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 March 31, 2023

OR

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

For the transition period from to

Commission file number 001-34375

PLUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**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 April 18, 2023 , there were 36,690,934 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.

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 12,723	$ 18,120
Other current assets	906	3,697
Total current assets	13,629	21,817
Property and equipment, net	1,276	1,324
Operating lease right-use-of assets	270	248
Goodwill	372	372
Intangible assets, net	79	94
Other assets	12	12
Total assets	$ 15,638	$ 23,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,495	$ 10,134
Operating lease liability	107	110
Term loan obligation, current	5,057	1,608
Deferred grant liability, current	1,137	—
Total current liabilities	12,796	11,852
Term loan obligation	—	3,786
Noncurrent operating lease liability	166	141
Deferred grant liability	—	1,643
Total liabilities	12,962	17,422
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 1,953 and 1,952 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 36,123,833 and 33,601,373 issued and outstanding at March 31, 2023 and December 31, 2022, respectively	36	34
Additional paid-in capital	474,630	473,596
Accumulated deficit	(471,990)	(467,185)
Total stockholders' equity	2,676	6,445
Total liabilities and stockholders' equity	$ 15,638	$ 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 March 31,	
	2023	2022
Grant revenue	$ 506	$ -
Operating expenses:		
Research and development	2,983	1,785
General and administrative	2,243	2,141
Total operating expenses	5,226	3,926
Operating loss	(4,720)	(3,926)
Other income (expense):		
Interest income	51	7
Interest expense	(134)	(198)
Change in fair value of liability instruments	—	1
Loss on disposal of property and equipment	(2)	—
Total other expense	(85)	(190)
Net loss	$ (4,805)	$ (4,116)
Net loss per share, basic and diluted	$ (0.14)	$ (0.19)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	34,800,260	21,507,061

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	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity
Balance at December 31, 2021	—	$ —	1,952	$ —	15,510,025	$ 16	$ 457,730	$ (446,910)	$ 10,836
Stock-based compensation	—	—	—	—	—	—	180	—	180
Sale of common stock, net	—	—	—	—	6,687,610	6	7,736	—	7,742
Net loss	—	—	—	—	—	—	—	(4,116)	(4,116)
Balance at March 31, 2022	—	$ —	1,952	$ —	22,197,635	$ 22	$ 465,646	$ (451,026)	$ 14,642
Balance at December 31, 2022	—	$ —	1,952	$ —	33,601,373	$ 34	$ 473,596	$ (467,185)	$ 6,445
Stock-based compensation	—	—	—	—	—	—	140	—	140
Sale of common stock, net	—	—	—	—	2,522,460	2	893	—	895
Issuance of Series F preferred stock	1	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	—	(4,805)	(4,805)
Balance at March 31, 2023	1	$ —	1,952	$ —	36,123,833	$ 36	$ 474,630	$ (471,990)	$ 2,676

See Accompanying Notes to these Condensed Financial Statements

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

	For the Three Months Ended March 31,	
	2023	**2022**
Cash flows used in operating activities:		
Net loss	$ (4,805)	$ (4,116)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	158	147
Amortization of deferred financing costs and debt discount	66	115
Change in fair value of liability instruments	—	(1)
Share-based compensation expense	140	180
Amortization of operating lease right-of-use assets	29	25
Loss on disposal of property and equipment	2	—
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Other current assets	2,791	459
Accounts payable and accrued expenses	(3,639)	(650)
Change in operating lease liabilities	(29)	(35)
Deferred revenue	(506)	—
Net cash used in operating activities	(5,793)	(3,876)
Cash flows used in investing activities:		
Purchases of property and equipment	(97)	(210)
Purchase of intangible assets	—	(117)
In process research and development acquired	—	(250)
Net cash used in investing activities	(97)	(577)
Cash flows from financing activities:		
Principal payments of term loan obligation	(402)	(402)
Proceeds from sale of common stock, net	895	7,694
Net cash provided by financing activities	493	7,292
Net (decrease) increase in cash and cash equivalents	(5,397)	2,839
Cash and cash equivalents at beginning of period	18,120	18,400
Cash and cash equivalents at end of period	$ 12,723	$ 21,239
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 73	$ 87
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	$ 25	$ 171
Right-of-use assets obtained in exchange for operating lease liability	$ 51	$ —

See Accompanying Notes to these Condensed Financial Statements

1. Basis of Presentation and New Accounting Standards

The accompanying unaudited condensed financial statements for the three months ended March 31, 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., and its subsidiaries (collectively, the "Company") have been included. Operating results for the three months ended March 31, 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.

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 there is not considered 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 ASC 606 or International Accounting Standards No. 20, Accounting for Government Grants and Disclosure of Government Assistance, by analogy, and revenue is recognized when the Company incurs expenses related to the grant for the amount the Company is entitled to under the provisions of the contract.

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

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

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 is permitted beginning in 2019. The Company has adopted the new guidance as of January 1, 2023, and it 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 grant revenue recognition, reviewing assets for impairment, and determining the assumptions used in measuring stock-based compensation expense.

As discussed in more detail in Note 7, on September 19, 2022, the Company entered into a Cancer Research Grant Contract (the "CPRIT Contract"), effective as of August 31, 2022, with the Cancer Prevention and Research Institute of Texas ("CPRIT"), pursuant to which the Company will receive up to $17.6 million to fund a portion of the clinical trials. The Company estimates

the amount of clinical trial costs that should be borne by CPRIT in accordance with the CPRIT Contract, based on the actual costs incurred and progress of the trial.

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

3. Liquidity and Going Concern

The Company incurred a net loss of $4.8 million for the three months ended March 31, 2023. The Company had an accumulated deficit of $472.0 million as of March 31, 2023. Additionally, the Company used net cash of $5.8 million to fund its operating activities for the three months ended March 31, 2023. 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 would cause the Company to default on it 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).

The Company intends to continue to actively monitor the closing bid price of its common stock and will evaluate available options to regain compliance with the Minimum Bid Requirement. Specifically, the Company has confirmed to Nasdaq that, if necessary, it will implement a reverse stock split of its outstanding common stock (if approved by the Company's stockholders) to attempt to regain compliance. The Company is scheduled to hold its annual meeting of stockholders on April 20, 2023 and one of the proposals for approval is an amendment to the Company's Amended and Restated Certificate of Incorporation, as amended (the "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). If the stockholders do not approve the amendment to the Charter to effect a reverse stock split, or if the Company does not otherwise regain compliance within the additional compliance period, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Requirement during the 180-day additional compliance period or maintain compliance with the other Nasdaq listing requirements.

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.

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 March 31, 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 months ended March 31, 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. In connection with the Term Loan, on May 29, 2015, the Company issued to Oxford warrants to purchase an aggregate of 188 shares of the Company's common stock at an exercise price of $5,175 per share. These warrants became exercisable as of November 30, 2015, and will expire on May 29, 2025 and, following authoritative accounting guidance, are equity classified and their respective fair value was recorded as a discount to the debt.

From September 2017 to July 2019, the Company entered into a total of eight 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, and increased the minimum liquidity covenant level to $2.0 million.

On March 29, 2020, the Company entered into the Ninth Amendment of the Loan and Security Agreement (the "Ninth Amendment"), pursuant to which Oxford agreed to defer 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.

Under authoritative guidance, the Ninth Amendment did not meet the criteria to be accounted for as a troubled debt restructuring. In addition, the Company performed a quantitative analysis and determined that the terms of the new debt and original debt instrument are not substantially different. Accordingly, the Ninth Amendment is accounted for as a debt modification. A new effective interest rate that equates the revised cash flows to the carrying amount of the original debt is computed and applied prospectively.

The Term Loan, as amended, is collateralized by a security interest in substantially all of the Company's existing and subsequently acquired assets, including its intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement, as amended. The intellectual property asset collateral will be released upon the Company achieving a certain liquidity level when the total principal outstanding under the Loan and Security Agreement is less than $3.0 million. As of March 31, 2023, there was $2.0 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 months ended March 31, 2023 and 2022 was $0.1 million and $0.2 million, respectively. Interest expense is calculated using the effective interest method; therefore it is inclusive of non-cash amortization in the amount of $0.1 million for each of the three months ended March 31, 2023 and 2022, related to the amortization of the debt discount, capitalized loan costs, and accretion of final payment.

The Loan and Security Agreement, as amended, contains customary indemnification obligations and customary events of default, including, among other things, the Company's failure to fulfill certain obligations under the Term Loan, as amended, and the occurrence of a material adverse change, which is defined as a material adverse change in the Company's business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan. In the event of default by the Company or a declaration of material adverse change by its lender, under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Term Loan, which could materially harm the Company's financial condition. As of March 31, 2023, the Company has not received any notification or indication from Oxford that it intends to invoke the material adverse change clause. However, due to the Company's current cash flow position and the substantial doubt about its ability to continue as a going concern, the entire principal amount of the Term Loan is presented as short-term. The Company will continue to evaluate the debt classification on a quarterly basis and evaluate for reclassification in the future should its financial condition improve.

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 common shares were related to outstanding but unexercised options, multiple series of convertible preferred stock, and warrants for all periods presented.

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

	As of March 31,	
	2023	2022
Outstanding stock options	2,014,245	1,170,873
Preferred stock	422,867	422,867
Outstanding warrants	2,141,189	2,141,378
Total	4,578,301	3,735,118

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 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 (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.

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 or ASC 606. Applying ASC 606 by analogy, the Company recognizes proceeds received under the CPRIT Contract as grant revenue on the statement of operations when related costs are incurred. The Company recognized $0.5 million and $0 in grant revenue from the CPRIT Contract during the three months ended March 31, 2023 and 2022, respectively.

8. Commitments and Contingencies

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company calculates the associated lease liability and corresponding right-of-use asset upon lease commencement using a discount rate based on the rate implicit in the lease or an incremental borrowing rate commensurate with the term of the lease. Lease renewable options are included in the estimation of lease term when it is reasonably certain that the Company will exercise such options.

The Company records lease liabilities within current liabilities or long-term liabilities based upon the length of time associated with the lease payments. The Company records its operating lease right-of-use assets as long-term assets. Right-of-use assets for finance leases are recorded within property and equipment, net in the condensed balance sheets. Leases with an initial term of 12 months or less are not recorded on the condensed balance sheets. Instead, the Company recognizes lease expense for these leases on a straight-line basis over the lease term in the condensed statements of operations.

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2025. The Company also leases certain office space in Austin, Texas under a month-to-month operating lease agreement and certain office space in Charlottesville, Virginia (the “Charlottesville Lease”). The 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. As of March 31, 2023, the 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%. The Company’s existing operating lease agreements generally provide for periodic rent increases, and renewal and termination options. The Company’s lease agreements do not contain any material variable lease payments, residual value guarantees or material restrictive covenants.

Certain leases require the Company to pay taxes, insurance, and maintenance. Payments for the transfer of goods or services such as common area maintenance and utilities represent non-lease components. The Company elected the package of practical expedients and therefore does not separate non-lease components from lease components.

The Company’s operating lease liabilities and corresponding right-of-use assets are included in the condensed balance sheets. As of March 31, 2023, the weighted average discount rate used to measure operating lease liabilities and the operating leases remaining term were 9.0% and 2.27 years, respectively.

The table below summarizes the Company’s lease costs from its unaudited condensed statements of operations, and cash payments from its unaudited condensed statements of cash flows during the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Lease expense:		
Total lease expense	$ 34	$ 45
Cash payment information:		
Operating cash used for operating leases	$ 34	$ 45

Total rent expenses for the three months ended March 31, 2023 and 2022 were $47,000 and $60,000, respectively, which includes leases in the table above, month-to-month operating leases, and common area maintenance charges.

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

Remainder of 2023	$ 103
2024	138
2025	51
2026	8
Thereafter	-
Total minimum lease payments	300
Less: amount representing interest	(27)
Present value of obligations under leases	273
Less: current portion	(107)
Noncurrent lease obligations	$ 166

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 (the “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 March 31, 2023, the Company did not have any clinical research study obligations.

Legal proceedings

On June 22, 2021, the Company was named as a defendant in an action brought by Lorem Vascular, Pte. Ltd. (“Lorem”) in the District Court for the District of Delaware. The complaint alleged false representations were made to Lorem regarding the manufacturing facility in the United Kingdom (the “UK Facility”) that Lorem purchased from the Company under the Asset and Equity Purchase Agreement, dated March 29, 2019, between the Company and Lorem (the “Lorem Agreement”). Lorem also claimed that false representations were made regarding the UK Facility’s certification to sell and distribute devices in the European Union and export such devices to China. In connection with these allegations, Lorem claimed entitlement to at least $6,000,000 in compensatory damages and operational costs and expenses (collectively, the “Lorem Claim”). On December 9, 2022, the Company entered into a settlement agreement (the “Settlement Agreement”) with Lorem to settle the Lorem Claim. 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

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 March 31, 2023, the Company accrued $1.0 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 1 share of Series F Preferred Stock. The Certificate of Designation provides 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"). The Series F Preferred Stock will be voted, without action by the holder, on any such proposal in the same proportion as shares of Common Stock are voted on such proposal. The Series F Preferred Stock otherwise has no voting rights except as otherwise required by the General Corporation Law of the State of Delaware.

The Series F Preferred Stock is 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 has 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 will not be entitled to receive dividends of any kind.

The outstanding share of Series F Preferred Stock shall be redeemed in whole, but not in part, at any time: (i) if such redemption is approved by the board of directors in its sole discretion or (ii) automatically and 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 will receive consideration of $1,000 in cash.

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.

Series B and C Preferred Stock

There were 1,014 shares of Series B Convertible Preferred Stock outstanding as of March 31, 2023 and December 31, 2022. There were 938 shares of Series C Preferred Stock outstanding as of March 31, 2023 and December 31, 2022.

As of March 31, 2023, there were 938 outstanding shares of Series C Preferred Stock that can be converted into an aggregate of 416,889 shares of common stock, and 1,014 shares of Series B Convertible Preferred Stock that can be converted into an aggregate of 5,978 shares of common stock.

Warrants

On September 25, 2019, the Company completed an underwritten public offering. The Company issued 289,000 shares of its common stock, along with pre-funded warrants to purchase 2,711,000 shares of its common stock and Series U Warrants to purchase 3,450,000 shares of its common stock at $5.00 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 75,000 shares of its common stock at $6.25 per share with a term of 5 years from the issuance date, in the form of Series U Warrants (the "Representative Warrants").

In accordance with authoritative guidance, the pre-funded warrants are classified as equity. The Series U Warrants and the Representative Warrants were initially classified at issuance as liabilities due to a contingent obligation for the Company to settle the Series U Warrants with cash upon certain change in control events. In 2020, all but 2,500 Series U Warrants were amended and met the requirements to be classified within stockholder's equity.

As of March 31, 2023, there were 2,141,000 outstanding Series U Warrants which can be exercised into an aggregate of 2,141,000 shares of common stock.

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 492,698 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 was declared effective to cover the resale of up to 9,500,000 shares of the Company's common stock comprised of (i) the 492,698 initial commitment shares, and (ii) up to 9,007,302 that the Company has reserved for issuance and sale to Lincoln Park under the Purchase Agreement from time to time from and after the date of this prospectus. The Company cannot sell more shares 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 4,000,000 shares under the 2022 Purchase Agreement for net proceeds of approximately $3.2 million. No shares were issued under the 2022 Purchase Agreement subsequent to December 31, 2022.

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 5,685,186 shares of its common stock under the 2020 Purchase Agreement for net proceeds of approximately $12.5 million. During the year issued December 31, 2022, the Company issued 5,665,000 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 1,031,371 shares of its common stock under the September 2022 Distribution Agreement for net proceeds of approximately $0.6 million. From January 1, 2023 through April 18, 2023, the Company issued 3,136,058 shares under the September 2022 Distribution Agreement for net proceeds of approximately $1.1 million.

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 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 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 shares, 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 6,902,279 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.

Stock Repurchase Program

On August 15, 2022, the Company announced that its Board of Directors has approved a share repurchase program pursuant to which the Company is authorized to repurchase up to $2.0 million of the Company's outstanding common stock. The timing and amount of any shares repurchased will be determined based on the Company's evaluation of market conditions and other factors, including consent of Oxford. Repurchases may be made from time to time on the open market over the course of 12 months. The Company is not obligated to acquire any shares and the program may be discontinued or suspended at any time. Through the date of filing of this Form 10-Q, the Company has not repurchased any of its common stock under this share repurchase program.

11. Stock-based Compensation

Under the Company's 2015 New Employee Incentive Plan (the "2015 Plan"), awards may only be granted to employees who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as a material inducement to entering into employment with the Company. As of March 31, 2023, there were 90,389 shares of common stock remaining and available for future issuances under the 2015 Plan.

The Company's 2020 Stock Incentive Plan (the "2020 Plan"), which replaced the Company's 2014 Equity Incentive Plan, provides for the award or sale of shares of common stock (including restricted stock), the award of stock units and stock appreciation rights, and the grant of both incentive stock options to purchase common stock to directors, officers, employees and consultants of the Company. The 2020 Plan, as amended, provides for the issuance of up to 3,550,000 shares of common stock, plus the number of shares available for issuance is increased to the extent that awards granted under the 2020 Plan and the Company's 2014 Equity Incentive Plan are forfeited or expire (except as otherwise provided in the 2020 Plan). As of March 31, 2023, there were 1,796,451 shares remaining and available for future issuances under the 2020 Plan.

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

A summary of activity for the three months ended March 31, 2023 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2022	1,175,016	$ 4.54	8.00	
Granted	839,266	$ 0.39		
Cancelled/forfeited	(37)	$ 26,059.46		
Balance as of March 31, 2023	2,014,245	$ 2.33	8.65	$ -
Vested and expected to vest at March 31, 2023	1,886,155	$ 2.41	8.59	$ -
Exercisable at March 31, 2023	756,581	$ 4.35	7.69	$ -

As of March 31, 2023, the total compensation cost related to non-vested stock options not yet recognized for all the Company's plans is approximately $1.1 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 2.3 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, 2022. 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 Quarterly Report on Form 10-Q. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on 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 recently 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 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 Current Good Manufacturing Practice (“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 varies 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. This in turn will provide a path to a registration 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.

At the European Society for Medical Oncology Congress, held September 9 to 13, 2022, we presented updated data from the ReSPECT-GBM trial, which evaluated 23 adult patients with recurrent GBM across eight cohorts and treated over a seven-year period. Key findings include:

- No DLTs have been observed and the procedure was very well tolerated with a strong safety profile. Minimal systemic radiation has been observed and the majority of adverse events have been mild or moderate and considered causally unrelated to rhenium (186Re) obisbemeda.
- Improved median OS rates correlated with the absorbed radiation tumor dose. When patients were stratified based on receipt of either a therapeutic or a subtherapeutic absorbed dose of radiation to the tumor, a statistically significant improvement in survival was observed. Specifically, patients receiving a therapeutic absorbed radiation dose (>100 Gray) had a median OS

of 22.9 months (95% CI of 8.8-42.3) compared to those receiving a subtherapeutic absorbed radiation dose (<100 Gray) whose median OS was 5.6 months (95% CI of 1.6-9.4).

- Feasibility to deliver up to at least 20 times more radiation to the tumor than the standard of care, EBRT. A maximum of 32.2 mCi in 12.3 mL of volume has been delivered in and near the tumors, and a maximum average absorbed dose of radiation of 740 Gray was successfully administered in a single procedure.
- Average absorbed radiation dose to the tumor increased in latter dosing cohorts with greater administered doses of rhenium (^{186}Re) obisbemeda β-particle radiation, larger drug CED infusate volumes, more catheters used (up to four versus one), and higher convection flow rates. In cohorts five and later, 82% of patients received a therapeutic radiation dose of >100Gray.
- Single-photon emission computerized tomography ("SPECT")/CT scanning was used during treatment to confirm treatment planning delivery during product infusion via CED and to compute tumor coverage and dosimetry. Post treatment imaging analyses, including MRI, relative cerebral blood volume analysis and treatment response assessment maps correlated with a positive tumor response and confirmed the presence of pseudo progression in patients with positive tumor responses.

At the Society for Neuro-Oncology Annual Meeting in November 2022, we presented patient data, which at that time included the results for 24 patients treated in the ReSPECT-GBM trial. As of the date of this SNO Annual Meeting, rhenium (^{186}Re) obisbemeda given by CED in recurrent GBM patients was observed in the trial to be feasible and well tolerated. Across all subjects in the first eight dosed cohorts (n=24), the median absorbed dose to the tumor volume increased as evaluated cohorts progressed, with patients receiving >100 Gy absorbed dose showing significant survival benefit versus patients receiving <100 Gy absorbed dose. Importantly, in a subset of patients where tumor coverage was greater than or equal to 75%, the median absorbed dose was 405 Gy (range 146-593). By contrast, given the protocol dose escalation design where early cohorts had protocol and prospectively defined lower doses, the absorbed doses were often therapeutically adequate for small tumors even with lower dose escalation administered doses. Small, absorbed doses to specific organs and whole body, are expected and well-tolerated. Based on observed and reported patient protocol observations and reporting and all available adverse event ("AE") data, rhenium (^{186}Re) obisbemeda has been, and continues to be, well-tolerated with AEs related to CED insertion that were limited and fully recovered. No AEs with an outcome of death, study discontinuation or study drug-related serious AEs have been reported.

Providing further information on medical society presentations in 2022, in the 24 subjects with recurrent GBM receiving a single administration of rhenium (^{186}Re) obisbemeda, the median OS for all 24 patients as of November 2022 was 8.8 months reflecting recent trial enrollment in the last half of 2022 and the impact of shorter OS in the subtherapeutic <100Gy, with four patients alive representing recent enrollment in the ongoing GBM development. Importantly, as noted above, earlier analyses showed in a subset of 13 patients receiving a presumed therapeutic absorbed radiation dose to the tumor (>100 Gy), the mean OS was 22.9 months, respectively, with seven of 13 patients alive. In contrast, in nine patients receiving a presumed sub-therapeutic absorbed radiation dose to the tumor (<100 Gy), the mean and median OS was 23.9 and 22.3 weeks, respectively. A Kaplan-Meier curve comparing patients with presumed therapeutic (>100 Gy) versus sub-therapeutic (<100 Gy) radiation dose to the tumor showed a statistically significant difference between the groups (p=.0003). It is hypothesized that targeted infusion of rhenium (^{186}Re) obisbemeda into the tumor by CED, which exposure and potential toxicity and concentrates radiation to the tumor and surrounding region of interest. 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.

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 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 (186Re) 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. Cohort 3 is currently enrolling, with protocol defined FDA review to allow proceeding with Cohort 4-7 expansion after the protocol defined observation period and independent DSMB review.

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.

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 second or third quarter of 2023.

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 188RNL-BAM technology from UTHSA, and began planning to develop the drug product and complete early preclinical studies to support a future FDA IND submission. Our intended initial clinical target is liver cancer which is the sixth most common and third deadliest cancer worldwide. It is a rare disease with increasing U.S. annual incidence (42,000) and deaths (30,000).

Recent Developments

Grant Agreement with CPRIT

As noted above in the LM development discussion, 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 ^{186}RNL 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 ^{186}RNL 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 $0.5 million of grant revenue during the three months ended March 31, 2023, which represents CPRIT's share of the costs incurred for our ^{186}RNL development for the treatment of patients with LM.

Research and development expenses

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

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

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 2,963	$ 1,760
Share-based compensation	20	25
Total research and development expenses	$ 2,983	$ 1,785

The increase of $1.2 million in research and development expenses for the three months ended March 31, 2023 as compared to the same period in 2022 was due primarily to a license agreement payment of $0.8 million to NanoTx resulting from the first patient treated in the GBM phase 2 trial, $0.9 million from treatment of 10 patients in Q1 2023 compared to 0 treated in Q1 2022 and a net decrease of $0.5 million in the costs related to the development of cGMP ^{186}RNL. In addition, there was an increase of $0.2 million related to personnel expenses offset by a decrease of $0.2 million related to legal and other professional expenses.

We expect aggregate research and development expenditures to remain consistent during the remainder of 2023 as compared to the corresponding comparable period ended December 31, 2022, due to an increase in licensing payments and an increase in patients treated 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 months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
General and administrative	$ 2,123	$ 1,986
Share-based compensation	120	155
Total general and administrative expenses	$ 2,243	$ 2,141

General and administrative expenses increased by approximately $0.1 million during the three months ended March 31, 2023, as compared to the same period in 2022. The increase was due primarily due to an increase of professional services of $0.4 million offset by a decrease in legal expenses of $0.3 million.

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 months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 20	$ 25
General and administrative	120	155
Total share-based compensation	$ 140	$ 180

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

Financing items

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

	Three Months Ended March 31,	
	2023	2022
Interest income	$ 51	$ 7
Interest expense	(134)	(198)
Change in fair value of liability instruments	—	1
Loss on disposal of property and equipment	(2)	—
Total	$ (85)	$ (190)

The decrease in interest expense for the three months ended March 31, 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 $0.4 million for the three months ended March 31, 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 March 31, 2023 and December 31, 2022 (in thousands):

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 12,723	$ 18,120
Current assets	$ 13,629	$ 21,817
Current liabilities	12,796	11,852
Working capital	$ 833	$ 9,965

We incurred net losses of $4.8 million for the three months ended March 31, 2023. We have an accumulated deficit of $472.0 million as of March 31, 2023. Additionally, we used net cash of $5.8 million to fund our operating activities for the three months ended March 31, 2023. These factors raise substantial doubt about our ability to continue as a going concern.

To date, our operating losses have been funded primarily from outside sources of invested capital from issuance of our common and preferred stocks, proceeds from our term loan with Oxford and grant funding. 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 ^{186}RNL 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 1,031,371 shares under the September 2022 Distribution Agreement for net proceeds of approximately $0.6 million. From January 1, 2023 through April 18, 2023, we issued 3,136,058 shares under the September 2022 Distribution Agreement for net proceeds of approximately $1.1 million.

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 9,500,000 shares of our common stock comprised of (i) the 492,698 initial commitment shares, and (ii) up to 9,007,302 shares that we have reserved for issuance and sale to Lincoln Park under the Purchase Agreement. An additional commitment fee equal to 2.5% of the remainder of the $50 million will be paid if and when we sell over $25.0 million of our common stock under the 2022 Purchase Agreement. The additional commitment fee

may be paid in cash, common stock, or a combination thereof. We cannot sell more shares under the 2022 Purchase Agreement without registering additional shares.

During the period from August 17, 2022 to December 31, 2022, the Company issued 4,000,000 shares under the 2022 Purchase Agreement for net proceeds of approximately $3.2 million. From January 1, 2023 to the date of filing of this Form 10-Q, we did not issue any shares under the 2022 Purchase Agreement.

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 6,902,279 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 three months ended March 31, 2023 and 2022 is summarized as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Net cash used in operating activities	$ (5,793)	$ (3,876)
Net cash used in investing activities	(97)	(577)
Net cash provided by financing activities	493	7,292
Net (decrease) increase in cash and cash equivalents	$ (5,397)	$ 2,839

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.

On March 31, 2022, we entered into the Sales Order with Medidata pursuant to which Medidata will build the SCA platform that facilitates the use of historical clinical data to incorporate into the Company's Phase 2 clinical trial of ^{186}RNL in GBM.

We are also obligated to make ongoing payments against the remaining principal, interest and final payments of approximately $5.2 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, as described in more detail in Note 8 of the accompanying condensed financial statements, 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 three months ended March 31, 2023 was $5.8 million compared to $3.9 million in the same period of 2022. Our operational cash use increased during the three months ended March 31, 2023 as compared to the same period in 2022, due primarily to increased expenditures for our research and development activities and payments and a net decrease in accounts payable and accrued expenses.

Investing activities

Net cash used in investing activities for the three months ended March 31, 2023 was related to purchases of fixed assets of $0.1 million. Net cash used in investing activities for the three months ended March 31, 2022 was related to cash payments of $0.3 million made for in process research and development assets from UTHSCSA and purchases of fixed assets and intangible assets of $0.3 million.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2023 was primarily related to sales of common stock of $0.9 million, net of offering cost through the September 2022 Distribution Agreement with Canaccord.

Net cash provided by financing activities for the three months ended March 31, 2022 was primarily related to sales of common stock of $7.7 million, net of offering cost through the 2022 Distribution Agreement with Canaccord and the 2020 Purchase Agreement with Lincoln Park.

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 the three months ended March 31, 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 Quarterly Report on 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 effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended March 31, 2023 that have materially affected, or are 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 Quarterly Report on 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.

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. On March 12, 2023, in a joint statement by the Department of the Treasury, Federal Reserve, and FDIC, it was announced that all depositors will be fully protected and will have access to all of their money starting on March 13, 2023. We do not hold cash deposits with SVB and do not otherwise have a business relationship with SVB. However, 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 March 31, 2023, we had an accumulated shareholders' deficit of approximately $472.0 million and approximately $12.7 million of cash and cash equivalents and $0.8 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 Quarterly Report on 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.

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

On March 3, 2023, we entered into a Subscription and Investment Representation Agreement (the "Subscription Agreement") with Richard J. Hawkins, Chairman of the board of directors, who is an accredited investor (the "Purchaser"), pursuant to which we issued and sold one share of our 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. The sale of one share of Series F Preferred Stock was exempt from registration under the exemption provided by Rule 506 of Regulation D, as promulgated under the Securities Act.

On March 3, 2023, we 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 Preferred Stock. The Certificate of Designation provides that the Preferred Stock will have 50,000,000 votes per share of Preferred Stock and will vote together with our common stock, $0.001 par value (the "Common Stock") as a single class exclusively with respect to any proposal to amend our Amended and Restated Certificate of Incorporation (as may be amended and/or restated from time to time, the "Amended Certificate") to effect a reverse stock split of the Common Stock ("Reverse Stock Split"). The Preferred Stock will be voted, without action by the holder, on any such proposal in the same proportion as shares of Common Stock are voted on such proposal. The Preferred Stock otherwise has no voting rights except as otherwise required by the General Corporation Law of the State of Delaware.

The Preferred Stock is not convertible into, or exchangeable for, shares of any other class or series of stock or other securities. The Preferred Stock has no rights with respect to any distribution of our assets, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up, whether voluntarily or involuntarily. The holder of the Preferred Stock will not be entitled to receive dividends of any kind.

The outstanding share of Preferred Stock shall be redeemed in whole, but not in part, at any time: (i) if such redemption is approved by the board of directors in its sole discretion or (ii) automatically and effective upon the approval by our stockholders of a Reverse Stock Split. Upon such redemption, the holder of the Preferred Stock will receive consideration of $1,000 in cash.

The Subscription Agreement contains customary representations and warranties and certain indemnification rights and obligations of the parties.

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	Amended and Restated Bylaws of Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 3.1	09/21/2021
3.7	Certificate of Designation of Series F Preferred Stock, dated March 3, 2023		8-K	001-34375 Exhibit 3.1	03/03/2023
10.1	Subscription and Investment Representation Agreement, dated March 3, 2023, by and between Plus Therapeutics, Inc. and the purchaser signatory thereto		8-K	001-34375 Exhibit 10.1	03/03/2023
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: April 20, 2023

Marc H. Hedrick

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

By: /s/ Andrew Sims

Dated: April 20, 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: April 20, 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: April 20, 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 March 31, 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: April 20, 2023

Marc H. Hedrick

President & Chief Executive Officer

By: /s/ Andrew Sims

Dated: April 20, 2023

Andrew Sims

Chief Financial Officer & VP of Finance