

**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, 2022

OR

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

For the transition period from _____ to _____

Commission file number 001-34375

PLUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation or organization)

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

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

78756
(Zip Code)

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised 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 14, 2022, there were 22,197,635 shares of the registrant's common stock outstanding.

PLUS THERAPEUTICS, INC.

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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; the Company’s strategic collaborations and license agreements, intellectual property, FDA 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, 2021, 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 regenerative medicine field, 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, 2021, and under “Part II – Item 1A – Risk Factors” in this Quarterly report. These risks and uncertainties could cause actual results to differ materially from expectations or those expressed in these forward-looking statements.

We encourage you to read the risks described under “Risk Factor Summary” and “Part II – Item 1A – Risk Factors” in this report carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance.

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,239	\$ 18,400
Other current assets	865	1,324
Total current assets	<u>22,104</u>	<u>19,724</u>
Property and equipment, net	1,558	1,477
Operating lease right-use-of assets	316	341
Goodwill	372	372
Intangible assets, net	150	51
Other assets	16	16
Total assets	<u>\$ 24,516</u>	<u>\$ 21,981</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,203	\$ 4,151
Operating lease liability	110	111
Term loan obligation, current	1,608	1,608
Total current liabilities	<u>4,921</u>	<u>5,870</u>
Noncurrent operating lease liability	235	269
Term loan obligation	4,718	5,005
Warrant liability	—	1
Total liabilities	<u>9,874</u>	<u>11,145</u>
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 22,197,635 and 15,510,025 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	22	16
Additional paid-in capital	465,646	457,730
Accumulated deficit	(451,026)	(446,910)
Total stockholders' equity	<u>14,642</u>	<u>10,836</u>
Total liabilities and stockholders' equity	<u>\$ 24,516</u>	<u>\$ 21,981</u>

See Accompanying Notes to these Condensed Financial Statements

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

	For the Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 1,785	\$ 1,127
General and administrative	2,141	1,352
Total operating expenses	<u>3,926</u>	<u>2,479</u>
Operating loss	<u>(3,926)</u>	<u>(2,479)</u>
Other income (expense):		
Interest income	7	4
Interest expense	(198)	(247)
Change in fair value of liability instruments	<u>1</u>	<u>2</u>
Total other expense	<u>(190)</u>	<u>(241)</u>
Net loss	<u>\$ (4,116)</u>	<u>\$ (2,720)</u>
Net loss per share, basic and diluted	\$ (0.19)	\$ (0.33)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	21,507,061	8,267,901

See Accompanying Notes to these Condensed Financial Statements

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

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	1,954	\$ —	6,749,028	\$ 7	\$ 436,535	\$ (433,511)	\$ 3,031
Stock-based compensation	—	—	—	—	107	—	107
Sale of common stock, net	—	—	2,534,879	2	7,076	—	7,078
Conversion of Series B Convertible Preferred Stock into common stock	(2)	—	118	—	—	—	—
Issuance of common stock for exercise of warrants	—	—	896,500	1	2,016	—	2,017
Net loss	—	—	—	—	—	(2,720)	(2,720)
Balance at March 31, 2021	<u>1,952</u>	<u>\$ —</u>	<u>10,180,525</u>	<u>\$ 10</u>	<u>\$ 445,734</u>	<u>\$ (436,231)</u>	<u>\$ 9,513</u>
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	<u>1,952</u>	<u>\$ —</u>	<u>22,197,635</u>	<u>\$ 22</u>	<u>\$ 465,646</u>	<u>\$ (451,026)</u>	<u>\$ 14,642</u>

See Accompanying Notes to these Condensed Financial Statements

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

	For the Three Months Ended March 31,	
	2022	2021
Cash flows used in operating activities:		
Net loss	\$ (4,116)	\$ (2,720)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	147	88
Amortization of deferred financing costs and debt discount	115	151
Change in fair value of liability instruments	(1)	(2)
Share-based compensation expense	180	107
Non-cash lease expense	(10)	1
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Other current assets	459	(170)
Accounts payable and accrued expenses	(650)	(461)
Net cash used in operating activities	<u>(3,876)</u>	<u>(3,006)</u>
Cash flows used in investing activities:		
Purchases of property and equipment	(210)	(84)
Purchase of intangible assets	(117)	—
In process research and development acquired	(250)	—
Net cash used in investing activities	<u>(577)</u>	<u>(84)</u>
Cash flows from financing activities:		
Principal payments of long-term obligations	(402)	—
Payment of financing lease liability	—	(6)
Proceeds from exercise of warrants	—	2,017
Proceeds from sale of common stock	7,694	7,180
Net cash provided by financing activities	<u>7,292</u>	<u>9,191</u>
Net increase in cash and cash equivalents	2,839	6,101
Cash and cash equivalents at beginning of period	18,400	8,346
Cash and cash equivalents at end of period	<u>\$ 21,239</u>	<u>\$ 14,447</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 87	\$ 96
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	\$ 171	\$ 102

See Accompanying Notes to these Condensed Financial Statements

PLUS THERAPEUTICS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2022
(UNAUDITED)

1. Basis of Presentation and New Accounting Standards

The accompanying unaudited condensed financial statements as of March 31, 2022 and for the three months ended March 31, 2022 and 2021 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, 2021 has been derived from the audited financial statements at December 31, 2021, 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, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. 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, 2021, filed with the Securities and Exchange Commission on February 24, 2022.

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 plans to adopt the new guidance on January 1, 2023, and it does not expect that adoption of this standard will have a material impact on its financial statements and related disclosures.

2. Use of Estimates

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

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

The Company incurred net losses of \$4.1 million for the three months ended March 31, 2022. The Company had an accumulated deficit of \$451.0 million as of March 31, 2022. Additionally, the Company used net cash of \$3.9 million to fund its operating activities for the three months ended March 31, 2022.

As disclosed in more detail in Note 9, the Company had entered into various financing agreements, and raised capital by issuing its common stock. The Company believes its current cash and cash equivalents will be sufficient to fund its operations for at least the next 12 months from the date these financial statements are issued.

The Company continues to seek additional capital through strategic transactions and from other financing alternatives. 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.

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 (“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.

The Series U Warrants will be 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, 2022, 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, 2022 and 2021 was not material.

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 is required to make interest only payments through May 1, 2021 and thereafter it 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 the authoritative accounting guidance, are equity classified and its respective fair value was recorded as a discount to the debt.

From September 2017 to March 2019, the Company entered into a total of seven amendments to the Term Loan which, amongst 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. The principal repayment start date was further deferred to November 1, 2021. In addition, pursuant to the Ninth Amendment, on April 1, 2020, the Company made a \$5.0 million paydown of principal upon execution of the Ninth Amendment and \$0.3 million of related final payment. In addition, an amendment fee of \$1.0 million will be payable in connection with the Ninth Amendment at the earlier of the maturity date, acceleration of the loans and the making of certain prepayments. All other major terms remained consistent.

Under authoritative guidance, the Ninth Amendment does 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 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 million. As of March 31, 2022, there was \$3.6 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 each of the three months ended March 31, 2022 and 2021 was \$0.2 million. 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, 2022 and 2021, 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, 2022, the Company has not received any notification or indication from Oxford to invoke the material adverse change clause.

6. Loss per Share

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding as calculated using the treasury stock method. Potential 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,	
	2022	2021
Outstanding stock options	1,170,873	691,263
Preferred stock	422,867	422,867
Outstanding warrants	2,141,378	2,141,378
Total	3,735,118	3,255,508

7. 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. On March 1, 2021, the Company entered into a lease agreement for office space in Charlottesville, Virginia (the "Charlottesville Lease"). The Charlottesville Lease has a term of 12 months and is renewable for four additional one-year periods. The minimum lease payment is \$30,000 for the first twelve months, subject to a 3% annual increase if and when the lease is renewed. The lease commencement date is April 1, 2021 and currently expires on March 31, 2023. The Company measured the operating lease right-of-use asset and related lease liability related to the Charlottesville Lease as of the lease commencement date. In addition, the Company has entered into leases for certain equipment under various operating and finance leases. During 2021, contractual terms of all finance leases had expired and the Company did not have any right-of-use assets or lease liabilities relating to finance leases as of March 31, 2022. 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, 2022, weighted average discount rate used to measure operating lease liabilities and the operating leases remaining term were 9.0% and 2.82%, respectively.

The table below summarizes the Company's lease costs from its unaudited condensed statement of operations, and cash payments from its unaudited condensed statement of cash flows during the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Lease expense:		
Operating lease expense	\$ 45	\$ 50
Finance lease expense:		
Depreciation of right-of-use assets	—	4
Total lease expense	\$ 45	\$ 54
Cash payment information:		
Operating cash used for operating leases	\$ 45	\$ 49
Financing cash used for finance leases	\$ —	\$ 6
Total cash paid for amounts included in the measurement of lease liabilities	\$ 45	\$ 55

Total rent expenses for the three months ended March 31, 2022 and 2021 were \$60,000 and \$50,000, 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, 2022 are as follows (in thousands):

	Operating Leases
Remainder of 2022	\$ 114
2023	137
2024	113
2025	18
Thereafter	—
Total minimum lease payments	\$ 382
Less: amount representing interest	(37)
Present value of obligations under leases	345
Less: current portion	(110)
Noncurrent lease obligations	\$ 235

Services Agreement and Statement of Work with Medidata

On March 31, 2022, the Company and Medidata Solutions, Inc. ("Medidata") entered into a Statement of Work (the "SOW"), 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 NanoLiposome (¹⁸⁶RNL) in recurrent glioblastoma ("GBM"). The SOW is governed under the terms of a services agreement (the "Services Agreement"), dated November 5, 2021.

The SOW has a term of six (6) months. The Company will pay Medidata \$1.45 million in managed services fees and a contingent managed services fee of \$150,000 if the U.S. Food & Drug Administration approves a path forward for the Company to use the SCA in its clinical trial of ¹⁸⁶RNL for treatment of GBM. The SOW may only be terminated for a material breach by either party or if the clinical study's authorization or approval is withdrawn by a regulatory agency.

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 RNL-Liposome Intermediate Drug Product. The MSA includes the transfer of analytical methods, development of microbiological methods, process transfer and optimization, intermediate drug product manufacturing, and stability studies for the Company, which has been initiated at Piramal's facility located in Lexington, Kentucky.

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

Other commitments and contingencies

The Company has entered into agreements with various research organizations for pre-clinical and clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, recruiting and enrolling patients, monitoring studies and data analysis. Payments under these agreements typically include fees for services and reimbursement of expenses. The timing of payments due under these agreements is estimated based on current study progress. As of March 31, 2022, 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 alleges 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 claims 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 claims entitlement to at least \$6,000,000 in compensatory damages and operational costs and expenses (collectively, the "Lorem Claim"). The Company believes that the Lorem Claim is without merit and is vigorously defending the case. No liability was accrued as of March 31, 2022.

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.

8. License Agreements

UT Health Science Center at San Antonio ("UTHSA") License Agreement

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

Pursuant to the UTHSA License Agreement, the Company was required to make an upfront payment, which was recorded as in-process research and development acquired in the condensed statement of operations for the year ended December 31, 2021. The upfront payment 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.

On May 7, 2020, all closing conditions under the NanoTx License Agreement were satisfied and the Company paid an upfront cash payment and issued 230,769 shares of its common stock to NanoTx. Cash and the fair value of common stock issued is recorded as in-process research and development expenses, pursuant to authoritative literature for asset acquisition, in the statement of operations and comprehensive loss for the year ended December 31, 2020.

9. 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. On September 21, 2021, Series A 3.6% Convertible Preferred Stock was eliminated. There were no shares of Series A 3.6% Convertible Preferred Stock immediately prior to September 21, 2021, or December 31, 2020. There were 1,014 shares of Series B Convertible Preferred Stock outstanding as of March 31, 2022 and December 31, 2021. There were 938 shares of Series C Preferred Stock outstanding as of March 31, 2022 and December 31, 2021.

As of March 31, 2022, 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, 2022, 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 Agreement

On September 30, 2020, the Company entered into 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.

On June 16, 2020, the Company received stockholder approval to permit issuances of the Company's common stock (including the issuance of more than 19.99% of the Company's common stock) to Lincoln Park pursuant to the 2020 Purchase Agreement. Based on the closing price of the Company's common stock of \$1.05 per share on March 16, 2020, the maximum number of shares the Company could issue and sell under the 2020 Purchase Agreement is approximately 23.8 million shares. Accordingly, the Company requested and received stockholder approval for the issuance of up to 23.8 million shares of the Company's common stock under the 2020 Purchase Agreement. The Company would seek additional stockholder approval before issuing more than 23.8 million shares.

Lincoln Park had no right to require the Company to sell any shares of common stock to Lincoln Park, but Lincoln Park was obligated to make purchases as the Company directs, subject to certain conditions.

Actual sales of shares of common stock to Lincoln Park under the 2020 Purchase Agreement depended 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 2020 Purchase Agreement to the Company depended on the frequency and prices at which the Company sold shares of its stock to Lincoln Park.

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 three months ended March 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.

On January 14, 2022, the Company entered into an Equity Distribution Agreement (the “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 shares (the “Shares”), with Canaccord acting as an agent for sales. Canaccord will use its commercially reasonable efforts to sell the Shares requested by the Company to be sold on its behalf. The Company has no obligation to sell any of the Shares. The Company may instruct Canaccord not to sell the Shares 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 2022 Distribution Agreement. During the three months ended March 31, 2022, the Company issued 1,022,610 shares under the 2022 Distribution Agreement for net proceeds of approximately \$0.7 million.

On October 23, 2020, the Company entered into an Equity Distribution Agreement (the “2020 Distribution Agreement”) with Canaccord. The Company had no obligation to sell any of the ATM Shares and it could instruct Canaccord not to sell the ATM Shares if the sales could not be effected at or above the price the Company designated from time to time and the Company could at any time suspend sales pursuant to the 2020 Distribution Agreement.

During the year ended December 31, 2021, the Company issued 2,179,193 shares under the 2020 Distribution Agreement for net proceeds of \$6.3 million. The 2020 Distribution Agreement has been terminated.

10. Stock-based Compensation

On February 6, 2020, the Company amended the Company’s 2015 New Employee Incentive Plan (the “2015 Plan”) to increase the total number of shares of common stock reserved for issuance under the plan by 250,000 shares. Awards may only be granted under the 2015 Plan 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, 2022, there were 90,389 shares of common stock remaining and available for future issuances under the 2015 Plan.

On June 16, 2020, the stockholders of the Company approved the Company’s 2020 Stock Incentive Plan (the “2020 Plan”), which replaced the Company’s 2014 Equity Incentive Plan. The 2020 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. The 2020 Plan provides for the issuance of up to 550,000 shares of common stock, and the number of shares available for issuance will be 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). On May 17, 2021, the stockholders of the Company approved an amendment and restatement to the 2020 Plan to increase the total number of shares of common stock reserved for issuance under the 2020 Plan by 1,000,000 shares. As of March 31, 2022, there were 640,212 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 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, 2022 is as follows:

	<u>Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value</u>
Balance as of December 31, 2021	1,170,890	\$ 5.01	9.00	
Granted	—	\$ —		
Cancelled/forfeited	(17)	\$ 24,706.00		
Balance as of March 31, 2022	<u>1,170,873</u>	<u>\$ 4.65</u>	<u>8.75</u>	<u>\$ -</u>
Vested and expected to vest at March 31, 2022	<u>460,217</u>	<u>\$ 8.04</u>	<u>8.47</u>	<u>\$ -</u>
Exercisable at March 31, 2022	<u>1,102,117</u>	<u>\$ 4.74</u>	<u>8.73</u>	<u>\$ -</u>

As of March 31, 2022, the total compensation cost related to non-vested stock options not yet recognized for all the Company’s plans is approximately \$1.3 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 2.79 years.

11. COVID-19 Pandemic and CARES Act

A novel strain of coronavirus (COVID-19) was declared a global pandemic by the World Health Organization in March 2020. COVID-19 has presented substantial public health and economic challenges and is affecting economies, financial markets and business operations around the world. While the Company has implemented additional health and safety precautions and protocols in response to the pandemic and government guidelines, the Company has not experienced a significant impact on its business and operations. However, the Company may experience disruptions that could adversely impact its business operations as well as its preclinical studies and clinical trials. The Company considered the impacts of COVID-19 on the assumptions and estimates used to prepare its financial statements and determined that there were no material adverse impacts on the Company's results of operations and financial position at March 31, 2022. The full extent to which the COVID-19 pandemic will directly or indirectly impact its business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national and international markets.

In response to the COVID-19 pandemic, the CARES Act was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act had no material impact on the Company's income tax provision for the year ended December 31, 2021 or the three months ended March 31, 2022. The Company continues to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows.

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, 2021, as filed on February 24, 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, 2021, 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 which 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 innovative, targeted radiotherapeutics for adults and children with rare and difficult-to-treat 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 within nanoliposomes and microspheres. Our formulations are intended to achieve elevated tumor absorbed radiation doses and extended retention times such that the clearance of the isotope occurs after significant radiation decay, which we believe 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 4-6 weeks (which is onerous for patients), radiation that inadvertently damages healthy cells and tissue, and a very limited amount of radiation that can be safely delivered, 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 efficacy, we hope to reduce the toxicity of radiation 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 NanoLiposome (“¹⁸⁶RNL”) is designed specifically to target central nervous system (“CNS”) cancers including recurrent glioblastoma, leptomeningeal metastases, and pediatric brain cancers by direct localized delivery utilizing approved standard-of-care tissue access such as with conduction enhanced delivery (“CED”) and intraventricular brain catheters (Ommaya reservoir). Our recently acquired radiotherapeutic candidate, Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere (“¹⁸⁸RNL-BAM”) is designed to treat many solid organ cancers including primary and secondary liver cancers.

Our headquarters and manufacturing facilities are in Texas and are nearby 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.

Pipeline

Our most advanced investigational drug, ¹⁸⁶RNL, is a patented radiotherapy potentially useful for patients with CNS and other cancers. Preclinical study data describing the use of ¹⁸⁶RNL for several cancer targets have been published in peer-reviewed journals. Besides glioblastoma, leptomeningeal metastases, and pediatric brain cancer, ¹⁸⁶RNL has been reported to have potential applications for head and neck cancer, ovarian cancer, breast cancer and peritoneal scirinosomatosis.

The ¹⁸⁶RNL technology was part of a licensed radiotherapeutic portfolio that we acquired from NanoTx, Corp. (“NanoTx”) on May 7, 2020. The licensed radiotherapeutic has been evaluated in preclinical studies for several cancer targets and we have an active \$3.0 million award from U.S. National Institutes of Health/National Cancer Institute which will provide financial support for the continued clinical development of ¹⁸⁶RNL for recurrent glioblastoma through the completion of a Phase 2 clinical trial including enrollment of up to 55 patients. Thus far, 23 patients have been treated in the Phase 1 clinical trial and the Phase 2 clinical trial has not yet been

initiated.

We are currently conducting the ReSPECT-GBM and ReSPECT-LM clinical trials for recurrent glioblastoma (“GBM”) and leptomeningeal metastases (“LM”), respectively. In addition, we anticipate seeking the U.S. Food and Drug Administration (“FDA”) Investigational New Drug (“IND”) approval for the ReSPECT-PBC clinical trial for pediatric brain cancer (“PBC”) in late 2022 or early 2023.

¹⁸⁶RNL versus External Beam Radiation Therapy

¹⁸⁶RNL is a novel injectable radiotherapy designed to deliver targeted, high dose radiation directly into glioblastoma tumors in a safe, effective, and convenient manner that may ultimately prolong patient survival. ¹⁸⁶RNL is composed of the radionuclide Rhenium-186 and a nanoliposomal carrier, and is infused in a highly targeted fashion, directly into the tumor via precision brain mapping and convection enhanced delivery (“CED”). Potential benefits of ¹⁸⁶RNL compared to standard external beam radiotherapy (“EBRT”) include:

- The ¹⁸⁶RNL radiation dose delivered to patients may be up to 20 times greater than what is possible with commonly used EBRT.
- ¹⁸⁶RNL can be visualized in real-time during administration, possibly giving clinicians better control of radiation dosing and distribution.
- ¹⁸⁶RNL potentially more effectively treats the bulk tumor and microscopic disease that has already invaded healthy tissue.
- ¹⁸⁶RNL is infused directly into the targeted tumor, bypassing the blood brain barrier, which 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.
- ¹⁸⁶RNL 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 5 days a week for approximately 4-6 weeks.

ReSPECT-GBM Trial for Recurrent GBM

GBM is the most common, complex, and aggressive primary brain cancer in adults. Annually in the U.S., there are 12,900 GBM cases diagnosed and approximately 10,000 patients succumb to the disease each year. The average life expectancy with primary glioblastoma is less than 24 months, with a one-year survival rate of 40.8% and a five-year survival rate of only 6.8%. GBM often causes and presents with headaches, seizures, vision changes and other significant neurological complications. Despite the best available medical treatments to eliminate the initial brain tumor, some microscopic disease frequently remains, with tumor regrowth within months. Approximately 90% or more of patients with primary GBM experience tumor recurrence. Complete surgical removal of GBM is not typically possible and GBM is often resistant or quickly develops resistance to most available 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.

For recurrent GBM, there are few currently approved treatments that 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 effective in many malignancies including glioblastoma, the maximum possible administered dose is limited by toxicity to the normal tissues surrounding the malignancy. In contrast, targeted radiopharmaceuticals that precisely deliver radiation in the form of beta particles such as Iodine-131 for thyroid cancer, are known to minimize exposure to normal cells and tissues which we hope will result in a safer and more effective treatment.

Interim results from our ongoing Phase 1/2a ReSPECT-GBM trial, suggest beta particle energy from our lead investigational drug ¹⁸⁶RNL may also have utility in treating GBM and other malignancies. More specifically, the preliminary data from ReSPECT-GBM indicates 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 without significant or dose limiting toxicities. In comparison, current EBRT protocols for recurrent GBM typically recommend a total maximum dose of about 35 Gy.

In September 2020, the FDA granted both Orphan Drug designation and Fast Track designations to ¹⁸⁶RNL for the treatment of patients with glioblastoma.

¹⁸⁶RNL is presently under clinical investigation in a multicenter, sequential cohort, open-label, volume and dose escalation study of the safety, tolerability, and distribution of ¹⁸⁶RNL given by CED to patients with recurrent or progressive malignant glioma after standard surgical, radiation, and/or chemotherapy treatment (NCT01906385). The study uses a modified Fibonacci dose escalation, followed by a planned expansion at the maximum tolerated dose/maximum feasible dose to determine efficacy. The trial is funded through Phase 2 in large part by a NIH/NCI grant. The planned enrollment in the NIH/NCI grant is 21 patients in the dose-escalation part of the study and 34 patients in the expansion cohort. The study is in its 8th dosing administration cohort and is under development

and internal review to potentially advance to a Phase 2 or registration trial.

At the Society for Neuro-Oncology Annual Meeting in November 2021, we presented patient data which at that time included the results for 22 patients treated in the ReSPECT-GBM trial. The trial, thus far, has shown that CED in recurrent GBM patients is feasible. Median absorbed dose to the tumor volume across all subjects in the first eight cohorts (n=22) was 267.5 Gy (range 8.9-740). In a subset of patients in whom tumor coverage was greater than or equal to 75%, the median absorbed dose was 405 Gy (range 146-593). By contrast, the median absorbed doses to the whole brain and the total body across all subjects were 0.55 Gy (range 0.001-2.728) and 0.09 Gy (range 0.001-0.182), respectively. Small doses, as delivered to the body, are typically well-tolerated. Based on observed and reported patient protocol activity and all available adverse event (“AE”) data, ¹⁸⁶RNL has been well-tolerated. No AEs with an outcome of death or study drug-related serious AEs have been reported. Furthermore, no patient has been discontinued from the study because of an AE. All AEs have been mild or moderate (Grade 1 or 2) in intensity, except for one case of Grade 3 vasogenic edema, which was considered by the investigator to be unrelated to the study drug. AEs considered by the investigator to be at least possibly related to ¹⁸⁶RNL have included Grade 1 to 2 skin and soft tissue infection, intermittent cephalgia, neck and jaw pain, nausea with or without vomiting, constipation, increased lethargy, difficulty walking (gait disturbance), worsening double vision, and dysuria. Scalp discomfort and tenderness related to the surgical procedure has also been reported.

In the 22 subjects with recurrent GBM receiving a single administration of ¹⁸⁶RNL, the mean & median OS for all 22 patients as of November 2021 was 48.1 & 33.1 weeks, respectively, with 7 patients alive. In a subset of 13 patients receiving a presumed therapeutic absorbed radiation dose to the tumor (>100 Gy), the mean & median OS was 64.8 & 47.1 weeks, respectively, with 7 of 13 patients alive. In contrast, in 9 patients receiving a presumed sub-therapeutic absorbed radiation dose to the tumor (<100 Gy), the mean and median OS was 23.9 & 22.3 weeks, respectively. A Kaplan-Meier curve comparing patients with presumed therapeutic vs. sub-therapeutic radiation dose to the tumor showed a statistically significant difference between the groups (p=.0002). It is hypothesized that targeted infusion of ¹⁸⁶RNL into the tumor by CED, bypassing the blood-brain barrier and normal brain and external tissues, significantly spares normal tissues from radiation exposure and potential toxicity and concentrates radiation to the tumor and surrounding region of interest.

ReSPECT-LM Clinical Trial for Leptomeningeal Metastases

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% of people with late-stage cancer, or 110,000 people in the U.S. each year. It is highly lethal with an average 1-year survival of just 7%. LM occurs with cancers that are most likely to spread to the central nervous system. The most common cancers to spread to the leptomeninges are breast cancer, lung cancer, melanoma and gastrointestinal cancers—though most solid tumors have the potential for LM spread.

The ReSPECT-LM Phase 1 clinical trial (ClinicalTrials.gov NCT05034497) is predicated in part upon preclinical studies in which tolerance to doses of ¹⁸⁶RNL as high as 1,075 Gy was shown in animal models with LM without significant observed toxicity. Furthermore, treatment led to marked reduction in tumor burden in both C6 and MDA-231 LM models.

In October 2021, the FDA announced clearance of our IND application for ¹⁸⁶RNL for the treatment of LM. Subsequently, in November 2021, the FDA granted a Fast Track designation for ¹⁸⁶RNL for the treatment of leptomeningeal metastases. We treated our first patient in the ReSPECT-LM Phase 1 clinical trial in Q1 2022.

The ReSPECT-LM multi-center, sequential cohort, open-label, dose escalation study is evaluating the safety, tolerability, and distribution of ¹⁸⁶RNL via 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.

ReSPECT-PBC Clinical Trial for Pediatric Brain Cancer

In August 2021, we announced plans for treating pediatric brain cancer at the 2021 American Association of Neurological Surgeons (“AANS”) 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.

Currently, we plan to investigate the use of ¹⁸⁶RNL in 2 pediatric brain cancers. High-grade glioma (HGG) is a rare, fast-growing CNS tumor that forms in glial cells of the brain and spinal cord. It can be found almost anywhere within the CNS, but is most commonly within the supratentorium in children ages 15-19. HGG tumors in children act differently from those in adults, causing headaches, seizures, and difficulty achieving developmental milestones depending on the tumor location. Approximately 360-400 children are diagnosed with HGG annually in North America and the 5-year survival rate is approximately 20%. In contrast to HGG, ependymoma is a rare, slow- or fast-growing (depending on the grade) primary CNS tumor that forms in ependymal cells in the brain and spinal cord—and may spread throughout the CNS, though infrequently. All ependymomas can recur, but patients are often tumor-free for years before testing shows tumor regrowth, either at the initial tumor site or elsewhere within the CNS. Symptoms depend on tumor location and size, usually including irritability, sleeplessness, vomiting, nausea, back pain, arm/leg weakness, and headaches.

Approximately 250 children are diagnosed with ependymoma annually in the U.S. while 71% of children with Grade II and 57% with

Grade III survive 5 years from diagnosis.

Based on the aggregate preclinical and clinical work completed to date in adult recurrent glioblastoma, we hypothesize that ¹⁸⁶RNL may offer potential clinical benefit for PBCs, such as high-grade glioma and ependymoma. We intend to submit an IND application to the FDA for ¹⁸⁶RNL for the treatment of PBC (high-grade glioma and ependymoma) in late 2022 or early 2023.

Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere Technology

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

Preclinical data from an *ex vivo* embolization experiment in which Technetium-99m-BAM was intra-arterially delivered to a bovine kidney perfusion model was presented at the recent 2021 Society of Interventional Radiology (“SIR”) Annual Scientific Meeting. The study concluded that the technology required for radiolabeling BAM could successfully deliver, embolize and retain radiation in the target organ. ¹⁸⁸RNL-BAM is a preclinical investigational drug we intend to further develop and move into clinical trials. Specifically, in 2022, we intend to transfer the ¹⁸⁸RNL-BAM technology from UT Health Science Center at San Antonio, fabricate and scale the drug product, and complete certain preclinical studies to support a future FDA IND submission. Our likely initial clinical target is liver cancer which is the 6th most common and 3rd deadliest cancer worldwide. It is a rare disease with increasing U.S. annual incidence (42,000) and deaths (30,000).

Recent Developments

Services Agreement and Statement of Work with Medidata

On March 31, 2022, we entered into a Statement of Work (the “SOW”) with Medidata Solutions, Inc. (“Medidata”), 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 ¹⁸⁶RNL in GBM.

The SOW has a term of six (6) months. We will pay Medidata \$1.45 million in managed services fees and a contingent managed services fee of \$150,000 if the U.S. Food & Drug Administration approves a path forward for us to use the SCA in its clinical trial of ¹⁸⁶RNL for treatment of GBM. The SOW may only be terminated for a material breach by either party or if the clinical study’s authorization or approval is withdrawn by a regulatory agency.

UT Health Science Center San Antonio (UTHSA) License Agreement

On December 31, 2021, we entered into an exclusive license agreement with UT Health Science Center at San Antonio for the global rights to develop and commercialize ¹⁸⁸RNL-BAM. Under the license agreement with UT Health Science Center at San Antonio, we are required to use commercial reasonable efforts to develop the ¹⁸⁸RNL-BAM product candidate acquired under the license agreement. Further, we are subject to future milestone, earn-out and other payments to UT Health Science Center at San Antonio all of which are tied to our commercialization and sale activities for product candidates.

Recent Financings

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

Results of Operations

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, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 1,760	\$ 1,106
Share-based compensation	25	21
Total research and development expenses	\$ 1,785	\$ 1,127

The increase of \$0.7 million in research and development expenses for the three months ended March 31, 2022 as compared to the same period in 2021 was due primarily to increased expenditures related to increase in development costs of 186RNL of \$0.5 million as we ramp up to plan for the pivotal trial, an increase of \$0.1 million in professional expenses and an increase of \$0.1 million in personnel expenses.

We expect aggregate research and development expenditures to increase in absolute dollars during 2022 due to the expected costs of development of the 186RNL™ therapy acquired from NanoTx and development expenses related to 188RNL-BAM.

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, 2022 and 2021 (in thousands):

	<u>Three Months Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
General and administrative	\$ 1,986	\$ 1,266
Share-based compensation	155	86
Total general and administrative expenses	<u>\$ 2,141</u>	<u>\$ 1,352</u>

General and administrative expenses increased by approximately \$0.8 million during the three months ended March 31, 2022 as compared to the same period in 2021. The increase was primarily due to an increase of \$0.6 million of legal, intellectual property and other professional expenses, and an increase of \$0.2 million of personnel related expenses.

We expect general and administrative expenditures to remain generally consistent in 2022 as compared with the year ended December 31, 2021, subject to litigation cost which is not predictable at this time.

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, 2022 and 2021 (in thousands):

	<u>Three Months Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Research and development	\$ 25	\$ 21
General and administrative	155	86
Total share-based compensation	<u>\$ 180</u>	<u>\$ 107</u>

The increases in our stock-based compensation was primarily due to increases in grants of stock-based options as well as higher grant-date fair value of stock-based awards.

Financing items

The following table summarizes interest income, interest expense, and other income and expense for the three months ended March 31, 2022 and 2021 (in thousands):

	<u>Three Months Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Interest income	\$ 7	\$ 4
Interest expense	(198)	(247)
Change in fair value of liability instruments	1	2
Total	<u>\$ (190)</u>	<u>\$ (241)</u>

The decrease in interest expense for the three months ended March 31, 2022 as compared to the same periods in 2021 was primarily due to the repayment of debt principal of \$0.3 million in 2021 and \$0.4 million during the first quarter of 2022.

We expect interest expense in 2022 to decrease as compared with 2021 due to scheduled debt principal repayments which commenced on November 1, 2021.

Liquidity and Capital Resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 21,239	\$ 18,400
Current assets	\$ 22,104	\$ 19,724
Current liabilities	4,921	5,870
Working capital	\$ 17,183	\$ 13,854

For the periods presented, operating losses have been funded primarily from outside sources of invested capital in our common stock. We believe that our cash and cash equivalents of \$21.2 million at March 31, 2022 will enable us to fund our current and planned operations for at least the next twelve months and beyond from the date these condensed financial statements were issued.

We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to fund our future clinical development programs and other operations. Our inability to raise additional cash would have a material and adverse impact on operations and would cause us to default on our loan.

On January 14, 2022, we entered into an Equity Distribution Agreement (the “2022 Distribution Agreement”) with Canaccord Genuity LLC (the “Agent”, or “Canaccord”), pursuant to which we may issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$5,000,000 (the “Shares”), depending on market demand, with the Agent acting as an agent for sales. Sales of the Shares 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, including, without limitation, sales made directly on or through the Nasdaq. Since January 14, 2022, we issued 1,022,610 shares under the 2022 Distribution Agreement for net proceeds of approximately \$0.7 million.

On October 23, 2020, we entered into an Equity Distribution Agreement (the “2020 Distribution Agreement”) with Canaccord, pursuant to which we could issue and sell, from time to time, our common stock in “at the market” offerings, depending on market demand, with Canaccord acting as an agent for sales. During 2021, we issued 2,179,193 shares under the 2020 Distribution Agreement for net proceeds of \$6.3 million. The 2020 Distribution Agreement has been terminated.

On September 30, 2020, we entered into the 2020 Purchase Agreement and a registration rights agreement with Lincoln Park, pursuant to which Lincoln Park committed to purchase up to \$25.0 million of our common stock. During 2021, we issued 5,685,186 shares of our common stock under the 2020 Purchase Agreement for total proceeds of \$12.5 million. During the three months ended March 31, 2022, we issued 5,665,000 shares of common stock for net proceeds of approximately \$7.0 million under the 2020 Purchase Agreement. We no longer have any additional shares of common stock registered to sell under the 2020 Purchase Agreement, and at this time we do not intend to register any additional shares of common stock under the 2020 Purchase Agreement.

We continue to seek additional capital through strategic transactions and other financing alternatives. Without additional capital, current working capital and cash generated from sales will not provide adequate funding for research 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. There may be continued market volatility due to the pandemic, downturn in global economy, or other events, which could cause our stock price to decline. This in turn will likely negatively impact our ability to raise funds through equity-related financings.

Should we be unable to raise additional cash from outside sources or if we are unable to do so in a timely manner or on commercially reasonable terms, it would have a material adverse impact on our operations.

Cash (used in) provided by operating, investing, and financing activities for the three months ended March 31, 2022 and 2021 is summarized as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	\$ (3,876)	\$ (3,006)
Net cash used in investing activities	(577)	(84)
Net cash provided by financing activities	7,292	9,191
Net increase in cash and cash equivalents	\$ 2,839	\$ 6,101

Material Cash Obligations

On March 31, 2022, we entered into the SOW with Medidata 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 186RNL in GBM.

During the six month term of the SOW, we will pay Medidata \$1.45 million in managed services fees. Further, if the U.S. Food & Drug Administration approves a path forward for us to use the SCA in its clinical trial of 186RNL for treatment of GBM, we will pay Medidata an additional contingent managed services fee of \$150,000.

We are also obligated to make ongoing principal and interest payments 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 7 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, 2022 was \$3.9 million compared to \$3.0 million in the same period of 2021. Our operational cash use increased during the three months ended March 31, 2022 as compared to the same period in 2021, due primarily to increased expenditures for our research and development activities.

Investing activities

Net cash used in investing activities for the three months ended March 31, 2022 were related to cash payments of \$0.3 million made for in process research and development assets from UTHSA and purchases of fixed assets and intangible assets of \$0.3 million. Net cash used in investing activities for the three months ended March 30, 2021 was primarily related to purchases of fixed assets.

Financing Activities

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.

Net cash provided by financing activities for the three months ended March 31, 2021 was primarily related to sales of common stock of \$7.2 million, net of offering cost through the 2020 Purchase Agreement with Lincoln Park and the 2022 Distribution Agreement with Canaccord, as well as \$2.0 million from exercise of warrants.

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, 2021 and there have been no material changes during the three months ended March 31, 2022.

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, 2022 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

On June 22, 2021, we were 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 alleges false representations were made to Lorem regarding the manufacturing facility in the United Kingdom (the “UK Facility”) that Lorem purchased from us under the Equity Purchase Agreement, dated March 29, 2019, between us and Lorem (the “Lorem Agreement”). Lorem also claims 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 claims entitlement to at least \$6,000,000 in compensatory damages and operational costs and expenses (collectively, the “Lorem Claim”). We believe that the Lorem Claim is without merit and we are vigorously defending the case.

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, 2021. There have been no material changes to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2021.

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
1.1	Distribution Agreement, dated January 14, 2022, by and among Plus Therapeutics, Inc. and Canaccord Genuity LLC		8-K	001-34375 Exhibit 1.1	01/14/2022
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
10.1+	Medidata Services Agreement and Statement of Work	X			
10.2	Distribution Agreement, dated January 14, 2022, by and among Plus Therapeutics, Inc. and Canaccord Genuity LLC.		8-K	011-34375 Exhibit 1.1	1/14/2022
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

+ Portions of this exhibit have been excluded in compliance with Item 601 of Regulation S-K.

* 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.

Dated: April 21, 2022

Dated: April 21, 2022

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick
Marc H. Hedrick
President & Chief Executive Officer (Duly Authorized Officer and Principal Executive Officer)

By: /s/ Andrew Sims
Andrew Sims
Chief Financial Officer (Duly Authorized Officer and Principal Financial Officer and Principal Accounting Officer)

Certain identified information has been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission because it is both (i) not material to investors and (ii) information that the Registrant treats as private or confidential. Such omitted information is indicated by brackets (“[]”) in this exhibit***



EXECUTION

MEDIDATA SERVICES AGREEMENT

This Medidata Services Agreement (“**Agreement**,” including all attachments hereto) is entered into as of November 05, 2021 (the “**Effective Date**”) by and between **Medidata Solutions, Inc.**, a Delaware corporation having its principal place of business at 350 Hudson Street, 9th Floor, New York, New York 10014 (together with any of its Affiliates that provide Services pursuant to Sales Orders executed hereunder, collectively, “**Medidata**”) and **Plus Therapeutics, Inc.**, having its place of business at 4200 Marathon Blvd., Suite 200, Austin, Texas, 78756, United States (“**Customer**”), on behalf of itself and any Authorized Affiliates.

1. DEFINITIONS

“**Affiliate**” means any corporation or other business entity controlled by, controlling, or under common control with Customer or Medidata, as applicable. For this purpose, “control” means (i) direct or indirect beneficial ownership of fifty (50%) percent or more of the voting control, or (ii) the power to direct or cause the direction of the management and policies of such corporation or other business entity.

“**Application Services**” means Medidata’s provision of (i) access to Medidata software applications and Documentation to Customer and its Authorized Users via Medidata’s hosted portal applications; (ii) the hosting and support services for such applications; and (iii) Medidata’s implementation of any applicable Improvements.

“**Authorized Affiliate**” means any Affiliate of Customer authorized by Customer to receive Services under the Agreement by entering into a Sales Order, subject in all cases to each such Affiliate being bound by the terms and conditions of the Agreement. Customer shall provide Medidata with advance written notification of any Authorized Affiliates. References in this Agreement to “Customer” shall mean, collectively, Customer and each of its Authorized Affiliates.

“**Authorized Users**” means employees, site investigators, study subjects, contractors and third party service providers of Customer, authorized by Customer to access the Subscription Services.

“**Confidential Information**” means all information provided by the disclosing party to the receiving party or any of its Affiliates for use in connection with the Services or this Agreement, including the terms and conditions of this Agreement, but does not include information that (i) the receiving party already knows prior to its disclosure by the disclosing party; (ii) becomes generally available to the public, except as a result of disclosure by the receiving party in violation of this Agreement; or (iii) becomes known to the receiving party on a non-confidential basis from a source other than the disclosing party.

“**Customer Data**” means the information that Customer and its Authorized Users have submitted, made available, stored and/or processed in conjunction with utilizing the Services, before or after the Effective Date. In addition, Customer Data includes information relating to Customer’s protocols, third-party contracts, third-party data and other descriptive data. Customer Data excludes [***].

“**Customer Infringement Event**” means (i) use of the Subscription Services other than as set forth herein and in the then-current version of the Documentation; (ii) combination, operation or use with software, information, data, or other materials, not approved or supplied by Medidata, if infringement (including, without limitation, contributory infringement) would have been avoided by use without such software, hardware, information, data, or other materials; or (iii) use of a superseded release of the Subscription Services if the infringement would have been avoided by use of the most current release of the Subscription Services made available by Medidata.

“**Device Provisioning**” means mobile technology device rental to Customer solely for Authorized Users’ provision of Customer Data for the applicable study during the Sales Order term in conjunction with Application Services, including: (i) device configuration setup, limited to pre-installed apps and (ii) shipment to/from the Customer specified destination.

“**Device Services**” means mobile device provisioning to Customer for use in conjunction with Application Services, including (i) Device Provisioning and/or (ii) Device Support.

“**Device Support**” means managed service call center support for Authorized Users of Device Services (sites, patients and monitors).

“**Documentation**” means Medidata’s online technical or functional user guides for the operation of the Subscription Services, as modified from time to time.

“**iMedidata**” means the hosted portal application (or any such successor application however named) provided, operated and controlled by Medidata, through which Authorized Users create or maintain accounts to access the Application Services.

“**Improvements**” means all updates, enhancements, error corrections, bug fixes, release notes, upgrades and changes to the Services, including derivative works thereof, as developed by Medidata from time to time (without use of Customer Confidential Information (except as set forth in Section 7.4)) in its sole discretion and made generally available for production access or use to Medidata’s customers.

“**Instructions**” means all provisions of this Agreement, any Sales Orders, and any written amendments to either, concerning the processing of Customer Data.

“**Intellectual Property Rights**” or “**IPR**” means all rights, title and interest to or in patent, copyright, trademark, service mark, trade secret, business or trade name, know-how and rights of a similar or corresponding character.

“**Managed Services**” means Medidata’s provision of guidance, analytics and reporting services in conjunction with Application Services on behalf of Customer.

“**Non-Production Environment**” means a non-production URL computing environment of the most current version of the Application Services that is not used to collect live Customer Data.

“**Personal Data**” means any Customer Data relating to an identified or identifiable natural person, as defined under Privacy Laws. Without limitation of the foregoing, an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to such person’s physical, physiological, mental, economic, cultural or social identity.

“**Professional Services**” means the implementation and related consulting services provided by or on behalf of Medidata to Customer during a specific period(s) of time for a fixed fee(s), unless otherwise agreed in a Sales Order(s).

“**Privacy Laws**” means all laws and regulations, including laws and regulations of the United States and European Union, the European Economic Area and their member states, applicable to the Processing of Personal Data under the Agreement, including the General Data Protection Regulation (Regulation (EU) 2016/679) (the “GDPR”), all as amended from time to time.

“**Sales Order**” shall mean the ordering documentation, including any exhibit, schedule or document attached to or referencing this Agreement, setting forth the specific Services to be provided by Medidata to Customer.

“**Services**” means the provision and development of the Subscription Services and the Professional Services, including any Improvements thereto, provided by Medidata to Customer.

“**Subscription Services**” means the Application Services, Managed Services, Device Services, or other subscription services, and any Combined Data (defined below) therein, provided by Medidata to Customer.

“**Tax(es)**” means any applicable services, sales, use, excise, goods, property, goods and services, value added (including proxy value added taxes), withholding, or other taxes or duties, whether international, national, state or local, which are levied or imposed by reason of the provision of the Services, excluding taxes on Medidata’s net income.

2. ACCESS TO THE SUBSCRIPTION SERVICES

2.1 Access. Customer shall access, and shall enable access to, the Subscription Services for use only by Customer and Authorized Users for Customer’s internal business purposes, including research and commercial analytics, in accordance with a Sales Order, and not for the benefit of any third party or for any other purpose. Customer and its Authorized Users shall access the Application Services and any Combined Data solely through Medidata’s hosted portal applications. Unless otherwise agreed upon by the parties in an applicable Sales Order, Customer shall have no other access to the Application Services and any Combined Data and shall not be entitled to download or otherwise receive a copy of the Application Services or any Combined Data. Customer shall be liable for the acts and omissions of all Authorized Affiliates and Authorized Users relating to this Agreement.

2.2 Access Restrictions. Customer shall not (i) modify, copy, translate or create any derivative works based on the Subscription Services; (ii) remove or alter any copyright notices, trademarks or other proprietary rights notices affixed to or contained within the Subscription Services; (iii) use the Subscription Services to provide hosting, service bureau, time sharing, outsourcing or other commercial services on behalf of any third parties; (iv) use or knowingly permit the use of any security testing tools in order to probe, scan or attempt to penetrate or ascertain the security of the Subscription Services; or (v) attempt to gain access to the Subscription Services or related systems or networks in a manner not set forth in the Documentation. Customer shall take all reasonable precautions to prevent any compromise of the security, integrity, or availability of the Customer Data or of any Medidata network or system. Customer shall notify Medidata without undue delay if Customer has reason to believe that such a compromise has occurred or is likely to occur. For the avoidance of doubt, such reasonable precautions include, without limitation, implementing routine scanning of systems using then-current virus scanning software and virus profiles, maintaining industry-standard security protections for any browsers or other software used to access the Subscription Services, and ensuring that all endpoints that connect to Medidata’s systems are secure. Customer will cooperate with Medidata and provide necessary information to Medidata to prevent, investigate and remediate the compromise of the security, integrity, or availability of the Customer Data, or of any Medidata network or system. If Customer fails to comply with the requirements of this Section, Medidata may prevent Customer from accessing the Subscription Services until acceptable security controls are implemented. Customer shall only enable access to and allow use of the Subscription Services in accordance with the Documentation.

2.3 Non-Production Use. Customer and its Authorized Users may have access to Application Services in a Non-Production Environment, as set forth in a Sales Order. Use of Application Services in a Non-Production Environment is provided “AS IS,” with respect to its performance. Section 11.1 of this Agreement shall not apply with respect to Application Services provided in a Non-Production Environment.

2.4 Medidata Single Sign-On Integration Requirements. Where Customer elects to create a single sign-on (“SSO”) integration with iMedidata® (“SSO Integration”) for use with Customer’s credential authorization system, it agrees to: (i) apply minimum technical requirements and comply with the acceptable use parameters (e.g., requirements for usernames, passwords, password reset, end point maintenance, and testing environments) set forth in <https://www.medidata.com/en/medidata-policies/>, as may be updated on reasonable notice by Medidata (“SSO Specifications”); (ii) promptly notify Medidata of errors or vulnerabilities discovered in Customer’s SSO Integration (to security@medidata.com); and (iii) assist Medidata with verifying Customer’s adherence to the SSO Specifications, including permitting an audit up to once annually on 45-day notice, or such audits as are required for cause. The SSO Integration may be terminated by Medidata on reasonable notice in its sole discretion.

3. COMPLIANCE

3.1 Applicable Laws. Each party shall comply with laws and regulations that affect its business generally and the provision or receipt of the Services pursuant to the Agreement, including any applicable anti-bribery, export control, clinical research (including generally accepted standards of good clinical practices (“GCP”) and Privacy Laws). Customer shall not use the Services in violation of applicable laws.

3.2 Industry-Specific Customer Duties with Respect to the Services. Customer shall:

3.2.1 be solely responsible, and assume all liability for, all operational aspects, decisions, results, and outcomes of its clinical trial(s) and related businesses including, as applicable (i) the design, structure and content of all protocols for clinical trials conducted pursuant to this Agreement; (ii) obtaining the legal basis for processing Customer Data, such as gaining consents or providing notices for study participants and Authorized Users required under Privacy Laws or GCP; (iii) the collection, quality and accuracy of Customer Data, including determination of the specific data collected; (iv) data protection agreements with any other controllers; (v) the manufacture, supply and handling of investigational products; (vi) regulatory submissions; and (vii) ensuring that Customer Data accessible via the Services is accessed only by appropriate Authorized Users;

3.2.2 obtain and provide Medidata with relevant information and materials, including protocols and amendments, data, third party licenses (including for specific medical dictionaries) or consents, and timely feedback, as reasonably required in order for Medidata to provide the Services; and

3.2.3 be responsible for having in place backup processes and mechanisms to perform critical functions to support the safety of subjects or uninterrupted clinical trial operations in the event of an unexpected outage.

4. SERVICES.

4.1 Sales Orders. Medidata shall perform Services in accordance with Medidata standard processes and policies and its Quality Management System (“QMS”). Medidata and Customer shall agree on the scope of Services, including any applications, clinical trial study and other non-study consulting parameters and fees, as well as assumptions, boundaries and service constraints. Prior to any material deviation from the Sales Order, the parties must authorize a written change order setting forth the additional scope of Services. Without limiting the generality of the foregoing, Medidata shall have no obligation to perform Services, and Customer shall have no obligation to accept or receive Services, until such time as the parties have entered into and executed a Sales Order or change order, as applicable.

4.2 Subcontractors. Except as limited in the Data Processing Exhibit, [***]. Any subcontracting shall not relieve Medidata from its obligations under this Agreement and Medidata shall be fully responsible and liable for any acts or omissions of its subcontractors in the performance of any Services.

5. HOSTING AND SUPPORT SERVICES / SERVICE LEVEL COMMITMENTS

Medidata shall provide access to and support of the Application Services in accordance with the Hosting and Support Services Policy posted at <https://www.medidata.com/en/policies>. This Hosting and Support Services Policy provides specific service level commitments which Medidata agrees to meet or exceed during the Term. Medidata shall actively monitor its compliance with these service commitments in accordance with the policy.

6. REGULATORY COMPLIANCE AND QUALITY MANAGEMENT; AUDIT

Medidata's Services are designed and conducted in accordance with its QMS which specifies the parties' roles and responsibilities and is designed to assist Customer in satisfying its compliance obligations under GCP and/or good post-marketing study practice. Medidata's QMS is captured through a set of controlled documents, maintained within Medidata's regulatory compliant electronic document management system. These Quality System Documents ("QSDs") are developed and maintained in accordance with applicable national and international regulatory requirements and industry standards and best practices. The QSDs include policies, standard operating procedures, work instructions, and other forms and templates. Medidata maintains Regulatory and Audit Policies posted at <https://www.medidata.com/policies>.

7. INTELLECTUAL PROPERTY; DATA RIGHTS

7.1 **Title to Services.** Medidata and its licensors own all IPR in and to the Services and Documentation. Full ownership of the Services (including in each case any Improvements) are and shall remain the proprietary, copyrighted and trade secret property of Medidata and its licensors. Notwithstanding the foregoing, Customer shall be entitled to independently develop procedures, test scripts, test scenarios, reports and interfaces using application programming interfaces provided by Medidata as part of the Application Services. Medidata reserves to itself all IPR not expressly granted pursuant to this Agreement. Medidata retains all IPR in reports or other materials provisioned to Customer in conjunction with the Services (e.g., incorporated functionality or formatting), exclusive of Customer Data.

7.2 **Materials.** Each party retains all IPR in and to all previously existing or newly created materials, methodologies, operating and applications software, programs, architecture data, processes, methods, creations, developments and technical information and intellectual property developed ("Developments") by such party, provided any newly created materials do not use or rely on the Confidential Information of the other party other than as expressly set forth in this Agreement or any Sales Order.

7.3 **Customer Data.** All right, title and ownership of Customer Data, including any derivatives thereof, is and shall remain solely and exclusively vested in Customer, including all IPR relating thereto. Medidata shall process Customer Data for the purpose of providing the Services to Customer pursuant to the Instructions.

7.4 **Medidata Uses.** Medidata will also process Customer Data in order to combine it with other data for inclusion in Medidata's analytical, statistical or benchmarking services ("Medidata Uses"). [***] (the "Combined Data"). The Medidata Uses are at Medidata's sole risk, and Medidata shall not rely upon Customer's legal basis in providing any Personal Data to Medidata for the Medidata Uses (e.g., patient consent). Medidata represents and warrants that all Medidata Uses are permitted by Privacy Laws. In addition, the Combined Data shall not disclose, or permit the identification of, any of Customer's Personal Data, Customer's identity or Customer's Confidential Information. The Instructions include that Medidata shall anonymize the Combined Data.

7.5 **Customer Access to Combined Data.** Customer shall only access or use Combined Data as set forth in Sections 2.1, 2.2 and 9.6 of this Agreement and as set forth in a Sales Order. Upon termination or expiration of the applicable Sales Order term, Customer shall (i) cease using the Combined Data and any derivatives; and (ii) destroy or return all copies or extracts thereof to Medidata. Customer represents and warrants that, with respect to Combined Data, it has implemented business processes that specifically prohibit reidentification, and that it will not, and will not permit any entity or person to, reidentify or attempt to reidentify any individual or the source of any data contained within the Combined Data (e.g., through combination with external data sources).

8. PAYMENT TERMS

8.1 **Payment and Fees.** Customer agrees to pay the fees set forth in the Sales Order(s) and in the manner set forth therein. Except as specifically set forth to the contrary under Article 11 (Limited Warranties and Exclusions) and Article 13 (Indemnification), all payment obligations under any Sales Order(s) are non-cancelable and all payments made are non-refundable. Medidata shall electronically invoice Customer at the e-mail address provided by Customer. Customer shall pay all invoices in US dollars or such other currency reflected in the Sales Order within [***].

8.2 **Taxes.**

8.2.1 Except as otherwise agreed in an applicable Sales Order, the fees do not include any Taxes. For purposes of reporting or collecting any present or future Taxes owed with respect to or as a result of this Agreement, Customer agrees to treat the Subscription Services as a service (and not as "royalties") and any amounts owed or owing under Section 8.1 as payments for fees from the provision of services. If Medidata has a legal obligation to pay or collect Taxes for which Customer is responsible under Section 8.2.1, Medidata shall invoice the appropriate amount to Customer, unless Customer provides Medidata with a valid tax exemption certificate authorized by the appropriate taxing authority.

8.2.2 All payments shall be made to Medidata without deductions or withholding based on any Taxes, unless agreed upon in advance by the parties. If the parties agree that payments made pursuant to Section 8.1 of this Agreement are properly subject to withholding under applicable laws, Customer agrees to provide Medidata with any information, certification, or other documentation as may reasonably be necessary to mitigate, reduce or eliminate any Tax that could be imposed that are attributable to fees paid to Medidata under this Agreement, including (but not limited to) cooperation in obtaining relief or exemption under the applicable double taxation treaty or the claiming of foreign tax credits.

9. TERM AND TERMINATION

9.1 **Term.** This Agreement shall commence on the Effective Date and continue unless terminated earlier in accordance with the provisions of this Article 9 (the "Term"). Upon execution of any Sales Order, neither party shall have the right to terminate such Sales Order, except as provided in Section 9.2 (Termination for Material Breach) and Section 9.4 (Termination of Sales Orders for Cancelled Studies).

9.2 **Termination for Material Breach.** In the event either party defaults in any material obligation in this Agreement or a Sales Order, the non-defaulting party shall give written notice of such default. If the party in default has not cured the default within [***] of receipt of the notice, the non-defaulting party may terminate this Agreement or the applicable Sales Order by delivering notice thereof to the defaulting party.

9.3 **Termination for Insolvency.** Either party may terminate this Agreement, effective immediately upon written notice, in the event that the other party: (i) makes a general assignment for the benefit of creditors; (ii) institutes proceedings seeking relief or reorganization under any laws relating to bankruptcy or insolvency; or (iii) has a court of competent jurisdiction appoint a receiver, liquidator or trustee over all or substantially all of such party's property or provides for the liquidation of such party's property or business affairs.

9.4 **Termination of Sales Orders for Cancelled Studies.** In the event that a regulatory agency withdraws authorization and approval to conduct an individual study which is the subject of a Sales Order under this Agreement or Customer reasonably determines that a study should terminate or be transferred from Customer to a clinical research organization that has been accredited by Medidata pursuant to Medidata's partner accreditation program, Customer may terminate the applicable single study Sales Order. In the event of a study termination or such transfer, Customer shall notify Medidata via the Study Termination Request Form posted at <https://www.medidata.com/en/study-termination-form/>. Such notification must be electronically signed by an authorized officer, or other duly authorized representative of Customer, and must be received by Medidata at least [***] in advance of the effective date of such study cancellation. For the avoidance of doubt, this Section 9.4 does not apply to multi-study Sales Orders.

9.5 **Study Suspension.** In the event that Customer reasonably determines that a study must be suspended, then Customer may suspend the applicable single study Sales Order (but not, for the avoidance of doubt, a multi-Study Sales Order) in accordance with the Study Postponement and Suspension Policy posted at <https://www.medidata.com/en/study-postponement-suspension-policy>.

9.6 **Effect of Termination.** Termination of this Agreement or a Sales Order shall terminate all Services provided by Medidata thereunder, and Customer and its Authorized Users shall cease all use of the applicable Services on the effective date of termination. Medidata shall invoice for Services rendered through the effective date of termination and any non-cancellable third-party fees accrued by Medidata in the provision of the Services prior to the effective date of termination. Notwithstanding the foregoing, if, upon the expiration of the Term or any termination of this Agreement for any reason other than termination by either party under Section 9.2 for a material breach by the other party, there are Sales Orders for ongoing Services which were effective prior to the effective date of such expiration or termination of this Agreement, the terms and conditions of this Agreement shall remain in full force and effect with regard to any such Sales Order(s) until the expiration or termination thereof.

9.7 **Return of Data Post Termination.** Medidata shall provide Customer with access to the Application Services during the term of the Sales Order for the purpose of downloading Customer Data in a durable format. If Customer Data is not available for download through the Application Services, upon request from Customer during the Sales Order term Medidata will deliver Customer Data to Customer in a durable format. If Customer requires Medidata's assistance to access Customer Data upon the expiration or termination of the Sales Order, Customer may acquire Medidata's Services pursuant to a separately executed Sales Order.

10. CONFIDENTIALITY

All Confidential Information disclosed under this Agreement shall remain the exclusive and confidential property of the disclosing party. The receiving party shall not disclose to any third party the Confidential Information of the disclosing party and shall use at least the same degree of care, discretion and diligence in protecting the Confidential Information of the disclosing party as it uses with respect to its own confidential information. The receiving party shall limit access to Confidential Information to: (i) its employees, consultants and advisors on a need-to-know basis and shall instruct those persons to keep such information confidential and (ii) auditors who are bound by confidentiality obligations. Medidata may disclose Customer's Confidential Information on a need-to-know basis to (x) Medidata's subcontractors who are performing the Services, provided that Medidata shall remain liable for any unauthorized disclosure of Customer's Confidential Information by those subcontractors and (y) employees of Medidata's Affiliates, provided such employees are instructed to keep the information confidential as set forth in this Agreement. If the receiving party is compelled to disclose any of the disclosing party's Confidential Information by court order or government regulation, it shall disclose only that portion thereof which it is compelled to disclose and shall reasonably cooperate with the disclosing party's efforts to obtain an order or other reliable assurance that confidential treatment will be accorded to the Confidential Information so disclosed. Subject to any applicable regulatory requirements, following receipt of a written request, the other party shall return to the requesting party, in whole or in part, the Confidential Information that has been disclosed in tangible form. A party may retain a copy of Confidential Information solely for archival purposes or applicable regulatory requirements.

11. LIMITED WARRANTIES AND EXCLUSIONS

11.1 **Medidata Warranties.** Medidata warrants to Customer that during the Term, the Subscription Services (i) will perform materially in accordance with the Documentation when used and accessed in accordance with the terms and conditions of this Agreement and (ii) the functionality of the Subscription Services will not be materially decreased. Customer shall provide Medidata with prompt notice of any claim under the warranties set forth above and, if applicable, provide Medidata with reasonable assistance required for Medidata to identify and repair any performance issues with the Subscription Services. Customer's sole and exclusive remedy for a breach of this warranty shall be that Medidata shall be required to use commercially reasonable efforts to provide modifications or fixes with respect to any noncompliant Subscription Services. If Medidata is unable to remedy the noncompliant Subscription Services, then Medidata shall refund pro-rata amounts paid by Customer to Medidata under the applicable Sales Order for such noncompliant Subscription Services and terminate Customer's access thereto.

11.2 **Exclusions.** Medidata is not liable for: (i) an Authorized User's use of the Subscription Services not in accordance with this Agreement or Sales Order; (ii) use of the Subscription Services by Customer with third party data, software or hardware which is incompatible with the Subscription Services or not recommended by Medidata; (iii) reduced performance or non-availability of the Subscription Services as a result of Customer's network connections; or (iv) errors in the Subscription Services resulting from Customer's configuration of the Subscription Services, in each case not specifically recommended in writing by Medidata.

11.3 **Mutual Warranties.** Each party represents and warrants to the other party that: (i) such party has the full corporate power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby and has taken all necessary corporate action to authorize the execution and delivery of this Agreement and (ii) this Agreement is and shall be the legal, valid, and binding obligation of such party and shall be enforceable in accordance with its terms.

11.4 **Disclaimer.** It shall be Customer's responsibility for determining the suitability of the Services for Customer's use. EXCEPT AS EXPRESSLY STATED IN [***], AND TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW, MEDIDATA AND ITS LICENSORS MAKE NO, AND HEREBY DISCLAIM ANY, REPRESENTATION, WARRANTY OR GUARANTY, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SERVICES PROVIDED UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTY: (1) OF MERCHANTABILITY; (2) OF FITNESS FOR A PARTICULAR PURPOSE; (3) ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, OR USAGE OF TRADE; OR (4) OF NON-INFRINGEMENT OF THIRD PARTY RIGHTS. EXCEPT AS SET FORTH IN [***], THE SERVICES ARE PROVIDED WITHOUT ANY FURTHER WARRANTIES OF ANY KIND. MEDIDATA AND ITS LICENSORS MAKE NO WARRANTY THAT OPERATION OF THE SUBSCRIPTION SERVICES WILL BE UNINTERRUPTED OR ERROR FREE OR THAT ALL DEFECTS WILL BE CORRECTED.

12. DISCLAIMERS OF DAMAGE AND LIMITATIONS OF LIABILITY

12.1 **Limit on Liability.** For all claims by either party against the other party, except with respect to [***], whether such claims are made in contract, tort, strict liability, or otherwise, the injured party's potential recovery in any [***] period shall be limited to [***] damages suffered by such party up to [***] during the [***] prior to such claim(s) for the specific Service(s) giving rise to such claim(s); and (ii) with respect to breaches of [***], an additional amount equal to [***] during the [***] prior to such claim(s) for the specific Service(s) giving rise to such claim(s) (the "[***] Cap").

12.2 **Exclusions to the Limitation on Liability.** The limitations in Section 12.1 shall not apply to: [***].

12.3 **Medidata Liability for Security Incidents.** In the event of a Security Incident (as defined in Section 7.2 of the Data Processing Exhibit to this Agreement) that is the direct result of the failure of Medidata to comply with the terms of this Agreement, Medidata shall bear [***]. Medidata and Customer shall mutually agree on the content and timing of any such notifications, in good faith and as needed to meet applicable legal requirements. Notwithstanding the preceding sentence, the parties agree that Medidata shall have no obligation to send notification letters or provide credit monitoring for Customer unless such letters are legally required or otherwise reasonably required to alert individuals of potential harm.

12.4 **Disclaimer of Certain Damages.** IN NO EVENT SHALL CUSTOMER OR MEDIDATA OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, INCIDENTAL, PUNITIVE, EXEMPLARY, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFIT OR COSTS OF SUBSTITUTE SERVICES) SUFFERED BY EITHER PARTY, HOWEVER CAUSED, REGARDLESS OF THE THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, OR OTHERWISE, EVEN IF THE OTHER PARTY HAS BEEN PREVIOUSLY ADVISED OF THE POSSIBILITY, OR HAS CONSTRUCTIVE KNOWLEDGE, OF SUCH DAMAGES, AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE. The foregoing exclusion shall not apply to claims for [***]; provided, however, that any consequential damages recovered by Customer or Medidata for claims pursuant to Article 10 will be subject to [***]. For the avoidance of doubt, any claim as a result of a breach of Article [***].

13. INDEMNIFICATION.

13.1 Medidata Indemnity.

13.1.1 Infringement. Subject to Section 13.3, Medidata will defend Customer against any third party claim and will indemnify Customer from any resulting damage awards, settlement amounts and reasonable attorney's fees in any cause of action to the extent such cause of action is based on a third party claim alleging that the Subscription Services, as provided by Medidata and used in accordance with the terms of this Agreement, infringe upon any Intellectual Property Rights of a third party. The foregoing infringement indemnity will not apply and Medidata will not be liable for any damages assessed in any cause of action to the extent such cause of action arises from a Customer Infringement Event or Medidata's use of Customer Data as contemplated by this Agreement. If any Subscription Service is held or believed to infringe on any third party's Intellectual Property Rights, Medidata may, in its sole discretion, (i) [***], (ii) [***], or (iii) if neither (i) nor (ii) are practical, terminate the applicable Sales Order as to the infringing Service and return to Customer any unearned fees prepaid by Customer to Medidata.

13.1.2 Indemnity for Medidata Uses. Subject to Section 13.3, Medidata will defend Customer against any third party claim and will indemnify Customer from any resulting damage awards or settlement amounts in any cause of action to the extent such cause of action is based on a third party claim alleging Medidata Uses as set forth in Section 7.4 violate Privacy Laws.

13.2 Customer Indemnity. Subject to Section 13.3, Customer will defend and will indemnify Medidata against any third party claim and from any resulting damage awards, settlement amounts and reasonable attorney's fees in any cause of action arising out of or relating to: (i) the occurrence of a Customer Infringement Event; (ii) any claim that any materials, software, or other items provided to Medidata by Customer infringes a third party's Intellectual Property Rights; (iii) [***]; or (iv) breach of Section 2.4.

13.3 Procedures. The indemnities set forth in this Agreement are conditioned on the following: (i) the party claiming indemnification (the "Indemnitee") shall promptly notify the indemnifying party (the "Indemnitor") of any matters in respect of which it seeks to be indemnified, and shall give the Indemnitor full cooperation and opportunity to control the response thereto and the defense thereof, including without limitation any settlement thereof; (ii) the Indemnitor shall have no obligation for any claim under this Agreement if the Indemnitee makes any admission, settlement or other communication regarding such claim without the prior written consent of the Indemnitor, which consent shall not be unreasonably withheld; and (iii) the Indemnitee's failure to promptly give notice to the Indemnitor shall affect the Indemnitor's obligation to indemnify the Indemnitee only to the extent the Indemnitor's rights are materially prejudiced by such failure. The Indemnitee may participate, at its own expense, in such defense and in any settlement discussions directly or through counsel of its choice. Each party will take all reasonable steps to mitigate any potential damages. If both the Indemnitor and the Indemnitee are negligent or otherwise at fault, or strictly liable without fault, then the indemnification obligations under this Article 13 shall continue, but the Indemnitor shall indemnify the Indemnitee only for the percentage of responsibility for the damage or injuries attributable to the Indemnitor.

13.4 Effect. THIS ARTICLE 13 STATES MEDIDATA'S ENTIRE LIABILITY AND CUSTOMER'S EXCLUSIVE REMEDY FOR THIRD-PARTY INFRINGEMENT AND/OR MISAPPROPRIATION, WHETHER SUCH ACTION, CLAIM OR PROCEEDING IS BASED ON BREACH OF WARRANTY OR ANY OTHER CAUSE OF ACTION, EXCEPT AS STATED ABOVE, MEDIDATA DISCLAIMS ALL INDEMNITIES, EXPRESS, IMPLIED OR STATUTORY FOR INTELLECTUAL PROPERTY INFRINGEMENT AND/OR MISAPPROPRIATION.

14. DATA PRIVACY AND SECURITY

14.1 Data Privacy.

14.1.1 Customer Representations. Customer represents that it is responsible for the legal basis under Privacy Laws of any Personal Data in the Customer Data made available to Medidata for processing pursuant to the Instructions. Customer agrees that, as between the parties, it is responsible for compliance as the data controller (or data exporter) under Privacy Laws with respect to the Services.

14.1.2 Medidata's Responsibilities. Medidata shall process Customer's Personal Data pursuant to the Instructions, including as set forth in Medidata's Data Processing Exhibit, inclusive of the Standard Contractual Clauses where applicable, which are incorporated herein by reference. Customer's Instructions are inclusive of all processing required to execute the Instructions. As set forth in the Data Processing Exhibit, Medidata agrees that it is responsible for compliance as the data processor (or data importer) under all Privacy Laws with respect to the Services.

14.1.3 Inapplicability of HIPAA. [***]

14.1.4 Unauthorized Disclosure. Without limitation of Medidata's obligations set forth in the Data Processing Exhibit, if either party believes that there has been a material disclosure under Privacy Law of Customer Data to anyone other than an authorized party or Medidata, such party must promptly notify the other party. For the purposes of this Section and the Data Processing Exhibit, Medidata shall notify Customer at lsereno@plustherapeutics.com. Additionally, each party will reasonably assist the other party in remediating or mitigating any potential damage, including any notification required under applicable Privacy Laws to be sent to individuals impacted or potentially impacted. Subject to Article 12, each party shall bear the costs of such remediation or mitigation to the extent the breach or Security Incident was caused by it.

14.2 Data Security.

14.2.1 Business Continuity; Disaster Recovery. Medidata maintains a commercially reasonable business continuity and disaster recovery plan and will follow such plan.

14.2.2 Data Security. Medidata utilizes administrative, physical and technical safeguards to protect Customer Data that are no less rigorous than accepted industry practices. Medidata verifies such physical and technical safeguards as described at <https://www.medidata.com/en/trust-and-transparency/>.

15. MISCELLANEOUS

15.1 Assignment. Except for either party's right to transfer this Agreement to an Affiliate, neither this Agreement nor any of the rights or obligations hereunder may be transferred or assigned directly or indirectly by either party without the prior written consent of the other party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, either party may transfer or assign this Agreement in connection with a sale of all or substantially all of its assets that relate to this Agreement or in connection with a change of control of such party.

15.2 Waiver. The failure of either party to enforce any of the provisions of this Agreement shall not constitute a waiver of the provisions or of the right of the party to enforce each and every provision contained in this Agreement.

15.3 Severability. If any provision of this Agreement for any reason shall be declared void, illegal, invalid or unenforceable in whole or in part, such provision shall be severable from all other provisions herein and shall not affect or impair the validity or enforceability of any other provisions of this Agreement.

15.4 Survival. The following provisions shall survive expiration or termination of this Agreement for any reason: Articles and Sections 7, 8, 9.6, 10, 12, 15.6 and 15.7.

15.5 Force majeure. Neither party shall be liable for any delay or failure to perform its obligations under this Agreement (except for Customer's obligation to pay fees to Medidata pursuant to Section 8.1 during the pendency of the Force Majeure event) if prevented from doing so by a cause or causes beyond its reasonable control. Without limiting the generality of the foregoing, such causes include, fires, floods, storms, earthquakes, riots, terrorism, strikes, blackouts, wars or war operations, restraints of government, utility or communications failures, computer hackers, denial of service attacks, software viruses, telecommunications slow-downs or failure, erroneous data transmission, or causes which could not with reasonable diligence, including compliance with Medidata's commercially reasonable disaster recovery plan, be controlled or prevented by the party.

15.6 Governing Law; Venue. This Agreement and any disputes arising out of or relating to the Agreement shall be governed by the laws of the State of New York without giving effect to its conflict of law provisions. Any disputes that may arise between Medidata and Customer regarding the performance or interpretation of this Agreement shall be subject to the exclusive jurisdiction of the state and federal courts of [***]. The parties hereby irrevocably consent to the exclusive jurisdiction of the state and federal courts [***] and waive any claim that any proceedings brought in such courts have been brought in an inconvenient forum. THE PARTIES HEREBY IRREVOCABLY WAIVE THEIR RIGHT TO TRIAL BY JURY.

15.7 Injunctive Relief. The parties acknowledge that violations of Articles 2, 7, 10 and 14.1 of this Agreement may result in irreparable harm to the non-violating party for which remedies other than injunctive relief may be inadequate, and that the non-violating party shall be entitled to seek from a court of competent jurisdiction injunctive or other equitable relief to restrain such unauthorized acts in addition to other appropriate remedies. In the event of any claimed breach of any provisions of this Agreement, and in the event a party requests any injunctive relief or other relief in equity to stop or enjoin any act or acts by the other party, the parties agree that the requesting party shall not be required to post any bond or other surety as a pre-condition to such relief being granted and enacted.

15.8 Notices. All notices required to be sent or given under this Agreement shall be sent in writing and will be deemed duly given and effective (i) immediately if delivered in person, or (ii) upon confirmation of signature recording delivery, if sent via a nationally recognized overnight courier service with signature notification requested. Notices shall be sent to the addresses set forth in the initial paragraph of the Agreement, or to any other address a party may identify in writing from time to time.

15.9 Publicity. Either party may publicly announce the existence of this Agreement and the general, non-confidential business terms contained herein provided that the other party has the opportunity to review and approve such announcement (such review and approval not to be unreasonably delayed or withheld). Customer further agrees to cooperate with Medidata to issue a press release announcing Customer's selection and/or usage of Medidata Services, the form of which shall be mutually agreed by both parties within one (1) week following the Effective Date of this Agreement. Medidata, with Customer approval, may identify Customer as a customer in Medidata's promotional and informational materials, including, website, presentations and other proposals to current and prospective customers of Medidata.

15.10 Independent Contractors. Medidata and Customer shall be and shall act as independent contractors, and neither party is authorized to act as an agent of the other party for any purpose. Neither party by virtue of this Agreement shall have any right, power, or authority to act or create any obligation, express or implied, on behalf of the other party.

15.11 Entire Agreement. This Agreement, including any Sales Order(s), constitutes the complete and exclusive statement of the terms and conditions between the parties, and supersedes all prior negotiations, agreements and representations. Each time a Sales Order is executed by the parties, a separate contract is formed between Medidata and Customer expressly incorporating the terms and conditions of this Agreement. The Agreement shall not be modified except by written consent of both parties. In the event of a conflict between the terms of this Agreement and those found within a Sales Order, the Sales Order shall control. Purchase orders or other similar ordering documentation submitted to Medidata by Customer will be for Customer's internal administrative purposes only and the terms and conditions contained in any purchase order or statements of work will have no force and effect and will not amend or modify this Agreement.

15.12 Counterparts. This Agreement and any Sales Order may be signed in two or more counterparts by original, .pdf (or similar format for scanned copies of documents), electronic signature or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

15.13 Amendment. This Agreement may not be modified, supplemented or amended, except by a writing signed by the authorized representatives of Medidata and Customer.

15.14 No Third Party Beneficiaries. Nothing in this Agreement creates, or will be deemed to create, third party beneficiaries of or under this Agreement. Customer agrees that Medidata's obligations in this Agreement are to Customer only, and Medidata has no obligation to any third party (including, without limitation, Customer's personnel, directors, officers, employees, Authorized Users and any regulatory authorities).

15.15 Headings. The headings used in this Agreement are for reference only and do not define, limit, or otherwise affect the meaning of any provisions hereof.

Each party executes this Agreement by its duly authorized representative, is legal, valid and binding obligation of the parties and shall be effective on the Effective Date.

SIGNATURE PAGE TO FOLLOW

PLUS THERAPEUTICS, INC.

MEDIDATA SOLUTIONS, INC.

By: /s/ Norman LaFrance

By: /s/ John Olszewski

Name: Norman LaFrance, MD, ME, FACP

Name: John Olszewski

Title: Chief Medical Officer, Senior VP Oncology R&D

Title: SVP, Sales Operations

Date: December 8, 2021

Date: December 8, 2021

Laura Modak/DWK

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Sales Order Number 4159062

Medidata Solutions, Inc.
350 Hudson Street 9th Floor
New York, NY 10014
USA
www.medidata.com
+1 212 918 1800

Customer ("Client") Name: Plus Therapeutics, Inc.
Client Address:
4200 Marathon Blvd., Suite 200
Austin, Texas 78756
United States
Client Sold To:
Plus Therapeutics, Inc.
4200 Marathon Blvd., Suite 200
Austin, Texas 78756
United States

Additional Information
Account Manager Contact: Laura Modak

Sales Order Effective Date: March 14, 2022
Sales Order End Date: September 13, 2022
Sales Order term (Services duration # months): 6
Study Protocol Number: NCT01906385
Transaction Type: Single Study
Therapeutic Area: Glioblastoma
Phase: III

Services

A. Subscription Services

Service	Parameters (metrics reflect maximum scope levels of the Services)
Managed Services	
Synthetic Control Arms ("SCA")	Client Access to Application: N As set forth in Exhibit 1

B. Subscription Services Terms

<p>Subscription Services Terms:</p> <ul style="list-style-type: none">• Service specific terms applicable to the Services pursuant to this Sales Order are incorporated herein by reference and may be accessed at https://www.medidata.com/en/policies-medidata-services• Medidata owns all Intellectual Property Rights (IPR) in and to the Managed Service(s) pursuant to this Sales Order and its component parts (as defined in the Managed Services Scope of Work), including information, methodologies, processes, tools or technical know-how involved in Medidata's provision of the Managed Service(s) or any deliverables set forth in this Sales Order.• Synthetic Control Arms is not generally available by Medidata to its partners and customers as of the Sales Order Effective Date. Until Synthetic Control Arms becomes generally available by Medidata to its partners and customers, it is provided without any warranty and Support Services. Medidata is not liable or responsible for Client's decisions regarding its clinical trials.

C. General Terms

<p>General Terms: The following additional terms shall apply to this Sales Order.</p> <ul style="list-style-type: none">• Assumes a single (1) agency submission/meeting at U.S. Food and Drug Administration ("FDA") - additional fees may apply for multiple agencies and/or interactions• Timing and fees to be finalized upon confirmation of specification with client• Assumes a single core SCA analysis - additional fees may apply for additional SCA analyses (e.g., interim, sensitivity, subsets, etc.)• Timelines are estimates based on study progress to be confirmed• The Contingent Managed Services Fees shall become due when the U.S. Food and Drug Administration ("FDA") provides any communication (except for an outright rejection of SCA) with respect to Phase 2/3 study of 186RNL (the "Regulatory Fee Trigger"). Client shall forward any meeting minutes and/or notices from the FDA concerning this matter to Medidata within forty-eight (48) hours of receipt.• Travel expenses: All travel expenses will conform to Client travel policies, and will be billable monthly on an actual cost basis. Any travel expenses in excess of five (5%) percent of the total Services fees will require prior written approval of the Client. Travel time shall be measured as the time between the origination and destination points. The initial four (4) hours of travel time shall not be charged to Client, travel time in excess of four (4) hours will be charged as travel expenses, at one hundred (\$100.00) dollars per hour.
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D. Fees and Billing

Billing Information:
Plus Therapeutics, Inc.
4200 Marathon Blvd., Suite 200
Austin, Texas 78756 United States

Delivery Method: ap@plustherapeutics.com

Sales Order Fees:

Managed Services Fees	\$1,450,000.00
Contingent Managed Services Fees	\$150,000.00
Total Fees	\$1,600,000.00
Currency:	USD

Client shall notify Medidata prior to the Sales Order Effective Date of any revisions to the billing information set forth above, such notice to be submitted via <https://www.medidata.com/en/customer-support/billing-address>. Client shall submit all purchase order documentation, as applicable, to invoicing@medidata.com within thirty (30) days of the Sales Order Effective Date.

Billing Schedule

Sub-Total Managed Services Fees (invoiced quarterly in advance, at USD \$725,000.00, for two (2) quarters)	\$1,450,000.00
Sub-Total Contingent Managed Services Fees (invoiced upon Regulatory Fee Trigger)	\$150,000.00
SUB-TOTAL FEES	USD 1,600,000.00
TOTAL FEES*	USD 1,600,000.00

*The Total Fees set forth above reflect the committed Services and associated use parameters set forth herein, and are exclusive of any of the following, to the extent applicable: (i) sales, use, value added, consumption and other indirect taxes which are the responsibility of Client, and (ii) pass-through reimbursable expenses for travel, which shall be charged on an actual cost basis.

The terms and conditions of the Medidata Services Agreement dated November 5, 2021, including any amendments executed thereto ("Agreement") executed between Client and Medidata shall apply to the Services provided under this Sales Order and this Sales Order shall be fully incorporated by reference into and made a part of the Agreement. Any attached Exhibit(s) shall be incorporated by reference into and made a part of this Sales Order. Should a conflict arise between this Sales Order and the Agreement, this Sales Order shall control.

The parties agree to the terms of this Sales Order and have caused their duly authorized representatives to execute this Sales Order as of the latest date set forth below, and made effective as of the Sales Order Effective Date.

SIGNATURE PAGE TO FOLLOW

PLUS THERAPEUTICS, INC.	MEDIDATA SOLUTIONS, INC.
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

**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 21, 2022

/s/ Marc H. Hedrick

Marc H. Hedrick,

President & Chief Executive Officer

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

I, Andrew Sims, certify that:

1. I have reviewed this 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 21, 2022

/s/ Andrew Sims

Andrew Sims

Chief Financial Officer

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, 2022 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.

Dated: April 21, 2022

By: /s/ Marc H. Hedrick

Marc H. Hedrick
President & Chief Executive Officer

Dated: April 21, 2022

By: /s/ Andrew Sims

Andrew Sims
Chief Financial Officer & VP of Finance