

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

FORM 10-K

(Mark One)

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

For the fiscal year ended

December 31, 2023

OR

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

For the transition period from _____ to _____

Commission file number 001-34375

PLUS THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE

(State or Other Jurisdiction of
Incorporation or Organization)

4200 MARATHON BLVD. SUITE 200, AUSTIN, TX
(Address of principal executive offices)

33-0827593
(I.R.S. Employer
Identification No.)

78756
(Zip Code)

Registrant's telephone number, including area code: (737) 255-7194

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	PSTV	Nasdaq Capital Market

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

None.

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

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

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

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

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

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-Accelerated Filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

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

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

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

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, was \$5.8 million based on the closing sales price of the registrant's common stock on June 30, 2023 as reported on the Nasdaq Capital Market, of \$2.02 per share.

As of February 26, 2024, there were 4,276,082 shares of the registrant's common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

None.

PLUS THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2023
TABLE OF CONTENTS

	<u>Page</u>
PART I	
Item 1. Business	8
Item 1A. Risk Factors	26
Item 1B. Unresolved Staff Comments	50
Item 1C. Cybersecurity	50
Item 2. Properties	51
Item 3. Legal Proceedings	51
Item 4. Mine Safety Disclosures	51
PART II	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	52
Item 6. [Reserved]	52
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	53
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	63
Item 8. Financial Statements and Supplementary Data	64
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	87
Item 9A. Controls and Procedures	87
Item 9B. Other Information	88
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection	88
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	88
Item 11. Executive Compensation	94
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	99

Item 13.	Certain Relationships and Related Transactions, and Director Independence	101
Item 14.	Principal Accounting Fees and Services	102

PART IV

Item 15.	Exhibits, Financial Statement Schedules	104
Item 16.	Form 10-K Summary	104

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain statements that may be deemed “forward-looking statements” within the meaning of U.S. securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate and similar expressions or future conditional verbs such as will, should, would, could or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

These statements include, without limitation, statements about our anticipated expenditures, including research and development, and general and administrative expenses; our strategic collaborations and license agreements, intellectual property, U.S. Food and Drug Administration and European Medicines Agency approvals and interactions and government regulation; the potential size of the market for our product candidates; our research and development efforts; 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; 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; anticipated progress in our current and future clinical trials; plans and strategies to create novel technologies; our IP strategy; competition; future development and/or expansion of our product candidates and therapies in our markets; sources of competition for any of our product candidates; our pipeline; our ability to generate product or development revenue and the sources of such revenue; our ability to obtain and maintain regulatory approvals; expectations as to our future performance; portions of the “Liquidity and Capital Resources” section of this report, including our 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 LLC (“Nasdaq”); our ability to repay or refinance some or all of our outstanding indebtedness and our ability to raise capital in the future; our ability to transfer drug product manufacturing to a contract drug manufacturing organization; potential enhancement of our cash position through development, marketing, and licensing arrangements; and a material security breach or cybersecurity attack affecting our operations and property. The forward-looking statements included in this report are also subject to a number of additional material risks and uncertainties, including but not limited to the risks described under the “Risk Factor Summary” and the “Risk Factors” included below.

We encourage you to read the risks described under “Risk Factors” and elsewhere in this report carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance.

RISK FACTOR SUMMARY

Below is a summary of the principal factors that may affect our business, financial condition, and results of operations. This summary does not address all of the risks that we face. Additional risks not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or results of operations in future periods. Further discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K ("Form 10-K") and our other filings with the SEC.

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.
- The volatility in the global capital markets may negatively impact our ability to obtain additional debt financings and modify our existing debt facilities and may increase the risk of non-compliance with covenants under our existing loan agreement.
- 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 (¹⁸⁶Re) obisbameda and ¹⁸⁸RNL-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 (¹⁸⁶Re) obisbameda and ¹⁸⁸RNL-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 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.

Risks Relating 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 Relating 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.
- 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 charter documents contain anti-takeover provisions.

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

PART I

Item 1. Business

References to “Plus Therapeutics,” the “Company,” “we,” “us” and “our” refer to Plus Therapeutics, Inc. References to “Notes” refer to the Notes to Financial Statements included herein (refer to Item 8).

General

Plus Therapeutics, Inc. 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.

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 (¹⁸⁶Re) obisbameda (formerly, “¹⁸⁶RNL”), 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 (“¹⁸⁸RNL-BAM”) is designed to treat many solid organ cancers including primary and secondary liver cancers by intra-arterial injection.

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, GMP-validated research and development and manufacturing facility in San Antonio, Texas, tailored to produce Current Good Manufacturing Practice (“cGMP”) rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 (¹⁸⁶Re) obisbameda, is a patented radiotherapy potentially useful for patients with CNS and other cancers. Preclinical study data describing the use of rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) obisbameda has been reported to have potential applications for head and neck cancer, ovarian cancer, breast cancer and peritoneal metastases.

The rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 United States Food and Drug Administration (“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 (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 (¹⁸⁶Re) obisbameda used in other clinical development programs, including LM and PBC.

Rhenium (¹⁸⁶Re) obisbameda versus External Beam Radiation Therapy for Recurrent GBM

Rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 (¹⁸⁶Re) obisbameda compared to standard external beam radiotherapy or EBRT include:

- The rhenium (¹⁸⁶Re) obisbameda radiation dose delivered to patients may be up to 20 times greater than what is possible with commonly used external beam radiation therapy (“EBRT”), which, unlike EBRT and proton beam devices, spares normal tissue and the brain from radiation exposure.
- Rhenium (¹⁸⁶Re) obisbameda can be visualized in real-time during administration, possibly giving clinicians better control of radiation dosing, distribution and retention.
- Rhenium (¹⁸⁶Re) obisbameda potentially more effectively treats a bulk tumor and microscopic disease that has already invaded healthy tissue.
- Rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 more than 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}Re) obisbameda is designed for and provides patient tolerability and safety. Though no rhenium (^{186}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}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}Re) obisbameda for the treatment of patients with GBM. In November 2021, the FDA granted Fast Track designation for rhenium (^{186}Re) obisbameda for the treatment of LM.

Rhenium (^{186}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}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}Re) obisbameda dose and will expand exploring higher radiation doses in larger volumes to treat larger tumors. Additionally, two or more rhenium (^{186}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, with the plan to add additional clinical sites to support the trial and 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}Re RNL (Rhenium- ^{186}Re Nanoliposome) (^{186}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 our lead radiotherapeutic, rhenium (^{186}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}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 (¹⁸⁶Re) 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® platform that facilitates the use of historical clinical data to incorporate into our Phase 2 clinical trial of rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 (¹⁸⁶Re) obisbameda for the treatment of LM, 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 (¹⁸⁶Re) 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 I 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 (¹⁸⁶Re) 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 (¹⁸⁶Re) 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.

Interim results showed that a single treatment with rhenium (¹⁸⁶Re) obisbameda showed a consistent decreased cerebrospinal fluid (“CSF”) tumor cell count/ml and was very well tolerated by all LM patients. Rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) obisbameda distribution throughout the subarachnoid space. On October 10, 2023, we announced we had completed Cohort 4 of the ReSPECT-LM Phase 1/2a dose escalation trial.

A single dose of rhenium (¹⁸⁶Re) obisbameda at 6.6 millicurie (“mCi”) in 5.0 mL, in Cohort 1, achieved absorbed doses of 18.7 to 29.0 Gy to the ventricles and cranial subarachnoid spaces, respectively. Cohort 2 has also completed with a 13.2 mCi administered dose in 5ml and was also well tolerated. Cohort 3 enrolled three patients through early April 2023 with a 26.4 mCi administered dose.

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

In November 2023, the FDA granted Orphan Drug designation to rhenium (¹⁸⁶Re) 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 will begin in the first quarter 2024 in our ongoing Phase 1 ReSPECT-LM trial of rhenium (¹⁸⁶Re) obisbameda in patients with LM.

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-IND meeting briefing package in which the FDA stated that we are not required to perform any additional preclinical or toxicology studies.

Since the initial FDA feedback and receiving important adult GBM data and experience with rhenium (¹⁸⁶Re) obisbameda and follow-up communications with the FDA, we plan to submit a pediatric brain tumor investigational new drug application (“IND”) to investigate the use of rhenium (¹⁸⁶Re) 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 progression free survival (“PFS”) of 11 ± 3% and three-year OS of 22% ± 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 ± 5% vs. 57 ± 10%; p = 0.026). Gross total resection compared to subtotal resection was associated with significantly improved OS (five-year OS = 75 ± 5% vs. 54 ± 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 (“UT”) 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, ¹⁸⁸RNL-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 the 2021 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. ¹⁸⁸RNL-BAM is a preclinical investigational drug we intend to further develop and move into clinical trials. Specifically, in 2022 we transferred the ¹⁸⁸RNL-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).

Licensing

On September 7, 2023, we entered into a Non-Exclusive License and Services Agreement (the “Biocept Agreement”) with Biocept, Inc (“Biocept”), pursuant to which Biocept granted us a non-exclusive license to use the Biocept proprietary cell enumeration test, CNside™. In exchange for the license, we 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 us, a tech transfer and validation fee of \$300,000 will be payable. In addition, we were granted an option for an exclusive worldwide license for \$1,000,000 exercisable on or before December 31, 2024, to process and perform cell enumeration testing for treatments for other patients including those on our 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 us unlikely. In addition, the Biocept Agreement is subject to provisions under the Bankruptcy Code.

On December 31, 2021, we entered into a Patent and Technology License Agreement (the “UTHSA License Agreement”) with UTHSA, pursuant to which UTHSA granted us 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 BAM containing nanoliposomes loaded with imaging and/or therapeutic payloads. Therapeutic payloads may include radiotherapeutics, chemotherapeutics, or thermotherapeutics.

The BAM technology is delivered directly into the intra-arterial vascular system via commonly utilized and standard interventional vascular catheters and techniques that allow precise placement into the arterial blood vessels feeding tumors. Once injected, BAM technology provides a potential dual therapeutic delivery—blocking blood flow to the tumors by alginate microsphere tumor capillary embolization with simultaneous delivery of very high doses of cytotoxic compounds including radiation, such as nanoliposome encapsulated bi-functionally chelated Re-188, for an extended time. Weeks later, the delivered BAM are physiologically metabolized allowing excretion from the body. Rhenium-188 is an attractive and ideal therapeutic isotope for this application because of its 16.9 hour half-life, 2.12MEV β -decay and \sim 3.8mm tissue path-length, and simultaneous 155Kev γ -decay that allow simultaneous SPECT/CT imaging with commonly available imaging equipment to easily and non-invasively monitor product administration, delivery and dosimetry absorbed dose evaluation.

We currently anticipate that we will initially focus on developing ^{188}RnL -BAM as a next-generation radioembolization therapy for liver cancer, in which BAM blocks the hepatic artery segments that supply blood to the malignant tumor while also providing ^{188}RnL radiotherapy directly to the tumor and surrounding tissue. According to the American Cancer Society, liver cancer is a rare disease with an increasing annual incidence and five-year overall survival of only 20%. We estimate that the global opportunity for localized embolization, chemoembolization, and radioembolization therapies for primary (hepatocellular carcinoma) and secondary (typically metastatic colorectal cancer, for example) liver cancer is \$1.3 billion.

The financial terms of the exclusive license agreement are primarily success-based with milestone and royalty payments contingent on achieving key clinical, regulatory and sales milestones.

The initial inventions and work behind the licensed patents and technologies were developed and led by William Phillips MD, Professor of Nuclear Medicine, and team at UTHSA. The ^{188}RnL -BAM technology incorporates Rhenium-188, or ^{188}Re , a unique isotope for radiotherapeutic embolization owing to its emission of a high energy (2.12Mev) electron (beta particle, 16.9 hour half-life with a 3.8mm decay path length). ^{188}Re also emits 155kev gamma energy that permits high quality, real-time imaging of the BAM construct delivery localization and confirmation. BAMs are not permanent and are anticipated to degrade over time, allowing restoration of blood flow, decreasing radiation resistance, and allowing for safer physiological clearance of ^{188}Re through the kidneys, which may minimize bone marrow toxicity.

The transaction terms include an upfront payment in cash. We are also required to pay development and sales milestone payments, if achieved, and a tiered single-digit royalty on U.S. and European sales. In addition, we may be obligated to pay an annual maintenance fee beginning in 2024.

On March 29, 2020, we entered into a Patent and Know-How License Agreement (the “NanoTx License Agreement”) with NanoTx, pursuant to which NanoTx granted us 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 our 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 CPRIT.

The licensed NanoTx portfolio benefits from proprietary nanoliposome-encapsulated technology to encapsulate radionuclides allowing direct local delivery for several cancer targets.

The licensed radiolabeled nanoliposome platform was developed by a multi-institutional consortium based in Texas at the Mays Cancer Center / UTHSA MD Anderson Cancer Center led by Dr. Andrew Brenner, MD, PhD, who is the Koltz Chair in Neuro-Oncology Research and Co-Leader of the Experimental and Developmental Therapeutics Program. The technology was previously owned by NanoTx and funded by both the NIH/NCI and CPRIT. There is an active \$3 million award from NIH/NCI which is expected to financially support the continued clinical development of rhenium (^{186}Re) obisbameda for recurrent glioblastoma.

Manufacturing

We have a dedicated nanoparticle research & development facility located in San Antonio, Texas. The facility and processes are designed to comply with cGMP per FDA and the European Medicines Agency (“EMA”) regulations for the manufacture of drug candidates for clinical trials, research, and development. As described below, upon completion of the research and development phase

of a drug candidate, certain parts of the manufacturing processes for such candidate may be transferred to contract manufactures to support clinical trials and commercial release. Upon approval of our drug candidates, we expect our manufacturing capabilities to include validated manufacturing processes for the drug product as well as a quality assurance product release process with the ability to ultimately scale-up the process to meet increasing market demands. We believe our strategic investments in our analytical, development and manufacturing capabilities, including personnel with expertise from drug discovery through drug development, will allow us to advance our product candidates more quickly. Expertise gained in manufacturing our drug products may be applied to other formulations in the future, further leveraging our capabilities. Our San Antonio facility is designed to enable us to develop drug substances, and drug products, in a cost-effective manner while retaining control over the intellectual property, process and timing of development activities. The use of a qualified Contract Drug Manufacturing Organization is entitled to be utilized to perform various manufacturing processes as we deem appropriate to meet our operational objectives. In addition, we have entered into master services agreements (“MSAs”) with third parties, including Piramal Pharma Solutions, Inc. (“Piramal”), ABX Advanced Biochemical Compounds GmbH, IsoTherapeutics Group, LLC, and Radiomedix, Inc. in connection with the development, manufacture, and supply of our rhenium (¹⁸⁶Re) obisbameda drug product.

Competition

Our business is conducted in intensely competitive and highly regulated markets. 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, and resources to devote to, developing drugs, conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercialization.

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 adverse side effects, and convenience of treatment procedures.

Competition for our product candidate, particularly rhenium (¹⁸⁶Re) obisbameda and ¹⁸⁸RNL-BAM may come from a single or combination therapy in the future.

Currently, there are many other entities pursuing drug development programs for the indications we are currently pursuing with our product candidates.

Significant competitors that have reported drug development programs at various clinical stages for the various indications listed include, but are not limited to:

Recurrent Glioblastoma

EnGeneIC, Berg, Istari, AstraZeneca, Novartis, PharmAbcine, Kairos, Midatech, Oncovir, Infuseon, Astellas, NanoPharmaceuticals, Erasca, OX2, Crimson BioPharm, TMUNITY, Pfizer, Arcus, Photolitec, Samus, DNatrix, ImmVira, BerGenBio, Boston Scientific, BeiGene, GSK, Bristol Myers Squibb, Lilly, Sumitomo, QED, Chimerix, Accenda, Oblato, VBI, INIGHTEC, Sonalase, VBL, Medicenna, Mimiva, Carthera, Gilead, CNS Pharmaceuticals, VAXIMM, Incyte, Celularity, Medicinova, Karyopharm, Nerviano Medical Sciences, Merck, Telix, Neonc, Nuvation Bio, Aadi, ERC, Kazia, Xoft, Basilea, Vigo, Biohaven, Bayer, Kintara, and others have reported drug development programs at various clinical stages for recurrent GBM.

Leptomeningeal Metastases

Angiochem, Y-mAbs, Roche, Bristol Myers Squibb, Merck, Kazia, AstraZeneca, Pfizer, Memorial Sloan Kettering, University of Virginia, Wake Forest University, University of Alabama Birmingham, and others have reported drug development programs at various clinical stages for LM.

Pediatric Brain Cancer

AstraZeneca, Bristol Myers Squibb, Chimerix, Celgene, Eli Lilly, Nektar Therapeutics, Istari Oncology, Novartis, NovoCure, Takeda, Y-mAbs, Cellectar, and others have reported drug development programs at various clinical stages for PBC.

Liver Cancer

Boston Scientific, SIR-TEX, Terumo, ABK Biomedical, and others have reported radioembolization therapy product development programs for liver cancer.

Intellectual Property

Our success depends in large part on our ability to protect our proprietary technology, and to operate without infringing on the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success also depends, in part, on our ability to avoid infringing patents issued to others.

We license the proprietary formulation and proprietary methods of manufacture of the nanoliposome-encapsulated radionucleotides, rhenium (^{186}Re) obisbameda and $^{188}\text{RnL-BAM}$ are covered by U.S. Patent No. 7,718,160, (the “160 Patent”) which will expire in December 2026. Patent term extension, codified in 35 U.S.C. §156, provides a means of recapturing time lost during the regulatory approval process. Based upon this regulation, we will apply for patent term extension for the ‘160 Patent for the time equal to the regulatory review period for rhenium (^{186}Re) obisbameda. This has the potential to extend patent coverage for this product for up to another five years. The ‘160 Patent covers rhenium (^{186}Re) obisbameda and $^{188}\text{RnL-BAM}$ and their method of manufacture. The patent family also contains granted patents in Canada (2,490,959), Europe, validated in United Kingdom, France, and Germany (1536843), and Australia (2003241598), which expired in May 2023.

$^{188}\text{RnL-BAM}$ is also covered by U.S. Patent Appl. No. 17/611,929 titled Radiotherapeutic Microspheres, to which we have a license. This application is directed to a method of producing liposome containing alginate microspheres. This application was filed on November 17, 2021, and any patent granted from or claiming priority to it is expected to expire in May 2040, not including any patent term adjustment or patent term extension. The patent family includes issued patents in Japan (7369793) and Singapore (11202112919W) in addition to applications in Canada (3140856) (allowed), Israel (288275), India (202117000000), Mexico (MX/a/2021/014300), Saudi Arabia (521430917), Thailand (2101007246), South Africa (2021/09366), Vietnam (1-2021-08154), Philippines (12021552927), China (202080037924.2), Europe (20809701.4), Brazil (BR112021023449-7), Singapore (10202303608P), Indonesia (P00202111333), Malaysia (PI2021006914), Australia (2020280044), and New Zealand (782354).

$^{188}\text{RnL-BAM}$ is also covered by PCT/US2022/018992 titled Loading Alginate Microspheres, to which we have a license. This application is directed to a method for post-manufacture loading of a liposome-containing hydrogel microsphere. This application was filed March 4, 2022, and any patent granted from applications claiming priority to this application are expected to expire in March 2042. National stage applications were filed in the United States (18/280,427), Australia (2022228358), Canada (3212641), Brazil (112023018053), South Korea (1020230169122), China (117241781), Europe (4301341), Mexico (MX/a/2023/010409), and Israel (305730).

We co-own PCT Application No. PCT/US2021/059969 and U.S. Patent Appl. No. 17/746,853, titled Radiolabeled Liposomes and Methods of Use Thereof, which are directed to methods of treating a disease, including but not limited to cancer, comprising administering ^{186}Re and ^{188}Re nanoliposomes via CED. These applications were filed on November 18, 2021 and May 17, 2022, respectively, and any patents issued from, in the case of the U.S. application, or claiming priority to them are expected to expire in November 2041, not including any patent term adjustment or patent term extension. National stage applications were filed in Australia (2021381376), Brazil (112023009541-7), Canada (3198991), China (2021800909262), Europe (21895620.9), Indonesia (P00202305319), Israel (302964), Japan (2023-553170), South Korea (10-2023-7020403), Malaysia (PI 2023002944), and Mexico (MX/a/2023/005857) in 2023.

We co-own PCT Application No. PCT/US2023/11564, titled Radiolabeled Liposomes and Methods of Use for Treating Leptomeningeal Metastases, which is directed to methods of treating Leptomeningeal Metastases comprising administering ^{186}Re and/or ^{188}Re nanoliposomes via an intraventricular reservoir. This application was filed on January 25, 2023, and any patent issued claiming priority to it is expected to expire in January 2043, not including any patent term adjustment or patent term extension. The 30-month deadline to file national stage applications claiming priority to PCT Application No. PCT/US2023/011564 is July 25, 2024.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. Our nanoparticle oncology drug candidates must receive regulatory approvals from the EMA and the FDA and from other government authorities prior to sale of the product candidates in their respective jurisdictions.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. Manufactures of pharmaceutical products may also be subject to state and local regulation. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as the imposition by the FDA or an institutional review board, or IRB, of a clinical hold, FDA refusal to approve pending new drug applications, or NDAs, or supplements, withdrawal of approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal investigation, penalties, or prosecution.

Product development for a new product or certain changes to an approved product in the United States typically involves:

- Completion of preclinical laboratory studies, formulation studies, and animal studies, some in compliance with the FDA's Good Laboratory Practices, or ("GLP"), regulations, and the Animal Welfare Act administered and enforced by the United States Department of Agriculture;
- Submission to the FDA of an investigational new drug application to support human clinical testing, which must become effective before clinical testing may commence;
- Approval by an institutional review board ("IRB") before each trial may be initiated at each clinical site;
- Performance of adequate and well-controlled clinical trials under protocols submitted to the FDA and reviewed and approved by each IRB, conducted in accordance with federal regulations and current Good Clinical Practices, or GCP, to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought;
- Submission of a New Drug Application ("NDA") to the FDA;
- Satisfactory completion of an FDA Advisory Committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facilities at which the product candidate is produced to assess compliance with current good manufacturing practices, or cGMP, and to assure that the facilities, methods and controls are adequate; and
- FDA review and approval of the NDA.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product candidate. The conduct of some preclinical tests must comply with federal regulations and requirements, including as applicable, GLP and the Animal Welfare Act. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Additional preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational drug product to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Foreign studies conducted under an IND generally must meet the same requirements that apply to studies being conducted in the United States. The informed written consent of each study patient must be obtained before the patient may begin participation in the clinical trial. The study protocol, study plan, and informed consent forms for each clinical trial must be reviewed and approved by an IRB for each clinical site, and the study must be conducted under the auspices of an IRB for each trial site. Investigators and IRBs must also comply with FDA regulations and guidelines, including those regarding oversight of study patient informed consent, complying with the study protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events.

Clinical trials to support drug products for marketing approval are typically conducted in three sequential phases, but the phases may overlap. Phase 1 involves the initial introduction of the drug product into healthy human subjects or patients. In Phase 1 trials, the

product is tested to assess safety, metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimal dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug product. A single Phase 3 trial with other confirmatory evidence may be sufficient in certain instances.

The decision to suspend or terminate development of a product candidate may be made by either a health authority body, such as the FDA, by an IRB, or by a company for various reasons and during any phase of clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. In most cases, in addition to sponsor oversight clinical trials are also overseen by an independent data safety monitoring board, or DSMB, which is a separate, independent group of qualified experts organized by the trial sponsor to evaluate at designated points in time whether or not a trial may move forward and/or should be modified. These decisions are based on unblinded access to data from the ongoing trial and generally involve determinations regarding the benefit-risk ratio for study patients and the scientific integrity and validity of the clinical trial.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

After completion of the required clinical testing, a drug product application is prepared and submitted to the FDA to request marketing approval for the product candidate in specific indications. FDA approval of the drug product is required before marketing of the product may begin in the United States. The drug product must include all relevant results of preclinical, clinical, and other testing and a compilation of data relating to the product candidate's pharmacology, chemistry, manufacture, and controls, including negative or ambiguous results as well as positive findings. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the product candidate to the satisfaction of the FDA. The cost of preparing and submitting a drug product application is substantial. Under the Prescription Drug User Fee Act, or PDUFA, the submission of most drug product applications is subject to a substantial application user fee, and the applicant under an approved drug product is also subject to an annual program fee for each prescription product, subject to certain limited deferrals, waivers and reductions that may be available. These fees are typically increased annually. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may refuse to accept for filing any NDA that it deems incomplete or not properly reviewable at the time of submission, in which case the NDA will have to be updated and resubmitted. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. The FDA's PDUFA review goal is to review 90% of priority applications within six months of filing and 90% of standard applications within 10 months of filing. Priority review may be granted to an application for a product candidate that the FDA determines has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for drug candidates that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug product is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug candidate is safe and effective in the intended indication.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA may issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and deny approval of a resubmitted NDA.

An approval letter authorizes commercial marketing of the drug candidate with specific prescribing information for specific indications. As a condition of approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug candidate outweigh the potential risks. REMS can include medication guides, communication plans for

healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing an NDA.

Expedited Programs

In the United States, a product may be granted Fast Track designation if it is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such condition. With Fast Track designation, the sponsor may be eligible for more frequent opportunities to obtain the FDA's feedback, and the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the remaining information. Even if a product receives Fast Track designation, the designation can be rescinded and provides no assurance that a product will be reviewed or approved more expeditiously than would otherwise have been the case, or that the product will be approved at all.

The FDA may designate a product candidate as a breakthrough therapy if it finds that the product candidate is intended, alone or in combination with one or more other product candidates or approved products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates designated as breakthrough therapies, more frequent interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Product candidates designated as breakthrough therapies by the FDA may also be eligible for six month priority review. The receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for designation.

Accelerated approval under FDA regulations allows a product designed to treat a serious or life-threatening disease or condition that provides a meaningful therapeutic advantage over available therapies to be approved on the basis of either an intermediate clinical endpoint or a surrogate endpoint that is reasonably likely to predict clinical benefit. Approvals of this kind typically include requirements for confirmatory clinical trials to be conducted with due diligence to validate the surrogate endpoint or otherwise confirm clinical benefit and for all promotional materials to be submitted to the FDA for review prior to dissemination.

The FDA may grant priority review to a product candidate, which sets the target date for FDA action on the application at six months from FDA filing, or eight months from the sponsor's submission. Priority Review may be granted where a product is intended to treat a serious or life-threatening disease or condition and, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in safety or efficacy compared to available therapy. If criteria are not met for Priority Review, the standard FDA review period is ten months from FDA filing or 12 months from sponsor submission. Priority Review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drug candidate products intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a product available in the United States for such disease or condition will be recovered from sales of the product in the United States.

After the FDA grants orphan drug designation, the generic identity of the drug product and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. However, orphan drug designation does entitle a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. In addition, if a product

receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for a biologic for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. The FDA can revoke a product's orphan drug exclusivity under certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same biologic for a different disease or condition.

Rare Pediatric Disease Priority Review Voucher Program

Under the Rare Pediatric Disease Priority Review Voucher program, the FDA may grant Rare Pediatric Disease designation for serious and life-threatening diseases that primarily affect children aged 18 years or younger and fewer than 200,000 individuals in the United States. The FDA may award a priority review voucher to the sponsor of an approved marketing application for a product that treats or prevents a Rare Pediatric Disease. The voucher entitles the sponsor to priority review of one subsequent marketing application.

A voucher may be awarded only for an application that:

- is a human drug application for the prevention or treatment of a Rare Pediatric Disease and does not contain an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in any other application;
- FDA deems eligible for priority review;
- is an original NDA or BLA;
- relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population;
- does not seek approval for an adult indication in the original rare pediatric disease product application; and
- is approved after September 30, 2016.

Before NDA or IND approval, the FDA may designate a product in development as a product for a rare pediatric disease, but such designation is not required to receive a voucher.

To receive a rare pediatric disease priority review voucher, a sponsor must notify the FDA, upon submission of the NDA or IND, of its intent to request a voucher. If the FDA determines that the NDA or IND is a rare pediatric disease product application, and if the NDA or IND is approved, the FDA will award the sponsor of the NDA or IND a voucher upon approval of the NDA or IND. The FDA may revoke a rare pediatric disease priority review voucher if the product for which it was awarded is not marketed in the U.S. within 1 year of the product's approval.

The voucher, which is transferable to another sponsor, may be submitted with a subsequent application and entitles the holder to priority review of the application. The sponsor submitting the priority review voucher must notify the FDA of its intent to submit the voucher with the application at least 90 days prior to submission of the application and must pay a priority review user fee in addition to any other required user fee. The FDA must take action on an application under priority review within six months of receipt of the application.

The Rare Pediatric Disease Priority Review Voucher program was renewed as part of the 2021 Coronavirus Response and Relief Supplemental Appropriations Act, allowing a product that is designated as a product for a rare pediatric disease prior to September 30, 2024 to be eligible to receive a rare pediatric disease priority review voucher upon approval of a qualifying NDA after September 30, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of the FDA-regulated products are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, certain NDAs must include an assessment, generally based on clinical trial data, of the safety and effectiveness of the product candidate in relevant pediatric populations. The FDA may waive or defer the requirement for a pediatric assessment, either at a company's request or by its own initiative, including waivers for certain products not likely to be used in a substantial number of pediatric patients. Products with orphan drug designation are exempt from these requirements for orphan-designated indications with no formal waiver process required. Any original NDA submitted on or after August 18, 2020 for a new active ingredient must contain reports on molecularly targeted pediatric cancer investigations, unless the requirement is waived or deferred, if the drug that is the subject of the application is intended for the treatment of an adult cancer and is directed at a molecular target that the FDA has determined is substantially relevant to the growth or progression of a pediatric cancer. This requirement applies even if the adult cancer indication does not occur in the pediatric population, and even if the drug is for an adult indication for which orphan designation has been granted.

Under the Pediatric Research Equity Act, or PREA, certain NDAs must include an assessment, generally based on clinical trial data, of the safety and effectiveness of the product candidate in relevant pediatric populations. The FDA may waive or defer the requirement for a pediatric assessment, either at a company's request or by its own initiative, including waivers for certain products not likely to be used in a substantial number of pediatric patients. Products with orphan drug designation are exempt from these requirements for orphan-designated indications with no formal waiver process required. Any original NDA for a new active ingredient must contain reports on molecularly targeted pediatric cancer investigations, unless the requirement is waived or deferred, if the drug that is the subject of the application is intended for the treatment of an adult cancer and is directed at a molecular target that the FDA has determined is substantially relevant to the growth or progression of a pediatric cancer. This requirement applies even if the adult cancer indication does not occur in the pediatric population, and even if the drug is for an adult indication for which orphan designation has been granted.

Patent Term Restoration

After approval, owners of relevant drug patents may apply for up to a five-year patent extension as compensation for patent term lost during product development and the FDA regulatory review process. The allowable patent term extension is calculated as one half of the drug's testing phase—the time between the effective date of an IND and NDA submission—and all of the review phase—the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Market Exclusivity

In the United States and elsewhere, certain regulatory exclusivities and patent rights can provide an approved drug product with protection from certain competitors' products for a period of time and within a certain scope. In the United States, those protections include regulatory exclusivity under the Hatch-Waxman Act, which provides periods of exclusivity for a branded drug product that would serve as an RLD for a generic drug applicant filing an ANDA under section 505(j) of the FD&C Act or as a listed drug for an applicant filing an NDA under section 505(b)(2) of the FD&C Act. If such a product is a "new chemical entity" ("NCE") generally meaning that the active moiety has never before been approved in any drug, there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification (as described above). Such a product that is not an NCE may qualify for a three-year period of exclusivity if its NDA contains new clinical data (other than bioavailability studies), derived from studies conducted by or for the sponsor, that were necessary for approval. In this instance, the three-year exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. This three-year exclusivity applies only to the conditions of approval that required submission of the clinical data.

Post-Approval Regulation

Once approved, drug products are subject to continuing extensive regulation by the FDA. If ongoing regulatory requirements are not met, or if safety problems occur after a product reaches market, the FDA may take actions to change the conditions under which the product is marketed, such as requiring labeling modifications, restricting distribution, or even withdrawing approval. In addition to FDA regulation, our business is also subject to extensive federal, state, local and foreign regulation.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements, which include requirements regarding organization and training of personnel, building and facilities, equipment, control of components and drug product containers, closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls and records and reports. The FDA inspects equipment, facilities and manufacturing processes before approval and conducts periodic re-inspections after approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. Failure to comply with applicable cGMP requirements or the conditions of the product's approval may lead the FDA to take enforcement actions, such as issuing a warning letter, or to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, imposition of operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor FDA compliance of the third parties on which we rely for manufacturing our product candidates, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP or other applicable FDA regulatory requirements.

Sales and Marketing. Once a product is approved, the advertising, promotion and marketing of the product will be subject to close regulation, including with regard to promotion to healthcare practitioners, direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet. In addition to FDA restrictions on marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry. Failure to comply with applicable requirements in this area may subject a company to adverse publicity, investigations and enforcement action by the FDA, the Department of Justice, the Office of the Inspector General of the Department of Health and Human Services, and/or state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Other Requirements. Companies that manufacture or distribute drug products pursuant to approved NDAs must meet numerous other regulatory requirements, including adverse event reporting, submission of periodic reports, and record-keeping obligations.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act, or ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or

used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus generally non-reimbursable, uses.

HIPAA created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. The reported data are posted in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties. Effective January 1, 2022, we began to be required to report on transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a

formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the E.U., governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

The ACA has substantially changed some aspects of healthcare financing and delivery by both governmental and private insurers. The ACA has affected existing government healthcare programs and resulted in the development of new programs.

Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs, that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP (which cap is now set to be removed effective January 1, 2024, which could increase our rebate liability particularly as we could be subject to an additional rebate in the amount that our AMP has exceeded the pace of inflation, if any);
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B drug discount program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Tax Cuts and Jobs Act was signed into law in December 2017, which eliminated certain requirements of the ACA, including the individual mandate. We cannot predict whether these challenges will continue or whether other proposals will be made or

adopted, or what impact these efforts may have on us. It is possible that the ACA, as currently enacted or may be amended in the future, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. We cannot be sure whether additional legislative changes will be enacted in the United States or outside of the United States, or whether regulatory changes, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

Other legislative changes relating to reimbursement have been adopted in the U.S. since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 (with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic). The law provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year. As long as these cuts remain in effect, they could adversely impact payment for any products we may commercialize in the future. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Additional legislative changes, regulatory changes, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, there has been increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate Program under the ACA. On December 31, 2020, CMS issued a final regulation that modified prior Medicaid Drug Rebate program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements (beginning in 2022); provide definitions for "line extension," "new formulation," and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula (beginning in 2022); and revise best price and average manufacturer price exclusions of manufacturer-sponsored patient benefit programs, specifically regarding applicability of such exclusions in the context of pharmacy benefit manager "accumulator" programs (beginning in 2023).

Federal law also requires that a company that participates in the Medicaid Drug Rebate Program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. For calendar quarters beginning January 1, 2022, manufacturers are required to report the average sales price for certain drugs under the Medicare program regardless of whether they participate in the Medicaid Drug Rebate Program. Manufacturers calculate average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Starting in 2023, manufacturers must pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages, for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount.

Statutory or regulatory changes or CMS guidance could affect the pricing calculations for our approved products, and could negatively impact our results of operations. For example, Congress could enact a Medicare Part B inflation rebate, under which manufacturers would owe additional rebates if the average sales price of a drug were to increase faster than the pace of inflation. In addition, Congress could enact a drug price negotiation program under which the prices for certain high Medicare spend single source drugs would be capped by reference to the non-federal average manufacturer price. This or any other legislative change could impact the market conditions for our products. We further expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the E.U., for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed.

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

To obtain regulatory approval of an investigational drug product under E.U. regulatory systems, we must submit a marketing authorization application. The application used to file the drug product in the United States is similar to that required in the E.U., with the exception of, among other things, country-specific document requirements.

For other countries outside of the E.U., such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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

Employees and Human Capital

As of December 31, 2023, we had 20 full-time employees. Of these full-time employees, ten were engaged in research and development, and ten were engaged in management, finance and administration. From time to time, we also employ independent contractors to support our operations. Our employees are not represented by any collective bargaining agreements and we have never experienced an organized work stoppage.

We believe that we must offer and maintain market competitive compensation and benefit programs for our employees in order to attract and retain qualified personnel. In addition to cash compensation, we provide equity compensation, a company-matched 401(k) Plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and employee assistance programs.

Corporate Information

We were initially formed as a California general partnership in July 1996 and incorporated in the State of Delaware in May 1997. We were formerly known as Cytori Therapeutics, Inc., before that as MacroPore Biosurgery, Inc. and before that as MacroPore, Inc. On July 20, 2019, we changed our name from Cytori Therapeutics, Inc. to Plus Therapeutics, Inc.

Our corporate offices are located at 4200 Marathon Blvd., Suite 200, Austin, TX. Our telephone number is (737) 255-7194. We maintain a website at the following address: www.plustherapeutics.com. The information on the Company's website is not incorporated by reference in this report. We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the Securities and Exchange Commission ("SEC") in accordance with the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q ("Form 10-Q"), and our Current Reports on Form 8-K. We make this information available on our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. In addition, we routinely post on the "Press Releases" page of our website news releases, announcements and other statements about our business and results of operations, some of which may contain information that may be deemed material to investors. Therefore, we encourage investors to monitor the "Press Releases" page of our website and review the information we post on that page.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at the following address: <http://www.sec.gov>.

Item 1A. Risk Factors

The risk factors described below, as well as statements described elsewhere in this Form 10-K, including our audited Financial Statements and the related notes and "Management's Discussion and Analysis of Financial Conditions and Results of Operations," or in other SEC filings, describe risks that could materially and adversely affect our business, financial condition, and results of operations, which could also cause the trading price of our equity securities to decline. These risks are not the only risks that we face. Our business, financial condition and results of operations could also be affected by additional factors that are not presently known to us or that we currently consider to be immaterial to our operations.

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, we incurred net losses of \$13.3 million and our net cash used in operating activities was \$12.9 million. As of December 31, 2023, our accumulated deficit was \$480.5 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 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 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 December 31, 2023, we had an accumulated stockholders' deficit of approximately \$480.5 million, a working capital deficit of approximately \$0.9 million, and approximately \$8.6 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 Form 10-K 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. As a result, we no longer meet the alternative compliance standards of market value of listed securities or net income from continuing operations for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1), which requires listed companies to maintain stockholders' equity of at least \$2.5 million. We expect to receive a written notice from Nasdaq staff indicating that we no longer meet the listing requirement subsequent to filing of this Form 10-K in March 2024, with a period to cure such noncompliance. We intend to evaluate various courses of action to regain compliance with Nasdaq Listing Rule 5550(b)(1) within the compliance period to be specified by Nasdaq. However, there can be no assurance that we will be able to regain compliance within such compliance period or, if we regain compliance, that we will not fall out of compliance with one of Nasdaq's continued listing standards at some future point in time and without raising additional capital it will continue to decline.

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;
- 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 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.

The volatility in the global capital markets may negatively impact our ability to obtain additional debt financings and modify our existing debt facilities and may increase the risk of non-compliance with covenants under our existing loan agreement.

Under the Loan and Security Agreement, dated May 29, 2015 (the “Loan and Security Agreement”), as amended, with Oxford Finance, LLC (“Oxford”), Oxford made a term loan to us in an aggregate principal amount of \$17.7 million (the “Term Loan”) subject to the terms and conditions set forth therein. As of December 31, 2023, the outstanding principal balance of the Term Loan was \$0.8 million. In addition, we are obligated to pay a final payment fee of \$3.2 million at the earlier of the maturity date, acceleration, or payment of the Term Loan.

The Term Loan accrues interest at a floating rate equal to the three-month LIBOR rate (with a floor of 1.00%) plus 7.95% per annum. Beginning November 1, 2021, we began to make payments of principal and accrued interest in equal monthly installments as required, to amortize the Term Loan through June 1, 2024.

As security for our obligations under the Loan and Security Agreement, we granted a security interest in substantially all of our existing and after-acquired assets, excluding our intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement. If we are unable to discharge these obligations, Oxford could foreclose on these assets, which would, at a minimum, have a severe material adverse effect on our ability to operate our business.

Our indebtedness to Oxford could adversely affect our operations and liquidity, by, among other things:

- causing us to use a larger portion of our cash flow to fund interest and principal payments, reducing the availability of cash to fund working capital and capital expenditures and other business activities;
- making it more difficult for us to take advantage of significant business opportunities, such as acquisition opportunities, and to react to changes in market or industry conditions; and
- limiting our ability to borrow additional monies in the future to fund working capital and capital expenditures and for other general corporate purposes.

The Loan and Security Agreement, as amended, includes certain reporting and other covenants, that, among other things, restrict our ability to (i) dispose of assets, (ii) change the business we conduct, (iii) make acquisitions, (iv) engage in mergers or consolidations, (v) incur additional indebtedness, (vi) create liens on assets, (vii) maintain any collateral account, (viii) pay dividends, (ix) make investments, loans or advances, (x) engage in certain transactions with affiliates, and (xi) prepay certain other indebtedness or amend other financing arrangements. If we fail to comply with any of these covenants or restrictions, such failure may result in an event of default, which if not cured or waived, could result in Oxford causing the outstanding loan amount to become immediately due and payable. If the maturity of our indebtedness is accelerated, we may not have, or be able to timely procure, sufficient cash resources to satisfy our debt obligations, and such acceleration would adversely affect our business and financial condition.

The global markets have experienced significant volatility and a continued downturn may affect our business, liquidity position, and financial results. This in turn may negatively impact our ability to remain in compliance with the financial and operating covenants under the Loan and Security Agreement and may restrict our ability to obtain covenant waivers, restructure or amend the terms of our existing debt, or obtain additional debt financing. If the maturity of our indebtedness is accelerated or if we are unable to amend the terms or obtain any necessary waivers under our debt facilities or obtain additional debt or other financing, it would materially and

adversely affect our liquidity position and ability to fund our operations. This in turn would materially harm our business and financial conditions.

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 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.

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.

While we have taken remediation measures, these review processes are too new to be fully tested and therefore we cannot assure investors that these measures will significantly improve or remediate the material weakness described above.

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 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.

Furthermore, if our remediation of the material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

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

Our ability to successfully develop and commercialize rhenium (¹⁸⁶Re) obisbameda and ¹⁸⁸RNL-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 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 (^{186}Re) obisbameda. Under the license agreement with NanoTx, we are required to use commercial reasonable efforts to develop the rhenium (^{186}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 ($^{188}\text{RNL-BAM}$). Under the license agreement with UTHSA, we are required to use commercial reasonable efforts to develop the $^{188}\text{RNL-BAM}$ 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.

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 (¹⁸⁶Re) obisbameda and ¹⁸⁸RNL-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 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 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;
- 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 contract research organization (“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 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 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.

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 ("ANDA") process for generic drugs off patent that allow for bioequivalence to an existing reference listing drug ("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
- 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 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 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 (¹⁸⁶Re) obisbameda for the treatment of patients with GBM. In November 2021, the FDA granted Fast Track designation to rhenium (¹⁸⁶Re) 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 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 ("IT 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 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 (¹⁸⁶Re) obisbameda and ¹⁸⁸RNL-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;
- 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 (“CPPA”). 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.

Risks Relating 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 (^{186}Re) obisbameda and $^{188}\text{RNL-BAM}$, 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;
- 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}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}Re) obisbameda or 188 RNL-BAM;
- the API used in rhenium (^{186}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.

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 used 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.

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 Relating 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 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;
- 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. An active trading market in our common stock may not 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 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 amended and restated certificate of incorporation and amended and restated 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, 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. Furthermore, our Loan and Security Agreement with Oxford currently prohibits our issuance of cash dividends. 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.

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.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Program

We have implemented a cybersecurity program to support both the effectiveness of our systems and our preparedness for information security risks. This program includes a number of safeguards, such as: password protection; multi-factor authentication; monitoring and alerting systems for internal and external threats; and regular evaluations of our cybersecurity program.

We use a risk-based approach with respect to our use and oversight of third-party service providers, tailoring processes according to the nature and sensitivity of the data accessed, processed, or stored by such third-party service provider. We use a number of means to assess cyber risks related to our third-party service providers, including conducting due diligence in connection with onboarding new vendors. We also seek to include appropriate security terms in our contracts, where applicable as part of our oversight of third party providers.

Process for Assessing, Identifying and Managing Material Risks from Cybersecurity Threats

We maintain an incident response program. In the event of a cybersecurity incident, designated personnel are responsible for assessing the severity of an incident and associated threat, containing the threat, remediating the threat, including recovery of data and access to systems, analyzing any reporting obligations associated with the incident, and performing post-incident analysis and program enhancements. We maintain a Data Breach Response Policy, which includes an Incident Response Plan (“IRP”) in the event of a significant cybersecurity incident. In the event of a significant cybersecurity incident, our Chief Financial Officer (“CFO”) will chair an incident response team to handle the incident. Such incident response team will include members of IT, finance (if applicable), legal, communications, human resources and any affected unit or department. IT, along with a designated forensic team, will use the IRP to guide the response.

Governance

Management Oversight

The controls and processes employed to assess, identify and manage material risks from cybersecurity threats are implemented and overseen by our Information Technology and Facilities Director (the “ITFD”). Our ITFD is a third-party consultant, from whom we have a dedicated resource who specializes in the industry, has over 25 years of experience addressing cybersecurity risks. Our ITFD is responsible for the day-to-day management of the cybersecurity program, including the prevention, detection, investigation, response to, and recovery from cybersecurity threats and incidents, and is regularly engaged to help ensure the cybersecurity program functions effectively in the face of evolving cybersecurity threats. Our CFO oversees the ITFD and briefs our Board on cybersecurity matters, including the nature and design of our cybersecurity program, and threats, events, and program enhancements.

Board Oversight

While the Board has overall responsibility for risk oversight, the Board recently delegated to the audit committee of the Board the responsibility for assisting the Board with cybersecurity disclosure matters. In its oversight role, the Board is expected to specifically consider risks that relate to the reputation of the Company and the general industry in which we operate, including with respect to privacy, information technology and cybersecurity and threats to technology infrastructure.

On a regular basis, the CFO reports to the Board on cybersecurity matters, including key risks, the potential impact of those exposures on the Company’s business, financial results, operations and reputation and the programs and steps implemented by management to monitor and mitigate risks.

Cybersecurity Risks

Our cybersecurity risk management processes are integrated into our overall approach to risk management. Given the nature and size of our Company, we do not have a dedicated enterprise risk function, but our executives regularly consider and evaluate risks to our Company. As part of that risk management process, members of our executive team identify, assess and evaluate risks impacting our operations across the Company, including those risks related to cybersecurity, and raise them for discussion with other executives, and where it is determined to be appropriate, issues are also raised to the Board for consideration.

As of the date of this report, we are not aware of any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected our business strategy, results of operations or financial condition or are reasonably

likely to have such a material effect. While we have implemented a cybersecurity program, the techniques used to infiltrate information technology systems continue to evolve. Accordingly, we may not be able to timely detect threats or anticipate and implement adequate security measures. For additional information regarding risks relating to privacy and cybersecurity, see “Item 1A—Risk Factors.”

Item 2. Properties

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, Virginia. We pay an aggregate of approximately \$16,000 in rent per month for these properties.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Prices

Market Information

The Company’s common stock is listed on the Nasdaq Capital Market under the symbol “PSTV.”

As of February 26, 2024, the Company had approximately four record holders of common stock. Because many of the Company’s outstanding shares are held by brokers and other institutions on behalf of stockholders, the Company is unable to estimate the total number of individual stockholders represented by these record holders.

The Company has never paid cash dividends to its stockholders. The Company intends to retain future earnings for use in its business and does not anticipate paying cash dividends on its common stock in the foreseeable future. Any future dividend policy will be determined by the Board and will be based upon various factors, including the Company’s results of operations, financial condition, current and anticipated cash needs, future prospects, contractual restrictions and other factors as the Board may deem relevant.

The information under the subheading “Equity Compensation Plan Information” under Item 12, Part III of this Form 10-K is incorporated herein by reference.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

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 over 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.

The following table presents information with respect to purchases of common stock of the Company during the three months ended December 31, 2023:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs ⁽¹⁾	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
October 1, 2023 - October 31, 2023	—	\$ —	—	—	\$500,000
November 1, 2023 - November 30, 2023	63,154	\$1.59	63,154	251,311	\$399,585
December 1, 2023 - December 31, 2023	15,405	\$1.85	15,405	200,587	\$371,086
Total	78,559	\$1.72	78,559	200,587	\$371,086

Item 6. [Reserved]

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

Our Management’s Discussion and Analysis of Financial Condition and Results of Operations includes the following sections:

- Overview that discusses our business.
- Results of Operations that includes a discussion of our revenue and expenses.
- Liquidity and Capital Resources that discusses key aspects of our statements of cash flows, changes in our financial position and our financial commitments.

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}Re) obisbameda (formerly, “ ^{186}RNL ”), 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.

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, GMP-validated research and development and manufacturing facility in San Antonio, Texas, tailored to produce Current Good Manufacturing Practice (“cGMP”) rhenium (^{186}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}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}Re) obisbameda, is a patented radiotherapy potentially useful for patients with CNS and other cancers. Preclinical study data describing the use of rhenium (^{186}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}Re) obisbameda has been reported to have potential applications for head and neck cancer, ovarian cancer, breast cancer and peritoneal metastases.

The rhenium (^{186}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}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 (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 (¹⁸⁶Re) obisbameda used in other clinical development programs, including LM and PBC.

Rhenium (¹⁸⁶Re) obisbameda versus External Beam Radiation Therapy for Recurrent GBM

Rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 (¹⁸⁶Re) obisbameda compared to standard external beam radiotherapy or EBRT include:

- The rhenium (186Re) obisbameda radiation dose delivered to patients may be up to 20 times greater than what is possible with commonly used external beam radiation therapy (“EBRT”), which, unlike EBRT and proton beam devices, spares normal tissue and the brain from radiation exposure.
- Rhenium (186Re) obisbameda can be visualized in real-time during administration, possibly giving clinicians better control of radiation dosing, distribution and retention.
- Rhenium (186Re) obisbameda potentially more effectively treats a bulk tumor and microscopic disease that has already invaded healthy tissue.
- Rhenium (186Re) 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 (186Re) 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 more than 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 (¹⁸⁶Re) obisbameda is designed for and provides patient tolerability and safety. Though no rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 (¹⁸⁶Re) obisbameda for the treatment of patients with GBM. In November 2021, the FDA granted Fast Track designation for rhenium (¹⁸⁶Re) obisbameda for the treatment of LM.

Rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 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 (¹⁸⁶Re) obisbameda dose and will expand exploring higher radiation doses in larger volumes to treat larger tumors. Additionally, two or more rhenium (¹⁸⁶Re) 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, with the plan to add additional clinical sites to support the trial and 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 ¹⁸⁶RNL (Rhenium-186 Nanoliposome) (¹⁸⁶Re) 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 our lead radiotherapeutic, rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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}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® platform that facilitates the use of historical clinical data to incorporate into our Phase 2 clinical trial of rhenium (^{186}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}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}Re) obisbameda for the treatment of LM, 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}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}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}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.

Interim results showed that a single treatment with rhenium (^{186}Re) obisbameda showed a consistent decreased cerebrospinal fluid (“CSF”) tumor cell count/ml and was very well tolerated by all LM patients. Rhenium (^{186}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}Re) obisbameda distribution throughout the subarachnoid space. On October 10, 2023, we announced we had completed Cohort 4 of the ReSPECT-LM Phase 1/2a dose escalation trial.

A single dose of rhenium (^{186}Re) obisbameda at 6.6 millicurie (“mCi”) in 5.0 mL, in Cohort 1, achieved absorbed doses of 18.7 to 29.0 Gy to the ventricles and cranial subarachnoid spaces, respectively. Cohort 2 has also completed with a 13.2 mCi administered dose in 5ml and was also well tolerated. Cohort 3 enrolled three patients through early April 2023 with a 26.4 mCi administered dose.

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

In November 2023, the FDA granted Orphan Drug designation to rhenium (^{186}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 will begin in the first quarter 2024 in our ongoing Phase 1 ReSPECT-LM trial of rhenium (^{186}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-IND meeting briefing package in which the FDA stated that we are not required to perform any additional preclinical or toxicology studies.

Since the initial FDA feedback and receiving important adult GBM data and experience with rhenium (¹⁸⁶Re) obisbameda and follow-up communications with the FDA, we plan to submit a pediatric brain tumor IND to investigate the use of rhenium (¹⁸⁶Re) 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 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, ¹⁸⁸RNL-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 the recent 2021 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. ¹⁸⁸RNL-BAM is a preclinical investigational drug we intend to further develop and move into clinical trials. Specifically, in 2022 we transferred the ¹⁸⁸RNL-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

Biocept License Agreement

On September 7, 2023, we entered into a Non-Exclusive License and Services Agreement (the “Biocept Agreement”) with Biocept, Inc (“Biocept”), pursuant to which Biocept granted us a non-exclusive license to use the Biocept proprietary cell enumeration test, CNside™. In exchange for the license, we 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 us, a tech transfer and validation fee of \$300,000 will be payable. In addition, we were granted an option for an exclusive worldwide license for \$1,000,000 exercisable on or before December 31, 2024, to process and perform cell enumeration testing for treatments for other patients including those on our 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 us unlikely. In addition, the Biocept Agreement is subject to provisions under the Bankruptcy Code.

Recent Financings

Refer to the “Liquidly and Capital Resources” section below for information on our recent financings.

Results of Operations

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 a grant of up to \$17.6 million (the “CPRIT Grant”) over a three-year period to fund the continued development of rhenium (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 (¹⁸⁶Re) 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.

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 (¹⁸⁶Re) 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 (¹⁸⁶Re) 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	\$ 8,544	\$ 10,238

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.

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	\$ 569	\$ 606

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	\$ 5	\$ (563)

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.

We expect interest expense in 2024 to decrease as compared with 2023 as the term loan matures on June 1, 2024.

Liquidity and Capital Resources

The Company has funded its research and development activities through raising capital by issuing securities and receipt of research grants. As of December 31, 2023, the Company had approximately \$8.6 million in cash and cash equivalents.

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at December 31, 2023 and 2022 (in thousands):

	As of December 31,	
	2023	2022
Cash and cash equivalents	\$ 8,554	\$ 18,120
Current assets	\$ 9,834	\$ 21,817
Current liabilities	10,727	11,852
Working capital (deficit)	\$ (893)	\$ 9,965

We incurred net losses of \$13.3 million for year ended December 31, 2023. We have an accumulated deficit of \$480.5 million as of December 31, 2023. Additionally, we used net cash of \$12.9 million to fund our operating activities for the year ended December 31, 2023. These factors raise substantial doubt about our ability to continue as a going concern.

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 our Term Loan with Oxford and grant funding. We have had, and will continue to have, an ongoing need to raise additional cash from outside sources to fund our future clinical development programs and other operations. There can be no assurance that we will be able to continue to raise additional capital in the future. Our inability to raise additional cash would have a material and adverse impact on our operations and would cause us to default on our Term Loan.

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 (¹⁸⁶Re) obisbameda for the treatment of patients with LM. 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 (186Re) 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.

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 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 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 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. 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 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 Purchase Agreement.

On August 17, 2022, a registration statement (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 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, 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 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.

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.

Based on our stockholders’ deficit of \$1.3 million as of December 31, 2023, we do not meet the minimum stockholders’ equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1). We expect to receive written notice from Nasdaq staff to that effect following the filing of this Form 10-K.

We continue 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 for research, sales and marketing efforts and product development activities at their current levels. If sufficient capital is not raised, we will at a minimum need to significantly reduce or curtail our research and development and other operations, and this would negatively affect our ability to achieve corporate growth goals.

Should we be unable to raise additional cash from outside sources, this would have a material adverse impact on our operations.

The accompanying financial statements have been prepared assuming we 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 year ended December 31, 2023 and 2022 is summarized as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Net cash used in operating activities	\$ (12,851)	\$ (12,972)
Net cash used in investing activities	(160)	(759)
Net cash provided by financing activities	3,445	13,451
Net decrease in cash and cash equivalents	\$ (9,566)	\$ (280)

Material Cash Obligations

Under the CPRIT Contract we receive matching funds for approximately two-thirds of the development costs for the development of rhenium (¹⁸⁶Re) 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.

Under our Term Loan with Oxford, we have ongoing principal and interest payment obligations and are required to make a final payment at maturity that in the aggregate will require approximately \$4.0 million by June 1, 2024 (See Note 5 of the accompanying financial statements for more information). 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 December 31, 2023. Refer to Note 6 of our Consolidated Financial Statements for further details on our lease obligations. In addition, we have no off-balance sheet arrangements (as defined in the rules and regulations of the SEC) 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 year ended December 31, 2023 was \$12.9 million compared to \$13.0 million in the same period of 2022. Overall, our operational cash use decreased slightly by \$0.1 million during the year ended December 31, 2023 as compared to the same period in 2022, due primarily to a reduction in net loss of \$6.9 million, offset by a net change in non cash charges of \$0.1 million, and a net change of operating assets and liabilities of \$6.7 million.

Investing activities

Net cash used in investing activities for the year ended December 31, 2023 was related to purchases of fixed assets of \$0.2 million. Net cash used in investing activities for year ended December 31, 2022 was primarily related to cash payments of \$0.5 million made for purchases of fixed assets and intangible assets, and \$0.3 million paid for in-process research and development.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was primarily related to the net proceeds from sales of common stock of \$5.2 million pursuant to the September 2022 Distribution Agreement with Canaccord and the 2022 Purchase Agreement with Lincoln Park, offset by \$1.6 million of principal repayment under our Term Loan, and \$0.1 million payment to purchase our common stock.

Net cash provided by financing activities for year ended December 31, 2022 was primarily related to sales of common stock of \$15.1 million, net of offering cost through the Purchase Agreements with Lincoln Park and the Distribution Agreements with Canaccord, offset by principal repayment of the Oxford Term Loan of \$1.6 million.

Critical Accounting 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, revenue, and expenses, and that affect our recognition and disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates and judgments, including those related to impairment assessment of our grants and awards, indefinite lived intangible assets, and share-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The following listing is not intended to be a comprehensive list of all of our accounting policies. Our significant accounting policies are described in Note 2 to our financial statements contained elsewhere in this Form 10-K. In many cases, the accounting treatment of a particular transaction is dictated by U.S. GAAP, with no need for our judgment in its application. There are also areas in which our judgment in selecting an available alternative would not produce a materially different result. We have identified the following as our critical accounting policies.

Grants and Awards

In applying the provisions of Accounting Standards Codification (“ASC”) Topic 606, Revenue from Contracts with Customers (“ASC 606”), we have 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 we do not consider there to be a transfer of control of goods or services. With respect to the grant, we evaluate if it has a collaboration in accordance with ASC Topic 808, Collaborative Arrangements (“ASC 808”). For grants outside the scope of ASC 808, we apply International Accounting Standards No. 20 (“IAS 20”), Accounting for Government Grants and Disclosure of Government Assistance, by analogy, and revenue is recognized when we incur expenses related to the grant for the amount we are entitled to under the provisions of the contract.

We also consider the guidance in ASC Topic 730, Research and Development, which requires an assessment, at the inception of the grant, of whether the agreement is a liability. If we are obligated to repay funds received regardless of the outcome of the related research and development activities, then we are required to estimate and recognize that liability. Alternatively, if we are 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.

Impairment of Goodwill

We perform our goodwill impairment analysis at the reporting unit level. For the years ended December 31, 2023 and 2022, our company has one reporting unit. We perform our annual impairment analysis by either doing a qualitative assessment of a reporting unit's fair value from the last quantitative assessment to determine if there is potential impairment, or comparing a reporting unit's estimated fair value to its carrying amount. If a quantitative assessment is performed the evaluation includes management estimates of cash flow projections based on internal future projections and/or use of a market approach by looking at market values of comparable companies. Our market capitalization is also considered as a part of this analysis.

In accordance with our accounting policy, we completed the annual evaluation for impairment of goodwill as of December 31, 2023 using the qualitative method and determined that no impairment existed.

Share-based Compensation

Compensation expense related to stock options granted is measured at the grant date based on the estimated fair value of the award and is recognized on an accelerated attribution method over the requisite service period. We determine the estimated fair value of each stock option on the date of grant using the Black-Scholes valuation model which uses assumptions regarding a number of complex and subjective variables. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. Expected volatility is based on an analysis of the historical volatility of our common stock. The expected term represents the period that we expect our stock options to be outstanding. The expected term assumption is estimated using the simplified method set forth in the SEC's Staff Accounting Bulletin 110, which is the mid-point between the option vesting date and the expiration date. We have never declared or paid dividends on our common stock and have no plans to do so in the foreseeable future. Changes in these assumptions may lead to variability with respect to the amount of stock compensation expense we recognize related to stock options.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

	<u>Page</u>
<u>Report of BDO USA, P.C., Independent Registered Public Accounting Firm (BDO USA, P.C.; Austin, TX; PCAOB ID#243)</u>	65
<u>Balance Sheets as of December 31, 2023 and 2022</u>	67
<u>Statements of Operations for the years ended December 31, 2023 and 2022</u>	68
<u>Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2023 and 2022</u>	69
<u>Statements of Cash Flows for the years ended December 31, 2023 and 2022</u>	70
<u>Notes to Financial Statements</u>	71

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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, 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 (¹⁸⁶Re) 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
Assets		
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	\$ 11,388	\$ 23,867
Liabilities and Stockholders' Equity (Deficit)		
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)	\$ 11,388	\$ 23,867

See Accompanying Notes to these Financial Statements

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

	For the Years Ended December 31,	
	2023	2022
Grant revenue	\$ 4,913	\$ 224
Operating expenses:		
Research and development	9,690	9,698
General and administrative	8,544	10,238
Total operating expenses	18,234	19,936
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)	5	(563)
Net loss	\$ (13,316)	\$ (20,275)
Net loss per share, basic and diluted	\$ (4.24)	\$ (11.58)
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	\$ —	\$ 473,628	\$ (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)
Net loss	—	—	—	—	—	—	—	—	(13,316)	(13,316)
Balance at December 31, 2023	—	\$ —	1,952	\$ —	4,522,656	5	(78,559)	\$ 479,274	\$ (480,501)	\$ (1,348)

See Accompanying Notes to these Financial Statements

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

	For the Years Ended December 31,	
	2023	2022
Cash flows used in operating activities:		
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>
Cash flows used in investing activities:		
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>
Cash flows from financing activities:		
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>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 222	\$ 327
Supplemental schedule of non-cash investing and financing activities:		
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 (the "Charter") 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, 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.

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 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	311,032	249,282

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
	\$ 1,280	\$ 3,697

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
	3,442	3,284
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 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.

The Company's future minimum annual lease payments under operating leases at December 31, 2023 are as follows (in thousands):

	Operating Leases
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 (¹⁸⁶Re) 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 (¹⁸⁶Re) 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 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.

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 (¹⁸⁶Re) obisbameda (previously known as ¹⁸⁶RNL) 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 (¹⁸⁶Re) 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.

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>
Deferred tax liabilities:		
Other	(43)	(53)
Total deferred tax liability	<u>(43)</u>	<u>(53)</u>
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.

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.

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. 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 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:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
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	140,109	\$ 37.48	8.07	\$ 7,000
Vested and expected to vest at December 31, 2023	133,810	\$ 38.62	8.02	\$ -
Exercisable at December 31, 2023	72,843	\$ 60.17	7.41	\$ 6,000

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:

	December 31, 2023	December 31, 2022
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>Years ended December 31,</u>	
	<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.

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

None.

Item 9A. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or furnished pursuant to the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal accounting officer and principal financial officer), as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer), of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Form 10-K. Based on the foregoing, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer) concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective at the reasonable assurance level due to a material weakness in our internal control over the application of appropriate accounting principles to significant and unusual grant revenue transactions as of December 31, 2023, as described below.

We previously reported on our Form 10-Q for the quarter ended June 30, 2023, that the Company did not design and maintain effective internal controls over the application of 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 represented 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.

Based on this evaluation, our principal executive officers and principal financial and accounting officers have concluded that as a result of the material weakness in our internal control over financial reporting, our disclosure controls and procedures were not effective as of December 31, 2023.

Notwithstanding the identified material weakness described above, our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer and principal accounting officer) believe the financial statements included in Form 10-K for the year ended December 31, 2023 fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP.

Material Weakness Remediation Plan

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. However, these review processes are relatively new to be fully tested and we cannot assure investors that these measures will significantly improve or remediate the material weakness described above.

(b) *Management's Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Securities Exchange Act as a process designed by, or under the supervision of, our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer) and effected by our Board, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and our Board; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have conducted an evaluation of the effectiveness of our internal control over financial reporting as of the end of the fiscal year covered by this Form 10-K based on the criteria set forth in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation, management concluded that our internal control over financial reporting was not effective as of December 31, 2023 based on the COSO criteria due to the material weakness identified as discussed above.

This report does not include an attestation report on internal control over financial reporting by the Company's independent registered public accounting firm since the Company is a smaller reporting company under the rules of the SEC.

(c) *Changes in Internal Control over Financial Reporting*

Except with respect to the changes in connection with the implementation of the steps to remediate the material weakness described above, there has been no change in our internal control over financial reporting during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

- (a) None.
- (b) None.
- (c) Insider Trading Arrangements

For the quarter ended December 31, 2023, none of the Company's directors or officers (as defined under SEC Rule 16a-1(f)) adopted, modified or terminated any contract, instruction or written plan for the purchase or sale of Company securities intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any 'non-Rule 10b5-1 trading arrangement' as defined under Item 408(c) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors

The following table sets forth the name, age, and committee appointments of each of our current directors as of December 31, 2023. Board term for board members listed below expire at the 2024 Annual Meeting of the Company.

Name	Age	Position with the Company and Principal Occupation
Howard Clowes	70	Non-Executive Director
An van Es-Johansson, M.D.	63	Non-Executive Director
Richard J. Hawkins	74	Chairman, Non-Executive Director
Marc H. Hedrick, M.D.	61	President, Chief Executive Officer and Director
Robert Lenk, PhD	75	Non-Executive Director
Greg Petersen	60	Non-Executive Director
Andrew Sims	51	Chief Financial Officer
Norman LaFrance, M.D.	76	Chief Medical Officer

Our Board is composed of a diverse group of professionals in their respective fields. Many of the current directors have or have held senior leadership experience at major domestic and international companies. In these positions, they have also gained experience in core management skills, such as strategic and financial planning, public company financial reporting, compliance, risk management, leadership development, and international business experience. Most of our directors also have experience serving on boards of directors and board committees of other public companies in the pharmaceutical industry, and have an understanding of corporate governance practices and trends, different business processes, challenges, and strategies. Further, our directors also have other experience that makes them valuable members, such as medical knowledge and research experience, which provides insight into strategic and operational issues faced by us.

The nominating and corporate governance committee and the Board believe that the above-mentioned attributes, along with the leadership skills and other experiences of our Board members described below, provide us with a diverse range of perspectives and judgment necessary to guide our strategies and monitor their execution.

Non-Employee Directors

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, 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.

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.

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.

Robert Lenk. 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.

Executive Officers

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.

Norman LaFrance, M.D. Dr. LaFrance joined us as Chief Medical Officer in November 2021. Prior to joining the Company, Dr. LaFrance served as Chief Medical Officer and Senior Vice President at Jubilant Pharma Ltd. from 2012 to 2022 where he was responsible for all Pharma Medical & Regulatory Affairs activities. Dr. LaFrance has spent more than four decades in the pharmaceutical and healthcare industry, academia and medical practice. His background includes strategic planning and management of pharmaceutical development for approval by the FDA as well as clinical and academic experience. In addition, Dr. LaFrance

practiced medicine for 10 years and held academic faculty appointments at Johns Hopkins University School of Medicine in the Departments of Medicine and Radiology and the Department of Radiological Sciences in the Johns Hopkins School of Hygiene and Public Health. He is double board certified in internal medicine and nuclear medicine. He is a graduate of the medical school at the University of Arizona and received his Bachelor of Science and Master of Engineering degrees in Nuclear Engineering and Science from Rensselaer Polytechnic Institute.

Term of Office

Our directors are elected for a term of one year and until their respective successors are elected and qualified, or until their earlier resignation, disqualification, or removal. Our executive officers are appointed by our Board and hold office for such terms as may be prescribed by our Board and until their successors are appointed, or until their earlier resignation or removal.

Involvement in Certain Legal Proceedings

None of our directors or executive officers have been involved in any events during the past ten years that would require disclosure under Item 401(f) of Regulation S-K.

Family Relationships

There are no family relationships among any of the directors or executive officers.

Independent Chairman

Our Board appointed Mr. Hawkins to serve as our independent Chairman of our Board in January 2018. As Chairman of our Board, Mr. Hawkins presides over meetings of our independent directors without management present. Mr. Hawkins also performs such additional duties as our Board may otherwise determine and delegate. Mr. Hawkins is an independent director and satisfies the independence requirements under Nasdaq listing standards.

Composition of Our Board

Our Board may establish the authorized number of directors from time to time by resolution. Our Board currently consists of six members.

No stockholder has any special rights regarding the election or designation of members of our Board. There is no contractual arrangement by which any of our directors are appointed to our Board. Our current directors will continue to serve as directors until our 2024 annual meeting of stockholders and until their successor is duly elected, or if sooner, until their earlier death, resignation, or removal.

Our Board held six meetings during 2023. No member of our Board attended fewer than 75% of the aggregate of (a) the total number of meetings of the Board (held during the period for which he or she was a director) and (b) the total number of meetings held by all committees of the Board on which such director served (held during the period that such director served). Members of our Board are invited and encouraged to attend our annual meeting of stockholders. In 2023, all members of our Board attended our annual meeting of stockholders.

Executive Sessions of Independent Directors

In order to promote open discussion among non-management directors, and as required under applicable Nasdaq rules, our Board conducts executive sessions of non-management directors during each regularly scheduled Board meeting and at such other times if requested by a non-management director. In 2023, the non-management directors met in executive session at least twice. The non-management directors provide feedback to executive management, as needed, promptly after the executive session. Mr. Hedrick does not participate in such sessions. As Chairman of our Board, Mr. Hawkins presides over meetings of our independent directors without management present.

Committees of Our Board

Our Board has established an audit committee, a compensation committee, and a nominating and corporate governance committee. The composition and responsibilities of each of these committees of our Board are described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Our Board may have or establish other committees as it deems necessary or appropriate from time to time. The composition and functioning of all of our committees comply with all applicable requirements of the Sarbanes-Oxley Act, Nasdaq and SEC rules and regulations.

Each committee has adopted a written charter, which is available on our website at <https://ir.plustherapeutics.com/governance/board-committees>. As of the date of this Form 10-K, the composition of our audit, compensation, and nominating and corporate governance committees were as follows:

Director	Independent	Compensation Committee	Audit Committee	Nominating and Corporate Governance Committee
An van Es-Johansson, MD	X		Member	Chairperson
Howard Clowes	X	Chairperson	Member	Member
Robert Lenk, PHD	X			Member
Greg Petersen	X	Member	Chairperson	

Audit Committee

Our audit committee currently consists of Mr. Clowes, Dr. van Es-Johansson and the audit committee chair, Mr. Petersen. The Board has determined that all members of the audit committee satisfied, the independence requirements under Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. The Board has determined that Mr. Petersen is an “audit committee financial expert” within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the Board has examined each audit committee member’s scope of experience and the nature of their employment. No member of the audit committee simultaneously serves on the audit committees of more than three public companies. During 2023, the audit committee met four times.

The primary purpose of the audit committee is to discharge the responsibilities of our Board with respect to our corporate accounting and financial reporting processes, systems of internal control, and financial-statement audits, and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- 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;
- 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 “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.

Compensation Committee

Our compensation committee consists of Mr. Clowes and Mr. Petersen, each of whom our Board has determined is independent under Nasdaq listing standards and a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act. During 2023, the compensation committee met two times.

The primary purpose of our compensation committee is to discharge the responsibilities of our Board in overseeing our compensation policies, plans, and programs for directors and employees and to review and determine the compensation to be paid to our executive officers and other senior management, as appropriate.

Specific responsibilities of our compensation committee include:

- 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.

See the sections titled “Item 11. Executive Compensation-Compensation Discussion and Analysis” and “- Director Compensation” for a description of our processes and procedures for the consideration and determination of executive officer and director compensation.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Mr. Clowes, Dr. Lenk, and Dr. van Es-Johansson, each of whom our Board has determined is independent under the Nasdaq listing standards, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment. The chair of our nominating and corporate governance committee is Dr. van Es-Johansson. During 2023, the nominating and corporate governance committee met two times.

Specific responsibilities of our nominating and corporate governance committee include:

- analyzing the expertise and experience of the Board and ensuring the membership of the Board consists of persons with sufficiently diverse and independent backgrounds;
- identifying, recruiting, evaluating and recommending to the Board individuals qualified to become members of the Board;
- reviewing the Board committee structure and recommending to the Board changes to such structure;
- reviewing and reassessing the adequacy of our Corporate Governance Guidelines and recommending any proposed changes;
- overseeing the annual self-evaluations of the Board and Board committees;
- reviewing and discussing with management disclosures in our annual proxy statement regarding director independence; and
- overseeing succession planning and processes for our Chief Executive Officer.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and 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 Business Conduct and Ethics has been posted on our website at 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 www.plustherapeutics.com. To date, there have been no waivers under our Code of Business Conduct and Ethics.

Hedging and Pledging Prohibition

Under our Insider Trading and Communications Policy, our directors, officers, employees, consultants and contractors (and each such individual’s family members, other members of a person’s household and entities controlled by a person covered by this policy, as described in the policy) are prohibited from engaging in the following transactions at any time: (i) engaging in short sales of our securities; (ii) trading in put options, call options or other derivative securities involving our securities on an exchange or in any other organized market; (iii) engaging in hedging or monetization transactions involving our securities, including through the use of

financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds; and (iv) holding our securities in a margin account or otherwise pledging our securities as collateral for loan.

Corporate Governance Guidelines

The Board has adopted Corporate Governance Guidelines, which addresses matters such as the Board's responsibilities and duties and the Board's composition and compensation. The Corporate Governance Guidelines are available on our website at <https://ir.plustherapeutics.com/governance/corporate-governance-materials>.

Stockholder Recommendation and Nominees

The nominating and corporate governance committee and our Board will review and evaluate candidates proposed by stockholders. The nominating and corporate governance committee and our Board will apply the same criteria, and follow substantially the same process in considering the candidates, as they do in considering other candidates. The factors generally considered by the nominating and corporate governance committee and our Board are set out in our Corporate Governance Guidelines, which are available on our website at <https://ir.plustherapeutics.com/governance/corporate-governance-materials>.

If a stockholder who is eligible to vote at the 2024 annual meeting of stockholders wishes to nominate a candidate to be considered for election as a director, it must comply with the procedures set forth in our Bylaws and give timely notice of the nomination in writing to our Secretary. Stockholder recommendations must include the following information to be considered by our governance and nominating committee: (a) all information relating to such recommended candidate as would be required to be disclosed for a director nominee pursuant to Regulation 14A under the Exchange (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected) and as required for stockholder nominations of director candidates pursuant to the Company's Amended and Restated Bylaws; (b) the names and addresses of the stockholders making the recommendation and the number of shares of the Company's common stock which are owned beneficially and of record by such stockholders; and (c) other appropriate biographical information and a statement as to the qualification of the nominee. There are no pre-established qualifications, qualities or skills at this time that any particular director nominee must possess and nominees are not discriminated against on the basis of race, religion, national origin, sexual orientation, disability or any other basis proscribed by law.

Stockholder recommendations to our Board should be sent to: Email stockholderrecommendations@plustherapeutics.com.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers and directors to file initial reports of ownership and reports of changes in ownership with the SEC and to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of the copies of such reports filed with the SEC and written representations from the reporting person that no other reports were required during the fiscal year ended December 31, 2023, all Section 16(a) filing requirements during that fiscal year were met, other than one Form 4 for Dr. Marc Hedrick that was not timely filed with respect to inadvertent trades made by Dr. Hedrick's custodian without authorization.

Item 11. Executive Compensation.

Our named executive officers ("NEOs"), which consist of our chief executive officer and the two other most highly compensated executive officers who were serving at the end of 2023, are:

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

Investors are encouraged to read the compensation discussion below in conjunction with the compensation tables and related notes, which include more detailed information about the compensation of our NEOs for 2023 and 2022.

2023 Summary Compensation Table

The table below summarizes the total compensation earned by each NEO in fiscal years ended December 31, 2023 and 2022.

NEO	Year	Salary (\$)	Option Awards (\$ (1))	Non-Equity Incentive Plan Compensation (\$ (2))	All Other Compensation (\$ (3))	Total (\$)
Marc H. Hedrick, M.D. <i>President and Chief Executive Officer</i>	2023	556,400	188,692	336,622	52,313	1,134,027
	2022	535,000	—	361,928	57,723	954,651
Andrew Sims <i>Chief Financial Officer</i>	2023	355,000	40,722	125,803	17,706	539,231
	2022	305,000	—	125,164	16,012	446,176
Norman LaFrance, M.D. <i>Chief Medical Officer</i>	2023	440,000	29,244	161,700	44,321	675,265
	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 this Form 10-K for the year ended December 31, 2023.

(2) The amounts in this column represent annual performance-based bonuses for 2023 and 2022.

(3) This column includes standard benefits which are 401K match, and health and life insurance premiums.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

On May 13, 2020 we entered into Amended and Restated Executive Employment Agreements with each of Dr. Hedrick (the “Hedrick Employment Agreement”) and Mr. Sims (the “Sims Employment Agreement”). On September 7, 2021, we entered into an Executive Employment Agreement with Dr. LaFrance, which was amended on November 8, 2021 (the “LaFrance Employment Agreement” and, together with the Hedrick Employment Agreement and the Sims Employment Agreement, the “Executive Employment Agreements”). The Executive Employment Agreements generally provide 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. Dr. Hedrick is also eligible for certain severance payments as described further below under “Additional Narrative Disclosure: Termination Based-Compensation” below.

Compensation Committee

The compensation committee operates in accordance with the compensation committee charter (the “Compensation Committee Charter”). The Compensation Committee Charter outlines responsibilities and duties of the members, sets forth the frequency of meetings, establishes and reviews the overall compensation policies and practices of the Company and also sets forth the process to review and approve the executive compensation program for the Chief Executive Officer and other executive officers, and make appropriate recommendations to the Board.

The compensation committee approves or makes recommendations to our Board on decisions concerning compensation of the executive management team and Board on a periodic basis to ensure that it is consistent with our short-term and long-term goals. The compensation committee assess the appropriateness of the nature and amount of compensation of our executives by reference to relevant employment market conditions with the overall objective of ensuring maximum stakeholder benefit from the recruitment and retention of a high-quality board and executive team.

Additionally, the compensation committee is responsible for evaluating the performance of the Company’s key senior executives. The Company’s Chief Executive Officer and other members of management regularly discuss the Company’s compensation issues with compensation committee members. The compensation committee reviews and recommends to the Board the overall bonus and equity incentive awards for employees of the Company. Additionally, the Company’s Chief Executive Officer makes recommendations to the compensation committee for review, modification (if applicable) and approval in relation to bonuses and equity incentive awards for members of the executive management team.

Compensation Setting Process

In the process of determining compensation for our NEOs, the compensation committee considers the current financial position of the Company, the strategic goals of the Company, and the performance of each of our NEOs. The compensation committee retained Larry Setren & Associates in December 2022 and Anderson Pay Advisors in January 2023, to perform an independent compensation review and to provide compensation research, analysis and recommendations. In addition, from time to time, the compensation committee considers the various components (described below) of our compensation program for executives in relation to compensation

paid by other public companies, compensation data from Radford Global Life Sciences Survey, their historical review of all executive officer compensation, and recommendations from our Chief Executive Officer (other than for his own compensation). The compensation committee has the sole authority to select, compensate and terminate its external advisors.

The compensation committee utilizes the following components of compensation (described further below) to strike an appropriate balance between promoting sustainable and excellent performance and discouraging any excessive risk-taking behavior:

- Base salary;
- Annual bonuses;
- Annual long-term equity compensation;
- Personal benefits and perquisites; and
- Acceleration and severance agreements tied to changes in control of the Company.

Base Salaries

For the Company's 2023 fiscal year, the annual base salaries for Dr. Hedrick, Mr. Sims and Dr. LaFrance were \$556,400, \$355,000 and \$440,000, respectively.

Annual Bonuses

Target bonuses are reviewed annually and established as a percentage of the executives' base salaries, generally based upon seniority of the officer and targeted at or near the median of the peer group and relevant survey data (including the Radford Global Life Sciences Survey). Each year, the compensation committee establishes corporate objectives related to the Company's clinical, financial and operational goals and sets each executive's respective bonus target percentages, taking into account recommendations from our Chief Executive Officer as it relates to individual objectives for executive positions other than the Chief Executive Officer. Our Chief Executive Officer's target bonus is set by the compensation committee to align entirely with our overall corporate objectives. Our other NEOs have additional individual goals the attainment of which comprises a specified percentage of their total bonus compensation. After each fiscal year-end, our Chief Executive Officer provides the compensation committee with a written evaluation showing actual performance as compared to corporate and/or individual objectives, and the compensation committee uses that information, along with the overall corporate performance, to determine what percentage of each executive's bonus target will be paid out as a bonus for that year. Overall, the compensation committee seeks to establish the corporate and individual functional goals to be challenging yet attainable, and stretch goals that are highly challenging.

Dr. Hedrick's target bonus for the Company's 2023 and 2022 fiscal years as a percentage of base salary was 55%. Mr. Sims' and Dr. LaFrance's target bonus for the Company's 2023 and 2022 fiscal years as a percentage of base salary was 35%.

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%. As our Chief Executive Officer's bonus is based exclusively on attainment of our corporate goals, Dr. Hedrick received \$336,622 or 110% of his target cash bonus. Based upon the attainment of 110% of the corporate goals, and (i) upon an attainment of 75% of his individual goals, our Chief Financial Officer, Mr. Sims, received \$125,803, or 101% of his target cash bonus; and (ii) upon an attainment of 100% of his individual goals, our Chief Medical Officer, Dr. LaFrance, received \$161,700, or 105% of his target cash bonus.

Long-Term Equity Compensation

We designed our long-term equity grant program to further align the interests of our executives with those of our stockholders and to reward the executives' longer-term performance. Historically, the compensation committee has granted stock options, although from time-to-time, to further increase the emphasis on compensation tied to performance, the compensation committee may grant other equity awards as allowed by the 2020 Stock Incentive Plan based on its judgment as to whether the complete compensation packages to our executives, including prior equity awards, are appropriate and sufficient to retain and incentivize the executives and whether the grants balance long-term versus short-term compensation. The compensation committee also considers our overall performance as well as the individual performance of each of our NEOs, the potential dilutive effect of restricted stock awards, the dilutive and overhang effect of the equity awards, and recommendations from the Chief Executive Officer (other than with respect to his own equity awards).

Stock options are granted with an exercise price equal to the fair market value of our common stock on the date of grant.

For the year ended December 31, 2023, our Chief Executive Officer was awarded stock options covering a total of 6,720 shares, our Chief Financial Officer was awarded stock options covering a total of 1,451 shares and our Chief Medical Officer was issued a stock option covering 1,047 shares. There were no new stock options awarded to our NEOs in 2022. You can find more information on the stock options granted to our Named Executive Officers below under “Outstanding Equity Awards at December 31, 2023.”

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. In keeping with our philosophy to provide total compensation that is competitive within our industry, we offer limited personal benefits and perquisites to executive officers. You can find more information on the amounts paid for these perquisites to or on behalf of our NEOs in our 2023 Summary Compensation Table.

Outstanding Equity Awards at December 31, 2023

The following table sets forth information regarding outstanding equity awards held by our NEOs as of December 31, 2023.

Name	Option Grant Date (1)	Number of Securities Underlying Unexercised Options (#) Exercisable (3)	Number of Securities Underlying Unexercised Unearned Options (#) Unexercisable (2)(3)	Option Exercise Price (\$ (3))	Option Expiration Date
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. 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, 1/4th of the shares subject to the award vest on the one-year anniversary of the vesting start date, while an additional 1/36th 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, 1/48th 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.

Potential Payments upon Termination or Change-in-control

Pursuant to the terms of the Executive Employment Agreements, if one of our NEOs is terminated without “cause” or resigns for “good reason,” (a “Severance Termination”), then such NEO 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 NEO 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 NEO’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 and LaFrance, 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 NEO 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 NEO 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 or Dr. LaFrance, 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 or Dr. LaFrance, the amount of the COBRA payment will be increased to 18 months; (iv) the acceleration of such NEO’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 NEO’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 NEOs remain employed by the Company as of the closing of such change in control, all of such NEO’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 NEOs that would provide additional compensation in connection with a retirement.

Director Compensation

The following table summarizes director compensation awarded to, earned by or paid to our non-employee directors who served on our Board during fiscal year 2023:

Non-Executive Director Name (1)	Fees Earned or Paid in Cash (2) (\$)	Option Awards (\$ (3)	Total (\$)
Richard J. Hawkins, Chairman	95,000	7,874	102,874
Howard Clowes	67,500	7,874	75,374
An van Es-Johansson	57,500	7,874	65,374
Robert Lenk	45,000	7,874	52,874
Greg Petersen	72,500	7,874	80,374

- (1) Dr. Hedrick is not included in this table as he is our chief executive officer and receives no extra compensation for his service as a director. The compensation received by Dr. Hedrick in his capacity as our chief executive officer is set forth in the 2023 Summary Compensation Table and further described in the "Narrative Disclosures to Summary Compensation Table."
- (2) Amounts are composed of the following: \$40,000 for fees as a Board member, \$37,500 for Chairman of the Board, \$27,500 for audit committee chairman, \$15,000 for compensation committee chairman, \$10,000 for nominating and corporate governance chairman, \$5,000 for compensation committee, nominating and corporate governance and audit committee members, and additional \$2,500 for audit committee member.
- (3) 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.

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

Equity Compensation Plan Information

The following table gives information as of December 31, 2023 about shares of our common stock that may be issued upon the exercise of outstanding options, and shares remaining available for issuance under all of our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted- average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders	10,675	\$ 170.12	6,024
Equity compensation plans not approved by security holders	129,434	26.54	180,607
Total	140,109	\$ 196.66	186,631

- (1) Represents (i) options outstanding that were issued under the 2004 Stock Option and Stock Purchase Plan which expired in August 2004 and (ii) the 2015 New Employee Incentive Plan.

(2) See Notes to the Financial Statements included elsewhere herein for a description of our 2020 Stock Incentive Plan.

Material Features of the Amended and Restated 2015 New Employment Incentive Plan and the 2020 Stock Incentive Plan

We adopted the 2015 Plan on December 29, 2015 pursuant to Rule 5653(c)(4) of the Nasdaq. The 2015 Plan was subsequently amended by the Board in May 2016 and January 2020.

Awards granted under the 2015 Plan were intended to constitute “employment inducement awards” under Nasdaq Listing Rule 5635(c)(4) and, therefore, the 2015 Plan was intended to be exempt from the Nasdaq Listing Rules regarding stockholder approval of stock option and stock purchase plans. The 2015 Plan provides for the grant of restricted stock unit awards, restricted stock awards, performance awards, unrestricted securities, stock-equivalent units, stock appreciation units, securities or debentures convertible into common stock or other forms. These awards may be granted to individuals who were then new employees, or were commencing employment with us or one of our subsidiaries following a bona fide period of non-employment with us, and for whom such awards were granted as a material inducement to commencing employment with us or one of our subsidiaries.

The 2015 Plan is administered by the compensation committee. The plan administrator has discretion to take action under the 2015 Plan, such as determining the purchase price, performance measures, any repurchase rights, as well as make adjustment to the terms of any Award to reflect, or related to, such changes in our capital structure or distributions as we deem appropriate, including modification of performance goals, performance award formulas, and performance periods. As of December 31, 2023, there were 6,024 shares of common stock remaining and available for issuance under the 2015 Plan.

On June 16, 2020, our stockholders approved our 2020 Plan, which replaced the Company’s 2014 Equity Incentive Plan. The 2020 Plan, as amended, provides for the issuance of up to 4,550,000 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 2014 Equity Incentive Plan are forfeited or expire (except as otherwise provided in the 2020 Plan).

The 2020 Plan provides for the direct 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 intended to qualify for preferential tax treatment under Section 422 of the Code and nonstatutory stock options to purchase common stock that do not qualify for such treatment under the Code. All employees (including officers) and directors of the Company or any subsidiary and any consultant who performs services for us or a subsidiary are eligible to purchase shares of common stock and to receive awards of shares or grants of nonstatutory stock options, stock units and stock appreciation rights. Only employees are eligible to receive grants of incentive stock options.

The 2020 Plan is administered by the compensation committee. Subject to the limitations set forth in the 2020 Plan, the compensation committee has the authority to determine, among other things, to whom awards will be granted, the number of shares subject to awards, the term during which an option, stock unit or stock appreciation right may be exercised and the rate at which the awards may vest or be earned, including any performance criteria to which they may be subject. The compensation committee also has the authority to determine the consideration and methodology of payment for awards.

The additional information required by this item will be set forth under the caption “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation — Equity Compensation Plan Information” in the Proxy Statement and is incorporated herein by reference

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership of our common stock as of December 31, 2023 (or earlier date for information based on filings with the SEC) by (a) each person known to us to own more than 5% of the outstanding shares of our common stock, (b) each director, (c) our named executive officers and (e) all current directors and executive officers as a group.

We believe, based on information provided to us or based on filings with the SEC, 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 beneficial ownership percentages set forth in the table below are based on 4,444,097 shares of our common stock were outstanding as of December 31, 2023.

Name and Address of Beneficial Owner (1)	Number of Shares of Common Stock Owned(2)	Number of Shares of Common Stock Subject to Awards/Warrants Exercisable Within 60 Days of December 31, 2023(3)	Total Number of Shares of Common Stock Beneficially Owned(4)(5)	Percent Ownership
Greater than 5% Stockholders				
None	—	—	—	— %
Directors and Named Executive Officers				
Marc H. Hedrick, M.D.	170	30,282	30,452	0.67 %
Andrew Sims	815	11,849	12,664	0.28 %
Norman LaFrance, M.D.	—	5,757	5,757	0.13 %
Howard Clowes	11,693	4,436	16,129	0.36 %
An van Es-Johansson	—	4,436	4,436	0.10 %
Richard J. Hawkins	1	6,813	6,814	0.15 %
Greg Petersen	24,166	4,436	28,602	0.63 %
Robert P. Lenk	25,160	4,436	29,596	0.65 %
All current executive officers and directors as a group (8 persons)	62,005	72,445	134,450	2.97 %

(1) Unless otherwise indicated, the address of each of the individuals is c/o Plus Therapeutics, Inc., 4200 Marathon Blvd. Suite 200, Austin, TX 78756.

(2) Unless otherwise indicated, represents shares of outstanding common stock owned by the named parties as of December 31, 2023.

(3) Shares of common stock subject to stock options or warrants currently exercisable or exercisable within 60 days of December 31, 2023 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.

(4) The amounts and percentages of common stock beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a “beneficial owner” of a security if that person has or shares “voting power,” which includes the power to vote or to direct the voting of such security, or “investment power,” which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities for which that person has a right to acquire beneficial ownership within 60 days.

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

Director Independence

The Board has unanimously determined that Mr. Clowes, Dr. van Es-Johansson, Mr. Hawkins, Dr. Lenk and Mr. Petersen are “independent” under the applicable standards of Nasdaq and the SEC.

Dr. Hedrick has served as the Company’s President and Chief Executive Officer since 2004 and 2014, respectively, and therefore is not an independent Director.

All of the directors who serve as members of the audit committee, the compensation committee and the governance and nominating committee are independent under our independence standards, Nasdaq listing standards and the applicable rules of the SEC.

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 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, which 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 the 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 will approve only those transactions that it determines are fair to us and in our best interests.

In 2023, there has not been, nor is there currently proposed, any related person transaction in which the Company or any of its subsidiaries was a participant, the amount involved exceeded or will exceed \$120,000 and in which any related person had or will have a direct or indirect material interest.

Item 14. Principal Accounting Fees and Services.

The following table summarizes the aggregate fees for professional services provided by BDO USA, P.C. and their respective affiliates (collectively, “BDO”):

	Fiscal Year Ended December 31, 2023	Fiscal Year Ended December 31, 2022
Audit Fees (1)	\$ 398,000	\$ 343,000
Audit Related Fees (2)	—	—
Tax Fees (3)	41,900	39,000
Total	<u>\$ 439,900</u>	<u>\$ 382,000</u>

- (1) Audit fees consist of fees for professional services performed by BDO for the audit of the financial statements included in our Form 10-K, the reviews of the financial statements included in our Form 10-Q, the reviews of registration statements and issuances of consents, and services that are normally provided in connection with statutory and regulatory filings or engagements.
- (2) Audit related fees consist of fees for assurance and related services, performed by BDO that are reasonably related to the performance of the audit or review of our financial statements.
- (3) Tax fees consist of fees for professional services performed by BDO with respect to tax compliance, tax advice, tax consulting and tax planning.

Our audit committee charter, which is available on our website at <https://ir.plustherapeutics.com/governance/board-committees>, requires the audit committee to pre-approve all audit and non-audit services to be provided by our independent registered public accounting firm in accordance with the charter of the audit committee. All services reported in the Audit, Audit-Related and Tax fees categories above were approved by the audit committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) (1) Financial Statements.

The responses to this portion of Item 15 are set forth under Part II, Item 8 above. The following documents statements are filed as part of this report:

Balance Sheets — December 31, 2023 and 2022
Statements of Operations — December 31, 2023 and 2022
Statements of Stockholders' Equity (Deficit) — December 31, 2023 and 2022
Statements of Cash Flows — December 31, 2023 and 2022
Notes to Financial Statements
Report of Independent Registered Public Accounting Firm

(a) (2) Financial Statement Schedules.

None.

(a) (3) Exhibits.

List of Exhibits required by Item 601 of Regulation S-K. See Item 15(b) below.

(b) Exhibits.

The exhibits listed in the accompanying "Exhibit Index" are filed, furnished or incorporated by reference as part of this Annual Report, as indicated.

Item 16. Form 10-K Summary.

None.

**EXHIBIT INDEX
PLUS THERAPEUTICS, INC.**

Exhibit Number	Exhibit Title	Filed with this Form 10-K	Form	Incorporated by Reference	
				File No.	Date Filed
3.1	<u>Composite Certificate of Incorporation.</u>		10-K	001-34375 Exhibit 3.1	03/11/2016
3.2	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation.</u>		8-K	001-34375 Exhibit 3.1	05/10/2016
3.3	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation.</u>		8-K	001-34375 Exhibit 3.1	05/23/2018
3.4	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation.</u>		8-K	001-34375 Exhibit 3.1	07/29/2019
3.5	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation.</u>		8-K	001-34375 Exhibit 3.1	08/06/2019
3.6	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation.</u>		8-K	001-34375 Exhibit 3.1	4/28/2023
3.7	<u>Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.</u>		8-K	001-34375 Exhibit 3.1	11/28/2017
3.8	<u>Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock.</u>		8-K	001-34375 Exhibit 3.1	07/25/2018
3.9	<u>Certificate of Designation of Series F Convertible Preferred Stock</u>		8-K	001-34375 Exhibit 3.1	03/03/2023
3.10	<u>Amended and Restated Bylaws of Plus Therapeutics, Inc.</u>		8-K	001-34375 Exhibit 3.2	09/21/2021
4.1	<u>Description of Securities.</u>		10-K	001-34375 Exhibit 4.1	03/30/2020
4.2	<u>Form of Common Stock Certificate.</u>		10-K	001-34375 Exhibit 4.33	03/09/2018
4.3	<u>Form of Series U Warrant.</u>		S-1/A	333-229485 Exhibit 4.37	09/16/2019
4.4	<u>Form of Warrant Amendment Agreement.</u>		8-K	011-34375 Exhibit 4.1	04/23/2020
4.5	<u>Form of Underwriters' Warrant Amendment Agreement.</u>		8-K	011-34375 Exhibit 4.1	10/05/2020
10.1+	<u>Patent and Know-How License Agreement, dated March 29, 2020, by and between Plus Therapeutics, Inc. and NanoTx, Corp.</u>		8-K	011-34375 Exhibit 10.1	3/30/2020
10.2+	<u>Patent & Technology License Agreement, dated December 31, 2021, by and between Plus Therapeutics, Inc. and the University of Texas Health Science Center at San Antonio.</u>		10-K	011-34375 Exhibit 10.2	2/24/2022
10.3	<u>Equity Distribution Agreement, dated September 9, 2022, by and between Plus Therapeutics, Inc. and Canaccord Genuity LLC.</u>		8-K	011-34375 Exhibit 1.1	09/09/2022
10.4	<u>Purchase Agreement, dated August 2, 2022, by and between Lincoln Park Capital Fund, LLC and Plus Therapeutics, Inc.</u>		8-K	011-34375 Exhibit 10.1	08/08/2022
10.5	<u>Registration Rights Agreement, dated August 2, 2022, by and between Plus Therapeutics, Inc. and Lincoln Park Capital Fund.</u>		8-K	001-34375 Exhibit 10.2	08/08/2022
10.6	<u>Loan and Security Agreement, dated May 29, 2015, by and among Plus Therapeutics, Inc. Oxford Finance, LLC, and lenders listed thereof.</u>		10-Q	001-34375 Exhibit 10.4	08/10/2015

10.7	First Amendment to Loan and Security Agreement, dated September 20, 2017, by and among Plus Therapeutics, Inc., Oxford Finance, LLC and lenders listed thereof.	S-1/A	333-219967 Exhibit 10.45	10/03/2017
10.8	Second Amendment to Loan and Security Agreement, dated June 19, 2018, by and among Plus Therapeutics, Inc., Oxford Finance, LLC and lenders listed thereof.	10-Q	001-34375 Exhibit 10.3	08/14/2018
10.9	Third Amendment to Loan and Security Agreement, dated August 31, 2018, by and among Plus Therapeutics, Inc., Oxford Finance, LLC and lenders listed thereof.	S-1	333-227485 Exhibit 10.51	09/21/2018
10.10	Fourth Amendment to Loan and Security Agreement, dated December 31, 2018, by and among Plus Therapeutics, Inc., Oxford Finance, LLC and lenders listed thereof.	S-1	333-229485 Exhibit 10.52	02/01/2019
10.11	Fifth Amendment to Loan and Security Agreement, dated January 31, 2019, by and among Plus Therapeutics, Inc., Oxford Finance, LLC and lenders listed thereof.	10-K	001-34375 Exhibit 10.55	03/29/2019
10.12	Sixth Amendment to Loan and Security Agreement, dated February 28, 2019, by and among Plus Therapeutics, Inc., Oxford Finance, LLC and lenders listed thereof.	10-K	001-34375 Exhibit 10.56	03/29/2019
10.13	Seventh Amendment to Loan and Security Agreement, dated April 24, 2019, by and among Plus Therapeutics, Inc., Oxford Finance, LLC and lenders listed thereof.	10-Q	001-34375 Exhibit 10.3	05/14/2019
10.14	Eight Amendment to Loan and Security Agreement, dated July 15, 2019, by and among Plus Therapeutics, Inc., Oxford Finance, LLC, and lenders listed thereof.	10-Q	001-34375 Exhibit 10.2	08/15/2019
10.15+	Ninth Amendment to Loan and Security Agreement, dated March 29, 2020, by and among Plus Therapeutics, Inc., Oxford Finance, LLC and lenders listed thereof.	8-K	011-34375 Exhibit 10.2	3/30/2020
10.16	Ten Amendment to Loan and Security Agreement, dated June 28, 2023, by and among Plus Therapeutics, Inc., Oxford Finance, LLC and lenders listed thereof.	X		
10.17#	Amended and Restated Employment Agreement, dated March 11, 2020, by and between Marc Hedrick and Plus Therapeutics, Inc.	10-Q	001-34375 Exhibit 10.6	5/16/2020
10.18#	Amended and Restated Employment Agreement, dated March 11, 2020, by and between Andrew Sims and Plus Therapeutics, Inc.	10-Q	001-34375 Exhibit 10.7	5/16/2020
10.19#	Employment Agreement, dated December 8, 2021, by and between Plus Therapeutics, Inc. and Normal LaFrance	8-K	001-34375 Exhibit 10.1	09/13/2021
10.20#	2015 New Employee Incentive Plan.	8-K	001-34375 Exhibit 10.1	01/05/2016
10.21#	First Amendment to the Plus Therapeutics, Inc. 2015 New Employee Incentive Plan, dated January 26, 2017.	10-K	001-34375 Exhibit 10.42	03/24/2017
10.22#	Second Amendment to the Plus Therapeutics, Inc. 2015 New Employee Incentive Plan, dated February 6, 2020.	10-K	001-34375 Exhibit 10.25	03/30/2020
10.23#	Form of Notice of Grant of Stock Option under the 2015 New Employee Incentive Plan.	S-8	333-210211 Exhibit 99.5	03/15/2016
10.24#	Form of Stock Option Agreement under the 2015 New Employee Incentive Plan.	S-8	333-210211 Exhibit 99.4	03/15/2016
10.25#	Plus Therapeutics, Inc. 2020 Stock Incentive Plan, as amended and restated.	8-K	001-34375 Exhibit 10.1	05/17/2021
10.26#	Form of Notice of Grant and Stock Option Agreement under the 2020 Stock Incentive Plan.	10-K	001-34375 Exhibit 10.26	02/24/2022

10.27+	Master Services Agreement, dated January 24, 2021, by and between Piramal Pharma Solutions, Inc. and Plus Therapeutics, Inc.		10-K	001-334275 Exhibit 10.24	02/22/2021
10.28#	Form of Indemnification Agreement.		8-K	001-34375 Exhibit 10.1	02/06/2020
10.29#	Form of Agreement for Acceleration and/or Severance.		10-K	001-34375 Exhibit 10.113	03/11/2016
10.30	Medidata Services Agreement and Statement of Work, dated November 5, 2021, by and between Medidata Solutions, Inc. and Plus Therapeutics, Inc.		10-Q	001-34375 Exhibit 10.1	04/21/2022
10.31	Cancer Research Grant Contract, effective August 31, 2022, by and between the Cancer Prevention and Research Institute of Texas and Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 10.1	09/22/2022
10.32	Subscription and Investment Representation Agreement, dated March 3, 2023, by and between Plus Therapeutics, Inc. and the purchaser signatory thereto.		8-K	001-34375 Exhibit 10.1	03/03/2023
10.33#	Plus Therapeutics, Inc. 2020 Stock Incentive Plan, as further amended and restated		8-K	001-34375 Exhibit 10.1	04/20/2023
10.34	Tenth Amendment to Loan and Security Agreement		10-Q	001-34375 Exhibit 10.2	08/14/2023
23.1	Consent of BDO USA, P.C., Independent Registered Public Accounting Firm.	X			
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1†	Certifications Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes - Oxley Act of 2002.	X			
97.1	Incentive Compensation Recovery Policy.	X			
101.INS	The following financial information from The Plus Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2023, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) Balance Sheets as of December 31, 2023 and 2022; (ii) Statements of Operations for the years ended December 31, 2023 and 2022; (iii) Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2023 and 2022; (iv) Statements of Cash Flows for the years ended December 31, 2023 and 2022; and (v) Notes to Financial Statements.	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X			

Indicates management contract or compensatory plan or arrangement.

+ Portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv).

† Furnished herewith.

SIGNATURES

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

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick, MD

Marc. H. Hedrick, MD

President & Chief Executive Officer

March 5, 2024

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Richard J. Hawkins</u> Richard J. Hawkins	<i>Chairman of the Board</i>	March 5, 2024
<u>/s/ Marc H. Hedrick, MD</u> Marc H. Hedrick, MD	<i>President & Chief Executive Officer (Principal Executive Officer)</i>	March 5, 2024
<u>/s/ Andrew Sims</u> Andrew Sims	<i>Chief Financial Officer and VP of Finance (Principal Financial and Accounting Officer)</i>	March 5, 2024
<u>/s/ An van Es-Johansson, MD</u> An van Es-Johansson, MD	<i>Director</i>	March 5, 2024
<u>/s/ Greg Petersen</u> Greg Petersen	<i>Director</i>	March 5, 2024
<u>/s/ Howard Clowes</u> Howard Clowes	<i>Director</i>	March 5, 2024
<u>/s/ Robert Lenk</u> Robert Lenk	<i>Director</i>	March 5, 2024

TENTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS TENTH AMENDMENT to Loan and Security Agreement (this “**Amendment**”) is made effective as of June 28, 2023 (the “**Amendment Date**”) and made, by and among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314 (in its individual capacity, “**Oxford**”; and in its capacity as Collateral Agent, “**Collateral Agent**”), the Lenders listed on Schedule 1.1 from time to time to the Loan Agreement (defined below) including Oxford in its capacity as a Lender (each a “**Lender**” and collectively, the “**Lenders**”) and PLUS THERAPEUTICS, INC., a Delaware corporation with offices located at 4200 Marathon Blvd., Suite 200, Austin, Texas 78756 (“**Borrower**”).

WHEREAS, Collateral Agent, Borrower and Lenders party thereto from time to time have entered into that certain Loan and Security Agreement, dated as of May 29, 2015 (as amended, supplemented or otherwise modified from time to time, the “**Loan Agreement**”) pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

WHEREAS, Borrower, Lenders and Collateral Agent desire to amend certain provisions of the Loan Agreement as provided herein and subject to the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, Lenders and Collateral Agent hereby agree as follows:

1. Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Loan Agreement.
2. Section 10 of the Loan Agreement is hereby amended by amending the address therein for Collateral Agent and Oxford as follows:

If to Collateral Agent or Oxford:

OXFORD FINANCE LLC
115 South Union Street, Suite 300
Alexandria, Virginia 22314 Attention: Legal Department
Fax: (703) 519-5225
Email: LegalDepartment@oxfordfinance.com

with a copy (which shall not constitute notice) to:

Greenberg Traurig, LLP
One International Place Boston, MA 02110
Attn: Abdullah Malik Fax: (617) 897-0983
Email: malikab@gtlaw.com

3. Section 13.1 of the Loan Agreement is hereby amended, effective as of July 1, 2023, by amending and restating the definition of Basic Rate therein as follows:

“**Basic Rate**” is, with respect to a Term Loan, as determined by Collateral Agent, the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the greater of (i) Eight and Ninety-Five Hundredths percent (8.95%); and (ii) the sum of (a) 1-month Term SOFR, (b) .10%, and (c) Seven and Ninety-Five Hundredths percent (7.95%). Notwithstanding the foregoing, (i) in no event shall the Basic Rate

for any Term Loan be less than Eight and Ninety-Five Hundredths percent (8.95%), (ii) upon the occurrence of a Benchmark Transition Event, Collateral Agent may, in good faith and with reference to the margin above such interest rate in this definition, amend this Agreement to replace the Benchmark with a replacement

interest rate and replacement margin above such interest rate that results in a substantially similar interest rate floor and total rate in effect immediately prior to the effectiveness of such replacement interest rate and replacement margin, and any such amendment shall become effective at 5:00 p.m. Eastern time on the third Business Day after Collateral Agent has notified Borrower of such amendment, and (iii) the Basic Rate for the Term Loans for the period from the June 1, 2023 through and including June 30, 2023 shall be as in effect prior to the Tenth Amendment Date. Any determination, decision or election that may be made by Collateral Agent pursuant hereto will be conclusive and binding absent manifest error and may be made in Collateral Agent's sole discretion and without consent from any other party.

4. Section 13.1 of the Loan Agreement is hereby further amended, effective as of July 1, 2023, by adding the following thereto in alphabetical order:

"1-Month CME Term SOFR" is the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website.

"Benchmark" is, initially, the 1-Month CME Term SOFR; provided, that if a Benchmark Transition Event has occurred with respect to the 1-Month CME Term SOFR or the then-current Benchmark, then **"Benchmark"** means the applicable replacement rate that has replaced the immediately preceding benchmark rate pursuant to the defined term "Basic Rate".

"Benchmark Transition Event" means the occurrence of one or more of the following events with respect to the then-current Benchmark:

(a) a public statement or publication of information by or on behalf of the administrator for such Benchmark announcing that such Person has ceased or will cease to provide such Benchmark, permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide such Benchmark;

(b) a public statement or publication of information by the regulatory supervisor for the administrator for such Benchmark, the U.S. Federal Reserve System, an insolvency official with jurisdiction over the administrator for such Benchmark, a resolution authority with jurisdiction over the administrator for such Benchmark or a court or an entity with similar insolvency or resolution authority over the administrator for such Benchmark, which states that the administrator for such Benchmark has ceased or will cease to provide such Benchmark permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide such Benchmark; or

(c) a public statement or publication of information by the regulatory supervisor for the administrator for such Benchmark announcing that such Benchmark is no longer representative or in compliance with the International Organization of Securities Commissions Principles for Financial Benchmarks.

"CME Term SOFR Administrator" is CME Group Benchmark Administration Limited, as administrator of the forward-looking term SOFR, or any successor administrator.

"CME Term SOFR Administrator's Website" is the website of the CME Group Benchmark Administrator at <http://www.cmegroup.com>, or any successor source.

"Tenth Amendment Date" is June 28, 2023.

5. Limitation of Amendment.

- a. The amendments set forth above are effective for the purposes set forth herein and shall be limited
-

precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any

2

right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

- b. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, are hereby ratified and confirmed and shall remain in full force and effect.
6. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:
- a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;
 - b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;
 - c. The organizational documents of Borrower delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by or on behalf of the Borrower to the Collateral Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;
 - d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not contravene (i) any material law or regulation binding on or affecting Borrower, (ii) any material contractual restriction with a Person binding on Borrower, (iii) any material order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;
 - e. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and
 - f. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.
7. Except as expressly set forth herein, the Loan Agreement shall continue in full force and effect without alteration or amendment.
8. The Borrower hereby remises, releases, acquits, satisfies and forever discharges the Lenders and Collateral Agent, their agents, employees, officers, directors, predecessors, attorneys and all others acting or purporting to act on behalf of or at the direction of the Lenders and Collateral Agent (“**Releasees**”), of and from any and all manner of actions, causes of action, suit, debts, accounts, covenants, contracts, controversies, agreements, variances, damages, judgments, claims and demands whatsoever, in law or in equity, which any of such parties ever had, now has or, to the extent arising from or in connection with any act, omission or state of
-

facts taken or existing on or prior to the date hereof, may have after the date hereof against the Releasees, for, upon or by reason of any matter, cause or thing whatsoever relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof and through the date hereof. Without

3

limiting the generality of the foregoing, the Borrower waives and affirmatively agrees not to allege or otherwise pursue any defenses, affirmative defenses, counterclaims, claims, causes of action, setoffs or other rights they do, shall or may have as of the date hereof, including the rights to contest: (a) the right of Collateral Agent and each Lender to exercise its rights and remedies described in the Loan Documents; (b) any provision of this Amendment or the Loan Documents; or (c) any conduct of the Lenders or other Releasees relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof.

9. This Amendment shall be deemed effective as of the Amendment Date upon (a) the due execution and delivery to Collateral Agent of this Amendment by each party hereto, and (b) Borrower's payment of all Lenders' Expenses incurred through the date hereof, which may be debited (or ACH'd) from the Designated Deposit Account in accordance with Section 2.3(d) of the Loan Agreement.
10. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument.
11. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of California.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Tenth Amendment to the Loan Agreement to be executed as of the date first set forth above.

BORROWER:

PLUS THERAPEUTICS, INC.

By__ Name: Andrew Sims
Title: VP and Chief Financial Officer

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By__ Name: Joshua Friedman
Title: Chief Financial Officer

Consent of Independent Registered Public Accounting Firm

Plus Therapeutics, Inc.
Austin, Texas

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-1 (Nos. 333-229485, 333-227485, 333-226205, 333-224502, 333-219967, 333-215365, 333-210628 and 333-249728, 333-253612, 333-259325, 333-266684, 333-275531, 333-275712 and 333-273823), Forms S-3 (Nos. 333-217988, 333-172787, 333-169822, 333-157023, 333-140875, 333-134129, 333-153233, 333-159912, 333-192409, 333-200090, 333-195846, 333-216947 and 333-249410) and Forms S-8 (Nos. 333-223566, 333-210211, 333-202858, 333-181764, 333-122691, 333-82074 and 333-239548) of Plus Therapeutics, Inc. (the “Company”) of our report dated March 5, 2024, relating to the financial statements, which appears in this Annual Report on Form 10-K. Our report contains an explanatory paragraph regarding the Company’s ability to continue as a going concern.

/s/ BDO USA, P.C.

Austin, Texas

March 5, 2024

**Certification of Principal Executive Officer Pursuant to
Securities Exchange Act Rule 13a-14(a)
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Marc H. Hedrick, certify that:

1. I have reviewed this Annual Report on Form 10-K of Plus Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2024

/s/ Marc H. Hedrick, MD

Marc. H. Hedrick,

President & Chief Executive Officer

**Certification of Principal Financial Officer Pursuant to
Securities Exchange Act Rule 13a-14(a)
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Andrew Sims, certify that:

1. I have reviewed this Annual Report on Form 10-K of Plus Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2024

/s/ Andrew Sims

Andrew Sims

Chief Financial Officer

CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350/ SECURITIES EXCHANGE ACT RULE 13a-14(b), AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES – OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Plus Therapeutics, Inc. for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on March 5, 2024, (the “Report”), Marc H. Hedrick, as President & Chief Executive Officer of Plus Therapeutics, Inc., and Andrew Sims, as Chief Financial Officer of Plus Therapeutics, Inc., each hereby certifies, respectively, that:

1. The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934.
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Plus Therapeutics, Inc.

Dated: March 5, 2024

By: /s/ Marc H. Hedrick, MD
Marc H. Hedrick, MD
President & Chief Executive Officer

Dated: March 5, 2024

By: /s/ Andrew Sims
Andrew Sims
Chief Financial Officer

Plus Therapeutics, Inc.
Incentive Compensation Recovery Policy

The Company is committed to conducting business in accordance with the highest ethical and legal standards, and the Board believes that a culture that emphasizes integrity and accountability is in the best interests of the Company and its stockholders and essential to the Company's success. The Board is adopting this Incentive Compensation Recovery Policy (this "Policy") to provide for the recovery of certain incentive compensation in the event of an Accounting Restatement.

Statement of Policy

In the event that the Company is required to prepare an Accounting Restatement, except as otherwise set forth in this Policy, the Company shall recover, reasonably promptly, the Excess Incentive Compensation received by any Covered Executive during the Recoupment Period.

This Policy applies to all Incentive Compensation received during the Recoupment Period by a person (a) after beginning service as a Covered Executive, (b) who served as a Covered Executive at any time during the performance period for that Incentive Compensation and (c) while the Company has a class of securities listed on the Nasdaq Stock Market LLC ("Nasdaq") or another national securities exchange or association. This Policy may therefore apply to a Covered Executive even after that person is no longer a Company employee or a Covered Executive at the time of recovery.

Incentive Compensation is deemed "received" for purposes of this Policy in the fiscal period during which the financial reporting measure specified in the Incentive Compensation award is attained, even if the payment or issuance of such Incentive Compensation occurs after the end of that period. For example, if the performance target for an award is based on total stockholder return, revenue, or net income (loss) for the year ended December 31, 2023, the award will be deemed to have been received in 2023 even if paid in 2024.

Exceptions

The Company is not required to recover Excess Incentive Compensation pursuant to this Policy to the extent the Compensation Committee (the "Committee") makes a determination that recovery would be impracticable for one of the following reasons (and the applicable procedural requirements are met):

- a) after making a reasonable and documented attempt to recover the Excess Incentive Compensation, which documentation will be provided to Nasdaq to the extent required, the Committee determines that the direct expenses that would be paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered; or
- b) the Committee determines that recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to

fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

Definitions

“*Accounting Restatement*” means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. For the avoidance of doubt, a restatement resulting solely from any one or more of the following is not an Accounting Restatement: retrospective application of a change in generally accepted accounting principles; retrospective revision to reportable segment information due to a change in the structure of an issuer’s internal organization; retrospective reclassification due to a discontinued operation; retrospective application of a change in reporting entity, such as from a reorganization of entities under common control; retrospective adjustment to provisional amounts in connection with a prior business combination; and retrospective revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

“*Covered Executive*” shall mean the Company’s Chief Executive Officer, President, Chief Financial Officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function, any other officer who performs a policy-making function for the Company, any other person who performs similar policy-making functions for the Company, and any other employee who may from time to time be deemed subject to this Policy by the Committee. For purposes of the foregoing, designation by the Board as an “Officer” for purposes of Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), shall constitute designation as a Covered Executive.

“*Excess Incentive Compensation*” means the amount of Incentive Compensation received during the Recoupment Period by any Covered Executive that exceeds the amount of Incentive Compensation that otherwise would have been received by such Covered Executive if the determination of the Incentive Compensation to be received had been determined based on restated amounts in the Accounting Restatement and without regard to any taxes paid.

“*Incentive Compensation*” means any compensation (including cash and equity compensation) that is granted, earned, or vested based wholly or in part upon the attainment of a financial reporting measure. For purposes of this definition, a “*financial reporting measure*” is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements and any measure derived wholly or in part from such measures, or (ii) the Company’s stock price and/or total shareholder return. A financial reporting measure need not be presented within the financial statements or included in a filing with the commission. Incentive Compensation subject to this Policy may be provided by the Company or subsidiaries or affiliates of the Company (“Company Affiliates”).

“*Recoupment Period*” means the three completed fiscal years preceding the Trigger Date, and any transition period (that results from a change in the Company’s fiscal year) of less than nine months within

or immediately following those three completed fiscal years, provided that any transition period of nine months or more shall count as a full fiscal year.

“*Trigger Date*” means the earlier to occur of: (a) the date the Board, the Audit Committee (or such other Committee of the Board as may be authorized to make such a conclusion), or the officer or officers of the Company authorized to take such action if action by the Board is not required concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; or (b) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement; in the case of both (a) and (b) regardless of if or when restated financial statements are filed.

Administration

This Policy is intended to comply with Nasdaq Listing Rule 5608, Section 10D of the Exchange Act, and Rule 10D-1(b)(1) as promulgated under the Exchange Act, and shall be interpreted in a manner consistent with those requirements. The Committee has full authority to interpret and administer this Policy. The Committee’s determinations under this Policy shall be final and binding on all persons, need not be uniform with respect to each individual covered by the Policy, and shall be given the maximum deference permitted by law.

The Committee has the authority to determine the appropriate means of recovering Excess Incentive Compensation based on the particular facts and circumstances, which could include, but is not limited to, seeking direct reimbursement, forfeiture of awards, offsets against other payments, and forfeiture of deferred compensation (subject to compliance with Section 409A of the Internal Revenue Code).

Subject to any limitations under applicable law, the Committee may authorize any officer or employee of the Company to take actions necessary or appropriate to carry out the purpose and intent of this Policy, provided that no such authorization shall relate to any recovery under this Policy that involves such officer or employee.

If the Committee cannot determine the amount of excess Incentive Compensation received by a Covered Executive directly from the information in the Accounting Restatement, such as in the case of Incentive Compensation tied to stock price or total stockholder return, then it shall make its determination based on its reasonable estimate of the effect of the Accounting Restatement and shall maintain documentation of such determination, including for purposes of providing such documentation to Nasdaq.

Except where an action is required by Nasdaq Listing Rule 5608, Section 10D of the Exchange Act or Rule 10D-1(b)(1) promulgated under the Exchange Act to be determined in a different matter, the Board may act to have the independent directors of the Board administer this Policy in place of the Committee in any particular circumstance.

Each Covered Executive shall sign an Incentive Compensation Recovery Policy Acknowledgement and Agreement in the form attached to this Policy as Exhibit A or such other form as approved by the Committee in its sole discretion; provided, however, that failure to sign such acknowledgement shall have no effect on the validation or effectiveness of this Policy.

No Indemnification or Advancement of Legal Fees

Notwithstanding the terms of any indemnification agreement, insurance policy, contractual arrangement, the governing documents of the Company or other document or arrangement, the Company shall not indemnify any Covered Executive against, or pay the premiums for any insurance policy to cover, any amounts recovered under this Policy or any expenses that a Covered Executive incurs in opposing Company efforts to recoup amounts pursuant to the Policy.

Non-Exclusive Remedy; Successors

Recovery of Incentive Compensation pursuant to this Policy shall not in any way limit or affect the rights of the Company to pursue disciplinary, legal, or other action or pursue any other remedies available to it. This Policy shall be in addition to, and is not intended to limit, any rights of the Company to recover Incentive Compensation from Covered Executives under any legal remedy available to the Company and applicable laws and regulations, including but not limited to the Sarbanes-Oxley Act of 2002, as amended, or pursuant to the terms of any other Company policy, employment agreement, equity award agreement, or similar agreement with a Covered Executive.

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

Amendment

This Policy may be amended from time to time by the Committee on the Board.

Effective Date

This Policy shall apply to any Incentive Compensation received on or after December 1, 2023.

EXHIBIT A – BROAD FORM OF ACKNOWLEDGMENT AND AGREEMENT

**PLUS THERAPEUTICS, INC.
INCENTIVE COMPENSATION RECOVERY POLICY
ACKNOWLEDGMENT AND AGREEMENT**

This Acknowledgment and Agreement (this “Agreement”) is entered into as of the ___ day of _____, 20[___], between Plus Therapeutics, Inc., a Delaware corporation (the “Company”), and _____ (the “Executive”), under the following circumstances:

WHEREAS, the Board of Directors of the Company (the “Board”) has adopted the Plus Therapeutics, Inc. Incentive Compensation Recovery Policy (the “Policy”);

WHEREAS, the Executive has been designated as a “Covered Executive” of the Company as defined in the Policy;

WHEREAS, in consideration of, and as a condition to the receipt of, future cash and equity-based awards, performance-based compensation, and other forms of cash or equity compensation made under the Company’s 2020 Stock Incentive Plan, or any other incentive compensation plan or program of the Company, the Executive and the Company are entering into this Agreement; and

WHEREAS, defined terms used but not defined in this Agreement shall have the meanings set forth in the Policy.

NOW, THEREFORE, the Company and the Executive hereby agree as follows:

1. The Executive hereby acknowledges receipt of the Policy, to which this Agreement is attached, and the terms of which are hereby incorporated into this Agreement by reference. The Executive has read and understands the Policy and has had the opportunity to ask questions to the Company regarding the Policy.
2. The Executive hereby acknowledges and agrees that the Policy shall apply to any Incentive Compensation as set forth in the Policy and that all such Incentive Compensation shall be subject to recovery under the Policy.
3. Any applicable award agreement or other document setting forth the terms and conditions of any Incentive Compensation granted to the Executive by the Board or the Compensation Committee of the Board (the “Committee”) shall be deemed to include the restrictions imposed by the Policy and incorporate the Policy. In the event of any inconsistency between the provisions of the Policy and the applicable award agreement or other document setting forth the terms and conditions of any Incentive Compensation granted to the Executive, the terms of the Policy shall govern unless the terms of such other agreement or other document would result in a greater recovery by the Company.
4. The Executive hereby acknowledges that, notwithstanding any indemnification agreement or other arrangement between the Company and the Executive, the Company shall not indemnify the

Executive against, or pay the premiums for any insurance policy to cover, losses incurred under the Policy.

5. In the event it is determined by the Company that any amounts granted, awarded, earned or paid to the Executive must be forfeited or reimbursed to the Company, the Executive will promptly take any action necessary to effectuate such forfeiture and/or reimbursement.
6. This Agreement and the Policy shall survive and continue in full force in accordance with their terms notwithstanding any termination of the Executive's employment with the Company and its affiliates.
7. This Agreement may be executed in two or more counterparts, and by facsimile or electronic transmission (such as PDF), each of which will be deemed to be an original but all of which, taken together, shall constitute one and the same Agreement.
8. This Agreement shall be governed by the laws of the State of Delaware, without reference to principles of conflict of laws.
9. No modifications or amendments of the terms of this Agreement shall be effective unless in writing and signed by the parties hereto or their respective duly authorized agents. The provisions of this Agreement shall inure to the benefit of, and be binding upon, the successors, administrators, heirs, legal representatives and assigns of the Executive, and the successors and assigns of the Company.

[Signature Page Follows]

A-2

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

Plus Therapeutics, Inc.

By: _____

Name:

Title:

[EXECUTIVE]

Name:

Title:
