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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from to

Commission file number 001-34375

PLUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

As of October 15, 2021, there were 15,360,025 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 contains "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," "believe," "anticipate," "will," "should," "would," "could," "may," "designed," "potential," "evaluate," "progressing," "proceeding," "exploring," "hopes," 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 regarding: our anticipated expenditures, including research and development, sales and marketing, and general and administrative expenses; anticipated benefits of strategic collaborations and license agreements, intellectual property, FDA approval process and government regulation; our ability to benefit from the NIH/NCI award for continued clinical development of Rhenium NanoLiposome (RNL) for recurrent glioblastoma; the ability of RNL to safely and effectively deliver radiation directly to the tumor at high doses; our ability to develop additional indications utilizing RNL and the clinical benefits of RNL in such indications; our ability to expand clinical testing of RNL to additional sites; the potential size of the market for our product candidates; our research and development efforts; our IP strategy; competition; future development and/or expansion of our product candidates and therapies in our markets; our ability to generate product or development revenue and the sources of such revenue; the amounts that we may be obligated to pay under license agreements; 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 need for additional financing and the availability thereof; our ability to fully access our equity line with Lincoln Park; any changes to our interest expenses; 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; expectations as to the impact of recently issued or adopted accounting standards; our expectations as to the impact of the COVID-19 pandemic on our business and operating results; our beliefs as to the impact of any liability that may arise as a result of any legal proceedings; and the potential enhancement of our cash position through development, marketing, and licensing arrangements.

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, litigation or 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, 2020, 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 Factors" and elsewhere in this report carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance.

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 21,280	$ 8,346
Other current assets	817	829
Total current assets	22,097	9,175
Property and equipment, net	1,646	1,820
Operating lease right-of-use assets	559	636
Goodwill	372	372
Intangible assets, net	60	86
Other assets	16	16
Total assets	$ 24,750	$ 12,105
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,630	$ 2,081
Operating lease liability	106	123
Term loan obligations, net of discount	6,752	6,335
Total current liabilities	9,488	8,539
Noncurrent operating lease liability	504	528
Warrant liability	3	7
Total liabilities	9,995	9,074
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 1,952 and 1,954 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 15,360,025 and 6,749,028 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	15	7
Additional paid-in capital	457,495	436,535
Accumulated deficit	(442,755)	(433,511)
Total stockholders' equity	14,755	3,031
Total liabilities and stockholders' equity	$ 24,750	$ 12,105

See Accompanying Notes to these Consolidated Condensed Financial Statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Development revenues:				
Government contracts and other	$ —	$ —	$ —	$ 303
Operating expenses:				
Research and development	1,491	336	3,724	1,604
In process research and development acquired from NanoTx	—	—	—	781
General and administrative	1,990	1,060	4,811	4,107
Loss on disposal of property and equipment	18	—	18	—
Total operating expenses	3,499	1,396	8,553	6,492
Loss from operations	(3,499)	(1,396)	(8,553)	(6,189)
Other income (expense):				
Interest income	5	2	13	47
Interest expense	(232)	(253)	(708)	(854)
Change in fair value of warrants	2	(81)	4	2,342
Total other income (expense)	(225)	(332)	(691)	1,535
Net loss	$ (3,724)	$ (1,728)	$ (9,244)	$ (4,654)
Net loss per share, basic and diluted	$ (0.28)	$ (0.39)	$ (0.84)	$ (1.13)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	13,264,230	4,402,221	10,961,284	4,113,928

See Accompanying Notes to these Consolidated Condensed Financial Statements

PLUS THERAPEUTICS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)
(in thousands)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	1,959	$ —	3,880,588	$ 4	$ 426,426	$ (425,270)	$ 1,160
Stock-based compensation	—	—	—	—	12	—	12
Net loss	—	—	—	—	—	(1,087)	(1,087)
Balance at March 31, 2020	1,959	$ —	3,880,588	$ 4	$ 426,438	$ (426,357)	$ 85
Issuance of common stock for exercise of warrants	—	—	162,500	—	366	—	366
Reclassification of warrant liabilities	—	—	—	—	4,264	—	4,264
Issuance of common stock for in process research and development acquired from NanoTx Therapeutics	—	—	230,769	—	381	—	381
Share-based compensation	—	—	—	—	43	—	43
Net loss	—	—	—	—	—	(1,839)	(1,839)
Balance at June 30, 2020	1,959	$ —	4,273,857	$ 4	$ 431,492	$ (428,196)	$ 3,300
Issuance of common stock for exercise of warrants	—	—	317,521	1	714	—	715
Reclassification of warrant liabilities	—	—	—	—	240	—	240
Conversion of Series B convertible preferred stock into common stock	(5)	—	37	—	—	—	—
Share-based compensation	—	—	—	—	94	—	94
Net loss	—	—	—	—	—	(1,728)	(1,728)
Balance at September 30, 2020	1,954	$ —	4,591,415	$ 5	$ 432,540	$ (429,924)	$ 2,621
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 of offering cost	—	—	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	1,952	$ —	10,180,525	$ 10	$ 445,734	$ (436,231)	$ 9,513
Sale of common stock, net of offering cost	—	—	1,907,000	2	5,092	—	5,094
Share-based compensation	—	—	—	—	138	—	138
Net loss	—	—	—	—	—	(2,800)	(2,800)
Balance at June 30, 2021	1,952	$ —	12,087,525	$ 12	$ 450,964	$ (439,031)	$ 11,945
Sale of common stock, net of offering cost	—	—	3,272,500	3	6,351	—	6,354
Share-based compensation	—	—	—	—	180	—	180
Net loss	—	—	—	—	—	(3,724)	(3,724)
Balance at September 30, 2021	1,952	$ —	15,360,025	$ 15	$ 457,495	$ (442,755)	$ 14,755

See Accompanying Notes to these Consolidated Condensed Financial Statements

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

	For the Nine Months Ended September 30,	
	2021	2020
Cash flows used in operating activities:		
Net loss	$ (9,244)	$ (4,654)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	266	273
Amortization of deferred financing costs and debt discount	417	428
Loss on disposal of property and equipment	18	—
In process research and development acquired from NanoTx Therapeutics	—	781
Non-cash lease expenses	36	2
Change in fair value of warrants	(4)	(2,342)
Stock-based compensation expense	425	149
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	—	1,169
Other current assets	12	516
Other assets	—	54
Accounts payable and accrued expenses	418	(1,586)
Net cash used in operating activities	(7,656)	(5,210)
Cash flows used in investing activities:		
Purchases of property and equipment	(134)	(37)
Proceeds from sale of property and equipment	50	—
In process research and development acquired from NanoTx Therapeutics	—	(400)
Net cash used in investing activities	(84)	(437)
Cash flows provided by (used in) financing activities:		
Principal payments of long-term obligations	-	(5,307)
Payment of financing lease liability	(8)	(93)
Proceeds from exercise of warrants	2,017	1,081
Proceeds from sale of common stock, net	18,665	—
Net cash provided by (used in) financing activities	20,674	(4,319)
Net increase (decrease) in cash and cash equivalents	12,934	(9,966)
Cash and cash equivalents at beginning of period	8,346	17,592
Cash and cash equivalents at end of period	21,280	7,626
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 292	$ 470
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	$ 139	$ 12
Right-of-use asset obtained in exchange for lease liabilities	$ 81	$ —
Issuance costs paid in common stock	$ —	$ 463
Common stock issued in payment for in process research and development	$ —	$ 381

See Accompanying Notes to these Consolidated Condensed Financial Statements

1. Basis of Presentation and New Accounting Standards

The accompanying unaudited consolidated condensed financial statements as of September 30, 2021 and for the nine months ended September 30, 2021 and 2020 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 consolidated condensed balance sheet at December 31, 2020 has been derived from the audited financial statements at December 31, 2020, 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 nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. These financial statements should be read in conjunction with the consolidated financial statements and notes therein included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission on February 22, 2021.

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 consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncement

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes, Simplifying the Accounting for Income Taxes ("ASU 2019-12"). The new guidance eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. ASU 2019-12 became effective for the Company on January 1, 2021. Adoption of ASU 2019-12 did not have a material impact on the Company's consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06"). ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in ASU 2020-06 are effective for smaller reporting companies as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU 2020-06 as of January 1, 2021, which did not have a material impact on its consolidated financial statements.

2. Use of Estimates

The preparation of consolidated 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, determining the assumptions used in measuring stock-based compensation expense and valuing warrants.

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

3. Liquidity and Going Concern

The Company incurred net losses of $9.2 million for the nine months ended September 30, 2021. The Company had an accumulated deficit of $442.8 million as of September 30, 2021. Additionally, the Company used net cash of $7.7 million to fund its operating activities for the nine months ended September 30, 2021. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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

On October 23, 2020, the Company entered into an Equity Distribution Agreement (the "Distribution Agreement") with Canaccord Genuity LLC ("Canaccord") pursuant to which it could issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to $10,000,000 (the "ATM Shares"), depending on market demand, with Canaccord acting as an agent for sales. Sales of the ATM Shares could be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended (the "Securities Act"), including, without limitation, sales made directly on or through the NASDAQ Capital Market. Canaccord was required to use its commercially reasonable efforts to sell the ATM Shares the Company requested to be sold on its behalf, consistent with Canaccord's normal trading and sales practices, under the terms and subject to the conditions set forth in the Distribution Agreement. The Company did not have an obligation to sell any of the ATM Shares. The Company 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 Distribution Agreement. During the year ended December 31, 2020, the Company issued 1,616,331 shares under the Distribution Agreement for net proceeds of approximately $3.2 million. During the nine months ended September 30, 2021, the Company issued 2,179,193 shares under the Distribution Agreement for net proceeds of $6.3 million. As of September 30, 2021, there were no remaining shares that may be issued and sold under the Distribution Agreement.

On September 30, 2020, the Company entered into a purchase agreement (the "2020 Purchase Agreement") and a registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park committed to purchase up to $25.0 million of its common stock. Under the terms and subject to the conditions of the 2020 Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $25.0 million of its common stock. Such sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing November 6, 2020, subject to satisfaction of certain conditions. The net proceeds under the 2020 Purchase Agreement will depend on the frequency and prices at which the Company sells shares of its common stock to Lincoln Park. During the year ended December 31, 2020, the Company issued 353,113 shares, excluding 180,701 shares issued as commitment fee, under the 2020 Purchase Agreement for net proceeds of approximately $0.7 million. During the nine months ended September 30, 2021, the Company issued 5,535,186 shares of its common stock under the 2020 Purchase Agreement for net proceeds of $12.3 million.

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

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

4. Fair Value Measurements

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

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

- Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable in active markets.

Warrants issued in an underwritten public offering in September 2019 ("Series U Warrants") are classified as liability instruments. 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 Company estimated the fair value of the Series U Warrants with the Black Scholes model. 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.

	September 30, 2021	December 31, 2020
Expected term	3 years	3.75 years
Common stock market price	$ 1.91	$ 2.02
Risk-free interest rate	0.53%	0.24%
Expected volatility	139%	149%
Resulting fair value (per warrant)	$ 1.25	$ 1.56

The following table summarizes the change in Level 3 warrant liability value for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended		Nine Months Ended	
Warrant liability	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Beginning balance	$ 5	$ 242	$ 7	$ 6,929
Change in fair value	(2)	81	(4)	(2,342)
Reclassification to equity	—	(240)	—	(4,504)
Ending balance	$ 3	$ 83	$ 3	$ 83

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 September 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 September 1, 2024. As the Company met the "Second I/O Extension Equity Event," as defined in the Ninth Amendment, the principal repayment start date has been 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. After giving effect to this payment, $4.3 million of principal remains outstanding under the Term Loan. In addition, an amendment fee of $1.0 million will be payable in connection with the 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 September 30, 2021, there was $4.3 million principal amount outstanding under the Term Loan, excluding the $3.2 million final payment fee, and the Company was in compliance with all of the debt covenants under the Loan and Security Agreement.

The Company's interest expense for the three months ended September 30, 2021 and 2020 was $0.2 million and $0.3 million, respectively. The Company's interest expense for the nine months ended September 30, 2021 and 2020 was $0.7 million and $0.9 million, respectively. Interest expense is calculated using the effective interest method; therefore it is inclusive of non-cash amortization in the amount of $0.1 million for each of the three months ended September 30, 2021 and 2020, and $0.4 million for each of the nine months ended September 30, 2021 and 2020, respectively, related to the amortization of the debt discount, capitalized loan costs, and accretion of final payment.

The Loan and Security Agreement, as amended, contains customary indemnification obligations and customary events of default, including, among other things, the Company's failure to fulfill certain obligations under the Term Loan, as amended, and the occurrence of a material adverse change, which is defined as a material adverse change in the Company's business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan. In the event of default by the Company or a declaration of material adverse change by its lender, under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Term Loan, which could materially harm the Company's financial condition. As of September 30, 2021, the Company has not received any notification or indication from Oxford to invoke the material adverse change clause. However, due to the Company's current cash flow position and the substantial doubt about its ability to continue as a going concern, the entire principal amount of the Term Loan is presented as short-term. The Company will continue to evaluate the debt classification on a quarterly basis and evaluate for reclassification in the future should its financial condition improve.

6. Loss per Share

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

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

	Nine Months Ended September 30,	
	2021	2020
Outstanding stock options	1,050,890	531,336
Outstanding warrants	2,141,378	3,121,125
Preferred stock	422,985	422,985
Total	3,615,253	4,075,446

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.

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 financing leases are recorded within property and equipment, net in the balance sheet. Leases with an initial term of 12 months

or less are not recorded on the balance sheet. Instead, the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2028. On October 1, 2021, the operating lease in San Antonio, Texas was amended so that the lease would expire in February 2025, with a 3% increase to the previously agreed-on annual minimum lease payments. 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"). In addition, the Company has entered into leases for certain equipment under various operating and finance leases. As of September 30, 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. The Company's existing operating lease agreements generally provide for periodic rent increases, and renewal and termination options. The Company's lease agreements do not contain any material variable lease payments, residual value guarantees or material restrictive covenants.

The Charlottesville Lease has a term of 12 months and 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 was April 1, 2021. At lease inception, the Company believed that it was reasonably certain that it would renew the Charlottesville Lease beyond its initial 12 months term to 36 months in total. As a result, the Company recorded the operating lease right-of-use asset and related lease liability related to the Charlottesville Lease as of the lease commencement date, using the applicable discount rate of 8.95%.

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 table below summarizes the Company's operating lease liabilities and corresponding right-of-use assets (in thousands, except years and rates):

	September 30, 2021
Assets	
Operating	$ 559
Total leased assets	$ 559
Liabilities	
Current:	
Operating	$ 106
Noncurrent:	
Operating	504
Total lease liabilities	$ 610
Weighted-average remaining lease term (years) - operating leases	5.97
Weighted-average discount rate - operating leases	7.0%

The table below summarizes the Company's lease costs from its unaudited consolidated condensed statement of operations, and cash payments from its unaudited consolidated condensed statement of cash flows during the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Lease expense:				
Operating lease expense	$ 58	$ 52	$ 166	$ 160
Finance lease expense:				
Depreciation of right-of-use assets	—	32	7	95
Interest expense on lease liabilities	—	1	—	4
Total lease expense	$ 58	$ 85	$ 173	$ 259
Cash payment information:				
Operating cash used for operating leases	$ 56	$ 56	$ 162	$ 155
Financing cash used for financing leases	—	42	8	93
Total cash paid for amounts included in the measurement of lease liabilities	$ 56	$ 98	$ 170	$ 248

Total rent expenses for the nine months ended September 30, 2021 and 2020 was $170,000 and $177,000, 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 and financing leases at September 30, 2021 are as follows (in thousands):

	Operating Leases
Remaining 2021	$ 44
2022	154
2023	131
2024	114
2025	108
Thereafter	234
Total minimum lease payments	$ 785
Less: amount representing interest	(175)
Present value of obligations under leases	$ 610
Less: current portion	(106)
Noncurrent lease obligations	$ 504

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 parties contemplate that the MSA will lead to clinical and commercial supply agreements between the Company and Piramal.

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

Other commitments and contingencies

The Company has entered into agreements with various research organizations for pre-clinical and clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, recruiting and enrolling patients, monitoring studies and data analysis. Payments under these agreements typically include fees for services and reimbursement of expenses. The timing of payments due under these agreements is estimated based on current study progress. As of September 30, 2021, 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 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 claims from Lorem are without merit and intends to vigorously defend the case and on August 12, 2021, the Company filed a Motion to Dismiss asking the District Court to dismiss the Lorem Claim. Lorem filed an opposition on September 9, 2021, which we responded to on September 30, 2021. As of October 21, 2021, the Company is waiting for the District Court's decision on our motion. No liability was accrued as of September 30, 2021.

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. 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 payment of $400,000 in cash and issued 230,769 shares of its common stock to NanoTx. Cash and the fair value of common stock issued totaled $781,000 and is recorded as in-process research and development expenses, pursuant to authoritative literature for asset acquisition, in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2020. Pursuant to the terms of the NanoTx License Agreement, the Company may be required to pay up to $136.5 million in development and sales milestone payments and a tiered single-digit royalty on U.S. and European sales.

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 and 1,016 shares of Series B Convertible Preferred Stock outstanding as of September 30, 2021 and December 31, 2020, respectively. There were 938 shares of Series C Preferred Stock outstanding as of each of September 30, 2021 and December 31, 2020.

As of September 30, 2021, 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 are 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.

Between April and September 2020, the Company entered into revised warrant agreements with the holders of 3,447,500 Series U Warrants (the "Warrant Amendments"). In return for reducing the strike price of the warrants to $2.25 per share, the warrant holders agreed to amend the settlement provisions upon a fundamental transaction such that the warrants would meet the requirements to be classified within stockholders' equity. In September 2020, the Company entered into revised warrant agreements for the Representative Warrants that reduced the strike price of the warrants to $2.81 per share, and the warrant holders agreed to amend the settlement provisions upon a fundamental transaction such that the Representative Warrants would meet the requirements to be classified within stockholders' equity. Accordingly, approximately $4.5 million of warrant liability was reclassified to stockholders' equity on the respective effective date of the Warrant Amendments. In addition, approximately $0.7 million of other income representing change in the fair value of amended warrants from April 1, 2020 to the respective effective date of the Warrant Amendments is recorded in the consolidated statement of operations for the year ended December 31, 2020.

As of September 30, 2021, 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 has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $25.0 million of the Company's common stock. Such sales of common stock by the Company are subject to certain limitations, and may 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.

The 2020 Purchase Agreement provides that the number of shares the Company may sell to Lincoln Park on any single business day in a regular purchase is 50,000, but that amount may be increased up to 100,000 shares, depending upon the market price of the Company's common stock at the time of sale and subject to a maximum limit of $500,000 per regular purchase. The purchase price per share for each such regular purchase is based on prevailing market prices of the Company's common stock immediately preceding the time of sale as computed under the 2020 Purchase Agreement. In addition to regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the 2020 Purchase Agreement. There are no trading volume requirements or restrictions under the Lincoln Park Purchase Agreement. There is no upper limit on the price per share that Lincoln Park must pay for common stock under a regular purchase or an accelerated purchase and in no event will shares be sold to Lincoln Park on a day when the Company's common stock closing sale price is less than $0.25 per share.

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

Actual sales of shares of common stock to Lincoln Park under the 2020 Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. The net proceeds under the 2020 Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park.

During the year ended December 31, 2020, the Company issued 353,113 shares, excluding 180,701 shares issued as a commitment fee, of common stock under the 2020 Purchase Agreement for total net proceeds of approximately $0.7 million. During the nine months ended September 30, 2021, the Company issued 5,535,186 shares of its common stock under the 2020 Purchase Agreement for net proceeds of approximately $12.3 million.

At-the-market Issuances

On October 23, 2020, the Company entered into the Distribution Agreement with Canaccord Genuity LLC ("Canaccord"), pursuant to which the Company issued and sold the ATM Shares, depending on market demand, with Canaccord acting as an agent for sales. 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 Distribution Agreement.

During the year ended December 31, 2020, the Company issued 1,616,331 shares under the Distribution Agreement for net proceeds of approximately $3.2 million. During the nine months ended September 30, 2021, the Company issued 2,179,193 shares under the Distribution Agreement for net proceeds of $6.3 million. As of September 30, 2021, there were no remaining shares that may be issued and sold under the Distribution Agreement.

10. Stock-based Compensation

Under the Company's amended 2015 New Employee Incentive Plan (the "2015 Plan"), awards may be granted to employees who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as a material inducement to entering into employment with the Company. As of September 30, 2021, there were 210,389 shares of common stock remaining and available for future issuances under the 2015 Plan.

On May 17, 2021, the stockholders of the Company approved an amendment and restatement to the Company's 2020 Stock Incentive Plan (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. 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 number of shares available for issuance to be increased to the extent that awards granted under the 2020 Plan and the Company's 2014 Equity Incentive Plan (as replaced by the 2020 Plan) are forfeited or expire (except as otherwise provided in the 2020 Plan). As of September 30, 2021, 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 one-year, two-year or four-year vesting schedule, with options vesting in equal installments on the monthly anniversary of the grant date and have a contractual term of 10 years.

A summary of activity for the nine months ended September 30, 2021 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in $,000)
Outstanding as of December 31, 2020	531,336	$ 10.01		
Granted	560,227	$ 2.70		
Cancelled/forfeited	(40,673)	$ 28.87		
Outstanding as of September 31, 2021	1,050,890	$ 5.38	9.1	$ —
Vested as of September 30, 2021	293,574	$ 12.67	8.9	$ —
Vested and expected to be vested as of September 30, 2021	974,134	$ 5.56	9.1	$ —

As of September 30, 2021, the total compensation cost related to non-vested stock options not yet recognized for all the Company's plans is approximately $1.5 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 3.0 years.

11. COVID-19 Pandemic and CARES Act

The COVID-19 pandemic 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 is currently continuing the clinical trials it has underway in sites across the U.S., and, although there has been no significant impact to date, the Company expects that COVID-19 precautions may directly or indirectly impact the timeline for some of its clinical trials. Some of the Company's clinical trial sites, including those located in areas severely impacted by the pandemic, placed new patient enrollment into clinical trials on hold or, for patients traveling from out-of-state, implemented a 14-day self-quarantine before appointments. In addition, some clinical trial sites imposed limited accessibility to conduct clinical monitoring and training on-site. As the accessibility of vaccines against COVID-19 and the number of adults who have received a vaccine has increased, several of the restrictions have been eased or lifted entirely. The Company considered the impacts of COVID-19 on the assumptions and estimates used to prepare its consolidated financial statements and determined that there were no material adverse impacts on the Company's results of operations and financial position at September 30, 2021. 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 Coronavirus Aid, Relief and Economic Security Act ("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 (QIP). The CARES Act had no material impact on the Company's income tax provision for the year ended December 31, 2020 or the nine months ended September 30, 2021. The programs under the CARES Act expired on September 6, 2021.

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, 2020, as filed on February 22, 2021, as amended by the Form 10-K/A filed on February 26, 2021. 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, 2020, 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.
- Significant changes since our most recent Annual Report on Form 10-K in the Critical Accounting Policies and Significant Estimates that we believe are important to understanding the assumptions and judgments underlying our financial statements.

Overview

Plus Therapeutics is a U.S. pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers. Plus' investigational drugs are intended for both adult and pediatric patients on a worldwide basis. Plus Therapeutics' headquarters and manufacturing facility are in Texas, in close proximity to world-class cancer institutions and researchers. Our dedicated team of engineers, physicians, scientists, and other professionals are committed to advancing our novel radiotherapeutic technology for the benefit of cancer patients and healthcare providers. Plus' technology includes nanoliposome-encapsulated, BMEDA-chelated Rhenium-186 radiotherapeutics. The nanoliposomes facilitate local and precise drug delivery and improved drug retention at the target site while Rhenium-186 releases high-energy beta particles for treatment and gamma photons for imaging. This radiotherapeutic platform, combined with advances in surgery, nuclear medicine, and radiation oncology, affords us the opportunity to treat multiple types of cancer. Our current pipeline is focused on treating rare and central nervous system tumors with significant unmet medical needs.

Pipeline

Plus Therapeutics' lead investigational drug, Rhenium-186 NanoLiposome (^{186}RNL), is a patented radiotherapy potentially useful for patients with recurrent glioblastoma (GBM). The RNL technology was part of a licensed radiotherapeutic portfolio that we acquired from NanoTx, Corp. ("NanoTx") on May 7, 2020. The licensed radiotherapeutic can be applied toward several cancer targets, and has 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 ^{186}RNL for recurrent glioblastoma through the completion of a Phase 2 clinical trial and enrollment of up to 55 patients.

Plus Therapeutics is currently conducting a clinical trial for ReSPECT GBM for Recurrent Glioblastoma and anticipates beginning a clinical trial for ReSPECT-LM Clinical Trial for Leptomeningeal Metastases in the fourth quarter of 2021:

ReSPECT-GBM Clinical Trial for Recurrent Glioblastoma

^{186}RNL is a novel injectable radiotherapy designed to deliver targeted high dose radiation directly into brain tumors in a safe, effective, and convenient manner to optimize patient outcomes. ^{186}RNL, which is composed of radionuclide Rhenium-186 (186Re) and a nanoliposomal carrier, is infused directly into the brain tumor via precision brain mapping and convection enhanced delivery. The ^{186}RNL radiation dose delivered to patients may be up to 20x greater than what is possible with external beam radiation therapy (EBRT). Some additional potential benefits of RNL compared to EBRT include:

- ^{186}RNL can be visualized in real-time during administration, possibly giving doctors better control of radiation dosing and distribution.
- Potentially more effectively treats the bulk tumor and microscopic disease in surrounding healthy tissue.
- Using a small catheter, ^{186}RNL is infused directly into the targeted tumor, which may reduce radiation exposure to healthy cells. By contrast, EBRT is less targeted and selective.

- RNL is given during a single 3- to 4-day in-patient hospital visit, while EBRT requires out-patient visits 5 days a week for approximately 4-6 weeks.

^{186}RNL is currently being evaluated for the treatment of recurrent glioblastoma in the Phase 1 multi-center ReSPECT-GBM dose-finding clinical trial. ReSPECT-GBM is evaluating the safety, tolerability, and distribution of ^{186}RNL for the treatment of recurrent glioblastoma. Thus far, ^{186}RNL has demonstrated safety and potential efficacy signals in patients with adequate dosing and tumor coverage with multiple patients surviving greater than 30 months, compared to a median survival of approximately 9 months with the current standard of care. The seventh dose escalation cohort of this trial has been completed. Recently, the ReSPECT-GBM trial data safety and monitoring board (DSMB) recommended that we proceed to the eighth dosing cohort which provides for a 40% increase in both drug volume and radiation dose. Thus far, treatment emergent serious adverse events have not been observed.

By infusing the ^{186}RNL drug directly into the tumor, bypassing the blood-brain barrier, normal brain and external tissues may be spared from radiation damage. We believe that radiation in the form of high energy electrons may be effective against glioblastoma if an adequate dose can be effectively delivered. For comparison, current EBRT protocols for recurrent glioblastoma typically recommend a total maximum dose of about 35 Gy. In contrast, thus far, we have been able to deliver up to 740 Gy of absorbed radiation to tumor issue without significant toxicities.

Recurrent glioblastoma (GBM) affects approximately 12,000 patients annually in the U.S. and is the most common and lethal form of brain cancer. The average life expectancy with 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 can cause headaches, seizures, vision changes and other neurological complications. Despite the best available medical treatments to eliminate the initial brain tumor, some microscopic disease frequently remains, with tumor regrowth within months. In fact, approximately 90% of patients experience tumor recurrence. This tumor type is incredibly difficult to remove completely, and often is resistant or quickly develops resistance to most available therapies. 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. There is no clear standard of care for recurrent GBM and even the few currently approved treatments, in aggregate, provide only marginal survival benefit. Current approved therapies are associated with significant side effects, which limit dosing and prolonged use.

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

ReSPECT-LM Clinical Trial for Leptomeningeal Metastases

Based on substantial preclinical work completed and published, ^{186}RNL is thought to have potential clinical benefits in other difficult to treat cancers for example leptomeningeal metastases and pediatric brain cancer. The ReSPECT-LM Phase 1 clinical trial builds upon preclinical studies in which tolerance to doses of ^{186}RNL as high as 1,075 Gy was shown in animal models with LM with no observed significant toxicity. Furthermore, treatment led to marked reduction in tumor burden in both C6 and MDA-231 LM models.

In October 2021, the Federal Drug Administration (FDA) announced clearance for the Company to proceed with the Investigational New Drug (IND) application for ^{186}RNL for the treatment of leptomeningeal metastases (LM). The Company expects to initiate patient accrual in a Phase 1 dose escalation trial of ^{186}RNL (ReSPECT-LM) in the fourth quarter of 2021.

The ReSPECT-LM multi-center, sequential cohort, open-label, dose escalation study will evaluate the safety, tolerability, and distribution of ^{186}RNL 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.

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 usually terminal 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 include the leptomeninges are breast cancer, lung cancer, and melanomas.

Future potential Trials

We are in the process of developing additional indications utilizing ^{186}RNL such as for pediatric brain cancer.

Plus Therapeutics also has two other clinical stage drugs in our pipeline which are:

1)DocePLUS™, a patented chemotherapy incorporating docetaxel for patients with solid tumors that has been evaluated in a completed U.S. single-center Phase 1 clinical trial; and
2)DoxoPLUS™, a generic chemotherapy incorporating doxorubicin that has been evaluated in a completed, bioequivalence clinical trial in the U.S., Canada, and Ukraine versus Janssen's CAELYX® in patients with ovarian cancer.

Current business activities related to both DocePLUS and DoxoPLUS are focused on identification of potential partners.

Recent Developments

Lincoln Park Purchase Agreement

On September 30, 2020, we entered into a purchase agreement (the "2020 Purchase Agreement") and registration rights agreement (the "LPC Registration Rights Agreement"). Under the 2020 Purchase Agreement Lincoln Park Capital Fund, LLC ("Lincoln Park") has committed to purchase up to $25.0 million of our common stock. Pursuant to the LPC Registration Rights Agreement, we have agreed to register any shares sold to Lincoln Park under the 2020 Purchase Agreement for resale by Lincoln Park. Refer to "Liquidity and Capital Resources" section below for additional details on the 2020 Purchase Agreement.

During the year ended December 31, 2020, we issued 353,113 shares, excluding 180,701 shares issued as commitment fee, under the 2020 Purchase Agreement for net proceeds of approximately $0.7 million. During the nine months ended September 30, 2021 we issued 5,535,186 shares of our common stock under the 2020 Purchase Agreement for total proceeds of $12.3 million.

COVID-19 Impact

The COVID-19 pandemic 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 is currently continuing the clinical trials it has underway in sites across the U.S., and, although there has been no significant impact to date, the Company expects that COVID-19 precautions may directly or indirectly impact the timeline for some of its clinical trials. Some of the Company's clinical trial sites, including those located in areas severely impacted by the pandemic, placed new patient enrollment into clinical trials on hold or, for patients traveling from out-of-state, implemented a 14-day self-quarantine before appointments. In addition, some clinical trial sites imposed limited accessibility to conduct clinical monitoring and training on-site. As the accessibility of vaccines against COVID-19 and the number of adults who have received a vaccine has increased, several of the restrictions have been eased or lifted entirely. The Company considered the impacts of COVID-19 on the assumptions and estimates used to prepare its consolidated financial statements and determined that there were no material adverse impacts on the Company's results of operations and financial position at September 30, 2021. 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 Coronavirus Aid, Relief and Economic Security Act ("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 (QIP). The CARES Act had no material impact on the Company's income tax provision for the year ended December 31, 2020 or the nine months ended September 30, 2021. The programs under the CARES Act expired on September 6, 2021.

Results of Operations

Development revenues

Under our government contract with BARDA, we recognized a total of $0 and $0.3 million in revenues for the three and nine months ended September 30, 2020, respectively, and $0 and $0.3 million in qualified expenditures for those periods. The BARDA contract was terminated in December 2019 and the close out process was completed in 2020. There were no revenue or expenses recognized relating to the BARDA contract during the nine months ended September 30, 2021, and we do not expect additional BARDA revenue in the near future.

Research and development expenses

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

The following table summarizes the components of our research and development expenses for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 1,475	$ 325	$ 3,666	$ 1,585
Stock-based compensation	16	11	58	19
Total research and development expenses	$ 1,491	$ 336	$ 3,724	$ 1,604

The increase of $1.2 million and $2.1 million in research and development expenses for the three and nine months ended September 30, 2021 as compared to the same periods in 2020 was due primarily to increased expenditures related to the development of RNL in compliance with current good manufacturing practices, or cGMP, requirements.

We expect aggregate research and development expenditures to increase in absolute dollars during the remainder of 2021 due to the expected costs of development of the RNL therapy acquired from NanoTx.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses, and general corporate expenses. The following table summarizes the general and administrative expenses for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
General and administrative	$ 1,826	$ 977	$ 4,444	$ 3,977
Stock-based compensation	164	83	367	130
Total general and administrative expenses	$ 1,990	$ 1,060	$ 4,811	$ 4,107

General and administrative expenses increase by approximately $0.9 million during the three months ended September 30, 2021 as compared to the same period in 2020. The increase was primarily due to an increase of $0.6 million in legal and professional expenses, an increase of $0.1 million for stock-based compensation expenses, an increase of $0.1 million in insurance expenses and $0.1 million in personnel costs. General and administrative expenses increased by $0.7 million during the nine months ended September 30, 2021, as compared to the same period in 2020. The increase was primarily driven by an increase of professional expenses of $0.5 million, and an increase of $0.2 million of stock based compensation expenses.

We expect general and administrative expenditures to remain consistent on a quarterly basis for the remainder of 2021 as compared with 2020.

Loss on disposal of property and equipment

Loss on disposal of property and equipment of $18,000 was due to the proceeds received for used property and equipment were lower than their carrying amount.

Stock-based compensation expense

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

The following table summarizes the components of our stock-based compensation expenses for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 16	11	$ 58	19
General and administrative	164	83	367	130
Total stock-based compensation	$ 180	$ 94	$ 425	$ 149

The increase in stock-based compensation expense for the three and nine months ended September 30, 2021 as compared to the same periods in 2020 is primarily related to increased stock options grants in the three and nine months ended September 30, 2021, as compared to the same periods in 2020.

We expect to continue to grant stock options (which will result in an expense) to our employees, directors, and, as appropriate, to non-employee service providers. In addition, previously-granted stock options will continue to vest in accordance with their original terms. As of September 30, 2021, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately $1.5 million which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 3.0 years.

Financing items

The following table summarizes interest income, interest expense, and other income and expense for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Interest income	$ 5	$ 2	$ 13	$ 47
Interest expense	(232)	(253)	(708)	(854)
Change in fair value of warrants	2	(81)	4	2,342
Total	$ (225)	$ (332)	$ (691)	$ 1,535

The decrease in interest expense for the three and nine months ended September 30, 2021 as compared to the same periods in 2020 was primarily due to the repayment of debt principal of $5.0 million in April 2020. The changes in fair value of our warrant liabilities are primarily due to fluctuations in the valuation inputs for the warrants. See Note 4 to the unaudited consolidated condensed financial statements included elsewhere herein for disclosure and discussion of our warrant liabilities.

We expect interest expense in 2021 to decrease as compared with 2020 due to the principal repayment of $5.0 million on April 1, 2020. In April, June, July and September 2020, we entered into revised warrant agreements with the holders of 3,447,500 Series U warrants and in September 2020, we entered into revised warrant agreements for 75,000 of warrants issued to H.C. Wainwright & Co., LLC, as representatives of the underwriters, in the form of Series U warrants. In return for reducing the strike price of the warrants, the warrant holders agreed to amend the settlement provisions upon fundamental transactions. The amended Series U warrants meet the requirements for equity classification under authoritative accounting guidance and are no longer subject to fair value accounting post amendment.

Liquidity and Capital Resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at September 30, 2021 and December 31, 2020 (in thousands):

	As of September 30, 2021	As of December 31, 2020
Cash and cash equivalents	$ 21,280	$ 8,346
Current assets	$ 22,097	$ 9,175
Current liabilities	9,488	8,539
Working capital	$ 12,609	$ 636

We incurred net losses of $9.2 million for the nine months ended September 30, 2021. We have an accumulated deficit of $442.8 million as of September 30, 2021. Additionally, we used net cash of $7.7 million to fund our operating activities for the nine months ended September 30, 2021. These factors raise substantial doubt about our ability to continue as a going concern.

To date, these operating losses have been funded primarily from outside sources of invested capital in our common stock, proceeds raised from the Loan and Security Agreement, and gross profits. 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 October 23, 2020, we entered into an Equity Distribution Agreement (the “Distribution Agreement”) with Canaccord Genuity LLC (“Canaccord”), pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $10,000,000 (the “ATM Shares”), depending on market demand, with Canaccord acting as an agent for sales. During the year ended December 31, 2020, we issued 1,616,331 shares under the Distribution Agreement for net proceeds of approximately $3.2 million. During the nine months ended September 30, 2021, we issued 2,179,193 shares under the Distribution Agreement for net

proceeds of $6.3 million. As of September 30, 2021, there were no remaining shares to issue and sell under the Distribution Agreement.

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. Under the terms and subject to the conditions of the 2020 Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $25.0 million of our common stock. Such sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing November 6, 2020, subject to satisfaction of certain conditions. The net proceeds under the 2020 Purchase Agreement will depend on the frequency and prices at which we sell shares of our common stock to Lincoln Park. We expect that any proceeds received from such sales to Lincoln Park will be used for working capital and general corporate purposes. During the year ended December 31, 2020, we issued 353,113 shares, excluding 180,701 shares issued as commitment fee, under the 2020 Purchase Agreement for net proceeds of approximately $0.7 million. On September 3, 2021, we filed a prospectus, which became effective on September 10, 2021, for the offer and sale of up to 5,865,000 shares of our common stock by Lincoln Park under the 2020 Purchase Agreement. During the nine months ended September 30, 2021, we issued 5,535,186 shares of our common stock under the 2020 Purchase Agreement for net proceeds of $12.3 million.

On March 29, 2020, we entered into the Ninth Amendment of the Loan and Security Agreement (the "Ninth Amendment") which amended that certain 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. Under the Ninth Amendment, among other things, Oxford agreed to defer the start date of principal repayments under the Loan and Security Agreement from May 1, 2020 to May 1, 2021. As we met the "Second I/O Extension Equity Event," as defined in the Ninth Amendment, the principal repayment start date has been deferred to November 1, 2021. In addition, on April 1, 2020, we made a $5.0 million paydown of principal under the Term Loan upon execution of the Ninth Amendment. As a result of this Ninth Amendment, the term of the Term Loan has been extended from September 1, 2021 to September 1, 2024, with all other major terms remained consistent.

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 is likely to be continued market volatility due to the COVID-19 pandemic, risk of inflation 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. Further, a continued global economic downturn may impair our ability to obtain additional financing through other means, such as strategic transactions or debt financing. The overall deterioration of the credit and financial markets due to the COVID-19 pandemic will likely generally reduce our ability to obtain additional financing to fund our operations.

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 nine months ended September 30, 2021 and 2020 is summarized as follows (in thousands):

	For the Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (7,656)	$ (5,210)
Net cash used in investing activities	(84)	(437)
Net cash provided by (used in) financing activities	20,674	(4,319)
Net increase (decrease) in cash and cash equivalents	$ 12,934	$ (9,966)

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2021 was $7.7 million compared to $5.2 million in the same period of 2020. Our operational cash use increased during the nine months ended September 30, 2021 as compared to the same period in 2020, due primarily to timing of cash payments made for operating assets and liabilities.

Investing activities

Net cash used in investing activities for the nine months ended September 30, 2021 were related to purchases of fixed assets of $134,000, offset by proceeds of $50,000 from sale of property and equipment. Net cash used in investing activities for the nine months

ended September 30, 2020 was primarily related to cash payments of $0.4 million made for in process research and development assets from NanoTx, and purchases of fixed assets.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2021 was primarily related to sales of common stock of $18.6 million, net of offering cost through the 2020 Purchase Agreement with Lincoln Park and the Distribution Agreement with Canaccord, as well as $2.0 million from exercise of warrants.

Net cash used for financing activities for the nine months ended September 30, 2020 was primarily related to repayment of $5.3 million of the Term Loan in April 2020, and cash payments for our finance leases, offset by cash proceeds received from warrant exercises of $1.1 million.

Critical Accounting Policies and Significant Estimates

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

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

Goodwill is reviewed for impairment annually or more frequently if indicators of impairment exist. We perform our impairment test annually during the fourth quarter. The Company operates 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, 2020 and there have been no material changes during the nine months ended September 30, 2021.

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 September 30, 2021 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 claims from Lorem are without merit and we intend to vigorously defend the case and on August 12, 2021, we filed a Motion to Dismiss asking the District Court to dismiss the Lorem Claim. Lorem filed an opposition on September 9, 2021, which we responded to on September 30, 2021. As of October 21, 2021 we are still waiting for the District Court’s decision on our motion. No liability was accrued as of September 30, 2021.

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, 2020. 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, 2020.

Item 6. Exhibits

EXHIBIT INDEX

PLUS THERAPEUTICS, INC.

Exhibit Number	Exhibit Title	Filed with this Form 10-Q	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	Amended and Restated Bylaws of Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 3.2	09/21/2021
3.2	Certification of Elimination of Series A Preferred Stock.		8-K	001-34375 Exhibit 3.2	09/21/2021
10.1	LaFrance Employment Agreement.		8-K	001-34375 Exhibit 10.1	09/13/2021
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1*	Certifications Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes - Oxley Act of 2002	X			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	X			
101.SCH	Inline XBRL Schema Document	X			
101.CAL	Inline XBRL Calculation Linkbase Document	X			
101.DEF	Inline XBRL Definition Linkbase Document	X			
101.LAB	Inline XBRL Label Linkbase Document	X			
101.PRE	Inline XBRL Presentation Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X			

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibit 32.1 hereto is deemed to accompany this Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the Company specifically incorporates it by reference.

SIGNATURES

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

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick

Dated: October 21, 2021

Marc H. Hedrick
President & Chief Executive Officer (Duly Authorized Officer and Principal Executive Officer)

By: /s/ Andrew Sims

Dated: October 21, 2021

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

EXHIBIT 31.1

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

I, Marc H. Hedrick, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Plus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: October 21, 2021
/s/ Marc H. Hedrick
Marc H. Hedrick,
President & Chief Executive Officer

EXHIBIT 31.2

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

I, Andrew Sims, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Plus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: October 21, 2021
/s/ Andrew Sims
Andrew Sims
Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Plus Therapeutics, Inc. for the quarterly period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof, Marc H. Hedrick, as President & Chief Executive Officer of Plus Therapeutics, Inc., and Andrew Sims, as VP of Finance and Chief Financial Officer of Plus Therapeutics, Inc., each hereby certifies, respectively, that:

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

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

By: /s/ Marc H. Hedrick

Dated: October 21, 2021

Marc H. Hedrick
President & Chief Executive Officer

By: /s/ Andrew Sims

Dated: October 21, 2021

Andrew Sims
Chief Financial Officer & VP of Finance