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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**33-0827593**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4200 MARATHON BLVD., SUITE 200, AUSTIN, TX	**78756**
(Address of principal executive offices)	**(Zip Code)**

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

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	PSTV	Nasdaq Capital Market

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	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of October 25, 2023 , there were 4,522,656 shares of the registrant's common stock outstanding.

PLUS THERAPEUTICS, INC.

INDEX

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report and the exhibits incorporated herein by reference contain "forward-looking statements" which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Statements other than statements of historical fact constitute "forward-looking statements." These forward-looking statements do not constitute guarantees of future performance. These forward-looking statements may be identified by terms such as "intend," "expect," "project," "believe," "anticipate," "initiate," "will," "should," "would," "could," "may," "designed," "potential," "evaluate," "hypothesize," "plan," "progressing," "proceeding," "exploring," "opportunity," "hopes," "suggest," and similar expressions, or the negative of such expressions. 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, FDA and EMA 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 effectively manage our gross profit margins; 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 potential need for additional financing and the availability thereof; our ability to continue as a going concern; our ability to remain listed on the Nasdaq Capital Market; 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 the drug product manufacture to a contract drug manufacturing organization; and the potential enhancement of our cash position through development, marketing, and licensing arrangements. 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 "Part I – Item 1A – Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, and under "Part II – Item 1A – Risk Factors" in this Quarterly Report. These risks and uncertainties could cause actual results to differ materially from expectations or those expressed in these forward-looking statements.

Our actual results may differ, including materially, from those anticipated in these forward-looking statements as a result of various factors, including, but not limited to, the following: the early stage of our product candidates and therapies, the results of our research and development activities, including uncertainties relating to the clinical trials of our product candidates and therapies; our liquidity and capital resources and our ability to raise additional cash, the outcome of our partnering/licensing efforts, risks associated with laws or regulatory requirements applicable to us, market conditions, product performance, potential litigation, and competition within the radiotherapeutics, and more generally, oncological medicine fields, among others. 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 "Part I – Item 1A – Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, and under "Part II – Item 1A – Risk Factors" in this Quarterly Report. These risks and uncertainties could cause actual results to differ materially from expectations or those expressed in these forward-looking statements.

We encourage you to read the risks described under "Risk Factor Summary" and "Part II – Item 1A – Risk Factors" 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.

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 11,006	$ 18,120
Grant receivable	91	—
Other current assets	487	3,697
Total current assets	11,584	21,817
Property and equipment, net	1,009	1,324
Operating lease right-of-use assets	232	248
Goodwill	372	372
Intangible assets, net	49	94
Other assets	32	12
Total assets	$ 13,278	$ 23,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,073	$ 10,134
Operating lease liability	117	110
Term loan obligation	4,348	1,608
Total current liabilities	10,538	11,852
Term loan obligation	—	3,786
Noncurrent operating lease liability	118	141
Deferred grant liability	—	1,643
Total liabilities	10,656	17,422
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 4,522,656 and 2,240,092 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	5	2
Additional paid-in capital	479,308	473,628
Accumulated deficit	(476,691)	(467,185)
Total stockholders' equity	2,622	6,445
Total liabilities and stockholders' equity	$ 13,278	$ 23,867

See Accompanying Notes to these Condensed Financial Statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Grant Revenue	$ 1,240	$ 73	$ 3,600	$ 73
Operating expenses:				
Research and development	2,493	2,945	6,896	7,560
General and administrative	1,998	2,222	6,165	6,653
Total operating expenses	4,491	5,167	13,061	14,213
Loss from operations	(3,251)	(5,094)	(9,461)	(14,140)
Other income (expense):				
Interest income	119	48	290	74
Interest expense	(87)	(173)	(333)	(552)
Loss on disposal of property and equipment	—	—	(2)	—
Change in fair value of liability instruments	—	—	—	1
Total other income (expense)	32	(125)	(45)	(477)
Net loss	$ (3,219)	$ (5,219)	$ (9,506)	$ (14,617)
Net loss per share, basic and diluted	$ (1.00)	$ (2.85)	$ (3.54)	$ (9.22)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	3,225,351	1,829,444	2,688,232	1,585,946

See Accompanying Notes to these Condensed Financial Statements

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

	Preferred stock		Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	—	$ —	1,952	$ —	1,034,002	$ 1	$ 457,745	$ (446,910)	$ 10,836
Stock-based compensation	—	—	—	—	—	—	180	—	180
Sale of common stock, net	—	—	—	—	445,840	—	7,742	—	7,742
Net loss	—	—	—	—	—	—	—	(4,116)	(4,116)
Balance at March 31, 2022	—	$ —	1,952	$ —	1,479,842	$ 1	$ 465,667	$ (451,026)	$ 14,642
Sale of common stock, net	—	—	—	—	18,070	—	152	—	152
Stock-based compensation	—	—	—	—	—	—	167	—	167
Net loss	—	—	—	—	—	—	—	(5,282)	(5,282)
Balance at June 30, 2022	—	$ —	1,952	$ —	1,497,912	$ 1	$ 465,986	$ (456,308)	$ 9,679
Sale of common stock, net	—	—	—	—	673,421	1	6,814	—	6,815
Stock-based compensation	—	—	—	—	—	—	129	—	129
Net loss	—	—	—	—	—	—	—	(5,219)	(5,219)
Balance at September 30, 2022	—	$ —	1,952	$ —	2,171,333	$ 2	$ 472,929	$ (461,527)	$ 11,404
Balance at December 31, 2022	—	$ —	1,952	$ —	2,240,092	$ 2	$ 473,628	$ (467,185)	$ 6,445
Stock-based compensation	—	—	—	—	—	—	140	—	140
Sale of common stock, net	—	—	—	—	168,164	—	895	—	895
Issuance of Series F preferred stock	1	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	—	(4,805)	(4,805)
Balance at March 31, 2023	1	$ —	1,952	$ —	2,408,256	$ 2	$ 474,664	$ (471,990)	$ 2,676
Redemption of Series F preferred stock	(1)	—	—	—	—	—	—	—	—
Fractional adjustment	—	—	—	—	(1,310)	—	—	—	—
Sale of common stock, net	—	—	—	—	472,674	1	1,327	—	1,328
Stock-based compensation	—	—	—	—	—	—	140	—	140
Net loss	—	—	—	—	—	—	—	(1,482)	(1,482)
Balance at June 30, 2023	—	$ —	1,952	$ —	2,879,620	$ 3	$ 476,131	$ (473,472)	$ 2,662
Sale of common stock, net	—	—	—	—	1,589,655	2	2,954	—	2,956
Issuance of common stock for in process research and development	—	—	—	—	53,381	—	75	—	75
Stock-based compensation	—	—	—	—	—	—	148	—	148
Net loss	—	—	—	—	—	—	—	(3,219)	(3,219)
Balance at September 30, 2023	—	$ —	1,952	$ —	4,522,656	$ 5	$ 479,308	$ (476,691)	$ 2,622

See Accompanying Notes to these Condensed Financial Statements

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

	For the Nine Months Ended September 30,	
	2023	**2022**
Cash flows used in operating activities:		
Net loss	$ (9,506)	$ (14,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	477	460
Amortization of deferred financing costs and debt discount	160	309
Stock issued for research and development	75	—
Loss on disposal of property and equipment	2	—
Stock-based compensation expense	428	476
Change in fair value of derivative instruments	—	(1)
Amortization of operating lease right-of-use assets	86	66
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Grant receivable	(91)	73
Other assets	3,190	642
Accounts payable and accrued expenses	(4,061)	1,955
Change in operating lease liabilities	(87)	(101)
Deferred grant liability	(1,643)	—
Net cash used in operating activities	(10,970)	(10,738)
Cash flows used in investing activities:		
Purchases of property and equipment	(118)	(381)
Purchase of intangible assets	—	(117)
In process research and development acquired	—	(250)
Net cash used in investing activities	(118)	(748)
Cash flows from financing activities:		
Principal payments of term loan obligation	(1,206)	(1,206)
Proceeds from sale of common stock, net of offering cost of $0.2 million and $0.7 million, respectively	5,180	14,558
Net cash provided by financing activities	3,974	13,352
Net increase (decrease) in cash and cash equivalents	(7,114)	1,866
Cash and cash equivalents at beginning of period	18,120	18,400
Cash and cash equivalents at end of period	$ 11,006	$ 20,266
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 186	$ 248
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	$ 1	$ 68
Right-of-use assets acquired by assuming operating lease liabilities	$ 71	$ —
Common stock issued in payment for in process research and development	$ 75	$ —

See Accompanying Notes to these Condensed Financial Statements

1. Basis of Presentation and New Accounting Standards

The accompanying unaudited condensed financial statements for the nine months ended September 30, 2023 and 2022 have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for annual financial statements. The condensed balance sheet at December 31, 2022 has been derived from the audited financial statements at December 31, 2022, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of Plus Therapeutics, Inc. (the "Company") have been included. Operating results for the nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. These financial statements should be read in conjunction with the financial statements and notes therein included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on February 23, 2023.

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 condensed financial statements in this Form 10-Q. The Company's financial statements, and all references thereto have been retroactively adjusted to reflect the reverse split unless specifically stated otherwise.

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

The Company also considers the guidance in ASC Topic 730, Research and Development, which requires an assessment, at the inception of 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.

Grant receivable represents qualified expenses incurred to date in excess of the amounts submitted for reimbursement. 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.

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 aren't 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.

2. Use of Estimates

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

3. Liquidity and Going Concern

The Company incurred a net loss of $9.5 million for the nine months ended September 30, 2023. The Company had an accumulated deficit of $476.7 million as of September 30, 2023. Additionally, the Company used net cash of $11.0 million to fund its operating activities for the nine months ended September 30, 2023. The Company's term loan (Note 5) matures on June 1, 2024 with total principal and final payment of $4.4 million due upon maturity. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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

On May 24, 2022, the Company received notice from The Nasdaq Stock Market LLC ("Nasdaq") that, because the closing bid price for the Company's common stock had fallen below $1.00 per share for 30 consecutive business days, the Company no longer complied with the minimum bid price requirement pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Requirement").

Nasdaq's notice had no immediate effect on the listing or trading of the Company's common stock. On November 22, 2022, the Company received a second letter from Nasdaq advising that the Company had been granted an additional 180 calendar days, or to May 22, 2023, to regain compliance with the Minimum Bid Requirement, in accordance with Nasdaq Listing Rule 5810(c)(3)(A).

On April 20, 2023, the Company held its annual meeting of stockholders and its stockholders approved an amendment to the Company's Charter, to effect a reverse stock split of its issued and outstanding shares of common stock, at a specific ratio, ranging from one-for-three (1:3) to one-for-fifteen (1:15). After receiving approval from the Board, on April 27, 2023, the Company filed the Amendment with the Secretary of State of the State of Delaware, to implement the Reverse Stock Split at the one-for-fifteen ratio (1:15). The Reverse Stock Split was effective on May 1, 2023, and the Company's common stock began trading on The Nasdaq Capital Market on a post-split basis on May 1, 2023. On May 15, 2023, the Company received written notice from Nasdaq notifying the Company that it had regained compliance with the Minimum Bid Requirement.

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

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

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

4. Fair Value Measurements

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

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

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

The following table summarizes the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2023 and December 31, 2022, respectively.

		Fair Value Measurements Using		
As of September 30, 2023	**Fair Value**	**Level 1**	**Level 2**	**Level 3**
Money market	$ 10,688,964	$ 10,688,964	$ —	$ —

		Fair Value Measurements Using		
As of December 31, 2022	**Fair Value**	**Level 1**	**Level 2**	**Level 3**
Money market	$ 17,573,584	$ 17,573,584	$ —	$ —

Certain warrants issued in an underwritten public offering in September 2019 (the "Series U Warrants") are classified as liability instruments. The Company estimated the fair value of the Series U Warrants with the Black Scholes model. Because some of the inputs to the Company's valuation model are either not observable or are not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability is classified as Level 3 in the fair value hierarchy.

Liability-classified Series U Warrants are marked to market as of each balance sheet date until they are exercised or upon expiration, with the changes in fair value recorded as non-operating income or loss in the statements of operations. As of September 30, 2023, the fair value of the Series U Warrants was immaterial, and the change in the fair value of liability classified Series U Warrants during the three and nine months ended September 30, 2023 and 2022 was immaterial.

5. Term Loan Obligations

On May 29, 2015, the Company entered into the Loan and Security Agreement (the "Loan and Security Agreement"), pursuant to which Oxford Finance, LLC ("Oxford") funded an aggregate principal amount of $17.7 million (the "Term Loan"), subject to the terms and conditions set forth in the Loan and Security Agreement. The Term Loan accrues interest at a floating rate of at least 8.95% per annum, comprised of a three-month LIBOR rate with a floor of 1.00% plus 7.95%. Pursuant to the Loan and Security Agreement, as amended, the Company made interest only payments through May 1, 2021, and thereafter is required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through June 1, 2024, the maturity date. At maturity of the Term Loan, or earlier repayment in full following voluntary prepayment or upon acceleration, the Company is required to make a final payment in an aggregate amount equal to approximately $3.2 million.

From September 2017 to March 2020, the Company entered into a total of nine amendments to the Term Loan that, among other things, extended the interest only period, required repayment of $3.1 million using the proceeds received from sale of the Company's former UK and Japan subsidiaries in April 2019, increased the final payment, increased the final payment fee upon

maturity or early repayment of the Term Loan, increased the minimum liquidity covenant level to $2.0 million and deferred the start date of principal repayment from May 1, 2020 to May 1, 2021 and extended the term of the Term Loan from September 1, 2021 to June 1, 2024.

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

The Term Loan, as amended, is collateralized by a security interest in substantially all of the Company's existing and subsequently acquired assets, including its intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement, as amended. The intellectual property asset collateral will be released upon the Company achieving a certain liquidity level when the total principal outstanding under the Loan and Security Agreement is less than $3.0 million. As of September 30, 2023, there was $1.2 million principal amount outstanding under the Term Loan, excluding the $3.2 million final payment fee, and the Company was in compliance with all of the debt covenants under the Loan and Security Agreement.

The Company's interest expense for the three and nine months ended September 30, 2023 and 2022 was $0.1 million and $0.2 million, and $0.3 million and $0.6 million, respectively. Interest expense is calculated using the effective interest method; therefore it is inclusive of non-cash amortization in the amount of $41,000 and $0.2 million for the three and nine months ended September 30, 2023, and $0.1 and $0.3 million for the three and nine months ended September 30, 2022, respectively, related to the amortization of the debt discount, capitalized loan costs, and accretion of final payment.

The Loan and Security Agreement, as amended, contains customary indemnification obligations and customary events of default, including, among other things, the Company's failure to fulfill certain obligations under the Term Loan, as amended, and the occurrence of a material adverse change, which is defined as a material adverse change in the Company's business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan. In the event of default by the Company or a declaration of material adverse change by its lender, under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Term Loan, which could materially harm the Company's financial condition. As of September 30, 2023, the Company has not received any notification or indication from Oxford that it intends to invoke the material adverse change clause.

6. Loss per Share

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

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

	September 30, 2023	September 30, 2022
Outstanding stock options	141,077	78,334
Outstanding warrants	142,733	142,747
Preferred stock	28,190	28,190
Total	312,000	249,271

7. 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 over a three-year period to fund the continued development of rhenium (^{186}Re) obisbemeda (previously known as ^{186}RNL) for the treatment of patients with leptomeningeal metastases ("LM"). The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of rhenium (^{186}Re) obisbemeda 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 $805,000 has been recorded as an increase in grant revenue in the nine months ended September 30, 2023.

The Company recognized $1.2 million and $3.6 million in grant revenue from the CPRIT Contract during the three and nine months ended September 30, 2023, respectively. The Company recognized $73,000 of CPRIT revenue in the three and nine months ended September 30, 2022.

8. Commitments and Contingencies

Leases

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2025. The Company also leases certain office space in Austin, Texas under a month-to-month operating lease agreement and certain office space in Charlottesville, Virginia (the "Charlottesville Lease"). The Charlottesville Lease has a term of 12 months and the Company has the ability to renew for three additional one-year periods. 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, as a discount rate of 13.47%.

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 (^{186}Re) obisbemeda 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 (^{186}Re) obisbemeda 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 September 30, 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 condensed 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.

9. License Agreements

Biocept License Agreement

On September 7, 2023, the Company entered into a Non-Exclusive License and Services Agreement (the "Biocept Agreement") with Biocept, Inc ("Biocept"), pursuant to which Biocept granted the Company a non-exclusive license to use the Biocept proprietary cell enumeration test, CNsideTM. 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 ("UTHSCSA") License Agreement

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

Pursuant to the UTHSCSA License Agreement, the Company was required to make an upfront payment, which was recorded as in process research and development acquired in the condensed 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 CPRIT. As of September 30, 2023, the Company accrued $1.3 million of payments due to NanoTx as a result of the CPRIT grant received (Note 7).

10. Stockholders' Equity

Preferred Stock

The Company has authorized 5,000,000 shares of preferred stock, par value $0.001 per share. The Company's Board of Directors 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 of directors of the Company, 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 September 30, 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 September 30, 2023, there were 142,733 outstanding Series U Warrants which can be exercised into an aggregate of 142,733 shares of common stock at a weighted average exercise price of $34.10 per share.

Common Stock

Lincoln Park Purchase Agreements

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. 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 September 30, 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, 2021, the Company issued 379,012 shares of its common stock under the 2020 Purchase Agreement for net proceeds of approximately $12.5 million. 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 may 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. Sales of the Company's common stock may be made by any method permitted by law deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended (the "Securities Act"), including, without limitation, sales made directly on or through the NASDAQ Capital Market. Canaccord will use its commercially

reasonable efforts to sell common stock requested by the Company to be sold on its behalf, consistent with Canaccord's normal trading and sales practices, under the terms and subject to the conditions set forth in the September 2022 Distribution Agreement. The Company has no obligation to sell any of its common stock. The Company may instruct Canaccord not to sell any common stock if the sales cannot be effected at or above the price designated by the Company from time to time and the Company may at any time suspend sales pursuant to the September 2022 Distribution Agreement. 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 September 30, 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.

The Company is 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 has 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 has agreed to provide customary indemnification rights to Canaccord.

The offering pursuant to the September 2022 Distribution Agreement will terminate upon the earlier of (1) the issuance and sale of all shares of the Company's common stock subject to the September 2022 Distribution Agreement, or (2) the termination of the September 2022 Distribution Agreement as permitted therein, including by either party at any time without liability of any party.

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.

11. Stock-based Compensation

Under the Company's 2015 New Employee Incentive Plan (the "2015 Plan"), awards may only be granted to employees who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as a material inducement to entering into employment with the Company. As of September 30, 2023, there were 6,023 shares of common stock remaining and available for future issuances under the 2015 Plan.

The Company's 2020 Stock Incentive Plan (the "2020 Plan"), which replaced the Company's 2014 Equity Incentive Plan, provides for the award or sale of shares of common stock (including restricted stock), the award of stock units and stock appreciation rights, and the grant of both incentive stock options to purchase common stock to directors, officers, employees and consultants of the Company. The 2020 Plan, as amended, provides for the issuance of up to 236,666 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 September 30, 2023, there were 179,640 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 nine months ended September 30, 2023 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in $,000)
Outstanding as of December 31, 2022	78,334	$ 68.10	9.00	
Granted	68,422	$ 5.00		
Cancelled/forfeited	(5,679)	$ 325.82		
Outstanding as of September 30, 2023	141,077	$ 37.47	8.32	$ 2
Vested and exercisable as of September 30, 2023	65,008	$ 65.51	7.53	$ —
Vested and expected to be vested as of September 30, 2023	133,570	$ 38.83	8.26	$ 2

As of September 30, 2023, the total compensation cost related to non-vested stock options not yet recognized for all the Company’s plans is approximately $0.8 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.95 years.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the unaudited financial information and the notes thereto included herein, as well as the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2022, as filed on February 23, 2023. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the caption "Cautionary Note Regarding Forward-Looking Statements" in this report, as well as under "Part I – Item 1A - Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, in other subsequent filings with the SEC, and elsewhere in this Form 10-Q. These statements, like all statements in this report, speak only as of the date of this Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

Our Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, includes the following sections:

Overview that discusses our operating results and some of the trends that affect our business.

Results of Operations that includes a more detailed 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, 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 (^{186}Re) obisbemeda (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}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) obisbemeda. 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) obisbemeda 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) obisbemeda, is a patented radiotherapy potentially useful for patients with CNS and other cancers. Preclinical study data describing the use of rhenium (^{186}Re) obisbemeda 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) obisbemeda has been reported to have potential applications for head and neck cancer, ovarian cancer, breast cancer and peritoneal metastases.

The rhenium (^{186}Re) obisbemeda technology was part of a licensed radiotherapeutic portfolio that we acquired from NanoTx, Corp. 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) obisbemeda 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 (^{186}Re) obisbemeda, for recurrent GBM.

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

Rhenium (^{186}Re) obisbemeda versus External Beam Radiation Therapy for Recurrent GBM

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

- The rhenium (^{186}Re) obisbemeda 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 (^{186}Re) obisbemeda can be visualized in real-time during administration, possibly giving clinicians better control of radiation dosing, distribution and retention.
- Rhenium (^{186}Re) obisbemeda potentially more effectively treats a bulk tumor and microscopic disease that has already invaded healthy tissue.
- Rhenium (^{186}Re) obisbemeda 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 (^{186}Re) obisbemeda 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) obisbemeda is designed for and provides patient tolerability and safety. Though no rhenium (^{186}Re) obisbemeda 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) obisbemeda 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) obisbemeda for the treatment of patients with GBM. In November 2021, the FDA granted Fast Track designation for rhenium (^{186}Re) obisbemeda for the treatment of LM.

Rhenium (^{186}Re) obisbemeda 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) obisbemeda 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 (^{186}Re) obisbemeda dose and will expand exploring higher radiation doses in larger volumes to treat larger tumors. Additionally, two or more rhenium (^{186}Re) obisbemeda 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 obisbemeda 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 in approximately 24 months.

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

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® (“SCA”) platform that facilitates the use of historical clinical data to incorporate into our Phase 2 clinical trial of rhenium (^{186}Re) obisbemeda 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) obisbemeda 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) obisbemeda 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) obisbemeda 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.

On September 19, 2022, we entered into a Cancer Research Grant Contract (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 (^{186}Re) obisbemeda 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) obisbemeda 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) obisbemeda showed a consistent decreased CSF tumor cell count/ml and was very well tolerated by all LM patients. Rhenium (^{186}Re) obisbemeda 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) obisbemeda 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) obisbemeda 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) obismeda at the Society for Neuro Oncology ASCO CNS Cancer Conference.

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 (^{186}Re) obisbemeda and follow-up communications with the FDA, we plan to submit a pediatric brain tumor IND to investigate the use of rhenium (^{186}Re)

obisbemeda in two pediatric brain cancers, high-grade glioma and ependymoma, in the fourth quarter of 2023 or the first 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 Health Science Center at San Antonio ("UTHSA") to expand our tumor targeting capabilities and precision radiotherapeutics pipeline. We intend to combine our Rhenium NanoLiposome technology with the BAM technology to create a novel radioembolization technology. Initially, we intend to utilize the Rhenium-188 isotope, ^{188}RNL-BAM for the intra-arterial embolization and local delivery of a high dose of targeted radiation for a variety of solid organ cancers such as hepatocellular cancer, hepatic metastases, pancreatic cancer and many others.

Preclinical data from an *ex vivo* embolization experiment in which Technetium99m-BAM was intra-arterially delivered to a bovine kidney perfusion model was presented at 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. ^{188}RNL-BAM is a preclinical investigational drug we intend to further develop and move into clinical trials. Specifically, in 2022 we transferred the ^{188}RNL-BAM technology from UTHSA, and began planning to develop the drug product and complete early preclinical studies to support a future FDA IND submission. Our intended initial clinical target is liver cancer which is the sixth most common and third deadliest cancer worldwide. It is a rare disease with increasing U.S. annual incidence (42,000) and deaths (30,000).

Recent Developments

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, CNsideTM. 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 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.

Grant Agreement with CPRIT

As noted above in the LM development discussion, on September 19, 2022, we entered into the CPRIT Contract, effective as of August 31, 2022, with CPRIT, pursuant to which CPRIT will provide us the CPRIT Grant over a three-year period to fund the continued development of rhenium (^{186}Re) obisbemeda for the treatment of patients with LM. The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar from Plus Therapeutics for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of rhenium (^{186}Re) obisbemeda 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.

Recent Financings

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

Results of Operations

Grant Revenue

We recognized $1.2 million and $3.6 million of grant revenue during the three and nine months ended September 30, 2023, which represents CPRIT’s share of the costs incurred for our rhenium (^{186}Re) obisbemeda development for the treatment of patients with LM.

We expect grant revenue will continue to increase during the remainder of 2023 and the remaining term of the CPRIT Grant through August 2025, as we plan 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 three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 2,477	$ 2,926	$ 6,846	$ 7,493
Stock-based compensation	16	19	50	67
Total research and development expenses	$ 2,493	$ 2,945	$ 6,896	$ 7,560

The decrease of $0.5 million in research and development expenses for the three months ended September 30, 2023 as compared to the same period in 2022 was due primarily to a decrease of $1.1 million in development of cGMP rhenium (^{186}Re) obisbemeda offset by an increase of $1.0 million from LM clinical trial expenses compared to $0 in the same period in 2022, a license agreement payment of $0.4 million to NanoTx resulting from the first patient treated in the GBM phase 2 trial and $0.1 million of expenses for Biocept Agreement. In addition, there was a $0.7 million reduction related to professional and legal expenses and a $0.2 million decrease of travel related and other expenses.

The decrease of $0.7 million in research and development expenses for the nine months ended September 30, 2023 as compared to the same period in 2022 was due primarily to a decrease of $2.6 million in development of cGMP rhenium (^{186}Re) obisbemeda, a decrease of $1.9 million of professional and legal expenses, offset by a license agreement payment of $1.2 million to NanoTx resulting from the first patient treated in the GBM phase 2 trial, $2.5 million from treatment of patients for LM clinical trial in 2023 compared to $0 in the same period in 2022, and $0.1 million of expenses for Biocept Agreement incurred in the third quarter of 2023.

We expect aggregate research and development expenditures to increase significantly during the remainder of 2023 as compared to the corresponding comparable period ended December 31, 2022, due to increased costs for *ReSPECT-LM* clinical trial under the CPRIT grant, 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 three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
General and administrative	$ 1,866	$ 2,112	$ 5,787	$ 6,244
Stock-based compensation	132	110	378	409
Total general and administrative expenses	$ 1,998	$ 2,222	$ 6,165	$ 6,653

General and administrative expenses decreased by approximately $0.2 million during the three months ended September 30, 2023, as compared to the same period in 2022. The decrease was due primarily to a decrease in legal expenses of $0.2 million.

General and administrative expenses decreased by approximately $0.5 million during the nine months ended September 30, 2023, as compared to the same period in 2022. The decrease was due primarily to a decrease of legal expenses of $0.5 million from expenditure incurred in 2022 related to litigation that was settled in the fourth quarter of 2022.

We expect general and administrative expenditures to remain generally consistent during the remainder of 2023 as compared with the corresponding comparable period ended December 31, 2022, exclusive of the impact of the one-time legal settlement costs and settlement related legal expenses in 2022.

Stock-based compensation expense

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

The following table summarizes the components of our stock-based compensation expenses for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 16	$ 19	$ 50	$ 67
General and administrative	132	110	378	409
Total stock-based compensation	$ 148	$ 129	$ 428	$ 476

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 three and nine months ended September 30, 2023 and 2022.

Financing items

The following table summarizes interest income, interest expense, and other income and expense for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Interest income	$ 119	$ 48	$ 290	$ 74
Interest expense	(87)	(173)	(333)	(552)
Loss on disposal of property and equipment	—	—	(2)	—
Change in fair value of liability instruments	—	—	—	1
Total	$ 32	$ (125)	$ (45)	$ (477)

The decrease in interest expense for the three and nine months ended September 30, 2023 as compared to the same period in 2022 was primarily due to the repayment of debt principal of $1.6 million during the year ended December 31, 2022, and $1.2 million for the nine months ended September 30, 2023, respectively.

We expect interest expense in 2023 to decrease as compared with 2022 due to scheduled debt principal repayments in 2023.

Liquidity and Capital Resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at September 30, 2023 and December 31, 2022 (in thousands):

	As of September 30, 2023	As of December 31, 2022
Cash and cash equivalents	$ 11,006	$ 18,120
Current assets	$ 11,584	$ 21,817
Current liabilities	10,538	11,852
Working capital	$ 1,046	$ 9,965

We incurred net losses of $9.5 million for the nine months ended September 30, 2023. We have an accumulated deficit of $476.7 million as of September 30, 2023. Additionally, we used net cash of $11.0 million to fund our operating activities for the nine months ended September 30, 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. However, 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 (^{186}Re) obisbemeda for the treatment of patients with LM.

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 may issue and sell, from time to time, shares of our 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. Sales of our common stock may be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended (the "Securities Act"), including, without limitation, sales made directly on or through the NASDAQ Capital Market. Canaccord will use its commercially reasonable efforts to sell common stock requested by the Company to be sold on its behalf, consistent with Canaccord's normal trading and sales practices, under the terms and subject to the conditions set forth in the September 2022 Distribution Agreement. We have no obligation to sell any of our common stock. We may instruct Canaccord not to sell any common stock if the sales cannot be effected at or above the price designated by us from time to time and we may at any time suspend sales pursuant to the September 2022 Distribution Agreement. During the period from September 9, 2022 to December 31, 2022, we issued 68,758 shares under the September 2022 Distribution Agreement for net proceeds of approximately $0.6 million. From January 1, 2023 through September 30, 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 492,698 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 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. On August 21, 2023, a new registration statement was declared effective covering the resale of up to 1,500,000 shares of our common stock that we have reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement.

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 September 30, 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, 2022, 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.

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 condensed 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 its ability to continue as a going concern.

Cash (used in) provided by operating, investing, and financing activities for the nine months ended September 30, 2023 and 2022 is summarized as follows (in thousands):

	For the Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	$ (10,970)	$ (10,738)
Net cash used in investing activities	(118)	(748)
Net cash provided by financing activities	3,974	13,352
Net increase (decrease) in cash and cash equivalents	$ (7,114)	$ 1,866

Material Cash Obligations

On September 19, 2022, we entered into the CPRIT Contract, effective as of August 31, 2022, pursuant to which we will continue the development of rhenium (^{186}Re) obisbemeda for the treatment of patients with LM, with CPRIT providing matching funds for approximately two-thirds of the total development costs, subject to various funding conditions. The CPRIT contract is effective for three years, unless otherwise terminated per 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.

We are also obligated to make ongoing payments against the remaining principal, interest and final payments of approximately $4.4 million in total under the Term Loan with Oxford through the maturity date of June 1, 2024 (See Note 5 of the accompanying

condensed 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.

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2023 was $11.0 million compared to $10.7 million in the same period of 2022. Our operational cash use increased by $0.3 million during the nine months ended September 30, 2023 as compared to the same period in 2022, due to a reduction of net loss of approximately $5.0 million, offset by a net change of operating assets and liabilities of approximately $5.3 million.

Investing activities

Net cash used in investing activities for the nine months ended September 30, 2023 was related to purchases of fixed assets of $0.1 million. Net cash used in investing activities for the nine months ended September 30, 2022 was related to cash payments of $250,000 made for in process research and development assets from UTHSA and purchases of fixed assets and intangible assets of $498,000.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 was primarily related to the net proceeds from sales of common stock of $5.2 million through the September 2022 Distribution Agreement with Canaccord and the 2022 Purchase Agreement, offset by $1.2 million of principal repayment under our Term Loan.

Net cash provided by financing activities for the nine months ended September 30, 2022 was primarily related to sales of common stock of $14.6 million, net of offering cost through the January and September 2022 Distribution Agreement with Canaccord and the 2020 Purchase Agreement with Lincoln Park, offset by $1.2 million of principal repayment under our Term Loan.

Critical Accounting Policies and Significant Estimates

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

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

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

We estimate the fair value of liability classified warrants using an option pricing model. Following the authoritative accounting guidance, warrants with potential cash settlement outside control of the Company are accounted for as liabilities, with changes in the fair value included in operating expenses.

We believe it is important for you to understand our most critical accounting policies. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and there have been no material changes during nine months ended September 30, 2023.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in our reports that we file or furnish 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 financial officer and principal accounting 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-Q. 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 September 30, 2023.

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 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, when CPRIT has no performance specific milestones in the grant outside of a reasonableness test to reimburse expenses. Despite the error management concluded that the previously issued financial statements were not materially misstated.

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

Notwithstanding the identified material weakness described above, our Chief Executive Officer and our Chief Financial Officer believe the condensed financial statements included in this Quarterly Report on Form 10-Q 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

We have taken steps to remediate the material weakness mentioned above, including strengthening our review process related to significant and unusual transactions. However, these review processes are too new to be fully tested and we cannot assure investors that these measures will significantly improve or remediate the material weakness described above.

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 September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

For a discussion of certain factors that could materially affect our business, financial condition, and operating results or that could cause actual results to differ materially from the results described in or implied by the forward-looking statements in this Form 10-Q, in addition to the information in the section entitled "Cautionary Statement Regarding Forward-Looking Statements," you should

carefully review and consider the information under "Part I, Item 1A- Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022. The risk factors below are in addition to and supplement (and with respect to certain matters, update) the risk factors discussed in our Annual Report on Form 10-K.

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.

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 September 30, 2023, we had an accumulated shareholders' deficit of approximately $476.7 million and approximately $11.0 million of cash and cash equivalents and $1.0 million of positive working capital available for use 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 condensed financial statements in this Form 10-Q are issued.

We have a history of generating losses and negative cash flows from operations. Our unaudited 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. If we are not able to resolve the going concern prior to the issuance of our financial statements for the fiscal year ending December 31, 2023, the reaction of investors to the inclusion of a going concern statement by our auditors, and our potential inability to continue as a going concern in future years could materially adversely affect our share price and our ability to raise new capital or enter into strategic alliances. 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.

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 Annual Report on Form 10-K and quarterly report on 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.

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, there is no assurance that we will be able to maintain compliance with this standard. As of September 30, 2023, our stockholders' equity was $2.6 million and without raising additional capital it will continue to decline. The market value of our listed securities was below $35 million and we did not have net income in the last three years. Accordingly, we may not continue to meet the continued listing standards in the future.

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On September 15, 2023, pursuant to the Biocept Agreement, we issued 53,381 unregistered shares to Biocept as an upfront payment, the fair value of which was $75,000. The unregistered shares are subject to resale restrictions under Rule 144.

Item 6. Exhibits

EXHIBIT INDEX
PLUS THERAPEUTICS, INC.

Exhibit Number	Exhibit Title	Filed with this Form 10-Q	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	Composite Certificate of Incorporation		10-K	001-34375 Exhibit 3.1	03/11/2016
3.2	Certificate of Amendment to Amended and Restated Certificate		8-K	001-34375 Exhibit 3.1	05/10/2016
3.3	Certificate of Amendment to Amended and Restated Certificate		8-K	001-34375 Exhibit 3.1	05/23/2018
3.4	Certificate of Amendment to Amended and Restated Certificate		8-K	001-34375 Exhibit 3.1	07/29/2019
3.5	Certificate of Amendment to Amended and Restated Certificate		8-K	001-34375 Exhibit 3.1	08/06/2019
3.6	Certificate of Amendment to Amended and Restated Certificate		8-K	001-34375 Exhibit 3.1	04/28/2023
3.7	Amended and Restated Bylaws of Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 3.1	09/21/2021
3.8	Certificate of Designation of Series F Preferred Stock, dated March 3, 2023		8-K	001-34375 Exhibit 3.1	03/03/2023
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			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	X			
101.SCH	Inline XBRL Schema Document	X			
101.CAL	Inline XBRL Calculation Linkbase Document	X			
101.DEF	Inline XBRL Definition Linkbase Document	X			
101.LAB	Inline XBRL Label Linkbase Document	X			
101.PRE	Inline XBRL Presentation Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X			

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibit 32.1 hereto is deemed to accompany this Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Exchange

Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the Company specifically incorporates it by reference.

SIGNATURES

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

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick

Dated: October 31, 2023

Marc H. Hedrick

President & Chief Executive Officer (Duly Authorized Officer and Principal Executive Officer)

By: /s/ Andrew Sims

Dated: October 31, 2023

Andrew Sims

Chief Financial Officer (Duly Authorized Officer and Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 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

I, Marc H. Hedrick, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2023
/s/ Marc H. Hedrick
Marc H. Hedrick,
President & Chief Executive Officer

EXHIBIT 31.2

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 quarterly report on Form 10-Q 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2023
/s/ Andrew Sims
Andrew Sims
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION 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 Quarterly Report on Form 10-Q of Plus Therapeutics, Inc. for the quarterly period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof, Marc H. Hedrick, as President & Chief Executive Officer of Plus Therapeutics, Inc., and Andrew Sims, as VP of Finance and Chief Financial Officer of Plus Therapeutics, Inc., each hereby certifies, respectively, that:

1. The Form 10-Q report of Plus Therapeutics, Inc. that this certification accompanies fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934.

2. The information contained in the Form 10-Q report of Plus Therapeutics, Inc. that this certification accompanies fairly presents, in all material respects, the financial condition and results of operations of Plus Therapeutics, Inc.

By: /s/ Marc H. Hedrick

Dated: October 31, 2023

Marc H. Hedrick

President & Chief Executive Officer

By: /s/ Andrew Sims

Dated: October 31, 2023

Andrew Sims

Chief Financial Officer & VP of Finance