

**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, 2022

OR

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

For the transition period from _____ to _____

Commission file number 001-34375

PLUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation or organization)

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

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

78756
(Zip Code)

(737) 255-7194

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

As of October 14, 2022, there were 33,601,373 shares of the registrant's common stock outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report and the exhibits incorporated herein by reference contain “forward-looking statements” which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Statements other than statements of historical fact—constitute “forward-looking statements.” These forward-looking statements do not constitute guarantees of future performance. These forward-looking statements may be identified by terms such as “intend,” “expect,” “project,” “believe,” “anticipate,” “initiate,” “will,” “should,” “would,” “could,” “may,” “designed,” “potential,” “evaluate,” “hypothesize,” “plan,” “progressing,” “proceeding,” “exploring,” “opportunity,” “hopes,” “suggest,” and similar expressions, or the negative of such expressions. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

These statements include, without limitation, statements about our anticipated expenditures, including research and development, and general and administrative expenses; the Company’s strategic collaborations and license agreements, intellectual property, FDA approvals and interactions and government regulation; the potential size of the market for our product candidates; our research and development efforts; results from our pre-clinical and clinical studies and the implications of such results regarding the efficacy or safety of our product candidates; the safety profile, pathways, and efficacy of our product candidates and formulations; anticipated advantages of our product candidates over other products available in the market and being developed; the populations that will most benefit from our product candidates and indications that will be pursued with each product candidate; anticipated progress in our current and future clinical trials; plans and strategies to create novel technologies; our IP strategy; our requirements to comply with the terms of our CPRIT Grant; competition; future development and/or expansion of our product candidates and therapies in our markets; sources of competition for any of our product candidates; our pipeline; our ability to generate product or development revenue and the sources of such revenue; our ability to effectively manage our gross profit margins; our ability to obtain and maintain regulatory approvals; expectations as to our future performance; portions of the “Liquidity and Capital Resources” section of this report, including our potential need for additional financing and the availability thereof; our ability to continue as a going concern; our ability to remain listed on the Nasdaq Capital Market; our ability to repay or refinance some or all of our outstanding indebtedness and our ability to raise capital in the future; our ability to repurchase shares of our common stock; our ability to transfer the drug product manufacture to a contract drug manufacturing organization; and the potential enhancement of our cash position through development, marketing, and licensing arrangements. The forward-looking statements included in this report are also subject to a number of additional material risks and uncertainties, including but not limited to the risks described under “Part I – Item 1A – Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021, and under “Part II – Item 1A – Risk Factors” in this Quarterly report. These risks and uncertainties could cause actual results to differ materially from expectations or those expressed in these forward-looking statements.

Our actual results may differ, including materially, from those anticipated in these forward-looking statements as a result of various factors, including, but not limited to, the following: the early stage of our product candidates and therapies, the results of our research and development activities, including uncertainties relating to the clinical trials of our product candidates and therapies; our liquidity and capital resources and our ability to raise additional cash, the outcome of our partnering/licensing efforts, risks associated with laws or regulatory requirements applicable to us, market conditions, product performance, potential litigation, and competition within the regenerative medicine field, among others. The forward-looking statements included in this report are also subject to a number of additional material risks and uncertainties, including but not limited to the risks described under “Part I – Item 1A – Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021, and under “Part II – Item 1A – Risk Factors” in this Quarterly report. These risks and uncertainties could cause actual results to differ materially from expectations or those expressed in these forward-looking statements.

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

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,266	\$ 18,400
Grant receivable	73	—
Other current assets	540	1,324
Total current assets	<u>20,879</u>	<u>19,724</u>
Property and equipment, net	1,453	1,477
Operating lease right-use-of assets	275	341
Goodwill	372	372
Intangible assets, net	113	51
Other assets	12	16
Total assets	<u>\$ 23,104</u>	<u>\$ 21,981</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,705	\$ 4,151
Operating lease liability	107	111
Term loan obligation, current	1,608	1,608
Total current liabilities	<u>7,420</u>	<u>5,870</u>
Noncurrent operating lease liability	172	269
Term loan obligation	4,108	5,005
Warrant liability	—	1
Total liabilities	<u>11,700</u>	<u>11,145</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 32,570,002 and 15,510,025 issued and outstanding at September 30, 2022 and December 31, 2021, respectively	32	16
Additional paid-in capital	472,899	457,730
Accumulated deficit	(461,527)	(446,910)
Total stockholders' equity	<u>11,404</u>	<u>10,836</u>
Total liabilities and stockholders' equity	<u>\$ 23,104</u>	<u>\$ 21,981</u>

See Accompanying Notes to these Condensed Financial Statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Grant revenue	\$ 73	\$ —	\$ 73	\$ —
Operating expenses:				
Research and development	2,945	1,491	7,560	3,724
General and administrative	2,222	1,990	6,653	4,811
Loss on disposal of property and equipment	—	18	—	18
Total operating expenses	<u>5,167</u>	<u>3,499</u>	<u>14,213</u>	<u>8,553</u>
Operating loss	<u>(5,094)</u>	<u>(3,499)</u>	<u>(14,140)</u>	<u>(8,553)</u>
Other income (expense):				
Interest income	48	5	74	13
Interest expense	(173)	(232)	(552)	(708)
Change in fair value of liability instruments	—	2	1	4
Total other expense	<u>(125)</u>	<u>(225)</u>	<u>(477)</u>	<u>(691)</u>
Net loss	<u>\$ (5,219)</u>	<u>\$ (3,724)</u>	<u>\$ (14,617)</u>	<u>\$ (9,244)</u>
Net loss per share, basic and diluted	\$ (0.19)	\$ (0.28)	\$ (0.61)	\$ (0.84)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	27,441,654	13,264,230	23,789,195	10,961,284

See Accompanying Notes to these Condensed Financial Statements

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

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	1,954	\$ —	6,749,028	\$ 7	\$ 436,535	\$ (433,511)	\$ 3,031
Stock-based compensation	—	—	—	—	107	—	107
Sale of common stock, net	—	—	2,534,879	2	7,076	—	7,078
Conversion of Series B Convertible Preferred Stock into common stock	(2)	—	118	—	—	—	—
Issuance of common stock for exercise of warrants	—	—	896,500	1	2,016	—	2,017
Net loss	—	—	—	—	—	(2,720)	(2,720)
Balance at March 31, 2021	<u>1,952</u>	<u>\$ —</u>	<u>10,180,525</u>	<u>\$ 10</u>	<u>\$ 445,734</u>	<u>\$ (436,231)</u>	<u>\$ 9,513</u>
Stock-based compensation	—	—	—	—	138	—	138
Sale of common stock, net	—	—	1,907,000	2	5,092	—	5,094
Net loss	—	—	—	—	—	(2,800)	(2,800)
Balance at June 30, 2021	<u>1,952</u>	<u>\$ —</u>	<u>12,087,525</u>	<u>\$ 12</u>	<u>\$ 450,964</u>	<u>\$ (439,031)</u>	<u>\$ 11,945</u>
Stock-based compensation	—	—	—	—	180	—	180
Sale of common stock, net	—	—	3,272,500	3	6,351	—	6,354
Net loss	—	—	—	—	—	(3,724)	(3,724)
Balance at September 30, 2021	<u>1,952</u>	<u>\$ —</u>	<u>15,360,025</u>	<u>\$ 15</u>	<u>\$ 457,495</u>	<u>\$ (442,755)</u>	<u>\$ 14,755</u>
Balance at December 31, 2021	1,952	\$ —	15,510,025	\$ 16	\$ 457,730	\$ (446,910)	\$ 10,836
Stock-based compensation	—	—	—	—	180	—	180
Sale of common stock, net	—	—	6,687,610	6	7,736	—	7,742
Net loss	—	—	—	—	—	(4,116)	(4,116)
Balance at March 31, 2022	<u>1,952</u>	<u>\$ —</u>	<u>22,197,635</u>	<u>\$ 22</u>	<u>\$ 465,646</u>	<u>\$ (451,026)</u>	<u>\$ 14,642</u>
Stock-based compensation	—	—	—	—	167	—	167
Sale of common stock, net	—	—	271,047	—	152	—	152
Net loss	—	—	—	—	—	(5,282)	(5,282)
Balance at June 30, 2022	<u>1,952</u>	<u>\$ —</u>	<u>22,468,682</u>	<u>\$ 22</u>	<u>\$ 465,965</u>	<u>\$ (456,308)</u>	<u>\$ 9,679</u>
Sale of common stock, net	—	—	10,101,320	10	6,805	—	6,815
Share-based compensation	—	—	—	—	129	—	129
Net loss	—	—	—	—	—	(5,219)	(5,219)
Balance at September 30, 2022	<u>1,952</u>	<u>\$ —</u>	<u>32,570,002</u>	<u>\$ 32</u>	<u>\$ 472,899</u>	<u>\$ (461,527)</u>	<u>\$ 11,404</u>

See Accompanying Notes to these Condensed Financial Statements

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

For the Nine Months Ended September 30,

	2022	2021
Cash flows used in operating activities:		
Net loss	\$ (14,617)	\$ (9,244)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	460	266
Amortization of deferred financing costs and debt discount	309	417
In process research and development acquired	—	18
Change in fair value of liability instruments	(1)	(4)
Stock-based compensation expense	476	425
Non-cash lease expense	(35)	36
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Grant receivable	73	—
Other current assets	642	12
Accounts payable and accrued expenses	1,955	418
Net cash used in operating activities	<u>(10,738)</u>	<u>(7,656)</u>
Cash flows used in investing activities:		
Purchases of property and equipment	(381)	(134)
Purchase of intangible assets	(117)	—
Proceeds from sale of property and equipment	—	50
In process research and development acquired	(250)	—
Net cash used in investing activities	<u>(748)</u>	<u>(84)</u>
Cash flows from financing activities:		
Principal payments of long-term obligations	(1,206)	—
Payment of financing lease liability	—	(8)
Proceeds from exercise of warrants	—	2,017
Proceeds from sale of common stock, net	14,558	18,665
Net cash provided by financing activities	<u>13,352</u>	<u>20,674</u>
Net increase in cash and cash equivalents	1,866	12,934
Cash and cash equivalents at beginning of period	18,400	8,346
Cash and cash equivalents at end of period	<u>\$ 20,266</u>	<u>\$ 21,280</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 248	\$ 292
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	\$ 68	\$ 139
Right-of-use asset obtained in exchange for lease liabilities	\$ —	\$ 81

See Accompanying Notes to these Condensed Financial Statements

PLUS THERAPEUTICS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
September 30, 2022
(UNAUDITED)

1. Basis of Presentation and New Accounting Standards

The accompanying unaudited condensed financial statements as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for annual financial statements. The condensed balance sheet at December 31, 2021 has been derived from the audited financial statements at December 31, 2021, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of Plus Therapeutics, Inc., and its subsidiaries (collectively, the “Company”) have been included. Operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. These financial statements should be read in conjunction with the financial statements and notes therein included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on February 24, 2022.

Grant Receivable and Revenue Recognition

In applying the provisions of Accounting Standards Codification (“ASC”) Topic 606, Revenue from Contracts with Customers (“ASC 606”), the Company has determined that government grants are out of the scope of ASC 606 because the funding entities do not meet the definition of a “customer”, as defined by ASC 606, as there is not considered to be a transfer of control of goods or services. With respect to the grant, the Company determines if it has a collaboration in accordance with ASC Topic 808, Collaborative Arrangements (“ASC 808”). For grants outside the scope of ASC 808, the Company applies ASC 606 or International Accounting Standards No. 20, Accounting for Government Grants and Disclosure of Government Assistance, by analogy, and revenue is recognized when the Company incurs expenses related to the grant for the amount the Company is entitled to under the provisions of the contract.

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

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

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren’t measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. This new guidance is effective in the first quarter of 2023 for calendar-year SEC filers that are smaller reporting companies as of the one-time determination date. Early adoption is permitted beginning in 2019. The Company plans to adopt the new guidance on January 1, 2023, and it does not expect that adoption of this standard will have a material impact on its financial statements and related disclosures.

2. Use of Estimates

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

As discussed in more detail in Note 7, on September 19, 2022, the Company entered into a Cancer Research Grant Contract (the “CPRIT Contract”), effective as of August 31, 2022, with the Cancer Prevention and Research Institute of Texas (“CPRIT”),

pursuant to which the Company will receive up to \$17.6 million to fund a portion of the clinical trials. The Company estimates the amount of clinical trial costs that should be borne by CPRIT in accordance with the CPRIT Contract, based on the actual costs incurred and progress of the trial.

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

3. Liquidity

The Company incurred net losses of \$14.6 million for the nine months ended September 30, 2022. The Company had an accumulated deficit of \$461.5 million as of September 30, 2022. Additionally, the Company used net cash of \$10.7 million to fund its operating activities for the nine months ended September 30, 2022.

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

The Company continues to seek additional capital through strategic transactions and from other financing alternatives. If sufficient capital is not raised, the Company will at a minimum need to significantly reduce or curtail its research and development and other operations, and this would negatively affect its ability to achieve corporate growth goals.

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

Nasdaq's notice has no immediate effect on the listing or trading of the Company's common stock. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided an initial compliance period of 180 calendar days, or until November 21, 2022, to regain compliance with the Minimum Bid Requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed \$1.00 per share for a minimum of 10 consecutive business days prior to November 21, 2022.

If the Company does not achieve compliance with the Minimum Bid Requirement by November 21, 2022, the Company may be eligible for an additional 180 calendar days to regain compliance. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other Nasdaq initial listing standards, with the exception of the Minimum Bid Requirement, and provide written notice of its intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split if necessary. If the Nasdaq staff determines that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible for such additional compliance period, Nasdaq will provide notice that the Company's common stock will be subject to delisting. In the event the Company receives notice that its common stock is being delisted, Nasdaq rules permit the Company to appeal any delisting determination by the Nasdaq staff.

There can be no assurance that the Company will be able to regain compliance with the Minimum Bid Requirement or maintain compliance with the other listing requirements.

4. Fair Value Measurements

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

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

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

inputs to the Company's valuation model are either not observable or are not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability is classified as Level 3 in the fair value hierarchy.

Liability-classified Series U Warrants are marked to market as of each balance sheet date until they are exercised or upon expiration, with the changes in fair value recorded as non-operating income or loss in the statements of operations. As of September 30, 2022, the fair value of the Series U Warrants was immaterial, and the change in the fair value of liability classified Series U Warrants during the three and nine months ended September 30, 2022 and 2021 was immaterial.

5. **Term Loan Obligations**

On May 29, 2015, the Company entered into the Loan and Security Agreement (the "Loan and Security Agreement"), pursuant to which Oxford Finance, LLC ("Oxford") funded an aggregate principal amount of \$17.7 million (the "Term Loan"), subject to the terms and conditions set forth in the Loan and Security Agreement. The Term Loan accrues interest at a floating rate of at least 8.95% per annum, comprised of a three-month LIBOR rate with a floor of 1.00% plus 7.95%. Pursuant to the Loan and Security Agreement, as amended, the Company made interest only payments through May 1, 2021 and thereafter is required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through June 1, 2024, the maturity date. At maturity of the Term Loan, or earlier repayment in full following voluntary prepayment or upon acceleration, the Company is required to make a final payment in an aggregate amount equal to approximately \$3.2 million. In connection with the Term Loan, on May 29, 2015, the Company issued to Oxford warrants to purchase an aggregate of 188 shares of the Company's common stock at an exercise price of \$5,175 per share. These warrants became exercisable as of November 30, 2015 and will expire on May 29, 2025 and, following authoritative accounting guidance, are equity classified and its respective fair value was recorded as a discount to the debt.

From September 2017 to July 2019, the Company entered into a total of eight amendments to the Term Loan which, amongst other things, extended the interest only period, required repayment of \$3.1 million using the proceeds received from sale of the Company's former UK and Japan subsidiaries in April 2019, increased the final payment, increased the final payment fee upon maturity or early repayment of the Term Loan, and increased the minimum liquidity covenant level to \$2.0 million.

On March 29, 2020, the Company entered into the Ninth Amendment of the Loan and Security Agreement (the "Ninth Amendment"), pursuant to which Oxford agreed to defer the start date of principal repayment from May 1, 2020 to May 1, 2021 and extended the term of the Term Loan from September 1, 2021 to June 1, 2024.

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

The Term Loan, as amended, is collateralized by a security interest in substantially all of the Company's existing and subsequently acquired assets, including its intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement, as amended. The intellectual property asset collateral will be released upon the Company achieving a certain liquidity level when the total principal outstanding under the Loan and Security Agreement is less than \$3.0 million. As of September 30, 2022, there was \$2.8 million principal amount outstanding under the Term Loan, excluding the \$3.2 million final payment fee, and the Company was in compliance with all of the debt covenants under the Loan and Security Agreement.

The Company's interest expense for the three months ended September 30, 2022 and 2021 was \$0.2 million. The Company's interest expense for the nine months ended September 30, 2022 and 2021 was \$0.6 million and \$0.7 million, respectively. Interest expense is calculated using the effective interest method; therefore it is inclusive of non-cash amortization in the amount of \$0.1 million for each of the three months ended September 30, 2022 and 2021, and \$0.3 million and \$0.4 million for the nine months ended September 30, 2022 and 2021, 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, 2022, the Company has not received any notification or indication from Oxford that it intends to invoke the material adverse change clause.

6. Loss per Share

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding as calculated using the treasury stock method. Potential 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:

	September 30,	
	2022	2021
Outstanding stock options	1,175,016	1,050,890
Preferred stock	422,867	422,985
Outstanding warrants	2,141,189	2,141,378
Total	3,739,072	3,615,253

7. Grant Revenue

On September 19, 2022, the Company entered into the CPRIT Contract, effective as of August 31, 2022, with CPRIT, pursuant to which CPRIT will provide the Company a grant of up to \$17.6 million (the "CPRIT Grant") over a three-year period to fund the continued development of Rhenium-186 NanoLiposome (¹⁸⁶RNL) for the treatment of patients with leptomeningeal metastases ("LM"). The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of ¹⁸⁶RNL based on specific dollar thresholds and tiered low single digit royalty rates until CPRIT receives the aggregate amount of 400% of the proceeds awarded under the CPRIT Grant, and certain reporting requirements.

The CPRIT Contract will terminate on August 30, 2025, unless terminated earlier by (a) the mutual written consent of all parties to the CPRIT Contract, (b) CPRIT for an event of default by the Company, (c) CPRIT, if the funds allocated to the CPRIT Grant become legally unavailable during the term of the CPRIT Contract and CPRIT is unable to obtain additional funds for such purposes, and (d) the Company for convenience. CPRIT may require the Company to repay some or all of the disbursed CPRIT Grant proceeds (with interest not to exceed 5% annually) in the event of the early termination of the CPRIT Contract by CPRIT for an event of default by the Company or by the Company for convenience.

The Company will retain ownership over any intellectual property developed under the contract ("Project Result"). With respect to non-commercial use of any Project Result, the Company agreed to grant to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license with right to sublicense any necessary additional intellectual property rights to exploit all Project Results by CPRIT, other governmental entities and agencies of the State of Texas, and private or independent institutions of higher education located in Texas, for education, research and other non-commercial purposes.

The Company determined that the CPRIT Contract is not in the scope of ASC 808 or ASC 606. Applying ASC 606 by analogy, the Company recognizes proceeds received under the CPRIT Contract as grant revenue on the statement of operations when related costs are incurred. The Company recognized \$73,000 in grant revenue from the CPRIT Contract during the three and nine months ended September 30, 2022.

8. Commitments and Contingencies

Leases

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

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

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2025. The Company also leases certain office space in Austin, Texas under a month-to-month operating lease agreement and certain office space in Charlottesville, Virginia (the “Charlottesville Lease”). The Charlottesville Lease has a term of 12 months and the Company has the ability to renew for three additional one-year periods. The Charlottesville Lease is currently set to expire on March 31, 2023. The Company measured the operating lease right-of-use asset and related lease liability related to the Charlottesville Lease as of the lease commencement date of April 1, 2021. In addition, the Company has entered into leases for certain equipment under various operating and finance leases. During 2021, contractual terms of all finance leases had expired and the Company did not have any right-of-use assets or lease liabilities relating to finance leases as of September 30, 2022. The Company’s existing operating lease agreements generally provide for periodic rent increases, and renewal and termination options. The Company’s lease agreements do not contain any material variable lease payments, residual value guarantees or material restrictive covenants.

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

The Company’s operating lease liabilities and corresponding right-of-use assets are included in the condensed balance sheets. As of September 30, 2022, weighted average discount rate used to measure operating lease liabilities and the operating leases remaining term were 9% and 2.27 years, respectively.

The table below summarizes the Company’s lease costs from its unaudited condensed statement of operations, and cash payments from its unaudited condensed statement of cash flows during the three and nine months ended September 30, 2022 and 2021 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Lease expense:				
Operating lease expense	\$ 34	\$ 58	\$ 126	\$ 166
Finance lease expense:				
Depreciation of right-of-use assets	-	-	-	7
Total lease expense	\$ 34	\$ 58	\$ 126	\$ 173
Cash payment information:				
Operating cash used for operating leases	\$ 34	\$ 56	\$ 125	\$ 162
Financing cash used for financing leases	-	-	-	8
Total cash paid for amounts included in the measurement of lease liabilities	\$ 34	\$ 56	\$ 125	\$ 170

Total rent expenses for the nine months ended September 30, 2022 and 2021 were \$163,000 and \$170,000, respectively, which includes leases in the table above, month-to-month operating leases, and common area maintenance charges.

The Company’s future minimum annual lease payments under operating leases at September 30, 2022 are as follows (in thousands):

	Operating Leases
Remainder of 2022	\$ 34
2023	137
2024	113
2025	18
Total minimum lease payments	\$ 302
Less: amount representing interest	(23)
Present value of obligations under leases	279
Less: current portion	(107)
Noncurrent lease obligations	\$ 172

Services Agreement and Sales Order with Medidata

On March 31, 2022, the Company and Medidata Solutions, Inc. (“Medidata”) entered into a Sales Order (the “Sales Order”), pursuant to which Medidata will build a Synthetic Control Arm[®] (SCA) platform that facilitates the use of historical clinical data to incorporate into the Company’s Phase 2 clinical trial of ¹⁸⁶RNL in recurrent glioblastoma (“GBM”). The Sales Order is governed under the terms of a services agreement (the “Services Agreement”), dated November 5, 2021.

The Sales Order has a term of six (6) months. The Sales Order may only be terminated for a material breach by either party, if the clinical study is terminated or if the clinical study’s authorization or approval is withdrawn by a regulatory agency.

Piramal Master Services Agreement

On January 8, 2021, the Company entered into a Master Services Agreement (the “MSA”) with Piramal Pharma Solutions, Inc. (“Piramal”), for Piramal to perform certain services related to the development, manufacture, and supply of the Company’s RNL-Liposome Intermediate Drug Product. The MSA includes the transfer of analytical methods, development of microbiological methods, process transfer and optimization, intermediate drug product manufacturing, and stability studies for the Company, which has been initiated at Piramal’s facility located in Lexington, Kentucky.

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

Other commitments and contingencies

The Company has entered into agreements with various research organizations for pre-clinical and clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, recruiting and enrolling patients, monitoring studies and data analysis. Payments under these agreements typically include fees for services and reimbursement of expenses. The timing of payments due under these agreements is estimated based on current study progress. As of September 30, 2022, the Company did not have any clinical research study obligations.

Legal proceedings

On June 22, 2021, the Company was named as a defendant in an action brought by Lorem Vascular, Pte. Ltd. (“Lorem”) in the District Court for the District of Delaware. The complaint alleges false representations were made to Lorem regarding the manufacturing facility in the United Kingdom (the “UK Facility”) that Lorem purchased from the Company under the Asset and Equity Purchase Agreement, dated March 29, 2019, between the Company and Lorem (the “Lorem Agreement”). Lorem also claims that false representations were made regarding the UK Facility’s certification to sell and distribute devices in the European Union and export such devices to China. In connection with these allegations, Lorem claims entitlement to at least \$6,000,000 in compensatory damages and operational costs and expenses (collectively, the “Lorem Claim”). The Company believes that the Lorem Claim is without merit and is vigorously defending the case. No liability was accrued as of September 30, 2022.

The Company is subject to various claims and contingencies related to legal proceedings. Due to their nature, such legal proceedings involve inherent uncertainties including, but not limited to, court rulings, negotiations between affected parties and governmental actions. Management assesses the probability of loss for such contingencies and accrues a liability and/or discloses the relevant circumstances, as appropriate.

9. License Agreements

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

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

Pursuant to the UTHSA License Agreement, the Company was required to make an upfront payment, which was recorded as in-process research and development acquired in the condensed statement of operations for the year ended December 31, 2021. The upfront payment of \$250,000 was paid in cash in January 2022.

NanoTx License Agreement

On March 29, 2020, the Company and NanoTx, Corp. (“NanoTx”) entered into a Patent and Know-How License Agreement (the “NanoTx License Agreement”), pursuant to which NanoTx granted the Company an irrevocable, perpetual, exclusive, fully paid-up license, with the right to sublicense and to make, develop, commercialize and otherwise exploit certain patents, know-how and technology related to the development of radiolabeled nanoliposomes.

10. Stockholders’ Equity

Preferred Stock

The Company has authorized 5,000,000 shares of preferred stock, par value \$0.001 per share. The Company’s Board of Directors is authorized to designate the terms and conditions of any preferred stock the Company issues without further action by the common stockholders. On September 21, 2021, Series A 3.6% Convertible Preferred Stock was eliminated. There were no shares of Series A 3.6% Convertible Preferred Stock immediately prior to September 21, 2021, or December 31, 2020. There were 1,014 shares of Series B Convertible Preferred Stock outstanding as of September 30, 2022 and December 31, 2021. There were 938 shares of Series C Preferred Stock outstanding as of September 30, 2022 and December 31, 2021.

As of September 30, 2022, there were 938 outstanding shares of Series C Preferred Stock that can be converted into an aggregate of 416,889 shares of common stock, and 1,014 shares of Series B Convertible Preferred Stock that can be converted into an aggregate of 5,978 shares of common stock.

Warrants

On September 25, 2019, the Company completed an underwritten public offering. The Company issued 289,000 shares of its common stock, along with pre-funded warrants to purchase 2,711,000 shares of its common stock and Series U Warrants to purchase 3,450,000 shares of its common stock at \$5.00 per share. The Series U Warrants have a term of five years from the issuance date. In addition, the Company issued warrants to H.C. Wainwright & Co., LLC, as representatives of the underwriters, to purchase 75,000 shares of its common stock at \$6.25 per share with a term of 5 years from the issuance date, in the form of Series U Warrants (the “Representative Warrants”).

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

As of September 30, 2022, there were 2,141,000 outstanding Series U Warrants which can be exercised into an aggregate of 2,141,000 shares of common stock.

Common Stock

Lincoln Park Purchase Agreements

On August 2, 2022, the Company entered into a purchase agreement (the “2022 Purchase Agreement”) and registration rights agreement pursuant to which Lincoln Park committed to purchase up to \$50.0 million of the Company’s common stock. Under the terms and subject to the conditions of the 2022 Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$50.0 million of the Company’s common stock. Such sales of common stock by the Company are subject to certain limitations, and can occur from time to time, at the Company’s sole discretion, over the 36-month period commencing on August 17, 2022, subject to the satisfaction of certain conditions. Lincoln Park has no right to require the Company to sell any shares of common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as the Company directs, subject to certain conditions.

On May 16, 2022, the Company received stockholder approval for purposes of the Nasdaq listing rules to permit issuances of up to 57.5 million shares of the Company’s common stock (including the issuance of more than 19.99% of the Company’s common stock) to Lincoln Park, and it was pursuant to that approval that the Company entered into the 2022 Purchase Agreement.

Upon execution of the 2022 Purchase Agreement, the Company paid \$125,000 in cash as the initial commitment fee, and issued 492,698 shares as the initial commitment shares, to Lincoln Park as consideration for its irrevocable commitment to purchase shares of the Company’s common stock at its direction under the Purchase Agreement. The Company has agreed to pay an additional commitment fee, which it may elect to pay in cash and/or shares of its common stock, upon receipt of \$25.0 million aggregate gross proceeds from sales of common stock to Lincoln Park under the 2022 Purchase Agreement.

On August 17, 2022, a registration statement was declared effective to cover the resale of up to 9,500,000 shares of the Company’s common stock comprised of (i) the 492,698 initial commitment shares, and (ii) up to 9,007,302 that the Company has reserved

for issuance and sale to Lincoln Park under the Purchase Agreement from time to time from and after the date of this prospectus. The Company cannot sell more shares under the 2022 Purchase Agreement without registering additional shares.

Actual sales of shares of common stock to Lincoln Park under the 2022 Purchase Agreement depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. The net proceeds under the 2022 Purchase Agreement to the Company depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park.

During the period from August 17, 2022 to September 30, 2022, the Company issued 4,000,000 shares under the 2022 Purchase Agreement for net proceeds of approximately \$3.2 million. From October 1, 2022 to the date of filing of this Form 10-Q, the Company did not issue any shares under the 2022 Purchase Agreement.

On September 30, 2020, the Company entered into a purchase agreement (the "2020 Purchase Agreement") and registration rights agreement pursuant to which Lincoln Park committed to purchase up to \$25.0 million of the Company's common stock. Under the terms and subject to the conditions of the 2020 Purchase Agreement, the Company had the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park was obligated to purchase up to \$25.0 million of the Company's common stock. Such sales of common stock by the Company were subject to certain limitations, and could occur from time to time, at the Company's sole discretion, over the 36-month period commencing on November 6, 2020, subject to the satisfaction of certain conditions.

On June 16, 2020, the Company received stockholder approval for purposes of the Nasdaq listing rules to permit issuances of up to 23.8 million shares of the Company's common stock (including the issuance of more than 19.99% of the Company's common stock) to Lincoln Park, and it was pursuant to that approval that the Company entered into the 2020 Purchase Agreement.

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

During the year ended December 31, 2021, the Company issued 5,685,186 shares of its common stock under the 2020 Purchase Agreement for net proceeds of approximately \$12.5 million. During the nine months ended September 30, 2022, the Company issued 5,665,000 shares of its common stock under the 2020 Purchase Agreement for net proceeds of approximately \$7.0 million. The Company no longer has any additional shares of common stock registered to sell under the 2020 Purchase Agreement.

At-the-market Issuances

On September 9, 2022, the Company entered into an Equity Distribution Agreement (the "September 2022 Distribution Agreement") with Canaccord Genuity LLC ("Canaccord"), pursuant to which the Company may issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$5,000,000, depending on market demand, with Canaccord acting as an agent for sales. Sales of the Company's common stock may be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended (the "Securities Act"), including, without limitation, sales made directly on or through the NASDAQ Capital Market. Canaccord will use its commercially reasonable efforts to sell common stock requested by the Company to be sold on its behalf, consistent with Canaccord's normal trading and sales practices, under the terms and subject to the conditions set forth in the September 2022 Distribution Agreement. The Company has no obligation to sell any of its common stock. The Company may instruct Canaccord not to sell any common stock if the sales cannot be effected at or above the price designated by the Company from time to time and the Company may at any time suspend sales pursuant to the September 2022 Distribution Agreement. During the period from September 9, 2022 to September 30, 2022, the Company did not issue any shares of its common stock under the September 2022 Distribution Agreement. From October 1, 2022 to the date of filing of this Form 10-Q, the Company issued 1,000,000 shares under the September 2022 Distribution Agreement for net proceeds of approximately \$0.6 million.

The Company is obligated to pay Canaccord a commission of up to 3.0% of the gross proceeds from the sale of its common stock under the September 2022 Distribution Agreement. The Company has also agreed to reimburse Canaccord for its reasonable documented out-of-pocket expenses, including fees and disbursements of its counsel, in the amount of \$50,000. In addition, the Company has agreed to provide customary indemnification rights to Canaccord.

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

On January 14, 2022, the Company entered into an Equity Distribution Agreement (the “January 2022 Distribution Agreement”) with Canaccord, pursuant to which the Company could issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$5,000,000 shares, with Canaccord acting as an agent for sales. The Company had no obligation to sell any of the Company’s shares and it could instruct Canaccord not to sell any shares if the sales could not be effected at or above the price designated by the Company from time to time and the Company could at any time suspend sales pursuant to the January 2022 Distribution Agreement. During the nine months ended September 30, 2022, the Company issued 6,902,279 shares under the January 2022 Distribution Agreement for net proceeds of approximately \$4.5 million. The January 2022 Distribution Agreement has been terminated after all available registered shares were fully utilized.

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

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

Stock Repurchase Program

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

11. Stock-based Compensation

Under the Company’s 2015 New Employee Incentive Plan (the “2015 Plan”), awards may only be granted to employees who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as a material inducement to entering into employment with the Company. As of September 30, 2022, there were 90,389 shares of common stock remaining and available for future issuances under the 2015 Plan.

The Company’s 2020 Stock Incentive Plan (the “2020 Plan”), which replaced the Company’s 2014 Equity Incentive Plan, provides for the award or sale of shares of common stock (including restricted stock), the award of stock units and stock appreciation rights, and the grant of both incentive stock options to purchase common stock to directors, officers, employees and consultants of the Company. The 2020 Plan, as amended, provides for the issuance of up to 3,500,000 shares of common stock, plus the number of shares available for issuance is increased to the extent that awards granted under the 2020 Plan and the Company’s 2014 Equity Incentive Plan are forfeited or expire (except as otherwise provided in the 2020 Plan). As of September 30, 2022, there were 627,212 shares remaining and available for future issuances under the 2020 Plan.

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

A summary of activity for the nine months ended September 30, 2022 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ('000's)
Balance as of December 31, 2021	1,170,890	\$ 5.01	9.00	
Granted	13,000	\$ 0.53		
Cancelled/forfeited	(8,874)	\$ 60.08		
Balance as of September 30, 2022	1,175,016	\$ 4.54	8.27	\$ -
Vested and expected to vest at September 30, 2022	1,126,448	\$ 4.59	8.25	\$ -
Exercisable at September 30, 2022	585,710	\$ 6.69	8.02	\$ -

As of September 30, 2022, the total compensation cost related to non-vested stock options not yet recognized for all the Company's plans is approximately \$1.1 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 2.40 years.

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

The following discussion and analysis should be read in conjunction with the unaudited financial information and the notes thereto included herein, as well as the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2021, as filed on February 24, 2022. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the caption “Cautionary Note Regarding Forward-Looking Statements” in this report, as well as under “Part I – Item 1A - Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021, in other subsequent filings with the SEC, and elsewhere in this Quarterly Report on Form 10-Q. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

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

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

Results of Operations that includes a more detailed discussion of our revenue and expenses.

Liquidity and Capital Resources that discusses key aspects of our statements of cash flows, changes in our financial position and our financial commitments.

Overview

Plus Therapeutics, Inc. is a U.S. pharmaceutical company developing innovative, targeted radiotherapeutics for adults and children with rare and difficult-to-treat cancers. Our novel radioactive drug formulations and therapeutic candidates are designed to deliver safe and effective doses of radiation to tumors. To achieve this, we have developed innovative approaches to drug formulation, including encapsulating radionuclides such as Rhenium isotopes within nanoliposomes and microspheres. Our formulations are intended to achieve elevated tumor absorbed radiation doses and extended retention times such that the clearance of the isotope occurs after significant radiation decay, which we believe will contribute and provide less normal tissue/organ exposure and improved safety margins.

Traditional approaches to radiation therapy for cancer such as external beam radiation have many disadvantages including continuous treatment for 4-6 weeks (which is onerous for patients), radiation that inadvertently damages healthy cells and tissue, and a limited amount of radiation that can be safely delivered, therefore, is frequently inadequate to fully destroy the cancer.

Our targeted radiotherapeutic platform and unique investigational drugs have the potential to overcome these disadvantages by directing higher, more powerful radiation doses at the tumor—and only the tumor—potentially in a single treatment. By minimizing radiation exposure to healthy tissues while simultaneously maximizing efficacy, we hope to reduce the toxicity of radiation for patients, improving their quality of life and life expectancy. Our radiotherapeutic platform, combined with advances in surgery, nuclear medicine, interventional radiology, and radiation oncology, affords us the opportunity to target a broad variety of cancer types.

Our lead radiotherapeutic candidate, Rhenium-186 NanoLiposome (“¹⁸⁶RNL”) is designed specifically to target central nervous system (“CNS”) cancers including recurrent glioblastoma, leptomeningeal metastases, and pediatric brain cancers by direct localized delivery utilizing convection-enhanced delivery (“CED”) and intraventricular (Ommaya reservoir) catheter systems. Our recently acquired radiotherapeutic candidate, Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere (“¹⁸⁸RNL-BAM”) is designed to treat many solid organ cancers including primary and secondary liver cancers by intra-arterial injection.

Our headquarters and manufacturing facilities are in Texas and are nearby world-class cancer institutions and researchers. Our dedicated team of engineers, physicians, scientists, and other professionals are committed to advancing our targeted radiotherapeutic technology for the benefit of cancer patients and healthcare providers worldwide and our current pipeline is focused on treating rare and difficult-to-treat cancers with significant unmet medical needs.

Pipeline

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

The ¹⁸⁶RNL technology was part of a licensed radiotherapeutic portfolio that we acquired from NanoTx, Corp. (“NanoTx”) on May 7, 2020. The licensed radiotherapeutic has been evaluated in preclinical studies for several cancer targets, and we have an active \$3.0 million award from U.S. National Institutes of Health/National Cancer Institute which will provide financial support for the continued clinical development of ¹⁸⁶RNL for recurrent glioblastoma through the completion of a Phase 2 clinical trial including enrollment of up

to 55 patients. Thus far, 24 patients have been treated in the Phase 1 clinical trial and the Phase 2 clinical trial has not yet been initiated.

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

On August 29, 2022 we announced feedback from our recent meeting with the FDA following receipt of formal minutes from a Type C meeting with the FDA specific to Chemistry, Manufacturing and Controls (“CMC”). The meeting focused on the Company’s Current Good Manufacturing Practice (cGMP) clinical and commercial manufacturing process for its lead investigational targeted radiotherapeutic, BMEDA-chelated ¹⁸⁶RNL, for GBM.

The FDA indicated agreement with the Company’s proposed application of cGMP guidance for radiotherapeutics, small molecule drug products and liposome drug products for Plus Therapeutics’ novel ¹⁸⁶RNL in support of ongoing and future glioblastoma clinical trials, manufacturing scale up and commercialization. Alignment with the FDA includes support of the Company’s proposed controls and release strategy for the new drug substance and new drug product. Because this product is identical for GBM and LM adult development and pediatric brain tumors, we believe this FDA alignment and feedback will apply to ¹⁸⁶RNL used in other clinical development programs, including leptomeningeal metastases and pediatric brain cancer.

¹⁸⁶RNL versus External Beam Radiation Therapy

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

- The ¹⁸⁶RNL radiation absorbed dose delivered to patients may be up to 20 times greater than what is delivered with commonly used EBRT where EBRT’s maximum absorbed dose is limited by normal tissue toxicity.
- ¹⁸⁶RNL can be visualized, and quantified, if necessary, in real-time during administration, possibly giving clinicians better control of radiation dosing, distribution and retention.
- ¹⁸⁶RNL potentially more effectively treats both the bulk tumor and microscopic disease that has already invaded nearby healthy tissue.
- ¹⁸⁶RNL is infused directly into the targeted tumor by CED catheter insertion using MRI guided software to avoid critical patient neurological structures and neural pathways and also bypasses the blood brain barrier, which delivers the therapeutic product where it is needed. Importantly, it reduces radiation exposure to healthy cells, in contrast to EBRT which passes through normal tissue to reach the tumor, continuing its path through the tumor, hence being less targeted and selective.
- ¹⁸⁶RNL is given during a single, short, in-patient hospital visit, and is available in all hospitals with nuclear medicine and neurosurgery, while EBRT requires out-patient visits 5 days a week for approximately 4-6 weeks.

ReSPECT-GBM Trial for Recurrent GBM

GBM is the most common, complex, and aggressive primary brain cancer in adults. Annually in the U.S., there are 13,100 GBM cases diagnosed and approximately 10,000 patients succumb to the disease each year. The average life expectancy with primary glioblastoma is less than 24 months, with a one-year survival rate of 40.8% and a five-year survival rate of only 6.8%. GBM often causes and presents with headaches, seizures, vision changes and other significant neurological complications. Despite the best available medical treatments to eliminate the initial brain tumor, some microscopic disease frequently remains, with tumor regrowth within months. More than 90% or more of patients with primary GBM experience tumor recurrence. Complete surgical removal of GBM is not typically possible and GBM is often resistant or quickly develops resistance to most available therapies. Even today, the treatment of GBM remains a significant challenge and it has been nearly a decade since the FDA approved a new therapy for this disease and this therapy has not been shown to improve overall survival.

For recurrent GBM, there are few currently approved treatments that in the aggregate, provide only marginal survival benefit. Furthermore, these therapies are associated with significant side effects and patient toxicity, which limit dosing and prolonged use.

While EBRT has been shown to be safe and effective in controlling some malignancies including glioblastoma, the maximum possible administered external beam radiation dose is limited by normal tissue toxicity surrounding the malignancy and to the entrance and exit paths of this external administered radiation. In contrast, targeted radiopharmaceuticals that precisely deliver radiation in the form of beta particles, are known to minimize exposure to normal cells and tissues which we hope will result in a safer and more effective treatment. An example of this is Iodine-131 for thyroid cancer which because of its systemic administration has some potential for

normal tissue toxicity. By comparison, local CED delivery of ^{186}RnL with nanoliposome encapsulation essentially mitigates this normal tissue toxicity potential.

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

^{186}RnL is presently under clinical investigation in a multicenter, sequential cohort, open-label, volume and dose escalation study of the safety, tolerability, and distribution of ^{186}RnL given by CED to patients with recurrent or progressive malignant glioma after standard surgical, radiation, and/or chemotherapy treatment (NCT01906385). The study uses a modified 3x3 Fibonacci dose escalation design, followed by a planned Phase 2 expansion trial at the maximum tolerated dose/maximum feasible dose or non-DLT dose limiting toxicity to further determine safety efficacy. The trial is funded through Phase 2 in large part by a NIH/NCI grant. The planned enrollment in the NIH/NCI grant is 21-30 patients in the dose-escalation part of the study and up to 34 patients in the expansion cohort. The study is in its 8th dosing administration cohort and is under development and internal review to advance to the expansion Phase 2 followed by a phase 3 registration trial.

On September 6, 2022, we announced a summary of our recent Type C clinical meeting with the FDA that focused on the ReSPECT-GBM trial. The FDA and the Company agreed that the ReSPECT-GBM clinical trial should proceed to the planned Phase 2. The key focus areas of clinical investigation of the Phase 2 trial will be: 1) further dose exploration, including both increased dosing and multiple doses, and 2) collecting additional safety and efficacy data to inform the design of the future registrational trial. Because no DLT administered doses have been observed, FDA and the Company also agreed to continue to dose cohort 8. There was further agreement with FDA that in a planned future registrational trial, overall survival should be used as the primary endpoint. The Company and the FDA also agreed to hold future meeting(s) to consider the use of external data to augment the control arm in the registrational trial.

At the European Society for Medical Oncology Congress, held September 9 to 13, 2022, the Company presented updated data from the ReSPECT-GBM trial, which evaluated 23 adult patients with recurrent GBM across 8 cohorts of increasing dose and treated over a seven-year period. Key findings include:

- No dose-limiting toxicities (“DLT”) have been observed and the procedure was very well tolerated with a strong safety profile. Minimal systemic radiation has been observed and the majority of adverse events have been mild or moderate and considered causally unrelated to ^{186}RnL .
- Improved median overall survival (“OS”) rates correlated with the absorbed radiation tumor dose. When patients were stratified based on receipt of either a therapeutic or a subtherapeutic absorbed dose of radiation to the tumor, a statistically significant improvement in survival was observed. Specifically, patients receiving a therapeutic absorbed radiation dose (>100 Gray) had a median OS of 22.9 (95% CI of 8.8-42.3) months compared to those receiving a subtherapeutic absorbed radiation dose (<100 Gray) whose median OS was 5.6 months (95% CI of 1.6-9.4). Currently, three patients remain alive, all in the therapeutic group.
- Feasibility to deliver up to at least 20 times more radiation to the tumor than the standard of care, EBRT. A maximum of 32.2 mCi in 12.3 mL of volume has been delivered in and near the tumors, and a maximum average absorbed dose of radiation of 740 Gray has been successfully administered in a single procedure.
- Average absorbed radiation dose to the tumor increased in latter dosing cohorts with greater administered doses of Re-186 β -particle radiation, larger drug CED infusate volumes, more catheters used (up to 4 versus 1), and higher convection flow rates. In cohorts 5 and later, 82% of patients received a therapeutic radiation dose of >100Gray.
- Single-photon emission computerized tomography and (SPECT)/CT scanning were used during treatment to compute tumor coverage and dosimetry. Post treatment imaging analyses, including MRI, relative cerebral blood volume (rCBV) analysis and treatment response assessment maps (TRAMs) correlated with a positive tumor response and confirmed the presence of pseudoprogression in patients with positive tumor responses.
- ReSPECT-GBM will proceed to an NIH and FDA approved Phase 2 trial in the U.S. at the current non-DLT ^{186}RnL dose and will expand exploring higher radiation doses in larger volumes to treat larger tumors. Additionally, two or more ^{186}RnL administrations, if indicated, will be evaluated, and reviewed with the FDA, as well as expanded safety, imaging and efficacy data to support a planned future registrational trial.

ReSPECT-LM Clinical Trial for Leptomeningeal Metastases

LM is a rare complication of cancer in which the disease spreads to the membranes (meninges) surrounding the brain and spinal cord. The incidence of LM is growing and occurs in approximately 5% of people with late-stage cancer, or 110,000 people in the U.S. each year and may be under-diagnosed. LM is highly lethal with an average 1-year survival of just 7%. LM occurs with cancers that are most likely to spread to the central nervous system but can occur in all solid tumors. The most common cancers to spread to the leptomeninges

are breast cancer, lung cancer, melanoma and gastrointestinal cancers, though, as noted, most solid tumors have the potential for LM spread.

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

In October 2021, the FDA announced clearance of our IND application for ^{186}Rn for the treatment of LM. Subsequently, in November 2021, the FDA granted a Fast Track designation for ^{186}Rn for the treatment of leptomeningeal metastases. We treated our first patient in the ReSPECT-LM Phase 1 clinical trial in Q1 2022 and completed the first cohort in Q2 2022.

On August 13, 2022, we announced that the dose administered in the first cohort of our Phase 1/2a dose escalation trial of ^{186}Rn for the treatment of patients with LM was well-tolerated with no treatment-related adverse events greater than grade 1, and that the three patients in the cohort experienced ^{186}Rn distribution throughout the cerebrospinal fluid (“CSF”) subarachnoid space and a decreased CSF cell count after treatment, each of which was durable out to 28 days.

On August 17, 2022, we announced that we were awarded a \$17.6 million Product Development Research grant by the Cancer Prevention and Research Institute of Texas (“CPRIT”), to fund the continued development of the ReSPECT-LM clinical trial through Phase 2.

The ReSPECT-LM multi-center, sequential cohort, open-label, dose escalation study is evaluating the safety, tolerability, and distribution of ^{186}Rn via intrathecal infusion to the ventricle of patients with LM after standard surgical, radiation, and/or chemotherapy treatment. The primary endpoint of the study is the incidence and severity of adverse events and dose limiting toxicities.

ReSPECT-PBC Clinical Trial for Pediatric Brain Cancer

In August 2021, we announced plans for treating pediatric brain cancer at the 2021 American Association of Neurological Surgeons (“AANS”) Annual Scientific Meeting. In July 2021, we reported that we had received FDA feedback pertaining to a pre-IND meeting briefing package in which the FDA stated that we are not required to perform any additional preclinical or toxicology studies.

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

Approximately 250 children are diagnosed with ependymoma annually in the U.S. while 71% of children with Grade II and 57% with Grade III survive 5 years from diagnosis.

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

Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere Technology

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

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

Recent Developments

Grant Agreement with CPRIT

On September 19, 2022, we entered into a Cancer Research Grant Contract (the “CPRIT Contract”), effective as of August 31, 2022, with CPRIT, pursuant to which CPRIT will provide us a grant of up to \$17.6 million (the “CPRIT Grant”) over a three-year period to fund the continued development of ¹⁸⁶RNL for the treatment of patients with LM. The CPRIT Grant is subject to customary CPRIT funding conditions, including, but not limited to, a matching fund requirement (one dollar from Plus Therapeutics for every two dollars awarded by CPRIT), revenue sharing obligations upon commercialization of ¹⁸⁶RNL based on specific dollar thresholds until CPRIT receives the aggregate amount of 400% of the proceeds awarded under the CPRIT Grant, and certain reporting requirements.

Services Agreement and Statement of Work with Biocept

On June 22, 2022, we announced a multi-year laboratory services agreement with Biocept, Inc. (“Biocept”) to employ their cerebrospinal fluid (“CSF”) assay, CNSide, in Plus Therapeutics’ ReSPECT-LM Phase 1/2a dose-escalation trial of Rhenium-186 NanoLiposome for the treatment of patients with (“LM”).

Services Agreement and Sales Order with Medidata

On March 31, 2022, we entered into a Sales Order (the “Sales Order”) with Medidata Solutions, Inc. (“Medidata”), pursuant to which Medidata will build a Synthetic Control Arm® (SCA) platform that facilitates the use of historical clinical data to incorporate into the Company’s Phase 2 clinical trial of ¹⁸⁶RNL in GBM.

The Sales Order has a term of six (6) months. The Sales Order may only be terminated for a material breach by either party, if the clinical study is terminated or if the clinical study’s authorization or approval is withdrawn by a regulatory agency.

UT Health Science Center San Antonio (UTHSCSA) License Agreement

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

Recent Financings

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

Results of Operations

Grant Revenue

We recognized \$73,000 of grant revenue during the three and nine months ended September 30, 2022, which represents CPRIT’s share of the costs incurred for our ¹⁸⁶RNL development for the treatment of patients with LM.

Research and development expenses

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

The following table summarizes the components of our research and development expenses for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 2,926	\$ 1,475	\$ 7,493	\$ 3,666
Share-based compensation	19	16	67	58
Total research and development expenses	<u>\$ 2,945</u>	<u>\$ 1,491</u>	<u>\$ 7,560</u>	<u>\$ 3,724</u>

The increase of \$1.6 million in research and development expenses for the three months ended September 30, 2022 as compared to the same period in 2021 was due primarily to an increase of \$0.4 million in development costs relating to the development of cGMP ¹⁸⁶RNL.

drug, an increase of \$0.8 million in other expenses which includes the development of the SCA, and an increase of \$0.3 million related to personnel and travel related expenses.

The increase of \$4.0 million in research and development expenses for the nine months ended September 30, 2022, as compared to the same period in 2021 was due primarily to an increase of \$1.8 million in development costs relating to the development of cGMP ¹⁸⁶RNL drug, and an increase of \$2.2 million in other expenses which includes the development of the SCA.

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

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses, and general corporate expenses. The following table summarizes the general and administrative expenses for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
General and administrative	\$ 2,112	\$ 1,826	\$ 6,244	\$ 4,444
Share-based compensation	110	164	409	367
Total general and administrative expenses	\$ 2,222	\$ 1,990	\$ 6,653	\$ 4,811

General and administrative expenses increased by approximately \$0.3 million and \$1.8 million during the three and nine months ended September 30, 2022, respectively, as compared to the same period in 2021. The increase during the three months ended September 30, 2022 was primarily due to an increase of \$0.2 million in litigation, legal fees and other professional expenses. The increase during the nine months ended September 30, 2022 was primarily due to an increase of \$1.6 million in litigation, legal fees, intellectual property and other professional expenses, and an increase of \$0.2 million in personnel related expenses.

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

Stock-based compensation expense

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

The following table summarizes the components of our stock-based compensation expenses for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 19	\$ 16	\$ 67	\$ 58
General and administrative	110	164	409	367
Total share-based compensation	\$ 129	\$ 180	\$ 476	\$ 425

The fluctuations in our stock-based compensation are due to increases or decreases of grants of stock-based options, vesting schedule of such grants, as well as grant-date fair value of stock-based awards.

Financing items

The following table summarizes interest income, interest expense, and other income and expense for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Interest income	\$ 48	\$ 5	\$ 74	\$ 13
Interest expense	(173)	(232)	(552)	(708)
Change in fair value of liability instruments	—	2	1	4
Total	<u>\$ (125)</u>	<u>\$ (225)</u>	<u>\$ (477)</u>	<u>\$ (691)</u>

The decrease in interest expense for the three and nine months ended September 30, 2022 as compared to the same periods in 2021 was primarily due to the repayment of debt principal of \$0.4 million and \$1.2 million for the three and nine months ended September 30, 2022, respectively, as compared to no principal payments during the same periods in 2021.

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

Liquidity and Capital Resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 20,266	\$ 18,400
Current assets	\$ 20,879	\$ 19,724
Current liabilities	7,420	5,870
Working capital	<u>\$ 13,459</u>	<u>\$ 13,854</u>

For the periods presented, operating losses have been funded primarily from outside sources of invested capital in our common stock. We believe that our cash and cash equivalents of 20.3 million at September 30, 2022 will enable us to fund our current and planned operations for at least the next twelve months and beyond from the date these condensed financial statements were issued.

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

On September 19, 2022, we entered into the CPRIT Contract, pursuant to which CPRIT will provide us with the CPRIT Grant of \$17.6 million subject to the terms of the CPRIT Contract, to fund approximately two-thirds of the continued development of ¹⁸⁶RNL for the treatment of patients with LM.

On September 9, 2022, we entered into an Equity Distribution Agreement (the "September 2022 Distribution Agreement") with Canaccord Genuity LLC ("Canaccord"), pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$5,000,000, depending on market demand, with Canaccord acting as an agent for sales. Sales of our common stock may be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended (the "Securities Act"), including, without limitation, sales made directly on or through the NASDAQ Capital Market. Canaccord will use its commercially reasonable efforts to sell common stock requested by the Company to be sold on its behalf, consistent with Canaccord's normal trading and sales practices, under the terms and subject to the conditions set forth in the September 2022 Distribution Agreement. We have no obligation to sell any of our common stock. We may instruct Canaccord not to sell any common stock if the sales cannot be effected at or above the price designated by us from time to time and we may at any time suspend sales pursuant to the September 2022 Distribution Agreement. During the period from September 9, 2022 to September 30, 2022, we did not issue any shares under the September 2022 Distribution Agreement. From October 1, 2022 to the date of filing of this Form 10-Q, we issued 1,000,000 shares under the September 2022 Distribution Agreement for net proceeds of approximately \$0.6 million.

On August 2, 2022, we entered into a purchase agreement (the "2022 Purchase Agreement") and registration rights agreement pursuant to which Lincoln Park committed to purchase up to \$50.0 million of shares of our common stock. Under the terms and subject to the

conditions of the 2022 Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$50.0 million of shares of our common stock, provided that we cannot sell more than 57.5 million shares pursuant to the 2022 Purchase Agreement. Sales of common stock by us are subject to certain limitations, and can occur from time to time, at our sole discretion, over the 36-month period commencing on August 17, 2022, subject to the satisfaction of certain conditions. Actual sales of shares of common stock to Lincoln Park under the 2022 Purchase Agreement depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. As consideration for Lincoln Park’s irrevocable commitment to purchase shares of our common stock upon the terms of and subject to satisfaction of the conditions set forth in the Purchase Agreement, we paid \$125,000 in cash as an Initial Commitment Fee and issued 492,698 Commitment Shares to Lincoln Park in consideration for its commitment to purchase shares of our common stock at our direction under the Purchase Agreement.

On August 17, 2022, a registration statement was declared effective covering the resale of up to 9,500,000 shares of our common stock comprised of (i) the 492,698 Commitment Shares, and (ii) up to 9,007,302 shares that we have reserved for issuance and sale to Lincoln Park under the Purchase Agreement. We cannot sell more shares under the 2022 Purchase Agreement without registering additional shares.

During the period from August 17, 2022 to September 30, 2022, the Company issued 4,000,000 shares under the 2022 Purchase Agreement for net proceeds of approximately \$3.3 million. From October 1, 2022 to the date of filing of this Form 10-Q, the Company did not issue any shares under the 2022 Purchase Agreement.

On January 14, 2022, we entered into an Equity Distribution Agreement (the “January 2022 Distribution Agreement”) with Canaccord, pursuant to which we could issue and sell, from time to time, shares of our common stock in “at the market” offerings, having an aggregate offering price of up to \$5,000,000, depending on market demand, with Canaccord acting as an agent for sales. During the nine months ended September 30, 2022, the Company issued 6,902,279 shares under the January 2022 Distribution Agreement for net proceeds of approximately \$4.8 million. The January 2022 Distribution Agreement has been terminated after all available registered shares were fully utilized.

On October 23, 2020, we entered into an Equity Distribution Agreement (the “2020 Distribution Agreement”) with Canaccord, pursuant to which we could issue and sell, from time to time, shares of our common stock in “at the market” offerings, having an aggregate offering price of up to \$10,000,000, depending on market demand, with Canaccord acting as an agent for sales. During 2021, we issued 2,179,193 shares under the 2020 Distribution Agreement for net proceeds of \$6.3 million. The 2020 Distribution Agreement has been terminated.

On September 30, 2020, we entered into the 2020 Purchase Agreement and a registration rights agreement with Lincoln Park, pursuant to which Lincoln Park committed to purchase up to \$25.0 million of our common stock. During 2021, we issued 5,685,186 shares of our common stock under the 2020 Purchase Agreement for total proceeds of \$12.5 million. During the three months ended March 31, 2022, we issued 5,665,000 shares of common stock for net proceeds of approximately \$7.0 million under the 2020 Purchase Agreement. The 2020 Purchase Agreement has been terminated.

We continue to seek additional capital through strategic transactions and other financing alternatives. Without additional capital, current working capital and cash generated from grants will not provide adequate funding for research and product development activities at their current levels. If sufficient capital is not raised, we will at a minimum need to significantly reduce or curtail our research and development and other operations, and this would negatively affect our ability to achieve corporate growth goals. There may be continued market volatility due to the pandemic, downturn in global economy, or other events, which could cause our stock price to decline. This in turn will likely negatively impact our ability to raise funds through equity-related financings.

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

Cash (used in) provided by operating, investing, and financing activities for the nine months ended September 30, 2022 and 2021 is summarized as follows (in thousands):

	For the Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	\$ (10,738)	\$ (7,656)
Net cash used in investing activities	(748)	(84)
Net cash provided by financing activities	13,352	20,674
Net increase in cash and cash equivalents	<u>\$ 1,866</u>	<u>\$ 12,934</u>

Material Cash Obligations

On September 19, 2022, we entered into the CPRIT Contract, effective as of August 31, 2022, pursuant to which we will continue the development of Rhenium-186 NanoLiposome (¹⁸⁶RNL) for the treatment of patients with leptomeningeal metastases (“LM”), with CPRIT providing matching funds for approximately two-thirds of the total development costs, subject to various funding conditions. The CPRIT contract is effective for three years, unless otherwise terminated per terms of the contract. CPRIT may require us to repay some or all of the disbursed CPRIT grant proceeds (with interest not to exceed 5% annually) in the event of the early termination of the CPRIT Contract.

On March 31, 2022, we entered into the Sales Order with Medidata pursuant to which Medidata will build a Synthetic Control Arm® (SCA) platform that facilitates the use of historical clinical data to incorporate into the Company’s Phase 2 clinical trial of 186RNL in GBM.

We are also obligated to make ongoing payments against the remaining principal and interest payments of approximately \$6.0 million in total under the Term Loan with Oxford through the maturity date of June 1, 2024 (See Note 5 of the accompanying condensed financial statements for more information). In addition, as described in more detail in Note 7 of the accompanying condensed financial statements, we are obligated to make operating lease payments for our office and laboratory space and we may be required to make payments under certain of our other contractual agreements.

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2022 was \$10.7 million compared to \$7.7 million in the same period of 2021. Our operational cash use increased during the nine months ended September 30, 2022 as compared to the same period in 2021, due primarily to increased expenditures for our research and development activities.

Investing activities

Net cash used in investing activities for the nine months ended September 30, 2022 was related to cash payments of \$250,000 made for in process research and development assets from UTHSA and purchases of fixed assets and intangible assets of \$498,000. Net cash used in investing activities for the nine months ended September 30, 2021 was purchases of fixed assets of \$134,000, offset by proceeds of \$50,000 from sale of property and equipment.

Financing Activities

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

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.

Critical Accounting Policies and Significant Estimates

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

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

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

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

We believe it is important for you to understand our most critical accounting policies. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and there have been no material changes during the nine months ended September 30, 2022.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in our reports that we file or furnish pursuant to the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer), as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer), of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer) concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On June 22, 2021, we were named as a defendant in an action brought by Lorem Vascular, Pte. Ltd. (“Lorem”) in the District Court for the District of Delaware. The complaint alleges false representations were made to Lorem regarding the manufacturing facility in the United Kingdom (the “UK Facility”) that Lorem purchased from us under the Equity Purchase Agreement, dated March 29, 2019, between us and Lorem (the “Lorem Agreement”). Lorem also claims that false representations were made regarding the UK Facility’s certification to sell and distribute devices in the European Union and export such devices to China. In connection with these allegations, Lorem claims entitlement to at least \$6,000,000 in compensatory damages and operational costs and expenses (collectively, the “Lorem Claim”). We believe that the Lorem Claim is without merit and we are vigorously defending the case.

Item 1A. Risk Factors

For a discussion of certain factors that could materially affect our business, financial condition, and operating results or that could cause actual results to differ materially from the results described in or implied by the forward-looking statements in this Quarterly Report on Form 10-Q, in addition to the information in the section entitled “Cautionary Statement Regarding Forward-Looking Statements,” you should carefully review and consider the information under “Part I, Item 1A- Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021. The risk factors below are in addition to and supplement (and with respect to certain matters, update) the risk factors discussed in our Annual Report on Form 10-K. Other than as set forth below, there have been no material changes to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock, including in connection with the sale or issuance of our common stock to Lincoln Park and the sale of the shares of common stock acquired by Lincoln Park and the sale of our common stock by Canaccord.

Our charter allows us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 5,000,000 shares of preferred stock. To raise additional capital, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that are lower than the prices paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, which could result in substantial dilution to the interests of existing stockholders.

On August 2, 2022, we entered into the 2022 Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park committed to purchase up to \$50.0 million (the “Commitment Amount”) of our common stock, subject to certain limitations. As consideration for Lincoln Park’s irrevocable commitment to purchase shares of our common stock upon the terms of and subject to satisfaction of the conditions set forth in the 2022 Purchase Agreement, upon execution of the 2022 Purchase Agreement, we agreed to pay Lincoln Park an initial commitment fee equal to 1.5% of the Commitment Amount. The initial commitment fee was paid upon execution of the 2022 Purchase Agreement through the issuance of 492,698 shares of common stock and \$125,000 in cash. An additional commitment fee equal to 2.5% of the remainder of the Commitment Amount will be paid if and when we sell over \$25.0 million of our common stock under the 2022 Purchase Agreement. The additional commitment fee may be paid in cash, common stock, or a combination of cash and common stock.

The remaining shares of our common stock that may be issued under the 2022 Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing August 17, 2022, subject to satisfaction of certain conditions. The purchase price for the shares that we may sell to Lincoln Park under the 2022 Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all or some of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

On September 9, 2022, we entered into the September 2022 Distribution Agreement with Canaccord, pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$5,000,000, depending on market demand, with Canaccord acting as an agent for sales. Sales of the Shares may be made by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) of the Securities Act, including, without limitation, sales made directly on or through the Nasdaq. Sales pursuant to the September 2022 Distribution Agreement, if any, could result in substantial dilution to the interest of other holders of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

Reliance on government funding for our programs may impose requirements that limit our ability to take certain actions, and subject it to potential financial penalties, which could materially and adversely affect its business, financial condition and results of operations.

A significant portion of our funding will come from a grant it received from CPRIT. The CPRIT Grant includes provisions that reflect the government’s substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to potentially require repayment of all or a portion of the grant award proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters that include any potential relocation outside of the State of Texas. After the CPRIT Grant ends, we are not permitted to retain any unused grant award proceeds without CPRIT’s approval, but our obligation to pay CPRIT sales-based royalty, if and when commercialization is achieved, and other obligations, including our obligation to repay the disbursed grant proceeds under certain circumstances, to maintain certain records and documentation, to notify CPRIT of certain unexpected adverse events and our obligation to use reasonable efforts to ensure that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing related to any aspect to our CPRIT project take place in Texas, survive the termination of the agreement.

Our award from CPRIT requires us to pay CPRIT a portion of our revenues from sales of certain products by us, or received from our licensees or sublicensees, at tiered percentages of revenue in the low- to mid-single digits until the aggregate amount of such payments equals 400% of the grant award proceeds, and thereafter at a rate of 0.5% for as long as we maintain government exclusivity, subject to our right, under certain circumstances, to make a one-time payment in a specified amount to CPRIT to terminate such payment obligations. In addition, the grant contract also contains a provision that provides for repayment to CPRIT of some amount not to exceed the full amount of the grant proceeds under certain specified circumstances involving relocation of our principal place of business outside Texas.

The CPRIT Grant requires us, as a Texas-based company, to meet certain criteria, including among other things, that we maintain our headquarters in Texas and use certain vendors, consultants and employees that are located in Texas. If we fail to maintain compliance with any such requirements that may apply to us now or in the future, we may be subject to potential liability and to termination of our contracts, and potentially full repayment of the CPRIT Grant.

We could be delisted from Nasdaq, which would seriously harm the liquidity of our stock and our ability to raise capital.

Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders.

On May 24, 2022, we received notice from Nasdaq that, because the closing bid price for our common stock had fallen below \$1.00 per share for 30 consecutive business days, we no longer complied with the minimum bid price requirement pursuant to Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Requirement”). Nasdaq’s notice had no immediate effect on the listing or trading of our common stock. Pursuant to Nasdaq Listing Rule 5810(c)(3) (A), we are provided an initial compliance period of 180 calendar days, or until November 21, 2022, to regain compliance with the Minimum Bid Requirement. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for a minimum of 10 consecutive business days prior to November 21, 2022. If we do not achieve compliance with the Minimum Bid Requirement by November 21, 2022, we may be eligible for an additional 180 calendar days to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other Nasdaq initial listing standards, with the exception of the Minimum Bid Requirement, and provide written notice of our intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split if necessary. If the Nasdaq staff determines that we will not be able to cure the deficiency, or if we are otherwise not eligible for such additional compliance period, Nasdaq will provide notice that our common stock will be subject to delisting. In the event we receive notice that our common stock is being delisted, Nasdaq rules permit us to appeal any delisting determination by the Nasdaq staff. There can be no assurance that the Company will be able to regain compliance with the Minimum Bid Requirement or maintain compliance with the other listing requirements.

If, for any reason, Nasdaq were to delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders:

- the liquidity and marketability of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

In addition, if we cease to be eligible to trade on Nasdaq, we may have to pursue trading on a less recognized or accepted market, such as the over the counter markets, our stock may be traded as a “penny stock” which would make transactions in our stock more difficult and cumbersome, and we may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to further decline.

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

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

**EXHIBIT INDEX
PLUS THERAPEUTICS, INC.**

Exhibit Number	Exhibit Title	Filed with this Form 10-Q	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	Composite Certificate of Incorporation		10-K	001-34375 Exhibit 3.1	03/11/2016
3.2	Certificate of Amendment to Amended and Restated Certificate		8-K	001-34375 Exhibit 3.1	05/10/2016
3.3	Certificate of Amendment to Amended and Restated Certificate		8-K	001-34375 Exhibit 3.1	05/23/2018
3.4	Certificate of Amendment to Amended and Restated Certificate		8-K	001-34375 Exhibit 3.1	07/29/2019
3.5	Certificate of Amendment to Amended and Restated Certificate		8-K	001-34375 Exhibit 3.1	08/06/2019
3.6	Amended and Restated Bylaws of Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 3.1	09/21/2021
10.1	Plus Therapeutics, Inc. 2020 Stock Incentive Plan, as amended		8-K	001-34375 Exhibit 10.1	05/20/2022
10.2	Purchase Agreement, dated August 2, 2022, by and between Plus Therapeutics, Inc. and Lincoln Park Capital Fund, LLC		8-K	001-34375 Exhibit 10.1	08/08/2022
10.3	Registration Rights Agreement, dated August 2, 2022, by and between Plus Therapeutics, Inc. and Lincoln Park Capital Fund, LLC		8-K	001-34375 Exhibit 10.2	08/08/2022
10.4	Distribution Agreement, dated September 9, 2022, by and among Plus Therapeutics, Inc. and Canaccord Genuity LLC		8-K	001-34375 Exhibit 1.1	09/09/2022
10.5	Cancer Research Grant Contract, effective August 31, 2022, by and between the Cancer Prevention and Research Institute of Texas and Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 10.1	09/22/2022
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.

Dated: October 20, 2022

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

Dated: October 20, 2022

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

**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 20, 2022

/s/ Marc H. Hedrick

Marc H. Hedrick,
President & Chief Executive Officer

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

I, Andrew Sims, certify that:

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

Date: October 20, 2022

/s/ Andrew Sims

Andrew Sims

Chief Financial Officer

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

In connection with the Quarterly Report on Form 10-Q of Plus Therapeutics, Inc. for the quarterly period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof, Marc H. Hedrick, as President & Chief Executive Officer of Plus Therapeutics, Inc., and Andrew Sims, as VP of Finance and Chief Financial Officer of Plus Therapeutics, Inc., each hereby certifies, respectively, that:

1. The Form 10-Q report of Plus Therapeutics, Inc. that this certification accompanies fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934.
2. The information contained in the Form 10-Q report of Plus Therapeutics, Inc. that this certification accompanies fairly presents, in all material respects, the financial condition and results of operations of Plus Therapeutics, Inc.

Dated: October 20, 2022

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

Dated: October 20, 2022

By: /s/ Andrew Sims
Andrew Sims
Chief Financial Officer & VP of Finance
