

**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 June 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 July 14, 2022, there were 22,532,005 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; competition; future development and/or expansion of our product candidates and therapies in our markets; sources of competition for any of our product candidates; our pipeline; our ability to generate product or development revenue and the sources of such revenue; our ability to effectively manage our gross profit margins; our ability to obtain and maintain regulatory approvals; expectations as to our future performance; portions of the “Liquidity and Capital Resources” section of this report, including our potential need for additional financing and the availability thereof; our ability to continue as a going concern; our ability to remain listed on the Nasdaq Capital Market; our ability to repay or refinance some or all of our outstanding indebtedness and our ability to raise capital in the future; our ability to transfer the drug product manufacture to a contract drug manufacturing organization; and the potential enhancement of our cash position through development, marketing, and licensing arrangements. The forward-looking statements included in this report are also subject to a number of additional material risks and uncertainties, including but not limited to the risks described under “Part I – Item 1A – Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021, and under “Part II – Item 1A – Risk Factors” in this Quarterly report. These risks and uncertainties could cause actual results to differ materially from expectations or those expressed in these forward-looking statements.*

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

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

**PART I. FINANCIAL INFORMATION**  
**Item 1. Financial Statements**

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 18,090	\$ 18,400
Other current assets	799	1,324
Total current assets	<u>18,889</u>	<u>19,724</u>
Property and equipment, net	1,560	1,477
Operating lease right-use-of assets	303	341
Goodwill	372	372
Intangible assets, net	131	51
Other assets	16	16
Total assets	<u>\$ 21,271</u>	<u>\$ 21,981</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,259	\$ 4,151
Operating lease liability	104	111
Term loan obligation, current	1,608	1,608
Total current liabilities	<u>6,971</u>	<u>5,870</u>
Noncurrent operating lease liability	202	269
Term loan obligation	4,419	5,005
Warrant liability	—	1
Total liabilities	<u>11,592</u>	<u>11,145</u>
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 22,468,682 and 15,510,025 issued and outstanding at June 30, 2022 and December 31, 2021, respectively	22	16
Additional paid-in capital	465,965	457,730
Accumulated deficit	(456,308)	(446,910)
Total stockholders' equity	<u>9,679</u>	<u>10,836</u>
Total liabilities and stockholders' equity	<u>\$ 21,271</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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
<b>Operating expenses:</b>				
Research and development	\$ 2,831	\$ 1,106	\$ 4,615	\$ 2,233
General and administrative	2,289	1,469	4,431	2,821
Total operating expenses	5,120	2,575	9,046	5,054
Operating loss	(5,120)	(2,575)	(9,046)	(5,054)
<b>Other income (expense):</b>				
Interest income	19	4	26	8
Interest expense	(181)	(229)	(379)	(476)
Change in fair value of liability instruments	—	—	1	2
Total other expense	(162)	(225)	(352)	(466)
Net loss	<u>\$ (5,282)</u>	<u>\$ (2,800)</u>	<u>\$ (9,398)</u>	<u>\$ (5,520)</u>
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.25)	\$ (0.43)	\$ (0.56)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	22,254,823	11,296,816	21,919,956	9,790,726

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>
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>

See Accompanying Notes to these Condensed Financial Statements

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

	<u>For the Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>
<b>Cash flows used in operating activities:</b>		
Net loss	\$ (9,398)	\$ (5,520)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	302	179
Amortization of deferred financing costs and debt discount	218	283
Change in fair value of liability instruments	(1)	(2)
Stock-based compensation expense	347	245
Change of operating lease assets and liabilities	(36)	—
Non-cash lease expense	—	4
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Other current assets	525	(11)
Accounts payable and accrued expenses	1,527	(583)
Net cash used in operating activities	<u>(6,516)</u>	<u>(5,405)</u>
<b>Cash flows (used in) investing activities:</b>		
Purchases of property and equipment	(348)	(80)
Purchases of intangible assets	(117)	—
In process research and development acquired	(250)	—
Net cash used in investing activities	<u>(715)</u>	<u>(80)</u>
<b>Cash flows from financing activities:</b>		
Principal payments of long-term obligations	(804)	—
Payment of financing lease liability	—	(8)
Proceeds from exercise of warrants	—	2,017
Proceeds from sale of common stock, net	7,725	12,291
Net cash provided by financing activities	<u>6,921</u>	<u>14,300</u>
Net increase (decrease) in cash and cash equivalents	<u>(310)</u>	<u>8,815</u>
Cash and cash equivalents at beginning of period	18,400	8,346
Cash and cash equivalents at end of period	<u>\$ 18,090</u>	<u>\$ 17,161</u>
<b>Supplemental disclosure of cash flows information:</b>		
Cash paid during period for:		
Interest	\$ 168	\$ 290
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Unpaid offering cost	\$ 50	\$ 119
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**  
**June 30, 2022**  
**(UNAUDITED)**

**1. Basis of Presentation and New Accounting Standards**

The accompanying unaudited condensed financial statements as of June 30, 2022 and for the three and six months ended June 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 six months ended June 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.

**Recently Issued Accounting Pronouncements**

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

**2. Use of Estimates**

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

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

**3. Liquidity**

The Company incurred net losses of \$9.4 million for the six months ended June 30, 2022. The Company had an accumulated deficit of \$456.3 million as of June 30, 2022. Additionally, the Company used net cash of \$6.5 million to fund its operating activities for the six months ended June 30, 2022.

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

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

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 June 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 six months ended June 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 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 June 30, 2022, there was \$3.1 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 June 30, 2022 and 2021 was \$0.2 million. The Company's interest expense for the six months ended June 30, 2022 and 2021 was \$0.4 and \$0.5 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 June 30, 2022 and 2021, and \$0.2 million and \$0.3 million for the six months ended June 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 June 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:

	As of June 30,	
	2022	2021
Outstanding stock options	1,183,873	1,090,890
Preferred stock	422,867	422,867
Outstanding warrants	2,141,189	2,141,378
Total	3,747,929	3,655,135

## 7. Commitments and Contingencies

### Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company calculates the associated lease liability

and corresponding right-of-use asset upon lease commencement using a discount rate based on the rate implicit in the lease or an incremental borrowing rate commensurate with the term of the lease. Lease renewable options are included in the estimation of lease term when it is reasonably certain that the Company will exercise such options.

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

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2025. The Company also leases certain office space in Austin, Texas under a month-to-month operating lease agreement and certain office space in Charlottesville, Virginia (the "Charlottesville Lease"). The Charlottesville Lease has a term of 12 months and we have 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 June 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 June 30, 2022, weighted average discount rate used to measure operating lease liabilities and the operating leases remaining term were 9.0% and 2.52 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 six months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<b>Lease expense:</b>				
Operating lease expense	\$ 46	\$ 58	\$ 92	\$ 108
<b>Finance lease expense:</b>				
Depreciation of right-of-use assets	-	3	-	7
<b>Total lease expense</b>	<b>\$ 46</b>	<b>\$ 61</b>	<b>\$ 92</b>	<b>\$ 115</b>
<b>Cash payment information:</b>				
Operating cash used for operating leases	\$ 54	\$ 56	\$ 91	\$ 106
Financing cash used for financing leases	-	3	-	8
<b>Total cash paid for amounts included in the measurement of lease liabilities</b>	<b>\$ 54</b>	<b>\$ 59</b>	<b>\$ 91</b>	<b>\$ 114</b>

Total rent expenses for the six months ended June 30, 2022 and 2021 were \$119,000 and \$112,000, 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 June 30, 2022 are as follows (in thousands):

	<b>Operating Leases</b>
Remainder of 2022	\$ 68
2023	137
2024	113
2025	17
Total minimum lease payments	\$ 335
Less: amount representing interest	(29)
Present value of obligations under leases	306
Less: current portion	(104)
Noncurrent lease obligations	\$ 202

#### *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<sup>®</sup> (SCA) platform that facilitates the use of historical clinical data to incorporate into the Company’s Phase 2 clinical trial of Rhenium-186 NanoLiposome (<sup>186</sup>RNL) 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 June 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 June 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.

## 8. License Agreements

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

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

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

## 9. Stockholders’ Equity

### **Preferred Stock**

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

As of June 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 June 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 Agreement*

On September 30, 2020, the Company entered into the 2020 Purchase Agreement and registration rights agreement pursuant to which Lincoln Park committed to purchase up to \$25.0 million of the Company’s common stock. Under the terms and subject to the conditions of the 2020 Purchase Agreement, the Company had the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park was obligated to purchase up to \$25.0 million of the Company’s common stock. Such sales of common stock by

the Company were subject to certain limitations, and could occur from time to time, at the Company's sole discretion, over the 36-month period commencing on November 6, 2020, subject to the satisfaction of certain conditions.

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

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

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

During the year ended December 31, 2021, the Company issued 5,685,186 shares of its common stock under the 2020 Purchase Agreement for net proceeds of approximately \$12.5 million. During the six months ended June 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 January 14, 2022, the Company entered into an Equity Distribution Agreement (the "2022 Distribution Agreement") with Canaccord Genuity LLC ("Canaccord"), pursuant to which the Company may issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$5,000,000 (the "Shares"), with Canaccord acting as an agent for sales. Canaccord will use its commercially reasonable efforts to sell the Shares requested by the Company to be sold on its behalf. The Company has no obligation to sell any of the Shares. The Company may instruct Canaccord not to sell the Shares if the sales cannot be effected at or above the price designated by the Company from time to time and the Company may at any time suspend sales pursuant to the 2022 Distribution Agreement. During the six months ended June 30, 2022, the Company issued 1,293,657 shares under the 2022 Distribution Agreement for net proceeds of approximately \$0.9 million.

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

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

## 10. 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 June 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 June 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 six months ended June 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	(17)	\$ 24,705.88		
Balance as of June 30, 2022	1,183,873	\$ 4.60	8.52	\$ -
Vested and expected to vest at June 30, 2022	1,124,553	\$ 4.68	8.50	\$ -
Exercisable at June 30, 2022	535,889	\$ 7.24	8.25	\$ -

As of June 30, 2022, the total compensation cost related to non-vested stock options not yet recognized for all the Company's plans is approximately \$1.2 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 2.63 years.

## 11. COVID-19 Pandemic and CARES Act

A novel strain of coronavirus (COVID-19) was declared a global pandemic by the World Health Organization in March 2020. COVID-19, including the resurgence of cases relating to the spread of new variants, has presented substantial public health and economic challenges and is affecting economies, financial markets and business operations around the world. While the Company has implemented additional health and safety precautions and protocols in response to the pandemic and government guidelines, the Company has not experienced a significant impact on its business and operations. However, the Company may experience disruptions that could adversely impact its business operations as well as its preclinical studies and clinical trials. The Company considered the impacts of COVID-19 on the assumptions and estimates used to prepare its financial statements and determined that there were no material adverse impacts on the Company's results of operations and financial position at June 30, 2022. The full extent to which the COVID-19 pandemic will directly or indirectly impact its business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national and international markets.

In response to the COVID-19 pandemic, the CARES Act was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act had no material impact on the Company's income tax provision for the year ended December 31, 2021 or the six months ended June 30, 2022. The Company continues to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows.

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

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

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

- Overview that discusses our operating results and some of the trends that affect our business.
- Results of Operations that includes a more detailed discussion of our revenue and expenses.
- Liquidity and Capital Resources which discusses key aspects of our statements of cash flows, changes in our financial position and our financial commitments.

### Overview

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

Traditional approaches to radiation therapy for cancer such as external beam radiation have many disadvantages including continuous treatment for 4-6 weeks (which is onerous for patients), radiation that inadvertently damages healthy cells and tissue, and a 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 (“<sup>186</sup>RNL”) 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 (“<sup>188</sup>RNL-BAM”) is designed to treat many solid organ cancers including primary and secondary liver cancers by intra-arterial injection.

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

The <sup>186</sup>RNL 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 <sup>186</sup>RNL for recurrent glioblastoma through the completion of a Phase 2 clinical trial including enrollment of up to 55 patients. Thus far, 23 patients have been treated in the Phase 1 clinical trial and the Phase 2 clinical trial has not yet been



initiated.

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

#### *<sup>186</sup>RNL versus External Beam Radiation Therapy*

<sup>186</sup>RNL 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. <sup>186</sup>RNL 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 <sup>186</sup>RNL compared to standard external beam radiotherapy (“EBRT”) include:

- The <sup>186</sup>RNL radiation dose delivered to patients may be up to 20 times greater than what is possible with commonly used EBRT.
- <sup>186</sup>RNL can be visualized in real-time during administration, possibly giving clinicians better control of radiation dosing and distribution.
- <sup>186</sup>RNL potentially more effectively treats the bulk tumor and microscopic disease that has already invaded healthy tissue.
- <sup>186</sup>RNL is infused directly into the targeted tumor, bypassing the blood brain barrier, which reduces radiation exposure to healthy cells, in contrast to EBRT which passes through normal tissue to reach the tumor, continuing its path through the tumor, hence being less targeted and selective.
- <sup>186</sup>RNL is given during a single, short, in-patient hospital visit, and is available in all hospitals with nuclear medicine and neurosurgery, while EBRT requires out-patient visits 5 days a week for approximately 4-6 weeks.

#### *ReSPECT-GBM Trial for Recurrent GBM*

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

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

While EBRT has been shown to be safe and effective in many malignancies including glioblastoma, the maximum possible administered dose is limited by toxicity to the normal tissues surrounding the malignancy. In contrast, targeted radiopharmaceuticals that precisely deliver radiation in the form of beta particles such as Iodine-131 for thyroid cancer, are known to minimize exposure to normal cells and tissues which we hope will result in a safer and more effective treatment.

Interim results from our ongoing Phase 1/2a ReSPECT-GBM trial, suggest beta particle energy from our lead investigational drug <sup>186</sup>RNL may also have utility in treating GBM and other malignancies. More specifically, the preliminary data from ReSPECT-GBM indicates that radiation, in the form of high energy beta particles or electrons, can be effective against GBM. Thus far, we have been able to deliver up to 740 Gy of absorbed radiation to tumor tissue without significant or dose limiting toxicities. In comparison, current EBRT protocols for recurrent GBM typically recommend a total maximum dose of about 35 Gy.

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

<sup>186</sup>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 <sup>186</sup>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 Fibonacci dose escalation, followed by a planned expansion at the maximum tolerated dose/maximum feasible dose to determine efficacy. The trial is funded through Phase 2 in large part by a NIH/NCI grant. The planned enrollment in the NIH/NCI grant is 21 patients in the dose-escalation part of the study and 34 patients in the expansion cohort. The study is in its 8<sup>th</sup> dosing administration cohort and is under development

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

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

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

#### *ReSPECT-LM Clinical Trial for Leptomeningeal Metastases*

LM is a rare complication of cancer in which the disease spreads to the membranes (meninges) surrounding the brain and spinal cord. The incidence of LM is growing and occurs in approximately 5% of people with late-stage cancer, or 110,000 people in the U.S. each year. It is highly lethal with an average 1-year survival of just 7%. LM occurs with cancers that are most likely to spread to the central nervous system. The most common cancers to spread to the leptomeninges are breast cancer, lung cancer, melanoma and gastrointestinal cancers—though most solid tumors have the potential for LM spread.

The ReSPECT-LM Phase 1 clinical trial (ClinicalTrials.gov NCT05034497) is predicated in part upon preclinical studies in which tolerance to doses of <sup>186</sup>RNL 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 <sup>186</sup>RNL for the treatment of LM. Subsequently, in November 2021, the FDA granted a Fast Track designation for <sup>186</sup>RNL 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.

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

#### *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 <sup>186</sup>RNL 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 <sup>186</sup>RNL 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 <sup>186</sup>RNL 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, <sup>188</sup>RNL-BAM for the intra-arterial embolization and local delivery of a high dose of targeted radiation for a variety of solid organ cancers such as hepatocellular cancer, hepatic metastases, pancreatic cancer and many others.

Preclinical data from an *ex vivo* embolization experiment in which 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. <sup>188</sup>RNL-BAM is a preclinical investigational drug we intend to further develop and move into clinical trials. Specifically, in 2022, we intend to transfer the <sup>188</sup>RNL-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 6<sup>th</sup> most common and 3<sup>rd</sup> deadliest cancer worldwide. It is a rare disease with increasing U.S. annual incidence (42,000) and deaths (30,000).

### **Recent Developments**

#### *Services Agreement and 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 <sup>186</sup>RNL 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 (UTHSA) License Agreement*

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

#### *Recent Financings*

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

### **Results of Operations**

#### *Research and development expenses*

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

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
Research and development	\$ 2,808	\$ 1,085	\$ 4,567	\$ 2,191
Share-based compensation	23	21	48	42
Total research and development expenses	<u>\$ 2,831</u>	<u>\$ 1,106</u>	<u>\$ 4,615</u>	<u>\$ 2,233</u>

The increase of \$1.7 million in research and development expenses for the three months ended June 30, 2022 as compared to the same period in 2021 was due primarily to an increase of \$0.8 million in development costs relating to the development of cGMP <sup>186</sup>RNL

drug, an increase of \$0.7 million in other expenses which includes the development of the SCA, and an increase of \$0.2 million in personnel expenses.

The increase of \$2.4 million in research and development expenses for the six months ended June 30, 2022, as compared to the same period in 2021 was due primarily to an increase of \$1.4 million in development costs relating to the development of cGMP <sup>186</sup>RNL drug, an increase of \$0.8 million in other expenses which includes the development of the SCA, and an increase of \$0.2 million in personnel expenses.

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 <sup>186</sup>RNL™ therapy acquired from NanoTx and development expenses related to <sup>188</sup>RNL-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 six months ended June 30, 2022 and 2021 (in thousands):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
General and administrative	\$ 2,145	\$ 1,352	\$ 4,132	\$ 2,618
Share-based compensation	144	117	299	203
<b>Total general and administrative expenses</b>	<b>\$ 2,289</b>	<b>\$ 1,469</b>	<b>\$ 4,431</b>	<b>\$ 2,821</b>

General and administrative expenses increased by approximately \$0.8 million and \$1.6 million during the three and six months ended June 30, 2022, respectively, as compared to the same period in 2021. The increase during the three months ended June 30, 2022 was primarily due to an increase of \$0.7 million in legal fees, intellectual property and other professional expenses, and an increase of \$0.1 million in personnel related expenses. The increase during the six months ended June 30, 2022 was primarily due to an increase of \$1.4 million in 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 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 six months ended June 30, 2022 and 2021 (in thousands):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Research and development	\$ 23	\$ 21	\$ 48	\$ 42
General and administrative	144	117	299	203
<b>Total share-based compensation</b>	<b>\$ 167</b>	<b>\$ 138</b>	<b>\$ 347</b>	<b>\$ 245</b>

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

## Financing items

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Interest income	\$ 19	\$ 4	\$ 26	\$ 8
Interest expense	(181)	(229)	(379)	(476)
Change in fair value of liability instruments	—	—	1	2
Total	<u>\$ (162)</u>	<u>\$ (225)</u>	<u>\$ (352)</u>	<u>\$ (466)</u>

The decrease in interest expense for the three and six months ended June 30, 2022 as compared to the same periods in 2021 was primarily due to the repayment of debt principal of \$0.4 million and \$0.8 million for the three and six months ended June 30, 2022 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 June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
Cash and cash equivalents	<u>\$ 18,090</u>	<u>\$ 18,400</u>
Current assets	\$ 18,889	\$ 19,724
Current liabilities	6,971	5,870
Working capital	<u>\$ 11,918</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 \$18.1 million at June 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 January 14, 2022, we entered into an Equity Distribution Agreement (the “2022 Distribution Agreement”) with Canaccord Genuity LLC (the “Agent”, or “Canaccord”), pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$5,000,000 (the “Shares”), depending on market demand, with the Agent acting as an agent for sales. Sales of the Shares may be made by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including, without limitation, sales made directly on or through the Nasdaq. Since January 14, 2022, we issued 1,293,657 shares under the 2022 Distribution Agreement for net proceeds of approximately \$0.9 million.

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

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

We continue to seek additional capital through strategic transactions and other financing alternatives. Without additional capital, current working capital and cash generated from sales will not provide adequate funding for research and product development

activities at their current levels. If sufficient capital is not raised, we will at a minimum need to significantly reduce or curtail our research and development and other operations, and this would negatively affect our ability to achieve corporate growth goals. There may be continued market volatility due to the pandemic, downturn in global economy, or other events, which could cause our stock price to decline. This in turn will likely negatively impact our ability to raise funds through equity-related financings.

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

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

	<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>
Net cash used in operating activities	\$ (6,516)	\$ (5,405)
Net cash used in investing activities	(715)	(80)
Net cash provided by financing activities	6,921	14,300
Net increase (decrease) in cash and cash equivalents	<u>\$ (310)</u>	<u>\$ 8,815</u>

#### *Material Cash Obligations*

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 <sup>186</sup>RNL in GBM.

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

#### *Operating activities*

Net cash used in operating activities for the six months ended June 30, 2022 was \$6.5 million compared to \$5.4 million in the same period of 2021. Our operational cash use increased during the six months ended June 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 six months ended June 30, 2022 was related to cash payments of \$0.2 million made for in process research and development assets from UTHSA and purchases of fixed assets and intangible assets of \$0.5 million. Net cash used in investing activities for the six months ended June 30, 2021 was primarily related to purchases of fixed assets.

#### *Financing Activities*

Net cash provided by financing activities for the six months ended June 30, 2022 was primarily related to sales of common stock of \$7.8 million, net of offering cost through the 2022 Distribution Agreement with Canaccord and the 2020 Purchase Agreement with Lincoln Park.

Net cash provided by financing activities for the six months ended June 30, 2021 was primarily related to sales of common stock of \$12.3 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 six months ended June 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 June 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.

***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.



## 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	<a href="#">Composite Certificate of Incorporation</a>		10-K	001-34375 Exhibit 3.1	03/11/2016
3.2	<a href="#">Certificate of Amendment to Amended and Restated Certificate</a>		8-K	001-34375 Exhibit 3.1	05/10/2016
3.3	<a href="#">Certificate of Amendment to Amended and Restated Certificate</a>		8-K	001-34375 Exhibit 3.1	05/23/2018
3.4	<a href="#">Certificate of Amendment to Amended and Restated Certificate</a>		8-K	001-34375 Exhibit 3.1	07/29/2019
3.5	<a href="#">Certificate of Amendment to Amended and Restated Certificate</a>		8-K	001-34375 Exhibit 3.1	08/06/2019
3.6	<a href="#">Amended and Restated Bylaws of Plus Therapeutics, Inc.</a>		8-K	001-34375 Exhibit 3.1	09/21/2021
10.1	<a href="#">Plus Therapeutics, Inc. 2020 Stock Incentive Plan, as amended</a>		8-K	001-34375 Exhibit 10.1	05/20/2022
31.1	<a href="#">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</a>	X			
31.2	<a href="#">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</a>	X			
32.1*	<a href="#">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</a>	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: July 21, 2022

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

Dated: July 21, 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: July 21, 2022

/s/ Marc H. Hedrick

Marc H. Hedrick,

*President & Chief Executive Officer*

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

I, Andrew Sims, certify that:

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

Date: July 21, 2022

/s/ Andrew Sims

Andrew Sims

*Chief Financial Officer*

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

In connection with the Quarterly Report on Form 10-Q of Plus Therapeutics, Inc. for the quarterly period ended June 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: July 21, 2022

By: /s/ Marc H. Hedrick

Marc H. Hedrick  
*President & Chief Executive Officer*

Dated: July 21, 2022

By: /s/ Andrew Sims

Andrew Sims  
*Chief Financial Officer & VP of Finance*