3 million on the Pershing Credit Facility, to repay the Oxford Term Loan in full, a payment amount that totaled approximately \$3.3 million, which included both the balance of outstanding principal and interest and the final payment fee due. The repayment in full of the Oxford Term Loan terminated Oxford's security interest in the Company's existing and after-acquired assets, as well as all other certain restrictions and covenants under the Oxford Term Loan.

Borrowings under the Pershing Credit Facility bear interest at the target interest rate set by the Federal Open Market Committee, subject to a floor of 5.5%, plus a spread of 1.75% and applicable fees of 0.5%, subject to a maximum interest rate of the then applicable Prime Rate as published in The Wall Street Journal plus 3.0%. Interest payments thereunder are calculated on a monthly basis and, unless paid, are added to the outstanding balance under the Pershing Credit Facility. The proceeds under the Pershing Credit Facility are available for working capital needs and other general corporate purposes. The Pershing Credit Facility includes certain covenants and restrictions, which may require the Company, on an on-going basis, to deposit additional funds or marketable securities in order to maintain the line of credit extended by Pershing.

The available credit line limit under the Pershing Credit Facility fluctuates based on the Company's request for extensions of credit from time to time, subject to the value of the collateralized marketable securities that the Company holds with Pershing, provided that the amount available to draw under the Pershing Credit Facility cannot exceed 91.5% of the value of the Company's collateralized marketable securities deposited with Pershing (the "Collateral"). Depending on the value of the Collateral that the Company holds with Pershing, Pershing may require the Company, on an on-going basis, to deposit additional funds or marketable securities in order to restore the level of the Collateral to an acceptable level. The amounts borrowed under the Pershing Credit Facility are due on demand.

The Pershing Credit Facility is secured by a general lien and security interest in the Company's Collateral held in its account with Pershing. Upon certain customary events of default, Pershing has the right, in its discretion, to liquidate, withdraw or sell all or any part of the Collateral and apply the proceeds to the amounts outstanding under the Pershing Credit Facility. The Pershing Credit Facility is also subject to certain customary terms and conditions.

### *May 2024 Private Placement*

On May 5, 2024, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain investors, including certain of the Company's directors and executive officers ("Company Insiders") (collectively, the "Purchasers"), for the sale and issuance by the Company of its securities (the "Initial Subscription"). On May 8, 2024, the Company entered into a first amendment to the Securities Purchase Agreement (the "Amendment") for the sale and issuance by the Company of additional securities to two of the Purchasers (the "Additional Subscription", and together with the Initial Subscription, the "May 2024 Private Placement"). The Securities Purchase Agreement, as amended, provides for the sale and issuance by the Company of an aggregate of 3,591,532 shares (the "Private Placement Shares") of the Company's common stock or, at the election of each Purchaser, pre-funded warrants (the "Pre-Funded Warrants"), exercisable immediately at an exercise price of \$0.001 per share (the "Pre-Funded Warrant Shares"), with each Private Placement Share or Pre-Funded Warrant accompanied by (i) a Series A common warrant ("Series A Warrants") to purchase one share of common stock (the "Series A Warrant Shares"), for an aggregate of 3,591,532 Series A Warrants, and (ii) one Series B common warrant ("Series B Warrants") to purchase one share of common stock (the "Series B Warrant Shares," and together with the Series A Warrant Shares, the "Common Warrant Shares"), for an aggregate of 3,591,532 Series B Warrants.

The combined purchase price for each Private Placement Share and Pre-Funded Warrant from the Initial Subscription was \$2.022, and \$2.158 from the Additional Subscription, in each case together with one

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accompanying Series A Warrant and one accompanying Series B Warrant, provided, that the Company Insiders participated in the Initial Subscription at an offering price of \$2.04 per Private Placement Share and accompanying Series A Warrant and Series B Warrant.

The exercise price of each Series A Warrant and Series B Warrant from the Initial Subscription is \$1.772 per share and \$1.908 per share in the Additional Subscription, provided that the exercise price for the Series A Warrants and Series B Warrants issued to the Company Insiders is \$1.79 per share. Subject to certain ownership limitations, the Series A Warrants will be exercisable until the five-year anniversary of issuance. Subject to certain ownership limitations, the Series B Warrants will be exercisable until the one-year anniversary of the declaration of effectiveness of a registration statement to be filed with the Securities and Exchange Commission covering the resale of the Common Warrant Shares. The Pre-Funded Warrant will not expire until exercised in full.

The May 2024 Private Offering closed on May 9, 2024 (the “May 2024 Private Placement Closing”). The aggregate gross proceeds at the May 2024 Private Placement Closing were approximately \$7.25 million, before deducting certain expenses payable by the Company, and excluding the proceeds, if any, from the exercise of the Series A Warrant, the Series B Warrant, and Pre-Funded Warrant.

The Company is evaluating the accounting treatment of the Series A Warrants, Series B Warrants and the Pre-Funded Warrants under the authoritative accounting guidance.

### *Biocept Asset Purchase*

On April 26, 2024, the Company acquired from Biocept, for a total cash payment of \$400,000, substantially all of the right, title and interest in CNside, including (i) intellectual property, (ii) inventory and raw materials, and (iii) data, information, results and reports pertaining to the completed and on-going clinical studies involving the use of the CNside test (including, but not limited to, the FORESEE clinical study), related to the development, making, selling, and exporting or importing of CNside, after the Company’s bid was approved by the United States Bankruptcy Court for the District of Delaware.

### *2015 Plan*

On June 6, 2024, the Company increased the number of shares available for issuance under the 2015 plan by 75,000 shares of common stock.

## Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors  
Plus Therapeutics, Inc.  
Austin, Texas

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of Plus Therapeutics, Inc. (the “Company”) as of December 31, 2023 and 2022, the related statements of operations, stockholders’ equity (deficit), and cash flows for each of the years then ended and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

### Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

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

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

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

### Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging,



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subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

### Determination of Research and Development Cost Associated With Recording of Grant Revenue

As described in Note 9 to the financial statements, in September 2022, the Company entered into a contract with the Cancer Prevention and Research Institute of Texas (“CPRIT”) pursuant to which CPRIT will provide the Company a grant of up to \$17.6 million (the “CPRIT Grant”) over a three-year period. The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, fund the continued development of rhenium (<sup>186</sup>Re) obisbameda for the treatment of patients with leptomeningeal metastases (“LM”). The Company recognized \$4.9 million in grant revenue from the CPRIT Grant during the year ended December 31, 2023.

We identified the determination of research and development costs incurred associated with the CPRIT Grant as a critical audit matter because of the subjectivity required to appropriately determine whether such costs satisfied the funding conditions. Auditing this element involved especially challenging and subjective auditor judgment due to the nature and extent of auditor effort required to address the matter.

The primary procedures we performed to address this critical audit matter included:

- Reviewing the CPRIT Grant agreement to understand the conditions for which research and development costs satisfy the funding conditions.
- Reviewing evidence of CPRIT’s approval of costs submitted by the Company that were applied to the CPRIT Grant funding conditions.
- Inspecting a sample of vendor agreements and invoice detail to determine whether certain charges satisfy the CPRIT Grant funding conditions.

/s/ BDO USA, P.C.

We have served as the Company’s auditor since 2016.

Austin, Texas  
March 5, 2024

**PLUS THERAPEUTICS, INC.**  
**BALANCE SHEETS**  
(in thousands, except share and par value data)

	As of December 31,	
	2023	2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,554	\$ 18,120
Other current assets	1,280	3,697
Total current assets	9,834	21,817
Property and equipment, net	906	1,324
Operating lease right-use-of assets	202	248
Goodwill	372	372
Intangible assets, net	42	94
Other assets	32	12
Total assets	<u>\$ 11,388</u>	<u>\$ 23,867</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,631	\$ 10,134
Operating lease liability	120	110
Term loan obligation, current	3,976	1,608
Total current liabilities	10,727	11,852
Noncurrent operating lease liability	85	141
Term loan obligation	—	3,786
Deferred grant liability	1,924	1,643
Total liabilities	12,736	17,422
Commitments and contingencies (Note 6)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding as of December 31, 2023 and 2022	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 4,522,656 issued and 4,444,097 outstanding as of December 31, 2023, 2,240,092 shares issued and outstanding as of December 31, 2022, respectively	5	2
Treasury stock (at cost, 78,559 shares as of December 31, 2023)	(126)	—
Additional paid-in capital	479,274	473,628
Accumulated deficit	(480,501)	(467,185)
Total stockholders' equity (deficit)	(1,348)	6,445
Total liabilities and stockholders' equity (deficit)	<u>\$ 11,388</u>	<u>\$ 23,867</u>

See Accompanying Notes to these Financial Statements

**PLUS THERAPEUTICS, INC.**  
**STATEMENTS OF OPERATIONS**  
**(in thousands, except share and per share data)**

	<b>For the Years Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Grant revenue	\$ 4,913	\$ 224
Operating expenses:		
Research and development	9,690	9,698
General and administrative	8,544	10,238
Total operating expenses	<u>18,234</u>	<u>19,936</u>
Operating loss	(13,321)	(19,712)
Other income (expense):		
Interest income	400	147
Interest expense	(395)	(711)
Change in fair value of liability instruments	—	1
Total other income (expense)	<u>5</u>	<u>(563)</u>
Net loss	<u>\$ (13,316)</u>	<u>\$ (20,275)</u>
Net loss per share, basic and diluted	<u>\$ (4.24)</u>	<u>\$ (11.58)</u>
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	3,140,925	1,750,350

See Accompanying Notes to these Financial Statements

**PLUS THERAPEUTICS, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
(in thousands, except share data)

	Preferred Stock		Convertible preferred stock		Common stock		Treasury Stock	Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	—	—	1,952	—	1,034,002	1	—	457,745	(446,910)	10,836
Share-based compensation	—	—	—	—	—	—	—	606	—	606
Sale of common stock, net	—	—	—	—	1,206,090	1	—	15,277	—	15,278
Net loss	—	—	—	—	—	—	—	—	(20,275)	(20,275)
Balance at December 31, 2022	—	\$ —	1,952	\$ —	2,240,092	\$ 2	—	\$ —	\$ (467,185)	\$ 6,445
Issuance of Series F preferred stock	1	—	—	—	—	—	—	—	—	—
Redemption of Series F preferred stock	(1)	—	—	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	—	—	—	569	—	569
Sale of common stock, net	—	—	—	—	2,230,493	3	—	5,002	—	5,005
Issuance of common stock for in process research and development	—	—	—	—	53,381	—	—	75	—	75
Fractional adjustment	—	—	—	—	(1,310)	—	—	—	—	—
Purchase of treasury stock	—	—	—	—	—	—	(78,559)	(126)	—	(126)
Net loss	—	—	—	—	—	—	—	—	(13,316)	(13,316)
Balance at December 31, 2023	—	\$ —	1,952	\$ —	4,522,656	\$ 5	(78,559)	\$ (126)	\$ (480,501)	\$ (1,348)

See Accompanying Notes to these Financial Statements

**PLUS THERAPEUTICS, INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)

	<b>For the Years Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows used in operating activities:</b>		
Net loss	\$ (13,316)	\$ (20,275)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	628	619
Amortization of deferred financing costs and debt discount	190	389
Common stock issued for research and development	75	—
Change in fair value of liability instruments	—	(1)
Loss on disposal of property and equipment	2	—
Share-based compensation expense	569	606
Reduction in the carrying amount of operating lease right-of-use assets	117	93
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Other assets	2,397	(2,369)
Accounts payable and accrued expenses	(3,677)	6,452
Change in operating lease liabilities	(117)	(129)
Deferred grant liability	281	1,643
Net cash used in operating activities	<u>(12,851)</u>	<u>(12,972)</u>
<b>Cash flows used in investing activities:</b>		
Purchases of property and equipment and intangible assets	(160)	(509)
In process research and development acquired	—	(250)
Net cash used in investing activities	<u>(160)</u>	<u>(759)</u>
<b>Cash flows from financing activities:</b>		
Principal payments of long-term obligations	(1,608)	(1,608)
Gross proceeds from sale of common stock	5,527	15,832
Payment of offering costs related to sale of common stock	(348)	(773)
Purchase of treasury stock	(126)	—
Net cash provided by financing activities	<u>3,445</u>	<u>13,451</u>
Net decrease in cash and cash equivalents	<u>(9,566)</u>	<u>(280)</u>
Cash and cash equivalents at beginning of period	18,120	18,400
Cash and cash equivalents at end of period	<u>\$ 8,554</u>	<u>\$ 18,120</u>
<b>Supplemental disclosure of cash flows information:</b>		
Cash paid during period for:		
Interest	\$ 222	\$ 327
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Unpaid offering cost	\$ 174	\$ —
Common stock issued in payment for in process research and development	\$ 75	\$ —
Right-of-use assets acquired by assuming operating lease liabilities	\$ 71	\$ —

See Accompanying Notes to these Financial Statements

**PLUS THERAPEUTICS, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**December 31, 2023**

**1. Organization and Operations**

**The Company**

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company focused on the development, manufacture and commercialization of complex and innovative treatments for patients battling cancer and other life-threatening diseases.

**Certain Risks and Uncertainties**

The Company's prospects are subject to the risks and uncertainties frequently encountered by companies in the early stages of development and commercialization, especially those companies in rapidly evolving and technologically advanced industries such as the biotech/medical device field. The Company's future viability largely depends on its ability to complete development of new products and receive regulatory approvals for those products. No assurance can be given that the Company's new products will be successfully developed, regulatory approvals will be granted, or acceptance of these products will be achieved.

**Going Concern**

The Company incurred net losses of \$13.3 million for the year ended December 31, 2023, and as of December 31, 2023, the Company had an accumulated deficit of \$480.5 million and cash and cash equivalents of \$8.6 million. Additionally, the Company used net cash of \$12.9 million to fund its operating activities for the year ended December 31, 2023. The Company's term loan has an outstanding principal of \$0.8 million principal and a \$3.2 million final payment fee due June 1, 2024 (Note 8). The Company expects that its research and development expenditures will increase in absolute dollars in 2024 and beyond. These factors raise substantial doubt about the Company's ability to continue as a going concern.

As disclosed in more detail in Note 12, the Company has entered into various financing agreements and raised capital by issuing its common stock.

Based on the Company's stockholders' deficit of \$1.3 million as of December 31, 2023, the Company does not meet the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1). The Company expects to receive written notice from Nasdaq staff to that effect following the filing of the Annual Report on Form 10-K in which these financial statements are included.

The Company continues to seek additional capital through strategic transactions and from other financing alternatives. Without additional capital, current working capital and cash generated from sales will not provide adequate funding to make debt repayments, for research, sales and marketing efforts and product development activities at their current levels. If sufficient capital is not raised, the Company will at a minimum need to significantly reduce or curtail its research and development and other operations, and this would negatively affect its ability to achieve corporate growth goals.

Should the Company fail to raise additional cash from outside sources, this would have a material adverse impact on its operations.

The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

### **Amendments to Certificate of Incorporation and Reverse Stock Split**

At the Annual Meeting of Stockholders of the Company held on April 20, 2023 (the “Annual Meeting”), the stockholders of the Company approved an amendment to the Company’s Amended and Restated Certificate of Incorporation to implement a reverse stock split of the Company’s common stock, par value \$0.001 per share, with the ratio to be determined by the Board of Directors (the “Board”) of the Company, within a range of not less than 1-for-3 and not greater than 1-for-15. Subsequently, on April 21, 2023, the Board determined to fix the ratio for the reverse stock split at 1-for-15, without any change to its par value (the “Reverse Stock Split”).

On April 27, 2023, following stockholder and Board approval, the Company filed a Certificate of Amendment to its Charter (the “Amendment”), with the Secretary of State of the State of Delaware to effectuate the Reverse Stock Split. The Amendment became effective on May 1, 2023. Upon effectiveness of the Reverse Stock Split, the number of shares of the Company’s common stock (x) issued and outstanding decreased from approximately 37.4 million shares to approximately 2.5 million shares; (y) reserved for issuance upon exercise of outstanding warrants and options decreased from approximately 2.0 million shares to approximately 0.1 million shares, and (z) reserved but unallocated under the Company’s current equity incentive plans decreased from approximately 3.0 million common shares to approximately 0.2 million common shares. The Company’s common stock began trading on the NASDAQ Capital Market on a post-split basis on May 1, 2023. The Company’s 5,000,000 shares of authorized Preferred Stock were not affected by the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split, and accordingly, the outstanding number of shares post Reverse Stock Split was adjusted down by approximately 1,310 (post-effect of Reverse Stock Split) shares. Proportional adjustments for the reverse stock split were made to the Company’s outstanding stock options, warrants and equity incentive plans for all periods presented in the financial statements in this Form 10-K. The Company’s financial statements, and all references thereto have been retroactively adjusted to reflect the reverse split unless specifically stated otherwise.

## **2. Summary of Significant Accounting Policies**

### **Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. The most significant estimates and critical accounting policies involve reviewing assets for impairment, and determining the assumptions used in measuring share-based compensation expense.

Actual results could differ from these estimates. Management’s estimates and assumptions are reviewed regularly, and the effects of revisions are reflected in the financial statements in the periods they are determined to be necessary.

### **Cash and cash equivalents**

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents.

Cash and cash equivalents include cash in readily available checking, savings accounts and money market accounts. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash balances due to the financial position of the depository institution in which those deposits are held.

### **Financial Instruments**

Financial instruments include cash equivalents, other current assets, accounts payable, accrued expenses, other liabilities and long-term debt. The carrying values of cash equivalents, other current assets, accounts payable,

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accrued expenses and other liabilities generally approximate fair value due to the short-term nature of these instruments. Based on level 3 inputs and the borrowing rates currently available for loans with similar terms, the Company believes the fair value of the long-term debt is materially consistent with its carrying value.

### **Property and Equipment**

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation expense, which includes the amortization of capitalized leasehold improvements, is provided for on a straight-line basis over the estimated useful lives of the assets, or the life of the lease, whichever is shorter, and range from three to five years. When assets are sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss, if any, is included in operations. Maintenance and repairs are charged to operations as incurred.

### **Impairment**

The Company assesses its property and equipment for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recoverable. Such long-lived assets are deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. The Company recognized no impairment losses during any of the periods presented in these financial statements.

### **Goodwill**

The Company's goodwill represents the excess of the cost over the fair value of net assets acquired from its business combinations. The determination of the value of goodwill arising from business combinations requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired.

Goodwill is not amortized; however, it is assessed for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. Goodwill is considered to be impaired if the Company determines that the carrying value of the reporting unit exceeds its fair value.

The Company performs its impairment test annually during the fourth quarter by comparing the Company's estimated fair value, calculated from the Company's market capitalization, to its carrying amount. The Company's annual evaluation for impairment of goodwill consists of one reporting unit. The Company completed its most recent annual evaluation for impairment as of December 31, 2023, when the Company had stockholders' deficit within its sole reporting unit of approximately \$1.3 million, and concluded that no impairment existed.

### **Grant Revenue Recognition**

In applying the provisions of Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), the Company has determined that government grants are out of the scope of ASC 606 because the funding entities do not meet the definition of a "customer," as defined by ASC 606, as there is not considered to be a transfer of control of goods or services. With respect to the grant, the Company determines if it is a collaboration arrangement in accordance with ASC Topic 808, Collaborative Arrangements ("ASC 808"). For grants outside the scope of ASC 808, the Company applies International Accounting Standards No. 20, Accounting for Government Grants and Disclosure of Government Assistance, by analogy, and revenue is recognized when the Company incurs expenses related to the grant for the amount the Company is entitled to under the provisions of the contract.



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The Company also considers the guidance in ASC Topic 730, Research and Development (“ASC 730”), which requires an assessment, at the inception of the grant, of whether the agreement is a liability. If the Company is obligated to repay funds received regardless of the outcome of the related research and development activities, then the Company is required to estimate and recognize that liability. Alternatively, if the Company is not required to repay the funds, then payments received are recorded as revenue or contra-expense as the expenses are incurred.

Deferred grant liability represents grant funds received or receivable for which the allowable expenses have not yet been incurred as of the balance sheet date.

### **Research and Development**

Research and development expenditures, which are charged to operations in the period incurred, include costs associated with the design, development, testing and enhancement of the Company’s products, regulatory fees, the purchase of laboratory supplies, and pre-clinical and clinical studies as well as salaries and benefits for the Company’s research and development employees.

### **Acquired In-Process Research and Development (IPR&D)**

Acquired IPR&D represents the value assigned to research and development assets that have not reached technological feasibility. Upon the acquisition of IPR&D, the Company completes an assessment of whether the acquisition constitutes the purchase of a single asset or group of assets. The Company considers multiple factors in this assessment, including the nature of the technology acquired, the presence or absence of separate cash flows, the development process and stage of completion, quantitative significance, and the Company’s rationale for entering into the transaction.

The Company tests IPR&D assets for impairment as of December 31 of each year or more frequently if indicators of impairment are present. The authoritative accounting guidance provides an optional qualitative assessment for any indicators that indefinite-lived intangible assets are impaired. If it is determined that it is more likely than not that the indefinite-lived intangible assets, including IPR&D, are impaired, the fair value of the indefinite-lived intangible assets is compared with the carrying amount and impairment is recorded for any excess of the carrying amount over the fair value of the indefinite-lived intangible assets. There was no impairment of the Company’s IPR&D assets during 2023 or 2022.

### **Deferred Financing Costs and Other Debt-Related Costs**

Deferred financing costs are capitalized, recorded as an offset to debt balances and amortized to interest expense over the term of the associated debt instrument using the effective interest method. If the maturity of the debt is accelerated because of default or early debt repayment, then the amortization would be accelerated.

### **Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income (loss) in the years in which those temporary differences are expected to be recovered or settled. Due to our history of losses, a full valuation allowance has been recognized against our deferred tax assets.

The Company’s policy is to recognize interest and penalties related to income tax matters in income tax expense. For the years ended December 31, 2023 and 2022, the Company has not recorded any interest or penalties related to income tax matters. The Company does not foresee any material changes to unrecognized tax benefits within the next twelve months.

### **Share-Based Compensation**

The Company recognizes the fair value of all share-based payment awards in our statements of operations over the requisite vesting period of each award, which approximates the period during which the employee and non-employee director is required to provide service in exchange for the award. The Company estimates the fair value of these options using the Black-Scholes option pricing model using assumptions for expected volatility, expected term, and risk-free interest rate. Expected volatility is based primarily on historical volatility and is computed using daily pricing observations for recent periods that correspond to the expected term of the options. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected life assumption using the simplified method which is an average of the contractual term of the option and its vesting period. The risk-free interest rate is the interest rate for treasury instruments with maturities that approximate the expected term.

### **Segment Information**

For the years ended December 31, 2023 and 2022, the Company is managed as a single operating segment, and therefore reports its results in one operating segment.

### **Loss Per Share**

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding as calculated using the treasury stock method. Potential common shares were related entirely to outstanding but unexercised options, warrants and convertible preferred stocks for all periods presented.

The Company excluded all potentially dilutive securities from the calculation of diluted loss per share attributable to common stockholders for the years ended December 31, 2023 and 2022, as their inclusion would be antidilutive.

### **Concentration Risk**

Although the Company's contracts with its vendors are not exclusive, the Company currently uses sole source providers for core materials used in its clinical trials.

### **Recently Issued Accounting Pronouncements**

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. This new guidance is effective in the first quarter of 2023 for calendar-year SEC filers that are smaller reporting companies as of the one-time determination date. Early adoption was permitted beginning in 2019. The Company adopted the new guidance as of January 1, 2023, which did not have a material impact on its financial statements and related disclosures.

### **3. Fair Value Measurements**

Fair value measurements are market-based measurements, not entity-specific measurements. Therefore, fair value measurements are determined based on the assumptions that market participants would use in pricing the

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asset or liability. The Company follows a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.
- Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable in active markets.

The Company has investments in money market accounts, which are included in cash and cash equivalents on the balance sheets. Fair value inputs for these investments are considered Level 1 measurements within the fair value hierarchy since money market account fair values are known and observable through daily published floating net asset values.

The following table summarizes the Company's fair value hierarchy for its financial assets measured at fair value on a recurring basis as of December 31, 2023 and December 31, 2022, respectively.

As of December 31, 2023	Fair Value	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
Money market	\$ 5,448,990	\$ 5,448,990	\$ —	\$ —

  

As of December 31, 2022	Fair Value	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
Money market	\$17,573,584	\$17,573,584	\$ —	\$ —

### Nonfinancial Assets and Liabilities

The Company applies fair value techniques on a non-recurring basis, if and when necessary, associated with: (1) valuing potential impairment losses related to goodwill which are accounted for pursuant to the authoritative guidance for intangibles—goodwill and other; and (2) valuing potential impairment losses related to long-lived assets which are accounted for pursuant to the authoritative guidance for property, plant and equipment.

### 4. Loss per Share

The following were excluded from the diluted loss per share calculation for the periods presented because their effect would be anti-dilutive:

	For the Year Ended December 31,	
	2023	2022
Outstanding stock options	140,109	78,334
Preferred stock	28,190	28,190
Outstanding warrants	142,733	142,758
Total	<u>311,032</u>	<u>249,282</u>

[Table of Contents](#)**5. Composition of Certain Financial Statement Captions****Other Current Assets**

As of December 31, 2023 and 2022, other current assets were comprised of the following (in thousands):

	December 31,	
	2023	2022
Prepaid services	\$ 644	\$2,999
Prepaid insurance	636	698
	<u>\$1,280</u>	<u>\$3,697</u>

**Property and Equipment, net**

As of December 31, 2023 and 2022, property and equipment, net, were comprised of the following (in thousands):

	December 31,	
	2023	2022
Office and computer equipment	\$ 1,632	\$ 1,474
Leasehold improvements	1,810	1,810
	<u>3,442</u>	<u>3,284</u>
Less accumulated depreciation	(2,536)	(1,960)
	<u>\$ 906</u>	<u>\$ 1,324</u>

Depreciation expense totaled \$0.6 million and \$0.5 million for the year ended December 31, 2023 and 2022, respectively.

**Intangible Assets, net**

As of December 31, 2023, intangible assets included the net book value of costs incurred for software upgrades. Amortization expenses totaled \$0.1 million for each of the years ended December 31, 2023 and 2022.

**Accounts Payable and Accrued Expenses**

As of December 31, 2023 and 2022, accounts payable and accrued expenses were comprised of the following (in thousands):

	December 31,	
	2023	2022
Accounts payable	\$4,758	\$ 8,364
Accrued payroll and bonus	987	989
Accrued professional fees	128	147
Accrued vacation and compensation	370	325
Accrued R&D studies	388	309
	<u>\$6,631</u>	<u>\$10,134</u>

**6. Commitments and Contingencies***Leases*

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the

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identified asset in exchange for consideration over a period of time. If both criteria are met, the Company calculates the associated lease liability and corresponding right-of-use asset upon lease commencement using a discount rate based on the rate implicit in the lease or an incremental borrowing rate commensurate with the term of the lease. Lease renewable options are included in the estimation of lease term when it is reasonably certain that the Company will exercise such options.

The Company records lease liabilities within current liabilities or long-term liabilities based upon the length of time associated with the lease payments. The Company records its operating lease right-of-use assets as long-term assets. Leases with an initial term of 12 months or less are not recorded on the balance sheets. Instead, the Company recognizes lease expense for these leases on a straight-line basis over the lease term in the statements of operations.

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2025. The Company also leases certain office space in Austin, Texas under a month-to-month operating lease agreement and certain office space in Charlottesville, Virginia (the "Charlottesville Lease"). The Company's existing operating lease agreements generally provide for periodic rent increases, and renewal and termination options. The Company's lease agreements do not contain any material variable lease payments, residual value guarantees or material restrictive covenants.

The Charlottesville Lease has a term of 12 months and the Company has the ability to renew for three additional one-year periods. The Charlottesville Lease is currently set to expire on March 31, 2024, and is renewable twice for twelve months each time. On March 31, 2023, Company believed that it was reasonably certain that the Charlottesville Lease will be renewed through March 31, 2026, and as a result, it remeasured the related lease liability as of March 31, 2023 to be \$80,000 using the then-in-effect discount rate of 12.76%. Effective July 1, 2023, the Company added additional office lease premises in Charlottesville, which was accounted for as a separate operating lease contract with a lease liability and corresponding right-of-use asset of \$19,000, at a discount rate of 13.47%.

Certain leases require the Company to pay taxes, insurance, and maintenance. Payments for the transfer of goods or services such as common area maintenance and utilities represent non-lease components. The Company elected the package of practical expedients and therefore does not separate non-lease components from lease components.

The Company's operating lease liabilities and corresponding right-of-use assets are included in the balance sheets. As of December 31, 2023, the weighted average discount rate used to measure operating lease liabilities and the operating leases remaining term were 10.67% and 1.6 years, respectively.

The table below summarizes the Company's operating lease costs from its statements of operations, and cash payments from its statements of cash flows.

	Year Ended December 31,	
	2023	2022
Lease expense:		
Operating lease expense	\$ 141	\$ 159
Total lease expense	<u>\$ 141</u>	<u>\$ 159</u>
Cash payment information:		
Operating cash used for operating leases	\$ 141	\$ 159
Total cash paid for amounts included in the measurement of lease liabilities	<u>\$ 141</u>	<u>\$ 159</u>

Total rent expenses for each of the years ended December 31, 2023 and 2022 was \$0.2 million, which includes leases in the table above, month-to-month operating leases, and common area maintenance charges.

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The Company's future minimum annual lease payments under operating leases at December 31, 2023 are as follows (in thousands):

	<u>Operating Leases</u>
2024	146
2025	60
2026	11
Total minimum lease payments	<u>\$ 217</u>
Less: amount representing interest	<u>(12)</u>
Present value of obligations under leases	205
Less: current portion	<u>(120)</u>
Noncurrent lease obligations	<u>\$ 85</u>

### *Services Agreement and Sales Order with Medidata*

On March 31, 2022, the Company and Medidata Solutions, Inc. ("Medidata") entered into a Sales Order (the "Sales Order"), pursuant to which Medidata will build a Synthetic Control Arm® ("SCA") platform that facilitates the use of historical clinical data to incorporate into the Company's Phase 2 clinical trial of rhenium (<sup>186</sup>Re) obisbameda in recurrent glioblastoma ("GBM"). The Sales Order is governed under the terms of a services agreement, dated November 5, 2021. The Sales Order had a term of six months, and work under the Sales Order has been completed.

### *Piramal Master Services Agreement*

On January 8, 2021, the Company entered into a Master Services Agreement (the "MSA") with Piramal Pharma Solutions, Inc. ("Piramal"), for Piramal to perform certain services related to the development, manufacture, and supply of the Company's rhenium (<sup>186</sup>Re) obisbameda-Liposome Intermediate Drug Product. The MSA includes the transfer of analytical methods, development of microbiological methods, process transfer and optimization, intermediate drug product manufacturing, and stability studies for the Company, which has been initiated at Piramal's facility located in Lexington, Kentucky.

The MSA has a term of five years and will automatically renew for successive one-year terms unless either party notifies the other no later than six months prior to the original term or any additional terms of its intention to not renew the MSA. The Company has the right to terminate the MSA for convenience upon thirty days' prior written notice. Either party may terminate the MSA upon an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party.

### *Other Commitments and Contingencies*

The Company has entered into agreements with various research organizations for pre-clinical and clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, recruiting and enrolling patients, monitoring studies and data analysis. Payments under these agreements typically include fees for services and reimbursement of expenses. The timing of payments due under these agreements is estimated based on current study progress. As of December 31, 2023, the Company did not have any clinical research study obligations.

### *Legal proceedings*

On December 9, 2022, the Company entered into a settlement agreement (the "Settlement Agreement") with Lorem Vascular, Pte. Ltd. ("Lorem") to settle a prior litigation matter. Under the terms of the Settlement

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Agreement, the Company made a payment to Lorem, and Lorem moved to dismiss the lawsuit with prejudice. The Settlement Agreement released the Company from all claims made by Lorem. The parties to the Settlement Agreement recognized that it did not constitute an admission of liability, wrongdoing, or any matter of fact or law. The Settlement was conditioned on the customary terms contained in the Settlement Agreement and was approved by the Court and the case was dismissed on January 17, 2023. As of December 31, 2022, the Company accrued the settlement amount, as well as the accounts that the Company has confirmed to be recoverable under its insurance claims on the matter. The net amount of \$1.4 million that was not recoverable under the Company's insurance has been reflected as an expense in the statement of operations for the year ended December 31, 2022. The full settlement amount was paid in January 2023. All legal costs related to the Lorem Claim were expensed as incurred.

The Company is subject to various claims and contingencies related to legal proceedings. Due to their nature, such legal proceedings involve inherent uncertainties including, but not limited to, court rulings, negotiations between affected parties and governmental actions. Management assesses the probability of loss for such contingencies and accrues a liability and/or discloses the relevant circumstances, as appropriate.

### **7. License Agreements**

#### *Biocept License Agreement*

On September 7, 2023, the Company entered into a Non-Exclusive License and Services Agreement (the "Biocept Agreement") with Biocept, Inc ("Biocept"), pursuant to which Biocept granted the Company a non-exclusive license to use the Biocept proprietary cell enumeration test, CNside™. In exchange for the license, the Company issued to Biocept 53,381 unregistered shares, the fair value of which was \$75,000. The Biocept Agreement also provides that if Biocept fully transfers the technology to the Company, a tech transfer and validation fee of \$300,000 will be payable. In addition, the Company was granted an option for an exclusive worldwide license for \$1,000,000 on or before December 31, 2024, to process and perform cell enumeration testing for treatments for other patients including those on the Company's radiotherapeutic drugs.

On October 16, 2023, Biocept filed a voluntary petition for relief under the provisions of Chapter 7 of Title 11 of the United States Bankruptcy Code, making the full transfer of the Biocept technology to the Company unlikely. In addition, the Biocept Agreement is subject to provisions under the Bankruptcy Code.

#### *UT Health Science Center at San Antonio ("UTHSA") License Agreement*

On December 31, 2021, the Company entered into a Patent and Know-How License Agreement (the "UTHSA License Agreement") with UTHSA, pursuant to which UTHSA granted the Company an irrevocable, perpetual, exclusive, fully paid-up license, with the right to sublicense and to make, develop, commercialize and otherwise exploit certain patents, know-how and technology related to the development of biodegradable alginate microspheres (BAM) containing nanoliposomes loaded with imaging and/or therapeutic payloads.

Pursuant to the UTHSA License Agreement, the Company was required to make an upfront payment, which was recorded as in-process research and development acquired in the statement of operations for the year ended December 31, 2021. The upfront payment of \$0.3 million was paid in cash in January 2022.

#### *NanoTx License Agreement*

On March 29, 2020, the Company and NanoTx, Corp. ("NanoTx") entered into a Patent and Know-How License Agreement (the "NanoTx License Agreement"), pursuant to which NanoTx granted the Company an irrevocable, perpetual, exclusive, fully paid-up license, with the right to sublicense and to make, develop, commercialize and otherwise exploit certain patents, know-how and technology related to the development of radiolabeled nanoliposomes.

The transaction terms included an upfront payment of \$0.4 million in cash and \$0.3 million in the Company's voting stock. The transaction terms also included success-based milestone and royalty payments contingent on key clinical, regulatory and sales milestones, as well as the requirement to pay 15% of any non-dilutive monetary awards or grants received from external agencies to support product development of the nanoliposome encapsulated BMEDA-chelated radioisotope, which includes grants from the Cancer Prevention & Research Institute of Texas ("CPRIT"). As of December 31, 2023, the Company accrued \$0.5 million of payments due to NanoTx as a result of the CPRIT grant received (Note 9).

## 8. Term Loan Obligations

On May 29, 2015, the Company entered into the Loan and Security Agreement (the "Loan and Security Agreement"), pursuant to which Oxford Finance, LLC ("Oxford") funded an aggregate principal amount of \$17.7 million (the "Term Loan"), subject to the terms and conditions set forth in the Loan and Security Agreement. The Term Loan accrued interest at a floating rate of at least 8.95% per annum, comprised of a three-month LIBOR rate with a floor of 1.00% plus 7.95%. Pursuant to the Loan and Security Agreement, as amended, the Company was required to make interest only payments through May 1, 2021 and thereafter it was required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through June 1, 2024, the maturity date. At maturity of the Term Loan, or earlier repayment in full following voluntary prepayment or upon acceleration, the Company is required to make a final payment in an aggregate amount equal to approximately \$3.2 million. In connection with the Term Loan, on May 29, 2015, the Company issued to Oxford warrants to purchase an aggregate of 188 shares of the Company's common stock at an exercise price of \$5,175 per share. These warrants became exercisable as of November 30, 2015 and will expire on May 29, 2025 and, following the authoritative accounting guidance, are equity classified and their respective fair value was recorded as a discount to the debt.

The Term Loan was collateralized by a security interest in substantially all of the Company's existing and subsequently acquired assets, including its intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement, as amended. The intellectual property asset collateral would be released upon the Company achieving a certain liquidity level when the total principal outstanding under the Loan and Security Agreement is less than \$3 million. As of December 31, 2023, there was \$0.8 million principal amount outstanding under the Term Loan, excluding the \$3.2 million final payment fee, and the Company was in compliance with all of the debt covenants under the Loan and Security Agreement.

The Company's interest expense for the years ended December 31, 2023 and 2022 was \$0.4 million and \$0.7 million, respectively. Interest expense is calculated using the effective interest method; therefore it is inclusive of non-cash amortization in the amount of \$0.2 million and \$0.4 million for the year ended December 31, 2023 and 2022, respectively, related to the amortization of the debt discount, deferred financing costs, and accretion of final payment.

The Loan and Security Agreement contains customary indemnification obligations and customary events of default, including, among other things, the Company's failure to fulfill certain obligations under the Term Loan, as amended, and the occurrence of a material adverse change, which is defined as a material adverse change in the Company's business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan. In the event of default by the Company or a declaration of material adverse change by its lender, under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Term Loan, which could materially harm the Company's financial condition. As of December 31, 2023, the Company has not received any notification or indication from Oxford to invoke the material adverse change clause.



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Additional information relating to the then-outstanding Term Loan as of December 31, 2023 and 2022 is presented in the following table (in thousands, except interest rate):

### Year ended December 31, 2023

<u>Origination Date</u>	<u>Original Loan Amount</u>	<u>Interest Rate*</u>	<u>Current Monthly Payment**</u>	<u>Amended expiration date</u>	<u>Remaining Principal (Face Value)</u>
May 2015	\$17,700	13.39%	\$ 134	June 1, 2024	\$ 804

### Year ended December 31, 2022

<u>Origination Date</u>	<u>Original Loan Amount</u>	<u>Interest Rate*</u>	<u>Monthly Payment**</u>	<u>Amended expiration date</u>	<u>Remaining Principal (Face Value)</u>
May 2015	\$17,700	8.95%	\$ 134	June 1, 2024	\$ 2,412

\* Three month LIBOR rate with a floor of 1% plus 7.95%

\*\* Monthly payment reflects principal and interest

## **9. Grant Revenue**

On September 19, 2022, the Company entered into the CPRIT Contract, effective as of August 31, 2022, with CPRIT, pursuant to which CPRIT will provide the Company with the CPRIT Grant of up to \$17.6 million over a three-year period to fund the continued development of rhenium (<sup>186</sup>Re) obisbameda (previously known as <sup>186</sup>RNL) for the treatment of patients with leptomeningeal metastases (“LM”). The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of rhenium (<sup>186</sup>Re) obisbameda based on specific dollar thresholds and tiered low single digit royalty rates until CPRIT receives the aggregate amount of 400% of the proceeds awarded under the CPRIT Grant, and certain reporting requirements.

The CPRIT Contract will terminate on August 30, 2025, unless terminated earlier by (a) the mutual written consent of all parties to the CPRIT Contract, (b) CPRIT for an event of default by the Company, (c) CPRIT, if the funds allocated to the CPRIT Grant become legally unavailable during the term of the CPRIT Contract and CPRIT is unable to obtain additional funds for such purposes, and (d) the Company for convenience. CPRIT may require the Company to repay some or all of the disbursed CPRIT Grant proceeds (with interest not to exceed 5% annually) in the event of the early termination of the CPRIT Contract by CPRIT for an event of default by the Company or by the Company for convenience, or if the Company relocates its principal place of business outside of the state of Texas during the CPRIT Contract term or within three years after the final payment of the grant funds.

The Company retains ownership over any intellectual property developed under the contract (each, a “Project Result”). With respect to non-commercial use of any Project Result, the Company granted to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license with right to sublicense any necessary additional intellectual property rights to exploit all Project Results by CPRIT, other governmental entities and agencies of the State of Texas, and private or independent institutions of higher education located in Texas, for education, research and other non-commercial purposes.

The Company determined that the CPRIT Contract is not in the scope of ASC 808, ASC 958-605, or ASC 606. Applying IAS 20 by analogy, the Company recognizes proceeds received under the CPRIT Contract as grant revenue on the statement of operations when related costs are incurred.

During the three months ended June 30, 2023, the Company identified eligible costs of approximately \$637,000 and \$168,000 that were incurred in the fourth quarter of 2022 and the three months ended March 31, 2023, respectively, that were reimbursable under the CPRIT arrangement. The Company determined that these costs should have been recorded in these respective periods as grant revenue. The Company assessed the impact of this error on the Company’s previously issued financial statements and determined that it was immaterial. As a result, an out-of-period adjustment of approximately \$637,000 has been recorded as an increase in grant revenue in the year ended December 31, 2023.

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The Company recognized \$4.9 million and \$0.2 million in grant revenue from the CPRIT Contract during the year ended December 31, 2023 and 2022, respectively.

### 10. Income Taxes

Pursuant to the Internal Revenue Code (“IRC”) of 1986, as amended, specifically IRC §382 (“Section 382”) and IRC §383, the Company’s ability to use net operating loss (“NOLs”) and R&D tax credit carry forwards (“tax attribute carry forwards”) to offset future taxable income is limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company’s use of federal and state NOLs and research credits could be limited further by the provisions of Section 382 depending upon the timing and amount of additional equity securities that the Company has issued or will issue. State NOL carryforwards may be similarly limited. If a change in ownership were to have occurred, NOL and tax credits carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by ownership changes, if any, will not impact the Company’s effective tax rate.

The Company has recorded a full valuation allowance against its net deferred tax assets and due to our net losses for the years ended December 31, 2023 and 2022, there was no provision or benefit for income taxes recorded.

A reconciliation of the total income tax provision tax rate to the statutory federal income tax rates of 21% for the years ended December 31, 2023 and 2022, respectively, is as follows:

	<u>2023</u>	<u>2022</u>
Income tax expense (benefit) at federal statutory rate	(21.0)%	(21.0)%
Change in valuation allowance	25.5%	22.5%
Income tax expense (benefit) at state statutory rate	(0.2)%	(0.2)%
Share based compensation	1.0%	0.9%
NOLs expiring and adjustments to NOL	(0.1)%	0.5%
Research credit	(5.1)%	(2.5)%
Return to provision	(0.1)%	(0.1)%
Change in state rate	—	(0.1)%
	<u>0.0%</u>	<u>0.0%</u>

The tax effects of temporary differences that give rise to significant portions of our deferred tax assets and deferred tax liabilities as of December 31, 2023 and 2022 are as follows (in thousands):

	<u>2023</u>	<u>2022</u>
Deferred tax assets:		
Accrued expenses	\$ 269	\$ 262
Share based compensation	99	107
Net operating loss carryforwards	13,397	12,605
Income tax credit carryforwards	1,630	956
Property and equipment, principally due to differences in depreciation	154	89
Intangible assets	3,527	2,073
Other, net	453	53
	<u>19,529</u>	<u>16,145</u>
Valuation allowance	(19,486)	(16,092)
Total deferred tax assets, net of allowance	<u>43</u>	<u>53</u>

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	<u>2023</u>	<u>2022</u>
Deferred tax liabilities:		
Other	(43)	(53)
Total deferred tax liability	(43)	(53)
Net deferred tax assets (liability)	<u>\$—</u>	<u>\$—</u>

The Company has established a valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets. The Company periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred tax assets are realizable, the valuation allowance will be reduced. The Company has recorded a full valuation allowance of \$19.5 million as of December 31, 2023 as it does not believe it is more likely than not the net deferred tax assets will be realized. The Company increased its valuation allowance by approximately \$3.4 million during the year ended December 31, 2023.

At December 31, 2023, the Company had federal and state tax loss carry forwards of approximately \$63.2 million, and \$2.6 million, respectively. The federal and state net operating loss carry forwards begin to expire in 2037 and 2038, if unused, respectively. The federal net operating loss carryover includes \$59.8 million of net operating losses generated after 2017. Federal net operating losses generated from 2018 onwards carryover indefinitely and may generally be used to offset up to 80% of future taxable income. At December 31, 2023, the Company had federal tax credit carry forwards of approximately \$1.9 million, before reduction for uncertain tax positions. The federal credits will begin to expire in 2039, if unused. In addition, at December 31, 2023, the Company had state tax credit carry forwards of approximately \$0.2 million, before reduction for uncertain tax positions. The state credits will begin to expire in 2043, if unused.

The Company follows the provisions of income tax guidance which provides recognition criteria and a related measurement model for uncertain tax positions taken or expected to be taken in income tax returns. The guidance requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax authorities. Tax positions that meet the more likely than not threshold are then measured using a probability weighted approach recognizing the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company has not recognized any liability for uncertain tax positions as of December 31, 2023 and 2022.

Following is a tabular reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2023 and 2022 (in thousands):

	<u>2023</u>	<u>2022</u>
Unrecognized Tax Benefits – Beginning	\$209	\$ 81
Gross decreases – tax positions in prior period	(16)	(1)
Gross increase – current-period tax positions	215	129
Unrecognized Tax Benefits – Ending	<u>\$408</u>	<u>\$209</u>

The unrecognized tax benefit amounts are reflected in the determination of the Company's deferred tax assets. If recognized, none of these amounts would affect the Company's effective tax rate, since it would be offset by an equal reduction in the deferred tax asset valuation allowance. The Company does not foresee material changes to its liability for uncertain tax benefits within the next twelve months.

The Company did not recognize interest related to unrecognized tax benefits in interest expense and penalties in operating expenses for the year ended December 31, 2023.

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The Company files income tax returns with the United States and various state jurisdictions. To its knowledge, the Company is currently not under examination by the Internal Revenue Service or any other taxing authority.

With few exceptions, the Company's tax years prior to 2020 are no longer open to examination by the taxing authority. While not open to examination, the tax attributes generated in tax years 2018 and forward remain subject to adjustment by the taxing authorities if utilized in tax years which are still open to examination.

### **11. Employee Benefit Plan**

The Company implemented a 401(k) retirement savings and profit sharing plan (the "Plan") effective January 1, 1999. During 2022, the Company commenced safe harbor matching contribution for up to 4% of eligible employee contributions. Total matching contribution under the Plan amounted to approximately \$107,000 and \$100,000 for the year ended December 31, 2023 and 2022, respectively.

### **12. Stockholders' Equity**

#### **Preferred Stock**

The Company has authorized 5,000,000 shares of preferred stock, par value \$0.001 per share. The Board is authorized to designate the terms and conditions of any preferred stock the Company issues without further action by the common stockholders.

#### *Series F Preferred Stock*

On March 3, 2023, the Company filed a certificate of designation (the "Certificate of Designation") with the Secretary of State of the State of Delaware, effective as of the time of filing, designating the rights, preferences, privileges and restrictions of the Series F Preferred Stock, with the total authorization of one (1) share of Series F Preferred Stock. The Certificate of Designation provided that the share of Series F Preferred Stock will have 50,000,000 votes per share of Series F Preferred Stock and will vote together with the Company's common stock, \$0.001 par value (the "Common Stock") as a single class exclusively with respect to any proposal to amend the Company's Charter to effect a reverse stock split of the Common Stock (the "Reverse Stock Split"). On March 3, 2023, the Company entered into a Subscription and Investment Representation Agreement (the "Subscription Agreement") with Richard J. Hawkins, Chairman of the Board, who is an accredited investor (the "Purchaser"), pursuant to which the Company agreed to issue and sell one (1) share of the Company's Series F Preferred Stock, par value \$0.001 per share (the "Preferred Stock"), to the Purchaser for \$1,000 in cash. The sale closed on March 3, 2023.

At the Company's annual meeting of stockholders held on April 20, 2023, the Series F Preferred Stock was voted, without action by the holder, on the proposal to approve the Reverse Stock Split in the same proportion as shares of Common Stock voted to approve the Reverse Stock Split. The Series F Preferred Stock otherwise had no voting rights except as otherwise required by the General Corporation Law of the State of Delaware.

The Series F Preferred Stock was not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The Series F Preferred Stock had no rights with respect to any distribution of assets of the Company, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of the Company, whether voluntarily or involuntarily. The holder of the Series F Preferred Stock was not entitled to receive dividends of any kind.

The outstanding share of Series F Preferred Stock was redeemed in whole, automatically effective upon the approval by the Company's stockholders of a Reverse Stock Split. Upon such redemption, the holder of the Series F Preferred Stock received consideration of \$1,000 in cash.

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### *Series B and C Preferred Stock*

As of December 31, 2023, there were 938 outstanding shares of Series C Preferred Stock that can be converted into an aggregate of 27,792 shares of common stock, and 1,014 shares of Series B Convertible Preferred Stock that can be converted into an aggregate of 398 shares of common stock.

### **Warrants**

On September 25, 2019, the Company completed an underwritten public offering. The Company issued 19,266 shares of its common stock, along with pre-funded warrants to purchase 180,733 shares of its common stock and Series U Warrants to purchase 230,000 shares of its common stock at \$75.00 per share. The Series U Warrants have a term of five years from the issuance date. In addition, the Company issued warrants to H.C. Wainwright & Co., LLC, as representatives of the underwriters, to purchase 5,000 shares of its common stock at \$93.75 per share with a term of 5 years from the issuance date, in the form of Series U Warrants (the “Representative Warrants”).

As of December 31, 2023, there were 142,733 outstanding Series U Warrants which can be exercised into an aggregate of 142,733 shares of common stock at the weighted average exercise price of \$34.10 per share.

### **Common Stock**

On August 2, 2022, the Company entered into a purchase agreement (the “2022 Purchase Agreement”) and registration rights agreement pursuant to which Lincoln Park committed to purchase up to \$50.0 million of the Company’s common stock. Under the terms and subject to the conditions of the 2022 Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$50.0 million of the Company’s common stock. Such sales of common stock by the Company are subject to certain limitations, and can occur from time to time, at the Company’s sole discretion, over the 36-month period commencing on August 17, 2022, subject to the satisfaction of certain conditions. Lincoln Park has no right to require the Company to sell any shares of common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as the Company directs, subject to certain conditions.

On May 16, 2022, the Company received stockholder approval for purposes of the Nasdaq listing rules to permit issuances of up to 57.5 million shares of the Company’s common stock (including the issuance of more than 19.99% of the Company’s common stock) to Lincoln Park, and it was pursuant to that approval that the Company entered into the 2022 Purchase Agreement.

Upon execution of the 2022 Purchase Agreement, the Company paid \$125,000 in cash as the initial commitment fee, and issued 32,846 shares as the initial commitment shares, to Lincoln Park as consideration for its irrevocable commitment to purchase shares of the Company’s common stock at its direction under the Purchase Agreement. The Company has agreed to pay an additional commitment fee, which it may elect to pay in cash and/or shares of its common stock, upon receipt of \$25.0 million aggregate gross proceeds from sales of common stock to Lincoln Park under the 2022 Purchase Agreement.

On August 17, 2022, a registration statement (the “First Registration Statement”) was declared effective to cover the resale of up to 633,333 shares of the Company’s common stock comprised of (i) the 32,846 initial commitment shares, and (ii) up to 600,486 that the Company has reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time from and after the date of the prospectus. The Company sold approximately 527,166 shares under the First Registration Statement.

On August 18, 2023, a second registration statement (the “Second Registration Statement”) was declared effective to cover the resale of up to an additional 1,500,000 shares of the Company’s common stock that the Company reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time.

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We sold 150,000 shares under the Second Registration Statement. The Company cannot sell more shares than registered under the Second Registration Statement under the 2022 Purchase Agreement without registering additional shares.

Actual sales of shares of common stock to Lincoln Park under the 2022 Purchase Agreement depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. The net proceeds under the 2022 Purchase Agreement to the Company depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park.

During the period from August 17, 2022 to December 31, 2022, the Company issued 266,666 shares under the 2022 Purchase Agreement for net proceeds of approximately \$3.2 million. The Company issued 410,500 shares under the 2022 Purchase Agreement for net proceeds of approximately \$1.0 million from January 1, 2023 to December 31, 2023.

On September 30, 2020, the Company entered into a purchase agreement (the “2020 Purchase Agreement”) and registration rights agreement pursuant to which Lincoln Park committed to purchase up to \$25.0 million of the Company’s common stock. Under the terms and subject to the conditions of the 2020 Purchase Agreement, the Company had the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park was obligated to purchase up to \$25.0 million of the Company’s common stock. Such sales of common stock by the Company were subject to certain limitations, and could occur from time to time, at the Company’s sole discretion, over the 36-month period commencing on November 6, 2020, subject to the satisfaction of certain conditions.

During the year ended December 31, 2022, the Company issued 377,666 shares of its common stock under the 2020 Purchase Agreement for net proceeds of approximately \$7.0 million. The Company no longer has any additional shares of common stock registered to sell under the 2020 Purchase Agreement and has terminated the 2020 Purchase Agreement.

### *At-the-market Issuances*

On September 9, 2022, the Company entered into an Equity Distribution Agreement (the “September 2022 Distribution Agreement”) with Canaccord Genuity LLC (“Canaccord”), pursuant to which the Company could issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$5,000,000, depending on market demand, with Canaccord acting as an agent for sales. During the period from September 9, 2022 to December 31, 2022, the Company issued 68,758 shares of its common stock under the September 2022 Distribution Agreement for net proceeds of approximately \$0.6 million. From January 1, 2023 through December 31, 2023, the Company issued 1,819,993 shares under the September 2022 Distribution Agreement for net proceeds of approximately \$4.3 million. The Company has reached the capacity for sales of shares under the September 2022 Distribution Agreement and the agreement has terminated.

The Company was obligated to pay Canaccord a commission of up to 3.0% of the gross proceeds from the sale of its common stock under the September 2022 Distribution Agreement. The Company also agreed to reimburse Canaccord for its reasonable documented out-of-pocket expenses, including fees and disbursements of its counsel, in the amount of \$50,000. In addition, the Company agreed to provide customary indemnification rights to Canaccord.

On January 14, 2022, the Company entered into an Equity Distribution Agreement (the “January 2022 Distribution Agreement”) with Canaccord, pursuant to which the Company could issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$5,000,000, with Canaccord acting as an agent for sales. The Company had no obligation to sell any of the Company’s shares and it could instruct Canaccord not to sell any shares if the sales could not be effected at or above the price designated by the Company from time to time and the Company could at any time suspend sales pursuant to the January 2022 Distribution Agreement. During the year ended December 31, 2022, the Company issued 460,151 shares under

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the January 2022 Distribution Agreement for net proceeds of approximately \$4.8 million. The January 2022 Distribution Agreement has been terminated after all available registered shares were fully utilized.

### *Share Repurchase Program and Treasury Stock*

On October 31, 2023, the Company announced that its Board has approved a share repurchase program (the “Share Repurchase Program”), with authorization to repurchase up to \$500,000 of the outstanding shares of the Company’s common stock. The Company intends to fund any repurchases under the Share Repurchase Program with available cash. The timing and amount of any shares repurchased will be determined based on the Company’s evaluation of market conditions and other factors, including consent of the Company’s lender. Repurchases may be made from time to time on the open market through October 31, 2024.

During the year ended December 31, 2023, the Company purchased 78,559 of its common shares for approximately \$126,000 as treasury stock. During the period January 1, 2024 through February 26, 2024, the Company purchased 168,015 of its common shares for approximately \$340,000 as treasury stock.

### **13. Share-based Compensation**

Under the Company’s 2015 New Employee Incentive Plan (the “2015 Plan”), awards may only be granted to employees who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as a material inducement to entering into employment with the Company. As of December 31, 2023, there were 6,024 shares of common stock remaining and available for future issuances under the 2015 Plan.

The Company’s 2020 Stock Incentive Plan (the “2020 Plan”), which replaced the Company’s 2014 Equity Incentive Plan, provides for the award or sale of shares of common stock (including restricted stock), the award of stock units and stock appreciation rights, and the grant of both incentive stock options to purchase common stock to directors, officers, employees and consultants of the Company. The 2020 Plan, as amended, provides for the issuance of up to 3,550,000 shares of common stock, plus the number of shares available for issuance is increased to the extent that awards granted under the 2020 Plan and the Company’s 2014 Equity Incentive Plan are forfeited or expire (except as otherwise provided in the 2020 Plan). As of December 31, 2023, there were 180,607 shares remaining and available for future issuances under the 2020 Plan.

Generally, options issued under the 2020 Plan are subject to a two-year or four-year vesting schedule with 25% of the options vesting on the one year anniversary of the grant date followed by equal monthly installment vesting, and have a contractual term of 10 years.

A summary of activity for the year ended December 31, 2023 is as follows:

	<u>Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value</u>
Balance as of December 31, 2022	78,334	\$ 68.16	8.00	
Granted	68,422	5.00		
Cancelled/forfeited	(6,647)	283.76		
Balance as of December 31, 2023	<u>140,109</u>	<u>\$ 37.48</u>	<u>8.07</u>	<u>\$ 7,000</u>
Vested and expected to vest at December 31, 2023	<u>133,810</u>	<u>\$ 38.62</u>	<u>8.02</u>	<u>\$ —</u>
Exercisable at December 31, 2023	<u>72,843</u>	<u>\$ 60.17</u>	<u>7.41</u>	<u>\$ 6,000</u>

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The Company settles exercises of stock options with newly issued shares of its common stock. There were no stock options exercised in 2023 or 2022.

The estimated fair value of options, including the effect of estimated forfeitures, is recognized over the requisite service period, which is typically the vesting period of each option. The fair value of each option awarded during the years ended December 31, 2023 and 2022 was estimated on the date of grant using the Black-Scholes-Merton option valuation model based on the following weighted-average assumptions:

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
Expected term	6.0 years	6.0 years
Risk-free interest rate	4.06%	2.83%
Expected volatility	127.0%	123.4%
Dividends	0%	0%
Resulting fair value	\$ 4.47	\$ 7.05

The weighted average risk-free interest rate represents the interest rate for treasury constant maturity instruments published by the Federal Reserve Board. If the term of available treasury constant maturity instruments is not equal to the expected term of an employee option, the Company uses the weighted average of the two Federal Reserve securities closest to the expected term of the employee option.

The dividend yield has been assumed to be zero as the Company (a) has never declared or paid any dividends and (b) does not currently anticipate paying any cash dividends on its outstanding shares of common stock in the foreseeable future.

The following table summarizes share-based compensation recognized during the years ended December 31, 2023 and 2022 in the statement of operations:

	<u>2023</u>	<u>2022</u>
Research and development	\$ 66	\$ 87
General and administrative	503	519
Total share-based compensation	<u>\$569</u>	<u>\$606</u>

As of December 31, 2023, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately \$0.7 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.8 years.



# Plus Therapeutics, Inc.



**Up to 10,774,596 Shares of Common Stock**

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**PROSPECTUS**

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**June 24, 2024**

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